Bloodborne Pathogens Exposure Control Plan

Number: NARP-8.010

H&S Management System: NAR H&S Management System

Effective Date: 7/1/2024

1.0 PURPOSE and SCOPE

1.1 Purpose

Bloodborne pathogens are infectious microorganisms in human blood that can cause disease in humans. All employees with potential occupational exposure are entitled to protection of occupational exposure to bloodborne pathogens and it is Philips' policy to employ safe work practices to eliminate and/or minimize occupational exposure to bloodborne pathogens. The purpose of this Bloodborne Pathogens (BBP) Exposure Control Plan is to detail exposure control measures including engineering and work practice controls, proper use of personal protective equipment, hepatitis B vaccinations and to provide training and other measures which can be used to control potential occupational exposures to bloodborne pathogens for individuals working for or on behalf of Philips North America.

1.2 Scope

☒ North America Market Org.		

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3.0 LEGAL AND OTHER REQUIREMENTS

3.1 External Regulatory Requirements

- United States (US) Occupational Safety and Health Administration (OSHA) Regulation 29 CFR 1910.1030, “Bloodborne Pathogens”
- Canada Occupational Safety and Health Regulations (SOR/86-304).

3.2 Internal Requirements

- PCSS 3.015, Handling Bloodborne Pathogens and Other Potentially Infectious Materials

4.0 ROLES / RESPONSIBILITIES

Role	Responsibility
EHS	• Assist management in selection of appropriate safety control measures, including safe work practices, procedures, PPE, engineering controls and training. • Conduct accident investigations and implement corrective actions if deemed necessary. • Manage the Hepatitis B Immunization program.
Managers	• Be knowledgeable of the content and provisions of this Bloodborne Pathogens Exposure Control Plan. • Identify employees under their direct responsibility who have potential occupational exposure and therefore, must be included in this Bloodborne Pathogens Program. (See Section 4.1) • Ensure appropriate personal protective equipment (PPE) is both available and in use. • Assist in completion of written documentation in the event of an exposure incident involving an employee under their responsibility. • Assist EHS Engineer on post exposure incident investigations and provide information any tasks and job classifications not already identified in this document.
Occupational Health Nurse	• Provide counseling in support of training and during post exposure incidents. • Review exposure incidents and manage post exposure evaluations and follow-up. • Ensure proper recording of exposure incidents on the injury/illness logs.

Role	Responsibility
Employees	• Be knowledgeable and comply with the content and provisions of this Exposure Control Plan. • Be knowledgeable and comply with the content found in NARP-8.030 Infection Control Policy. • Complete all training as assigned. • Complete and submit the Field Hepatitis B Immunization Accept/ Decline form NARF-8.031 as required for US employees only. • Practice Universal Precautions. • Seek immediate medical attention in the event of an exposure incident and follow up with a prompt report of the incident to their supervisor, the customer, and to the Philips Occupational Health Nurse.

5.0 OPERATIONAL CONTROLS

5.1 Exposure Determination

5.1.1 Job Classifications

There are no job classifications in which ALL employees are considered to be occupationally exposed. The following job classifications have been identified to include employees with the potential for occupational exposure to BBP or OPIM:

- Field Service Engineers
- Clinical Application & Education Specialists
- Sales / Marketing Demonstration
- Sales Representatives
- Clinical Product Specialists
- Managers in Field Service, Sales and Operations
- Equipment Refurbishment / Repair Technicians
- Employees, regardless of job classification, who perform any of the tasks listed below.

5.1.2 Occupational Exposure Tasks

The following tasks have been identified as having the potential to cause occupational exposure to BBP or OPIM.

- Working in areas where body fluids are present in or around Philips' equipment such as patient care rooms, operating rooms, and other hospital/clinic patient areas.
- Handling products or parts returned from patient care sites such as hospitals, clinics and bio-labs before the parts/products have gone through the decontamination process.
- Handling potentially contaminated equipment, products, or parts.
- Providing first-aid / CPR as a "designated" responder.

5.2 Methods of Exposure Control

Various strategies are available to control hazards and minimize risk of exposure to bloodborne pathogens. These include applying Universal Precautions, making use of available engineering controls, using work practice controls, using PPE and proper management of housekeeping and waste.

