

Facilitator's Guide

Public Health Laboratory
Core Competency Seminar
E-modules



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Introduction

Welcome to the Facilitator Guide to accompany the Public Health Laboratories' Core Competency Seminar series. The series consists of three online modules on Effective Communications, Quality Management Systems and Safety, Emergency Management and Response and a Learner's Guide.

This Facilitator Guide is to assist you train your laboratory staff. The guide contains answers to all the knowledge checks, suggestions for how to conduct the exercises as group activities and examples of some of the expected answers or examples to the questions or activities in the exercises. These answers or examples can be used by you to help you get your students talking. All information that is only in the this facilitator guideline is in italics so you know what your students see vs what you can utilize.

The e-modules and additional resources are available on the TEPHINET web site at: www.tephinet.org.

Effective Communications

Knowledge Checks

1. Which of the following is NOT a technique of an effective communicator?
 - a. Uses techniques to relax and engage the audience,
 - b. Tailors content to the intended audience,
 - c. Uses technical terminology to demonstrate expertise, or
 - d. Improves skills through practice and continued training?

The correct answer is C. Using technical terminology to demonstrate expertise is NOT a technique of an effective communicator. It is best to avoid technical language.

2. Which of the following elements define risk communication? Choose all that apply.
 - a. Occurs between experts or officials and people who face threat or hazard,
 - b. Involves covering up potentially embarrassing decisions,
 - c. Helps people make informed decisions, and/or
 - d. Involves the real-time exchange of information?

The correct answers are A, C, and D. Risk communication does occur between experts and people at risk, helps people make informed decisions, and involves the real-time exchange of information. It does NOT involve covering up embarrassing decisions.

3. What are some of the factors of successful risk communication? Choose two of the following:
 - a. Tailor communications to the audience (internal vs. external, scientists vs. media, etc.).
 - b. Use your instincts to communicate with leaders vs. preparing in advance so you don't sound rehearsed.
 - c. Focus on facts.
 - d. Be vague about next steps so you can change your mind if more information comes in.

The correct answers are A and C. Tailoring your message and focusing on facts are two factors of successful risk communications. Communicating by instinct and being vague are NOT success factors.

Effective Communication Exercise #1

Planning Communication

Now that you have completed the module on Effective Communications, let's put the knowledge to some practical use. Using the same scenario from the module, assume you are Anthony and need to inform your supervisor about the positive test results for Oz Fever. Think of the steps you need to take to communicate your needs.

1. What will happen if you do not plan your communication message?

This explains why a clear concise message is needed.

- a. Panic and confusion***
 - b. Disbelief***
2. Who needs to receive this first communication?
 - a. This will vary facility to facility, but most often, it should start with your immediate supervisor***
 - b. Suggest that if not already in place, a communication list be created and create a list of everyone who needs to be notified and who should notify them***
 3. What information do you need to gather?
 - a. Patient results***
 - b. Quality control results (to verify accuracy of results)***
 - c. Availability of test kits or equipment and reagents on hand***
 - d. Where to order additional test kits or equipment and reagents***
 - e. Cost per test for additional test kits or reagents***
 - f. Staffing concerns (number of trained staff and their availability)***
 4. Write a short introductory paragraph or outline of your talking points and practice with a partner.

Ask 3-5 participants to share their talking points and as a group give constructive ideas for improvement.

Note these four steps can be used for all the scenarios in the module, depending on the responsibilities of the members of the training class. For example, you can substitute Paul as laboratory director, he also needs to determine who his audience is (he may have multiple audiences, determine what information is appropriate to share with each audience, then add a step where he explains next steps and where additional information will be available, have class determine what some of those next steps might be.

Effective Communication Exercise #2

Communicating Clearly and Effectively

You can use your skills from the Effective Communication Module for planning messages or announcements for other encounters that require good communication. For example, use your skills to create an agenda for a staff meeting where you must announce some coming changes in the laboratory.

Suggest that the students take time to read the Supplemental Information on Communications included in the Learner's Manual. Please note these responses are only guidelines and ideas for you as facilitator to stimulate conversation in the training session or can be made into a presentation if your audience needs more training on this topic, each laboratory must determine what is required for their own situation and convey that information.

