



May 05, 2016

## Risk Assessment Best Practices

Dear Biosafety Officials:

The Association of Public Health Laboratories (APHL) has established a Biosafety and Biosecurity Committee (BBC) to assist public health laboratories with strengthening biosafety and biosecurity programs across the United States. A key activity of the BBC is to develop and promote biosafety and biosecurity tools (for example-risk assessments).

Risk assessments are an essential component of maintaining safety within a laboratory. The goal of a risk assessment is to identify and mitigate the risks of working in a laboratory environment. While all laboratories (including public health laboratories) should be performing risk assessments, the content and design of the template may be unique to the facility. Risk assessments must be performed regularly based on procedure or agent, and when there are changes in agents, procedures, equipment or staff. Risks identified by the assessment should be prioritized, and a mitigation plan should be established based on that prioritization. In other words, the highest risks should be mitigated relatively more than lower risks. The mitigation plan should be documented and clearly communicated to all relevant personnel. A risk assessment should follow the workflow from pre-analytical processes (sample receipt), through the laboratory (analytical), to post-analytical processes (waste disposal) and be reviewed by leadership (lab directors). It must be noted that risk assessments are dynamic documents that must be updated if any of the working assumptions for that protocol (equipment, personnel, materials) changes.

### Components of a Risk Assessment

Key components of a risk assessment should address:

#### Workforce

- Identify personnel (individuals) who will be affected throughout the work-flow
- Assess the competency and experience of laboratory personnel
- Identify which trainings to offer staff
- Consider staff enrollment in occupational health programs

#### Risk Characterization

- Identify hazards
- Consider risk group of the agent
- Classify the potential for exposure (modes of transmission, potential for spill or inhalation, organism concentrations, virulence, etc.)
- Identify activities which may increase risk of exposure
  - Classify which instruments will be used to process each sample and identify potential for exposure

- Evaluate and prioritize risks
  - Determine the likelihood and consequences of a specific risk found during the assessment. Using that information, develop a strategy to mitigate that risk.

## Risk Mitigation

- Develop Risk Mitigation Strategies
  - Identify required safety practices to address the identified risks
    - Includes personal protective equipment, engineering controls, additional training, standard operating procedures, assessment strategies for staff proficiencies, and drills, etc.
  - Determine whether additional risk mitigation strategies are necessary
    - For instance, consider upgrades of equipment and implementation of new training programs
- Communicate risks and mitigation strategies to staff
  - Provide a mechanism of communication within the laboratory and a known place of record for all risk assessments and mitigation strategies.
- Validate Risk Mitigation Strategies
  - Review risk assessment and mitigation strategies after implementation to ensure that measures were effective.

## Example Risk Assessment Templates

While risk assessments should be created to be unique and specific to every individual laboratory facility, certain components must be included within every assessment. As a starting point, the following examples provide guidance for performing and documenting risk assessments.

1. [Alaska](#)-Table
  - a. Procedural risk assessments-table with specific activity, hazard, controls, likelihood, and future controls. This type of risk assessment includes a risk matrix which assesses the likelihood of an event occurring and pairs it with consequences
  - b. Contact Katherine Ross at ([katherine.ross@alaska.gov](mailto:katherine.ross@alaska.gov)) for any questions
2. [Arizona](#)-Questionnaire
  - a. A quick questionnaire which identifies the procedure and then highlights all precautions in place.
  - b. Contact Joseph Manfrida at ([joseph.manfrida@azdhs.gov](mailto:joseph.manfrida@azdhs.gov)) for any questions.
3. [Colorado](#)-Table
  - a. A risk assessment which is divided into sections (agent, procedure, equipment, and staff) and then breaks down the mitigation measures in place.
  - b. Contact Peter Davis at ([peter.davis@state.co.us](mailto:peter.davis@state.co.us)) for any questions.
4. [Florida](#)-Verbal Guidelines
  - a. This document walks readers through a step by step process of doing a risk assessment, what to consider, and how to account for specific procedures.
  - b. Contact Edgar Kopp ([Edgar.Kopp@flhealth.gov](mailto:Edgar.Kopp@flhealth.gov)) for any questions.
5. [Iowa](#)-Matrix

- a. A risk assessment form which identifies hazards, presents a risk assessment matrix (likelihood and consequences) and then selects control measures.
  - b. Contact Drew Fayram at ([drew-fayram@uiowa.edu](mailto:drew-fayram@uiowa.edu)) for any questions.
6. New York-Table
- a. A table format risk assessment which identifies methods and procedures, hazards, required practices, and triggers to implement enhanced precautions.
  - b. Contact Dave Hill ([david.hill@health.ny.gov](mailto:david.hill@health.ny.gov)) for any questions.

In addition to the examples provided, the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 5<sup>th</sup> edition and the *World Health Organization (WHO), Laboratory Biosafety Manual*, 3<sup>rd</sup> edition are good resources to use while developing risk assessments.

As APHL continues to collect and review risk assessments, we will share model examples with public health laboratories. We encourage you to share your practices and provide feedback on these examples with APHL staff at: [biosafety@aphl.org](mailto:biosafety@aphl.org) and/or via the APHL Biosafety Officials (BSO) ListServ.

Regards,



Michael Pentella, PhD, D(ABMM)  
Chair, APHL Biosafety and Biosecurity Committee  
Director, Bureau of Laboratory Sciences  
Massachusetts State Public Health Laboratory

# Alaska Public Health Laboratory Procedural Risk Assessments

<b>Policy</b>	<p>The Alaska State Public Health Laboratory (ASPHL) will perform risk assessments to maintain a safe working environment.</p> <ul style="list-style-type: none"> <li>• Risk assessments are reviewed annually and when significant changes occur.</li> <li>• The Lab Director, Lab Manager(s) and the Safety Officer are responsible for ensuring completion and review of risk assessments.</li> </ul>				
<b>Purpose</b>	<p>The purpose of this document is to provide a risk assessment procedure that helps to identify and minimize laboratory risks, and develop mitigation and routine assessments.</p>				
<b>Definitions</b>	<p><b>Hazard:</b> 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. For example, hazards can include an object, chemical, infectious agent or the way work is carried out.</p> <p><b>Mitigation:</b> Measures taken to reduce the risk (likelihood and/ or consequence) of a hazard.</p> <p><b>Risk:</b> the chance, high or low, that someone could be harmed (injury, damage or loss) by these other hazards, together with an indication of how serious the harm could be.</p> <p><b>Risk Assessment:</b> a risk assessment an action or series of actions taken to recognize or identify hazards and to measure the risk of probability that something will happen because of that hazard. The severities of the consequences are also taken into account, allowing for assessment of if enough precautions have been taken or more are necessary.</p> <ul style="list-style-type: none"> <li>• Biological: used to identify hazards for a specific infectious agent</li> <li>• Job Safety: used to identify hazards for a specific task or activity</li> <li>• Procedural: combines biological and job safety risks in a comprehensive manner</li> </ul> <p><b>Risk Management:</b> assessment, analysis and management of risks. It is simply recognizing which events (hazards) may lead to harm in the future and minimizing their likelihood (how often?) and consequence (how bad?).</p> <p><b>Work Practice Controls:</b> 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.</p>				
<b>Notes</b>	<p><u>Planning is vital to the successful completion of a risk assessment.</u></p>				
<b>Procedure</b>	<p>1. <b>Risk Assessment (RA) Planning</b></p> <table border="1" data-bbox="321 1495 1318 1705"> <thead> <tr> <th data-bbox="321 1495 475 1537">Step</th> <th data-bbox="475 1495 1318 1537">Action</th> </tr> </thead> <tbody> <tr> <td data-bbox="321 1537 475 1705">1</td> <td data-bbox="475 1537 1318 1705">                     Establish a group, include representation from:                     <ul style="list-style-type: none"> <li>• Management</li> <li>• Safety specialist(s)</li> <li>• People with expertise/experience with the activity and potential hazards</li> </ul> </td> </tr> </tbody> </table>	Step	Action	1	Establish a group, include representation from: <ul style="list-style-type: none"> <li>• Management</li> <li>• Safety specialist(s)</li> <li>• People with expertise/experience with the activity and potential hazards</li> </ul>
Step	Action				
1	Establish a group, include representation from: <ul style="list-style-type: none"> <li>• Management</li> <li>• Safety specialist(s)</li> <li>• People with expertise/experience with the activity and potential hazards</li> </ul>				

# Alaska Public Health Laboratory Procedural Risk Assessments

2	<p>Decide.</p> <p>List, rank and set priorities for processes/procedures/hazardous activities. List activities with hazards that present unacceptable risks, based on those most likely to occur and with the most severe consequences:</p> <ul style="list-style-type: none"> <li>• With the highest injury or illness rates</li> <li>• With the potential to cause severe or disabling injuries or illness, even if there is no history of previous accidents</li> <li>• In which occurrence of simple human error could lead to a severe accident or injury</li> <li>• That are new or have undergone changes</li> </ul>
3	<p>Gather information.</p> <ul style="list-style-type: none"> <li>• Review the process/procedure/activity being assessed</li> <li>• Walk around the workplace – consider the activities, processes or substances used that could cause harm</li> <li>• Check the manufacturer’s instructions for potential hazards</li> <li>• Look back at accident, illness and surveillance reports</li> <li>• Employee training records and competency assessments</li> <li>• Review the Safety Data Sheets for chemical hazards and suggested guidelines for safe handling (PPE, fume hood, etc.)</li> <li>• Review the organism/agent’s properties</li> <li>• Think about long-term hazards to health – what chemicals are used?</li> </ul>
4	<p>Understand the limitations of a Risk Assessment</p> <ul style="list-style-type: none"> <li>• Subjective process that involves professional judgements based on knowledge and experience of past events</li> <li>• Potential hazards identified may be based on incomplete knowledge</li> <li>• People differ in what constitutes a risk, and what constitutes an acceptable risk</li> <li>• There are many ways to conduct a risk assessment</li> <li>• It is not usually possible to eliminate all risks; aim for what is ‘reasonably practical’. This means avoid any unnecessary risk; it is not practical to anticipate unforeseeable risks</li> </ul>
5	<p>Print and review the Procedural Risk Assessment Form</p>

## 2. Identify Activities or Specific Tasks

Step	Action
1	Consider from the time a specimen is collected until it is permanently disposed.
2	<p>Go through the process/procedure step by step.</p> <ul style="list-style-type: none"> <li>• Collection</li> <li>• Processing</li> <li>• Manipulation</li> <li>• Disposal</li> </ul>
3	List the steps/activity/specific tasks of the procedure in the first column of the Risk Assessment Form. This can be very specific or more general. Refer to Table 1 Examples of Activities or Specific Tasks.

## 3. Identify the Hazards – What can go wrong?

Step	Action
1	For each activity, ask what can go wrong?

# Alaska Public Health Laboratory Procedural Risk Assessments

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. Refer to Table 2 Potential Hazard Examples.
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## 4. Identify the Current Controls

Step	Action
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 3 for types and examples of Work Practice Controls. There may be several controls in place for each hazard.

## 5. Likelihood

Step	Action
1	<p>Consider the <b>Likelihood – Refer to Tables 4-6</b></p> <ul style="list-style-type: none"> <li>• How often is the task done? Does this make the harm more or less likely?</li> <li>• How often are people near the hazard?</li> <li>• Has it ever happened before? How often?</li> <li>• What is the likelihood of the consequence identified happening?                             <ul style="list-style-type: none"> <li>• Rare: May happen only in exceptional circumstances</li> <li>• Unlikely: Might happen at some time</li> <li>• Possible: Could occur occasionally</li> <li>• Likely: Will probably occur in most circumstances</li> <li>• Almost Certain: Expected to occur in most circumstances</li> </ul> </li> </ul>

## 6. Consequence/ Review Biological Risk Assessments

Step	Action
1	Review potential pathogens that may be observed/isolated/considered in the lab in addition to Blood-Borne Pathogens. Refer to Tables 8, 9, and 10.
2	<p>Recommended step: Complete a Biological Risk Assessment Worksheet for potential pathogens that may be encountered. <a href="http://www.cdc.gov/biosafety/publications/BiologicalRiskAssessmentWorksheet.pdf">http://www.cdc.gov/biosafety/publications/BiologicalRiskAssessmentWorksheet.pdf</a> This will define standard environmental and administrative controls and PPE.</p>
3	<p>Recommended step: Review NIH risk classification for potential pathogens: American Biological Safety Association <a href="https://my.absa.org">https://my.absa.org</a></p>
4	<p>Recommended step: Review Canada Public Health Pathogen Safety Data sheets and risk assessment: <a href="http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php">http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php</a></p>
5	<p>Consequence matrix:</p> <ul style="list-style-type: none"> <li>• Minimal: Hazard or near miss requiring reporting and follow up action</li> <li>• Minor: Potential First Aid Injury</li> <li>• Moderate: Potential Medical Treatment Injury or Illness</li> <li>• Major: Potential Lost Time Injury, non-permanent disability</li> <li>• Severe: Potential fatality or injury or illness with permanent disability</li> </ul>

## 7. Estimate Risk: How likely could something go wrong? How bad could it be?

Step	Action
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# Alaska Public Health Laboratory Procedural Risk Assessments

1	Estimate Risk: Risks are evaluated according to the likelihood of occurrence and severity of consequences – refer to Table 11 Risk Matrix to determine over risk.
2	There are many factors to consider when determining risk. <ul style="list-style-type: none"> <li>• Personnel factors Tables 4 and 5</li> <li>• Laboratory Environment Table 6</li> <li>• Possible Outcomes Table 7</li> <li>• Routes of transmission and host entry portals Table 8</li> <li>• Organism/Agent Considerations Table 9</li> </ul>

## 8. Mitigate Remaining hazards/Actions based on Risk Matrix

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. <ul style="list-style-type: none"> <li>• Extreme Risk: Target resolution within 1 month</li> <li>• High Risk: Target resolution within 3 months</li> <li>• Medium Risk: Target resolution within 6 months</li> </ul>
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 <ul style="list-style-type: none"> <li>• New procedures</li> <li>• Training, instruction, and information</li> <li>• Supervision</li> </ul>
4	Total elimination of the hazard is not always possible.
5	Ensure the Laboratory Director, Lab Management, Safety personnel, and the lab employees performing the activity are aware of associated risks and hazards.