5.2.1 Universal Precautions

Universal Precautions should be followed at all times. Universal Precautions require that all human blood and unknown body fluids be treated as if they were infectious.

5.2.2 Other Potentially Infectious Material (OPIM) means:

- 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); and
- 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.

5.3 Engineering Controls

Engineering Controls are devices or equipment that eliminate or minimize exposure by isolating or removing the bloodborne pathogens hazard from the workplace. In the clinical environment, a sharps container is a common engineering control.

5.4 Administrative Controls

Administrative controls, also called work practice controls, include activities such as:

- Actively surveying work environment for potential BBP or OPIM;
- Inspecting carefully for sharps, needles, sharp edges, nails etc. in the work environments, in and around product equipment;
- Not reaching blindly areas (areas not readily visible) where BBP or other OPIM could exist without proper PPE;
- Washing hands and any other exposed skin with soap and water immediately upon removal of PPE, after decontamination and after any potential contact with blood or OPIM

- Housekeeping: Ensure facilities, work areas and equipment are kept in a clean and sanitary condition and waste materials properly managed.

- Promptly requesting site personnel to decontaminate surfaces that may have become contaminated with blood or OPIM; this includes, to the extent feasible, the decontamination of parts or equipment prior to servicing or sending to other recipients such as vendors or refurbishment centers.

- Prohibiting eating, drinking, smoking, applying cosmetics/lip balm and handling contact lenses in work areas where potentially contaminated product / equipment is present.

- Cleaning and disinfecting surfaces, material or equipment that presents the potential for exposure to bloodborne pathogens or other OPIM. This includes, to the extent feasible, the decontamination of parts or equipment prior to servicing or sending to other recipients such as vendors or refurbishment centers.

5.5 Personal Protective Equipment (PPE)

PPE consists of clothing or equipment that prevents direct contact with blood or other body fluids. PPE may include gloves, eye protection, gowns, laboratory coats, aprons, face shields, masks, and other gear. PPE account set up and ordering information may be found in NARP 8.240 Personal Protective Equipment policy. See Appendix B for PPE requirements, additional PPE may be required by the Customer to enter specific areas of the Customer site, operating rooms, patient rooms, etc.

- Gloves (Nitrile or Latex) shall be worn if hand contact is reasonably expected with blood, OPIM, other body fluids, or with contaminated surfaces.

- Disposable, single-use gloves shall not be washed or decontaminated for re-use.

- Gloves are to be changed as soon as possible after they are damaged or contaminated.

- Eye protection, face shields and masks shall be worn whenever it is likely that blood or other body fluids might splash, spray or splatter into eyes, nose, or mouth. Or as required by a customer site.
- Other protective clothing such as gowns, aprons, surgical caps, hoods, and shoe covers shall be worn when gross contamination is expected, such as in a hospital operating room or as required by the site.

5.6 Contaminated Equipment

It is the responsibility of the healthcare facility to properly decontaminate its medical device equipment, patient rooms, operating rooms, and other clinical areas. Philips North America employees have the right to request that facility personnel (Site Infection Control) to decontaminate a medical device or other grossly contaminated area, prior to entering the area

and/or handling or repairing the medical equipment. However, this may not always be possible, therefore, the following apply:

- All rules and/or guidelines of the healthcare facility where the decontamination procedure is taking place must be followed at all times.
- For heavily contaminated products or equipment, contact the Facility's Environmental Services or Infection Control Department to decontaminate the product/area. Do not attempt decontaminate if employee health and safety is at risk!
- Contaminated sharps shall be removed from the equipment and placed in containers that are closable, leak proof, puncture resistant, red in color and/or labeled with the biohazard legend while wearing disposable gloves. (Sharps Containers)
- Contaminated cleaning materials and gloves should be discarded into receptacles designated as biohazardous regulated waste.
- Contaminated materials that cannot be decontaminated such as patient positioning straps and pads should be disposed of as biohazardous regulated waste.

5.7 Disinfection of Environmental Surfaces / Equipment

This Exposure Control Plan does not prescribe specific disinfecting materials but references the Center of Disease Control approved disinfectants of environmental surfaces at healthcare facilities. Ensure to pay attention and adhere to the disinfectant label instructions and always don PPE before attempting to disinfect any surface.

