Learner’s Guide
Public Health Laboratory
Core Competency Seminar
E-modules
Acknowledgements and Disclaimers

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Introduction

Welcome to the Public Health Laboratory Core Competency Seminar series. The series consists of three online modules and this Learner’s Guide. These tools will provide the opportunity to learn more about some of the foundations and skills required for staff in a successful public health laboratory. The three topics included in the series are: Effective Communications, Quality Management Systems and Safety, Emergency Management and Response. The modules and exercises in the guide will also help you prepare to train your laboratory staff and share best practices with colleagues in your region to strengthen public health response capacity.

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

The Learner’s Guide is designed to reinforce the information in the three e-modules by providing the material from each module, exercises that may be completed individually or in a group setting and with some exercises, some supplemental information is provided to assist you with the exercises. If you are unable to access the e-modules, the Learner’s Guide may be used independently as well. The activities will also help you prepare to train your laboratory staff and share best practices with colleagues in your region to strengthen public health response capacity.

There is a supplemental Facilitator Guide which contains additional information and suggestions for completing the exercises which may be used by supervisors or trainers.

Additional resources related to the topics presented in the modules may be found on the TEPHINET web site at www.tephinet.org.

Please note that even though this seminar series was developed for public health laboratories, the concepts are the same for other types of laboratories and may be used by anyone who is interested in improving laboratory practice.
Effective Communications

Objectives

Upon completion of this module, you should be able to:

- Describe the principles of clear and accurate communication in a public health setting
- Explain the importance of circumstances and audience in planning all communication
- Define risk communication and understand how it differs from routine communications.

Internal vs. External Communications

Effective *internal* communication between staff is essential to maintain and improve quality management systems, satisfy customers, and further national public health goals.

Effective *external* communication is necessary to disseminate public health information to both the public and government officials. By highlighting the importance of laboratory contributions in support of public health, we can ensure continued interest and support of the public health laboratory system.

What Is an Effective Communicator?

Public health laboratory scientists are frequently called upon to communicate highly sensitive technical information to a variety of audiences across a range of situations. In addition to emergency response, communication can include reports for colleagues or upper management, or various types of interactions with the public. Effective communicators tailor content to the intended audience using an appropriate level of detail.

They are concise, do not use unnecessary technical language and state details in plain language wherever possible. They use techniques to relax and engage their audience, thereby involving them and creating a compelling message. Finally, effective communicators know that clear communication is a skill; one that they improve through practice and continued training.

Understanding the Audience

Whether speaking or writing, especially about complex subjects, it is important to consider the circumstances in which you will be communicating. Answer the following important “who, what, where” questions to help you frame your messages:

- Will the communication be internal or external?
- If internal, will your audience be peers and colleagues, or leadership?
- If external, who will be your audience?
- Will communication be written or verbal?

Laboratory leaders will be communicating with peers as well as a wider audience. Consider the differences. With peers, you may be able to assume a certain level of background and technical
knowledge about some subjects. Wider audiences have more complex needs. How do you determine those needs? Where possible, interact with your target audience. Ask questions to discover who they are and what they know. Consider what terms and concepts may need to be explained and respond accordingly.

Consider also the best communication method to reach the audience, such as email, social media platforms or a combination of methods. Cultural differences are an important consideration, especially with diverse audiences or audiences with backgrounds significantly different from your own. In this case it is particularly important for you to provide a way for your audience to ask questions and get more information. In short, tailoring how you provide information to your audience means finding ways to send the right message in the right way to the right people.

**Communicating Clearly**

An effective communicator is also someone who is careful with technical language. Using specific and technical information may be best when discussing work with colleagues, but audience background should be considered when communicating with others. Usually it is best to be brief, with a logical structure that is to the point and targeted wherever possible. Make sure your audience understands your key messages by highlighting them in some way. If it is necessary to share technical information, use clear headings and visuals like tables, charts, graphs, images and video to emphasize and clarify your key messages. Keep it as simple as possible, however, since a complicated graph can be just as confusing as technical language.

**Communicating in a Crisis**

In times of crisis, affected people take in, process and act on information differently. Because of this, a special communication strategy is needed to help people cope with the situation. This strategy is known as *risk communication*. Risk communication can be defined as the real-time exchange of information, advice and opinions between experts or officials and people who face a threat or hazard to their survival, health or economic or social well-being. The purpose of this communication is to ensure that everyone at risk can make informed decisions to lessen the effects of the threat. Potential threats relevant to the public health laboratory include disease outbreaks, natural disasters and chemical and radiation exposures.

Risk communication to laboratory leaders and other officials should be tailored to meet their specific needs. In general, the crisis goals of leadership are to implement a response plan that reduces illness, injury and death while avoiding misuse of resources. It will be their job to reassure the public to avoid panic, so they will need concise information quickly. Details about process and procedures that are non-essential to understanding results and facts should not be shared in communications with leadership. Relate facts and key messages and provide details only if asked.
It is also important to include plans, future actions and any predictions and estimates that are within the scope of one’s knowledge, such as cost or spread of disease if these will be important to managing the response.

The public will want to know facts that will allow them to protect themselves and make informed decisions, allowing them to engage in the recovery process. This helps people to feel empowered and reduces fear and uncertainty. People under stress tend to focus on negative aspects rather than positive. Issues of trust and control over the situation become exaggerated. By giving people facts that allow them to participate in the response, they can prepare mentally and take actions that reduce anxiety.

**Risk Communication Example**

Anthony is manager of the arbovirus section in his national public health laboratory. He is responsible for reporting test results and for ordering equipment, reagents and supplies so that the laboratory can maintain its daily reference operations. Today, two specimens tested positive for “Oz Fever,” (a made-up disease we’re using as an example only). Anthony has been thorough and is certain of these results but is concerned because Oz Fever was declared to be interrupted in his country two years ago. He must report these results to his supervisor right away.