## 9. Risk Control Plan – specific control measures

Step	Action
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. Include Engineering and Administrative Controls and PPE.

## 10. Annually Review the Risk Assessment/Monitor

Step	Action
1	Monitoring the control plan will help ensure the controls remain effective.

## Alaska Public Health Laboratory Procedural Risk Assessments

	1	<p>Few procedures stay the same. New equipment, substances and procedures can lead to new hazards. A review is recommended:</p> <ul style="list-style-type: none"> <li>• When the control measure is not effective in controlling risk</li> <li>• A new hazard or risk is identified</li> <li>• A change in the work process or flow</li> <li>• A change or addition to equipment or instruments</li> <li>• New employees</li> <li>• Moving to a new work area</li> <li>• Introduction of new chemicals or substances</li> <li>• When new information becomes available</li> <li>• When indicated by a continual monitor</li> </ul>	
	2	<p>Outline the practices: What is monitored? And how often?</p> <ul style="list-style-type: none"> <li>• Competency and training records</li> <li>• Unusual occurrence Reports</li> <li>• Injury, illness reports</li> <li>• Instrument maintenance logs</li> <li>• Direct observation of PPE</li> <li>• New or changes to the procedure</li> <li>• New or changes to the equipment</li> <li>• Annual procedure review</li> </ul>	
	3	<p>Revise policies and procedures to prevent recurrence of problems Discuss RA with appropriate staff</p>	
	4	<p>Document all RA activities</p>	
<b>Related Procedures</b>	<p>Procedural Risk Assessment Form Risk Matrix Control sheet</p>		
<b>References</b>	<ol style="list-style-type: none"> <li>1. CDC/National Institutes of Health. Biosafety in microbiological and biomedical laboratories. 5<sup>th</sup> ed. Available at <a href="http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf">http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf</a>.</li> <li>2. CDC. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. MMWR January 6, 2012 supplement/Vol. 61. Available at <a href="http://www.cdc.gov/mmwr/pdf/other/su6101.pdf">http://www.cdc.gov/mmwr/pdf/other/su6101.pdf</a></li> </ol>		

# Alaska Public Health Laboratory Procedural Risk Assessments

Activity / Task / Location:	Approved By:  Signature and Date
Developed by:	Date:

Identify Hazards	Controls and Work Practices	Risk Assessment			Control Plan		
Activities or Specific Tasks	Hazards	Current Controls: Engineering, Administrative, and PPE	Likelihood	Consequence	Est. Risk	Additional Controls/Process Improvements Needed to Reduce Risk to the Lowest Possible Level	When will additional controls be implemented? (Date)

**Alaska Public Health Laboratory Procedural Risk Assessments**


# Alaska Public Health Laboratory Procedural Risk Assessments

## Risk Control Plan

**Risk Control  
Plan for:** \_\_\_\_\_

**Date:** \_\_\_\_\_

<b>Type of Control</b>	<b>Controls required to maintain or minimize potential hazards: Describe the practices, procedures and resources needed to ensure the safety of the activity.</b>
<b>Engineering</b>	
<b>Administrative Employee education/competency</b>	
<b>PPE</b>	
<b>Other</b> <ul style="list-style-type: none"><li>• <b>Elimination</b></li><li>• <b>Substitution</b></li><li>• <b>Isolation</b></li></ul>	

## Risk Assessment Monitors

The following items are monitored to ensure the process/procedure/activity is compliant

**Alaska Public Health Laboratory Procedural Risk Assessments**

Monitor (list)	Frequency

# Alaska Public Health Laboratory Procedural Risk Assessments

Table 1 Examples of Activities or Specific Tasks
Centrifuging
Cleaning up spills
Contact with fomites or contaminated surfaces
Handling biological waste
Inoculating media and automated identification systems
Leaky specimen containers
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, splitting, or decanting liquids
Preparing smears, heat fixing or staining slides
Primary specimen processing
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 vacutainers
Use of animals
Use of sharps
Vortexing

Table 2 Potential Hazard Examples
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

# Alaska Public Health Laboratory Procedural Risk Assessments

**Table 3 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 by using the “hierarchy of controls”. The Hierarchy of Controls are:

Order No.		Control	Definition	Examples
1	Most Effective and Reliable	Eliminate	Removing the hazard  <i>NOTE: Depending on the type of hazard eliminating the hazard may not be possible if the is substantial impact to the end result. In which case, eliminate as many risks associated with the hazard.</i>	<ul style="list-style-type: none"> <li>Remove a hazardous piece of equipment from service</li> <li>Consider safety when selecting new instruments</li> </ul>
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,	<ul style="list-style-type: none"> <li>Substituting a hazardous substance with a non-hazardous (or less hazardous) substance.</li> <li>Storing chemicals in a fume cabinet.</li> </ul>
3		Engineering	Physical control, including mechanical device or process, room change, etc. Use mechanical solutions (device or process) to control the risk. Redesign a process or piece of equipment to make it less hazardous.	<ul style="list-style-type: none"> <li>Use safety syringe for injections.</li> <li>Working in an appropriate Biosafety Level</li> </ul>
4	Least Effective and Reliable	Administrative* / Personal Protective Equipment*	Administrative: Work methods or procedures that are designed to minimize exposure to a hazard.  <i>NOTE: These include training, implementing safe work practices and standard operating procedures, job rotation.</i>  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.	<ul style="list-style-type: none"> <li>Not allowing mouth pipetting.</li> <li>Good housekeeping</li> <li>Gloves, lab coat, safety glasses</li> </ul>

**Table 4 Likelihood 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 to the	The longer someone is exposed to a hazard, the greater the likelihood that harm may

## Alaska Public Health Laboratory Procedural Risk Assessments

hazard?	result.
How effective are current controls in reducing risk?	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?	<ul style="list-style-type: none"> <li>• Did the environmental conditions change?</li> <li>• Is there insufficient light and ventilation?</li> <li>• Did the work level increase?</li> </ul>
Could the way people act and behave affect the likelihood of a hazard causing harm?	The possibility that people may make mistakes, misuse items, become distracted or panic in particular situations need to be taken into account. The effects of fatigue or stress may 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. These could include contractors or students.

**Table 5 Likelihood/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

**Table 6 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?

## Alaska Public Health Laboratory Procedural Risk Assessments

**Table 7 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?

**Table 8 Activity Risk Considerations**

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

**Table 9 Organism/Agent Considerations**

Ability to produce toxins or enzymes
Concentration, volume
Consequence (high risk pathogens)
Ease and method of transmissibility
Frequency of exposure
Genetically modified, attenuated, or multiply resistant microorganisms
Infectious dose, potential for infection
Invasiveness
Natural reservoir
Potential for survival in the laboratory environment
Prevalence in community
Resistance to disinfectants or antibiotics
Routes of transmission

# Alaska Public Health Laboratory Procedural Risk Assessments

**Table 10 Possible Long-term Outcomes**

Colonization leading to carrier state
Asymptomatic infection
Infection – chronic or acute
Illness and morbidity
Disease and sequelae
Toxicity, oncogenicity, allergenicity
Death

**Table 11**

## RISK MATRIX

Choose the most appropriate Likelihood and the most appropriate Consequence to reach the risk rating.

		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	<b>Rare:</b> May happen only in exceptional circumstances	LOW	LOW	LOW	LOW	MEDIUM
	<b>Unlikely:</b> Could happen at some time	LOW	LOW	MEDIUM	MEDIUM	HIGH
	<b>Possible:</b> Might occur occasionally	LOW	MEDIUM	HIGH	HIGH	HIGH
	<b>Likely:</b> Will probably occur in most circumstances	LOW	MEDIUM	HIGH	HIGH	EXTREME
	<b>Almost Certain :</b> Expected to occur in most circumstances	MEDIUM	HIGH	HIGH	EXTREME	EXTREME

**Table 12 Actions required based on Risk Matrix**

<b>LOW</b>	Risk is tolerable; manage by well-established, routine process/procedures
<b>MEDIUM</b>	A Control Plan must be developed; existing controls need to be reviewed. Target resolution (ideally reduction to low level of risk) should be within 6 months.
<b>HIGH</b>	A “high” risk may also require immediate assessment and senior staff consideration; a Control Plan must be developed; regular monitoring and reported on to the relevant management/steering committee. Target resolution (ideally reduction to low level of risk) should be within 3 months.
<b>EXTREME</b>	An “extreme” risk requires immediate assessment and senior staff consideration is required; a detailed Control Plan must be developed, and consideration should be given to ceasing the activity unless the risk can be reduced to a level of high or less; regular monitoring and reported on to the relevant management/steering committee. Target resolution (ideally reduction to low level of risk) should be within 1 month.

## Arizona Public Health Laboratory Biological Risk Assessment Worksheet

<b>Supervisor:</b>	<b>Assessment Date:</b>	<b>Assessor:</b>
<b>Location:</b>	<b>Department:</b>	

### Section I: SOP, Agent & Material Hazards

1. Procedure, method, or SOP title:
2. Agent or Specimen:
  - a. Agent disinfectant susceptibility:
  - b. Infectious dose:
  - c. Mode of transmission:
  - d. Agent stability (survival outside of host):
  - e. Nature/type of specimen:
3. Vaccine Available (Y/N):
4. Risk Group of Agent (check [www.absa.org](http://www.absa.org)){inactivated agents = risk group 1}:
5. Is there a splash potential? (Y/N)
6. Does the procedure generate aerosol? (Y/N)
7. Does the procedure generate a high concentration? (Y/N)
8. Hazardous chemical reagents with hazard class:
9. Physical hazards:
10. Waste generated and disposal method:

Date Developed: 1/15/2016  
Last update: 1/15/2016

ADHS  
hjm

# Arizona Public Health Laboratory Biological Risk Assessment Worksheet

## Section II: Biosafety Precautions

1. Biological Safety Level: (BSL-1, BSL-2, BSL-3, BSL-4)
2. PPE / Engineering Controls Needed for Procedure
  - a. Biological Safety Cabinet; Class (I,II,III, or N/A):
  - b. Glove type required (latex, neoprene, or other):
  - c. Eye safety glasses, goggles, face shield or safety shield required (Y/N):
  - d. Lab coat or water resistant gown required:
  - e. Respirator N-95, N-100 or PAPR required:
3. Medical Protection and Surveillance
  - a. Medical monitoring recommended (Y/N):
  - b. Vaccine recommended (Y/N):      If Yes, Type:
  - d. Respiratory protection program enrollment (Y/N):
4. Enhanced training required:
5. Comments and Observations (general safety, sterile technique, donning / doffing):

## **Biosafety Assessor's Signature and Date**

Date Developed: 1/15/2016  
Last update: 1/15/2016

ADHS  
hjm



**COLORADO**  
Department of Public  
Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

Tracking #: \_\_\_\_\_

# Biological Risk Assessment

Entity: \_\_\_\_\_ Building/Lab Room #: \_\_\_\_\_ Inspector Name: \_\_\_\_\_

## Purpose

The purpose of this document is to assist in the selection of biosafety levels, microbiology practices, use of safety equipment, and facility safeguards to prevent laboratory-acquired infections (LAI) and environmental exposures. Risk assessments should be performed by a qualified individual(s) and the observations compared before conclusions are made and mitigation measures implemented.

A risk assessment should be performed: before analysis begins, whenever the procedure location is moved, when laboratories are renovated, when new employees begin working, when reagents are changed (manufacturer, type of reagent, etc.), before new equipment is used, and repeated when changes are made to the procedure, facility, and the employee.

The conclusions of the risk assessment will be reviewed with staff and management. The Biological Risk Assessment inspectors, staff, and management will discuss implementation of mitigation measures. Finally, a follow-up risk assessment will be performed to determine the effectiveness of the mitigation measures.