1. List what is important in a planning a meeting
 - a. ***Decide who needs to attend (required and optional)***
 - b. ***What is the goal of the meeting?***
 - c. ***Decide what topics to be discussed and who will lead each topic***
 - d. ***How long should the meeting be?***
 - e. ***Where will the meeting be held and is there room for everyone?***

2. What is necessary in planning an agenda?
 - a. ***Include start and end times***
 - b. ***Make sure those that are required to attend know they are required to be there***
 - c. ***List topics***
 - a. ***Do not say: Upcoming changes, instead give some detail, for example: new sample accessing procedures or cross training schedule.***
 - d. ***List who will present on each topic and how long they will have to speak***
 - e. ***Some meetings can allow for others to bring forward an agenda item, be clear on when they must provide you with their information***
 - a. ***They should provide agenda topic, description and amount of time needed so you can determine if it will fit or if a separate meeting is needed. Let them know if you are including their topics or if not, when***
 - f. ***Distribute the agenda to all participants prior to the meeting***

3. Write a sample agenda for a one-hour laboratory staff meeting. Use your own format or this sample format:

(Remind participants there are many options for what an agenda could like)

Time	Location	Who Should attend
Agenda Topic	Presenter	Time

Ask 2-4 participants to share their sample agenda for a one-hour laboratory staff meeting and as a group discuss what works and what might be missing.

Quality Management Systems (QMS)

Knowledge Checks

1. When receiving the samples, our new employee Raymond discovered that the internal temperature of the refrigerator where he would be storing the samples is too high.

Which QSE would apply to refrigerator temperatures?

- A. Equipment,
- B. Facilities and Safety,
- C. Information Management, or
- D. Purchasing and Inventory?

The correct answer is A, the Equipment QSE, which covers maintenance and use of equipment, such as refrigerators.

2. In Raymond's sample testing, the results of his quality control check are outside of expected range.

Which QSE would apply?

- A. Documents and Records,
- B. Process Management,
- C. Non-Conformance Management, or
- D. None of the above

The correct answer is C, the Non-Conformance Management QSE, which addresses out-of-range results from quality control checks. This situation is a non-conformance and could call for a root cause analysis.

3. Raymond is about to place cultures in an autoclave to destroy them, when he notices the rubber seals on the door are worn and could potentially fail.

Which QSE(s) would apply to this situation, which, if followed, could prevent an accident from occurring?

- A. Equipment,
- B. Assessments,
- C. Facilities and Safety, or
- D. Both A and C?

The correct answer is D, both the Equipment and the Facilities and Safety QSEs.

The Equipment QSE addresses equipment use and maintenance. This could ensure that operators complete checks before using the autoclave, and that a maintenance schedule was followed. Both procedures could prevent use of an autoclave with worn rubber seals.

The Facilities and Safety QSE is also relevant here. It addresses use of PPE that could ensure that the autoclave operator was wearing respiratory protection. Safety protocols could also ensure that an unsafe condition was reported and addressed (in this case, worn rubber seals).

QMS Exercise #1

Developing or Evaluating a Quality Management System (QMS)

SWOT Analysis of Current QMS

Introduce this topic to class by having them read the information below or summarizing it to the class. Might be helpful to explain this exercise will help them begin thinking about what they are already doing well and that they most likely already have some important parts of a QMS in place, they just might not call it by that name. Also, that by conducting a SWOT analysis as a group exercise in their own laboratory can help obtain buy-in from their staff, making them a part of celebrating the strengths of the laboratory and having them give ideas of how to make improvements.

There are many tools used in various business practices which can be used in the laboratory to build or evaluate a process or system. The one that will be used here is called a SWOT Analysis. It is a strategic analytical tool for assessing strengths and weaknesses of a system or process, analyzing opportunities available as well potential or actual threats (challenges). Strengths and weaknesses are internal to the business or in this case to the laboratory meaning that they can be used to influence and manipulate (possibly have some control over). Opportunities and threats are external, meaning that they can only be reacted to. Most of the time laboratories will not be able to influence them.



Strengths = characteristics that make the organization or process strong (Example: qualified staff)

Weaknesses = areas that need improvement or are lacking (Example: lack of guidance)

Opportunities = favorable situations and/or factors that could strengthen the organization or process (Example: new testing technology)

Threats = unfavorable situations and factors that could create or be problems for the organization or process (Example: funding cuts)

- **Ask group to take 10 minutes to think about their current QMS and write out 3-5 bullets under each on their worksheet**
- **Have participants share some of their ideas, capture them on flip charts under each category**
- **There are no right answers, these are just examples**
- **Next step is in their labs to look at the weaknesses and decide where to start, explain how to obtain buy-in, let staff be involved in choosing what to work on, remember small successes bring in more buy-in, so often it is helpful to start with a weakness that can be easily corrected.**
- **When a weakness is corrected, remind all to acknowledge it in some way, this also shows staff their efforts are appreciated and can assist with buy-in**
- **Also keep in mind the opportunities can be things that some of them might not have been thought of before (like applying for grants)**
- **Remind group to use this tool in other areas of the lab, like biosafety/security to tie into next module**