Experience with Oz Fever tells Anthony that many more in the country may become ill with the disease in the coming weeks and he must have more test kits right away. Anthony must convince his supervisor to release funds so that he can order more kits and other supplies to prepare for the surge in Oz Fever. He knows that news of the return of Oz Fever will be unexpected and will not be well-received. He needs to relate all relevant details clearly and concisely, so he plans the conversation with his supervisor beforehand.

Since Anthony is an effective communicator, he knows that leaders are most interested in information that will help them make decisions. Leaders are usually less interested in the process used to arrive at the conclusions. Anthony will bring the test results with him, as well as costs associated with the resources that he will need, such as test kits, equipment and supplies.

He communicates what is important. He focuses on the impact of Oz Fever using the facts, his positive test results. He focuses on the future and provides estimates of his laboratory’s needs to handle the potential of an outbreak. Anthony will bring the test results with him, as well as costs associated with the resources that he will need, such as test kits, equipment and supplies. He will also make suggestions as to what the laboratory response plan should be.

Anthony convinces his supervisor of the need for increased surge capacity for Oz Fever and will get the supplies and equipment that his laboratory needs.
**Internal Communication Example**

Paul is the director at Anthony’s laboratory. Paul oversees all laboratory operations and is responsible for all high-level communication to national officials, particularly the Ministry of Health. He is often called upon by the press to give statements and interviews.

After Anthony’s supervisor informed Paul of the Oz Fever situation, Paul developed an internal communication plan for his staff. Laboratory personnel needed to know the agency’s response plans. This included a short list of action steps and any changes in staffing such as reassignments, deployments to other laboratories, and incoming staff to handle the surge in testing and reporting activities.

**External Communication Example**

Paul informed the Ministry of Health so that national emergency response plans can be developed, and the public can be made aware of the potential for acquiring this disease. Meanwhile, the media has contacted Paul for comment. Even though the pressure to release information immediately is intense, Paul understands that the early stages of such a crisis are often characterized by confusion, intense media interest and incomplete information. Paul knows that conflicting statements add to confusion and will cause the public to lose trust in the country’s ability to handle the crisis.

Before commenting, Paul makes the Ministry aware of the request and ensures that his comments are aligned with Ministry statements.

One external risk communication goal is to address public anxiety. Paul makes clear statements to the media about the situation and explains exactly what actions the laboratory is taking to prevent the spread of Oz Fever. Paul’s first external risk communication goal is to address public anxiety. He makes clear statements to the media about the situation and explains exactly what actions the laboratory is taking to prevent the spread of Oz Fever.

Paul provides three key messages to the public in easily understood terms.

- First, he briefly describes Oz Fever and its symptoms.
- Second, he tells the public how to prevent contracting it.
- Third, he provides an avenue for more information. In this case, he gives an Internet address that provides details about tests the laboratory will perform, how soon results can be expected, and situational updates.

These key messages will serve to reduce public anxiety and uncertainty, while allowing people to take action, find more information and protect their families.

Paul then works with other public emergency officials to develop a course of action that people in affected areas can take. He prepares briefing documents for government officials that outline potential public health risks and describes actions that the laboratory is taking to keep the public safe. He works closely with laboratory management to continuously gather information about the number of affected persons to release the right information at the right time until the Oz Fever outbreak is over.

Because Paul’s audience is so diverse, he tailors all required communications as needed.
Risk Communication Success Factors

Both Anthony and Paul know that failure to communicate risk effectively can do more harm than good. They practiced clear risk communication skills to inform stakeholders and avoid potentially serious consequences.

Anthony planned the conversation with his supervisor and brought the necessary evidence to convince her of the situation. He also described specific needs for the laboratory response including test kits, equipment and supplies, so that his supervisor could quickly request the capital he needed to handle testing for the outbreak.

In his role as Laboratory Director, Paul implemented an agency-wide response plan, and communicated this plan to diverse external audiences. He met the needs of each audience by directly addressing their concerns in a clear and consistent manner. Working with other agencies, Paul made sure each target audience got the right information at the right time.

Key Points to Remember

To be effective, risk communications should be provided early in a crisis situation. Information released late may appear disorganized, or worse, dishonest.

Messages should be short, informative and relevant to the current status of the crisis. Sharing minor details unnecessarily might result in information overload and complicate your message unnecessarily.

All messages should include action steps. Sharing the action steps leaders will take shows forward planning and that there is situational control which will help to ease fear and uncertainty. Providing positive action steps that affected people can take allows them to protect themselves and participate in the response. This fosters a sense of unity and lessens the impact of the crisis.

Finally, all officials should provide consistent risk communications and repeat them frequently. This will prevent confusion and the spread of rumors and will ensure that communications reach a wider audience, thereby increasing the response impact.
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?

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?

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.
Effective Communication Supplemental Information

COMMUNICATION WITH YOUR COLLEAGUES

Here are a few general tips for communicating effectively with colleagues:

1. **Listen** - Effective communication is as much about listening as speaking.
   - Actively listen when communicating with colleagues.
   - Engage your audience through asking questions and checking for understanding. Not only will this enable you to better strengthen your understanding of your audience, it will also make a better impression and increase the effectiveness of your message.

2. **Be aware of your tone** - Sometimes clarity and linguistic aptitude are not enough. When tone is perceived incorrectly, it impedes effective communication as your audience becomes more concerned with how you are saying something and less concerned with what you are saying.
   - Body language, levels of eye contact and the pace of your speech can also communicate a specific tone.
   - The intended tone is difficult to communicate in writing. In such cases, consider how you are delivering your message. Sometimes meeting in person or making a phone call is the most effective way to communicate on sensitive subjects where tone is especially important.

