LABORATORY RISK ASSESSMENT POLICY and PROCEDURE

Laboratory Director _____ *Date* _____

Clinical Division Director _____ *Date* _____

Biological Safety Officer _____ *Date* _____

Policy

The Tennessee Department of Health, Division of Laboratory Services (TDHLS) requires a risk assessment be performed on all work conducted in a state laboratory. These risk assessments will be used to develop policies, SOPs, testing and operational procedures, and PPE requirements.

These risk assessments are designed to be living documents and will be modified according to Section M below.

The Lab Director, Lab Manager(s) and the Safety Officer are responsible for ensuring completion and review of risk assessments.

Purpose

The purpose of this document is to provide a risk assessment procedure that helps to identify and minimize laboratory risks, and develop hazard mitigation to ensure all work can proceed as safely as possible.

Responsibilities

It is the responsibility of the Laboratory Supervisor to conduct a biosafety risk assessment before conducting any procedure in the laboratory. All laboratory staff members must be familiar with the risk assessments in which they are involved and follow all SOPs and policies and procedures that are developed from those risk assessments. To adequately assess risk, the hazards associated with the chemical or biological agent must be assessed. Equipment, procedures, and competency of the laboratory staff must all be considered when assessing risk.

Definitions

Hazard: A hazard is the potential for harm. A hazard is often associated with a condition or activity that, if left uncontrolled, can result in an injury or illness or property damage. For example, hazards can include an object, chemical, infectious agent or the way work is carried out.

Risk Control or Mitigation: Measures taken to reduce or eliminate the risk (likelihood and/ or consequence) of a hazard.

Risk: The chance or probability, high or low, that someone could be harmed (injury, damage or loss) by the hazard/s, together with an indication of how serious the harm could be.

Work Practice Controls: Methods to control risks - also known as mitigation. These include engineering controls such as biosafety cabinets, administrative controls such as written procedures, and personal protective equipment (PPE) such as lab coats and gloves.

Risk Assessment Procedure

A. Identify the activity
B. Identify the individuals who should be involved in the process. At a minimum representation should include: Individuals who are most familiar with the task or process, the Biosafety Officer (BSO), laboratorians, affected parties (like maintenance, housekeeping, and administrative staff)
C. Understand the limitations of a Risk Assessment
    1. Subjective process that involves professional judgements based on knowledge and experience of past events.
    2. Potential hazards identified may be based on incomplete knowledge, people differ in what constitutes a risk, and what is an acceptable level of risk.
    3. It is not usually possible to eliminate all risks; aim for what is reasonably practical. This means avoiding any unnecessary risk; it is not practical to anticipate unforeseeable risks.
D. Consider processes/procedures/hazardous activities.
    1. Evaluate activities with hazards that present risks, prioritizing them based on those most likely to occur and with the most severe consequences. This will be based on preliminary assessments.
E. Gather information
    1. Review the process/procedure/activity being assessed.
    2. Walk around the workplace – consider the activities, processes or substances used that could cause harm.
    3. Check the manufacturer's instructions for potential hazards.
    4. Check accident, illness and surveillance reports.
    5. Review the Chemical and Biological Safety Data Sheets for hazards and suggested guidelines for safe handling (PPE, BSC, fume hood, etc.).
    6. Review the organism/agent's properties, stability and persistence in the environment.
    7. Think about long-term hazards to health (for example and if more than one chemical is used the synergistic effects may be greater than the combined risks listed on the individual MSDSs).
F. Breakdown the work process in to Activities or Specific Tasks
    1. Consider all steps in a procedure. For example, review the steps from the time a specimen is collected until it is permanently disposed.
    2. Go through the process/procedure step by step. Collection, processing, testing, storing, disposal. Pre-analytical, Analytical, Post-analytical phases.
    3. List the steps/activity/specific tasks of the procedure in the first column of the Risk Assessment **Form 1**. Each step of the process should be identified. Refer to **Table A** - Examples of Activities or Specific Tasks.

G. Identify the Hazards – What can go wrong?
    1. For each activity/task, ask what can go wrong?
    2. List potential hazards in the appropriate column on the Risk Assessment **Form 1**. Each activity or task may have more than one hazard associated with it. Hazards are rarely a simple case of one singular cause resulting in one singular effect. Be specific as possible. Refer to **Table A** - Potential Hazard Examples.

