



Bureau of Public Health Laboratories

Conducting a Biosafety Risk Assessment

Standard Operating Procedure

The purpose of this document is to provide a guideline for developing biosafety risk assessments for procedures in clinical or public health laboratories. This standard operating procedure (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

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I. Purpose:

- a. The purpose of this document is to provide a guideline for developing biosafety risk assessments for procedures in clinical or public health laboratories. This standard operating procedure (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:

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- Implementation of New Controls ➤ [Explanation](#) ➔ [Procedure](#)
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- Reevaluation of Risk Assessment ➤ [Explanation](#) ➔ [Procedure](#)

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 risks are called biorisks. 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 as to impede laboratory work or create an unnecessary burden for staff. Complex and cumbersome safeguards can result in the circumvention of the practices meant for safety (BMBL 5th 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 (PPE) (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 inexperienced 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



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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 singular way to do a risk assessment, there are five basic steps that can be used to perform a risk assessment that applies to all laboratories (MMWR, 2012):
 - a. **Identify the hazards.** Note the potential for infection. Ask questions such as what is the most common mode of transmission? Is transmission in the laboratory most likely to happen from surfaces, cuts, inhalation, or exposure to mucous membranes? 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 activities, practices, procedures, and 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. Consider the layout of the facility where the specimen will be processed and determine if an open work space is being used or whether separate spaces are required 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 the training and experience of staff in dealing with an agent or in biosafety when dealing with unknown agents. Consider the laboratory personnel's attitude toward biosafety and adherence to safety rules and precautions currently in place. Consider the age and medical status of laboratory workers, including pregnancy and immune status. 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? Is post-exposure prophylaxis available?
 - e. **Develop, implement, and evaluate controls to minimize the risk for exposure.** Once the risks have been evaluated, controls can be put in place to mitigate them. Engineering controls include primary barriers such as a biological safety cabinet (BSC) and secondary barriers like facility design. Administrative controls are those that institute policies and procedures for the laboratory. These include signage, prohibition of eating or drinking in the laboratory, 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



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

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

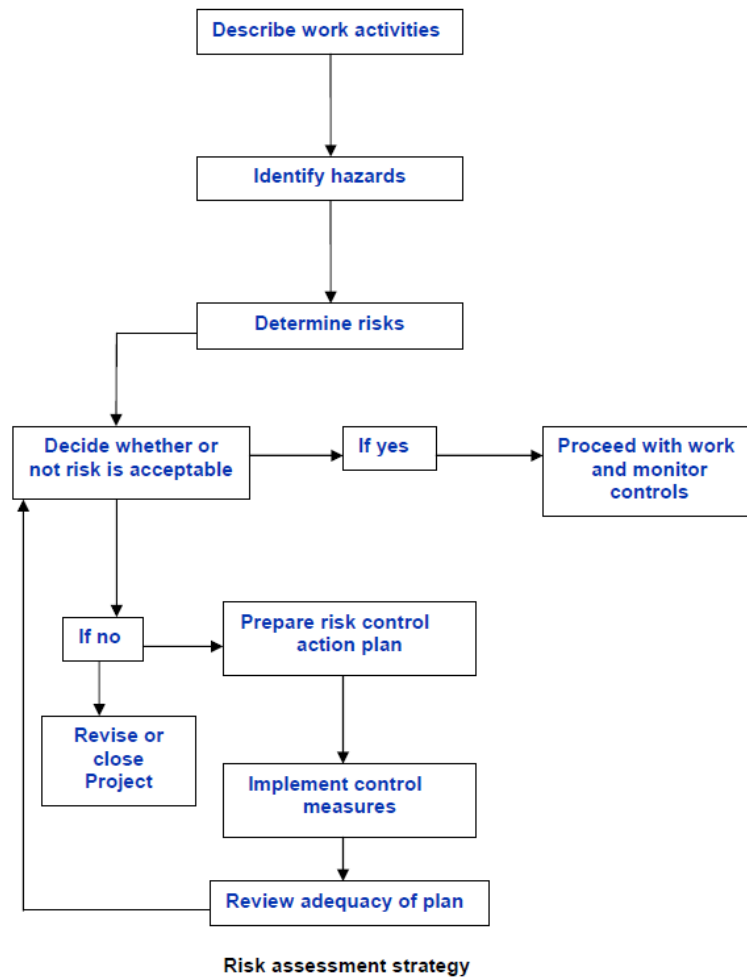


Figure 1 - From Laboratory Biorisk Management - Guidelines for the Implementation of CWA 15793:2008.