Strengths (What is good about your laboratory's QMS?)	Weaknesses (What could be improved?)
<p><i>Qualified staff</i></p> <p><i>Written procedures and policies</i></p> <p><i>Proficiency testing program</i></p> <p><i>Document control system</i></p> <p><i>Dedicated QA officer</i></p> <p><i>Management buy-in</i></p> <p><i>Laboratory adheres to highest standard</i></p> <p><i>ISO accredited</i></p>	<p><i>Lack of guidance</i></p> <p><i>Staff shortage</i></p> <p><i>Communication</i></p> <p><i>Written policies</i></p> <p><i>Lack of dedicated quality management staff</i></p> <p><i>Departments/areas without oversight</i></p> <p><i>No employee buy-in</i></p> <p><i>Time for all responsibilities</i></p> <p><i>Lack of corrective action follow-up</i></p>
Opportunities (What is available for helping to improve?)	Threats (What could wipe your system out, destroy or undermine it)
<p><i>New testing technology</i></p> <p><i>New resources</i></p> <p><i>Additional funding through grants or other programs</i></p> <p><i>Attending conferences or trainings</i></p>	<p><i>Funding cuts</i></p> <p><i>Lack of potential new staff</i></p> <p><i>Retention of qualified staff</i></p> <p><i>Outdated equipment</i></p> <p><i>Loss of accreditation</i></p> <p><i>Public perception</i></p>

QMS Exercise #2

Choosing Quality Indicators

An important part of the Quality Management System is the Quality Indicators (QI) QSE, which are measures that make use of readily available data that can be indicative of a quality issue. The indicators should be able to be measured numerically and make use of known correct parameters. An indicator can be chosen in response to a problem (i.e. many unacceptable samples are arriving in the laboratory) or ensure that no problems exist (i.e. are the test reports containing all information needed by the test requestor). To be most effective there should be unique quality indicators that look at all parts of the laboratory, such as in the pre-examination, examination and post-examination phases.

Either have the students read the following steps or use as a group discussion or feel free to substitute one of your experiences that will demonstrate the following steps.

Steps for an Indicator Measurement Activity

Step 1: Decide on a measurable indicator, for this example we will use turnaround time

Step 2: Develop how the measurement will take place. A decision by the laboratory manager or person in charge of QI needs to be made if timing begins when the sample is obtained or when it arrives in the laboratory, or both to see if there is a delay somewhere in the transport process, is the measurement complete when the report is generated or when it is received by the test requestor? How many samples to look at? Are only samples looked at that arrive during a certain time of day or all samples for a week or a month (in most cases, not recommended to go longer than that, so if a problem is found it can be addressed)? There are no right or wrong answers, but one does want to be sure there are enough samples to get a good example of what usually happens in the laboratory (i.e. do not choose to only look at samples that arrive during a time that you already know is not very active, unless you think there is a problem during a certain time frame). Also decide what type of documentation will be kept and by whom. If needed design a worksheet.

Step 3: Begin collecting data and record the findings. In addition to the time arrived and time reported, you might want to consider recording where the sample came from as this will help identify if a particular clinic or courier is causing a delay.

Step 4: Analyze the data. Take all the data and determine an average turnaround time. Many ways to look at the data, such as how many are below or above average? Or could be by day of the week or time of day or type of sample or from what location. You may use graphs or ranking system to see where any problems might be. Decide if there is a problem and identify what it is (i.e. Clinic X holds all their samples until the end of the day to bring to the laboratory, so patients seen first thing in the morning have a longer turnaround time).

Step 5: Determine what action should be taken. Some things to think about include: Are laboratory policies or procedures clear on how soon a sample should be transported after it is obtained? Have these policies and procedures been clearly communicated? Is additional training needed?

Step 6: After whatever corrective is taken, repeat the measurement process (may be for a shorter time) to ensure all understand the corrective action and are working with the new guidance or policy. If not, maybe additional communication or training is needed. Be sure all steps are documented.

Either as a group or break students into groups of 2-3, have them list 3-5 possible Quality Indicators for each of the sample testing processes. Then in small groups have them choose one indicator and describe what will be measured, how to measure it and what remedial action is needed. Depending on time, ask for volunteers to share their quality indicator, measurement, expected outcomes, and how they would correct any potential adverse findings with the group.

