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INTERNATIONAL BIOLOGICAL and CHEMICAL THREAT REDUCTION

Laboratory Hazard Identification and Risk Assessment Scenario

Introduction to Working Groups

Sandia National Laboratories is a multimission laboratory managed and operated by National Technology and Engineering Solutions of Sandia, LLC, a wholly owned subsidiary of Honeywell International, Inc., for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-NA0003525.

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Scenario Overview

- This scenario describes a laboratory with several independent departments that have varying hazards and risks.

- We will break up into groups and each group will represent a laboratory department. Groups will be expected to identify the hazards and analyze the risks their respective department.

- Subsequently, all groups will present their findings, identify similarities and differences in risk, and will begin to understand how hazard identification and risk assessment can be done collectively by an institution with distinct departments and/or by laboratory networks.

The Central Veterinary Laboratory Overview

The CVL is located in a large city in a country who's animal population suffers from a multitude of reportable infectious diseases

- Responsible for the diagnosis and characterization of animal diseases
- Consists of six departments: 1) Bacteriology; 2) Virology; 3) Parasitology; 4) Necropsy; 5) Molecular Biology/PCR; 6) Sample Receiving
- Each department operates independently, but occasionally refer samples to other departments when a challenging case is encountered
- Located in an area with an increased risk of terrorism; however, the laboratory does not have robust security systems in place

*** OIE Delegate has recently nominated a new Laboratory Focal Point, the CVL Laboratory Director, who hopes to adopt and implement a risk assessment approach both within the CVL and across the national veterinary laboratory network, but the process hasn't begun yet*

Scenario Objectives

The Central Veterinary Laboratory represents a laboratory with independently functioning departments. The concepts used to identify hazards, analyze risk, and establish a standardized process to conduct risk assessment can also be applied to laboratory networks.

- The objectives of this exercise are as follows:

1. Identify laboratory hazards and consider the impact that they may have on laboratory staff and their families, the community, the surrounding animal population, and the environment
2. Consider these hazards, characterize as safety and security risks, and evaluate the potential likelihood and consequences of each adverse effect
3. Begin to consider standardization of the risk analysis process across departments within a laboratory as well as across laboratory networks
4. Understand their role as Laboratory Focal Points in mobilizing the national veterinary laboratory network to adopt and implement biological risk assessment

Scenario Guidelines

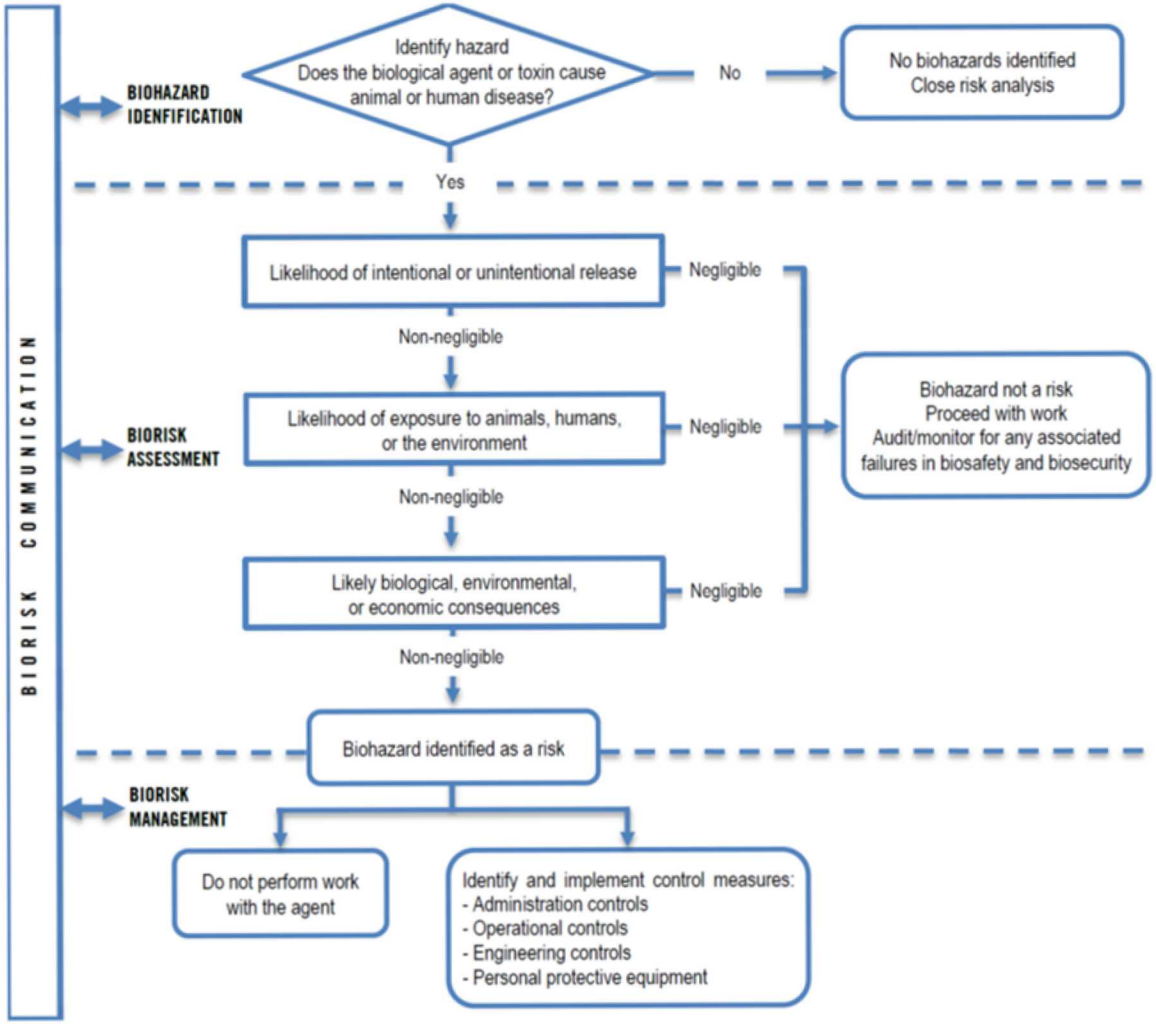
The described scenario was developed to enable you to consider a pathway to standardize risk analysis and risk mitigation within a laboratory and across laboratory networks

