SAFETY MANAGEMENT PLAN
FOR
HAZARDOUS BIOLOGICAL MATERIALS
AT THE
DUKE UNIVERSITY HOSPITAL AND CLINICS
2016

I. Introduction

The Hazardous Biological Materials Management Plan defines the mechanisms for oversight for controlling exposures to biological materials in the workplace. The related policies and procedures are developed to provide guidance for worker safety when handling or exposure to biological agents. The policies are based on regulatory requirements or current safety guidelines. This Plan applies to Duke University Hospital and Clinics, the Private Diagnostic Clinics (PDCs), the Duke Primary Care practices, and the Clinical Laboratories.

II. Organization of Participants

The administration and oversight of occupational safety management for handling biological hazardous materials is primarily the responsibility of the Biological Safety Division of the Occupational and Environmental Safety Office. Specific responsibilities for members of this Division include:

- Patient Care Workers - Biological Hazards, EOC: Janis Matthews, MT(ASCP)SM, MPH
- Patient Care Workers - Biological Hazards, EOC: Gina Green, RN, MSN, CCM
- Laboratory Workers – Biological/Chemical Hazards: Mary Brock, BS, RBP
- Laboratory Workers - Biological/Chemical Hazards: Rashida Lawrence, MPH, SLS (ASCP), RBP
- Both Lab Workers and Hospital – Biological/Chemical And EOC review: Catherine Joyner, MS
- All workers – Laboratory Safety, BBPs: Raymond Hackney, DrPH, CIH, CBSP
- All workers – IBC, Select Agents, BBPs, administration: Debra Hunt, DrPH, MT(ASCP), CBSP

The administration and oversight of patient exposures to and infection with biological agents is the primary responsibility of the Hospital Infection Control Unit.

III. Management (IC.01.03.01, EP 1-5, IC.01.04.01, EP 1-4, and IC.02.01.01, EP 1.2)

A. Patient Care. The primary policies for managing biological hazards in the Duke University Hospital and Clinics, and the PDCs, include the Bloodborne Pathogens Exposure Control Plan and the TB Exposure Control Plan. These policies are found in the Duke University Safety Manual (Section VI), the Duke University Laboratory Safety Manual, and the Hospital Infection Control Manual. Both of these plans are subject to annual update and approval by the DUSC and the HICC.

B. Laboratories. The primary policies for managing biological hazards in the Hospital Clinical Laboratories are included in the Duke Clinical, Departmental, and Core Lab Safety Manual, and are based on the Bloodborne Pathogens Exposures Control Plan, the CDC/NIIH Guidelines for Biosafety in Biomedical and Microbiological Laboratories, the guidelines of the Clinical and Laboratory Standards Institute, and the standards of the College of American Pathologists. Policies for other Duke University Health Systems laboratories are included in the Duke University Laboratory Safety Manual.
C. **Integration with Infection Control.** Based on both the past experience with Biological Materials being a part of the management process for the Environment of Care (EOC) and the necessary interactions with many of the EOC functions, Biological Materials will continue to be integrated in the overall planning and management of the EOC under the Safety Management Plan and the Hazardous Materials and Wastes management Plan. Integration with the relevant Infection Prevention/Control standards and the elements of performance will be achieved through collaboration between the DUSC and the Hospital Infection Control Committee (HICC). The Chair of the DUSC is a standing member of the HICC and the Infection Prevention Department is represented on the membership of the DUSC. In addition, the function leaders for Biological Materials and Wastes will be invited to present appropriate updates to the HICC.

IV. **Biological Safety Management Activities**

A. **Risk Assessment.** Assessment of risk for the Biological Safety management activities are accomplished through a number of audits and data collection. All hospital inpatient units, clinics, and support departments are subject to a comprehensive safety audit on a semi-annual basis. The audits (the Joint Commission (JC) Environment of Care Surveys) assess the hazards, the control measures, and employee knowledge regarding biological safety in the workplace, as well as other EOC safety concerns. Results are reviewed and reported to the DUSC, which allows prioritization of improvement projects.

The Clinical Laboratories are audited by the Laboratory Safety Group for compliance with CAP expectations. All Research Laboratories are audited annually or as needed for safety compliance with appropriate Laboratory standards (CDC Biosafety in Microbiological and Biomedical Laboratories, OSHA Lab Standard, Select Agents and Toxins Regulation, etc.).

Additional risks are determined during quarterly review of blood/body fluid exposure data that have been reported to Employee Occupational Health and Wellness. Such review determines the need for interventional activities to prevent such exposures, such as re-evaluation of safer sharps devices or training.