3. **Use email wisely** - Effective email communication can be a subject unto itself.
   - Never write when you are frustrated or angry. It is usually best to return to the task later.
   - Use “reply all” only when necessary, especially with large groups of recipients. Effective communicators specifically target their audience while limiting their content to what is most relevant.
   - Be brief. Use subject lines effectively and avoid text presented as a “wall of words”. Instead, use white space, bold text, bullet points and paragraph headings.
   - Any important questions or action items should be in the first few lines of your content. Email is not an effective medium for large pieces of detailed content. Large segments will likely go unread and unanswered. Consider a face-to-face meeting instead.

**MEETINGS**

Meetings can be an effective form of communication, as they allow for a great deal of interactivity. Here are some tips:

- **Have an agenda** - Meetings are more organized and time efficient if there is a clearly stated purpose, along with a list of topics to be discussed. Agendas in themselves are effective communication tools, as they can also serve as a framework for notetaking and questions.
- **Have a set end time** - Having a definite end time helps ensure that participants stay on task, maintain focus and accomplish what is set out in the agenda.
- **End with next steps** - Spending the last few minutes discussing next steps serves as an effective summary and enables participants to have a clear understanding of deadlines and the specific tasks they need to accomplish.
**COMMUNICATING WITH LEADERSHIP**

Communicating with laboratory leaders can be quite different from communicating with peers. As always, it is important to tailor your content to your audience. What is your leader’s background? What information will they need from a person in your position? What are their priorities?

The key term to keep in mind when communicating with laboratory managers and directors is focus.

Focus on impact, not process. Effective communicators focus on what is important to their audience. Leaders are most interested in information that will help them make decisions. With certain exceptions, leaders are less interested in the process you used to arrive at your conclusions. Developing and finding ways to repeat a concise message that communicates what is important will aid in maintaining focus.

Focus on the future. Unless your leadership is asking you to justify a particular action, they are most likely interested in information that will help them make decisions about the future.

Focus on the facts. Leaders may require specific supporting data behind your conclusions in order to make sound decisions but will be less interested in long explanations.

Focus on a compelling message. Although facts are important, storytelling can be an effective communication method for educating leaders about public health laboratory science.

For example, a story about a child being saved due to timely newborn screening or how testing prevented a foodborne illness from spreading can provide a powerful backdrop to illustrating the importance of and uses for public health laboratory science.
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?

2. Who needs to receive this first communication?

3. What information do you need to gather?

4. Write a short introductory paragraph or outline of your talking points and practice with a partner.
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.

1. List what is important in planning a meeting

2. What is necessary in planning an agenda?

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Location</th>
<th>Who Should attend</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Agenda Topic</td>
<td>Presenter</td>
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Quality Management Systems (QMS)

Objectives

Upon completion of this module, you should be able to:

- List the principles of a quality management system as they apply to laboratory operations;
- Illustrate the laboratory’s relevant organizational structure and processes;
- Identify non-conforming events using given pre-examination, examination, and post-examination indicators; and,
- Describe policies, processes and procedures related to the QMS Continuous Quality Improvement, or CQI, program.

What is a Quality Management System?

A quality management system, or QMS, can be viewed as a set of policies, processes, and procedures that provide a comprehensive structure for both the planning and execution of the many complex operations that take place in a public health laboratory. It can also be seen as a guiding philosophy that ensures that laboratory processes are managed for quality.

A QMS has broad impact. It ensures that staff are properly trained. It ensures equipment is monitored for performance and accuracy. It ensures that the complex processes surrounding the generating, interpreting, and recording of data are executed consistently. Moreover, when problems arise, a QMS ensures consistent mitigation of these issues.

Implementing a QMS

Implementation of a QMS is an evolving state in many laboratories. Depending on the size and complexity of operations, a public health laboratory may have one or more managers dedicated to defining the processes and developing the documentation required to implement a quality framework. The consequences of not developing a robust QMS are far-reaching. This can include inefficiencies such as cost overruns and invalidated tests, negative impact on individual patient treatment with inaccurate test results and, ultimately, regulatory sanctions such as loss of accreditation or certification.

There is currently no comprehensive QMS that can be applied to all public health laboratories around the world, since each country has its own set of public health regulations. A framework of what elements should be included in a QMS was developed by the Clinical Laboratory Standards Institute, or CLSI. These elements are organized as the “12 quality system essentials.” The framework was originally found in CLSI’s standard GP26-A3 and was combined with ISO 15189 to develop materials and trainings on QMS. As part of its International Health Regulations, or IHR, the World Health Organization, or WHO, offers materials and training for its laboratory quality management system, or LQMS, in six languages. These are free of charge to the public.
Quality System Essentials

The 12 quality system essentials, or QSEs, are used in this module to better understand what a comprehensive QMS may look like. Remember that this is a general framework or guideline that can be applied according to the needs of the individual laboratory. It provides a good understanding of the different and overlapping aspects of a laboratory’s operations that a QMS may impact.

The twelve QSEs in a comprehensive QMS are:

- Organization
- Personnel
- Equipment
- Facilities and Safety
- Purchasing and Inventory
- Information Management
- Documents and Records
- Assessments
- Process Improvements
- Customer Service
- Process Control or Management
- Occurrence Management—more specifically, Non-Conformance Management.

The QSEs are not listed in any specific order; all are necessary for a strong, robust QMS.

Organization QSE

The Organization QSE describes the organizational structure of the laboratory, personnel roles and responsibilities, hiring and management policies, and policies for communication within the laboratory.

Personnel QSE

The Personnel QSE addresses training processes, such as new employee orientation and continuing education, competency assessment, personnel qualification standards, and policies on knowledge retention. This last one is particularly important due to the consequences of losing expertise when experienced personnel leave the laboratory. Institutional knowledge is retained through effective documentation and development of procedures that will be used to train newly hired laboratory staff.

