GBRMC

Developing and Validating Standard Operating Procedures

Student Guide

2016

GLOBAL BIORISK MANAGEMENT CURRICULUM


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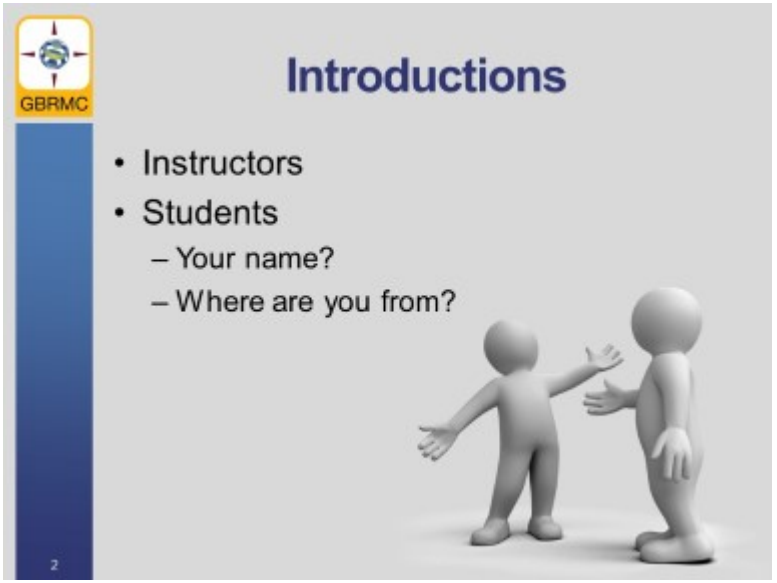
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Introductions
• Instructors
• Students
– Your name?
– Where are you from?
2

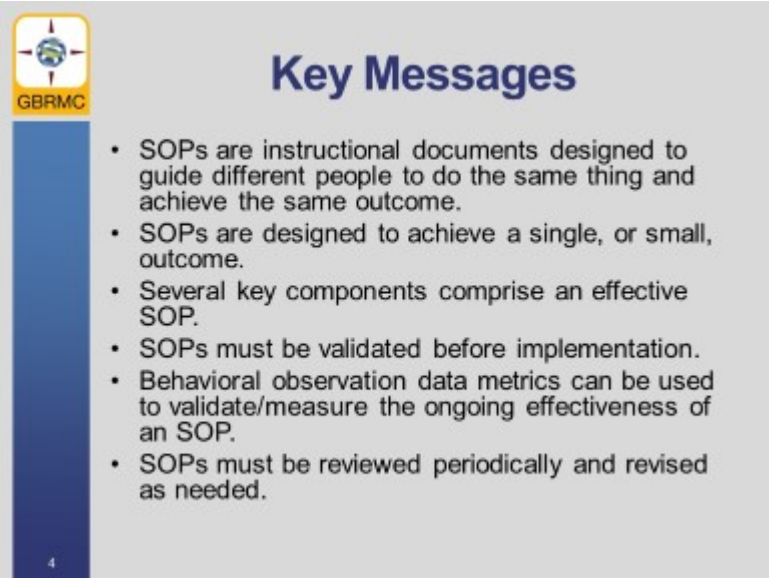
Action Plan

By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

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?

3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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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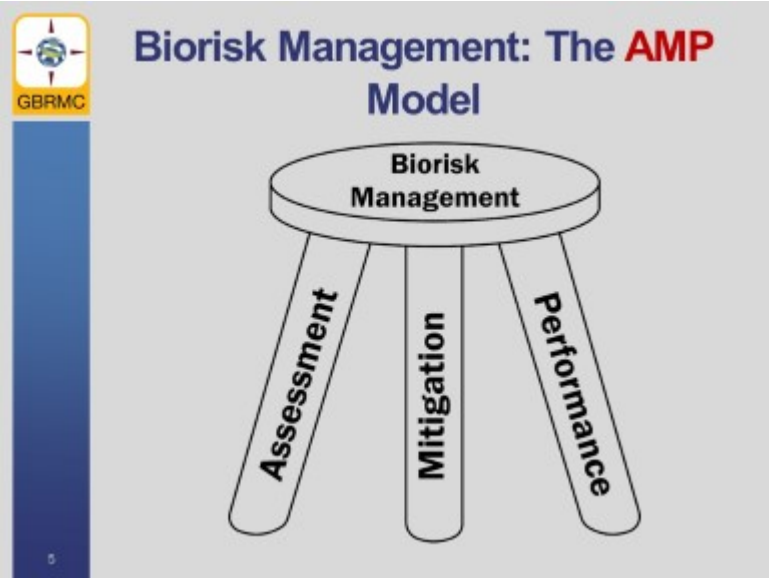
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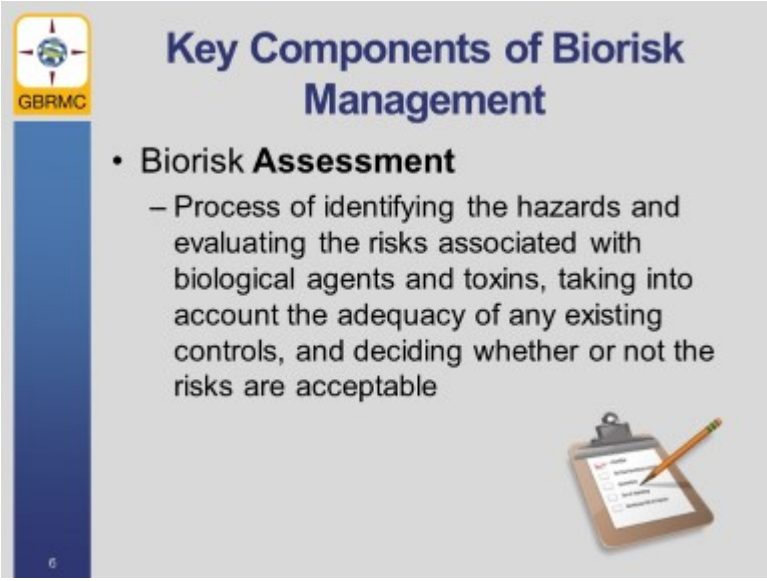
Biorisk Management: The AMP Model
Biorisk Management
Assessment
Mitigation
Performance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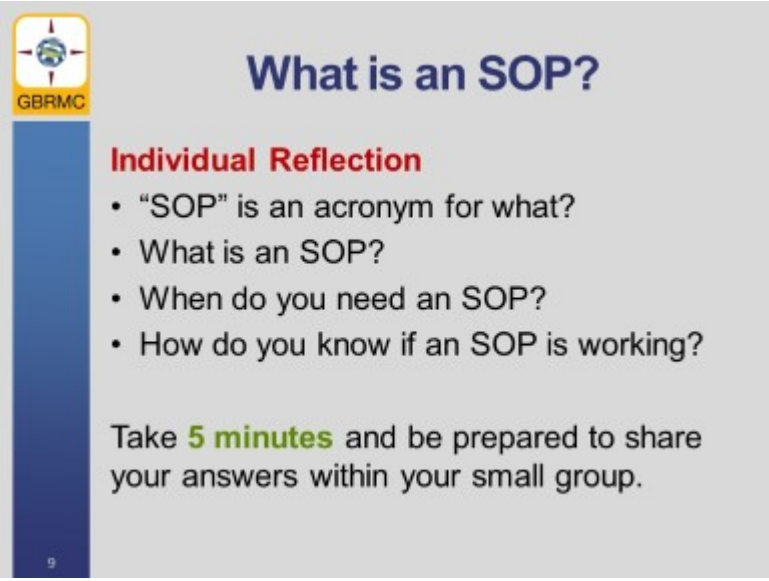
Key Components of Biorisk Management
• Biorisk **Assessment**
– Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable

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

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



S =

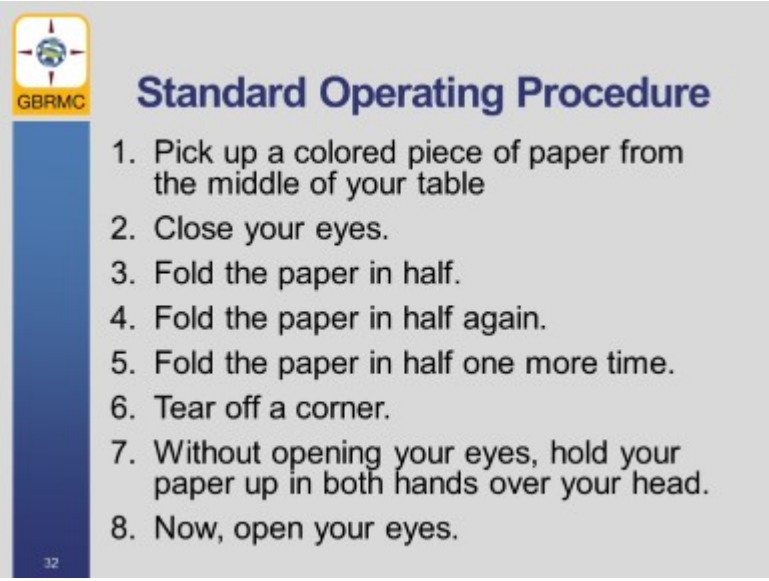
O =

P =

What is an SOP?

When do you need an SOP?

How do you know if an SOP is working?



How many different outcomes resulted from this simple SOP?

Why were there different results?

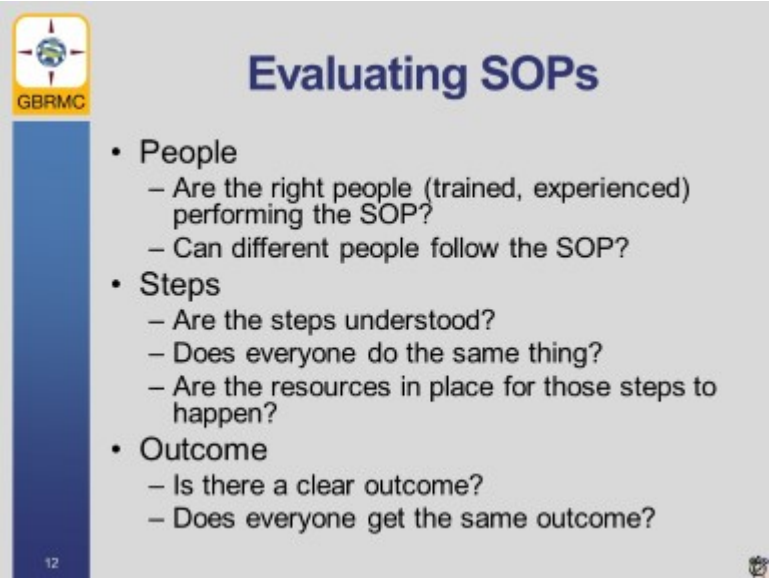
What is missing in this SOP?

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



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:

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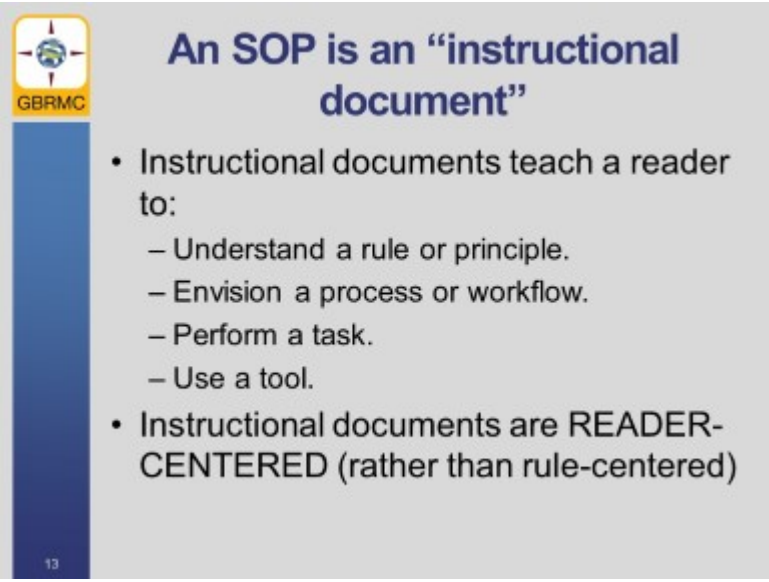
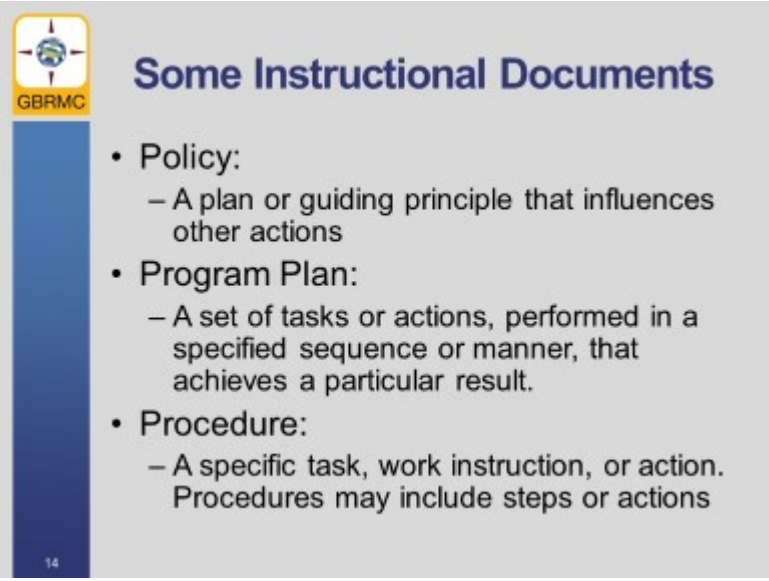


