



Developing and Validating Standard Operating Procedures

Student Guide

2016

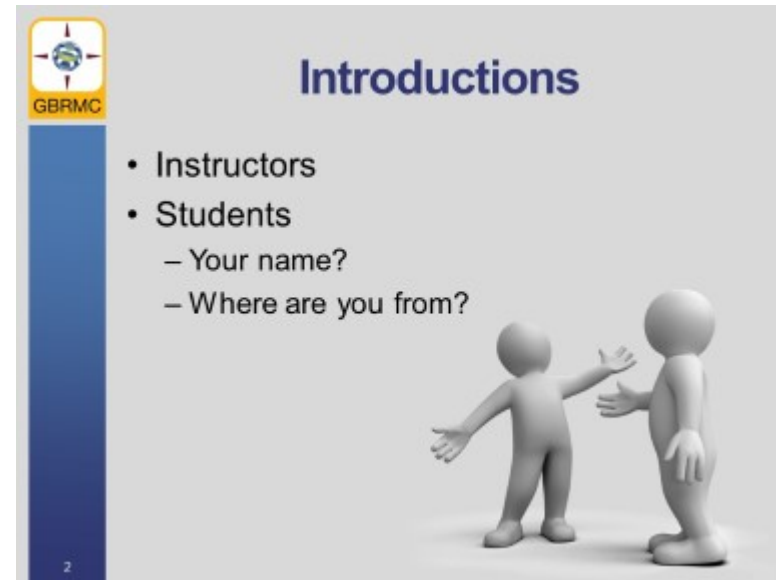


GLOBAL BIORISK MANAGEMENT CURRICULUM

Developing and Validating Standard Operating Procedures



Welcome & Introductions



Action Plan

By the end of this lesson, I would like to:

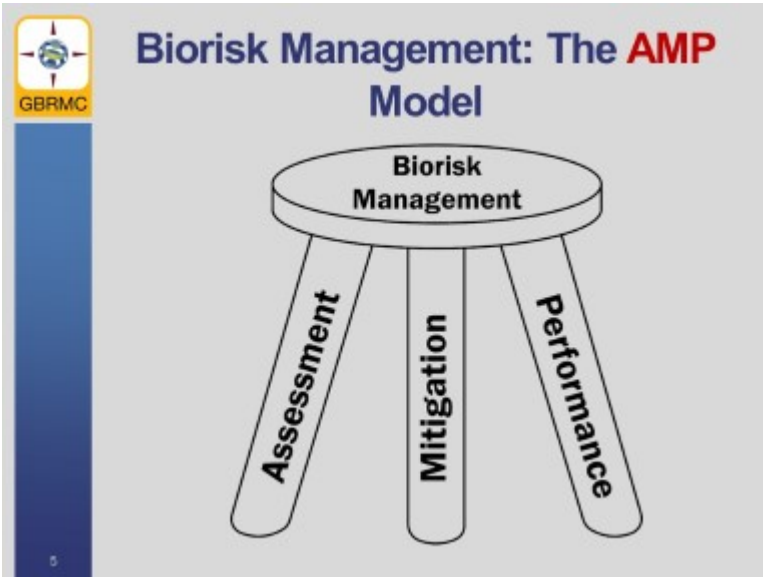
KNOW		FEEL		BE ABLE TO DO	
<i>Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.</i>					
What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?		



Key Messages


- SOPs are instructional documents designed to guide different people to do the same thing and achieve the same outcome.
- SOPs are designed to achieve a single, or small, outcome.
- Several key components comprise an effective SOP.
- SOPs must be validated before implementation.
- Behavioral observation data metrics can be used to validate/measure the ongoing effectiveness of an SOP.
- SOPs must be reviewed periodically and revised as needed.

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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



The slide features a yellow square logo with a globe and the text 'GBRMC' in the top left corner, followed by a blue vertical bar. The title is 'Key Components of Biorisk Management'. A single bullet point is listed: 'Biorisk Assessment', which is further detailed by a sub-bullet: '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'. In the bottom right corner, there is a small icon of a clipboard with a checklist and a pencil.



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



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Key Components of Biorisk Management

- **Biorisk Performance**
 - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.



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What is an SOP?

Individual Reflection

- "SOP" is an acronym for what?
- What is an SOP?
- When do you need an SOP?
- How do you know if an SOP is working?

Take **5 minutes** and be prepared to share your answers within your small group.

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S =

O =

P =

What is an SOP?

When do you need an SOP?

How do you know if an SOP is working?

Developing and Validating Standard Operating Procedures

What is an SOP?



