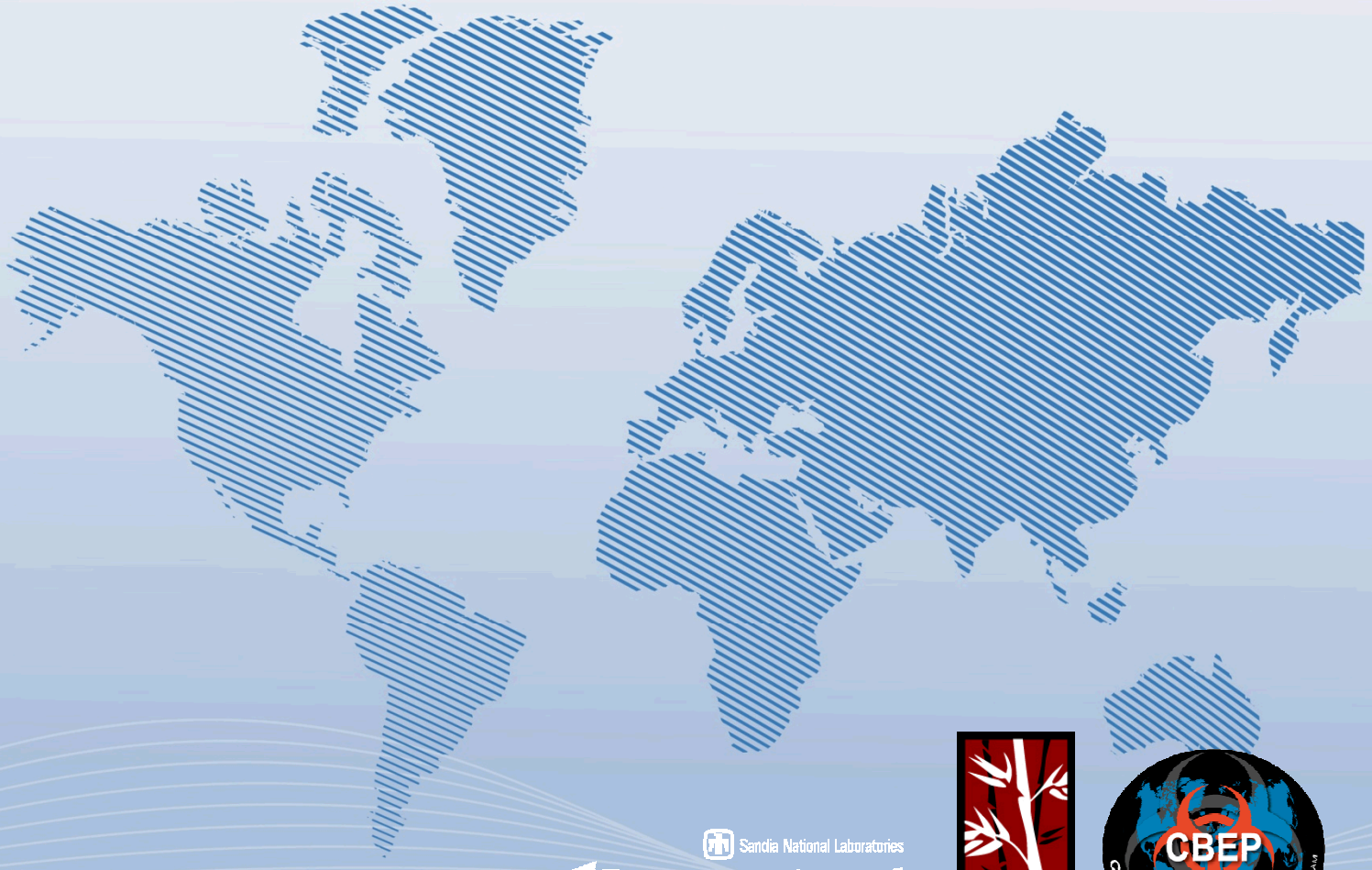
SAND2013-6800P

CoVAB Workshop Scenarios

Instructor Guide



Sandia National Laboratories
International
BIOLOGICAL THREAT REDUCTION

BIOSECURITY ENGAGEMENT PROGRAM

CBEP
Cooperative Biological Engagement Program

Scenario 1— hemorrhagic fever in National Park

Message for Student

Setting: Working in small groups read the following scenario and complete the risk assessment for field investigation scenarios. Focus on the risk assessment strategies and biosafety and biosecurity precautions you may need to implement in the field. For the questions presented, consider why the answers would be relevant from a field biosafety and biosecurity standpoint.

