

PROCEDURE: PCD-000559

Title: Bloodborne Pathogens Exposure Control Plan

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1. INTRODUCTION

Bioventus LLC is committed to providing a safe and healthy work environment for all employees. In accordance with the OSHA Bloodborne Pathogens standard, 29 CFR 1910.1030, the following exposure control plan has been developed, and is intended to eliminate or minimize occupational exposure to bloodborne pathogens (BBP).

2. SCOPE

This plan is a key document in assisting Bioventus in implementing the BBP standard, and applies to any employee who has the potential for exposure to a bloodborne pathogen as part of their job duties. This plan includes:

- Determination of employee exposure
- Implementation of various methods of exposure control including:
 - Universal precautions
 - Engineering and work practice controls
 - Personal Protective Equipment
 - Housekeeping
- Hepatitis B vaccinations
- Post-exposure evaluation and follow-up
- Procedures for evaluating circumstances surrounding and exposure incident
- Training and communication of hazards to employees
- Recordkeeping

3. REFERENCES

3.1. External Standards and Regulations

Reference	Description
29 CFR 1910.1030	OSHA Bloodborne Pathogens Standard
29 CFR 1910.1020	OSHA Standard for Access to Employee Exposure and Medical Records
29 CFR 1904	OSHA Recording and Reporting of Occupational Injuries and Illnesses

3.2. Internal Procedures and Documents

Reference	Description
WIN-000351	Decontamination of Returned Products

4. DEFINITIONS

Term or Abbreviation	Definition
BBP	Bloodborne Pathogen
HIV	Human Immunodeficiency Virus
HCV	Hepatitis C Virus
HBV	Hepatitis B Virus
NIOSH	National Institute for Occupational Safety and Health
OSHA	U.S. Occupational Health and Safety Administration
PPE	Personal Protective Equipment

5. ROLES AND RESPONSIBILITIES

The Facilities & EHS department is responsible for implementation of the BBP program and this Exposure Control Plan. They will maintain, review and update the Exposure Control Plan at least annually, or whenever necessary, to include new or modified tasks and procedures.

Those employees who have been determined to have occupational exposure to blood or other potentially infectious materials must comply with procedures and work practices outlined in this Exposure Control Plan.

The Service and Repair department will maintain and provide all necessary personal protective equipment (PPE), engineering controls, labels and other equipment (i.e. red bags) as required by this plan. They will also ensure that adequate supplies of PPE and equipment are available in the appropriate sizes.

The Human Resources department will be responsible for ensuring that all medical actions required are performed and that appropriate employee health and OSHA records are maintained.

The Facilities/EHS department will be responsible for training, documentation of training, and making this Exposure Control Plan available to employees, OSHA and NIOSH representatives, when requested.

6. EMPLOYEE EXPOSURE DETERMINATION

The following is a list of all job classifications at Bioventus in which **all** employees in the job group may have exposure to bloodborne pathogens:

<u>Job Title</u>	<u>Department / Location</u>
Production & Manufacturing Techs	Operations (Memphis, Valencia, Farmingdale)
Assemblers & Machinists	Operations (Memphis, Valencia, Farmingdale)
Material Handlers	Operations (Memphis, Valencia, Farmingdale)
Service & Repair Techs	Operations (Memphis, Valencia, Farmingdale)
Facilities & Maintenance Techs	Operations (Memphis, Valencia, Farmingdale)
Janitorial Staff	3 rd Party Contractor (Facilities)
Laboratory Techs	QC (Memphis, Valencia, Farmingdale)
Sales Associates	Commercial Sales (US, International)

The following is a list of job classifications at Bioventus in which **some** employees in the job group may have occupational exposure.

<u>Job Title</u>	<u>Department / Location</u>	<u>Task / Procedure</u>
Production Supervisors	Operations (Memphis, Valencia, Farmingdale)	Emergency Response
Shipping/Receiving Supervisors	Operations (Memphis, Valencia, Farmingdale)	Emergency Response
Facilities Coordinators	Operations (Memphis, Valencia, Farmingdale)	Emergency Response

Part-time and full-time temporary/contract workers are covered by this plan. All required PPE for work on site will be provided by Bioventus. Training for bloodborne pathogens will also be provided by Bioventus. For temp/contract workers employed by a third party, Hepatitis B vaccinations will be provided by their employer, as per agreement with Bioventus LLC.

7. METHODS OF IMPLEMENTATION AND CONTROL

7.1. Training and Program Reviews

Employees covered by the bloodborne pathogens standard will receive training on this plan upon commencement of their employment, and annually thereafter. All employees may review this plan at any time during their work hours by contacting the Director, Facilities, Maintenance and EHS. If requested, Bioventus will provide an employee with a copy of this Exposure control plan within 5 days of the request.