## Section I: Microbiological Risks

Microbe of Investigation: \_\_\_\_\_ Vaccine Available?: Yes  No  Form of Microbe: \_\_\_\_\_

Microbe Risk Group\*: 1  2  3  4  (absa.org for reference) \*Inactivated Microbes = Risk Group 1

Procedure Name: \_\_\_\_\_

Microbes Genetically Modified?: Yes  No  Unknown

For Risk Group 2-4:

Likelihood that an exposure would cause an LAI: Very Likely  Likely  Moderate  Unlikely  Rare

Severity of consequences if an LAI occurred: (check all that apply)

Carrier  Acute Infection  Chronic Infection  Asymptomatic Infection  Death

## Section II: Microbiological Risks Mitigation Measures

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



### Section III: Procedure Risks

**Manipulation of sharps:** Yes  No     **Sharps container available?:** Yes  No   
 (Subculturing positive blood culture bottles, making blood smears, expelling air from tubes or bottles, withdrawing needles from stoppers, separating needles from syringes, aspirating and transferring body fluids, harvesting tissues, use of pipette tips)

**Manipulation of inoculating needles, loops, or pipettes:** Yes  No   
 (Flaming loops, cooling loops in culture media, subculturing and streaking culture media, expelling last drop from pipette)

**Manipulation of specimens and cultures:** Yes  No   
 (Centrifugation, vortexing, use of an aerosol chamber, sonicating, setting-up cultures, removing caps or swabs from culture containers, opening lyophilized cultures, opening cryotubes, filtering specimens under vacuum, preparing isolates for automated identification/susceptibility testing, preparing smears, performing heat fixing, staining slides, performing catalase test, performing serology, rapid antigen test, wet preps, slide agglutinations, lackadaisical disposal of biohazard waste, high spill potential)

**Potential to generate aerosols:** Yes  No   
 (Pipetting, subculturing positive blood culture bottles, expelling air from tubes or bottles, withdrawing needles from stoppers, aspirating and transferring body fluids, harvesting tissues, flaming loops, cooling loops in culture media, subculturing and streaking culture media, expelling last drop from pipettes, centrifugation, vortexing, use of an aerosol chamber, sonicating, setting-up cultures, removing caps or swabs from culture containers, opening lyophilized cultures, opening cryotubes, filtering specimens under vacuum, preparing isolates for automated identification/susceptibility testing, use of an automated identification system, preparing smears, performing heat fixing, staining slides, performing catalase tests, rapid antigen test, wet preps, slide agglutinations, high spill potential)

**Use of animals:** Yes  No     **Genus species of animal:** \_\_\_\_\_    **N/A**

**Production of large volumes or concentrations of potential pathogens:** Yes  No   
 (Cell, viral, fungal, and microbial cultures)

**Unaccompanied Work in the Laboratory:** Yes  No

### Section IV: Procedure Risks Mitigation Measures

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### Section V: Staff Capability

Has testing personnel read and signed off on the applicable SOP(s): Yes  No

Has testing personnel been observed to be competent in collection, preparation, handling, and processing: Yes  No

Has testing personnel been trained to perform relevant instrument maintenance and function checks: Yes  No  N/A

Has testing personnel been observed to complete the procedure safely: Yes  No

Testing personnel has completed:

Biosafety Training <input type="checkbox"/> N/A <input type="checkbox"/>	Biosecurity Training <input type="checkbox"/> N/A <input type="checkbox"/>
Chemical Hygiene Training <input type="checkbox"/> N/A <input type="checkbox"/>	QA Training <input type="checkbox"/> N/A <input type="checkbox"/>



### Section VI: Staff Capability Mitigation Measures

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### Section VII: Facility & Equipment Risks

Facility BSL: 1  2  3  4    
 Work Practices BSL: 1  2  3  4    
 Floor Plan: Open  Separate Room  Alcove   
 Biological Safety Cabinet: Class I  Class II  Class III  No    
 BSC Certified: Yes  No   
 Properly Maintained Autoclave: Yes  No  N/A   
 Hand-washing Sink: Yes  No    
 Non-porous Chairs: Yes  No  N/A    
 Impervious Bench Tops: Yes  No   
**Personal Protective Equipment Available:**  
 Gloves: Latex  Nitrile  Vinyl  Other   
 Protective Eyewear: Safety Glasses  Goggles  Face Shield  N/A   
 Protective Clothing: Labcoat  Coveralls  Impermeable Gown  Impermeable Closed-front Gown  Tyvek Jumpsuit   
 Respiratory Protection: Surgical Mask  N95  PAPR  N/A   
 Is staff fit-tested, at least annually?: Yes  No  N/A   
 Other: Booties  \_\_\_\_\_   
 Improperly Maintained Equipment: Yes  No   
 If yes, list equipment that is improperly maintained: \_\_\_\_\_  
 \_\_\_\_\_

### Section VIII: Facility & Equipment Risks Mitigation Measures

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Bureau of Public Health Laboratories

# Conducting a Biosafety Risk Assessment

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## Standard Operating Procedure

The purpose of this document is to provide a guideline for developing a biosafety risk assessment for a procedure in a clinical or public health laboratory. This SOP includes instructions and tools for conducting a risk assessment and tools and resources for implementing risk mitigation plans. Each laboratory section should participate in its own risk assessment and mitigation using the information presented in this SOP and accompanying tools and resources. Management, supervisors, and laboratory workers should be involved in performing the risk assessment and implementing the safety measures that are decided upon. This document can be referred to as the initial risk assessment is performed and in the future on an annual basis or as conditions in the laboratory change.



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## Signature Page

<b>Prepared by:</b>	<b>Effective</b>	<b>Supersedes Procedure #</b>
Emilie Cooper Edgar W. Kopp IV	2/9/2016	N/A

<b>Approved by:</b>	<b>Date</b>	<b>Signature</b>
Laboratory Director		
Departmental Review		N/A

<b>Revisions:</b>	<b>Date</b>	<b>Signature</b>

<b>Annual Review:</b>	<b>Date</b>	<b>Signature</b>



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**I. Purpose:**

a. The purpose of this document is to provide a guideline for developing a biosafety risk assessment for a procedure in a clinical or public health laboratory. This SOP includes instructions and tools for conducting a risk assessment and tools and resources for implementing risk mitigation plans. Each laboratory section should participate in its own risk assessment and mitigation using the information presented in this SOP and accompanying tools and resources. Management, supervisors, and laboratory workers should be involved in performing the risk assessment and implementing the safety measures that are decided upon. This document can be referred to as the initial risk assessment is performed and in the future on an annual basis or as conditions in the laboratory change.

**II. Scope:**

a. Biosafety risk assessment is useful in every section of a laboratory that could be exposed to biological agents or toxins. This risk assessment SOP provides information on how to perform and use biosafety risk assessment to improve the safety of the clinical or public health laboratory.

**III. Reagents/Media:**

N/A

**IV. Supplies/Materials:**

N/A

**V. Equipment:**

N/A

**VI. Safety Precautions:**

N/A

**VII. Sample Requirements:**

N/A

**VIII. Quality Control:**

N/A

**IX. Procedures:**

a. Risk Assessment Overview:

i. ➤ Explanation:

1. Risk assessment can have multiple applications in a laboratory, including being used to improve quality. As used in this SOP, a risk assessment is a systematic process of evaluating the potential risks that may be involved in a projected activity or undertaking. A risk can be based on either a hazard (biosafety) or a threat (biosecurity). A hazard is a source, situation, or act with the potential for harm while a threat is a person who has intent or ability to cause harm (Salerno, 2015). Collectively, these



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risks are called biorisk. While both biosafety and biosecurity are important, this SOP will focus exclusively on biosafety risk assessment. Any use of the terms “risk assessment” or “risk mitigation” in this SOP is in reference to biosafety risk.

2. During a risk assessment, information is gathered regarding any hazardous substances or activities, and possible risks associated with exposure are evaluated. After the risks have been identified, strategies are developed to diminish exposure chances and provide protection. It is important to remember that there is not just one correct way to conduct a risk assessment and risk assessments should not be one size fits all. Risk assessments are meant to be developed based on where they will be used and the hazardous substances or activities that are found in the place they will be used. Although a risk assessment should be thorough and safeguards put in place when a risk or deficiency is identified, those safeguards should not be so strenuous so as to impede laboratory work or create a burden for staff. Complex and cumbersome safeguards can result in the circumvention of the practices meant for safety (BMBL 5<sup>th</sup> ed.pg 9). Risk assessments should consider safeguards including elimination or substitution, engineering or facility controls, administrative controls (which include laboratory policies and guidelines, practices, and procedures), and personal protective equipment (Salerno, 2015).
3. Risk assessments should be fluid, rather than rigid, to allow for evolution with time and changing risks. Ideally, a risk assessment should be performed before any new work is begun. The assessment should be done again when risks change. These changes can occur even when experiments or processes do not (Salerno, 2015). Examples of changes that should include a new risk assessment include, but are not limited to, work with new organisms, different or new procedures, new or changing laboratory workers, laboratory renovation or move, and changes in the security or threat levels in the area (Salerno, 2015). The risk assessment should be reevaluated at least on an annual basis. A valid, well rounded risk assessment is the product of biosafety staff, laboratory staff, and laboratory management working together and communicating about the hazards that occur in that laboratory (Salerno, 2015). The goal of the risk assessment and risk mitigation processes is to make a laboratory environment safe and to minimize the risk to laboratory personnel and the community at large. Risk assessment should be part of an overall culture of safety in an institution.
4. Although there is no one way to do a risk assessment, there are a few basic steps that can be used to perform a risk assessment that applies to all laboratories. First, identify the hazards that are present. Second, identify the activities that might cause exposure to these hazards. Consider activities such as centrifugation, opening specimen packaging, or waste disposal. Next, consider the competencies, education, and experience of the laboratory personnel with these activities, procedures, and agents. Fouth, evaluate and prioritize the risks. Consider how likely these activities are to cause exposure or harm. Finally, develop and



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implement controls and evaluate controls that have been put into place to recognize how effective they are (MMWR, 2012).

5. There are five basic steps to performing a risk assessment.
  - a. **Identify the hazards.** Note the potential for infection. Ask questions such as what is the most common mode of transmission? In the lab is transmission most likely to happen from surfaces or cuts or inhalation or exposure to mucous membranes or inhalation? How frequently and in what concentration is the organism isolated? If possible, it is important to know the virulence and pathogenicity of the agent when determining the risks it presents.
  - b. **Identify the activities that might cause exposure.** Determine what instrumentation will be used to process and test the sample containing the organism. For example, if centrifugation will be used the potential for aerosolization is a risk factor to consider. The facility where the specimen will be processed to determine if an open work space is being used or if the laboratory uses separate spaces for specific activities. The workflow of the specimen testing from one area of the lab to another should also be considered.
  - c. **Consider the competency and experience of laboratory personnel.** Assess what the training and the experience of the staff is with an agent or in biosafety when dealing with unknown agents. Consider the lab personnel's attitude toward biosafety and adherence to safety rules and precautions that are already in place. Consider the age and genetic predisposition/medical status of lab workers. Stress, fatigue and demands on the time of lab workers should also be taken into consideration.
  - d. **Evaluate and prioritize risks.** What is the likelihood of occurrence for the risk? This could range from almost certain to rare. What is the severity of consequences if the risk does occur? Can the infected person become a carrier? Will death occur upon exposure?
  - e. **Develop, implement, and evaluate controls to minimize the risk for exposure.** Once the risks have been evaluated, controls can be put into place to mitigate them. Engineering controls include primary barriers such as a BSC and secondary barriers like facility design. Administrative controls are those that institute policies and procedures for the lab. These include signage, prohibition of eating or drinking in the lab, limiting the use of sharps and emphasizing the need for routine housekeeping measures. PPE is the final barrier between the lab personnel and the risk. Along with general PPE such as gloves, specific PPE should be evaluated for each risk and implemented accordingly. This could include the use of face shields or respirators. All of these controls must be routinely evaluated for usefulness and failures should be documented and addressed. More detailed



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information on controls can be found in the section titled "[Analysis of Procedure's Steps Using Risk Assessment Hazard Exposure Activities and Controls Worksheet.](#)"

6. The basic steps for risk assessment are shown in the flow chart below:

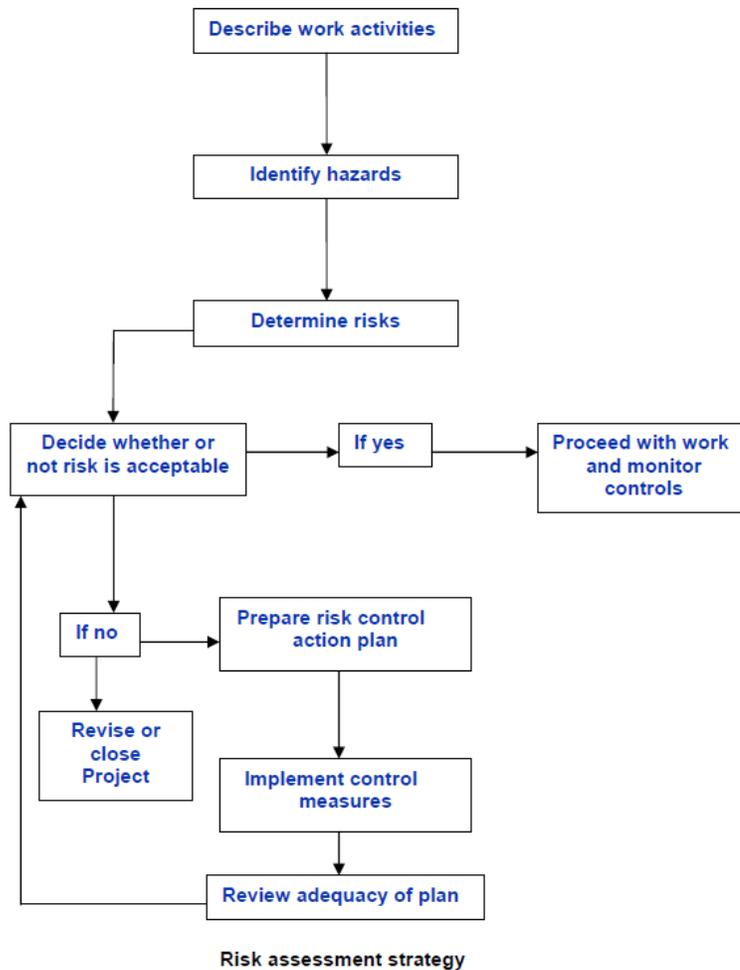


Figure 1 - From Laboratory Biorisk Management - Guidelines for the Implementation of CWA 15793:2008

7. With the above ideas in mind, this biosafety risk assessment SOP will guide the user through creating a written biosafety risk assessment for a clinical or public health laboratory procedure.
8. With the understanding that these labs perform procedures where a specimen may contain more than just the agent for which it's being tested, this SOP strives to include hazards from any agents in a specimen, not just the ones for which a procedure is testing.
9. If desired, one can conduct an assessment on each of the lab's SOPs, or one can conduct an assessment on each general type of procedure.