Equipment QSE

The Equipment QSE specifies how equipment is acquired, installed, operated and maintained. This can include validation or verification, maintenance procedures, calibration procedures, and decontaminating and decommissioning protocols.
Facilities & Safety QSE
The Facilities and Safety QSE addresses the laboratory’s physical space. This can include building maintenance schedules and responsibilities, security policies and protocols, specimen transport, regulated hazardous waste disposal, and building safety features. (For more information see the module on Safety, Emergency Management and Response)

Purchasing & Inventory QSE
The Purchasing and Inventory QSE describes the laboratory’s procurement processes such as contracts, vendor selection and ordering. It also describes inventory processes including receiving, storing and managing reagents, supplies and equipment.

Information Management QSE
The Information Management QSE addresses information stored in both paper and electronic record keeping systems. This QSE addresses operation of the Laboratory Information Management System, or LIMS, technical support, and information security issues such as computer access and use, records disposal, transmission of public health information, and data integrity and backup procedures.

Documents & Records QSE
The Documents and Records QSE addresses document control and records management. In the laboratory, documents communicate information about policies, processes and procedures. Records capture results data and other information on worksheets, forms and charts.

Document control is an important part of effective quality management since many policies and procedures are constantly updated and revised. Policy documents describe what must be done, process documents describe how it happens and procedure documents describe how to do it.

All documents must be indexed and curated. This requires a system of numbering or coding, and tracking. When documents are updated, revisions must be identified as subordinate to the original, and older versions archived. Laboratory personnel must receive training on the contents of new and updated policy, process and procedure documents.

Records retention, disposal and archiving procedures also fall within the scope of this QSE and will vary greatly according to legal and jurisdictional requirements.

Assessments QSE
The Assessments QSE addresses protocols for internal or external monitoring to verify that practices continue to meet regulatory requirements or to determine how well a process or procedure is functioning as part of the overall QMS. Policies, procedures and data related to this QSE can include a variety of audits, tests, and reviews, including proficiency testing, internal and external laboratory inspections, and accreditations.
Process Improvements QSE

The Process Improvements QSE specifies a process for improving, assessing and monitoring the laboratory’s operational protocols and procedures. This includes the development of policies and procedures for determining and executing quality initiatives and establishing quality improvement goals. Management reviews and both customer and stakeholder feedback will identify problems that will inform corrective actions and lead to implementation of new and improved quality standards.

Customer Service QSE

The Customer Service QSE addresses the laboratory’s internal and external customers. It identifies who the customers are, describes their individual needs, and measures customer satisfaction. Internal customers can include colleagues, other departments and internal branch laboratories. External customers are typically recipients of final test results and conclusions, such as other public health laboratories, clinicians and patients.

The processes and procedures of this QSE are designed to ensure that all customers receive high-quality data that is consistent and meets their expectations for timeliness and format. Documents might also include processes for complaint identification, recording and resolution.

Process Control (Process Management)

The Process Control QSE specifies how the laboratory develops, disseminates, controls and changes workflow processes specifically for the three phases of specimen testing: pre-examination, examination, and post-examination. Pre-examination processes and procedures include those for requesting, receiving, and handling specimens, data entry and criteria for specimen rejection. Examination processes and procedures include those for method verification and validation, as well as corrective actions for out-of-range quality controls. Processes and procedures for the post-examination phase include data reporting and specimen archiving.

The Process Control or Process Management QSE is not to be confused with the Process Improvements QSE.

Occurrence Management (Non-Conformance Management)

The Non-Conformance Management or Occurrence Management QSE (the terms are used interchangeably) describes the laboratory’s policy and methods of detecting, investigating, reporting and preventing events that do not conform to existing processes and procedures. A non-conformance, also known as a non-conforming event, is an unexpected outcome or result that indicates a problem. This might be an instrument falling out of normal operating range or a test run with results that are uncharacteristic and cannot be easily explained.
In other words, a non-conformance indicates a breakdown in quality, such as a process failure or a technical issue. Non-conforming events of low consequence should be recorded and reviewed on a frequent basis, such as monthly or quarterly, to keep track of trends and identify problems that require further action. An example of this might be receipt of a box of supplies that is missing the packing slip.

Non-conforming events of high consequence require a type of investigation called root cause analysis. Root cause analysis is a method of problem solving used to identify the causes of accidents, mistakes and problems. Examples of this are a laboratory incident, or incorrect test results provided to customers. Once a root cause is identified, specific corrective action is taken.

**Quality Indicators**

Another important quality concept is the quality indicator. Quality indicators are measures that make use of readily available data that can be indicative of a quality issue. They are indicators that can typically be measured numerically and make use of known correct parameters.

For example, let’s consider quality indicators in the samples testing process. As you may know, the process has three phases: pre-examination, examination and post-examination.

- A pre-examination quality indicator could be a metric about the sample itself, such as correct sample labeling or temperature. These indicators can be measured and there are known correct indicators.
- An indicator during the examination phase could be something like the operating parameters of an instrument. Any indication that testing has fallen outside known parameters could be a signal that something is wrong.
- Post-examination indicators would involve analysis of the test results. This could include wildly erroneous results or errors on the sample report.

As you can see, failure of any of these indicators requires thorough investigation and attention to restore quality. If a problem is identified, corrective action must be taken, then the indicator needs to be repeated to ensure the action was effective.

**Continuous Quality Improvement**

Continuous Quality Improvement, or CQI, is a management philosophy that recognizes that most work processes can be incrementally improved. A CQI approach is proactive rather than reactive, and encourages continual evaluation and improvement of processes, rather than waiting for something to go wrong before changes are made. A healthy laboratory QMS will follow the CQI philosophy by incorporating recurring audits and evaluations of policies, processes, and procedures.