Guidelines from the Center for Disease Control for decontamination of spills of blood or OPIM on environmental surfaces:

- Disinfect areas contaminated with blood spills using an EPA-registered tuberculocidal agent, or
- A registered germicide on the EPA's Registered Antimicrobial Products Effective Against Bloodborne Pathogens: Human immunodeficiency virus (HIV), Hepatitis B and Hepatitis C
- Or, if sodium hypochlorite solutions (bleach) are selected use a 1:100 dilution (e.g., 1:100 dilution of a 5.25-6.15% sodium hypochlorite provides 525-615 ppm available chlorine) to decontaminate nonporous surfaces after a small spill (e.g., <10 mL) of either blood or OPIM. (Referenced from: www.cdc.gov)

NOTE: If a spill involves large amounts (e.g., >10 mL) of blood or OPIM à **Do NOT attempt to decontaminate, contact the Site's Environmental or Infection Control Services.**

WARNING! *Equipment specific work instructions should be consulted for materials and procedures compatible with that equipment. Failure to do so may result in loss of functionality or irreparable damage.*

- Washing hands and any other exposed areas of skin immediately upon removal of personal protective equipment after decontamination has occurred and after any contact with blood or OPIM.
- If decontamination is not feasible, and you need to return the equipment refer to Section 7.0 of this document.

5.8 Shipping and Labeling of Contaminated Equipment

If equipment or parts destined for return shipping are expected or may be reasonably anticipated to be contaminated with blood or OPIM, decontamination, as stated in this procedure, is required before any contaminated item or part may be shipped. If decontamination is NOT feasible, proper shipping procedures must be followed to properly contain the contamination, warn downstream recipients, and comply with regulatory requirements.

If decontamination prior to return shipping is not feasible, the biohazard contaminated equipment must be shipped in accordance with this procedure outlined below to comply with OSHA and the Department of Transportation (DOT). This procedure outlines how to box, tag and offer for shipment, a known contaminated part or OPIM. See Addenda A of this document for a quick reference guide.

The following instructions, comply with DOT and OSHA:

1. Apply a biohazard label to the equipment, which identifies or states which specific portion of the equipment has not been decontaminated. Labels are available via PPE process.

2. Place the item into a primary leak proof container (box, bag, etc.) encasing the item to be shipped; if the leak proof container can be punctured it must be placed into a secondary container;

3. Close the leak proof container holding the contaminated equipment;

4. Place an orange or red biohazard label on the outside of the leak proof container.

5. Place the Primary, labeled container, or box into a secondary shipping box. This secondary box does NOT need to be labeled with a bio-hazard sticker and may be offered for shipment per normal shipping procedures.

NOTE: The U.S. Department of Transportation (DOT) 49 CFR 173.134 (b), does not regulated shipments of used contaminated medical equipment as hazardous if it conforms to the

packaging requirements stated above which are in compliance with OSHA 29 CFR 1910.1030. This exemption (173.134 b) does not apply to equipment being sent for disposal. In Canada, if medical equipment that is not a dangerous good is contaminated with a substance that may be potentially infectious, but the equipment is contained in the packaging stated above, it would not be subject to Transportation of Dangerous Goods regulations.

5.9 Waste Disposal

The performance of tasks in accordance with portions of this procedure may result in the generation of materials requiring contaminated disposal. These materials may include but are not limited to PPE, disinfectant materials, and expendable equipment components.

5.9.1 Decontaminated Waste Articles/Disposable Parts

Material or equipment that has been thoroughly decontaminated may be disposed of as ordinary waste.

5.9.2 Disposal of Contaminated Waste

Materials or equipment that are not destined for return shipping and remain contaminated or cannot be decontaminated must be disposed of as regulated waste. This requires placement within a labeled container suitable for such waste. Two types of containers are specified depending upon whether the contaminated materials are sharps or other regulated waste.

Contaminated sharps are to be discarded as soon as feasible in containers that are closable, leak proof, puncture resistant, red in color and are labeled with the biohazard legend.