Activity 1: List three possible Quality Indicators for each of the samples testing processes

(Depending on time, post responses on flip charts so all can copy for use later)

Pre-examination phase

- 1. Unsatisfactory samples***
- 2. Missing information on sample label***
- 3. Missing information on test request***
- 4. Sample not at correct temperature***
- 5. Courier transport time***
- 6. Customer complaints***

Examination phase

- 1. Out of range test controls***
- 2. Proficiency testing performance***
- 3. Sample quality***
- 4. Sample quantity***
- 5. Instrument failure***

Post-examination phase

- 1. Turnaround times (time from collection to report generated)***
- 2. Turnaround times (time from sample arrival to report generated)***
- 3. Accuracy of report (missing information)***
- 4. Accuracy of report (correct results)***
- 5. Delivery of results***
- 6. Sample archiving***
- 7. Report archiving***

Activity 2: Choose one indicator and describe what will be measured, how to measure it, what the analysis might show and what remedial action is needed.

Indicator: ***Accuracy of test report***

How to measure: ***Develop a customer survey to ask sample submitters questions that will determine if there are receiving what they need on reports, are they easy to read and understand, what suggestions for improvement they might have. Should surveys be mailed or emailed? How much time should they have to complete the survey? Who will analysis results?***

Conduct assessment: ***Send out surveys***

Analysis: ***Compile the data, look for areas from multiple sources that are dissatisfied or areas that have positive feedback (always good to celebrate successes***

Action: ***Make suggested improvements to the report, documents all steps in process***

Repeat: ***Consider repeating the customer survey on an annual basis***

After the group has had time to read through the steps, ask if anyone has a quality indicator story they would like to share (either a success or a challenge).

QMS Exercise #3

Creating a Quality Management System Manual

The first step in creating a QMS manual is to decide what is needed to include, how to organize it and where to get the information. In most cases much of the information is already available in various procedure and policy manuals, it is just finding the time to put everything together. To help you get started this exercise will help you think about ways to put your manual together. Here we will use the 12 QSE's as a guideline on organizing your manual. Below is a list of policies, procedures and documents that might be found in a laboratory. Next to each document, policy or procedure name, put the number of which QSE should include that document, policy or procedure.

12 Quality System Essentials (QSE):

- | | |
|-----------------------------|-------------------------------|
| 1. Organization | 7. Documents and Records |
| 2. Customer Service | 8. Information Management |
| 3. Facilities and Safety | 9. Non-conformance Management |
| 4. Personnel | 10. Assessments |
| 5. Purchasing and Inventory | 11. Process Improvements |
| 6. Equipment | 12. Process Management |

You can do this either as an individual exercise or as a group with you leading the discussion. If doing individually, when completed if time permits, ask them to share those that they had trouble with and try to get discussion on how others selected their QMS. When completing the exercise as a group and there are differing suggestions for location of a particular document, ask some to share their reasons for where they placed it. Remember some documents may need to be placed in more than one location and there are no wrong answers.

If performing this exercise in your own lab, you can gather your laboratory documents and as a group sort them by which ever organization method you choose to use, create your table of contents, place in a notebook and end with a binder with all documents where your staff can find them.

Building A QMS Manual Exercise

For each Documents, Policies and Procedures enter the number of which QSE each falls under, in some cases there maybe more than one appropriate location, there are no wrong answers, each individual laboratory will decide what works for them and so staff can easily find information that is needed.

Customer satisfaction survey	<u>2</u>
Specimen acceptance and rejection	<u>12</u>
Corrective action review and follow-up	<u>10</u>
Document control	<u>7</u>
Administration policies	<u>1</u>
Training logs	<u>4</u>
Selection/purchasing of equipment	<u>5 or 6</u>
Choosing of quality improvement indicators	<u>11</u>
Safety plan	<u>3</u>
Quality control	<u>6</u>
Corrective action(s)	<u>9 or 11</u>
Monitoring of electronic data integrity	<u>8</u>
Archiving patient results and QC data	<u>7</u>
Monitoring event trends	<u>9</u>
Personnel list with emergency contacts	<u>4</u>
Internal audits	<u>10</u>
Floor plans	<u>3</u>
Instrument maintenance logs	<u>6</u>
Quality improvement results & actions	<u>11</u>
Handling of customer complaints	<u>2</u>
Computer Use Policy	<u>8</u>
Organization Chart	<u>1</u>
Storing of reagents and supplies	<u>5</u>
Pre-examination workflow processes	<u>12</u>
Root cause analysis	<u>9</u>
Risk analysis	<u>3</u>

Safety, Emergency Management, and Response

Knowledge Checks

1. What do you assess to determine level of risk? Choose two.

- A. Laboratory Biosafety Level, or BSL,
- B. Likelihood that a hazard will cause an accident,
- C. Severity of outcome if an accident were to occur, and/or
- D. Staff experience and training?