6. 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.
7. With the understanding that these laboratories perform procedures where a specimen may contain more than just the agent(s) for which it is being tested, this SOP strives to include hazards from all agents in a specimen, not just the one(s) for which a procedure is testing.



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8. If desired, one can conduct an assessment on each of the laboratory's SOPs, or one can conduct an assessment on each general type of procedure.
 - a. For example, if a laboratory has an SOP for performing an influenza direct fluorescent antibody test (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.
9. 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 procedures and related documents referenced herein should help a clinical or public health laboratory readily create a thorough and practical risk assessment. 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 risk assessment format, any thorough risk assessment should incorporate the ideas described in this SOP.
10. In all procedures described here, it is assumed that the user is creating the written risk assessment on the computer.
11. 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: Organizational List.](#)"
12. Terminology notes:
 - a. "Assay" is a procedure for analyzing the presence, amount, or activity of a target of interest. Specific laboratory procedure SOPs and more general procedures typically incorporate one or more assays.
 - b. "Institution" is the larger organization in which the laboratory is located.
 - i. For example, this might be "Florida Department of Health, Bureau of Public Health Laboratories – Jacksonville, Jacksonville, Florida" or "Florida's Favorite Hospital, Orlampa, Florida."
 - c. "Instrument" is a piece of laboratory equipment that is used to assist in the completion of a procedure. Often, an instrument is at least partially automated and is used to obtain measurements or results of a specimen.
 - d. "Laboratory Unit/Section/Department" is the place where the laboratory procedure being assessed is performed. It is usually part of a larger organization, referred to here as the Institution.
 - i. For example, this might be "Microbiology" or "Molecular Diagnostics."
 - e. "Method" is a systematic, particular form of procedure that is used to help accomplish part of the greater procedure. It can include manual or automated steps, including the use of one or more instruments.



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- f. "Risk Group" is a classification recommended by the World Health Organization (WHO) for laboratory use that describes four general risk groups based on an agent's principal characteristics (capability to infect and cause disease in a susceptible human or animal host, virulence as measured by the severity of disease, and the availability of preventive measures and effective treatments for the disease) and the route of transmission of the natural disease. They correlate with but do not equate to biosafety levels. The risk assessment determines the degree of correlation between an agent's risk group classification and biosafety level (BMBL 5th Edition).
- 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 this Standard Operating Procedure ("Conducting a Biosafety Risk Assessment" Standard Operating Procedure, biosafety-risk-assessment), "[Biosafety Risk Assessment: Organizational List](#)," "[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 for which this procedure tests. 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 "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.
 - ii. In the "Agents or Targets Tested by This Procedure" field, type in the names of all agents or targets for which this procedure tests.
 - A. For example, if the procedure is a rhinovirus RT-PCR, type "rhinovirus."



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- iii. In the “Names of Individuals Involved in Conducting the Assessment” box, type in the names and lab roles (or position titles) of anyone involved in this assessment.
4. Save the document and close it.
- c. Preparing Laboratory Procedure SOPs:
 - i. ➤ Explanation:
 1. All laboratory procedures should have an accurate, up-to-date SOP that reflects the work that is actually being done. While this is standard laboratory practice, it is also important because the risk assessment should be informed by, and perhaps lead to, changes in a laboratory procedure SOP.
 - a. All laboratory procedure 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 related 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 procedure SOPs must include all these components.
 - ii. ➔ Procedure:
 1. Prior to performing a risk assessment, steps should be taken to ensure that the laboratory procedure 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 its written SOP.
 - b. If it is found that the SOP is missing steps:
 - i. Add the missing steps to the SOP.
 - ii. Ensure the appropriate director signs off on the updated SOP.
 - iii. Train applicable staff on the updated SOP.
 - c. If all steps are included in the SOP, but are either not being done or are being done differently than described, update the SOP as necessary:
 - i. If the steps in the SOP are accurate and required:
 - A. Add additional clarification to the SOP to ensure the steps are being performed correctly.
 - B. Ensure the appropriate director signs off on the updated SOP.
 - C. Train applicable staff on the updated SOP.
 - ii. If any steps in the SOP should be removed or are inaccurate:
 - A. Remove or correct the inaccurate step(s) in the SOP as necessary.



