

**SAFETY MANAGEMENT PLAN
FOR
HAZARDOUS BIOLOGICAL MATERIALS
AT THE
DUKE UNIVERSITY HOSPITAL AND CLINICS
2025**

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 Duke Health Integrated Practice, 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	Sarah Mikati, MSN, RN
Patient Care Workers & Laboratory Workers – Biohazards	Andrea Vogel, PhD, CBSP(ABSA)
Patient Care Workers & Laboratory Workers – Biohazards	Collin Coleman, PhD
Patient Care Workers —Biological Hazards, EOC	Zacariah (Zac) Cole, MPH
Laboratory Workers – Biological/Chemical Hazards,	Mary Brock, BS, RBP, CBSP(ABSA)
All workers – IBC, DURC, Select Agents, BBP, Admin.	Antony Schwartz, PhD, CBSP, SM(NRCM)

The administration and oversight of patient exposures to and infection with biological agents is the primary responsibility of Duke Infection Prevention and Hospital Epidemiology.

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 DHIP, include the Bloodborne Pathogens Exposure Control Plan and the TB Exposure Control Plan. Both plans are subject to annual update and approval by the DUSC and the HICC. These policies are found in the Duke University Safety Manual (Section VI), the Duke University Laboratory Safety Manual, and the Hospital Infection Control Manual.
- 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 latest edition of the CDC/NIH Guidelines for Biosafety in Biomedical and Microbiological Laboratories (BMBL), 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 an 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 Division and the Biological Safety Division 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.) by the Laboratory Safety Division or the Biological Safety Division.

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 (DUSC) 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 is 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 919-684-8115, off-site) and the Safety Reporting System on-line (SRS). Potential employee exposures to TB are followed by Biological Safety personnel through chart review, contact of supervisors in the affected areas of exposure, and recommendations for Employee Health follow-up.

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 Emergency Response & Incident Reporting Guide 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. Updates to 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 data collected in collaboration with EOHW. Compliance with EOHW requirements for biological issues (N95 respirator fit-testing,) are monitored through the OESO Safety Management System (SMS). PI activities are based on the quarterly evaluation of the data 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 hazards.

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 for 2025 for the handling of biological hazardous materials in the workplace include the following:

- A. Reported blood or body fluid exposures to housestaff from suture needles.** The data collection efforts in collaboration with EOHW allows us to review trends of specific exposures on a quarterly basis. Biological Safety has focused on reducing the rate of suture needle injuries per 1000 house staff employees because this is the highest type of injury. The rate in 2015 was 58 and

has been set as the baseline. From 2016 to 2020, the 5-year average was 50.2, with the highest being 74 (2017) and the lowest being 31 (2019). In 2021, 2022 and 2023, the rate was 52, 48 and 73, respectively. The goal for 2024 was to decrease the injury rate to 50 suture needle injuries per 1000 house staff, however, the total rate in 2024 increased to 94. This rate was higher than any of the previous years. Biosafety is working collaboratively with Graduate Medical Education (GME) to reduce these injuries by tracking injuries down to the program level (where feasible), proposing training tailored to the needs of the individual programs after careful observation of their practices, and holistically assessing the potential for injuries considering factors such as elective versus emergency procedures, simple versus complicated surgical procedures, etc. Additionally, we plan to expend our entire efforts to reduce suture needle injuries. Due to these aggressive efforts, Biosafety, in conjunction with GME, has set the goal for 2025 to reduce suture needle injuries to 40 per 1000 house staff.

- B. Reported blood or body fluid eye exposures to nursing staff.** The number of *eye exposures* relative to total blood and body fluids exposures reported among nursing staff remained relatively high compared to other exposures during 2018 (45/59, 76%), 2019 (44/58, 76%), 2020 (46/76, 60%), and 2021 (56/91, 62%) with an average of 47.75/71 exposures per year, i.e., 67% of the exposures. We have set this as the baseline level. Coincidentally, in the fall of 2021, eye protection for clinical staff was made mandatory due to the COVID-19 pandemic. This gave us a natural data point, the 2022 year, to assess whether instituting mandatory eye protection helped reduce the number of blood and body fluid exposures to the eye. In 2022, the number of eye exposures were 56 out of 83 total exposures, 67%, with 2023 numbers remaining relatively the same. Despite the implementation of mandatory eye protection, the share of eye exposures relative to the total bloody and body fluid exposures remains the same. We will continue to track these exposures to understand why eye protection did not lower the share of eye exposures and implement interventions to assess if there any effects. The goal for 2024 will be to reduce the share of eye exposures to 50% of total blood and body fluid exposures among nursing staff. Biosafety has not been able to address this effort comprehensively in 2024 due to personnel changes and reprioritization of efforts to address federal policy changes. Given that suture needle injuries are trending higher than normal, we will suspend our ‘eye exposure’ efforts temporarily in 2025 to fully focus on reducing suture needle injuries among house staff.

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 2025 for Biological Safety include:
- Assist the Clinical Microbiology (CMB) Laboratory in the Wadsworth Building with annual BSL3 recertification. A primary focus for Biological Safety will be to coordinate with the CMB BSL 3 Containment Laboratories (Mycobacteriology and Mycology) in achieving successful re-certification and to ensure compliance with all safety guidelines and requirements. Additionally, we will assist CMB in developing and implementing procedures for operating the mycobacteriology laboratory at lower containment level when they are not actively working with Mtb.
 - Assist the Laboratory Safety Division with on-going projects. The Biological Safety Division will assist with developing new projects for the Operations Manager of the Division.

- Continue to monitor the blood and body fluid exposure data and survey results for suture needle injuries in house staff, and to work with the Graduate Medical School House Staff Office to enhance methods of prevention. Other exposures will be assessed for potential interventions.
- Continue to support regulatory compliance via the EOC Audit Process in the Hospitals and Clinics. Ensure these deficiencies are being addressed in a timely manner with responsible departments.
- Assist the OESO training coordinator with the development of more effective biological safety training modules. This may mean modules that are more tailored to specific work groups or topics.

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.