Further, new techniques and products are thoroughly tested prior to implementation, and are only adopted if they improve operational accuracy, timeliness and safety. The CQI approach improves quality while increasing personnel and customer satisfaction.
CQI Example

Raymond is concluding his first week as a new employee at a national public health laboratory. He has just been tasked with testing a number of samples for the presence of a pathogen. Coming from an academic background, Raymond is familiar with using control samples in testing. However, as he examines the protocols and procedures he needs to follow to conduct the test, he is surprised to learn that the quality procedures are extensive and are more than just running quality control samples as he is used to. Instead, the processes and procedures are part of a quality management system which impacts just about every aspect of laboratory operations.

Raymond has discovered a slightly more efficient way to process specimens as they are delivered to his laboratory. Instead of simply letting Raymond take shortcuts and follow his own new and slightly improved process, Raymond’s supervisor takes a CQI approach. He encourages Raymond to experiment using his new process and document the results. If successful, Raymond’s improved process would be adopted by the entire team.

In this example, Raymond’s process improvement was successful. It allows the couriers delivering the specimens and clinicians waiting for test results (who are the laboratory’s external customers), and Raymond’s colleagues (who are the laboratory’s internal customers), to all work more efficiently.

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

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

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
QMS Exercise #1

Developing or Evaluating a Quality Management System (QMS)

SWOT Analysis of Current QMS

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)
<table>
<thead>
<tr>
<th>Strengths (What is good about your laboratory’s QMS?)</th>
<th>Weaknesses (What could be improved?)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Opportunities (What is available for helping to improve?)</td>
<td>Threats (What could wipe your system out, destroy or undermine it)</td>
</tr>
<tr>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>
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.

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

Pre-examination phase

Examination phase

Post-examination phase

**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:

How to measure:

Conduct assessment:

Analysis:

Action:

Repeat:
Quality Management Systems Supplemental Information

COMPONENTS OF A LABORATORY QUALITY MANAGEMENT SYSTEM (QMS) MANUAL

While the structure of a QMS Manual allows for flexibility, the content should include a description of the laboratory’s goals, policies, procedures, roles, responsibilities and monitoring process for each of the QSEs. Each organization should first identify all of its accreditors and requirements to determine if it is more efficient to have multiple quality manuals, a single overarching quality manual or one quality manual with multiple process management appendices to address each accredited area of the laboratory. This template follows the latter option to allow each appendix to be updated independently during annual updates.

TITLE PAGE: The title page should contain the following:

- Title of the manual
- Name and address of the organization
- Document control information (version, number, etc.)

INTRODUCTION: Provide a brief overview/history of the laboratory. Include physical location, certifications, licenses, relation to parent organization, hours of service, short summary of each laboratory unit/discipline. Items to consider including:

- Goals and objectives of laboratory
- Mission/vision statement
- Scope of the quality manual—areas to which this QM applies; include a statement that quality is everyone’s responsibility
- Description of how the manual will be maintained, reviewed and updated
- Quality policy

State the purpose for the quality manual, i.e., it is a set of documents that describe the structure and contents of the laboratory’s QMS.

TABLE OF CONTENTS: List the titles and parts of the manual organized in the order in which they appear. Can be organized in whatever way makes sense for your laboratory, such as:

- By QSE
- By laboratory section
- To match organization chart

ACRONYMS/ABBREVIATIONS: Include a list of acronyms and abbreviations used throughout the document.

DEFINITIONS: Include a list of definitions of terms which may need clarification throughout the document.
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
4. Personnel                                    10. Assessments
5. Purchasing and Inventory                      11. Process Improvements
**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

Specimen acceptance and rejection

Corrective action review and follow-up

Document control

Administration policies

Training logs

Selection/purchasing of equipment

Choosing of quality improvement indicators

Safety plan

Quality control

Corrective action(s)

Monitoring of electronic data integrity

Archiving patient results and QC data

Monitoring event trends

Personnel list with emergency contacts

Internal audits

Floor plans

Instrument maintenance logs

Quality improvement results & actions

Handling of customer complaints

Computer Use Policy

Organization Chart

Storing of reagents and supplies

Pre-examination workflow processes

Root cause analysis

Risk analysis
Safety, Emergency Management, and Response

Objectives

Upon completion of this module, you should be able to:

- Outline how to identify, assess and mitigate hazards in the public health laboratory
- Describe public health laboratory emergency response protocols
- Describe a public health laboratory emergency response plan and any other necessary emergency preparedness activities.

Culture of Safety

Safety focuses on the occupational and personal safety of staff members and the environments in which they work. It is essential that leaders and managers prepare and implement a comprehensive safety plan for those working in the public health laboratory. Once in place, a safety plan must be promoted and practiced to ensure the protection of the laboratory facility, its staff and the surrounding environment from hazards and risks related to laboratory operations and services. Please note that the three images used do not represent an exhaustive list of personal protective equipment.

Another critical aspect to maintaining safety in the laboratory is to build group acceptance by providing positive feedback that enhances the “psychology of safety,” or as it’s more commonly called, the “culture of safety.” Safety culture can be 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 culture of safety recognizes that to err is human and establishes procedures and processes to minimize errors and avoid harm. This includes written safety procedures that staff must follow. Safety culture also encourages reporting of actual and potential situations which might place staff members and others at risk, assesses those risks openly and implements redundant systems to keep risk to the absolute minimum.

To be effective, all staff members must become part of the culture of safety. This is because safety involves not only yourself and your work environment, but also all others working in the laboratory. Safety culture is the background against which all staff members must perform all aspects of their jobs.

Breakdown in Culture of Safety Example

Isabel has been working in her public health laboratory for a few months. During her time there, there have been no safety incidents and she has gotten comfortable working with the various specimens, even though many of them can be potentially dangerous.
Isabel was using an autoclave to destroy *Mycobacterium tuberculosis* cultures after specimen testing was completed. She was using a biosafety containment unit and was wearing a lab coat and gloves. Please note that the first image of Isabel in the module uses a stock photo with a short sleeve lab coat, best practices encourage the use of long sleeve lab coats to promote safety and prevent contamination. 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.