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- B. Ensure the appropriate director signs off on the updated SOP.
- C. Train applicable staff on the updated SOP.
2. Ensure that laboratory procedure SOPs collectively encompass the entire laboratory process. If they do not:
 - a. Update the SOP(s) as necessary.
 - b. Ensure the appropriate director signs off on the updated SOP.
 - c. Train applicable staff on 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 laboratory. These are referred to as biological hazards or biohazards. Some of these biohazards are expected because the agent(s) the laboratory procedure is testing for is known, but some biohazards are unexpected because the specimen could contain agents or toxins other than the one(s) for which the procedure tests.
 - b. Biohazards in a laboratory can be present as a function of exposure from the procedure or assay being performed, including handling of the specimen being tested, processing of the specimen, disposing of the waste being generated, and 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 biohazard can be substituted or eliminated or which engineering/facility controls, administrative practices, and PPE can be used to mitigate the risks of the hazard. (See section "Procedure Analysis Using Risk Assessment Hazard Exposure Activities and Controls Worksheet.")
 - 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



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- A. Google Scholar (<http://scholar.google.com/>) is one 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 by the procedure in question along with important considerations for safe handling of 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 by 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 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.
 - 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 agent evaluation worksheets for the agents or toxins just listed in the "Biosafety Risk Assessment: Biological Agent Summary Worksheet."
 - f. If the agent or toxin evaluation worksheet is present, one can use the existing evaluation for that agent or toxin. Copy the appropriate evaluation worksheet to the current risk assessment's folder.
 - i. One should consider creating a new evaluation if the existing one is out of date to make sure the latest risk information is considered. This is especially important for emerging diseases.
 - g. If any agent or toxin evaluation worksheets 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,



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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 agent evaluation worksheet to the current 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 attempted when possible. The assessment of chemical hazards includes having safety data sheets (SDSs) for all chemicals in the laboratory and readily available to staff for use. Consider 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 procedure-specific considerations, including amount and concentration. This will ensure that 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



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considerations 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 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 SDS for each chemical, indicate in its row of the worksheet if there could be a large amount or high concentration of the particular chemical when it is used in this procedure. Also indicate what the most significant hazards are for the chemical using the GHS Classification for hazards.

e. Save the document and close it.

e. Procedure Analysis 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, toxins, and chemicals. By looking at every aspect of a procedure (specimen receipt, specimen handling, 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 go wrong”) and as a result where control measures are needed to make sure this exposure does not happen.
2. Once the procedure is examined and activities with potential for exposure are determined, appropriate control 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 another 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 bacterium that reduces the risk for infection but still allows for accurate testing is an example of substitution that serves as an effective control.
 - b. The second is an engineering control. Engineering controls are physical changes to a laboratory, workstation, or equipment that reduces risk. A BSC is an example of an engineering control.



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- c. The third is administrative. Guidelines and policies are examples of administrative controls. Staff proficiencies and competencies are also considered administrative controls as are laboratory signage, labeling, and markings.
 - d. The fourth is following SOPs and implementing policies that reduce the chance for things like needle sticks, generating aerosols, and splash hazards.
 - e. Finally, PPE is an important control and should be considered the last level of protection. PPE is anything worn by laboratory workers 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 (A/WP) Controls. This includes elimination or substitution, administrative, and practices and procedures (including SOPs).
 - b. Engineering (Eng) Controls is as described above.
 - c. Personal Protective Equipment (PPE) Controls is as described above.
 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](#)
 - 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 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 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



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- scientific literature. This repository will continually expand as new hazards and controls are identified.
8. For instruments and methods not present in the repository and for which information can not 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 the current risk assessment’s folder and open it.
 2. Using the laboratory procedure SOP and your knowledge of the work, list the 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
 - 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 laboratory (via package shipment, courier, pneumatic tube, or hand delivery)
 - ii. Specimen (or specimen package) receipt in laboratory
 - 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



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- 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
 - 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 laboratory, including:
 - i. Packaging and shipping a specimen from the laboratory being assessed to another laboratory (reference laboratory, state public health laboratory, CDC, etc.)
 5. If one or more of these phases is described in a separate laboratory procedure SOP, the user may wish to perform a separate risk assessment for each laboratory procedure 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 am 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.



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- b. Eng.
 - c. PPE.
 - 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 does not 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 does not 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 cannot 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](#)).
 - 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 only applies 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 control procedure in agreement 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 procedural 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 institution’s 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.



