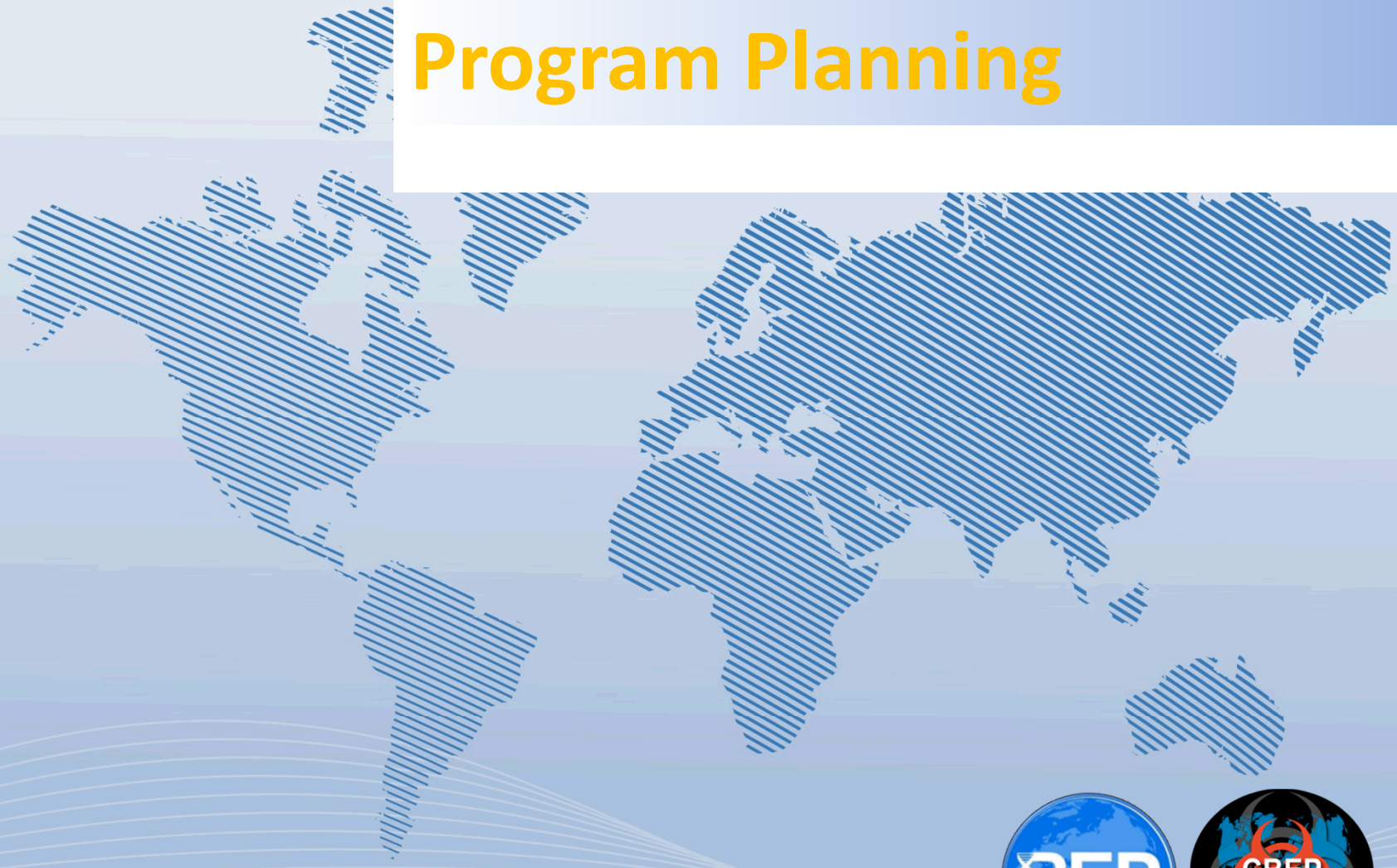
SAND2014-2081P

Infectious Substance Program Planning



Biorisk Management: the AMP Model

Biorisk Management =
Assessment, Mitigation, Performance

Key Components of Biorisk Management

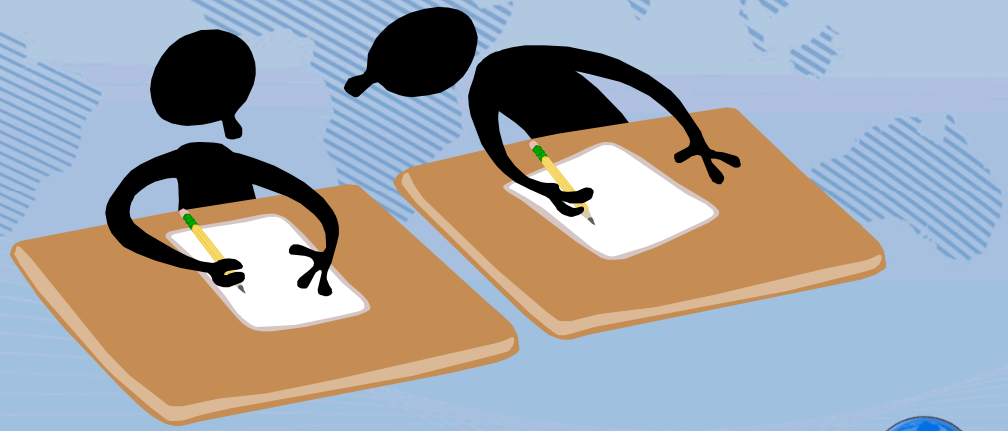
- Biorisk **Assessment**
  - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable

Key Components of Biorisk Management

- Biorisk **Mitigation**
  - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins

Key Components of Biorisk Management

- **Performance**
  - The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.



Planning

What exactly is **planning**?

Planning

Planning is the development of mechanisms or procedures, in advance, to achieve a particular goal.

Planning

Infectious substance shipping program planning is normally the responsibility of an institution's **management**.

Top level **decision-makers** must come together to determine the best approach for handling **a shipping program** in a particular institution.

Planning

Management has the **authority** to make **medium** and **long-term decisions** and allocate appropriate **resources** towards an **infectious substance shipping program**.

Management, however, needs the expertise and advice of other **personnel** in the institution to adequately make **plans**.

Why?

Planning

Often, **management** can develop high-level policy and delegate details to those **personnel** more familiar with daily operations and technical work.

Planning