Other regulated waste is to be placed in containers that are closable, constructed to contain all contents and prevent leakage, red in color and are labeled with the biohazard legend. Ex: Biohazard bag

NOTE: Some materials may be regulated by other criteria such as environmental standards.

5.10 HEPATITIS B VACCINATIONS

5.10.1 Canada

Certain Field roles may result in occupational exposure to bloodborne pathogens through contact with contaminated equipment within the healthcare facility. Hepatitis B is a bloodborne pathogen for which a vaccination is available and may be obtained to protect oneself from obtaining Hepatitis B. If one has already received the Hepatitis B vaccination series, no further

action is needed. The vaccine is HIGHLY effective but there is no guarantee you won't get Hep. B even when vaccinated.

Philips encourages all employees who have the potential to be occupationally exposed to BBP, to obtain the hepatitis B vaccination as a best practice to protect oneself and prevent transmission of the disease. Although such immunization/vaccination is voluntary, it is important to note that anyone who does not obtain the vaccination remains 'At Risk' for acquiring Hepatitis B.

For Canadian employees who would like to o obtain the hepatitis B vaccination series please contact your family's primary care physician or other healthcare provider.

5.10.2 United States

Upon initial assignment, employees must sign and submit the Hepatitis B Immunization Accept/ Decline Form, NARF-8.031, either accepting, declining or stating that he/she has already received the immunizations. Employees who decline the form, are expected to understand that be declining the vaccination, they remain "At Risk" for acquiring Hepatitis B, a serious disease. Any employee initially declining the vaccine may, at any time, later decide to receive the vaccination series which will be provided at no cost to the employee.

5.11 Post Exposure Evaluation and Follow Up

Following any exposure incident, the employee shall immediately:

1. Wash or flush the affected area thoroughly with soap and water; flush splashes of water to the nose, mouth or skin; irrigate eyes with clean water or saline solution;

2. Report to the nearest emergency department or other appropriate Health Care Professional (HCP) for evaluation and treatment, as needed.

3. Report the incident to:

- The Philips Occupational Nurse or Case Manager.
- The employee's Manager
- The customer if the incident occurs at a customer site

4. Ensure all normal procedures are followed for submitting an accident/incident report.

6.0 RISK MANAGEMENT

BBP exposure risk assessments for field roles are documented as per NARP-8.250 Job Hazard Identification and Risk Assessment.

7.0 TRAINING

Training to this policy as well as UL title Bloodborne Pathogens (BBP) will be assigned via Philips University.

8.0 DOCUMENT CONTROL & RECORDS

This document is stored and Managed in the Americas Health & Safety Document Management SharePoint and will be reviewed annually. Vaccination Accept/Decline forms will be stored in the NA H&S SharePoint.

9.0 MANAGEMENT OF CHANGE

If one encounters a different environment than expected or anticipated upon entering the customer premises, STOP WORK and contact/notify the Site for any changes or additional exposure control requirements (PPE etc.).

10.0 TERMS & DEFINITIONS

Term	Definition
Blood	Human blood, human blood components, and products made from human blood.
Bloodborne Pathogens (BBP)	Pathogenic microorganisms that are present in human blood and can cause disease in humans, including, but not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
Contaminated	The presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.
Contaminated Sharps	Any contaminated object that can penetrate the skin such as needles, scalpels, or broken glass.
Decontamination	The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface. As a result, the surface or item is no longer capable of transmitting infectious particles and the surface is rendered safe for handling, use or disposal
Engineering Controls	Mechanical devices that isolate or remove the bloodborne pathogens hazard from the workplace. Includes sharps containers, shielding, or self-sheathing needles.
Exposure Incident	Specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.
Hand Washing Facilities	A facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.
Healthcare Professional (HCP)	A person whose legally permitted scope of practice allows him or her to independently perform Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.
HBV	Hepatitis B Virus

Term	Definition
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
Occupational Exposure	Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.
Other Potentially Infectious Materials (OPIM)	Other Potentially Infectious Materials - Include: human body fluids and human tissue or organs, and any material or equipment that may have been in contact with human body fluids.
Parenteral	Piercing of the skin or mucous membranes through such events as cuts, abrasions or needle-sticks.
Personal Protective Equipment (PPE)	Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard is not considered to be personal protective equipment.
Regulated Waste	Liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.
Source Individual	Any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee.
Universal Precautions	An approach to infection control under which all human blood and all human body fluids are treated as if infectious.
Work Practice Controls	Controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