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- a. For example, if a lab has an SOP for performing an influenza DFA and an SOP for performing an adenovirus DFA, one can conduct an assessment of each of these SOPs separately or together since most of the procedural steps are likely the same.
10. While this SOP guides the user through creating a written biosafety risk assessment for a procedure, the user should keep in mind that there is no one way to do a risk assessment. All of the procedures and related documents referenced herein should help a clinical or public health laboratory readily create a thorough and practical risk assessment. That said, it is ultimately up to the institution and its staff to decide how to best approach a risk assessment. Management may determine that certain procedures and documents described here should be modified or expanded upon. Regardless of the format of the risk assessment, any thorough risk assessment should incorporate the ideas described in this SOP.
11. In all of the procedures described here, it assumed that the user is creating the written risk assessment on the computer.
12. For an overview of the steps in this risk assessment SOP and the documents that will be generated over its course, refer to the [“Biosafety Risk Assessment Flowchart.”](#)
- ii. ➔ Procedure:
  1. Open the institution’s “Biosafety Risk Assessment” folder.
    - a. If it does not already exist, create one.
  2. If they are not already there, place a copy of the [“Biosafety Risk Assessment Flowchart,”](#) [“Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository,”](#) and [“Biosafety Risk Assessment Control Failure Worksheet”](#) in this institution’s “Biosafety Risk Assessment” folder.
- b. Documentation:
  - i. ➤ Explanation:
    1. As a first step in creating a written biosafety risk assessment, the user will create documentation of the procedure being assessed along with the agents or targets that this procedure tests for. This documentation also includes the personnel involved in the creation and approval of the assessment and the dates on which it occurred.
  - ii. ➔ Procedure:
    1. Create a folder for this risk assessment and name it appropriately.
    2. Place a copy of the [“Biosafety Risk Assessment Documentation Worksheet”](#) in this risk assessment’s folder and open it.
    3. Document the risk assessment by typing in the appropriate fields.
      - a. Field notes:
        - i. In the “Institution” and “Laboratory Unit/Section/Department” fields, type in the lab information for the procedure being assessed.
          - A. For example, “Institution” might be “Florida Department of Health, Bureau of Public Health Laboratories – Jacksonville, Jacksonville, Florida”



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- or “Florida’s Favorite Hospital, Orlampa, Florida.”
        - “Laboratory Unit/Section/Department” might be “Microbiology” or “Molecular Diagnostics.”
      - ii. In the “Name of Procedure Being Assessed” field, type in the name of the specific or general procedure being assessed.
        - A. If you are assessing a specific SOP, use that SOP’s name. If you are assessing a more general procedure that encompasses multiple SOPs, use a descriptive general name.
        - B. Optionally, in the fields below “Name of Procedure Being Assessed,” type in specific SOP information.
      - iii. In the “Agents or Targets Tested by This Procedure” field, type in all of the agents or targets that this procedure tests for.
        - A. For example, if the procedure is a rhinovirus RT-PCR, type “rhinovirus.”
      - iv. In the “Names of Individuals Involved in Conducting the Assessment” box, type in the names and lab roles (or position titles) of anyone who was involved in this assessment.
    - 4. Save the document and close it.
  - c. Preparing Standard Operating Procedures (SOPs):
    - i. ➤ Explanation:
      - 1. All laboratory procedures should have an accurate, up-to-date SOP that reflects the work that is actually being done. This is important both as standard laboratory practice and because the risk assessment should be informed by and perhaps lead to changes in a laboratory procedure’s SOP.
        - a. All SOPs should be in the institution’s approved format with all sections completed as necessary. This is important because earlier formats may not include important points as they relate to a risk assessment, including but not limited to safety precautions.
      - 2. The risk assessment will cover the entire laboratory process, including specimen receipt, specimen handling, all steps of the testing process, specimen storage or disposal, waste handling, and specimen shipment from the lab. As a result, laboratory SOPs must include all of these components.
    - ii. ➔ Procedure:
      - 1. Prior to performing a risk assessment, steps should be taken to ensure that the SOP reflects the actual work.
        - a. With input from applicable supervisors and laboratory staff, compare the bench work currently being done for a procedure to the written SOP.



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- b. If it is found that the SOP is missing steps that should have been included:
  - i. Add the missing steps to the SOP.
  - ii. The director should sign off on the updated SOP.
  - iii. Train applicable staff so that they are versed in the updated SOP.
- c. If steps are included in the SOP but are either not being done or are being done differently than described in the SOP, update the SOP as necessary:
  - i. If the steps in the SOP are accurate and should be followed:
    - A. If considered helpful, add additional clarification to the SOP to ensure that the steps are being performed correctly.
    - B. The director should sign off on the updated SOP if necessary.
    - C. Train applicable staff so that they are versed in the current or updated SOP.
  - ii. If the steps in the SOP should be removed or are inaccurate:
    - A. Update the SOP as necessary.
    - B. The director should sign off on the updated SOP.
    - C. Train applicable staff so that they are versed in the updated SOP.
2. Ensure that SOPs collectively encompass the entire laboratory process. If they do not:
  - a. Update the SOP(s) as necessary.
  - b. The director should sign off on the updated SOP.
  - c. Train applicable staff so that they are versed in the updated SOP.
- d. Consideration of Biological and Chemical Hazards:
  - i. Biological Hazards:
    1. ➤ Explanation:
      - a. Work in a clinical or public health laboratory often involves specimens that contain biological agents or toxins, and these present a hazard to people in the lab, resulting in biological hazards (or biohazards). Some of these hazards are expected because you know what the lab procedure is testing for, but some are unexpected because the specimen could contain agents or toxins other than the ones of interest in the procedure.
      - b. Biological hazards in a laboratory can come as a function of exposure from the procedure or assay being performed, from the specimen being tested, from the waste being generated, or other sources. The identification and mitigation of the risks should be considered from sample receipt to specimen testing through destruction or shipment of the specimen. Consider if the identified



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biological hazard can be substituted or eliminated or which engineering/facility controls, administrative practices, and PPE can be used to mitigate the risks of the hazard.

- c. Some resources to consider for help in characterizing biohazards include:
    - i. [Canadian Pathogen Safety Data Sheets and Risk Assessment](#)
    - ii. [HHS/CDC/NIH Biosafety in Microbiological and Biomedical Laboratories 5th Edition](#)
    - iii. [American Biological Safety Association \(ABSA\) Risk Group Database](#)
    - iv. [World Health Organization \(WHO\) Biorisk management for disease specific recommendations](#)
    - v. [U.S. Food and Drug Administration \(FDA\) Handbook of Foodborne Pathogenic Microorganisms and Natural Toxins \(AKA The Bad Bug Book\)](#)
    - vi. [Clinical and Laboratory Standards Institute \(CLSI\) Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition](#)
    - vii. Peer-reviewed scientific literature
      - A. Google Scholar (<http://scholar.google.com/>) is an example of a search engine for peer-reviewed scientific literature. Other methods can be useful and can capture other articles not found using Google Scholar.
  - d. As part of the risk assessment, the user will create a list of biological agents or toxins that could be in specimens tested in the procedure in question along with important considerations for these agents or toxins. This will ensure that special agent/toxin-specific considerations are accounted for in the risk assessment.
2. ➔ Procedure:
- a. Place a copy of the "[Biosafety Risk Assessment Biological Agent Summary Worksheet](#)" in this risk assessment's folder and open it.
  - b. Create a list of biological agents or toxins that could be in specimens tested in the procedure in question along with important procedure-dependent considerations by typing in the appropriate fields, checking the appropriate boxes, and choosing from the appropriate dropdown boxes.
    - i. Field notes:
      - A. In the "Agent/Toxin" column of the "Biological Agents and Toxins That Could Be in Specimens That Are Being Tested by This Procedure" box, type in all of the biological agents and toxins that could be in a specimen tested by the procedure being assessed, not just the ones you are most expecting.
  - c. Save the document and close it.



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- d. Open the institution's "Biosafety Risk Assessment Biological Agent Evaluation Worksheet" folder.
    - i. If it does not already exist, create one.
  - e. Look in the folder for the agents or toxins just listed in the "Biosafety Risk Assessment Biological Agent Summary Worksheet."
  - f. If the agent or toxin is present, one can use the existing evaluation for that agent or toxin. Copy the appropriate evaluation to this risk assessment's folder.
    - i. One should consider creating a new evaluation if the existing one is reasonably old so that the latest information is considered. This is especially important for emerging diseases.
  - g. If any agents or toxins are missing, for each missing agent/toxin:
    - i. Place a copy of the "[Biosafety Risk Assessment Biological Agent Evaluation Worksheet](#)" in the institution's "Biosafety Risk Assessment Biological Agent Evaluation Worksheet" folder and rename it so it matches the following formatting, where "AGENT NAME" is the agent/toxin's name and "YYYY-MM-DD" is the date on which this evaluation was completed in year-month-day format:
      - A. Biosafety Risk Assessment Biological Agent Evaluation Worksheet - AGENT NAME - YYYY-MM-DD
    - ii. Open the just-renamed "Biosafety Risk Assessment Biological Agent Evaluation Worksheet" and evaluate the agent or toxin for important procedure-independent considerations by typing in the appropriate fields and checking the appropriate boxes.
      - A. Refer to the above "[resources to consider for help in characterizing biohazards](#)" for agent and toxin information for these fields and boxes.
      - B. The [Canadian Pathogen Safety Data Sheets and Risk Assessment](#) website is especially useful.
      - C. Field notes:
        - a. Cite the sources used in the "Information Sources Used for Evaluation" box.
    - iii. Save the document and close it.
    - iv. Copy this evaluation to this risk assessment's folder.
- ii. Chemical Hazards:
1. ➤ Explanation:
    - a. Although most of the scope of this SOP is dedicated to looking at biohazards, chemical hazards in a laboratory should also be considered. Any chemical that is used in a procedure or assay should be considered for its risk. Elimination of toxic chemicals should be considered. If elimination is not possible, substitution for a less toxic or non-toxic chemical should be assessed. This



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consideration of chemical hazards includes having safety data sheets (SDS) in the laboratory and readily available to staff for use. Consider if the identified chemical hazard can be substituted or eliminated or which engineering/facility controls, administrative, practices, and PPE can be used to mitigate the risks of the hazard.