Question (Outcome):

What biosafety and biosecurity precautions are necessary in the field?

How do field conditions change your risk assessment?

Record: Record answers on post it notes and then put the post it notes on the flip chart

Reporting: Your group will be randomly selected to share its answers for one of the questions. Select a spokesperson for the group to share with the class.

Timing: Spend <Minutes> on this exercise. Remember there are two sets of questions to answer.

Messages for Instructor

Walk around if possible and check on the groups' progress.

If a group is having difficulty deciding what agent to suspect, this scenario is based on an Ebola virus outbreak investigation. Remind participants there is no "wrong" answer and that the agent is only important because it may alter the transmission routes or ability to cause disease to the field investigation team. When answering questions, redirect students to focus, not on the technical steps of an outbreak investigation, rather the biosafety and biosecurity principles they would need to employee in the field.

Reporting: Assign groups a question or two to share their answers with the larger group.

Ask the larger group if there is anything additional they came up with that was not included in the answers presented.

Risk Assessment for Field Work

Expected answers, Step 1—Risk Assessment for field work questions

- **What etiological agent would you suspect?**

Ebola virus and Marburg virus, Rift Valley Fever virus

- **Describe the hazards and/or threats present in the field situation**

Infectious carcasses of the chimps, potential contamination of soil. Infection potentially spread to other animals in the park. Agent probably infective for humans. In terms of threats, possible interest by adversaries in acquiring the infectious agent from a source easily accessible (the National Park).

- **What mitigation is currently present in the field situation?**

Physical distance between the chimps and the team. Possibly isolation of the area with the dead chimps from other animals or human visitors of the park.

Expected answers, Step 2 – Work through the following exercise to determine the Consequences of an exposure to the suspected etiological agent.

Consequence 4 (catastrophic).

- **What factors did you consider when coming up with this number?**

The etiological agent is still unknown, but we can assess potential consequences basing on the highest possible risk profile compatible with the situation. In this case it may be an hemorrhagic fever virus infectious for humans (probably Ebola).

Expected answers, Step 3 – Work through the following exercise to determine the Likelihood of an exposure to the suspected etiological agent.

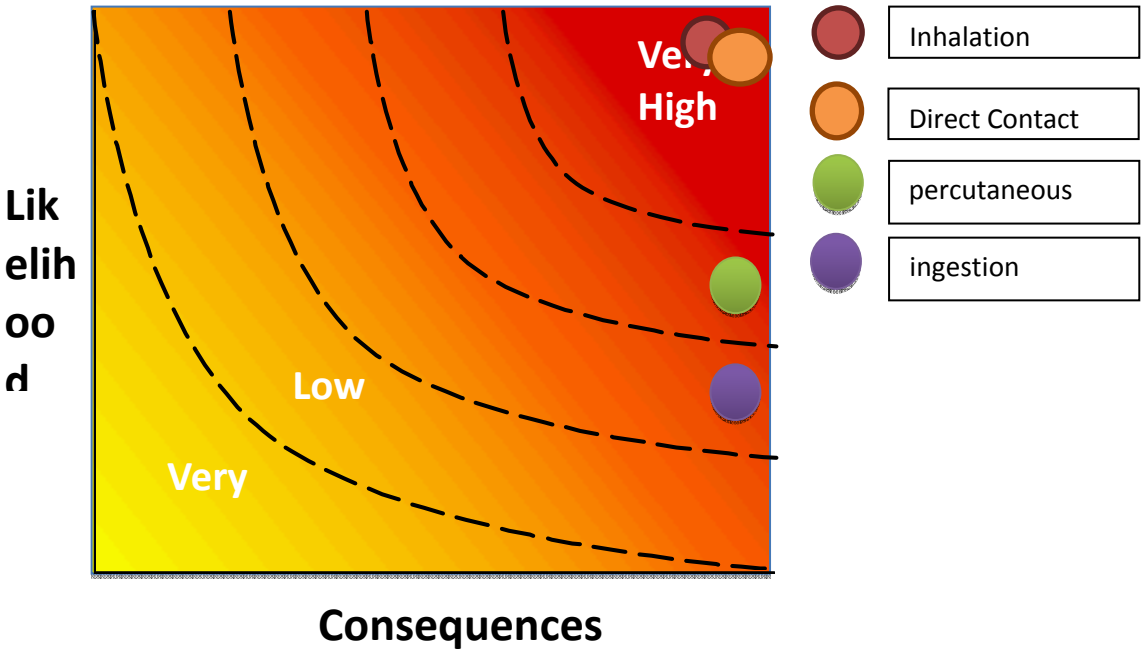
Likelihood of inhalation exposure: IV (visiting the field situation in the park with infected carcasses and possibly other sick animals).