11.0 REFERENCES

Document Number	Document Name
NARF-8.031	Hepatitis B Immunization Accept/ Decline Form
NARP-8.030	NAR Infection Control Policy
NARP 8.240	Personal Protective Equipment

12.0 REVISION HISTORY

Revision	Description of Changes
A	Change market references from PHNA to NAR. Convert to H&S template.

13.0 ADDENDA

Addenda Letter	Addenda Title
A	NAR Shipping Contaminated Parts/Equipment
B	Safety/Personal Protective Equipment (PPE) Requirements

Addenda A – NAR Shipping Contaminated Parts/Equipment

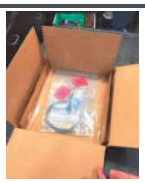
When decontamination is not feasible on equipment which contains either:

1. Known contamination OR

2. Is reasonably expected to be contaminated with blood or Other Potentially Infectious Material (OPIM),

Ensure the following shipping procedure is followed to warn downstream recipients and comply with Department of Transportation and OSHA regulatory requirements.

This quick guide provides step-by-step instructions to compliantly prepare and offer for shipment an item that is known or reasonably believed to be contaminated.

How to Ship Contaminated Parts			
1	**Don PPE**		➔ Put on Personal Protective Equipment.
2	**Primary Leak Proof Container**		➔ Drain any free liquid if necessary and then place the contaminated equipment into a primary leak proof container (box, bag, etc.)
3	**Label Primary Container**		➔ Close the leak proof container ➔ Label primary container with biohazard label.
4	**Label Secondary Container**		➔ Place primary labeled container into a secondary container. The secondary container must be watertight. ➔ Label Secondary Container with biohazard label
5	**Internal Packaging**	 	➔ Pack the secondary container into a shipping box, with sufficient cushioning material to prevent movement.
6	**Include Contamination List**		➔ Include a List in the shipping box Identifying: 1. Item Contaminated i.e.: **"Pot"** 2. Type of Contamination, if known: i.e. **"Blood"** 3. Specific location of the contamination on the part i.e.: **"Inside Internal Connection"**

7	**Offer for Shipment**		➔ Prepare for shipment per normal shipping/return procedures. **NOTE**: Do NOT put a biohazard label on the shipping box! *When packed as outlined in this document, contaminated equipment may be offered for shipment per normal shipping procedures.*

Addenda B - Safety/Personal Protective Equipment (PPE) Requirements

Based upon an assessment of workplace hazards, the following is the minimum level of personal protection required for the hazards and/or the operations listed. Each employee is expected to wear the minimum protection listed below when exposed to the particular hazard or involved in the specific operation.

Hazard or Operation	Safety/Personal Protective Equipment Required[3]			
	Eyes/Face[1]	Hand	Body	Other
Bloodborne Pathogens or Other Potentially Infectious Materials	Combinations of masks, face shields and safety glasses with solid sideshields or chemical splash-goggles if splash, splatter, spray or droplets of body fluids can be reasonably expected	Disposable nitrile or latex[2] gloves if hands might come into contact with blood or infectious materials or with potentially contaminated surfaces	A gown, lab coat or apron to keep contamination away from the body or outer coating when gross contamination can be reasonably expected.	

Footnotes: [1] In the U.S., the protective eyewear must be marked with a trademark identifying the manufacturer and with "Z87" indicating that it has been manufactured in accordance with ANSI Z87. In Canada, eye or face protectors that meet the standards set out in CSA Standard Z94.3-M1982, Industrial Eye and Face Protectors, shall be used.

[2] Instead of latex, using nitrile gloves, which are also impermeable to blood and other infectious materials, will eliminate the latex allergy risk from using latex PPE.

[3] At customer sites, if the customer's level of PPE exceeds that in the table above, wear the same level of protection as the customer.

REMEMBER: Use the PPE that will protect you from any reasonably anticipated exposure.