- b. Information on chemical hygiene can be found in the [CDC NIOSH Pocket Guide to Chemical Hazards](#).
  - c. As part of the risk assessment, the user will create a list of chemicals that may be used in the procedure in question along with important considerations for them as they relate to this particular procedure, including amount and concentration. This will ensure that special chemical-specific considerations are accounted for in the risk assessment.
2. → Procedure:
- a. Place a copy of the "[Biosafety Risk Assessment Chemical Summary Worksheet](#)" in this risk assessment's folder and open it.
  - b. Create a list of chemicals that may be used in the procedure in question along with important procedure-dependent considerations for them by typing in the appropriate fields and checking the appropriate boxes.
    - i. Field notes:
      - A. In the "Chemical Name" column of the "Chemicals That May Be Used in This Procedure" box, type in all of the chemicals used in the procedure being assessed.
    - c. Gather applicable chemical SDSs for all chemicals listed in the "Biosafety Risk Assessment Chemical Summary Worksheet." If the SDS is available digitally, copy the SDS to this risk assessment's folder.
      - i. The "[Chemical Hygiene Information](#)" part of the Related Documents section has links to some chemical SDS resources. Other resources may be used as well.
    - d. Consulting the SDSs, for each chemical, indicate in its row if there could be a large amount or high concentration of the particular chemical when it is used in this procedure.
    - e. Save the document and close it.
  - e. Analysis of Procedure's Steps Using Risk Assessment Hazard Exposure Activities and Controls Worksheet:
    - i. ➤ Explanation:
      1. At the core of a risk assessment is the analysis of what activities may expose a laboratorian to the hazards associated with biological agents and toxins. By looking at every aspect of a procedure (specimen receipt, specimen handling, the testing process, specimen storage, specimen disposal, waste handling, and specimen shipment from lab), the user can identify where a laboratorian could be exposed to a hazard ("what could



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- go wrong”) and as a result where control measures are needed to make sure this exposure doesn’t happen.
2. Once the procedure is examined and activities with exposure potential are determined, appropriate controls measures can be found to minimize the chance of exposure.
  3. Control measures are ways to mitigate identified risks (“how to keep things from going wrong”). There are generally five categories of controls:
    - a. The first is elimination or substitution. If a risk can be removed from a laboratory it is eliminated. However, elimination is not always possible. Sometimes substitution of one material, chemical, process, etc. with something else that is less of a hazard or threat can reduce the risk posed by the original object. For example, using an alternative strain of a bacteria that reduces the risk for infection but still allows the research to continue is an effective control.
    - b. The second kind of control is an engineering control. Engineering controls are physical changes to a laboratory, workstation, or equipment that reduces risk. A biological safety cabinet is an example of an engineering control.
    - c. The third category of control is administrative. Guidelines and policies are examples of administrative controls. Staff proficiencies and competencies are also considered administrative controls as is laboratory signage, labeling, and markings.
    - d. The fourth control measure, practices and procedures, includes following standard operating procedures (SOPs) and implementing policies that reduce the chance for things like needle sticks, generating aerosols, and splash hazards.
    - e. Finally, personal protective equipment (PPE) is an important control. PPE is anything worn by the laboratory worker to protect them from biological or chemical hazards. PPE includes, but is not limited to, gloves, gowns, lab coats, respirators, and face shields (Salerno, 2015).
  4. For the purposes of this risk assessment, controls have been grouped into three broader categories:
    - a. Administrative and Work Practice Control (AWP). This includes elimination or substitution, administrative, and practices and procedures.
    - b. Engineering Control (Eng). This includes engineering practices.
    - c. Personal Protective Equipment Control (PPE). This includes personal protective equipment.
  5. Authoritative biosafety resources, the scientific literature, and instrument manuals should be consulted for information on possible exposure activities and recommended controls. Some good biosafety resources include:
    - a. [HHS/CDC/NIH Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 5th Edition](#)



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- b. [Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories](#)
  - c. [Clinical and Laboratory Standards Institute \(CLSI\) Protection of Laboratory Workers From Occupationally Acquired Infections: Approved Guideline Third Edition](#)
  - d. [World Health Organization \(WHO\) Laboratory Biosafety Manual Third Edition](#)
  - e. [Government of Canada Canadian Biosafety Standards and Guidelines for Facilities Handling Human and Terrestrial Animal Pathogens, Prions, and Biological Toxins First Edition](#)
6. As part of this risk assessment, the user will create a list of general activities involved in all aspects of a procedure, the hazards those activities could pose, what controls are currently being used, what controls are recommended in the scientific literature and biosafety resources to mitigate that risk, and whether or not changes in controls should be made based on a comparison of current and recommended controls. This will be done in the "[Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet](#)."
  7. To aid in the creation of this list, common procedure activities, their hazards, and their recommended controls have been compiled in the "[Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository](#)" using information from good biosafety resources and the scientific literature. This repository will continually expand as new hazards and controls are identified.
  8. For instruments and methods that are not present in the repository and for which information can't readily be found, the user can use the "[Biosafety Risk Assessment Instrument-Method Worksheet](#)" to begin to evaluate an instrument or method.
- ii. → Procedure:
1. Place a copy of the "[Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet](#)" in this risk assessment's folder and open it.
  2. Using the procedure's SOP and your knowledge of the work, list the general activities performed as part of the procedure in the "Activity/Practice/Procedure" column.
    - a. Think of this broadly as "what are you doing?"
    - b. Examples include "centrifuging" and "catalase testing."
    - c. Refer to the "Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository" for known examples ([see below](#)).
  3. In the "Phase" column, indicate in what phase of the procedure this activity occurs, including:
    - a. Specimen receipt.
    - b. Specimen handling.
    - c. Testing process.
    - d. Specimen storage.
    - e. Specimen disposal.



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- f. Waste handling.
- g. Specimen shipment from lab.
- 4. **Note:** In describing the activities and phases, think of the entire procedure. This includes the following:
  - a. Specimen receipt, including:
    - i. Specimen transportation or shipment to lab (via package shipment, courier, pneumatic tube, or hand delivery).
    - ii. Specimen (or specimen package) receipt in lab.
    - iii. Transfer of specimen (or specimen package) to testing area.
  - b. Specimen handling, including:
    - i. Opening specimen package or secondary container.
    - ii. Specimen accessioning and preparation prior to testing, including:
      - A. Specimen container handling during accessioning (scanning into a computer, recording on a log, etc.).
      - B. Specimen container labeling.
      - C. Paperwork handling.
      - D. Transportation of specimen between testing areas prior to the testing process.
  - c. Testing process, including:
    - i. Specimen aliquoting.
    - ii. Specimen (or specimen product) manipulations via reagent or mechanical means.
    - iii. Loading specimen (or specimen product) onto instruments.
    - iv. Unloading specimen (or specimen product) from instruments.
    - v. Using instruments or other equipment.
    - vi. Servicing or moving instruments or other equipment.
    - vii. Moving/transporting specimen (or specimen product) during the testing process.
    - viii. Observing specimen (or specimen product), such as when observing bacterial cultures or using a microscope to look for cytopathic effect.
    - ix. Disinfection or decontamination that occurs during the course of testing (such as after using BSCs or instruments).
    - x. Cell culture/culture on nutrient plates of viruses or bacteria.
  - d. Specimen storage, including:
    - i. Moving a specimen (or specimen product) into or out of storage (such as refrigerators, freezers, or incubators).
  - e. Specimen disposal, including:
    - i. Removing a specimen (or specimen product) from the lab, eventually or immediately into the medical waste stream.
  - f. Waste handling, including:
    - i. Handling and disposing of waste generated:
      - A. During specimen receipt.



Vision: To be the Healthiest State in the Nation

- B. During specimen handling.
- C. During the testing process.
- D. During specimen storage.
- E. During specimen disposal.
- F. As a result of disinfection or decontamination activities.
- g. Specimen shipment from lab, including:
  - i. Packaging and shipping a specimen from the lab being assessed to another lab (reference lab, state public health lab, CDC, etc.).
- 5. If one or more of these phases is described in a separate SOP, the user may wish to perform a separate risk assessment for the other SOP. However, all of these phases should be assessed in a risk assessment, whether together or separately.
- 6. In the “Potential Hazard(s)” column, indicate what hazards might be present during that activity.
  - a. Think of this as “what could go wrong while I’m doing this?”
  - b. Refer to the “Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository” for known examples ([see below](#)).
- 7. In the “Current Control Type” column, indicate the current type of control that is being used to mitigate this risk, including:
  - a. A/WP (Administrative and Work Practice Control).
  - b. Eng (Engineering Control).
  - c. PPE (Personal Protective Equipment Control).
  - d. **Note:** If more than one type of control is used to mitigate this risk, use a separate row for the other type(s) of control.
- 8. In the “Current Control” column, indicate the control that is currently being used to mitigate this risk and that corresponds to the appropriate control type.
  - a. Think of this as “how can we make sure this hazard doesn’t happen?”
  - b. Examples include “removable rotors” and “work in BSC.”
- 9. In the “Recom. Control Type” and “Recommended Control” columns, indicate the type and description of the control that is recommended to mitigate this risk. Recommendations should be taken from [authoritative biosafety resources](#), the scientific literature, and instrument manuals.
  - a. Think of this as “what do the experts say we should do to make sure this hazard doesn’t happen?”
  - b. Refer to the “Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository” for known examples ([see below](#)).
  - c. For recommended controls for instruments and methods that are not present in the repository and for which information can’t readily be found in biosafety resources, the literature, or manuals, the user can use the Instrument-Method Worksheet to begin to evaluate an instrument or method ([see below](#)).



Vision: To be the Healthiest State in the Nation

- d. **Note:** If more than one type of control is used to mitigate this risk, use a separate row for the other type(s) of control.
10. In the “Special Considerations” column, indicate if this control applies specifically to certain circumstances.
11. In the “Source of Control Recommendation” and “Chapter/Page #” columns, indicate where this control recommendation was found.
  - a. For “Source of Control Recommendation,” you may use an abbreviation and give more detail in the “References” sheet.
12. Compare the current and recommended controls. If the recommended control is different from the current control, select “Yes” in the “Change Needed?” column and indicate in the “Change to be Made” column what must be done to bring the current procedure in line with the recommendations.
13. The [“Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository”](#) is provided to facilitate the creation of this list. It includes common procedure activities, their hazards, and their recommended controls as described in authoritative biosafety resources and the scientific literature.
  - a. Prior to looking up hazards and recommended controls, one may wish to refer to the repository.
    - i. Your institution’s current copy is located in the institution’s “Biosafety Risk Assessment” folder.
    - ii. The current copy is the most recent version in that folder.
    - iii. Refer to the “Activities and Controls” and “New Activities and Controls” sheets.
  - b. The repository is formatted in the same way as the “Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet.” This enables you to copy and paste the content of the “Recom. Control Type,” “Recommended Control,” “Special Considerations,” “Source of Control Recommendation,” and “Chapter/Page #” columns directly from the repository into the worksheet.
  - c. **Note:** The repository will be updated over time with additional activities, hazards, and recommended controls. Always check to see if there is a more recent version.
    - i. If there is a more recent version than the one currently in the institution’s “Biosafety Risk Assessment” folder:
      - A. Download the new version to your desktop.
      - B. Open the current version and the new version.
      - C. In the new version, delete the “New Activities and Controls” and “New References” (purple) sheets.
      - D. Copy the “New Activities and Controls” and “New References” (purple) sheets from the current version to the new version.
      - E. Close the current version without saving.
      - F. Save the new version and close it.
      - G. Move the new version to the institution’s “Biosafety Risk Assessment” folder.



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14. For specific instruments and methods:

- a. As with other parts of the procedure being assessed, refer to the "Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository" for documented potential hazards and recommended controls for specific instruments and methods.
- b. There are many instruments and methods used in clinical laboratories, and as a result, there is a significant chance that the instrument or method being considered will not be found in the "Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository." It is especially important to consult the scientific literature and manufacturer documentation for instruments and methods.
- c. If insufficient information is available through the "Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository," scientific literature, and manufacturer documentation, or if one wants to supplement this information, use the "[Biosafety Risk Assessment Instrument-Method Worksheet](#)" to help evaluate the potential hazards of specific instruments or methods and determine what controls should be used to mitigate them.
  - i. Place a copy of the "[Biosafety Risk Assessment Instrument-Method Worksheet](#)" in this risk assessment's folder and rename it so it matches the following formatting, where "INSTRUMENT-METHOD" is the instrument or method's name and "YYYY-MM-DD" is the date on which this evaluation was completed in year-month-day format:
    - A. Biosafety Risk Assessment Instrument-Method Worksheet - INSTRUMENT-METHOD - YYYY-MM-DD
  - ii. Open the just-renamed "Biosafety Risk Assessment Instrument-Method Worksheet" and evaluate the potential hazards of the instrument or method and determine what controls should be used to mitigate them by checking the appropriate boxes.
    - A. In the "Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet," the instrument or method being evaluated would fall under "Activity/Practice/Procedure." The Instrument/Method Worksheet will help determine the "Potential Hazard(s)" and associated "Recommended Control."
  - iii. Save the document and close it.

f. Analysis of Overall Procedural Considerations:

i. ➤ Explanation:

1. As previously mentioned, risk assessment should be part of the culture of safety in an institution. This means that all of the parts of an institution should be assessed. To help with this process, the "[Biosafety Risk](#)



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- [Assessment General Considerations Worksheet](#)” identifies several hazards commonly encountered in a laboratory over a wide range of activities. By taking the time to check and answer the questions, a laboratory can identify where more consideration needs to be given to a particular activity or procedure. This activity will also help ask more general questions about the laboratory procedures.
2. For example, new equipment necessitates a review of the risk assessment to identify any new risks that might be associated with the new equipment and how to mitigate those risks. If, however, the new equipment does not have risk identified and protections in place for those risks, the laboratory that has already implemented a culture of safety will already be asking questions like “What could go wrong” and “How can we prevent that from happening?” (Trevan, 2015). These questions can be applied throughout the laboratory in both specific situations, like the new equipment, and for general procedural considerations.
- ii. ➔ Procedure:
1. Place a copy of the [“Biosafety Risk Assessment General Considerations Worksheet”](#) in this risk assessment’s folder and open it.
  2. Analyze overall procedural considerations, including ones specific to the procedure being considered, the laboratory, and the institution, by typing in the appropriate fields and checking the appropriate boxes.
    - a. **Note:** Each section heading is immediately followed by a note describing the intended audience of its considerations. If a section is not applicable to this procedure, laboratory unit/section/department, or institution, then choose or write “N/A” as necessary.
  3. Save the document and close it.
- g. Competency Assessment of Laboratory Personnel:
- i. ➤ Explanation:
    1. Risk assessments should include an initial and periodic check of the competency of the laboratory staff to identify any deficiencies. Carelessness and complacency are also important to note as it can lead to accidents or exposures (BMBL 5<sup>th</sup> ed. pg 15). Education of laboratory staff is essential. This training should not only be about the testing in the lab but also about the hazards in the laboratory and how to work safely there.
    2. There are four competency domains to consider: Skill Domain I: Potential Hazards, Skill Domain II: Hazard Controls, Skill Domain III: Administrative Controls, Skill Domain IV: Emergency preparedness and response (MMWR Guidelines for Biosafety Laboratory Competency, 2011 and Pentella, 2015). These competencies are tiered into three levels depending on the role the staff has in the laboratory. These tiers are entry level, mid-level, and senior level (Pentella, 2015).
    3. Skill domain I is focused on recognizing and understanding the hazards in the laboratory. It has four subdomains: biological materials, research animals, chemical materials, and radiological materials (Pentella, 2015).