The Director, Facilities, Maintenance and EHS is responsible for reviewing and updating the Exposure Control plan annually, or more frequent if necessary. Updates should be made to reflect any new or modified tasks and procedures which affect occupational exposure, and to reflect new or revised employee positions with occupational exposure.

7.2. Universal Precautions

All employees shall utilize universal precautions. Universal precautions are a common approach to infection control, in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens.

7.3. Engineering Controls and Work Practices

Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens.

Engineering controls are controls that isolate or remove the bloodborne pathogen hazard from the work place. Examples of engineering controls are: sharps disposal containers, self-sheathing needles, and red bag containers for biohazardous waste.

Work practice controls are controls that reduce the likelihood of exposure by altering the manner in which a task is performed. Examples of work practice controls are: enforcing hand washing procedures following the removal of gloves, restricting eating and drinking in work areas; and decontaminating equipment before servicing.

Bioventus will identify the need for changes in engineering control and work practices through review of OSHA records and incidents and through routine EHS inspections performed by production, maintenance and management employees. The Director, Facilities, Maintenance and EHS will ensure effective implementation of these recommendations.

The following engineering and work practice controls will be utilized by Bioventus as part of this plan:

7.3.1. Handwashing

Even if there is no known exposure, all employees are required to wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment. Alcohol based hand sanitizer may be used for disinfection if hands are not visibly soiled.

Following exposure to blood or other potentially infectious materials, employees shall wash hands and any other exposed skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible.

7.3.2. Work Area Restrictions

In work areas where there is a reasonable likelihood of exposure to blood or other potentially infectious materials – production, quality, laboratory and warehouse areas – employees are not permitted to eat or handle contact lenses. Employees may have water in these work areas, as long as they remain in a sealed container. In laboratories, food and beverages are not to be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials could be present.

7.3.3. Sharps Containers & Biohazardous Waste Containers

Contaminated sharps, including needles, broken glass or other sharp items contaminated with blood or other potentially infectious body fluids will be disposed of in sharps containers. Sharps containers will be puncture resistant, labeled with a biohazard label, leak proof, and shall be disposed of according to regulatory requirements.

Contaminated PPE or other materials that are contaminated with blood or other potentially infectious body fluids will be disposed of in a biohazardous waste receptacle (i.e. red bag), and disposed of according to regulatory requirements.

Receptacles for sharps and biohazardous waste will be kept in first aid areas (located in OPS2 Production, OPS4 Warehouse and Office areas). The Facilities/Maintenance department will be responsible for inspecting, maintaining and replacing sharps and biohazardous containers on a regular frequency, to prevent overfilling.

7.3.4. Contaminated Equipment

Equipment which has become contaminated with blood or other potentially infectious material shall be examined prior to servicing or shipping and shall be decontaminated as necessary unless the decontamination of the equipment is not feasible.

Any returned Bioventus product shall be decontaminated according to [WIN-000351] prior to servicing or shipping.

7.3.5. Personal Protective Equipment

PPE is provided to employees at no cost to them. PPE 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. Training for PPE is provided by the Facilities/EHS Department and covers the use of the appropriate PPE for the tasks or procedures employees will perform.

The types of PPE available to employees, depending on their role, includes: safety glasses, gloves, face shields and lab coats. They may be obtained through the Facilities/EHS Department.

All employees using PPE must observe the following precautions:

- Wash hands immediately or as soon as feasible after removal of gloves or other PPE.
- Remove PPE after it becomes contaminated, and before leaving the work area.
- Used PPE may be disposed of in biohazardous containers, if contaminated.
- Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or other potentially infectious body fluid, and when handling or touching contaminated surfaces.
- Replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
- Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- Never wash or decontaminate disposable gloves for reuse.
- Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or other potentially infectious body fluids pose a hazard to the eye, nose, or mouth.
- Remove immediately or as soon as feasible any garment contaminated by blood or other potentially infectious material, in such a way as to avoid contact with the outer surface.

7.3.6. Housekeeping

Regulated waste (contaminated sharps / biohazardous waste) will be placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded, and closed prior to removal to prevent spillage or protrusion of contents during handling.

The Facilities/EHS department is responsible for inspecting, replacing and properly disposing of regulated waste containers that are full.

Contaminated sharps shall be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof on sides and bottoms, and labeled or color coded appropriately.

Broken glassware which may be contaminated should be picked up using mechanical means, such as a brush and dust pan.

8. HEPATITIS B VACCINATIONS

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 series will be available after employees complete BBP training and within 10 days of initial assignment.

The Facilities/EHS Department will provide training to employees on Hepatitis B vaccinations addressing the safety, benefits, efficacy, methods of administration, and availability.

Vaccination is encouraged unless:

1. documentation exists that the employee has previously received the series
2. an employee wishes to submit to antibody testing which reveals that the employee is immune, or
3. medical evaluation shows that vaccination is contraindicated.

