State of Maryland
Department of Health
Laboratories Administration
1770 Ashland Avenue
Baltimore, MD 21205

Biosafety Risk Assessment
Standard Operating Procedure (SOP)
For Clinical Laboratories

Revision History

Biosafety Risk Assessment SOP for Clinical Laboratories

REVISION	COMMENTS	DATE
Original	Centers for Disease Control and Prevention recommends the implementation of a standard operating procedure for writing biosafety risk assessments for infectious pathogens/agents or for laboratory procedures.	11/1/2016
Version 1.2	Revisions in format and appendix B. Additional information added to improve understanding of risk assessment procedure	8/7/2017

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I INTRODUCTION

a) PURPOSE
The purpose of the Biosafety Risk Assessment SOP for Clinical Laboratories is to create a universal guideline for the laboratory staff to write a comprehensive risk assessment, to ensure safety, and minimize the possibility of an accidental exposure and laboratory acquired infections.

i) Definitions.
(1) Risk is defined as probability that harm, injury, or disease will occur.
(2) Hazard is defined as something which causes harm, injury, or disease.
(3) Risk Assessment is a process that involves hazard identification and evaluating hazard control. This is followed by determining the mitigation strategies necessary to provide protection.
(4) Mitigation is the actions and control measures put into place to reduce or eliminate risk(s) associated with a hazard.

ii) Mitigation Hierarchy of Controls:
(1) Elimination,
(2) Substitution,
(3) Engineering controls,
(4) Administrative controls, and lastly
(5) Personal protective equipment.

II RISK ASSESSMENT

a) When should a Risk Assessment be completed?
i) When laboratory changes occur due to:
(1) Moving into a new facility,
(2) Laboratory renovation,
(3) New infectious agent,
(4) New use of reagents,
(5) New piece of equipment being implemented,
(6) New techniques or procedures being implemented, and
(7) New regulations or guidelines that specify changes to laboratory procedures.

b) Risk Assessment process:
i) Hazard identification
(1) What type of pathogen/infectious substance, equipment and or procedure is it?
(2) Does exposure to the substance, equipment or procedure produce any adverse effects? If yes, what are the circumstance associated with the exposure?
(3) What laboratory procedures will be conducted with the pathogen, or agent, and at what dosage volumes (level of infectivity)?

ii) Evaluate the risks of the hazard
(1) Infectious dose
(2) Contagiousness
(3) Environmental stability
(4) Infectious period
(5) Availability of vaccine/treatment
(6) Incubation period, and
(7) Mode of transmission

iii) Exposure assessment of the hazard
(1) Needle stick/sharps,

(2) Inhalation of aerosol,
(3) Ingestion,
(4) Ocular/Mucosal splash or contact,
(5) Lab animal/vector,
(6) Persons affected in adjacent workspace, and
(7) Unknown route.

iv) Determine and implement controls to mitigate the risk
(1) Elimination – can the hazard be completely removed from the lab?
(2) Substitution – can another type of lab space be used?
(3) Engineering Controls –
(a) Biosafety Level (BSL) containment needs,
(i) BSL-2 or BSL-3?
(ii) BSL-2 workflow: open or closed lab space?
(iii) BSL-3 agent: is it a select agent?
(b) Biological Safety Cabinet (BSC) – ducted or not ducted?
(c) Chemical Fume Hood (CFH) – metal or polypropylene
(d) Snorkels,
(e) Waste management and disposal, i.e., autoclave

(4) Administrative Controls
(a) Standard Operating Procedure(s) SOPs,
(b) Staff experience and competency,
(c) Training,
(d) Signage,
(e) Access authorization, and
(f) Medical surveillance – employee vaccination/titer checks.

(5) PPE
Proper technique for donning and doffing PPE is as important as having the correct PPE
(a) Laboratories Administration required PPE for BSL-2 labs: lab coat and eye protection – face shield or safety glasses. Gloves are a task specific piece of PPE shall be specified in the lab/section/unit' SOPM.
(b) Refer to current BSL-3 SOPM for required PPE.
(c) Refer to current Laboratories Administration's *Respiratory Protection Program Policy*.

v) Review effectiveness of controls and adjust controls as needed.
(1) Review incidents, corrective actions, or lab accidents/exposure.
(2) Perform root-cause analysis of any incident, corrective action, or lab accident exposure.

Use Risk Assessment Matrix in Table 1 below to access the risk level associated with each hazard identified in above section. Based on the likelihood and consequence determined from the table, identify the risk level of each hazard.

Use Table 2 and Table 3 to determine control actions and hierarchy of control measures for each task/procedure.