H. Identify the Current Controls
    1. Risk control is a method of managing the risk with the primary emphasis on controlling the hazards at the source.
    2. List the controls that are in place for each hazard. Refer to **Table B** for types and examples of Work Practice Controls. There may be several controls in place for each hazard.

I. Likelihood of Hazard Occurring
    1. Consider the Likelihood – Refer to **Table C**
    2. How often is the task done? Does this make the harm more or less likely?
    3. How often are people near the hazard?
    4. Has it ever happened before? How often?
    5. What is the likelihood of the hazard identified happening?
        1) Rare: May happen only in exceptional circumstances
        2) Unlikely: Might happen at some time
        3) Possible: Could occur occasionally
        4) Likely: Will probably occur in most circumstances
        5) Almost Certain: Expected to occur in most circumstances

J. Consequence if the hazard did occur
        1) Minimal: Hazard or near miss requiring reporting and follow up action
        2) Minor: Potential First Aid Injury
        3) Moderate: Potential Medical Treatment Injury or Illness
        4) Major: Potential Lost Time Injury, non-permanent disability
        5) Severe: Potential fatality or injury or illness with permanent disability

K. Mitigate Remaining Hazards/Actions based on Risk Matrix – refer to Table C

Step	Action
1	If the risk assessment identifies a number of unaddressed hazards, rank them in order of importance and address the most serious risks first.
2	Identify long-term solutions for the risks with the biggest consequences, as well as those risks most likely to cause accidents or ill health. • Extreme Risk: Stop work immediately unless it can be reduced to a high or medium risk. Involve senior management • High Risk: Target resolution within 2 weeks • Medium Risk: Target resolution within 1 month
3	The control measures implemented will usually require changes to the way work is done due to new or modified equipment or processes, new or different chemicals, or new PPE. In these situations, it is usually necessary to support the new control measure with • New procedures • Training, instruction, and information • Supervision
4	Total elimination of the hazard is not always possible.
5	Ensure the Laboratory Director, BSO, Lab Management, Safety personnel, and the lab employees performing the activity are aware of associated risks and hazards.

L. Develop Risk Control Plan

1. The Risk Control Plan describes practices, procedures, and resources needed to ensure the safety of an activity.
2. List the controls required for the activity on Form 2. Include Engineering and Administrative Controls and PPE.

M. Review the Risk Assessment/Monitor

1. The plan should be reviewed at least annually
2. When operational conditions change
3. When equipment changes
4. Following an accident or incident
5. When personnel changes
6. When new knowledge is obtained regarding the hazards associated with the work.

References

1. CDC/National Institutes of Health. Biosafety in microbiological and biomedical laboratories. 5th ed. http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf.
2. CDC. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. MMWR January 6, 2012 supplement/Vol. 61. http://www.cdc.gov/mmwr/pdf/other/su6101.pdf
3. Canadian Center for Occupational Health Job Hazard Analysis https://www.ccohs.ca/oshanswers/hsprograms/job-haz.html
4. Public Health Agency Canada, Pathogen Data Safety Sheets and Risk Assessment http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php

Procedure/Process:	Location:	Date:	Approved:
List Team Members:			

*Determine using Risk Matrix, Table C

Identify Hazards		Identify Controls	Risk Assessment			Control Plan	
List Specific Task/Activity	**Hazard**	**Current Controls, Engineering, Administrative, PPE**	**Likelihood**	**Consequence**	**Risk Level ***	**Recommended Controls**	**Date Due**

Identify Hazards		Identify Controls	Risk Assessment			Control Plan	
List Specific Task	**Hazard**	**Current Controls, Engineering, Administrative, PPE**	**Likelihood**	**Consequence**	**Risk Level ***	**Recommended Controls**	**Date Due**