Planning should result in a **document**, developed by **management** in cooperation with an institution's **personnel** (and others), that outlines, at a high-level, how the **infectious substance shipping program** will operate.

Some Instructional Documents

- Policy:
  - A guiding principle or statement that influences other actions through commitment and intent.
- Program Plan:
  - Program: A system that provides framework for the scope, roles and responsibilities, and steps to implement the policy.
  - Plan: A set of tasks or actions, performed in a specified sequence or manner, that achieves a particular result.
- Procedure:
  - A specific task, work instruction, or action. Procedures may include steps or actions

Targeting an Infectious Substance Shipping Program Plan

Group Exercise:

In your groups, spend **10 minutes** answering these questions:

Who writes this document?

Who is the audience?

What is the intended purpose?

Program Planning

Group Exercise:

In your groups, spend **5 minutes** brainstorming all the topics that an **infectious substance shipping** program plan should contain. Put each topic on an individual sticky note.

Remember the answers from the previous activity to help you target the topics.

Program Variations

Variations of infectious substance shipping programs.

1. **Centralized** –
   - One office responsible for shipping.
2. **Decentralized** –
   - Each lab or person is responsible for shipping.
3. **Hybrid** –
   - High risk samples (category A) are shipped through a centralized office. Lower risk samples (category B) are shipped by each individual lab or person.

Question: What are the **advantages** and **disadvantages** of each type of shipping program?