Use Table 4 to review and approve effectiveness of the control measures taken to address risks

Table 1: Risk Assessment Matrix

RISK ASSESSMENT MATRIX Choose the most appropriate Likelihood and the most appropriate Consequence to reach the risk rating		**Hazard Consequence**				
		Insignificant: No treatment required. Require report and follow up action	**Minor:** Injury requiring First Aid treatment	**Moderate:** Injury requiring medical treatment or lost time	**Major:** Serious injury requiring medical treatment or hospitalization	**Critical:** Loss of life, permanent disability or multiple serious injuries
Hazard Likelihood	**Highly likely:** Expected to occur in most circumstances	Medium	Medium	High	Extreme	Extreme
	Likely: Probably occur in most circumstances routine exposure is likely	Low	Medium	High	High	Extreme
	Possible: Might occur occasionally	Low	Medium	High	High	High
	Unlikely: Not likely to occur but could happen	Low	Low	Medium	Medium	High
	Rare: May happen only in exceptional circumstances	Low	Low	Low	Medium	Medium

Table 2: Control Actions required based on Risk Matrix

Assessed Risk Level		**Description of Risk Level**	**Control Actions**
	Low	If an incident were to occur, there would be little risk	Risk is tolerable, manage by well-established routine process/procedures. Undertake the activity with the existing controls in place.
	Medium	If an incident were to occur, there would be some chance that an injury requiring First Aid would result.	Additional controls are advised. Control plan must be developed and existing controls need to be reviewed. Target resolution (ideally reduction to low level of risk) should be within 6 months.
	High	If an incident were to occur, it would be likely that an injury requiring medical treatment would result.	May require immediate assessment and senior staff consideration. Control plan must be developed, regular monitoring and reporting on to the relevant management.
	Extreme	If an incident were to occur, it would be likely that a	Requires immediate assessment and senior staff consideration. Detailed control plan must be developed. Significant control measures will need to

		permanent, debilitating injury or death would result.	be implemented to ensure safety. Consider alternatives to doing the activity unless the risk can be reduced to a level of high or less, regular monitoring and reporting to relevant management.

Based on the assessed risk level for each hazard, determine whether additional control measures should be implemented.

Table 3: Hierarchy of Control Measures

Table E. Hierarchy of Control Measures		
Most Effective (High Level)		**Elimination:** remove the hazard completely from the workplace or activity
		**Substitution:** replace a hazard with a less dangerous one (e.g. a less hazardous chemical)
		Redesign: make equipment or processes safer (e.g. raise a bench to reduce bending)
	Engineering /Design Controls	**Isolation:** separate people from the hazard (e.g. perform work in biosafety cabinet)
	Administrative Controls	**Administration:** putting rules, signage, or training in place to make a workplace safer (e.g. blood borne pathogens training, biosafety training, etc.)
Least Effective (Low Level)	**Personal Protective Equipment (PPE)**	**PPE:** protective clothing and equipment (e.g. gloves, lab coat, safety glasses, respirator, etc.)

Table 4: Risk Management Worksheet

To be completed by laboratory staff during and/or after they perform work with control measures in place		**Yes**	**No**
1. Are the planned control measures sufficient and effective in minimizing the level of risk?			
2. Have there been any changes to the planned control measures?			
3. Are any changes and/or additional control measures required in the future?			
Details:			
Risk Management Worksheet Authorization (to be signed by Unit Supervisor and Division Manager/Chief)	Review completed by:	Position/Title:	
	Signature:	Date:	
	Review completed by:	Position/Title:	
	Signature:	Date:	

c) Appendix B Biosafety Risk Assessment Checklist

i) Division Chiefs, Managers, Developmental Scientists, and Divisional Quality Assurance Officers shall utilize Appendix B for infectious agent and procedural/process Biosafety Risk Assessment in their laboratory sections.

III APPENDICES

APPENDIX A

References

1. Association of Public Health Laboratories, “APHL Risk Assessment Template for Zika Testing.” March 1, 2016.

2. Association of Public Health Laboratories, “APHL Risk Assessment Best Practices and Example.”

3. Biosafety in Microbiological and Biomedical Laboratories, 5th Ed. (2009). U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health.