The correct answers are B and C.

Assessing risk involves considering the likelihood that a hazard will cause an accident and the severity of outcome if an accident were to occur.

BSLs and staff experience/training are potential hazards to assess.

2. Which two types of hazard controls are the most effective? Choose the correct pair.

- A. Engineering and Administrative,
- B. Personal Protective Equipment and Substitution,
- C. Elimination and Substitution, or
- D. Elimination and Engineering?

The correct answer is C. The most effective types of hazard controls are Elimination and Substitution.

3. Which of the following should you consider in developing a laboratory emergency response plan?

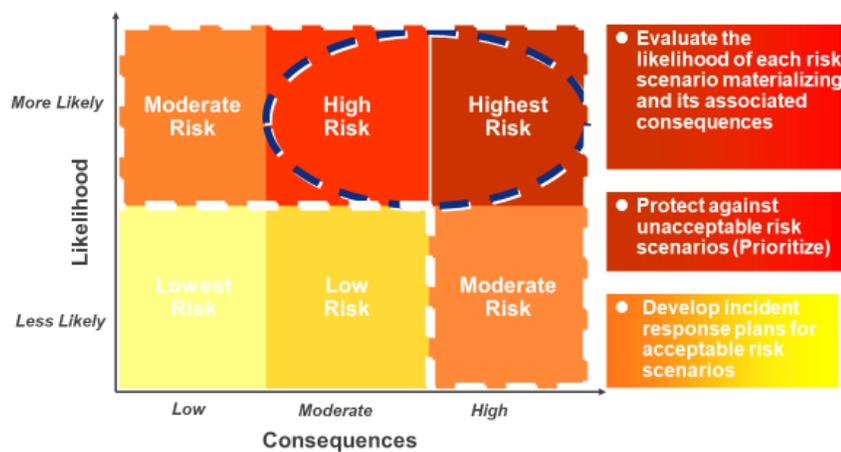
- A. Potential and past threats,
- B. Availability of resources,
- C. Pathogen characteristics, or
- D. All of the above?

The correct answer is D. When developing an emergency response plan, you should consider ALL these elements and more, depending on the features and needs of your laboratory.

Safety, Emergency Management, and Response

Biosafety Risk Assessment Exercise #1

As mentioned in the module, there are many different ways a Risk Assessment may be performed. There is no one size fits all for a risk assessment, and a risk assessment performed for a procedure in one laboratory may not be appropriate for the same procedure in another laboratory. Each laboratory must decide what type of risk assessment best meets their needs. As risks are identified, use graph below to determine likelihood and consequence of the risk.



Included in this exercise are two additional template examples:

- Exercise #1: 5 P's: pathogen, people, place, PPE, procedures
- Template RA #A Pathogen Risk assessment
- Template RA #B Risk Assessment

You may use these examples in your laboratory as is or edit in any way that meets the needs of the procedure, process or pathogen.

Exercise #1: 5 P's: Procedure, pathogen, place, PPE, personnel

Using the 5 P's, as in the example chart below, complete the chart on the next page to perform a risk assessment on a procedure or process from your laboratory.

Have the students work in pairs, using the example in the chart (or an example from your own experience), review what steps are needed to perform the 5P risk assessment and depending on time available have them go through all steps for at least one hazard. Remind them to evaluate the level of risk for each hazard and then determine if changes need to be made. Then have some of the pairs present to the group and ask for some feedback.

- Break the procedure down into individual components/steps (Procedure)
- Define 2-3 potential hazards for the procedure (Pathogen or safety)
- Evaluate the risk level of each hazard identified
- Determine what controls can be implemented for those hazards (Place)
- List what PPE should be used (PPE)
- What training is required? (Personnel)

PROCEDURE OR PROCESS (Procedure) – specific tasks	PRINCIPAL STEP(S) (Procedure)	POTENTIAL SAFETY OR HEALTH HAZARD(S) (Pathogen)	RECOMMENDED CONTROL(S) Work Practice Controls (Place)	EQUIPMENT TO BE USED (PPE)	TRAINING REQUIREMENT(S) (Personnel)
Phlebotomy	1. Gather equipment 2. Prep the patient 3. Locate the vein With the patient's arm extended, inspect the antecubital fossa. Look for a visible, good-sized vein,, apply the tourniquet 3 to 4 inches above the <u>venipuncture</u> site. 4. Wash your hand , dry with clean towel and put on gloves. 5. Disinfect the site 6. Draw blood, fill the tube. 7. Discard needle 8. Place blood tube in rack, match label 9. Clean-up	Exposure to bloodborne pathogens Identify one or two	Wear PPE Identify other work practice controls	Lab coat and gloves What else?	BBP training Other?