Program Variations

	Centralized	Decentralized	Hybrid
Advantages			
Disadvantages			

Program Variations

	Centralized	Decentralized	Hybrid
Advantages	• Less training needed • Works well in smaller facilities • More accountability	• More control • Flexible • Good for lab to field transport • Better for large institutions	• Risk based • Have control over the highest risk • Has accountability • Good for larger institutions
Disadvantages	• Dependent on centralized office • Less flexibility • Less control	• More opportunity for mistakes • More training needed • Less accountability	• Mistakes in determining risk • Needs additional training • Resource intense

Program Planning, Step 1

The goal of this exercise is to create, as a class, a matrix of information that will guide you in writing a comprehensive **infectious substance shipping** program plan.

In your group: Fill out the matrix based on what your institution currently does for **infectious substance shipping**.

Take **30 minutes**.

Program Planning, Step 2

In your group: Now, based on what you currently do, continue to fill out the matrix to show how you would design an infectious substance shipping program at your facility.

Take **30 minutes**.

Shipping Program Planning

	Personnel Who is involved? Who is responsible?	**Resources** Facilities, Time, Supplies, Other	**Action** How is it accomplished?
Risk Assessment			
Packaging, Marking, Labeling & Documentation			
Training			
Recordkeeping			
Security			

Shipping Program Planning

	Personnel Who is involved? Who is responsible?	**Resources** Facilities, Time, Supplies, Other	**Action** How is it accomplished?
Emergency Response			
Review and Approval			
Personnel Assurance			
Performance Measures			
Other			

Shipping Program Planning

	Personnel Who is involved? Who is responsible?	**Resources** Facilities, Time, Supplies, Other	**Action** How is it accomplished?
Risk Assessment	Biosafety officer Lab manager	Time to conduct risk assessment and understand current shipping procedures and improve them.	Biosafety officer coordinates with lab management and laboratory staff to conduct risk assessment
Packaging, Marking, Labeling & Documentation	Laboratory staff with supervision from lab manager or centralized shipping office. Environmental Health and Safety. Security. Procurement	Packaging material, experienced personnel to purchase material. SOPs	The lab manager will delegate a laboratory staff member to keep track of all shipping materials and procure them when they run out.
Training	Certified shipping trainers. Laboratory staff.	Training room, training materials, packaging materials, time for training and time for preparation	Certified shipping trainers will provide annual shipping training for all laboratory workers in the facility.
Recordkeeping	Procurement, Environmental Health and Safety, Biosafety officer, Trainers	Record storage, security, communication lines	Depending on the records kept, the personnel will need access to the records.
Security	Security personnel, biosafety officer, lab manager	Transport containers – carts, training, communication contacts list	Security personnel call biosafety officer when a package arrives to verify sender, or when packages are leaving the security personnel contacts the biosafety officer to verify

Shipping Program Planning

	Personnel Who is involved? Who is responsible?	**Resources** Facilities, Time, Supplies, Other	**Action** How is it accomplished?
Emergency Response	Biosafety officer, security personnel, laboratory staff, management	Time and resources to run a drill. Training. Spill clean-up. Communication.	If an emergency occurs then the person responding to the incident will notify the biosafety officer who will notify management and also work to resolve the situation.
Review and Approval	All shipping requests must go through the centralized shipping office and get management approval before anything is shipped.	Personnel responsible for reviewing requests and providing guidance. Training. Awareness.	Establish a central person responsible for monitoring shipping requests.
Personnel Assurance	Shipping carrier, biosafety officer	Memorandum of understanding. Material transfer agreement. Information about shipping procedures and track record.	An appropriate shipping carrier will be determined by an extensive review of all possible carriers and their safety and security records.
Performance Measures	Biosafety officer, management, trainers, laboratory workers	Time and value for tracking performance, trained personnel	Every year the biosafety officer will administer a survey that asks those who are involved in shipping to evaluate aspects of the program for future improvement.
Other			

Validating an Infectious Substance Shipping Program Plan

You now have the basic structure of a program plan – the functions and the resources required. Now let's see if it would work with some examples of common and not-so-common **shipping scenarios**.