4. Skill domain II relates to the use of primary and secondary barriers to prevent exposure. This domain covers assessing the competency of staff to decontaminate and dispose of hazardous waste. The four subdomains are PPE, engineering controls-equipment (primary barriers), engineering controls-facility (secondary barriers), and decontamination and waste control management (Pentella, 2015).
  5. Skill domain III is focused on administrative controls such as signage and labeling that reduce the duration, frequency, and severity of exposure to hazardous materials or situations. Subdomains include hazardous communication and signage, guidelines and regulatory compliance, safety program management, occupational health program, and risk management (Pentella, 2015).
  6. Skill domain IV is about emergency preparedness and response. This is about how a facility plans for emergencies in the laboratory. The three subdomains are emergencies and incident response, exposure prevention and hazard mitigation, and exercises and drills (Pentella, 2015).
  7. More information on assessing competencies can found in the MMWR reports "[Competency Guidelines for Public Health Laboratory Professionals](#)" and "[Guidelines for Biosafety Laboratory Competency](#)."
- ii. ➔ Procedure:
1. Using the information contained in the above explanation, check your laboratory unit/section/department's training and personnel competency assessment documents.
    - a. Update the documents as necessary to ensure that they reflect the competencies described above. If desired, create separate general biosafety training and competency assessment documents.
    - b. If any updates or additions are made, train personnel accordingly, preferably including hands-on training.
  2. Perform competency assessments of all personnel on a regular basis as called for by regulations and institutional policies.
    - a. If it was found that updates or additions to training and competency assessment documents were necessary, all impacted personnel should have their competency assessed after training is completed.
- h. Implementation of New Controls:
- i. ➤ Explanation:
    1. After hazards have been identified and controls considered, the "[Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet](#)" should be used to identify what controls are already in place and what controls are missing and should be added to mitigate risks. Each type of control should be evaluated for effectiveness and its mitigation properties.
    2. Additional control changes are also determined using the "[Biosafety Risk Assessment Biological Agent Summary Worksheet](#)," applicable "[Biosafety Risk Assessment Biological Agent Evaluation Worksheets](#)," the "[Biosafety](#)



Vision: To be the Healthiest State in the Nation

- [Risk Assessment Chemical Summary Worksheet](#),” applicable chemical SDSs, the [“Biosafety Risk Assessment General Considerations Worksheet,”](#) and the [“Biosafety Risk Assessment Risk Likelihood and Consequences Evaluation Worksheet.”](#)
3. Controls should be written into the procedure manual and any SOPs that are in use. For example, when describing a procedure, indicate in what area of the lab it should be performed in, such as the BSL-3 or in the BSC, or when talking about PPE, indicate that some equipment, such as respirators, can be tiresome to the wearer so that can be taken into account (Pentella, 2015).
  4. The implementation of new controls should be done with education of the staff. Signage and reminders of how to properly use any controls, new and old, are helpful. The laboratorians should also be evaluated for competency after the controls have been put into place and education has been given.
- ii. → Procedure:
1. **Note:** Following this SOP and using its related documents may show that additional controls are recommended over the currently-used controls. Ideally, all recommended controls will be used to ensure that all personnel are as safe as possible. With that being said, after consulting with staff and management, it may be deemed impractical or cost-prohibitive to implement all identified new controls. If this is the case, one should prioritize the risks identified and address controlling the risks in order of severity, examining the likelihood and consequences of the hazard.
    - a. In such a situation, use the [“Biosafety Risk Assessment Risk Likelihood and Consequences Evaluation Worksheet”](#) to help evaluate the risk of each hazard that has recommended controls being considered for implementation. Controls whose risk is more severe (has an evaluation closer to the top right of the worksheet’s chart) should be given priority.
  2. In this risk assessment’s folder, open the “Biosafety Risk Assessment Biological Agent Summary Worksheet,” related “Biosafety Risk Assessment Biological Agent Evaluation Worksheets,” and the “Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet.”
  3. Looking at the “Biosafety Risk Assessment Biological Agent Evaluation Worksheets:”
    - a. Update this risk assessment’s “Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet” if necessary to reflect vaccine, disinfectant, PPE, and post-exposure treatment recommendations, adding new controls to the “Recommended Control” column.
    - b. If the agent/toxin poses an inhalation, percutaneous exposure, mucosal membrane, or ingestion risk, update this risk assessment’s “Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet” if necessary to ensure that it





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7. Close the “Biosafety Risk Assessment Chemical Summary Worksheet” and related chemical SDSs.
  8. Looking at the “Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet,” look for all controls that have “Yes” in the “Change Needed?” column.
    - a. For these controls, discuss the content of the “Change to be Made” column with relevant personnel, supervisors, and managers.
    - b. If the change is ultimately decided by supervisors and managers to be beneficial, update the affected SOP(s) and procedure manual as necessary.
  9. In this risk assessment’s folder, open the “Biosafety Risk Assessment General Considerations Worksheet.”
    - a. Looking at the non-N/A considerations, consider whether the status of the institution, laboratory, and procedure matches the necessary practices, policies, and amenities to best protect personnel and the environment.
      - i. This is especially important for considerations with a “No” answer.
    - b. For practices, policies, and amenities that are not considered sufficient, discuss them with relevant personnel, supervisors, and managers, and institution management.
    - c. If changes are ultimately decided by supervisors, managers, and institution management to be beneficial, update the affected SOP(s) and procedure manual as necessary.
  10. Close the “Biosafety Risk Assessment General Considerations Worksheet.”
  11. The director should sign off on the updated SOP(s).
  12. Review the risk assessment findings and updated procedures with applicable personnel and train them as necessary using the updated SOP(s).
  13. Looking at the personnel competency assessments, use group and one-on-one training to address group and individual competency deficiencies.
  14. Purchase any additional PPE or engineering controls as necessary to implement the new controls.
  15. Use all new controls henceforth.
- i. Evaluation of Existing and New Controls:
- i. ➤ Explanation:
    1. Both new and existing controls should be evaluated and changed or updated as needed based upon an evaluation of their effectiveness over time. Evaluation of effectiveness includes things like injury and illness tracking, physical inspection, accident reports, occupational health assessments, and observation. Asking questions like “Has this control solved the problems,” “Is the identified risk contained,” “Has the effectiveness of the control been documented,” and “Have new hazards been identified and mitigated via controls” can help assess a control for

- effectiveness in mitigation (Canadian Center for Occupational Health and Safety website).
2. When a control is reevaluated and deemed ineffective or a control failure occurs, such incidents should be documented and tracked and kept for future reference. This can be done using a simple form such as the "[Biosafety Risk Assessment Control Failure Worksheet](#)."
  3. The documentation of a control failure should lead to the implementation of changes in procedure and possibly performing a new risk assessment. If a safety protocol or procedure is changed, it is important that the staff be trained. This could also serve as a safety refresher for all of the safety policies that have been established. SOPs relating to the areas where the control failure was observed should be updated to reflect the changes that were made.

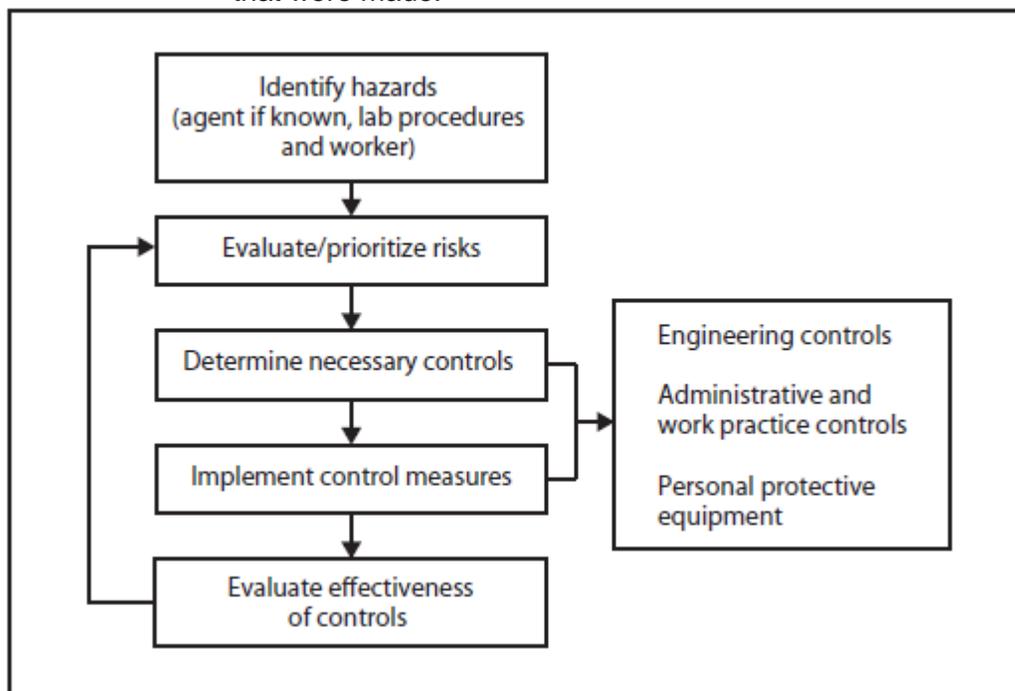


Figure 2 - From Guidelines for Safe Work Practices in Human and Animal Diagnostic Laboratories MMWR Jan 2012

ii. ➔ Procedure:

1. Establish and utilize tools that will allow you to monitor the effectiveness of already-existing and newly-implemented controls. Examples include:
  - a. Audits
  - b. Inspections
  - c. Questionnaires
  - d. Interviews
  - e. Training evaluations
  - f. Incident reports
  - g. **Note:** Pages 147-148 of Salerno (2015) detail the description, advantages, and disadvantages of the above tools. As the greater



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“Evaluating Biorisk Management Performance” chapter notes, these tools provide some utility in measuring control performance but are often done in a reactive manner. The chapter advocates for and fully describes a proactive performance measurement-based approach to evaluating the effectiveness of existing and new controls.

2. Optionally, when the current control(s) (if any) failed to prevent an exposure to a hazard resulting in personnel and the environment being exposed to a hazard, track the control failure in “[Biosafety Risk Assessment Control Failure Worksheet](#).”
  - a. This can occur either through a failure of the current control (because of malfunctioning or misuse) or because inadequate/ineffective controls are in place.
  - b. Examples of failure of the current control because of malfunctioning or misuse include:
    - i. A/WP: individuals not following the work practices and procedures set in place, including not using engineering controls and PPE controls appropriately.
    - ii. Eng: mechanical failure like a defective BSC.
    - iii. PPE: individuals not using correct PPE, using PPE incorrectly, or defective PPE.
  - c. In the event of control failure due to misuse, the following steps are prudent:
    - i. Train personnel to drive home existing procedures.
    - ii. Update SOPs to emphasize/clarify existing procedures.
3. If, through evaluation of controls, it is found that a previously-unidentified or new hazard is present, reevaluation of the risk assessment is necessary as follows.
  - j. Reevaluation of Risk Assessment:
    - i. ➤ Explanation:
      1. Risk assessment should be redone at least annually and under circumstances such as:
        - a. Implementation of new assays.
        - b. Implementation of new methods.
        - c. A new pathogen is detected or used in the laboratory.
        - d. Equipment is moved.
        - e. New equipment is introduced.
        - f. The potential for aerosolization is introduced.
        - g. The potential for needle sticks is introduced.
        - h. The laboratory or laboratory section is physically moved.
        - i. Significant changes in staffing.
        - j. When a near miss or accident occurs.
        - k. When a new hazard is identified.
      2. When a risk assessment is performed again, whether it is a scheduled annual review or after a qualifying event like those listed above, the same steps that were used to conduct the initial risk assessment can be used again. The risk assessment process is an ongoing one, but one that uses



the same basic steps, no matter when or for what reason it is performed. If the risk assessment is being performed because a new hazard has been identified, document and track the new hazard in the “New Activities and Controls” sheet in the institution’s current copy of the “[Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository](#).” Seek out new controls for the hazard and add these to the repository.

ii. ➔ Procedure:

1. Annually or in the event of any of the circumstances [described above](#), perform the risk assessment again according to this SOP.
  - a. At a minimum, review the most recent risk assessment for the procedure, looking for completeness and accuracy.
    - i. Create a new version and update it with any additions or corrections as necessary and address the steps outlined above including updating SOP(s), training staff, addressing competency needs, and implementing new controls.
  - b. If a new hazard is identified, document it in the institution’s current copy of the “[Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository](#).” Add it, its phase, its activity/practice/procedure, the recommended control(s) you determine for it, and the source(s) of the control recommendation(s) to the “New Activities and Controls” and “New References” sheets as appropriate.
  - c. Be mindful that new hazards, agent/toxin characteristics, or controls may have been identified in the “[Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository](#),” updated versions of [authoritative biosafety resources](#), the scientific literature, and updated versions of instrument manuals since the last risk assessment was performed.