Standard Operating Procedure

1. Pick up a colored piece of paper from the middle of your table
2. Close your eyes.
3. Fold the paper in half.
4. Fold the paper in half again.
5. Fold the paper in half one more time.
6. Tear off a corner.
7. Without opening your eyes, hold your paper up in both hands over your head.
8. Now, open your eyes.

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How many different outcomes resulted from this simple SOP?

Why were there different results?

What is missing in this SOP?



The goal of an SOP:

- Different people
 - Doing the same thing
 - Getting the same result
- S.G. Kaufman


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SOPs involve:

1. People
2. Steps
3. A Single Outcome

For more details on S.G. Kaufman's approach to SOPs, please visit:

<http://www.sph.emory.edu/CPHPR/biosafetytraining/etraining/index2.html>



Evaluating SOPs

- People
 - Are the right people (trained, experienced) performing the SOP?
 - Can different people follow the SOP?
- Steps
 - Are the steps understood?
 - Does everyone do the same thing?
 - Are the resources in place for those steps to happen?
- Outcome
 - Is there a clear outcome?
 - Does everyone get the same outcome?

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For the paper folding SOP:

1. Did you understand the SOP?
2. Could you physically do what the SOP asked?
3. Was the outcome the intended outcome?
4. Did different individual achieve the same outcome?

For more details on S.G. Kaufman's approach to SOPs, please visit:

<http://www.sph.emory.edu/CPHPR/biosafetytraining/etraining/index2.html>



An SOP is an “instructional document”

- Instructional documents teach a reader to:
 - Understand a rule or principle.
 - Envision a process or workflow.
 - Perform a task.
 - Use a tool.
- Instructional documents are **READER-CENTERED** (rather than rule-centered)

The audience for an instructional document is the person who will follow the instructions. An SOP is not simply “putting something into writing.”



Some Instructional Documents

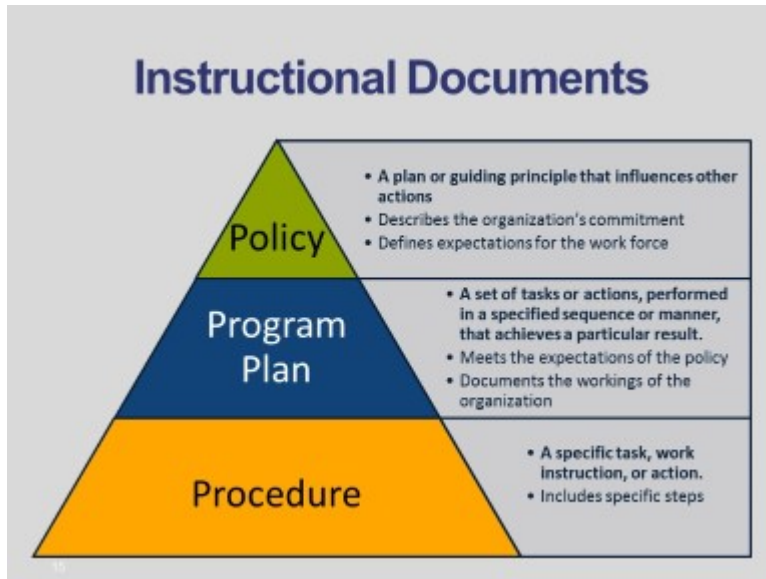
- Policy:
 - A plan or guiding principle that influences other actions
- Program Plan:
 - A set of tasks or actions, performed in a specified sequence or manner, that achieves a particular result.
- Procedure:
 - A specific task, work instruction, or action. Procedures may include steps or actions

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What is an example of a policy?

What is an example of a plan?

What is an example of a procedure?



What is an example of a policy?

What is an example of a plan?

What is an example of a procedure?



Group Activity, Part 1:

In your groups, decide if the following statement is a **Policy**, **Program Plan**, or **Procedure**?

Dispose of biologically contaminated waste in a responsible, safe, and secure manner.

Take **2 minutes** and be prepared to share your results with the class.

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For a policy . . .

Who writes a policy?

Who is the audience?

What is the intended purpose?



Group Activity, Part 2:

In your groups, decide if the following is a **Policy**, **Program Plan**, or **Procedure**?

In order to dispose of contaminated waste appropriately, the following must be in place (for example):

1. Identification of all roles involved in waste disposal
2. Training for all roles involved in waste disposal
3. Waste segregation plan
4. Labeled waste containers and bags
5. In-lab waste treatment
6. Method of storage before transport
7. Method of transport from point of generation to point of final decontamination and disposal
8. Method of final decontamination and disposal

Take **2 minutes** and be prepared to share your results with the class.