An investigation of both the incident and existing procedures determined that it was unclear who was responsible for maintaining the autoclave. It also determined that there was no personal protective equipment, or PPE, requirement sufficient to protect an operator from exposure should the autoclave fail.

Several of Isabel’s co-workers had noticed that the rubber seal on the autoclave door needed replacement but did not report it to management. The equipment was left in disrepair until it failed. Subsequently, Isabel and her co-workers had to be tested for tuberculosis.

After the incident, management instituted revised operating procedures for the autoclave. The new procedures require operators to wear respiratory protection whenever operating an autoclave. They also require that operators stop using an autoclave any time there is a deviation in its condition and report the need for immediate maintenance to a designated equipment manager.

The cause of this incident was a deficiency or breakdown in the culture of safety. Organizations with a deficient safety culture are characterized by complacency and an attitude that safety measures are only important when someone is watching or when an inspection is anticipated.

In the case of the autoclave, the operators knew that the door seal needed replacement, but since a safety culture was lacking, each of them failed to take responsibility for ensuring safety and reporting the problem. This resulted in Isabel and her colleagues being exposed to a dangerous pathogen.

**Positive Safety Culture**

Organizations with a positive safety culture are characterized by communications founded on mutual trust, shared perceptions of the importance of safety, and confidence in the efficacy of preventive measures. Such organizations promote accountability and education to improve safety. They report laboratory incidents and potential pathogen exposures for objective analyses to prevent reoccurrence.

**Risk Analysis in the Laboratory**

Promoting a safety culture involves proactively assessing hazards and risks and working to mitigate them. To assess the risk of specific safety scenarios in laboratory work, first identify existing hazards with biologic materials. Then for each hazard being reviewed, recognize and prioritize the risks.
associated with it. Use various safety scenarios to analyze each risk to determine what changes would mitigate or remove the risk.

Carry out the proposed changes and test that they are effective. Continue evaluating the mitigation strategy to ensure that it is eliminating the identified risk without causing any additional risk.

**Hazard vs. Risk**

In an occupational safety context, a *hazard* is any source of potential damage, harm or adverse health effects. Exposure to a hazard doesn’t necessarily mean that you will come to harm.

*Risk* is the chance or probability that a person will be harmed if exposed to a hazard. The level of risk involved is determined by the combination of the likelihood of exposure to the hazard and the severity of harm should exposure to the hazard occur.

For example: a tiger is a hazard.

- A tiger in the open is a high risk.
- A tiger behind bars is a moderate risk.
- A tiger cub behind bars is a low risk.

Here’s a laboratory related example:

- *Brucella* is a highly infectious pathogen that can cause infection when inhaled. It is the hazard.
- If *Brucella* is handled in a biological cabinet, as opposed to out in the open, the risk of harm is decreased.
- If it is handled in a cabinet with gloves and lab coat, risk is decreased further.
- If handled in a cabinet with gloves, lab coat, and respiratory protection, risk is decreased to low to moderate.

**Identifying Hazards**

The first step in understanding risk is to identify all the hazards associated with the laboratory procedure under assessment. All pathogens have the potential to cause infection if handled improperly, but some pathogens are very infectious and require isolation and use of special equipment and procedures.

Certain procedures used to manipulate the pathogen may pose further hazards. Use of needles and glassware may cause injury. Centrifuging, vortexing and pipetting, among other procedures, may cause aerosols—small droplets that may be inhaled without adequate protection.

The laboratory itself must have specific safety features if highly infectious and/or virulent pathogens are handled. These labs use designations called Biosafety Levels, or BSLs, that specify the safeguards needed for pathogens. The BSL increases in number from BSL1 to BSL4 as the hazard posed by the pathogen increases. Staff experience must also be considered when identifying hazards. Undergraduate students with little experience should not work with dangerous pathogens using procedures that may cause injury or aerosolization. Only experienced staff should work with these organisms.
Assessing Risk

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. This will allow you to determine the risks associated with each laboratory procedure. Then categorize each risk as low, medium, or high.

For all operations that you determine are medium or high risk, mitigate those risks to prevent potential incidents and accidents. Sometimes, low-risk procedures are not mitigated since the cost in personnel time and comfort may outweigh the advantage of prevention measures or controls.

Mitigating Risk

Once risks are assessed, how do you mitigate them? The Hierarchy of Hazard Controls is a system used to minimize or eliminate exposure to hazards. Control methods at the top of the graphic are more effective and protective than those at the bottom. Following this hierarchy normally leads to the implementation of safer systems, where the risk of illness or injury has been substantially reduced.

The most effective controls are elimination and substitution, which entail physically removing or replacing the hazard. This is not always possible in a public health laboratory context, since one purpose of the laboratory is to test dangerous pathogens. However, other hazards such as tripping hazards, overloaded electrical plugs, and malfunctioning equipment can be removed or replaced.

Engineering controls do not eliminate hazards but rather isolate people from them or provide tools to help them mitigate the effects. This can include solutions such as locked doors restricting access to the laboratory, eye wash and shower stations, and specialized cabinets and ventilation systems.

Administrative controls involve the way people work. This can include standard operating procedures, or SOPs, equipment manuals, staff training and installation of signs and warning labels.

Personal Protective Equipment, or PPE, includes gloves, laboratory coats, safety glasses and respirators. These are considered the last line of defense because PPE may fail without warning.