What is the level of risk for the identified hazard?

Needlestick is moderate to high risk to the laboratory staff performing the phlebotomy, use the chart above to explain work controls of proper PPE, not recapping needle, and training on how to wear PPE.

PROCEDURE or PROCESS Specific Tasks (Procedure)	PRINCIPAL STEPS (Procedure)	SAFETY or HEALTH HAZARD(S) (Pathogen)	RECOMMENDED CONTROL(S) Work Practice Controls (Place)	EQUIPMENT TO BE USED (PPE)	TRAINING REQUIRED (Personnel)

What is the level of risk for the identified hazard?

Would this require mitigation? If so what steps should be taken?

Sample Risk Assessment Template A

<i>Name of Process – General Precautions</i>				
Pathogen(s): There is a potential to be exposed to _____ during _____ process dependent on _____.				
Infectious Dose: Dependent on the pathogen.				
Routes of Transmission: List any that are appropriate for example: <ul style="list-style-type: none"> • Parenteral inoculation from a needle stick or other sharps • Ingestion from spill or splash into mouth • Contact from touching, or from a spill or splash onto a mucous membrane or non-intact skin • Inhalation of infectious aerosol 				
Current Requirement(s):				
<i>Process Assessment</i>				
Pre-analytic				
<input type="checkbox"/> Process Name				
Process Step	Potential Hazards	Initial Risk Level	Control (Mitigation)	Residual Risk Level
			Required: <input type="checkbox"/> Optimal: <input type="checkbox"/>	
Comments:				

Sample Risk Assessment Template B

**<Name of Organization>
Biosafety Risk Assessment Tool**

Department/Section:

Assessor:

Date:

Purpose of the Risk Assessor: <Initial Assessment, New test, New instrument, New staff etc.)

How was the risk assessment done?

The Laboratory adapted a process to document risk assessment in a laboratory setting following guidance from the *Five Steps to Risk Assessment* located on the European Agency for Safety and Health at Work website <http://hw.osha.europa.eu>.

1: To identify the hazards, the Risk Assessor will:

- Review safety (biological and chemical) references, professional websites and peer-reviewed publications for current information pertinent to the laboratory setting with all lab staff. During the risk process, staff will be asked to think carefully about their work processes, encouraged to ask questions, and bring up concerns at any time during the process.
- Review current laboratory receipt, handling and testing SOPs and the instrument “hazards” section within the instrument operations manual for safety information.
- Perform a literature search of peer-reviewed journals to be fully aware of risks associated with handling human samples and laboratory acquired infections.
- Engage input from all staff while tracing the path of the specimen through the laboratory from specimen receipt to reporting while noting potential safety risks on this form.
- Review employee training records with an emphasis on all laboratory safety trainings including blood borne pathogens, biohazardous waste disposal, spill response, medical surveillance, etc.
- Review biohazardous and chemical waste generated within the laboratory and the process for safe handling and disposal.
- Review the laboratory problem log and corrective action history of the laboratory for safety-related issues.

- 2: The Risk Assessor and Lab Supervisor will examine factors inherent to the risk organism and the different laboratory operations taking into account the risk to (specimen receiving, data entry, and laboratory staff) based on the following measures:
 - Potential for improper specimen packaging (leaking container or broken tube)
 - Volume and type of specimens received
 - Agent stability in the environment
 - Type of work proposed and its impact on laboratory containment level, personal protection equipment and/or measures employed
 - Risk of spills and/or aerosol generation while processing or testing the specimens
 - Hazards of biochemical and/or chemical waste during handling, temporary storage, and disposal
- 3: For each hazard, the Risk Assessor and Laboratory Supervisor will note what controls are in place to manage the hazards based on CDC BMBL, Lab Safety SOPs, and the Hazard Section within the package insert and the automated instrument manual. Suggested changes will be indicated on the risk assessment form along with a responsible individual.
- 4: The Lab Manager and Lab Director will conduct a review of the draft risk assessment and make changes as needed. The Lab Director will review the findings and approve the final recommendations prior to implementation. Upon completion, the Lab Manager will initial that the changes were completed. The risk assessment will be repeated as needed or whenever the laboratory operation changes.
- 5: The Lab Manager and Supervisor will discuss the findings with the laboratory staff and make a copy of the report for all staff to review and sign-off on. Changes to the SOPs and the lab environment, once approved, followed by training will be made to increase the awareness of risk and the level of safety.
6. The Institutional Safety Representative will perform a post-implementation audit 3 months to review compliance with this document.