- A fictional Central Veterinary Laboratory with seven independent departments
- Risk assessments will be done for each laboratory department where the group identifies 2 hazards and conducts a safety and security risk assessment on each
- Each group will have 5 minutes to present their findings
- Larger group will collectively use the risk assessments to briefly conduct a gap analysis of the entire lab
- Larger group will then discuss how risk assessment can be standardized and applied to a laboratory network and begin to develop a brief consensus on the path forward for standardization of risk assessment across laboratory networks

Considerations

- What are the hazards?
- Characterize the identified hazards/risks
  - What procedures are done with the identified hazards?
  - Do the procedures increase or decrease the hazard risk?
  - What can go wrong? (Safety and Security)
  - Is the hazard present outside of the laboratory?
  - Does prophylaxis exist?
  - Do efficacious therapies exist?
- Assess Risk
  - What is the impact of a release on the animal and human populations?
  - What are the likelihood and consequences of a release?
  - Use the flow chart from the OIE Terrestrial Manual Chapter 1.1.4. to work through risk assessment.
  - Are there existing mitigation measures?

Flowchart 1: Biological risk analysis process



Note: The biological risk management process should address all laboratory processes and procedures associated with the specific hazard (biological agent or toxin). The biological risk assessment and biological risk control planning involves a team of individuals who understand the organisational aspects of the laboratory, the biology and pathogenesis of the agent, and the impacts of exposures and accidental or intentional release of the biological agent or toxin.

From: OIE Terrestrial Manual, Chapter 1.1.4

Logistical Instructions

- Create six groups with approximately equal numbers
- Each group will conduct a risk assessment of a laboratory department
- The entire group will reconvene
- A representative of each group will present their findings to the larger group
- Larger group will work collectively to discuss the findings and conduct a gap analysis of the larger laboratory and propose a path

Reporting Instructions

Report back on two priority hazards

- Describe the hazard and why it is a hazard
- Describe the likelihood of intentional or unintentional release and briefly explain why this is likely or unlikely.
- Describe the likelihood of exposure to animals, humans, and/or the environment and briefly explain why this is likely or unlikely.
- Describe the likely biological, environmental, and/or economic consequences.
- Indicate whether or not it is a risk and does it require implementation of biorisk management methods?

Scenario Agenda

- Scenario objectives, guidelines, and working groups: 10:40 – 11:00
- Hazard identification and risk assessment exercise: 11:20 – 11:50
- Report results: 11:50 – 12:35 (each group will have 5 minutes to report)
- Group discussion and consensus: 12:35 – 1:00

GAP Analysis for the CVL Departments

Although the above departments function somewhat independently, they are all part of the Central Veterinary Laboratory. In many cases, the individual departments handle dangerous pathogens and have similar practices. Similarly, laboratories can function somewhat independently, but are all part of the national veterinary laboratory network.

At the laboratory level:

- What steps can the CVL take to improve its overall risk analysis process?
- How can this process be standardized so that all the departments analyze the risks similarly?
- How can the departments work together to create a standard process?
- How are policies established and formalized at the level of the department and the CVL?
- How do some of the concepts of standardization at the department level apply to laboratory networks?

GAP Analysis at the Network Level

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At the laboratory network level:

- How do you, as the laboratory focal point, find out if biological risk assessments have been undertaken in the wider national veterinary laboratory network?
- How do you manage this information once you obtain it?
- How are policies established and formalized at the level of a laboratory network?
- What arguments can you provide to your OIE Delegate to advocate for the commencement or continuation of the national laboratory network's laboratory risk assessments?
- With whom do you need to communicate in order to obtain buy-in from the laboratories in your country to participate?

Develop a consensus statement regarding describing an assessment/risk mitigation process for the networks. The statement would include: 1) the value to stakeholders (individual laboratories, laboratory networks, delegate, and policy makers at the ministry level); 2) the methods that would be used determine the current state in laboratories within the network; 3) a process to solicit delegate/policy maker buy-in for establishing a standard risk assessment/biorisk management process; 4) and a process to generate buy-in at the laboratory level.

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Conclusions

1. Hazard identification is essential because these hazards may impact laboratory staff and their families, the community, the surrounding animal population, and the environment. Release can often have global significance.

2. Understanding the risk assessment process is fundamental, so that you as a Focal Point can help establish policies to raise awareness of the risks and establish policies to standardize risk assessment within individual laboratories and across your laboratory networks.

3. It is important for you to establish your role in mobilizing the national veterinary laboratory network to adopt and implement biological risk assessment.