Likelihood of percutaneous exposure: III (possible if collecting samples).

Likelihood of ingestional exposure: II (may occur if not using correctly PPE).

Likelihood of Direct Contact: IV (analyzing animals and collecting samples).

Expected Answers, Step 4 – Graph the values that you determined for the Likelihood and Consequences of an exposure to the suspected etiological agent on the graph provided.



Expected answers, Step 5 – Risk Evaluation. Take a minute to ask whether this risk would be acceptable?

- **What factors did you consider in evaluating the risk?**

Field situation, available mitigation measures, access to the area by potential threats.

Risk Mitigation for Field Work

Expected answers, Step 1 – Identifying Mitigation Measures

- **Based on your scenario, identify at least 10 risk mitigation measures. Hint: Remember that mitigation measures should address both safety and security. List them here:**

Administrative controls: policies and guidelines on isolation of the area; closure of the National Park; collection of specimens; transport of specimens; handling and transport of carcasses; waste management; etc. Procedures for collection of specimens and samples; appropriate donning of PPE; proper waste disposal. PPE: gloves, protection for skin and foot, face and eye, respiratory protection.

Expected answers, Step 2 – Understanding the Advantages and Disadvantages of Risk Mitigation Measures

- **Pick one of the mitigation measures identified above and list the advantages and disadvantages of this mitigation measure, or that particular category of mitigation measures.**

- **b) Fill out the following table:**

Control Measure	Advantages	Disadvantages
Elimination or Substitution	Eliminate the risk	Not feasible if connected with the unknown agent
Engineering	Reliable (cabinets, etc)	Not always feasible in a field situation. May be expensive. Need proper training for correct use
Administrative	Ensure communication among the correct roles and responsibilities. May include improbable events, substituting experience. May optimize the use of resources.	Need communication, enforcement, training of personnel on following the policies.
Practices & Procedures	Provide detailed instructions.	Need training for personnel and enforcement
PPE	Provide physical barriers.	Should be available when necessary, and according to the risk situation. Require use of correct practices.

Expected answers, Step 3 – Writing Draft SOPs

PPE

- **What PPE is appropriate to protect yourself from the agent in your scenario? Why?**

  Gloves, foot, eye and face protections, respiratory protection. Because of possible exposure routes via inhalation and direct contact.

- **Where is the PPE stored?**

- **Where is the PPE disposed of or cleaned?**

Disposed in sealed container and treated for disinfection or final disposal upon return to the lab.

- **Are there any other considerations?**

Sample Collection

- **What type of samples will you be collecting? Why?**

Blood samples from the chimps and the colombus monkey.

- **How will you collect samples safety?**

Specimen collection, transport and shipping kits.

- **How will the samples be stored?**

- **Are there any other considerations?**

Waste Disposal

- **What types of waste will be generated?**

Who is at increased risk if contaminated biological materials are not handled and treated properly?

Other animals in the Park. Members of the field team. Workers and visitors to the Park. Those who will handle waste. Depending on area location, surrounding community. Environment.

- **What potential incidents could occur?**

Contact, percutaneous or inhalation exposure to the infective agent. Exposure to untreated waste materials. Contamination of water reservoirs in the Park. Missing samples, mislabeling or problem in shipping/transport, including missing samples. Security breaches including not authorized personnel acceding to the area.

- **How can the risk associated with biological waste be mitigated?**

Waste storage and transport. Sharp containers. Practices and procedures including Segregation, collection, storage, transport, treatment and final disposal of waste.

- **Are there any other considerations?**

Sample Transport

- **Why might transport security be particularly important for working in the Field?**

To ensure only authorized parties can accede to the samples, the waste and any other hazard material in the way to the lab. To reduce the risk of illicit acquisition of high risk biological agents. Also samples are not collected in a controlled area (access control can be implemented only partially in the Park).