Table A

Examples of Specific Tasks
Centrifuging
Cleaning up spills
Contact with fomites or contaminated surfaces
Handling biological waste
Inoculating media and automated identification systems
Disposal of leaky specimen containers
Handling of loose caps on containers
Manipulating inoculation needles, loops, and pipettes
Manipulating needles, syringes and sharps
Manipulating specimens and cultures
Mixing, blending, grinding, shaking, sonicating, vortexing specimens or cultures
Pipetting
Performing rapid tests (catalase)
Performing serology, rapid antigen tests, wet preps, slide agglutinations
Pouring, aliquotting, or decanting liquids
Preparing smears, heat fixing or staining slides
Processing specimens
Reading culture plates
Removing caps or swabs
Spilling/dropping
Splashing infectious material
Streaking plates
Subculturing
Throwing contaminated items into biohazardous waste
Transporting specimens/materials throughout the clinical environment (inside and outside of the lab)
Uncapping/opening vacutainer tubes or specimen containers
Use of animals/ inoculating animals
Use of sharps
Vortexing

Examples of Potential Hazard
Exposure to biohazardous material through inhalation of infectious aerosols (list specific tasks)
Exposure to biohazardous material via direct contact of specimens, specimen containers, patient's skin, or contaminated work surfaces with employee's skin
Exposure to biohazardous materials through ingestion or mucous membranes
Exposure to bloodborne pathogens
Parenteral inoculations with syringe needles or other contaminated sharps

Possible cuts from sharps used in specimen collection
Spills and splashes onto skin or mucous membranes

Activity Risk Considerations Activities/practices	Entry Route
Mouth pipetting Splashing Eating, drinking, applying cosmetics in lab Use of personal electronic devices	Ingestion/oral Gastrointestinal tract
Using needles/syringes Broken glass or other sharps Using scalpels Waste disposal	Non-intact skin/percutaneous
Splashing or spilling into eye, mouth, nose Working on contaminated surfaces Handling contaminated equipment Improper use of loops, needles, swabs with specimens Pipetting Vortexing	Contact with Mucous Membranes
Using needles and syringes Manipulating specimens and cultures Spill cleanup Centrifugation Vortexing Pipetting	Inhalation of aerosols Lungs/respiratory

Personnel Considerations
Age
Behavior
Duration and frequency of exposure
Education, experience, competence
Genetic predisposition
Immune status
Overall health
Perception (attitude, follows safety precautions, takes shortcuts, ect)
Preexisting conditions
Pregnancy
Stress, fatigue, mental status

Likelihood/Laboratory Environment Factors
Equipment: is it maintained? Is it operated according to the manufacturer's instructions?
Facility – BSL2, BSL3, workspace, biological safety cabinets (BSCs), ventilation, lighting: Is there enough room? Is it cluttered? Is it clean?
Procedures performed?
Sample matrix: serum, spinal fluid, cultures?

Consequence Considerations
What type of harm could occur? How severe is the harm? Could the hazard cause death, serious injuries, illness or only minor injuries requiring first aid?
What factors could influence the severity of harm that occurs? For example, the distance someone might fall or the concentration of a particular substance will determine the level of harm that is possible. The harm may occur immediately or it may take time to become apparent.
How many people are exposed to the hazard and how many could be harmed in and outside the workplace?
Could one failure lead to other failures?
Could a small event escalate to a much larger event with more serious consequences?

Possible Long-term Outcomes
Colonization leading to carrier state
Asymptomatic infection
Infection – chronic or acute
Illness and morbidity
Disease and sequellae
Toxicity, oncogenicity, allergenicity
Death

Adverse Event Considerations	
How often are people exposed to the hazard?	A hazard may exist all of the time or it may only exist occasionally. The more often a hazard is present, the greater the likelihood it will result in harm.
How long might people be exposed?	Longer exposure to a hazard, the greater the likelihood that harm may result
In most cases the risks being assessed will already be subject to some control measures.	The likelihood of harm resulting from the risk will depend upon how adequate and effective the current measures are.
Are hazards more likely to cause harm because of the working environment?	Did the environment conditions change? Is there insufficient light and ventilation? Did the work level increase?
Could the way people act and behave affect the likelihood of a hazard causing harm?	The possibility that people may make mistakes, misues items, become distracted or panic in particular situations needs to be taken into account. The effects of fatigue or stress ma make it more likely that harm will occur.
Do the differences between individuals in the workplace make it more likely for harm to occur?	Newer or young workers may be more likely to suffer harm because of inexperience. People who do not normally work at the workplace will have less knowledge than employees who normally work there and may be more likely to suffer harm. This could include contractors or students.