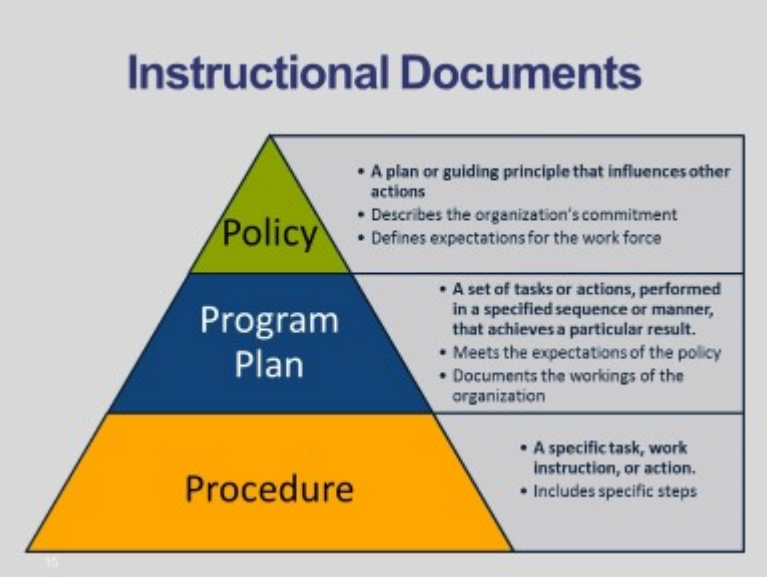
The audience for an instructional document is the person who will follow the instructions. An SOP is not simply "putting something into writing."



What is an example of a policy?

What is an example of a plan?

What is an example of a procedure?



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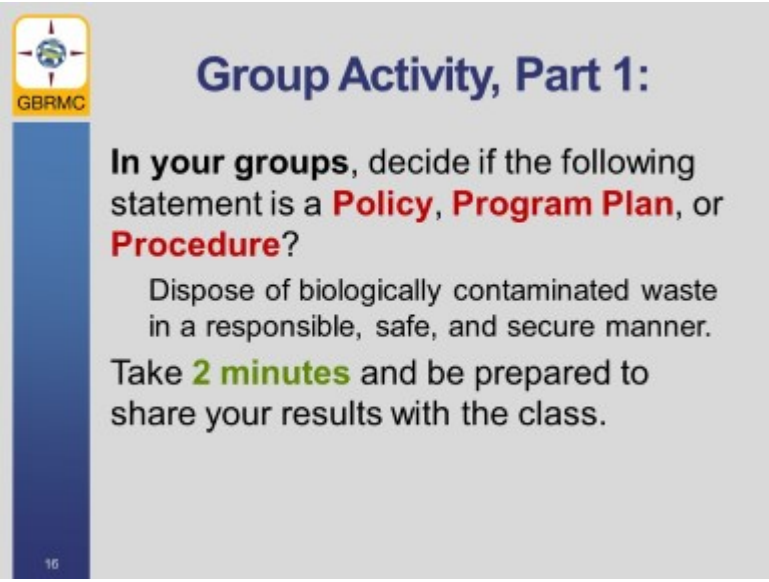
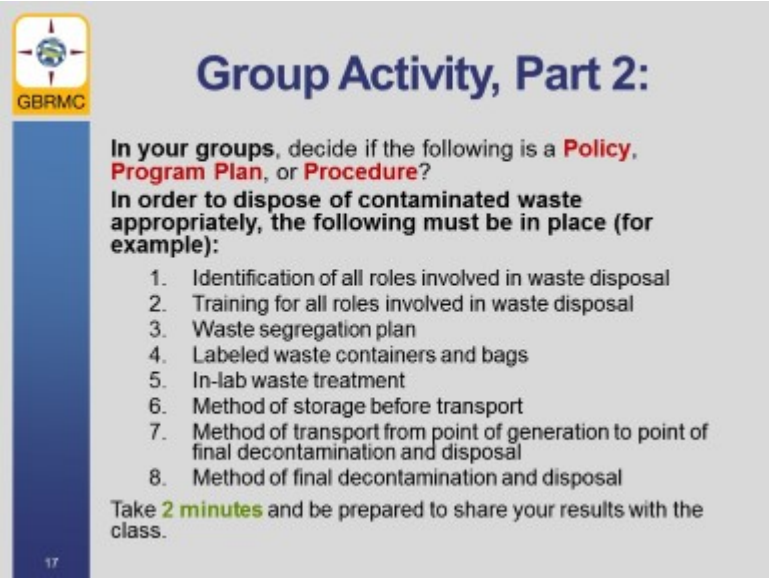


For a policy . . .

Who writes a policy?

Who is the audience?