**X. Results (Qualitative/Quantitative):**

N/A

**XI. Inoperable Test System:**

N/A

**XII. References:**

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Vision: To be the Healthiest State in the Nation

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- l. World Health Organization (WHO) Laboratory Biosafety Manual Third Edition.
  - i. [http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_CSR\\_LYO\\_2004\\_11/en/](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/)

### XIII. Related Documents:

- a. Biosafety risk assessment documents/worksheets/tools:
  - i. "Biosafety Risk Assessment Flowchart"
    - 1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Flowchart
  - ii. "Biosafety Risk Assessment Documentation Worksheet"
    - 1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Documentation\_Worksheet
  - iii. "Biosafety Risk Assessment Biological Agent Summary Worksheet"
    - 1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Biological\_Agent\_Summary\_Worksheet
  - iv. "Biosafety Risk Assessment Biological Agent Evaluation Worksheet"
    - 1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Biological\_Agent\_Evaluation\_Worksheet
  - v. "Biosafety Risk Assessment Chemical Summary Worksheet"
    - 1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Chemical\_Summary\_Worksheet
  - vi. "Biosafety Risk Assessment Hazard Exposure Activities and Controls Worksheet"



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1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Hazard\_Exposure\_Activities\_and\_Controls\_Worksheet
- vii. "Biosafety Risk Assessment Instrument-Method Worksheet"
  1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Instrument-Method\_Worksheet
- viii. "Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository"
  1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Hazard\_Exposure\_Activities\_and\_Controls\_Repository
- ix. "Biosafety Risk Assessment General Considerations Worksheet"
  1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_General\_Considerations\_Worksheet
- x. "Biosafety Risk Assessment Risk Likelihood and Consequences Evaluation Worksheet"
  1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Risk\_Likelihood\_and\_Consequences\_Evaluation\_Worksheet
- xi. "Biosafety Risk Assessment Control Failure Worksheet"
  1. FDOH.BPHL.Biosafety\_Risk\_Assessment\_Control\_Failure\_Worksheet
- b. Biological agent/toxin information:
  - i. American Biological Safety Association (ABSA) Risk Group Database:
    1. <https://my.absa.org/tiki-index.php?page=Riskgroups>
  - ii. Canadian Pathogen Safety Data Sheets and Risk Assessment:
    1. <http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php>
  - iii. Clinical and Laboratory Standards Institute (CLSI) Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition:
    1. <https://utahflowcytometry.files.wordpress.com/2012/11/blood-borne-2.pdf>
  - iv. HHS/CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition:
    1. <http://www.cdc.gov/biosafety/publications/bmbl5/>
  - v. U.S. Food and Drug Administration (FDA) Handbook of Foodborne Pathogenic Microorganisms and Natural Toxins (AKA The Bad Bug Book):
    1. <http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/>
  - vi. World Health Organization (WHO) Biorisk management for disease specific recommendations:
    1. [http://www.who.int/ihr/publications/bioriskmanagement\\_3/en/](http://www.who.int/ihr/publications/bioriskmanagement_3/en/)
- c. Chemical hygiene information:
  - i. Centers for Disease Control and Prevention (CDC) NIOSH Pocket Guide to Chemical Hazards:
    1. <http://www.cdc.gov/niosh/npg/>
  - ii. Fisher Scientific SDS:
    1. <https://www.fishersci.com/us/en/catalog/search/sdshome>
  - iii. Thermo Fisher Scientific MSDS:
    1. [http://www.thermofishersci.in/technical\\_msds/](http://www.thermofishersci.in/technical_msds/)
  - iv. United States Department of Labor Occupational Safety & Health Administration (OSHA) Occupational Chemical Database:
    1. <https://www.osha.gov/chemicaldata/>



2. <http://www.ccohs.ca/topics/hazards/chemical/chemicals/>

**XIV. Attachments:**



# LABORATORY RISK ASSESSMENT TOOL

## STATE HYGIENIC LABORATORY AT THE UNIVERSITY OF IOWA

### Overview:

The SHL Laboratory Risk Assessment Tool is intended to guide laboratory staff through the risk assessment process for the work they regularly perform. Throughout this process, a mindset of “what COULD go wrong” should be maintained. The goal of the risk assessment process is to identify and minimize all potential risks that may adversely affect 1) the health and safety of laboratory staff, 2) the health and safety of non-laboratory staff, 3) the health and safety of the general public, and 4) the quality of work being performed. For additional information on biosafety and the risk assessment process, please refer to the [list of resources](#) provided in this document.

### Step 1. Identify the hazards.

Please select ALL potential hazards listed below that could affect the laboratory section being assessed. Where appropriate, provide additional details describing specific hazards. If more space is needed, please attach an additional page(s).

<b>Biological</b>
<input type="checkbox"/> Blood/Body fluid <input type="checkbox"/> Bacteria <input type="checkbox"/> Viruses <input type="checkbox"/> Parasites <input type="checkbox"/> Fungus <input type="checkbox"/> Toxins <input type="checkbox"/> Waste <input type="checkbox"/> Other/Details: Enter other biological hazards or details here.
<b>Chemical (Refer to the label and Safety Data Sheet (SDS) for the classification and management of all chemicals)</b>
<input type="checkbox"/> Non-hazardous chemical(s) <input type="checkbox"/> Hazardous Chemicals <input type="checkbox"/> Waste <input type="checkbox"/> Other/Details: Enter other chemical hazards or details here.
<b>Radiological (includes ultraviolet light sources)</b>
<input type="checkbox"/> External radiation sources (resulting from close proximity to, limited shielding of, or prolonged exposure to source) <input type="checkbox"/> Internal radiation sources (e.g. resulting from ingestion, inhalation, inoculation, or skin absorption) <input type="checkbox"/> Waste <input type="checkbox"/> Other/Details: Enter other radiological hazards or details here.
<b>Physical and Environmental</b>
<input type="checkbox"/> Heat <input type="checkbox"/> Cold <input type="checkbox"/> Sharps <input type="checkbox"/> Loud noise <input type="checkbox"/> Electrocutation <input type="checkbox"/> Allergens <input type="checkbox"/> Pinch/crush/scrape <input type="checkbox"/> Repetitive movements (e.g. bending, crouching, pipetting) <input type="checkbox"/> Heavy lifting <input type="checkbox"/> Reaching <input type="checkbox"/> Slip/trip/fall <input type="checkbox"/> Other/Details: Enter other physical/environmental hazards or details here.
<b>Procedure, Equipment, and Instrumentation</b>
<input type="checkbox"/> Aerosols <input type="checkbox"/> Splash/splatter/spray <input type="checkbox"/> Vapors <input type="checkbox"/> Steam <input type="checkbox"/> Small volume spills <input type="checkbox"/> Large volume spills <input type="checkbox"/> Surface contamination <input type="checkbox"/> Explosion (contents under pressure) <input type="checkbox"/> Projectiles (e.g. failed centrifuge) <input type="checkbox"/> Other/Details: Enter other procedure/equipment/instrumentation hazards or details here.
<b>Facilities and Systems</b>
<input type="checkbox"/> Electricity (e.g. power outage) <input type="checkbox"/> Gas (e.g. interior lines) <input type="checkbox"/> Pressurized gas (e.g. gas cylinders) <input type="checkbox"/> Air handlers/HVAC <input type="checkbox"/> Other/Details: Enter other facilities/systems hazards or details here.
<b>Critical Incident</b>
<input type="checkbox"/> Fire <input type="checkbox"/> Severe weather <input type="checkbox"/> Intruder <input type="checkbox"/> Lockdown <input type="checkbox"/> Evacuation <input type="checkbox"/> Disruption <input type="checkbox"/> Other/Details: Enter other critical incident hazards or details here.
<b>People</b>
<input type="checkbox"/> Students <input type="checkbox"/> Visitors <input type="checkbox"/> Staff <input type="checkbox"/> Psychological/Stress <input type="checkbox"/> Other/Details: Enter other people hazards or details here.
<b>Other hazards and/or additional details (if more space is needed, please attach an additional page(s))</b>
Please provide additional hazard details here.

## Step 2. Assess the level of risk.

Use tables A through C below to assess the risk level associated with each hazard identified in Step 1, above.

**Table A.** Likelihood of hazard occurrence.

Hazard Likelihood	Description of Likelihood
1. Rare	Will only occur in exceptional circumstances
2. Unlikely	Not likely to occur within the foreseeable future
3. Possible	May occur within the foreseeable future, sporadic exposure is possible
4. Likely	Likely to occur within the foreseeable future, routine exposure is likely
5. Highly Likely	Almost certain to occur within the foreseeable future, consistent exposure is highly likely

**Table B.** Consequence of hazard occurrence.

Hazard Consequence	Description of Consequence
1. Insignificant	No treatment required
2. Minor	Minor injury requiring First Aid treatment (e.g. minor cuts, bruises, bumps)
3. Moderate	Injury requiring medical treatment or lost time
4. Major	Serious injury (injuries) requiring specialist medical treatment or hospitalization
5. Critical	Loss of life, permanent disability or multiple serious injuries

**Table C.** Based on the likelihood and consequence determined above, identify the risk level of each hazard using the Risk Assessment Matrix below.

Risk Assessment Matrix		Hazard Consequence				
		Insignificant	Minor	Moderate	Major	Critical
Hazard Likelihood	Highly likely	Medium	Medium	High	Extreme	Extreme
	Likely	Low	Medium	High	High	Extreme
	Possible	Low	Medium	High	High	High
	Unlikely	Low	Low	Medium	Medium	High
	Rare	Low	Low	Low	Medium	Medium

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

Assessed Risk Level		Description of Risk Level	Actions
<input type="checkbox"/>	Low	If an incident were to occur, there would be little likelihood that an injury would result.	Undertake the activity with the existing controls in place.
<input type="checkbox"/>	Medium	If an incident were to occur, there would be some chance that an injury requiring First Aid would result.	Additional controls are advised.
<input type="checkbox"/>	High	If an incident were to occur, it would be likely that an injury requiring medical treatment would result.	Control will need to be in place before the activity is undertaken.
<input type="checkbox"/>	Extreme	If an incident were to occur, it would be likely that a permanent, debilitating injury or death would result.	Consider alternatives to doing the activity. Significant control measures will need to be implemented to ensure safety.

[\(Return to top\)](#)

### Step 3. Identify control measures and complete the Laboratory Risk Management Worksheet.

Using the following guidance, complete the Laboratory Risk Management Worksheet found in [Appendix A](#).

- A. List the specific task being performed.
- B. List the identified hazard associated with that task.
- C. List the risk level determined for that hazard in Step 2, above.
- D. Describe the control measure you will implement to eliminate or mitigate the risk. **Note:** Control measures should be implemented in accordance with the preferred **hierarchy of control** (see Table E below). If a lower level control measure (such as Administrative Controls or PPE) is to be implemented without higher level controls, it is important that the reasons are approved by supervisor.
- E. List the risk level (refer to Steps 1 and 2) remaining with the described control measure in place.
- F. Describe how the described control measure will be implemented (e.g. implement precautions into SOP and/or ensure employees are trained in hazards/precautions).
- G. Describe how this control measure will be supervised (e.g. daily by supervisor, monthly by safety committee, annually by associate director).

**NOTE:** The Laboratory Risk Management Worksheet should be completed by laboratory staff who regularly perform the work being assessed. The completed worksheet should then be reviewed and signed by the section supervisor and the division associate director.

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

### Step 4. Monitor and review the control measures and complete the Risk Management Hotwash Worksheet.

After performing work with the implemented control measures identified in Step 3 above, complete the Risk Management Hotwash Worksheet found in [Appendix B](#).

**NOTE:** The Risk Management Hotwash Worksheet should be completed by laboratory staff who regularly perform the work being assessed. The completed worksheet should then be reviewed and signed by the section supervisor and the division associate director.

[\(Return to top\)](#)

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## Resources

The creation of this guidance document involved the review and integration of information from many resources, listed below. If additional information is desired, these resources should be consulted.

[Biosafety in Microbiological and Biomedical Laboratories, 5<sup>th</sup> Ed.](#) (2009). U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health.

Chapter 12 Prevention of Lab-acquired Infections. (2015). Manual of Clinical Microbiology, 11<sup>th</sup> Ed.

Chapter 12.6 Health and Lab Work. Section IV Humans. (2006). Exposure – A Guide to Sources of Infections.

[Department of the Army Form DA FORM 7566. Composite Risk Management Worksheet.](#) (2005). Department of the Army.

[Health and Safety Risk Assessment Template.](#) (2012). Queensland Government, Department of Education, Training and Employment.