Include training on proper use and function of PPE as part of laboratory employee orientation and refresh as needed. This training should include procedures for donning, or putting on, as well as doffing, or taking off, PPE, and disposing of contaminated PPE. In addition, since gloves can be punctured, and respirators can malfunction, you must train personnel to inspect PPE for flaws or damage prior to wear.
Biorisk Management

How do we protect the public from unwanted release of dangerous pathogens from the laboratory? Biosafety practices are essential to the protection of laboratory staff and the immediate environment. These lessen the chance that dangerous pathogens will unintentionally leave the laboratory and expose the public to infection. However, biosafety practices alone cannot protect the public from intentional misuse of pathogens. Biosecurity measures must also be in place. These are practices and controls that reduce the risk of loss, theft, misuse, diversion of, or intentional unauthorized release of biological materials.

Together, biosafety and biosecurity practices constitute a biorisk management strategy designed to reduce the risk of unintentional and intentional exposure or release of dangerous pathogens from the laboratory.

Biosecurity Basics

Although historically rare, persons with bad intentions have used illicitly obtained pathogens to harm others. To protect the public from such actions, we must secure our laboratories to limit entry to those who wish to do harm.

One preventive step includes careful investigation of potential staff during the hiring process. Another is the restriction of all entryways and storage areas so that only staff who require access can enter. A rigorous inventory system should be in place to keep track of specimens, cultures, and other infectious materials, a process known as inventory control. This requires creating a detailed electronic list of all laboratory samples, including their location. It also requires recording all movement of samples, such as a change in freezer location. Such records must be maintained throughout each sample’s life cycle.

Protocols for inactivating or killing pathogens must be proven by experimentation prior to implementing SOPs for pathogen waste disposal. These SOPs for discarding contaminated materials should be revisited annually or at each alteration of the SOP to ensure that they are working. These steps will protect the waste stream and environment and prevent infectious materials from getting into the wrong hands.

Culture of Security

In addition to safety culture, laboratories need to foster a security culture as well. Information security is a hazard in a public health laboratory. Laboratory information systems contain sensitive information, such as the location of dangerous pathogens documented in the inventory control system.

Other sensitive information is private patient information. The physical safety measures we’ve discussed so far do not ensure that patient information is kept private. Whether stored in electronic network files on or on paper in filing cabinets, access to these materials must be limited to prevent disclosure of private patient data.
Protecting Patient Data

Private patient information falls into two categories, Personal Health Information, or PHI, and Personally Identifiable Information, or PII. PHI might be misused to prevent someone from obtaining employment or life insurance or may lead to stigmatization. PII often includes a patient’s name, but might only include demographics such as age, sex, race and disease. When combined, these data may allow others to identify the individual. Both PHI and PII must be kept safe to ensure public confidence and prevent lawsuits. Antivirus software, firewalls, and other best practices must be implemented to prevent data breaches.

Personal Safety & Security

Personal safety and security are important both inside and outside of the laboratory. Staff vulnerability increases during transitions to and from the laboratory. Opening and closing secured outer doors and walking in proximity of the building, especially after dark, present hazards to personnel. Adequate outdoor lighting is one engineering control that can be used to mitigate risk from these hazards. To decrease the likelihood that laboratory accidents and security breaches will occur, administrative controls that prevent unauthorized visitors should be in place and practiced. Staff should maintain situational awareness to avoid becoming a victim of theft or violence. Use the buddy system! No one should work in the laboratory or office alone at night without security personnel present.

Workplace violence, sexual harassment and bullying represent internal hazards to laboratory staff. These situations cause emotional and sometimes physical damage to personnel that might result in distraction and accidents. Persons who are victim to these types of abuse should report the specifics of these encounters to their supervisor, or if the abuser is the supervisor, to that person’s supervisor.

Emergency Management & Response

Emergency management and response encompasses events such as natural disasters, public health emergencies and facility or operation failures. It includes the laboratory’s responsibility to detect and respond to real or potential biological, chemical or radiological threats.

Effective emergency management and response requires anticipating potential dangerous situations and developing procedures to prevent or deal with each situation. The challenge in carrying out these procedures is to protect the public from harm while maintaining baseline laboratory functions.

Emergency Management Planning Example

Beatrice is a supervisor in a national public health laboratory located in a largely rural country. Each year, the laboratory must respond to hazards that occur during seasonal rain and flooding. These include vector-borne disease outbreaks such as Dengue Fever, Chikungunya and Zika Virus.

The local hospital has notified the laboratory that 150 patient specimens will be arriving for arboviral testing. Beatrice has been asked to help create an emergency response plan in answer to this situation.
Let’s look at some of the factors that Beatrice considers when developing her emergency plan.

The national laboratory has 30 staff members who perform laboratory reference testing on specimens sent from its districts and private and public hospital laboratories. Beatrice 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 by the laboratory as well as delivering these to the appropriate specialty labs. Beatrice knows that she will need more staff if the outbreak worsens, and begins to coordinate training of ten more staff members from other sections. She also begins to repurpose the parasitic and mycotic disease reference laboratories, and trains two additional staff members to accession incoming specimens.

Beatrice implements a comprehensive training and communications program for use between the national laboratory director and staff to all external stakeholders, including hospitals, district laboratories, supply vendors, and the Ministry of Health. She alerts local emergency response coordinators and private local couriers of the potential for increased capacity related to shipment of specimens. Since Beatrice knows that standing water from rain may make the situation worse, she 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.

Finally, she 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.

Emergency Preparedness & Response

As you can see, an effective response to this one emergency requires considerable planning and coordination with many outside entities, as well as effectively executing training and communication strategies. By cross-training staff and repurposing laboratory space, Beatrice will be able to maintain daily operations while implementing surge capacity. This cross-training combined with her clear communication plan will help everyone perform their jobs in an effective way and prevent further disaster.

In other circumstances, laboratory staff may need to work closely with first responders, such as fire and police officers, as well as municipal, district, and federal agencies, such as the Ministries of Health and Agriculture. In addition to having plans in place to deal with specific community emergencies, such as what Beatrice worked on in response to a potential vector-borne disease outbreak, a laboratory must have contingencies in place to protect the integrity of the laboratory itself. It needs emergency response plans to respond to internal or external threats.
**Internal Threats**

An infectious disease outbreak affects the surrounding community but is internal since outbreak response is an important function of the public health laboratory.