What is the intended purpose?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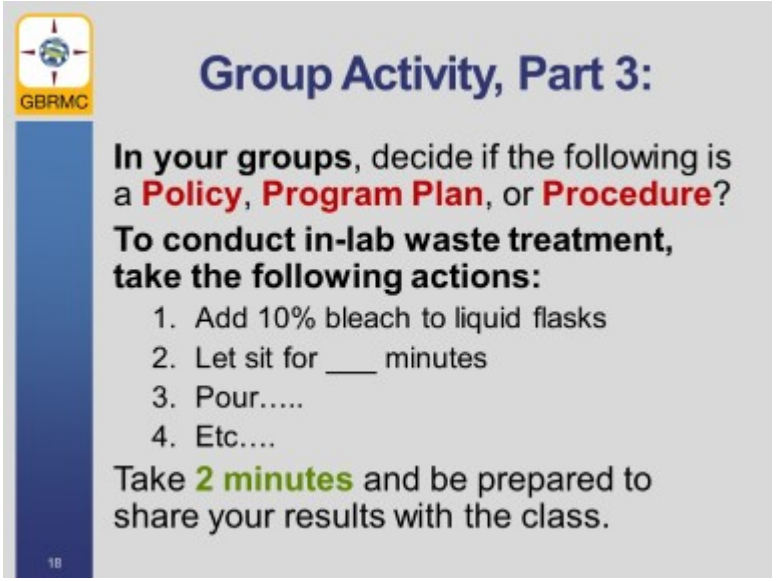
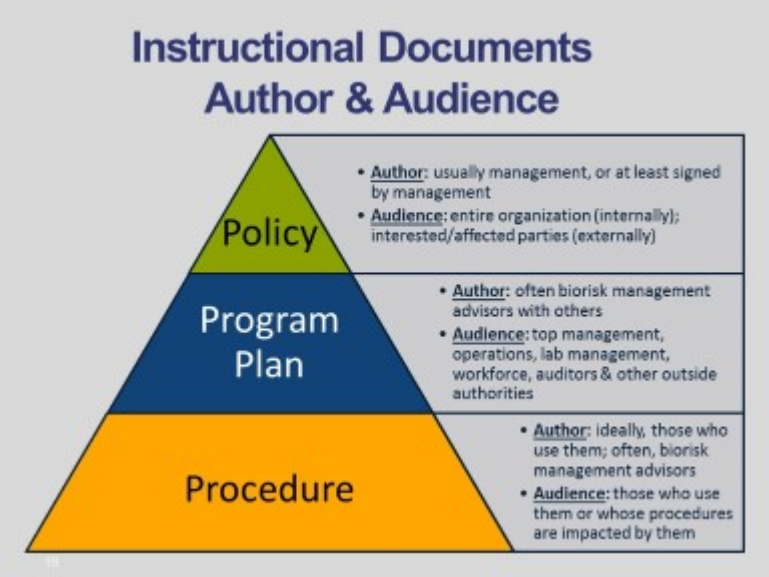
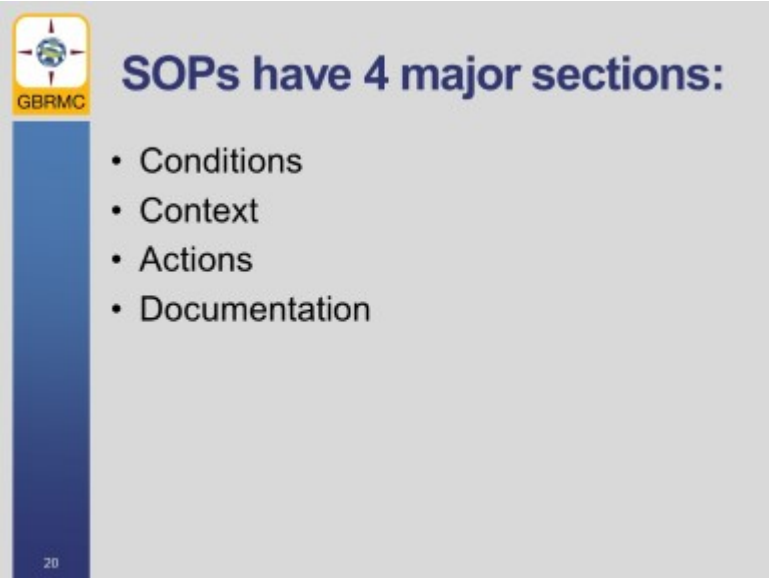
Group Activity, Part 2:
In your groups, decide if the following is a Policy, Program Plan, or Procedure?
In order to dispose of contaminated waste appropriately, the following must be in place (for example):
1. Identification of all roles involved in waste disposal
2. Training for all roles involved 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.
17


GBRMC
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.
18


Instructional Documents
Author & Audience
Policy
Program Plan
Procedure
• Author: usually management, or at least signed by management
• Audience: entire organization (internally); interested/affected parties (externally)
• Author: often biorisk management advisors with others
• Audience: top management, operations, lab management, workforce, auditors & other outside authorities
• Author: ideally, those who use them; often, biorisk management advisors
• Audience: those who use them or whose procedures are impacted by them

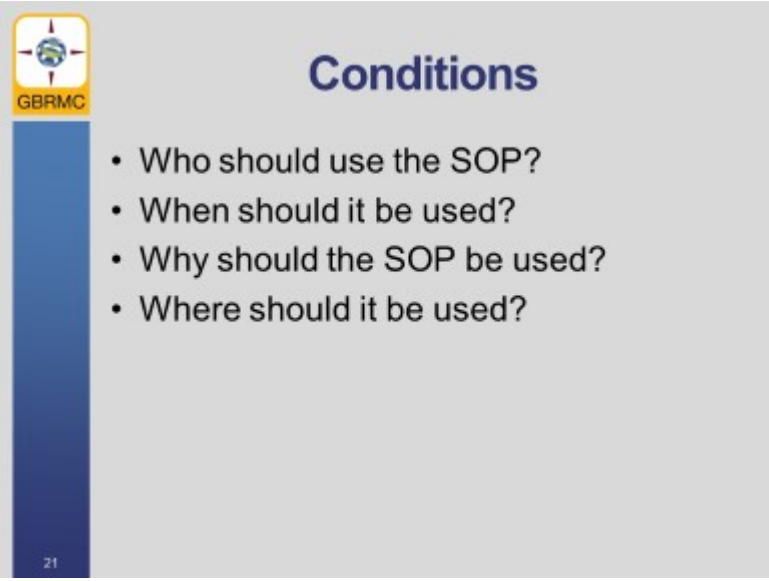


Please refer to the next page for a basic pattern for an SOP. This pattern is a document that can be used to guide the information that needs to be included.

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		



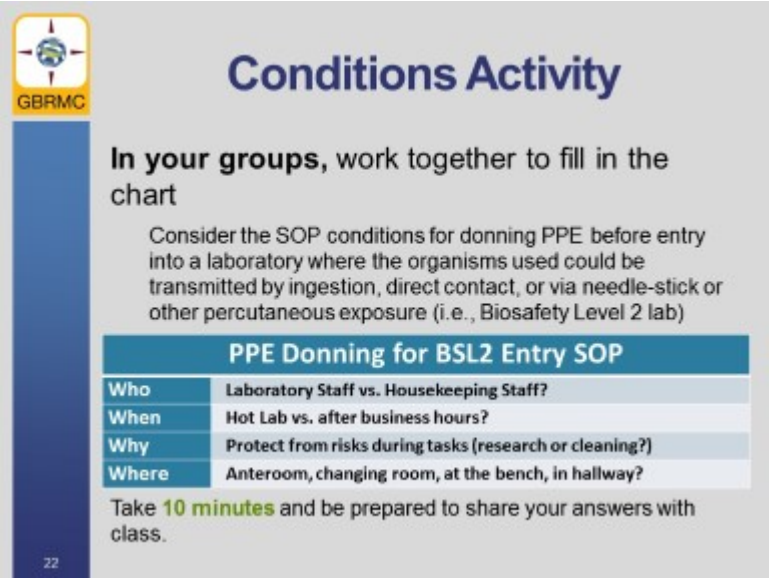
Consider the SOP conditions for entry into a laboratory where the organisms used could be transmitted by ingestion, direct contact, or via needlestick or other percutaneous exposure (e.g., Biosafety Level 2 lab).