What are the hazards? (location/ hazard)	Who might be harmed and how?	What are you already doing?	What further action is necessary	Action by whom?	Action by when?	Done

References:

1. OSHA Blood Borne Pathogen Standard (1910.1030). www.osha.gov
2. BMBL, 5th edition (<http://www.cdc.gov/biosafety/publications/bmb15/>).
3. Sewell et al. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guidelines – Third Edition (M29-A3) Wayne, PA: CLSI, 2005.
4. CDC Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians. 2013. MMWR. 62(18):362-265.
5. <Insert additional references pertinent to the specific risk assessment>

Reviewed by:

Risk Assessor / Date: _____

Comments:

Supervisor / Date: _____

Comments:

Lab Manager / Date: _____

Comments:

Institutional Safety Representative/ Date: _____

Comments:

Laboratory Director/ Date: _____

Comments:

Safety, Emergency Management, and Response

Biosafety Risk Assessment Exercise #2

Background

Using Isabel's case from the learning module as an example, perform a risk assessment to determine hazards and risks as well as how to mitigate these.

"Isabel was using an autoclave to destroy Mycobacterium tuberculosis cultures after specimens testing was completed.

She was using a biosafety containment unit and was wearing a lab coat and gloves. However, she was not wearing any respiratory protection.

The rubber seal on the autoclave door failed and contaminated steam was released into the room. This exposed Isabel and her co-workers to the TB pathogen."

Additional information about *M. tuberculosis*

M. tuberculosis is carried in airborne particles, called droplet nuclei, of 1– 5 microns in diameter. Infectious droplet nuclei are generated when persons who have pulmonary or laryngeal TB disease cough, sneeze, shout, or sing. Depending on the environment, these tiny particles can remain suspended in the air for several hours. *M. tuberculosis* is transmitted through the air, not by surface contact. Transmission occurs when a person inhales droplet nuclei containing *M. tuberculosis*, and the droplet nuclei traverse the mouth or nasal passages, upper respiratory tract, and bronchi to reach the alveoli of the lungs. Infectiousness is directly related to number of tubercle bacilli inhaled. BSL-2 containment with BSL-3 practices.

Biosafety Risk Assessments: A How To

New Risk Assessments in Four (easy) Steps

1. Agent Summary (includes etiology, transmission, infectious dose etc.)
2. Summary of hazardous procedures: attach SOP and how risk is mitigated
3. Determination of appropriate BioSafety Level (e.g., BSL2 or BSL3?)
 - Containment practices, PPE, Engineering controls
4. Proficiency & training plan for staff

Existing Risk Assessment for Review

1. Review existing risk assessment
2. Research current information
3. Evaluate differences of emerging strains to existing strains
4. Review with content experts and staff

Define Aerosol and Droplets

- **Suspensions** that may not be seen or smelled, but can be inhaled
 - ▣ **Droplet:** 5-30 μm and can travel ~3-6 ft; not transmissible over long distances
 - ▣ **Aerosol:** finer mist, travels up to 10 ft; transmissible over long distances
 - ▣ Depends on pathogen, size of particles, air quality, etc.
 - ▣ May require up to 1 hour or longer to settle

What procedures generate aerosols?

- *Heating to create steam*
- *Pipetting (vigorous mixing)*
- *Mix*
- *Vortex shaking*
- *Centrifuging*
- *Inoculation of biochemicals or blood culture bottles*
- *Shedding of samples*
- *Loading of syringes*
- *Subcultures in outdoor work station*
- *Splashes*
- *Hot loop in broth or media*
- *Laser, cell sorters*
- *Grind or open lyophilized cultures*
- *Enter or open containers at non-environmental pressures, p. eg fermenters, freezer vials*
- *Homogenization*
- *Sonication*
- *Flow cytometry*

What techniques can you use to minimize aerosols?

What not to do

- *Use Bunsen burners when you have alternatives*
- *Open the plugs of the blood collection containers*
- *Blow the last drop of the pipette*
- *Mix by suction + expulsion*
- *Open the centrifuge immediately after the rupture of a sample*
- *Operate the cryostat to cut the tissue without closing the window*

What to do

- *Download the liquid from the side of the container*
- *Release as close as possible to the contents*
- *Use capped tubes when mixing or vortexing*
- *Be careful with the needles (gauze pad with alcohol in the septum of the blood culture bottle)*
- *Use aids for pipettes with filters*
- *Change procedures*

What is the proper PPE in this scenario?