B. **Reporting.** Specific reporting responsibilities include seeking Duke University Safety Committee review and approval of the planning objectives of the Biological Safety Division, along with an end-of-year summary of progress toward accomplishing those objectives (program effectiveness evaluation). The DUSC also approves the Performance Improvement (PI) Plan for the Division, along with quarterly reporting of the monitoring results, and routine reporting of safety management activities such as response to individual incidents, training, or monitoring results. This information is communicated to the governing body through routine reports to the Executive Committee of the Medical Center and the Medical Center Trustees Committee.

C. **Policy Development and Periodic Review.** All policies related to the management of biological hazardous materials in the workplace setting are submitted to the DUSC for consideration and approval, with final approval from the Executive Committee of the Medical Staff (ECMS).

The Duke University Bloodborne Pathogen Exposure Control Plan and the TB Exposure Control Plan are reviewed and approved by the DUSC and the Hospital Infection Control Committee at least annually. They are located in the Duke University Safety Manual and the Infection Control Manual and are found on the safety website (www.safety.duke.edu).

D. **Planning Objectives.** The Director of the Biological Safety Division is responsible for the development of annual Planning Objectives for the Division. These objectives are developed in accordance with the mission of the Institution, the objectives of the Department, any applicable laws or regulations, and all relevant accreditation standards; and they define the focus for resource utilization by the Division. Many of the objectives include measurable outcomes and, thus, establish performance standards for the Division. The Biological Safety Planning Objectives are submitted to the Duke University Safety Committee for annual approval.
E. **Incident Reporting/Emergency Response.**

1. **Incident Reporting.** All occupational exposures to or injuries from biological materials are to be reported by employees to the Employee Occupational Health and Wellness Services (EOHW). All occupational injuries are reported to the Workers’ Compensation Office using an AO-16 Accident and Injury Report form and/or the on-line Safety Reporting System (SRS). Additionally, workers experiencing blood or body fluid exposures are encouraged to report such injuries through the 24 hour Exposure Hotline (115 or 684-8115, off-site) and the Safety Reporting System on-line (SRS). Potential employee exposures to TB are followed by Biological Safety personnel through chart review and contact of supervisors in the affected areas of exposure.

Exposure definitions and follow-up procedures are included in the Bloodborne Pathogens Exposure Control Plan, the TB Exposure Control Plan, and other protocols as found in the Infection Control Manual. The Biological Safety Division evaluates reported exposures and monitors trends. Many of the Planning Objectives and PI Projects of the Division involve routine evaluation and improvement activities aimed at reducing such exposures.

2. **Information regarding reporting of exposures and reduction of exposures to bloodborne pathogens and TB is found on the Biological Safety Poster posted in all major areas of the hospital, as well as the Safety Manual and Infection Control Manual.**

3. **Emergency Response.** Information regarding spills of biohazardous materials is provided in the Emergency Response & Incident Reporting Guide, and the Bloodborne Pathogens ECP.

F. **Training.** Policies and procedures for handling biohazardous materials are included in the new employee Orientation and annual update training programs. Orientation training includes all OSHA required training for Bloodborne Pathogens and Tuberculosis, such as hazards, selection of personal protective equipment, epidemiology, symptoms, exposures and reporting, spill clean ups, regulations, and methods of exposure control specific to Duke. Update training programs utilize information gathered from audits, exposure data, and PI projects that reflect experience with change in risk or control procedures.

V. **Performance Monitoring.**

A. **Performance Improvement Plan (PI).** The Director of the Biological Safety Division is responsible for development of the Performance Improvement Plan, which is based on the priorities identified by the Division and the DUSC. The DUSC approves the Plan each year, and all PI activity is reported at least quarterly to the DUSC. For PI activities for the Biological Safety Division, see the Biological Safety Performance Improvement Standards.

B. **Effectiveness Monitoring.** In addition to the PI activities and reporting, the effectiveness of the biological safety management program is assessed through a number of audits and data collection. Primarily, reported employee blood/body fluid exposure data are entered and evaluated through the EPInet database. Compliance with EOHW requirements for biological issues (N95 respirator fit-testing, tuberculin skin testing) are monitored through the OESO Safety Management System (SMS). PI activities are based on the quarterly evaluation of the data in EPInet and the SMS. In addition, Environment of Care survey data is presented quarterly to the DUSC for monitoring purposes for a number of safety issues, including biological.