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Group Activity, Part 3:

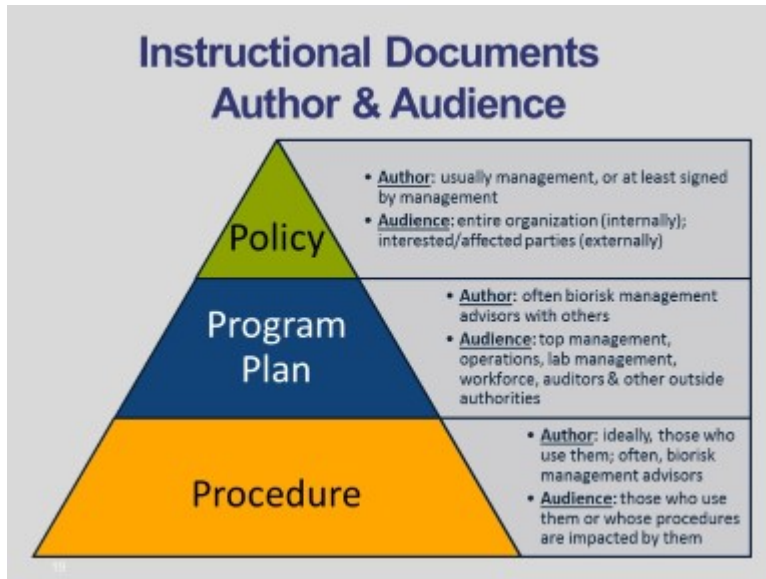
In your groups, decide if the following is a **Policy**, **Program Plan**, or **Procedure**?

To conduct in-lab waste treatment, take the following actions:

1. Add 10% bleach to liquid flasks
2. Let sit for ___ minutes
3. Pour.....
4. Etc....

Take **2 minutes** and be prepared to share your results with the class.

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SOPs have 4 major sections:

- Conditions
- Context
- Actions
- Documentation

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Please refer to the next page for a basic pattern for an SOP. This pattern is a document that can be used to guide the information that needs to be included.

All of these sections are equally and critically important. Often SOP writers' focus only on the ACTIONS and forget to specify the conditions and context. Also, referrals, references, and cross-references are important to provide a sense for where this SOP fits into the larger program.

Standard Operating Procedure Pattern

Conditions	
Who should use the SOP?	
When should it be used?	
Why should the SOP be used?	
Where should it be used?	
Context	
Input(s):	
Output:	
Preparation:	
Actions: What steps must be taken to move from the input to the output?	
Step 1	
Step 2	
Step 3	
Step 4	
Step 5	
Documentation	
Cross-references	
Regulatory dependencies/sources	



Conditions

- Who should use the SOP?
- When should it be used?
- Why should the SOP be used?
- Where should it be used?

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Consider the SOP conditions for entry into a laboratory where the organisms used could be transmitted by ingestion, direct contact, or via needlestick or other percutaneous exposure (e.g., Biosafety Level 2 lab).

Who should use the SOP?

When should it be used?

Why should the SOP be used?

Where should it be used?



Conditions Activity

In your groups, work together to fill in the chart

Consider the SOP conditions for donning PPE before entry into a laboratory where the organisms used could be transmitted by ingestion, direct contact, or via needle-stick or other percutaneous exposure (i.e., Biosafety Level 2 lab)

PPE Donning for BSL2 Entry SOP

Who	Laboratory Staff vs. Housekeeping Staff?
When	Hot Lab vs. after business hours?
Why	Protect from risks during tasks (research or cleaning?)
Where	Anteroom, changing room, at the bench, in hallway?

Take **10 minutes** and be prepared to share your answers with class.


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Who:


When:

Why:

Where:


 **Context**

- Basic process:
Input + Actions = Output
- Input (starting point)
- Output (end result/outcome)
- Preparation: What is presumed to be ready (as part of input) when actions begin?




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What if our **input** is a contaminated syringe & needle to be discarded? The **output** would be a contaminated syringe & needle safely disposed in compliance with local regulations. What kind of **preparation** might need to be in place?



Actions

- What steps must be taken to move from the INPUT to the OUTPUT?



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This is the guts of the SOP. How do you get from an unfolded sheet of paper (input) to a specifically folded and torn piece of paper (output)?




Documentation

- Cross-references
- Regulatory sources

Plenary Discussion

Can you think of anything else that might be included in/with an SOP?