However, if an employee chooses to decline vaccination, the employee must sign a declination form (Appendix 1). Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept as part of the employee's HR file.

Vaccination will be provided by each site's third-party employee medical provider/clinic.

9. POST-EXPOSURE EVALUATION AND FOLLOW-UP

Should an exposure incident occur, employees should contact their people manager, HR Benefits Manager and the Director, Facilities, Maintenance and EHS.

An immediately available confidential medical evaluation and follow-up will be conducted by the site's third-party medical provider/clinic.

Following initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

- Document the routes of exposure and how the exposure occurred.
- Identify and document the source individual (unless established that identification is infeasible or prohibited by state or local law).
- Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
 - If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.

- Ensure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
- After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status.
 - If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

10. ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

The HR Department and employee's supervisor ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard.

The HR Department and employee's supervisor ensures that the health care professional evaluating an employee after an exposure incident receives the following:

- a description of the employee's job duties relevant to the exposure incident
- route(s) of exposure
- circumstances of exposure
- if possible, results of the source individual's blood test
- relevant employee medical records, including vaccination status

The medical provider will provide the employee with a copy of the evaluating health care professional's written opinion within 15 days after completion of the evaluation. A copy of this should also go to the HR Department

11. PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AND EXPOSURE

The employee's supervisor will review the circumstances of all exposure incidents to determine:

- engineering controls in use at the time
- work practices followed
- protective equipment or clothing that was used at the time of the exposure incident (gloves, eye shields, etc.)

- location of the incident
- task being performed when the incident occurred
- employee's training

The employee's supervisor will provide an incident report to the Director, Facilities, Maintenance and EHS, who will make the necessary reporting as required. If it is determined through the incident investigation, that revisions need to be made to this Exposure Control Plan, the Director, Facilities, Maintenance and EHS will ensure that appropriate changes are made. (Changes may include adding employees to the exposure determination list, etc.)

12. EMPLOYEE TRAINING

All employees who have been identified in this plan to have occupational exposure to bloodborne pathogens will receive training upon initial assignment, and annually thereafter. The training will be conducted by the Director, Facilities, Maintenance and EHS or local HR Manager.

Training will include the following:

- Epidemiology and symptomatology of bloodborne diseases
- Modes of transmission of bloodborne pathogens
- The Bioventus Exposure Control plan
 - Points of the plan
 - Lines of responsibility
 - How the plan will be implemented
- Tasks that might cause exposure to blood or other potentially infectious materials at this facility(s)
- Control methods which will be used in the facilities to control exposure to blood or other potentially infectious materials.
- Personal protective equipment available
- Post-exposure evaluation and follow up
- Signs and labels used that the facility
- Hepatitis B vaccine program

13. RECORDKEEPING

Training records will be completed for each employee upon completion of training. These documents will be kept for at least three years by the Facilities/EHS department.

The training records must include:

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

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to the Director, Facilities, Maintenance and EHS.

14. MEDICAL RECORDS

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records." The HR Department is responsible for maintenance of the required medical records. These confidential records are kept in the employee's HR record for at least the duration of employment plus 30 years.

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to the HR Department

15. OSHA RECORDKEEPING

An exposure incident is evaluated to determine if the case meets OSHA's Recordkeeping Requirements (29 CFR 1904). This determination and the recording activities are performed by the Director, Facilities, Maintenance and EHS.

APPENDIX 1. HEPATITUS B VACCINATION DECLINATION

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.

Signed: __ (Employee Name) _____

Date: _____

Document Detail

Type: Procedures

Document No.: PCD-000559[A]

Title: Bloodborne Pathogens Exposure Control Plan

Owner: BARRY.MITCHELL Barry Mitchell

Status: RELEASED

Review

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off Date</u>	<u>Sign-off By</u>
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1	BV Doc Owner / Author BV Doc Owner / Author	BARRY.MITCHELL Barry Mitchell	07-Feb-2024 6:10 pm	BARRY.MITCHELL
1	BV Doc Approver BV Doc Approver	MELISSA.BAKER Melissa Baker	12-Feb-2024 5:00 pm	MELISSA.BAKER
1	BV Regulatory Affairs BV Regulatory Affairs	KELLIE.STEFANIAK Kellie Stefaniak	13-Feb-2024 8:50 pm	KELLIE.STEFANIAK
1	BV Doc Approver BV Doc Approver	MARK.SCHAEFER Mark Schaefer	12-Feb-2024 7:04 pm	MARK.SCHAEFER
1	BV Doc Approver BV Doc Approver	KATRINA.CHURCH Katrina Church	07-Feb-2024 5:40 pm	KATRINA.CHURCH
2	BV Configuration Analyst BV Configuration Analyst	AMBER.PLOTNER Amber Plotner	14-Feb-2024 4:22 pm	AMBER.PLOTNER