Who should use the SOP?

When should it be used?

Why should the SOP be used?

Where should it be used?

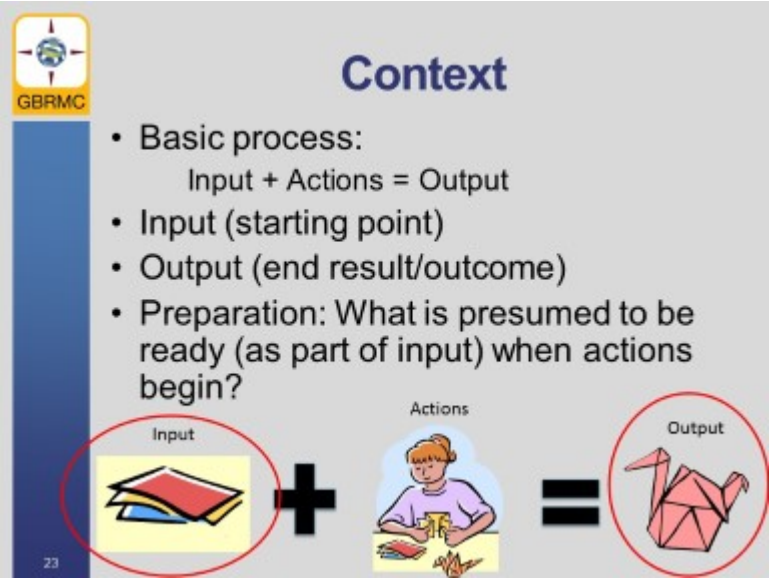


Who:

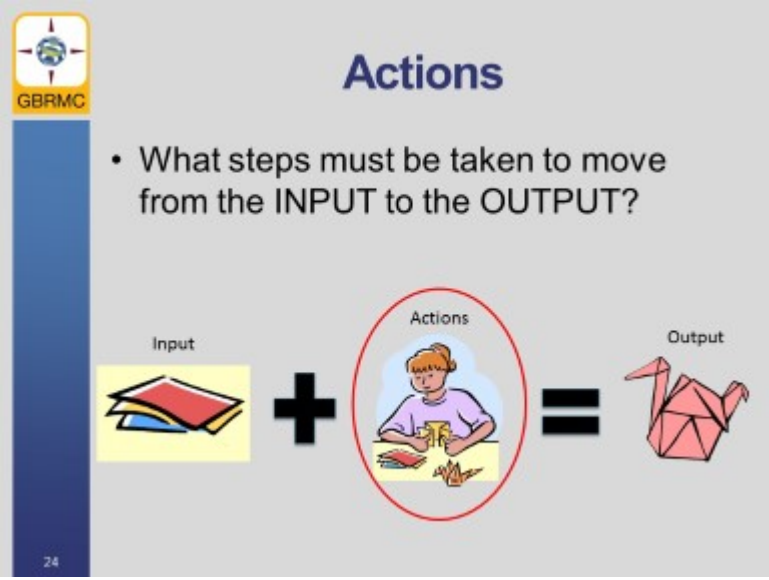
When:

Why:

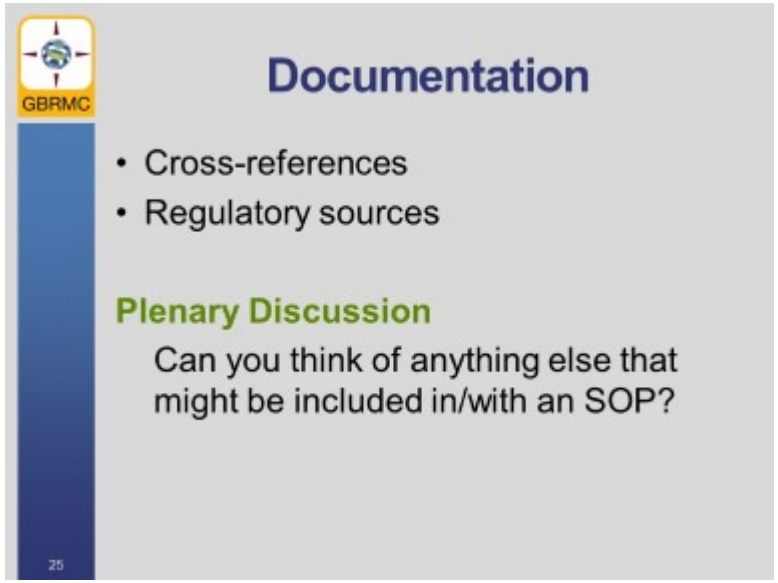
Where:



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?