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- 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-tabbed) sheets.
 - D. Copy the “New Activities and Controls” and “New References” (purple-tabbed) sheets from the current version to the new version of the repository.
 - 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.
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 methods and safe use of particular instruments.
 - 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 sufficient information is not 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



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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 stated, risk assessment should be part of the culture of safety in an institution. This means that all applicable parts of an institution should be assessed. To help with this process, the “[Biosafety Risk Assessment: General Considerations Worksheet](#)” identifies several hazards commonly encountered in a laboratory including a wide range of activities. By taking the time to check and answer the questions, laboratory personnel can identify where more consideration needs to be given to ensure the risk is minimized for a particular activity or procedure. The “Biosafety Risk Assessment: General Considerations Worksheet” 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 using the new equipment and how to mitigate those risks. If, however, the new equipment does not have any 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 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 those specific to the procedure being considered, the laboratory unit/section/department, and the institution, by typing in the appropriate fields and checking the appropriate boxes.



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- 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 should also be noted, as these attitudes can lead to accidents or exposures (BMBL 5th ed. pg 15). Education of laboratory staff is essential. This training should include not only training in testing procedures used in the laboratory but also training on hazards present 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, and Skill Domain IV: Emergency Preparedness and Response. These competencies are tiered into three levels depending on the role of the staff in the laboratory. These tiers are entry level, mid-level, and senior level (MMWR Guidelines for Biosafety Laboratory Competency, 2011 and 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 includes 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 focused on emergency preparedness and response, which includes 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:



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1. Using the skill domains described above, check your laboratory unit/section/department's training and personnel competency assessment documents.
 - a. Update the documents as necessary to ensure they reflect the needed competencies. 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 required by regulations and institutional policies.
 - a. If updates or additions to training and competency assessment documents are 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 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 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 laboratory procedure SOPs that are in use. For example, when describing a procedure, indicate in what area of the laboratory it should be performed, such as the BSL-3 or in the BSC, and indicate that some PPE, such as respirators, can be tiresome to the wearer so that can be taken into account (Pentella, 2015).
 4. Staff should be educated about newly implemented controls. 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 risk assessment 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 personnel are as safe as possible. However, 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 control the risks in order of severity, examining the likelihood and consequences of the hazard.



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- 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 associated with more severe risks (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 includes appropriate controls for these exposure routes, adding new controls to the “Recommended Control” column.
 - i. This is especially important for routes by which the agent/toxin has a low infectious dose and when the agent/toxin is very stable outside of a host.
 - c. Pay particular attention to agents/toxins that could be readily found in specimens tested by this procedure as determined by the “Location” and “Non-Human Specimen Sources” sections.
 - d. Looking at the [“Biosafety Risk Assessment: Biological Agent Summary Worksheet,”](#) pay particular attention to agents/toxins that are expected to be in a high concentration in specimens tested by this procedure or that have a high probability of being in specimens tested by this procedure.
 - i. Ideally, all agents/toxins should be given consideration. When this is not feasible, emphasis should be placed on the more concentrated or likely specimens.
 - ii. If it is likely that a large volume of specimen will be tested by this procedure, all anticipated agents/toxins should be given consideration to the greatest extent possible.
 - e. Compare the current and recommended controls. If the recommended controls are different from the current controls, 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.
4. Close the “Biosafety Risk Assessment: Biological Agent Summary Worksheet” and related “Biosafety Risk Assessment: Biological Agent Evaluation Worksheets.”



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5. In this risk assessment's folder, open the "Biosafety Risk Assessment: Chemical Summary Worksheet" and related chemical SDSs.
6. Looking at the chemical SDSs:
 - a. Update this risk assessment's "Biosafety Risk Assessment: Hazard Exposure Activities and Controls Worksheet" if necessary to reflect chemical handling and disposal safety recommendations, adding new controls to the "Recommended Control" column.
 - b. Looking at the "Biosafety Risk Assessment: Chemical Summary Worksheet," pay particular attention to chemicals that are expected to be used in a large amount or at a high concentration during this procedure or that pose significant hazards.
 - i. Ideally, all chemicals being used in the procedure should be given consideration. When this is not feasible, emphasis should be placed on chemicals in larger amounts, higher concentrations, or are extremely dangerous due to the hazards they pose.
 - c. 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.
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 laboratory procedure SOP(s) and procedure manual(s) as necessary.
9. In this risk assessment's folder, open the "Biosafety Risk Assessment: General Considerations Worksheet."
 - a. Reviewing the non-N/A considerations, consider if the status of the institution, laboratory, and procedure matches the necessary practices, policies, and amenities needed 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, managers, and institution management.
 - c. If changes are ultimately decided by supervisors, managers, and institution management to be beneficial, update the affected laboratory procedure SOP(s) and procedure manual(s) as necessary.