1. **Your small group** will be assigned one **shipping** scenario.
2. Walk through the program plan and determine if it provides enough guidance to effectively manage the **scenario**.
3. If, after the walk-through, you feel that additional information/guidance is required, use sticky notes to add that to the matrix cell where it is required.

Remember that the plan is NOT a standard operation procedure so the specifics about exactly what to do won't be included – focus on assuring that the resources are described for each functional step in the process.

Take **20 minutes** for this validation activity.

Program Planning

Group Exercise:

In your groups, spend **10 minutes** to review the provided sample infectious substance shipping policies and program plans.

List 2 items that you found **useful** and 2 items that you **did not find useful**. Be prepared to report out to the class.

Program Planning – Part 3

Group Exercise:

In your groups, revise and draft your infectious substance shipping program plan into a document.

Take **1 hour**.

Provide/Receive Feedback

- Each group will have an opportunity to read the other group's program plans and provide feedback.
- Take **10 minutes** for each program plan.
- How did it go?

Providing feedback

- Be respectful of the work that has been done.
- Start with “I like. . .” and list the good points.
- Don’t say, “I like this, but. . .”
- When making suggestions, use phrases like, “This might be more effective if. . .” or “Have you thought about this. . .?”
- Be objective. Don’t try to “fix the problem.”
- Allow the writer of the SOP to ask questions.
- Listen to responses respectfully. If the writer does not agree with you, it is OK.

Program Planning – Part 4

Group Exercise:

In your groups, spend **30 minutes** revising your institute-specific **infectious substance shipping** program plan.

Preparation for Implementation

The **Preparation** process includes assuring that all the resources or actions identified in the plan are available or readily acquired. This includes **training** of **personnel**, acquisition and storage of **equipment** and **supplies**, and **physical modifications** to equipment and **buildings** when possible, and desirable.

Preparation for Implementation

Think about the different types of **personnel** who work in a typical **lab** or **institution**.

Question: How should each of these be involved in the **preparation** process?

Please **discuss** for **5 minutes** in your **groups** and be prepared to share with the class.

Action Plan

What do you need to do to **implement an infectious substance shipping** plan for your organization?

Activity: Individually, list 5 to 10 actions that you need to take to create an organizational incident management plan and to prepare to implement the plan. Use the worksheet in your workbook.

Then categorize them as follows:

A = fairly easy to accomplish on your own

B= fairly easy to accomplish but involves other people and/or an extended period of time

C = more difficult to accomplish because it requires extensive change

D = more difficult to accomplish because it requires extensive resources

E = extremely difficult to accomplish

Action Plan

Actions Req'd	Difficulty *	Who is involved	Time req'd	Resources needed	Add'l Challenges	Next steps	Due Date

***A** = fairly easy to accomplish on your own; **B**= fairly easy to accomplish but involves other people and/or an extended period of time; C = more difficult to accomplish because it requires extensive change; D = more difficult to accomplish because it requires extensive resources; E = extremely difficult to accomplish

Planning & Preparation Action Plan

Activity: Pick 1 “A” category actions, 1 “B”, “C”, or “D” actions, and 1 “E” action.

Using the remainder of the worksheet, determine who else needs to be involved, the time & resources needed, and additional challenges. Plan one or two next steps and a due date for each of these 3 actions.

Note: the actions that require other people, additional resources, extensive change, or that are generally more difficult will take more effort to accomplish. However, taking small steps on all types of tasks, rather than just the easier ones, will better assure that you ultimately will be successful in accomplishing them.

Infectious Substance Shipping

Group Exercise:

In your groups, prepare a presentation that outlines your institute-specific **infectious substance shipping** plan.

Review of Infectious Substance Shipping Program Planning

Review

To wrap-up, let's discuss what we learned about

Infectious Substance Shipping Program Planning

What did we learn?	What does it mean?	Where do we go from here?

Thank You!

Don't forget to complete your evaluation!