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)?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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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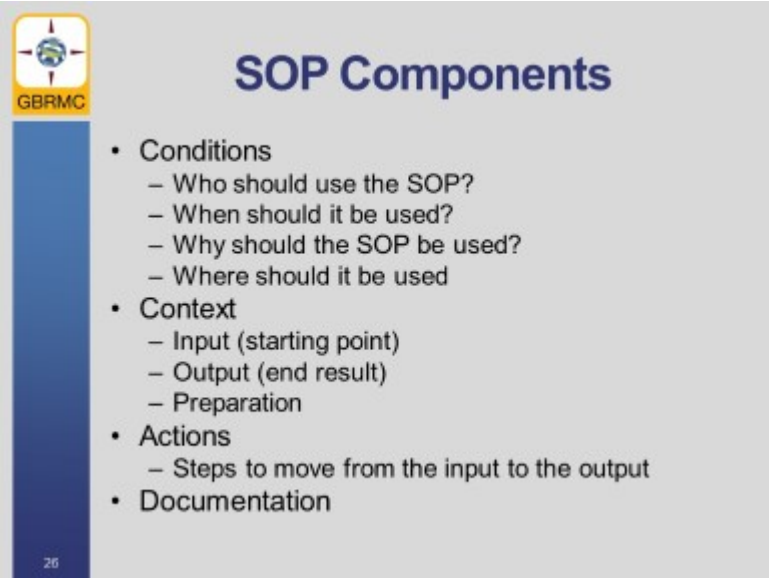
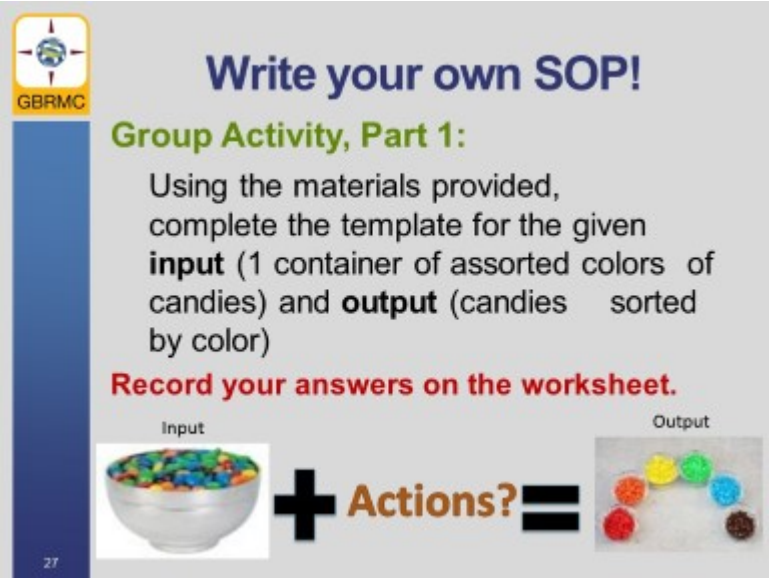


Look at the procedure you brought with you today.

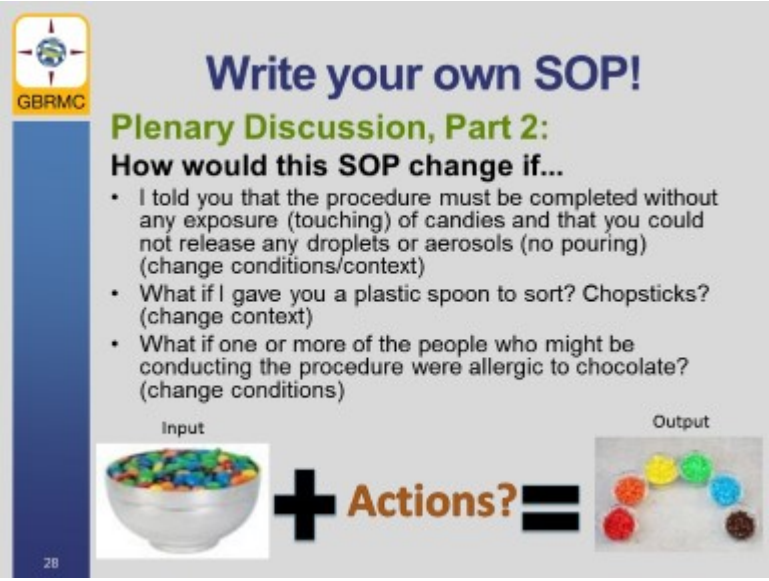
1. Determine which pieces of the procedure fit into the different components on the template in the workbook.
2. Which pieces in the template are not included in your procedure?
3. Are there pieces in your procedure that don't fit into the template?
4. Evaluate those pieces to see if they "belong" to 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?

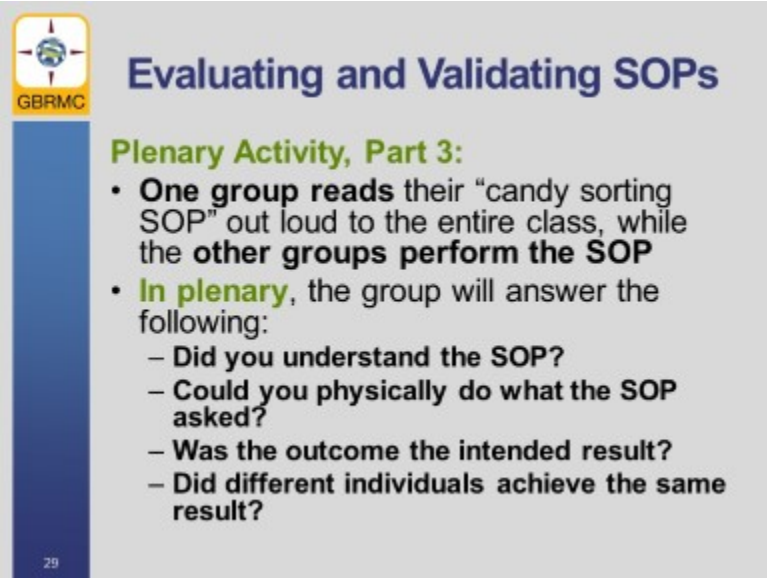


Using the M&M sorting template on the next page and the materials provided at your table, complete the template for the input and output given.

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		


GBRMC
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)
Input
Actions?
Output
28

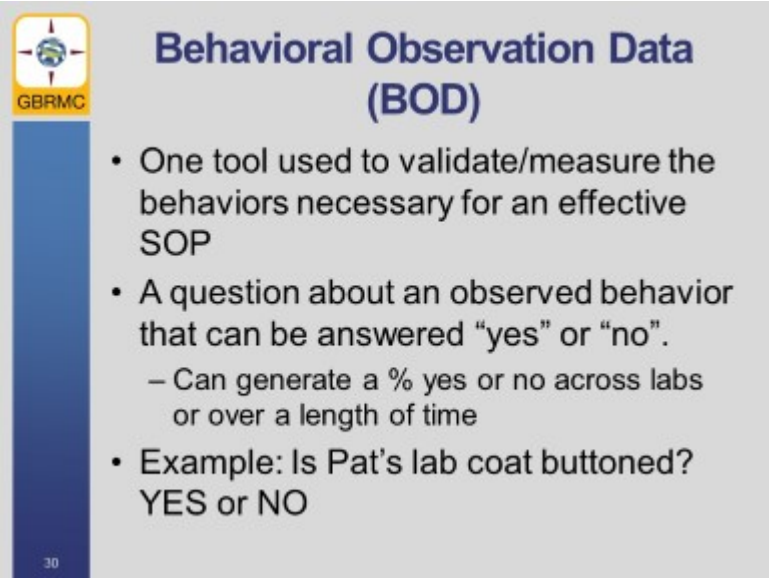


Could you execute the SOP?