4. Hierarchy of Controls. (2015). U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH).

5. *Laboratory Safety Manual* (current issue)

APPENDIX B

Biological Safety Risk Assessment Checklist	
Item	**Response**
1. Indicate the biosafety level (BSL) established in each Unit and required PPE. (BSL-1, BSL-2, Enhanced BSL-2, BSL-3, N/A)	
2. Is there potential for aerosol generation?	Yes, please indicate the task. (e.g. sonicate, vortex, centrifuge, etc.)
3. Equipment such as centrifuges, incubators, freezers involved in the use and storage of infectious materials have biosafety labels affixed?	Laboratories (open and closed) are labelled with biohazardous warning label at each entrance
4. Buckets with safety caps/cups or aerosol tight rotor lids used when centrifuging infectious materials?	
5. Is health monitoring performed in each Unit?	If yes, please indicate frequency and the process (LAB TO COMPLETE) Please refer to current MDH Laboratory Safety Manual
6. Are vaccines recommended for work in each Unit?	*If yes, please indicate how employees are informed of the vaccines?* *What vaccines are recommended?* Please refer to current MDH Laboratory Safety Manual
7. Are sharps used?	*If yes, please indicate the sharp (needle, blades, etc.) Does the sharp include safety device feature?*
8. Does work include a Biological Safety Cabinet?	*If yes, indicate if the BSC has been certified within the past year, the air vents are not blocked, and the sash is in place and operable?* [LAB TO COMPLETE]

Chemical Safety		
Item	**Response (Yes)**	**Response (No)**
1. Proper labeling: All containers labeled with the name of chemical?		
2. Fire Department Permit posted on the laboratory door?		
3. Updated chemical inventory?		
4. Material Safety Data Sheets/Safety Data Sheets accessible to staff?		
5. Incompatible chemicals segregated?		
6. Flammable liquids stored: rated chemical cabinets?		
7. Flammable liquids stored: stored in flammable-rated refrigerators/freezers?		
8. Excessive chemicals stored in chemical storage room?		
9. Compressed gas cylinders properly stored in laboratory?		
10. Chemicals stored at eye-level?		
11. Acids and bases stored:		
a. Cabinet?		
b. Labeled area?		
c. Free from metals?		
12. Chemical fume hoods:		
a. Certified within past year?		
b. Sash closed when not in use?		
c. Exhaust air not blocked by large equipment or containers?		
d. Used for hazardous/toxic or flammable procedures?		
Comments:		

Personal Protective Equipment		
Item	**Response (Yes)**	**Response (No)**
1. Laboratory staff aware of personal protective equipment (PPE) requirements for this laboratory		
2. Laboratory staff/employee aware of occupational health information?		
3. Does staff receive annual PPE competency assessments?		
4. PPE Care:		
a. Appropriately stored in laboratory?		
b. Inspected prior to use and in good condition?		
c. Worn in laboratory area?		
5. PPE Required:		
a. Facial shields/eye protection/splash guards?		
b. Disposable aprons, laboratory coats?		
c. Appropriate gloves?		
d. Double gloves required for work under the BSC		
e. Cryo or autoclave gloves?		
6. Closed-toe shoes that cover entire foot worn in laboratory?		
Comments:		

Emergency Preparedness		
Item	**Response (Yes)**	**Response (No)**
1. Emergency contact information posted?		
2. First aid kit maintained?		
3. Biological spill kit maintained?		
4. Staff aware of occupational injury procedures?		
Comments:		

Documentation and Training –		
Item	**Response (Yes)**	**Response (No)**
1. Employee(s) completed right-to-know training?		
2. Employee(s) completed unit-specific training?		
3. Employee(s) read and understand safety and health plans?		
4. Door sign up-to-date and posted?		
5. Laboratory microwaves and refrigerators labeled with “Not for Food or Drink – Biohazard”?		
Comments:		

Waste Management -		
Item	**Response (Yes)**	**Response (No)**
1. Chemical waste containers:		
a. Labeled with chemical name and percent of each chemical?		
b. Properly sealed?		
c. In good condition for transport?		
2. Biohazard waste containers?		
3. Broken glass placed in appropriate receptacle?		
4. Sharps container		
Comments:		

Engineering Controls		
Item	**Response (Yes)**	**Response (No)**
1. Laminar Flow Hoods		
2. Transport Containers		
Comments:		

At Risk Employees: (Laboratories Administration Safety Manual, section 12.0)		
Unit Name:		
Name	**Signature**	**Date**

Read & Signed by		
Unit Name:		
Testing Personnel – Printed Name	**Signature**	**Date**

This risk assessment should be reviewed annually or after any major changes (e.g., new facility, new method, changes in information for organism/agent, etc.). Reviews have been carried out on the following dates. Minor changes should be recorded under Amendments. Major changes require a new risk assessment to be performed.

Prepared by:			
	Printed Name	**Signature**	**Date**

Reviewed by:			
	Printed Name	**Signature**	**Date**

Approved by:			
	Printed Name	**Signature**	**Date**