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SOP Components

- Conditions
 - Who should use the SOP?
 - When should it be used?
 - Why should the SOP be used?
 - Where should it be used
- Context
 - Input (starting point)
 - Output (end result)
 - Preparation
- Actions
 - Steps to move from the input to the output
- Documentation

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Look at the procedure you brought with you today.

1. Determine which pieces of the procedure fit into the different components on the template in the workbook.
2. Which pieces in the template are not included in your procedure?
3. Are there pieces in your procedure that don't fit into the template?
4. Evaluate those pieces to see if they "belong" to the procedure (conditions, context, or actions). If not, where do they need to be captured? If yes, how should they be captured in the SOP?



Write your own SOP!

Group Activity, Part 1:

Using the materials provided, complete the template for the given **input** (1 container of assorted colors of candies) and **output** (candies sorted by color)

Record your answers on the worksheet.



Using the M&M sorting template on the next page and the materials provided at your table, complete the template for the input and output given.

Standard Operating Procedure Pattern – M&Ms

Conditions	
Who should use the SOP?	
When should it be used?	
Why should the SOP be used?	
Where should it be used?	
Context	
Input(s):	1 container of assorted colors of M&Ms (or similar candies)
Output:	Multiple containers each holding only one color of M&Ms with all candies from the original container being distributed.
Preparation:	
Actions: What steps must be taken to move from the input to the output?	
Step 1	
Step 2	
Step 3	
Step 4	
Step 5	
Documentation	
Cross-references	
Regulatory dependencies/sources	



Write your own SOP!

Plenary Discussion, Part 2:

How would this SOP change if...

- I told you that the procedure must be completed without any exposure (touching) of candies and that you could not release any droplets or aerosols (no pouring) (change conditions/context)
- What if I gave you a plastic spoon to sort? Chopsticks? (change context)
- What if one or more of the people who might be conducting the procedure were allergic to chocolate? (change conditions)



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Evaluating and Validating SOPs

Plenary Activity, Part 3:

- **One group reads** their “candy sorting SOP” out loud to the entire class, while the **other groups perform the SOP**
- **In plenary**, the group will answer the following:
 - Did you understand the SOP?
 - Could you physically do what the SOP asked?
 - Was the outcome the intended result?
 - Did different individuals achieve the same result?

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Could you execute the SOP?

Could you physically do what the SOP asked?

Did you reach the intended outcome?

Did different individuals achieve the same result?



Behavioral Observation Data (BOD)

- One tool used to validate/measure the behaviors necessary for an effective SOP
- A question about an observed behavior that can be answered “yes” or “no”.
 - Can generate a % yes or no across labs or over a length of time
- Example: Is Pat’s lab coat buttoned?
YES or NO

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Examples:

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BOD Exercise

Group Exercise:

Using the SOP worksheet, work in your small group:

- Re-write the paper-folding SOP
- Write at least one BOD for each step

Remember to decide what your output will be (what the paper will look like after it is unfolded) BEFORE you start writing the SOP.

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How can BOD be applied to your SOP?



Standard Operating Procedure

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Notes:



Reflection...

- How could the behavioral observation data process be used in laboratory operations?
- Look at the procedure you brought with you.
- Pick one or two steps and write BODs that would validate those steps.

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How can BOD be applied to your SOP?



BOD “Ethics”

- Just one tool used in safety industry (and others).
 - MUST not stand alone.
- Critical to involve those who will be observed when the BOD questions are developed.
- MUST be used consistently for all.
- Use as “self-audit” (as well as in observation) will help reduce self-consciousness in those observed.

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Name some considerations of BOD:



Unexpected Benefits to BOD

- Observers will also improve.
- When expected behavior is standardized and well-communicated, it is easier to see when behaviors change.

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Examples:

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Keeping SOPs Current

- What can happen, over time, to compliance with SOPs?
- How do you make sure that SOPs remain relevant?
- How do you increase the likelihood that SOPs will be followed?

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Notes:



Review and Revision of SOPs

- How often?
- When?
- How?

- Look at the procedure you brought with you.
 - Is there any sign it has been reviewed or revised?
 - How would you undertake a review or revision?
 - What needs to happen before you could review or revise the document?
 - What are obstacles to getting the document revised?
 - What are solutions for routinely reviewing and revising SOPs?


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How Often?

When?

How?

Review your SOP:



Review of SOPs

To wrap-up, let's discuss what we learned about writing and testing **standard operating procedures** . . .

What did we learn?

What does it mean?

Where do we go from here?

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Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
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Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?