Hierarchy of Controls (2015). The National Institute for Occupational Safety and Health (NIOSH). Center for Disease Control and Prevention. <http://www.cdc.gov/niosh/topics/hierarchy/>.

[Laboratory Biosafety Manual, 3<sup>rd</sup> Ed.](#) (2004). World Health Organization.

[Managing Health and Safety Risks.](#) (2012). Queensland Government, Department of Education, Training and Employment.

[Morbidity and Mortality Weekly Report \(MMWR\) Supplement/Vol. 61](#) (2012). U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

[NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) (2013). Department of Health and Human Services, National Institutes of Health.

[Pamphlet 385-69. Safety. Safety Standards for Microbiological and Biomedical Laboratories](#) (2013). Department of the Army.

[\(Return to top\)](#)

## Appendix A

### SHL LABORATORY RISK MANAGEMENT WORKSHEET

For instructions on use of this form, [see guidance information above](#). Determine risk levels using the [Risk Assessment Matrix](#) above.

**LABORATORY SECTION AND/OR PROCEDURE:** Enter the name of the laboratory section and/or procedure here. **DATE PREPARED:** Select today's date.

**PREPARED BY:** Enter your name here. **TITLE/POSITION:** Enter your title or position here.

A. TASK	B. HAZARD	C. INITIAL RISK LEVEL	D. CONTROL MEASURES	E. RESIDUAL RISK LEVEL	F. HOW TO IMPLEMENT	G. HOW TO SUPERVISE (WHO)
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?

Iowa SHL Laboratory Risk Assessment Tool

Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?
Describe the task.	Describe the hazard.	Select the risk level.	Describe the appropriate control measures.	Select the risk level.	Describe how the control measures will be implemented.	Who will be responsible for this process?

OVERALL RISK LEVEL FOR THIS SECTION OR PROCEDURE AFTER CONTROL MEASURES HAVE BEEN IMPLEMENTED (SUPERVISOR PLEASE CHECK ONE):				
<input type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High <input type="checkbox"/> Extreme				
<b>RISK MANAGEMENT AUTHORIZATION</b> (TO BE SIGNED BY SECTION SUPERVISOR AND ASSOCIATE DIRECTOR)	Enter name here.	Enter title/position here.	Select today's date.	
	<b>SECTION SUPERVISOR</b>	<b>TITLE/POSITION</b>	<b>DATE</b>	<b>SIGNATURE</b>
	Enter name here.	Enter title/position here.	Select today's date.	
	<b>ASSOCIATE DIRECTOR</b>	<b>TITLE/POSITION</b>	<b>DATE</b>	<b>SIGNATURE</b>

[\(Return to top\)](#)

### Appendix B. Risk Management Hotwash Worksheet

<i>To be completed by laboratory staff during and/or after they perform work with control measures in place.</i>	<b>Yes</b>	<b>No</b>
1. Are the planned control measures sufficient and effective in minimizing the level of risk?	<input type="checkbox"/>	<input type="checkbox"/>
2. Have there been any changes to the planned control measures?	<input type="checkbox"/>	<input type="checkbox"/>
3. Are any changes and/or additional control measures required in the future?	<input type="checkbox"/>	<input type="checkbox"/>

DETAILS: Please provide any additional information here.

<b>Hotwash Authorization</b> (TO BE SIGNED BY SECTION SUPERVISOR AND ASSOCIATE DIRECTOR)	<b>SECTION SUPERVISOR:</b> Enter name here.	<b>POSITION/TITLE:</b> Enter position/title here.
	<b>SIGNATURE:</b>	<b>DATE:</b> Select today's date.
	<b>ASSOCIATE DIRECTOR:</b> Enter name here.	<b>POSITION/TITLE:</b> Enter position/title here.
	<b>SIGNATURE:</b>	<b>DATE:</b> Select today's date.

[\(Return to top\)](#)

**New York State Department of Health  
Wadsworth Center--Biohazard Risk Assessment**

<b>New York State Department of Health  Wadsworth Center  Clinical Laboratory</b>	<b>Biohazard Risk Assessment</b>	
	<b>QS-21.01AppA</b>	<b>Rev. No. Initial</b>
	<b>Effective Date: 12/27/10</b>	
	1 of 9	

**1. Purpose**

This is a guide for the completion of the Biohazard Risk Assessment Form (QS-21FormA). A Biohazard Risk Assessment is completed by each laboratory section utilizing this guide along with the *Biosafety in Microbiological and Biomedical Laboratories, 5<sup>th</sup> edition* and *WHO, Laboratory Biosafety Manual, 3<sup>rd</sup> edition* and the video *Essentials in Biosafety*. These documents and a link to the video can be found on the QMS Wiki.

**2. References**

- 2.1 Biosafety in Microbiological and Biomedical Laboratories (BMBL). U.S. Department of Health and Human Services, Public Health Service and Centers for Disease control and Prevention and National Institutes of Health. 5<sup>th</sup> Edition. December 2009.
- 2.2 Clinical Laboratory Safety. Clinical Laboratory Standards Institute Approved Guideline. GP17-A2, 2<sup>nd</sup> edition. 2004.
- 2.3 *Essentials in Biosafety: Overview of Biosafety Principles and Use of the Biological Safety Cabinet*. <http://www.wadsworth.org/testing/lrn/resources.html>
- 2.4 NYSDOH Clinical Laboratory Standards of Practice, Part 1- General Systems, Part 2 - Specialty Requirements. January 2008. Revised Safety Standards August 2010. <http://www.wadsworth.org/labcert/clep/standards.htm>
- 2.5 OSHA Bloodborne Pathogens: [www.osha.gov/SLTC/bloodbornepathogens](http://www.osha.gov/SLTC/bloodbornepathogens)
- 2.6 World Health Organization. Laboratory Biosafety Manual. 3<sup>rd</sup> edition. Geneva. 2004.

**3. Requirements** (as stated in the NYS DOH CLEP Safety Standards, August 2010).

- 3.1 Each laboratory section (permit category) shall have an infectious agent risk assessment which is approved by the Assistant Laboratory Director, Wadsworth Center Director of Safety and Security.
- 3.2 Laboratory sections may use the form attached to this SOP (QS-21FormA) or documentation approved by the Director of Safety and Security.
- 3.3 The risk assessment will:
  - Be reviewed annually by the Assistant Laboratory Director and revised as needed.
  - Minimally meet Biosafety level 2 (BSL-2) criteria and incorporate, as appropriate, the use of a certified class II (or higher) biological safety cabinet (BSC) and/or

**New York State Department of Health  
Wadsworth Center--Biohazard Risk Assessment**

other containment equipment/devices and practices intended to prevent release of infectious aerosols into the work environment.

- Incorporate use of appropriate personal protective equipment (PPE) such as lab coat or gowns, face shields and disposable gloves intended to protect the worker from splashes, spills or other direct contact with infectious specimens or materials.
- When applicable, include a written plan to be implemented in the event that an agent suspected of exceeding the laboratory's Biosafety level/practices is encountered. The plan shall include provisions for:
  - Immediate notification of the laboratory supervisor and/or assistant director/and safety officer;
  - Cessation of work with the material until appropriate safety practices and PPE can be put into place or the specimen is transferred to the appropriate laboratory section;
  - Implementation of the post-exposure response protocol, if applicable.
- Ensure that staff is trained and proficient regarding the laboratory's biohazard risks, use of PPE and safety equipment.

**4. Background Information** (from the Biological Risk Assessment Section of BMBL5)

4.1 The primary factors to consider in risk assessment and selection of precautions fall into two broad categories:

- Agent hazards
- Laboratory procedure hazards

4.2 **Hazardous Characteristics of an agent** are:

- Its capability to infect and cause disease in a susceptible human or animal host
- Its virulence as measured by the severity of disease
- The availability of preventive measures and effective treatments for the disease
  - Infective dose
  - Stability in the environment
  - Host range
  - Endemic nature

4.3 **Hazardous characteristics of Laboratory Procedures:**

- Probable routes of transmission of laboratory infection, which include:
  - Direct skin, eye or mucosal membrane exposure to an agent
  - Parenteral inoculation by a syringe needle or other contaminated sharp, or by bites from infected animals and arthropod vectors
  - Ingestion of liquid suspension of an infectious agent, or by contaminated hand to mouth exposure
  - Inhalation of infectious aerosols. Sources of infectious aerosols include, but are not limited to:
    - Pipetting
    - Blenders
    - Non-self contained centrifuges
    - Sonicators
    - Vortex Mixers

**5. Assessing the Risk and Selecting Appropriate Safeguards** (Complete QS-21.01FormA during the assessment process).

**New York State Department of Health  
Wadsworth Center--Biohazard Risk Assessment**

- 5.1 Describe the specimen type(s) and principal agent risks for the laboratory section.
  - 5.2 Identify each method or procedure.
  - 5.3 List all the Risk Factor(s) associated with each method or procedure.
  - 5.4 Identify Hazards associated with each method or procedure.
  - 5.5 Identify the required practices and safety equipment (i.e., primary barriers and personal protective equipment) needed for each risk factor.
  - 5.6 Identify triggers for implementation of enhanced precautions for high risk agents as appropriate.
  - 5.7 Identify additional enhancements in practices or safety equipment.
- 6. Evaluate the proficiencies of staff regarding safe practices and the integrity of safety equipment.**  
All staff within the laboratory section shall be trained on the biohazard risks for the methods/tasks that they performed. Competency shall be assessed annually along with other safety procedures.

**7. Documentation**

- 7.1 Upon completion and approval by the Assistant Director of the laboratory section, the Biohazard Risk Assessment Form (QS-21FormA), will be sent to the David Hill, Director of Safety and Security for review and approval.
- 7.2 The approved Biohazard Risk Assessment (QS-21FormA) will be maintained in the laboratory section. Copies of the approved assessment will be maintained in the WC Safety Office and the QA Office
- 7.3 Annually, each Biohazard Risk Assessment is reviewed by the Assistant Director and revised as needed.
  - If a revision is needed, the Biohazard Risk Assessment will need to be reviewed and approved by the Director of Safety and Security.
  - Copies of the revised Biohazard Risk Assessment will be forwarded to the QA Office.

**New York State Department of Health  
Wadsworth Center--Biohazard Risk Assessment**

- A. Laboratory:**
- B. Biosafety level:**
- C. Room Number(s):**
- D. Description of specimen type(s) and principal agent risks:**

**Method or Procedure:**

<b>Risk Factor(s)</b>	<b>Hazards</b>	<b>Required practices, primary barriers, and safety equipment</b>	<b>Triggers for implementation of enhanced precautions for high risk agents</b>

**Method or Procedure:**

<b>Risk Factor(s)</b>	<b>Hazards</b>	<b>Required practices, primary barriers, and safety equipment</b>	<b>Triggers for implementation of enhanced precautions for high risk agents</b>

**Method or Procedure:**

<b>Risk Factor(s)</b>	<b>Hazards</b>	<b>Required practices, primary barriers, and safety equipment</b>	<b>Triggers for implementation of enhanced precautions for high risk agents</b>

**New York State Department of Health  
Wadsworth Center--Biohazard Risk Assessment**

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**Method or Procedure:**

<b>Risk Factor(s)</b>	<b>Hazards</b>	<b>Required practices, primary barriers, and safety equipment</b>	<b>Triggers for implementation of enhanced precautions for high risk agents</b>

**Method or Procedure:**

<b>Risk Factor(s)</b>	<b>Hazards</b>	<b>Required practices, primary barriers, and safety equipment</b>	<b>Triggers for implementation of enhanced precautions for high risk agents</b>

**Method or Procedure:**

<b>Risk Factor(s)</b>	<b>Hazards</b>	<b>Required practices, primary barriers, and safety equipment</b>	<b>Triggers for implementation of enhanced precautions for high risk agents</b>

**Comments:**

**Approvals:**

**New York State Department of Health  
Wadsworth Center--Biohazard Risk Assessment**

**Section**

**Assistant**

**Director:**

**Date:**

\_\_\_\_\_

\_\_\_\_\_

**Biosafety Officer:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Annual Review**

<b>Director or Designee</b>	<b>Signature</b>	<b>Date</b>



**New York State Department of Health  
Wadsworth Center--Biohazard Risk Assessment**

<b>Revision</b>	<b>Date</b>	<b>Responsible Person</b>	<b>Description of Change</b>
1			1 <sup>st</sup> release in document control system

Appendix A – Document Number: QS-21.01AppA-Biohazard Risk Assessment

<b>Revision</b>	<b>Date</b>	<b>Responsible Person</b>	<b>Description of Change</b>
1			1 <sup>st</sup> release in document control system

Form A – Document Number: QS-21.01Form A-Biohazard Risk Assessment

<b>Revision</b>	<b>Date</b>	<b>Responsible Person</b>	<b>Description of Change</b>
1			1 <sup>st</sup> release in document control system

**Distribution:**

Documented on Form QS-07 - Document Distribution and Retrieval

**Training:**

Section Specific SOP

Center-wide SOP - Section reviewing SOP: \_\_\_\_\_

The following Laboratory Staff have read, understood, agreed to reference and use the most recent version of all documents within this Controlled Document Series. All employees must read and sign-off on the entire Controlled Document Series once. All employees must review and sign-off on all subsequent revisions (training not required for