Laboratories must also prepare for other internal emergencies and have contingency plans for:

- Electrical, chemical, or deliberately set fires
- Extreme shortage and unavailability of reagents and supplies
- Bomb threats
- Delivery or deposit of suspicious packages on laboratory property
- Intruders or violence within the workplace among laboratory staff
- High-volume chemical spills that require professional clean up
- Air contamination with noxious chemical fumes, biological organisms or smoke.

**External Threats**

Examples of external emergencies are:

- Natural disasters such as hurricanes and earthquakes
- Labor strikes and healthcare facility closures
- Industrial accidents such as chemical spills that pollute drinking water
- Major transportation accidents such as multiple wrecks of vehicles, planes, and/or trains
- Acts of bioterrorism such as pipe bomb explosions and mass injury or casualty.

Note that industrial accidents and natural disasters that directly affect the laboratory itself are both internal and external emergencies!

**Emergency Response Plans**

Both internal and external threats require careful risk assessment, planning, and effective communication with the appropriate people both in and out of the laboratory environment. A positive culture of laboratory safety and security go a long way in preventing many of these emergencies, but administrative controls and emergency response plans should encompass these circumstances.

An emergency response plan is a document outlining the actions laboratory leadership must take in response to an internal or external threat. These plans vary by laboratory, but in general they are relatively brief and easily accessible.

**Creating an Emergency Response Plan**

Creating an emergency response plan is a substantial process that may involve personnel from many parts of the laboratory. Planners must analyze the internal hazards identified through risk assessment, as discussed earlier in the module. Important factors to consider when developing an emergency response plan are pathogen characteristics and facility design. During plan development, existing hazard controls are analyzed and internal staff roles and responsibilities are created.
In addition to considering what could happen, planners must also look at what has happened in the past. The physical location of the laboratory, as well as the surrounding environment, must also be included in the plan. Planners then turn to the availability and capabilities of the resources required to respond to an emergency. For internal threats, existing personnel may assume new roles and responsibilities. For external threats, factors such as the availability and response times for fire, police and emergency medical services are incorporated into the plan. At this stage, planners begin to develop hazard- and threat-specific emergency procedures.

Communications and training are also important considerations, and both are essential parts of effective emergency response plans. As we have seen from our example, resources required to respond to an emergency can include the public and outside entities such as couriers and other businesses. Written procedures alone are insufficient; they must know what to do and how to do it. Training includes regular tabletop exercises and drills to practice for different emergencies. As plans are executed in practice, they are reviewed and revised as needed.

**General Safety Plan**

Emergency response plans are detailed, specific to predicted emergencies, and often involve people and organizations outside the laboratory. In addition, laboratories should have a general safety plan. A general safety plan is an internal plan outlining incidents that could possibly happen in and around the laboratory, as well as information that laboratory leadership can use for planning. The general safety plan works along with safety and security protocols and procedures, and can include information about necessary training for staff, rescue procedures and needed security measures.

Specific emergency procedures for fire and gas leaks, power outages, alarms in the lab, suspicious packages, bomb threats and workplace violence should also be included in the plan. General safety plans contain basic information that is applicable across all sections of the laboratory, but also specific information depending on work with dangerous pathogens and laboratory design and engineering controls for biocontainment.
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?

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?

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?
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.

- 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)

<table>
<thead>
<tr>
<th>PROCEDURE OR PROCESS</th>
<th>PRINCIPAL STEP(S)</th>
<th>POTENTIAL SAFETY OR HEALTH HAZARD(S)</th>
<th>RECOMMENDED CONTROL(S) WORK PRACTICE CONTROLS</th>
<th>EQUIPMENT TO BE USED (PPE)</th>
<th>TRAINING REQUIREMENT(S) (Personnel)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlebotomy</td>
<td>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 venipuncture 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</td>
<td>Exposure to bloodborne pathogens Identify one or two</td>
<td>Wear PPE Identify other work practice controls</td>
<td>Lab coat and gloves</td>
<td>BBP training</td>
</tr>
</tbody>
</table>

What is the level of risk for the identified hazard?
<table>
<thead>
<tr>
<th>PROCEDURE or PROCESS</th>
<th>PRINCIPAL STEPS</th>
<th>SAFETY or HEALTH HAZARD(S)</th>
<th>RECOMMENDED CONTROL(S)</th>
<th>EQUIPMENT TO BE USED</th>
<th>TRAINING REQUIRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Tasks (Procedure)</td>
<td>(Procedure)</td>
<td>(Pathogen)</td>
<td>Work Practice Controls (Place)</td>
<td>(PPE)</td>
<td>(Personnel)</td>
</tr>
</tbody>
</table>

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**

### Name of Process – General Precautions

**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:
- 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):

### Process Assessment

**Pre-analytic**

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Potential Hazards</th>
<th>Initial Risk Level</th>
<th>Control (Mitigation)</th>
<th>Residual Risk Level</th>
</tr>
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<tbody>
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</table>

**Required:**

**Optimal:**

### 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.
<table>
<thead>
<tr>
<th>What are the hazards? (location/ hazard)</th>
<th>Who might be harmed and how?</th>
<th>What are you already doing?</th>
<th>What further action is necessary</th>
<th>Action by whom?</th>
<th>Action by when?</th>
<th>Done</th>
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References:

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?

What techniques can you use to minimize aerosols?

What is the proper PPE in this scenario?
Safety, Emergency Management, and Response
Creating an Emergency Response Plan Exercise #3

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.
Safety, Emergency Management, and Response

Knowledge Check Questions Exercise #4

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________

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)
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