- **What can you do to determine your transport security needs?**

Distance and transport time to the lab, also in consideration of possible specimens deterioration. Best solutions to maintain Chain of Custody with trustworthy parties. Determine if there is pre-approval from responsible authority.

- **What are some ways biological materials that can be kept secure in the field and during transport?**

Isolation of the area; access control and authorization to the area and especially high risk agents.

- **Are there any other considerations?**

Risk Mitigation for Lab Work

Expected answers, Step 1 – Ways to mitigate risk in the laboratory – MC&A and Good Laboratory Practices

- **Now that your samples from the field have arrived in the lab please consider the following:**

    a. **Material – What information should we keep track of?**

What materials exist, where the materials are, who is accountable for them. Also for each agent: quantity, form, detail, scope.

b. Control – How will the material be controlled?

Physically, to prevent unauthorized access (example: locks, access restrictions). Administratively, for example policies for disposing of materials, periodic inventory checks, labeling and tracking of material.

c. Accountability – Who will be accountable for the material?

Who is in the best position to answer questions about the associated material.

d. List one good laboratory practice that you'd like to implement regarding the samples from your scenario? Why?

For example Wearing PPE, Marking and labeling containers, Proper segregation of waste, Transporting biohazardous materials in closed, durable, leak-proof containers, Keep an inventory, …

Biorisk Management Performance

Expected answers, Step 1 – Ways to include Biorisk Management Performance in Field and Laboratory work

- **What are some ways that BRM performance could be measured for your scenario? Please explain and give an example.**

Audits and inspections, performance indicators, observations, interviews, surveys and questionnaires.

One example could be interviews to the team who went to the field situation on how the potentially hazardous situation was approached upon arrival; if and after how much time the area has been secured including access control; if anyone external to the team (including personnel of the Park) had been in contact with the hazard, and if this has been recorded; if and how samples have been collected; if PPE was proper; how was sample transport security assured; how was waste handled in the field, during transport, and in the lab.

- **How would this information feed back into your Risk Assessment?**

Assess if policies and procedures are apt to face field situation. Check if policies and procedures are correctly understood and applied by all relevant personnel.

Scenario 2— Vesicular disease in transhumant cattle

Message for Student

Setting: Working in small groups read the following scenario and complete the risk assessment for field investigation scenarios. Focus on the risk assessment strategies and biosafety and biosecurity precautions you may need to implement in the field. For the questions presented, consider why the answers would be relevant from a field biosafety and biosecurity standpoint.

Question (Outcome):

What biosafety and biosecurity precautions are necessary in the field?

How do field conditions change your risk assessment?

Record: Record answers on post it notes and then put the post it notes on the flip chart

Reporting: Your group will be randomly selected to share its answers for one of the questions. Select a spokesperson for the group to share with the class.

Timing: Spend <Minutes> on this exercise. Remember there are two sets of questions to answer.

Messages for Instructor

Walk around if possible and check on the groups' progress.

If a group is having difficulty deciding what agent to suspect, this scenario is based on a Foot-and-Mouth Disease virus investigation. Remind participants there is no "wrong" answer and that the agent is only important because it may alter the transmission routes or ability to cause disease to the field investigation team. When answering questions, redirect students to focus, not on the technical steps of an outbreak investigation, rather the biosafety and biosecurity principles they would need to employee in the field.

Reporting: Assign groups a question or two to share their answers with the larger group.

Ask the larger group if there is anything additional they came up with that was not included in the answers presented.

Risk Assessment for Field Work

Expected answers, Step 1 – Analyze the situation and identify the hazards.

- **What etiological agent(s) would you suspect?**

Vesicular disease viruses as FMDV, Vesicular Stomatitis Indiana Virus VSIV. They have the same clinical signs and the mention in the scenario of only oral mucosa vesicles may lead some to VSIV. Swine

Vesicular Disease (SVD) and Vesicular Exanthema of Swine Virus (VESV) have also the same clinical signs but only affect pigs.

- **Describe the hazards and/or threats present in the field situation:**

With FMD, infection can occur through direct contact with secretions or expired air of infected animals, consumption of uncooked meat or raw milk contaminated with animal body fluids, laboratory accidents. The transhumant farming context also makes difficult to secure the biological agent from potential threats.