Identify any operation where respiratory protection is required

- Have a respiratory protection plan

Safety, Emergency Management, and Response

Creating an Emergency Response Plan Exercise #3

Break up into pairs and discuss. Each pair will present followed by a group discussion after each. If the class is having trouble getting started, use one of the examples below to help the class along the right direction.

Using Beatrice's scenario as described in the module as an example, describe how you would develop an emergency response plan for a surge in Zika cases during an outbreak. Use examples from your own laboratory if possible.

What factors should you consider? List and explain each.

- ***Pathogens (Zika)***
- ***Potential and past threats (seasonal and/or outbreak)***
- ***Physical location (e.g. regions with certain species of mosquitos, standing water from rain)***
- ***Availability and capability of resources***
 - ***Staffing (Currently has only ten staff who have been trained to perform the tests needed to diagnose arboviral diseases. One laboratorian is responsible for accessioning all specimens received.)***
 - ***External partners (e.g. between the national laboratory director and staff to all external stakeholders, including hospitals, district laboratories, supply vendors, and the Ministry of Health)***
 - ***Cross-training to improve surge capacity (e.g. coordinate training of ten more staff members from other sections)***
 - ***Availability of Reagents and equipment (e.g. determining how much to keep on hand and have a plan for how to rapidly obtain more)***
 - ***Repurposing laboratory spaces and functions (repurpose the parasitic and mycotic disease reference laboratories)***
 - ***Maintaining baseline operations and implementing surge capacity (Recommends to the health ministry that they notify near neighbor countries who could offer help with the outbreak response if it grows beyond the capability of the national laboratory)***
- ***Communication and training plans (Urges the Ministry of Health to begin a public relations campaign to reduce mosquito breeding. In addition, she recommends that the Ministry of Agriculture begin spraying larvicide in known breeding pools.)***

Planning and coordinating (Alert local emergency response coordinators and private local couriers of the potential for increased capacity related to shipment of specimens)

Safety, Emergency Management, and Response

Knowledge Check Questions Exercise #4

To be worked on individually or together then discussed as a class so all have correct answers

1. Safety culture is not defined as the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management.

A. True

B. False

2. For safety culture to be effective, only some staff members must become part of the culture of safety.

A. True

B. False

3. Safety focuses on the occupational and personal safety of staff members and the environments in which they work.

A. True

B. False

4. During a risk assessment, for each hazard identified, you must determine both the likelihood that the hazard will cause an accident and the severity of outcome if that accident were to occur.

A. True

B. False

5. Which of the following are potential hazards identified during a risk assessment? Select all that apply.

A. Pathogens: Mode of transmission, pathogenicity, infectious dose, treatment, life stage, drug resistance

B. Procedures: Sharps, spills/splashes, aerosols

C. Space constraints: Biosafety Level (BSL), workflow, equipment reliability

D. Staff experience: Level of experience required should reflect pathogen hazard and technique used

6. Name two methods used to mitigate laboratory risk. _____ and _____

(any 2 from list below)

- 1) Administrative Controls
- 2) Engineering Controls
- 3) Personal Protective Equipment
- 4) Elimination and Substitution

7. What are some biosecurity basic precautions?

- A. Paint the windows black
- B. Limit access to labs and specimen storage**
- C. Maintain inventory control**
- D. Follow protocols for inactivation and disposal**

8. Private patient data includes: Select all that apply.

- A. Personal Health Information (PHI)**
- B. Personally Identifiable Information (PII)**
- C. What you ate for dinner (AFD)
- D. Your bed time (BT)

9. How can you protect private patient data? Select all that apply.

- A. Antivirus software**
- B. Firewalls**
- C. Other data protection best practices**
- D. Closing your eyes

10. Which are personnel safety and security internal hazards? Select all that apply.

- A. Workplace violence**
- B. Sexual harassment**
- C. Bullying**
- D. Physical harm**

11. Which are personnel safety and security external hazards? Select all that apply.

A. Unauthorized persons in the building or laboratory space

B. Inadequate lighting in entryways, parking lot

C. Working late and alone

D. Talking to your supervisor

12. Emergency management and response encompasses events such as:

A. Natural disasters

B. Public health emergencies

C. Facility or operation failures

D. All of the above

13. Which of the following is part of emergency planning?

A. Staffing

B. Training and communications

C. External partners

D. All of the above.

14. Emergency response plans are detailed, specific to predicted emergencies, and often involve people and organizations outside the laboratory.

A. True

B. False

15. General safety plans do not contain basic information that is applicable across all sections of the laboratory.

A. True

B. False