Risk Control

Risk control is a method of managing the risk with the primary emphasis on controlling the hazards at source. For a risk that is assessed as "high", steps should be taken immediately to minimize risk of injury. The method of ensuring that risks are controlled effectively is done by using the "hierarchy of controls". The Hierarchy of Controls is:

Order No.		Control	Definition	Examples
1	Most Effective and Reliable 	Eliminate	Removing the hazard *NOTE: Depending on the type of hazard eliminating the hazard may not be possible if there is substantial impact to the end result. In which case, eliminate as many risks associated with the hazard as possible.*	• Remove a hazardous piece of equipment from service • Consider safety when selecting new instruments
2		Substitute / Isolation	Substitution: Replacing a hazardous substance or process with a less hazardous one. Isolation: Separate the source of harm from people by distance or by using barriers. Isolating the hazard from the person at risk,	• Substituting a hazardous substance with a non-hazardous (or less hazardous) substance. • Storing chemicals in a fume cabinet.
3		Engineering	Physical control, including mechanical device or process, room change, etc. Use mechanical solutions (device or process) to control the risk. Redesign or move a process or piece of equipment to make it less hazardous.	• Use safety syringe for injections. • Working in an appropriate Biosafety Level
4	Least Effective and Reliable	Administrative / Personal Protective Equipment	Administrative: Work methods or procedures that are designed to minimize exposure to a hazard. NOTE: *These include training, implementing safe work practices and standard operating procedures, job rotation.* Personal Protective Equipment (PPE): Item worn to provide a barrier between the wearer and the hazard. PPE limits exposure to the harmful effects of a hazard but only if workers wear and use the PPE correctly, and if it does not fail.	• Not allowing mouth pipetting. • Good housekeeping • Gloves, lab coat, safety glasses

TN Department of Health

Version 1 July 2016 TNDHLS Risk Matrix Table C

This Risk Matrix should be used to complete Form 1 of the Risk Assessment and identify Risk Level. Follow these steps:

1. Determine likelihood of specific hazard and record in appropriate column
2. Determine consequence of specific hazard and record in appropriate column
3. Determine Risk Level using Likelihood and Consequence using Risk Matrix below
4. Record in appropriate column on Form 1

LOW	Risk is tolerable; manage by well-established, routine process/procedures
MEDIUM	A Control Plan must be developed; existing controls need to be reviewed. Target resolution (ideally reduction to low level of risk) should be within 1 month.
HIGH	A "high" risk may also require immediate assessment and senior staff consideration; a Control Plan must be developed; regular monitoring and reports made to the relevant management/safety committee. Target resolution (ideally reduction to low level of risk) should be within 2 weeks
EXTREME	An "extreme" risk requires immediate assessment and senior staff consideration is required; a detailed Control Plan must be developed, the activity should be stopped immediately unless the risk can be reduced to a level of high or less; regular monitoring and reports made to the relevant management/safety committee.

		Consequence				
		Minimal: Hazard or near miss requiring reporting and follow up action	**Minor**: Potential First Aid injury	**Moderate**: Potential Medical Treatment Injury or illness	**Major**: Potential Lost Time Injury, non-permanent disability	**Severe**: Potential Fatality or Injury or illness with permanent disability
Likelihood	**Rare**: May happen only in exceptional circumstances	**LOW**	**LOW**	**LOW**	**LOW**	**MEDIUM**
	Unlikely: Could happen at some time	**LOW**	**LOW**	**MEDIUM**	**MEDIUM**	**HIGH**
	Possible: Might occur occasionally	**LOW**	**MEDIUM**	**HIGH**	**HIGH**	**HIGH**
	Likely: Will probably occur in most circumstances	**LOW**	**MEDIUM**	**HIGH**	**HIGH**	**EXTREME**
	Almost Certain : Expected to occur in most circumstances	**MEDIUM**	**HIGH**	**HIGH**	**EXTREME**	**EXTREME**

Activity or Process:
Date:

Type of Control	Controls required to maintain or minimize potential hazards: Describe the practices, procedures and resources needed to ensure the safety of the activity
Engineering	
Administrative **Employee education/competency**	
PPE	
Other • **Elimination** • **Substitution** • **Isolation**	