- **What mitigation is currently present in the field situation?**

Livestock enclosure of the kraal (palisade, fencing) to keep cattle to move outside it. Keeps the herd separate from others but do not prevent contact among animals or possible fluid contacts with animals or humans

Expected answers, Step 2 – Work through the following exercise to determine the Consequences of an exposure to the suspected etiological agent.

Consequence 3 (High)

- **What factors did you consider when coming up with this number?**

It's a serious animal disease and can cause death or permanent disability in animals (for example due to secondary bacterial infection of ruptured vesicles); it causes great economic losses due to both slaughtering of many animals to prevent spread and of reduced milk production of recovered cattle. However animals often recover from the disease and fatality in humans is extremely rare.

Expected answers, Step 3 – Work through the following exercise to determine the Likelihood of an exposure to the suspected etiological agent.

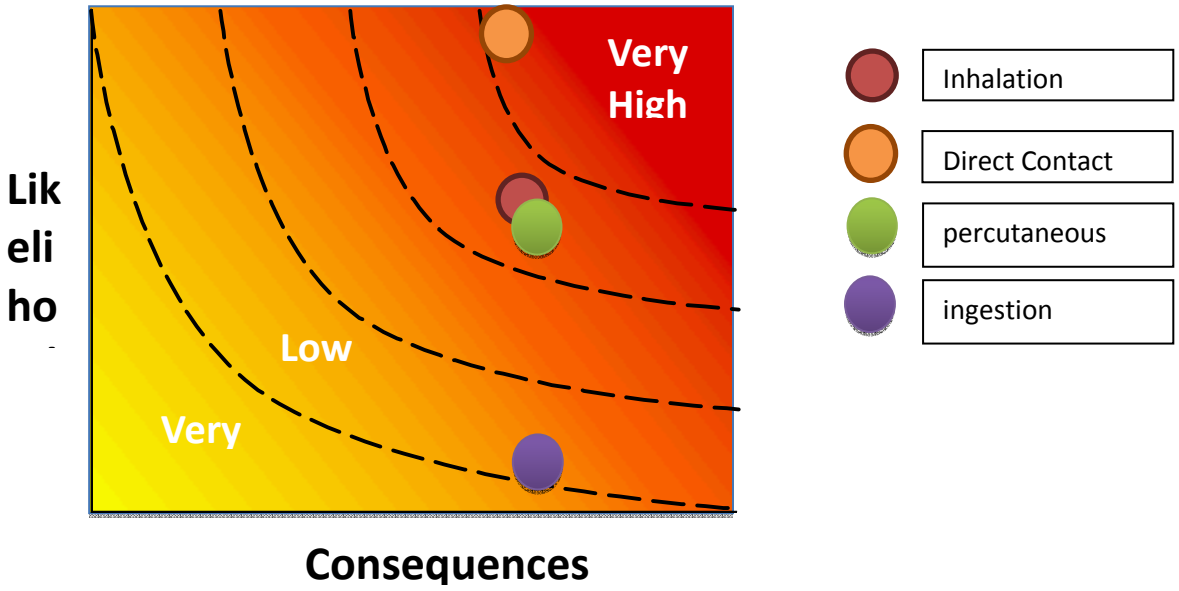
Likelihood of inhalation exposure: III (visiting the herd with probably infected and sick animals).

Likelihood of percutaneous exposure: III (possible if collecting samples).

Likelihood of Direct Contact: IV (visiting animals and collecting body fluids samples).

Likelihood of ingestional exposure: I

Expected answers, Step 4 – Graph the values that you determined for the Likelihood and Consequences of an exposure to the suspected etiological agent on the graph provided.



Expected answers, Step 5 – Risk Evaluation. Take a minute to ask whether this risk would be acceptable?

- **What factors did you consider in evaluating the risk?**

Field situation, available mitigation measures, access to the area by potential threats.

Risk Mitigation for Field Work

Expected answers, Step 1 – Identifying Mitigation Measures

- **Based on your scenario, identify at least 10 risk mitigation measures. Hint: Remember that mitigation measures should address both safety and security. List them here:**

Administrative controls: policies and guidelines on isolation of the area; policies for isolation or segregation of sick animals; collection of specimens; transport of specimens; waste management; etc. Procedures for collection of specimens and samples; appropriate donning of PPE; proper waste disposal. PPE: gloves, protection for skin and foot, face.

