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Risk Assessment Policy

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I. POLICY OR PRINCIPLE

A. Background

Insert your facility name requires a risk assessment be performed when a new test is developed, new instrumentation, or a major change is implemented to a current procedure. The risk assessment should be conducted early in the implementation stages of a new test/procedure to allow for planning of equipment location and workflow development to be performed optimally for safety of the worker. These risk assessments will be used to develop policies, Standard Operating Procedures (SOPs), testing and operational procedures, and Personal Protective Equipment (PPE) requirements.

These risk assessments are designed to be living documents and will be modified or reviewed according to the following list:

1. Annually
2. When operational conditions or workflow change
3. When equipment changes
4. Following an accident or incident
5. If new information is learned regarding the associated hazards

B. 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. No process is without risk but minimizing risk to the extent possible is the goal.

II. SCOPE

Enter your lab staff titles here are responsible for ensuring completion and review of risk assessments. *Enter your lab staff title here* will give final approval of the risk assessment and mitigation strategies determined to be followed. If a risk assessment is for a new process, it is important to include *enter your staff title here* for guidance and as a reference. Risk assessments should be reviewed and approved by *enter your lab staff title here.*

III. ABBREVIATIONS AND GLOSSARY

BSC: Biological Safety Cabinet

Control Plan: Practices, procedures, and resources needed to ensure the safety of an activity that is implemented if additional mitigation is needed beyond the current controls.

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.

PPE: Personal protective equipment

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.

SOP: Standard Operating Procedure

TDH-DLS: Tennessee Department of Health, Division of Laboratory Services

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.

IV. RESPONSIBILITY

It is the responsibility of the section supervisor and/or manager to initiate risk assessment before conducting any procedure in the laboratory. It is highly recommended that testing personnel participate in the risk assessment process. All laboratory staff must be familiar with the risk assessments and follow all SOPs and policies 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.

V. PROCESS

A. Identify what process needs to be assessed for risks.

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, safety officer, and manager(s).

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.

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 workspace – 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.). Biological Safety Data Sheets may be found at Canada Pathogen Safety Data Sheets.
6. Review the organism/agent properties, stability, and persistence in the environment.
7. Think about long-term hazards to health (for example, 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 into 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, and Post-analytical phases should all be considered.
   3. List the steps/activity/specific tasks considered hazardous.

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. 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.

H. Identify the Current Controls (Mitigation)
   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 **currently** in place for each hazard. There may be several controls in place for each hazard.

I. Likelihood of Hazard Occurring
   1. Consider the Likelihood
   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?
    a. Rare: May happen only in exceptional circumstances
    b. Unlikely: Might happen at some time
    c. Possible: Could occur occasionally
    d. Likely: Will probably occur in most circumstances
    e. 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 below:

		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 sometime	**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**

LOW	Risk is tolerable; manage by well-established, routine processes/procedure
MEDIUM	Control Plan must be developed; existing controls need to be reviewed. Target resolution should be within 1 month.
HIGH	High risk may also require immediate assessment by senior staff; Control Plan must be developed; regular monitoring and reports to the safety officer. Target resolution should be within 2 weeks.
EXTREME	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 risk can be reduced to a level of high or less. Regular monitoring and reports to the safety officer.

L. Develop Risk Control Plan
The Risk Control Plan describes practices, procedures, and resources needed to ensure the safety of an activity. **This is only completed if additional mitigation is needed beyond the current controls.**

M. Upload the Risk Assessment into MediaLab under the section folder named Risk Assessments and select appropriate workflow. Once process in MediaLab is initiated by the section manager, collaboration and approval workflows will occur automatically.

N. Include all mitigation strategies needed into the Standard Operating Procedure Safety section. The Risk Assessment may be linked to the SOP as well for ease of comparison.

VI. REFERENCES

A. CDC/National Institutes of Health. Biosafety in microbiological and biomedical laboratories. 6thed. https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

B. 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

C. Canadian Center for Occupational Health Job Hazard Analysis https://www.ccohs.ca/oshanswers/hsprograms/job-haz.html

D. 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

VII. ATTACHMENTS