VI. **Performance Improvement Standards.** Many of the Planning Objectives of the Biological Safety Division include measurable outcomes, and establish Performance Improvement Standards for the handling of hazardous biological materials. Performance standards are also incorporated into the PI
Plan for the Division. The Performance Improvement (PI) Standards or Monitored Activities for 2016 for the handling of biological hazardous materials in the workplace include the following:

A. **Monitored. Reported blood or body fluid exposures that pose a high risk for bloodborne pathogen transmission.** High-risk blood or body fluid exposures will be closely reviewed and monitored for impact of reduction strategies, such as implementation of safety devices. High risk devices include:
   1. IV catheter needles
   2. Winged steel needles (“butterflies”)
   3. Phlebotomy needles
   4. Capillary Tubes
   5. Hypodermic needles used for blood transfer
   6. Blood Gas Needles

Data is determined from the 1998 through 2016 Employee Exposure Surveillance Information through the NaSH surveillance system (until 1/2015), then the EPInet database. The percentage of reduction of reported exposures associated with the high risk devices since has been stabilized for the past several years (60-68% reduction). In 2015, there was a 74.8% reduction.

B. **Monitored. Reported blood or body fluid exposures from hypodermic needles/syringes.** Needlesticks from hypodermic needles/syringes represent the second highest percentage of reported exposures. Safety hypodermic needles were implemented housewide by December, 2002. Data will be monitored to determine impact. Baseline data was determined from 1998 through 2001 employee exposure surveillance information (NaSH). Because of the increasing numbers of employees and facilities in Duke Medicine over the years, the Biological Safety Division reviewed the rate of injuries per 100,000 hypodermic needles/syringes per year from 2008 through 2014, and discovered there was not a significant nor consistent increase in that time period. The Biological Safety Division will monitor these numbers for this management plan. In 2015, there was a reduction of 24% in the number of reported exposures associated with these devices.

C. **Performance Improvement. Reported blood or body fluid exposures from housestaff from sharps in the Operating Rooms.** Such exposures to be monitored include injuries from suture needles, scalpels, and other sharp objects. The EPInet surveillance system allows review of such exposures on a quarterly basis. Baseline data was determined from the 1998 through 2014 Employee Exposure Surveillance Information through NaSH. The 2015 goal was to monitor the reduction in numbers of injuries due to sharps since 2005, the year that the OR safety committee was established. Since most of the percutaneous injuries in the OR are associated with suture needlesticks to housestaff, Biological Safety has focused on the review of the # of suture needle injuries and the rate of all exposures per 1000 employees. Therefore, the Biological Safety Division will work with the housestaff office and EOHW to establish best parameters for measurement based on the 2015 data analysis. The rate of suture needle injuries per 1000 housestaff employees for 2015 was 59.7. This rate will be used as the baseline to determine improvements.

D. **Performance Improvement. Compliance rates for annual airborne N95 respirator fit-testing for tuberculosis (TB) and annual TB skin testing (TST) to meet a minimum level of 90% in 2013.** Compliance values for these two requirements were collected through 2015. The OESO Safety Management System was utilized to obtain the baseline data and will be used on a quarterly basis to monitor the improvements in compliance rates as current risk classifications are updated and corrected and individuals and departments are collaborated with to increase compliance with these two EOHW requirements. In 2015, the N95 respirator fit-testing compliance rate for all employees was 85.8%, and the goal was 90%. The goal for 2016 will continue to be 90% compliance. The annual TST compliance rate for all employees in 2015 was 89.3% and the goal for 2016 will remain at 90%. 
VII. Management Plan Evaluation. The Director of Biological Safety will evaluate the Biological Safety management Plan annually for its scope, objectives, performance, and effectiveness. Any changes in scope will be addressed during the annual update of the Plan, and any changes in the range of application or interactions will be incorporated into the updated Plan.

A. Annual planning objectives will be developed through interactions with the Division employees, the DUSC members, and hospital administration. These objectives will address the primary operational initiatives for maintaining and enhancing the “biological safety” of the Environment of Care. Progress toward accomplishing these objectives will be reported at least quarterly to the DUSC. The Planning Objectives for 2016 for Biological Safety include:

a. Continue to enhance the monitoring tools and methods of prevention for blood-contaminated suture injuries to housestaff in the operating rooms and the rates of compliance for respirator fit-testing for minimization of TB exposures and TB skin testing.
b. Continue to support regulatory compliance via the audit processes (EOC and Lab Safety). Ensure that any deficiencies are being addressed in a timely manner with the department(s) responsible.
c. Continue to work with the OESO IT team to implement better methods to track lab safety compliance information through a “scorecard” approach that analyzes results and follow-up from annual lab safety audits recorded in the lab safety management database.
d. Review the 2015 Laboratory Safety Survey results and focus on common issues expressed by responders. These may include more appropriate safety training modules on-line that address specific needs of researchers instead of required comprehensive training that may include extraneous information. This may also include more inclusion of laboratory staff in the safety audit process instead of only the laboratory safety contact.

B. A year-end summary of the effectiveness in accomplishing these objectives will also be presented.

C. The performance of the Plan will be assessed through progress in achieving the Performance Improvement Standards defined within the Plan. The annual evaluations, updates, and planning efforts will be presented for DUSC review and action during the first quarter of the new “calendar” year.