Could you physically do what the SOP asked?

Did you reach the intended outcome?

Did different individuals achieve the same result?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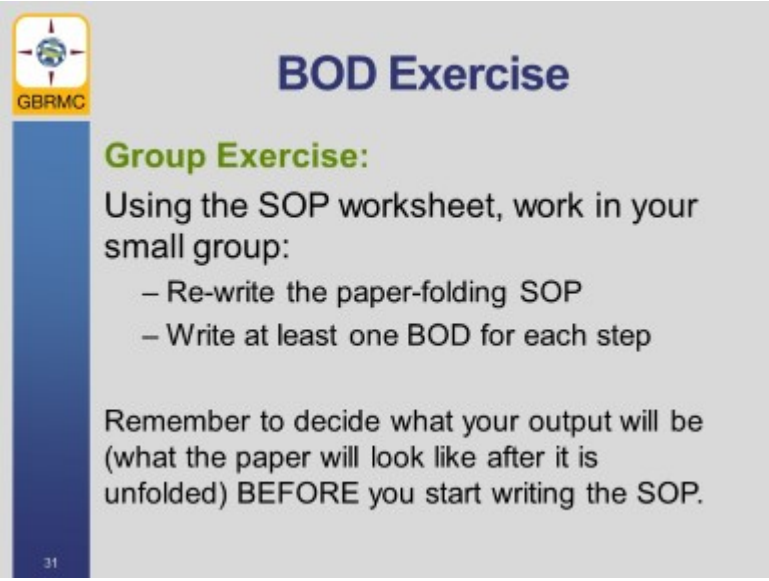
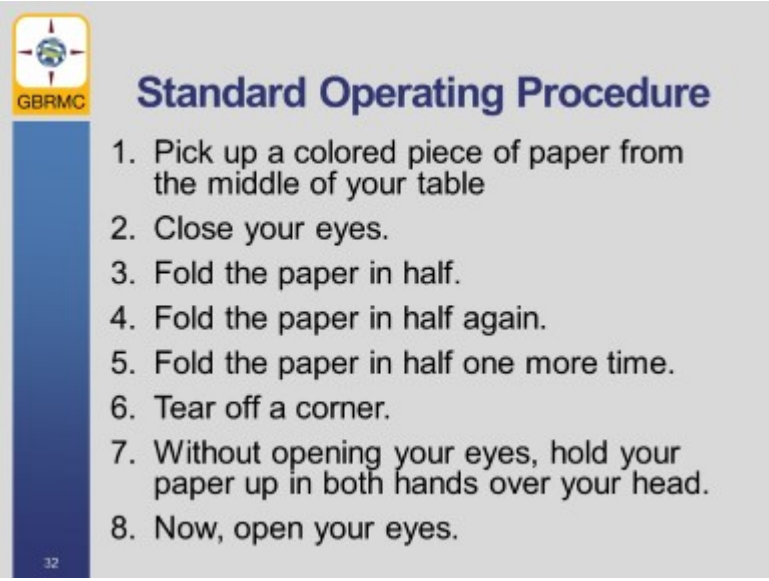
Behavioral Observation Data (BOD)
• One tool used to validate/measure the behaviors necessary for an effective SOP
• A question about an observed behavior that can be answered "yes" or "no".
– Can generate a % yes or no across labs or over a length of time
• Example: Is Pat's lab coat buttoned? YES or NO
30

Examples:



How can BOD be applied to your SOP?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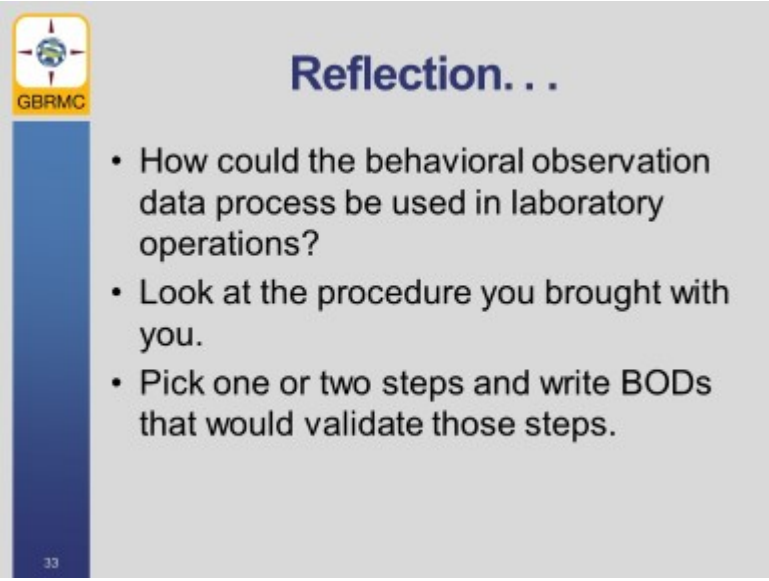
Standard Operating Procedure
1. Pick up a colored piece of paper from the middle of your table
2. Close your eyes.
3. Fold the paper in half.
4. Fold the paper in half again.
5. Fold the paper in half one more time.
6. Tear off a corner.
7. Without opening your eyes, hold your paper up in both hands over your head.
8. Now, open your eyes.
32

Notes:



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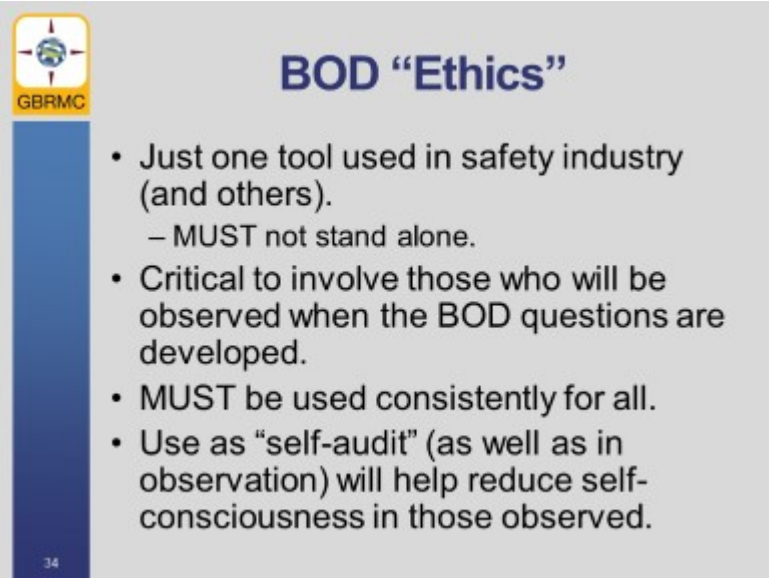
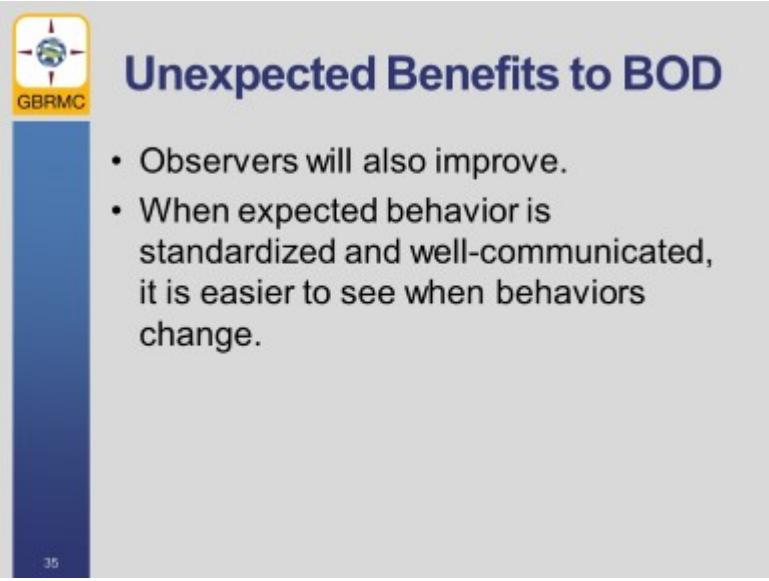


Name some considerations of BOD: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Unexpected Benefits to BOD
• Observers will also improve.
• When expected behavior is standardized and well-communicated, it is easier to see when behaviors change.
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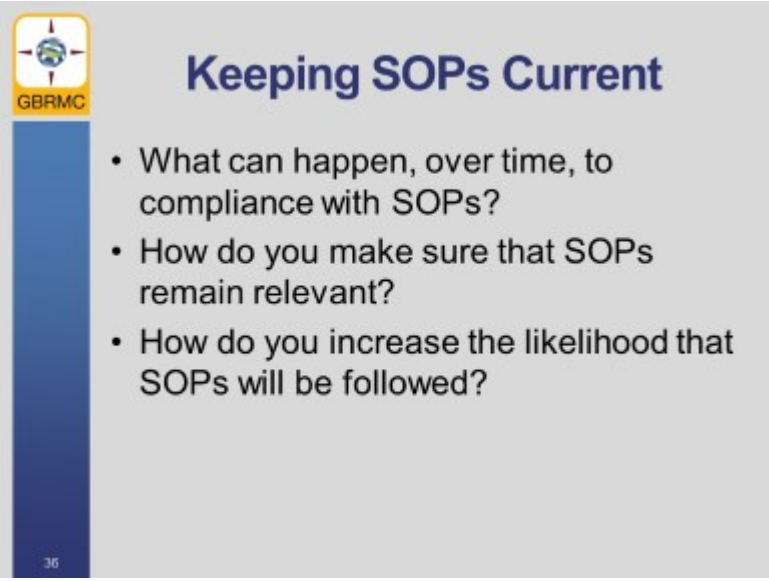
Examples: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Keeping SOPs Current
• What can happen, over time, to compliance with SOPs?
• How do you make sure that SOPs remain relevant?
• How do you increase the likelihood that SOPs will be followed?
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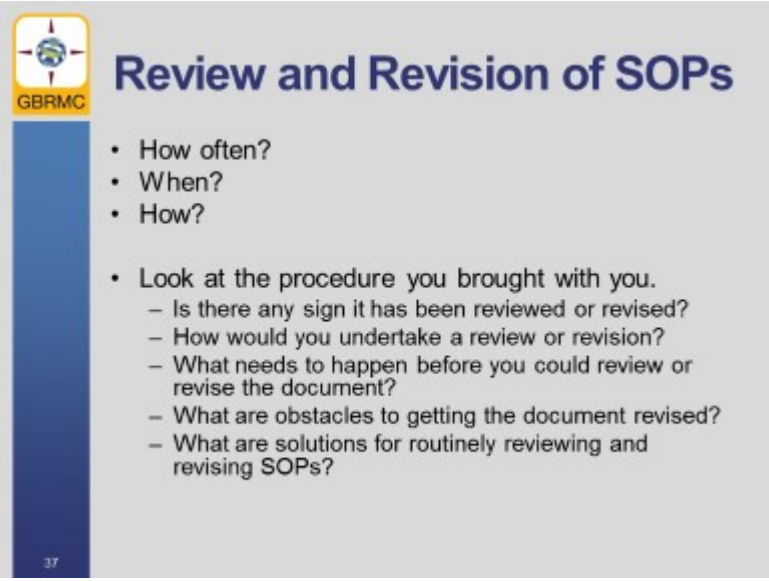
Notes:

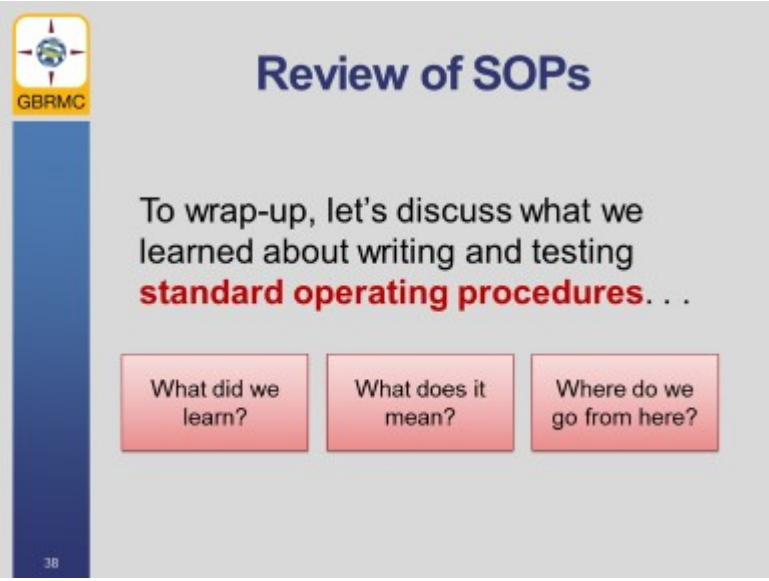


How Often?

When?

How?

Review your SOP: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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?
38

Action Plan

By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

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?

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