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10. Close the “Biosafety Risk Assessment: General Considerations Worksheet.”
 11. The laboratory 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 laboratory procedure 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, but is not limited to, injury and illness tracking, physical inspection, accident reports, occupational health assessments, and observation. Asking questions such as “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 changes in procedure and possibly performing a new risk assessment. If a safety protocol or procedure is changed, it is important that staff is trained. This could also serve as a safety refresher for all 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.

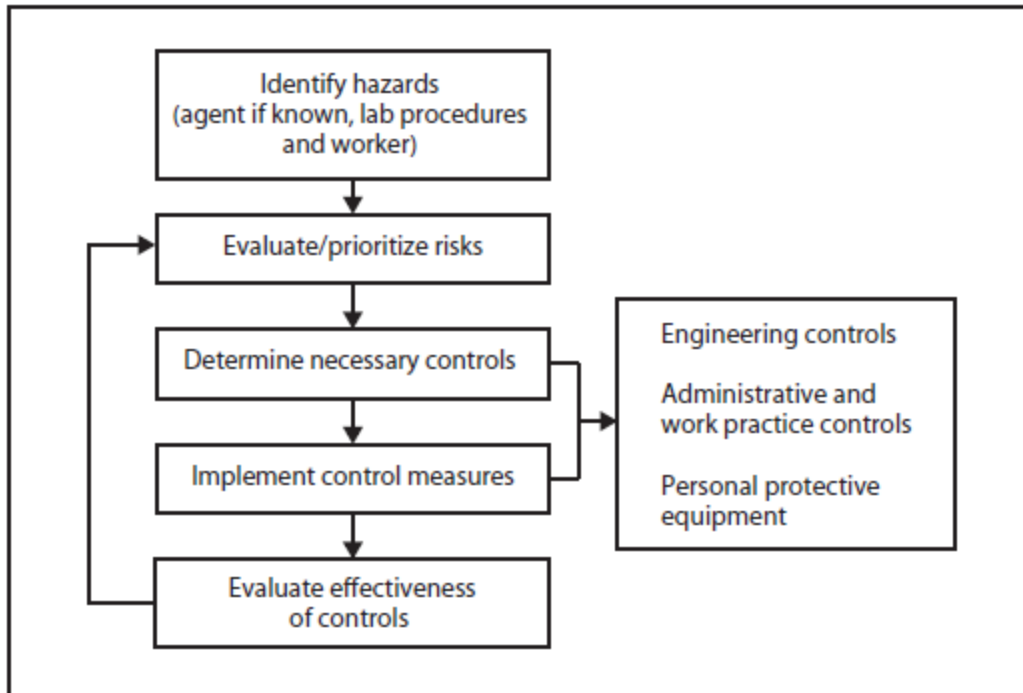


Figure 2 - From Guidelines for Safe Work Practices in Human and Animal Diagnostic Laboratories MMWR Jan 2012. Figure indicates steps for evaluating and implementing controls as part of a risk assessment.

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 descriptions, advantages, and disadvantages of the above tools. As the “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. Exposure can occur either through a failure of the current control (because of malfunctioning or misuse) or because inadequate/ineffective controls are in place.



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- 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 such as 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 may be necessary:
 - i. Train personnel to reinforce 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 conducted 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 redone, 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 ongoing and uses the same basic steps, regardless of 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 another risk assessment 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



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- 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, recommended control(s), 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:

- a. Competency Guidelines for Public Health Laboratory Professionals. (2015). *Morbidity and Mortality Weekly Report (MMWR)*, 64(Supplement).
 - i. <http://stacks.cdc.gov/view/cdc/31045>
- b. European Committee for Standardization. CEN Workshop Agreement (CWA) 16393: Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008. (January 2012).
 - i. http://www.internationalbiosafety.org/images/IFBA_docs/CWA%2016393.pdf
- c. Evaluating Biorisk Management Performance. (2015). In R. Salerno & J. Gaudio (Eds.), *Laboratory Biorisk Management: Biosafety and Biosecurity* (p. 147). CRC Press.
- d. Government of Canada Canadian Biosafety Standards and Guidelines for Facilities Handling Human and Terrestrial Animal Pathogens, Prions, and Biological Toxins First Edition.
 - i. <http://canadianbiosafetystandards.collaboration.gc.ca/index-eng.php>
- e. Guidelines for Biosafety Laboratory Competency. (2011). *Morbidity and Mortality Weekly Report (MMWR)*, 60(Supplement).
 - i. <http://stacks.cdc.gov/view/cdc/11597>
- f. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. (2012). *Morbidity and Mortality Weekly Report (MMWR)*, 61(Supplement).
 - i. <http://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
- g. Hazard Control. Canadian Centre for Occupational Health and Safety (2014, December 2). Retrieved December 16, 2015.
 - i. http://www.ccohs.ca/oshanswers/hsprograms/hazard_control.html
- h. Pentella, M. (2015). A Rational Approach to Emerging Pathogen Biosafety Considerations [Powerpoint].
- i. The AMP Model. (2015). In R. Salerno & J. Gaudio (Eds.), *Laboratory Biorisk Management: Biosafety and Biosecurity* (p. 33). CRC Press.



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- j. Trevan, T. (2015). Rethink Biosafety. *Nature*, 527, 155-158.
 - i. <http://www.nature.com/news/biological-research-rethink-biosafety-1.18747>
- k. U.S. Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition.
 - i. <http://www.cdc.gov/biosafety/publications/bmb15/>
- 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/

XIII. Related Documents:

- a. Biosafety risk assessment documents/worksheets/tools:
 - i. **Note:** The most recent versions of the following documents/worksheets/tools can be found at <http://www.floridahealth.gov/programs-and-services/public-health-laboratories/>.
 - ii. "Biosafety Risk Assessment: Organizational List"
 - 1. biosafety-risk-assessment-organizational-list
 - iii. "Biosafety Risk Assessment: Documentation Worksheet"
 - 1. biosafety-risk-assessment-documentation-worksheet
 - iv. "Biosafety Risk Assessment: Biological Agent Summary Worksheet"
 - 1. biosafety-risk-assessment-biological-agent-summary-worksheet
 - v. "Biosafety Risk Assessment: Biological Agent Evaluation Worksheet"
 - 1. biosafety-risk-assessment-biological-agent-evaluation-worksheet
 - vi. "Biosafety Risk Assessment: Chemical Summary Worksheet"
 - 1. biosafety-risk-assessment-chemical-summary-worksheet
 - vii. "Biosafety Risk Assessment: Hazard Exposure Activities and Controls Worksheet"
 - 1. bra-hazard-exposure-activities-and-controls-worksheet
 - viii. "Biosafety Risk Assessment: Instrument-Method Worksheet"
 - 1. biosafety-risk-assessment-instrument-method-worksheet
 - ix. "Biosafety Risk Assessment: Hazard Exposure Activities and Controls Repository"
 - 1. bra-hazard-exposure-activities-and-controls-repository
 - x. "Biosafety Risk Assessment: General Considerations Worksheet"
 - 1. biosafety-risk-assessment-general-considerations-worksheet
 - xi. "Biosafety Risk Assessment: Risk Likelihood and Consequences Evaluation Worksheet"
 - 1. biosafety-risk-assessment-risk-likelihood-and-consequences-evaluation-worksheet
 - xii. "Biosafety Risk Assessment: Control Failure Worksheet"
 - 1. bra-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>



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- 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/bmb15/>
- 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/
- c. Chemical hygiene information:
 - i. Canadian Centre for Occupational Health and Safety (CCOHS) Chemicals:
 - 1. <http://www.ccohs.ca/topics/hazards/chemical/chemicals/>
 - ii. Centers for Disease Control and Prevention (CDC) NIOSH Pocket Guide to Chemical Hazards:
 - 1. <http://www.cdc.gov/niosh/npg/>
 - iii. Fisher Scientific SDS:
 - 1. <https://www.fishersci.com/us/en/catalog/search/sdshome>
 - iv. Thermo Fisher Scientific MSDS:
 - 1. http://www.thermofishersci.in/technical_msds/
 - v. United States Department of Labor Occupational Safety & Health Administration (OSHA) Occupational Chemical Database:
 - 1. <https://www.osha.gov/chemicaldata/>

XIV. Attachments:

N/A

These resources are the product of research from respected biosafety sources that were combined to help create a biorisk program. Please follow your own professional judgement, your institution's established guidelines, and any applicable local, state, and federal requirements.