Expected answers, Step 2 – Understanding the Advantages and Disadvantages of Risk Mitigation Measures

- **Pick one of the mitigation measures identified above and list the advantages and disadvantages of this mitigation measure, or that particular category of mitigation measures.**

- **Fill out the following table:**

Control Measure	Advantages	Disadvantages
Elimination or Substitution	Eliminate the risk	Not feasible if connected with the unknown agent
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Practices & Procedures	Provide detailed instructions.	Need training for personnel and enforcement
PPE	Provide physical barriers.	Should be available when necessary, and according to the risk situation. Require use of correct practices.

Expected answers, Step 3 – Writing Draft SOPs

PPE

- **What PPE is appropriate to protect yourself from the agent in your scenario? Why?**

Gloves, possibly foot, skin and face protections.

- **Where is the PPE stored?**

- **Where is the PPE disposed of or cleaned?**

Disposed in sealed container and treated for disinfection or final disposal upon return to the lab.

- **Are there any other considerations?**

Sample Collection

- **What type of samples will you be collecting? Why?**

If students are thinking to a vesicular disease virus, and/or specifically to FMD, they should aim at collecting specimens from epithelium tissue or vesicular fluids from an unrupted or recently rupted vesicle. If epithelial tissue is not available, for example for suspected infection in the absence of clinical signs, samples of OP fluid can be collected by means of a probang (sputum) cup.

- **How will you collect samples safety?**

- **How will the samples be stored?**

- **Are there any other considerations?**

Waste Disposal

- **What types of waste will be generated?**

- **Who is at increased risk if contaminated biological materials are not handled and treated properly?**

Other animals in the herd. Members of the field team. Shepherds and other workers. Those who will handle waste. Surrounding community. Environment.

- **What potential incidents could occur?**

Contact, percutaneous or inhalation exposure to the infective agent. Exposure to untreated waste materials. Contamination of water reservoirs. Missing samples, mislabeling or problem in shipping/transport, including missing samples. Security breaches including not authorized personnel acceding to the area.

- **How can the risk associated with biological waste be mitigated?**

Waste storage and transport. Sharp containers. Practices and procedures including Segregation, collection, storage, transport, treatment and final disposal of waste.

- **Are there any other considerations?**

Sample Transport

- **Why might transport security be particularly important for working in the Field?**

To ensure only authorized parties can accede to the samples, the waste and any other hazard material in the way to the lab. To reduce the risk of illicit acquisition of hazardous biological agents. Also samples are not collected in a controlled area (probably access control can be implemented only partially in the kraal).

- **What can you do to determine your transport security needs?**

Distance and transport time to the lab, also in consideration of possible specimens deterioration. Best solutions to maintain Chain of Custody with trustworthy parties. Determine if there is pre-approval for transport or shipment by a responsible authority.

- **What are some ways biological materials that can be kept secure in the field and during transport?**

Isolation of the area.

- **Are there any other considerations?**

Risk Mitigation for Lab Work

Expected answers, Step 1 – Ways to mitigate risk in the laboratory – MC&A and Good Laboratory Practices

- **Now that your samples from the field have arrived in the lab please consider the following:**

    a. **Material – What information should we keep track of?**

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c. **Accountability – Who will be accountable for the material?**

Who is in the best position to answer questions about the associated material.

d. **List one good laboratory practice that you'd like to implement regarding the samples from your scenario? Why?**

For example Wearing PPE, Marking and labeling containers, Proper segregation of waste, Transporting biohazardous materials in closed, durable, leak-proof containers, keep an inventory, etc…

Biorisk Management Performance

Expected answers, Step 1 – Ways to include Biorisk Management Performance in Field and Laboratory work

- **What are some ways that BRM performance could be measured for your scenario? Please explain and give an example.**

Audits and inspections, performance indicators, observations, interviews, surveys and questionnaires.

One example could be interviews to the team who went to the field situation on how the potentially hazardous situation was approached upon arrival; if and after how much time the area has been secured including access control; if anyone external to the team (including workers, shepherds) had been in contact with the hazard, and if this has been recorded; if and how samples have been collected; if PPE was proper; how was sample transport security assured; how was waste handled in the field, during transport, and in the lab.

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