Biosafety Risk Management Program
Standard Operating Procedure
Delaware Public Health Laboratory

Principle of Test: The purpose of a Biosafety Risk Management Program is to maintain biosafety within the Delaware Public Health Laboratory (DPHL). The major components of the program include: risk assessments, validation of risk mitigation strategies and communication and training of the workforce. All levels of staff (technologists, supervisors, administrative leaders) must be involved in the processes of a biosafety risk management program. It is advisable for the Chemical Safety Official to inspect the laboratories during the same time period as many tests require a variety of chemicals.

Clinical Utility: DPHL performs testing on a variety of specimen types: clinical, environmental, grown cultures, food and water. When a biosafety risk management program is followed, exposures will be decreased and laboratory acquired infections/injuries will be reduced. Although the risk when performing laboratory testing is never zero, utilizing all the necessary safety equipment and procedures for each test, is the most reliable way to avoid an exposure. Every effort should be made to remove hazards from sharps, splash/spills and/or aerosol production in order to protect the health of the workforce, their families and the environment.

Special Requirements: Due to the nature of the laboratory work performed at DPHL, BSL2 and/or BSL3 work practices, equipment and facilities controls may be required depending on the risk assessment for each type of test and specimen/sample source. The reference section at the end will be used for determination of needed supplies and equipment.

Reagents/Equipment: Equipment selection will depend on test requested and the source/type of the specimen/sample.

1. Personal Protection Equipment available:

    N95 (must be fit-tested)
    Disposable Gloves (latex and nitrile)
    Disposable Face Shields
    Safety Glasses (must be worn by people who wear contacts)
    Disposable Lab Coats
    Disposable Solid-Front Lab Coats
    Disposable Coveralls
    Disposable Boot Covers (non-slip)
    PAPR helmets and shrouds (no fit-testing necessary) battery and belt
    New PPE coming soon (MaxAir DLC CAPR), no fit-testing necessary

2. Small Equipment:

    Disposal plastic pipettes
    Disposal loops and needles
    Sharps containers
    Biohazard Bench-Top Keeper
    Biohazard bags of varying sizes

Disposable scalpels
Bench-top pads
4 x 4's

3. Large Equipment available:

   Biosafety Cabinets (Class I, II and III)
   Centrifuges with safety caps
   Centrifuges with sealed rotors
   Pass-through or regular autoclave

Test Procedure: The three major components of the program include risk assessments, risk mitigation strategies and communication and training of the workforce to effectively consider all risks when performing a test.

1. **Risk Assessment Procedure:** A risk assessment must be performed annually **AND** when a new reagent or piece of equipment is introduced into a previous test, when there is a change in the procedure of a test and/or **before** a new test is brought on-line. Appendix A contains a detailed template to assist in the following two processes.
   a. The first process involves hazard identification and hazard control. Information is gathered regarding the pathogen, potential host (workforce) and equipment needed for protection from the agent.
   b. The second process is to determine and prioritize the risk involved (likelihood and consequence). Evaluate and prioritize the risk associated with the laboratory testing to assess the likelihood of an exposure and severity of consequences if a laboratory acquired infection or other injury occurred.
2. **Risk Mitigation Strategies:**
   a. This process serves to help determine what additional safety precautions (controls) are needed to reduce the risk to an acceptable level. This includes engineering controls, administrative controls and work practices.
3. **Communication and Training:**
   a. This process assures that all risk mitigation strategies (controls) are not only implemented, but are effectively communicated to all the workforce. Workforce will perform the testing and evaluate their effectiveness of the controls. Workforce must also report all incidents, accidents, and illnesses to their supervisor or administrative leadership, regardless of how small, as a laboratory acquired infection must be ruled out.

Reading and Reporting Results: Written records must be kept to document all completed risk assessments (Appendix A). The form provided will indicate the workforce member responsible for the risk mitigation strategy. The Biosafety Committee must review all risk assessments and provide the necessary communication to the workforce (email and during the huddle) to ensure all biosafety information is disseminated to everyone. Risk assessments will be performed by the Biosafety Official and another member of the Biosafety Committee annually. It is recommended that a different bench tech lead the inspection each year as supervisors do not always perform all the different tests. The supervisor may assist as necessary.

Quality Control: Annual risk assessments are performed in all laboratories, media preparation, washroom, and the warehouse at least once a year. Any new concerns will be discussed and evaluated. Also, the Biosafety Official and Biosafety Committee members will introduce any newly acquired information from meetings, conferences and/or webinars concerning biosafety at the committee meeting. After evaluation, appropriate changes to procedures and purchase of new equipment will occur if necessary.

References:

1. Biosafety in Microbiological and Biomedical Laboratories, US Department of Health and Human Services, Public Health Service (Centers for Disease Control and Prevention and National Institutes of Health), 5th Edition (February 2007)
2. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition, Clinical Laboratory Standards Institute, M29-A4 (May 2014).
3. Guidelines for Safe Work Practices in human and Animal Medical Diagnostic Laboratories – Recommendations of a Centers for Disease Control and Prevention-convened Biosafety Blue Ribbon Panel. MMWR Supplement/Vol. 61 (January 2012).
4. Biological Safety: Principles and Practices, edited by Diane O Fleming, Debra L. Hunt, ASM Press, 2000.
5. ABSA International, Risk Group Data Base, https://my.absa.org/tiki-index.php?page=Riskgroups

Appendix:

A. Risk Assessment Template
B. Risk Assessment Letter to Delaware Hospital Laboratories and Infection Control Practitioners