SAND2012-2506P

Developing, Evaluating, and Validating Standard Operating Procedures

Instructor's Guide

Sandia National Laboratories
International
BIOLOGICAL THREAT REDUCTION

BIOSECURITY ENGAGEMENT PROGRAM

CBEP
Cooperative Biological Engagement Program

Welcome & Introductions

Slide 1

Introduce Instructor(s):

[Introduce others associated with the training, as appropriate]

Name

Affiliation

Representation (I'm here on behalf of. . .)

Quick Experience Glimpse

Relevancy of the Course to your experience

Welcome & Introductions

Before you introduce yourselves, I'd like to provide some reminders about this facility and the training:

1. Restrooms are. . .
2. Exits are. . .
3. Evacuation procedures are. . .
4. [any escort or restricted access procedures]
5. We will have intermittent breaks during the course, but please feel free (or not) to take a quick break if you need to at other times during the course
6. Beverages and snacks will be available at (time) and at (location). You may/may not eat and drink in this room
7. Please silence any cell phones or other noise-making devices.
8. Others. . .

Slide 2

Welcome & Introductions

Let's go around the room and let each of you introduce yourself. Please tell us your name, where you work (organization and/or title, as appropriate), and what you hope to gain from the course.

Ground rules

This will be a very interactive session and you will learn the most if you participate fully. We will not intentionally force any one to speak or to do an activity that embarrasses them – if you are uncomfortable, please speak to one of the leaders. For those of you who like to talk, please share your expertise but be aware of those around you who may be quieter and give them time to share their opinion as well. We ask that everyone respect the break times and report back promptly when asked to do so. But most of all, we want to make this a fun time to learn, so remember to smile and enjoy yourself!

Transition to Objectives

Goal

To review the Action Plan and Learning Objectives for the course and to solicit any additional learning goals from the participants.

Time

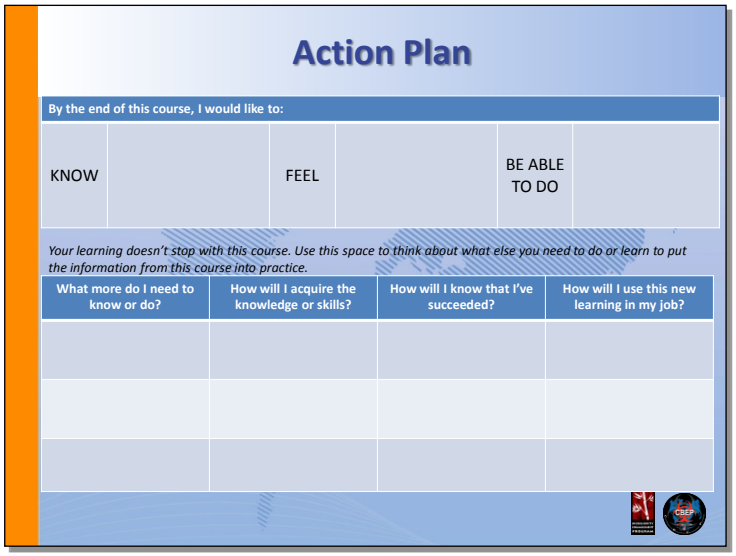
20 minutes

Welcome & Introductions

Key Messages for Instructor

1. SOPs are instructional documents designed to guide “different people doing one thing the same way and achieving the same outcome.” (Kaufman)
2. SOPs are (generally) designed to achieve a single, or small, outcome – for example, correctly disposing of laboratory waste (e.g., what should I do with this contaminated glove?)
3. There are many acceptable ways to write an SOP; however, there are key components that can comprise an effective SOP.
4. Pre-designed SOP templates can be used for developing biorisk management SOPs.
5. SOPs must be evaluated to assure that individuals can understand and physically accomplish the procedure.
6. SOPs validation must be done to assure that all individuals are accomplishing the intended outcome of the SOP
7. To consistently measure the ongoing effectiveness of an SOP, behavioral observation data metrics can be used.
8. SOPs must be reviewed periodically and revised as needed.

Slide 3



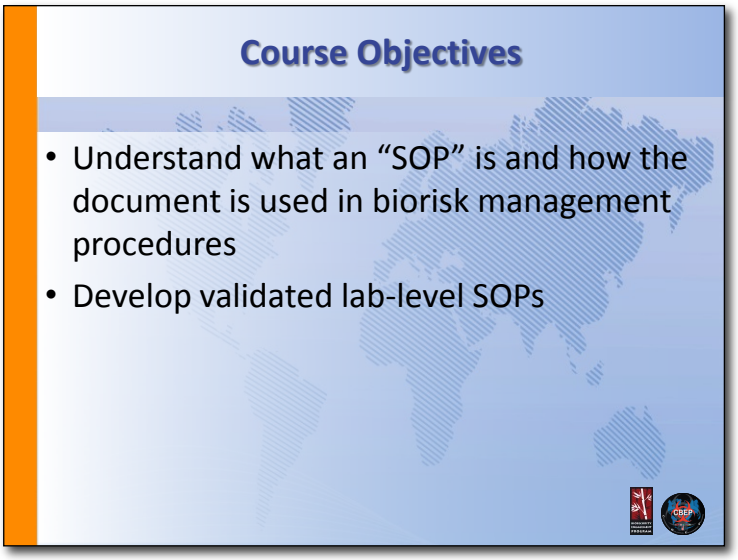
Welcome & Introductions

Instructions for the Action Plan handout:

- The Action Plan handout is on page __ of the student guide.
- It is designed to help you assess your learning of the material as we go through the course. It is also referred to as a learning contract.
- Go over each section of the Action Plan. . .
- The sections KNOW, FEEL and DO are designed to help outline personal learning objectives for this course.
- Ask each participant to think about what they would like to be able to KNOW, FEEL, and DO once this course is completed
- Tell the students that this is their own Action Plan. It does not need to be shared with anyone. It can be used during the course and after the course to help continually reach learning goals.
- Allow 5 minutes

Welcome & Introductions

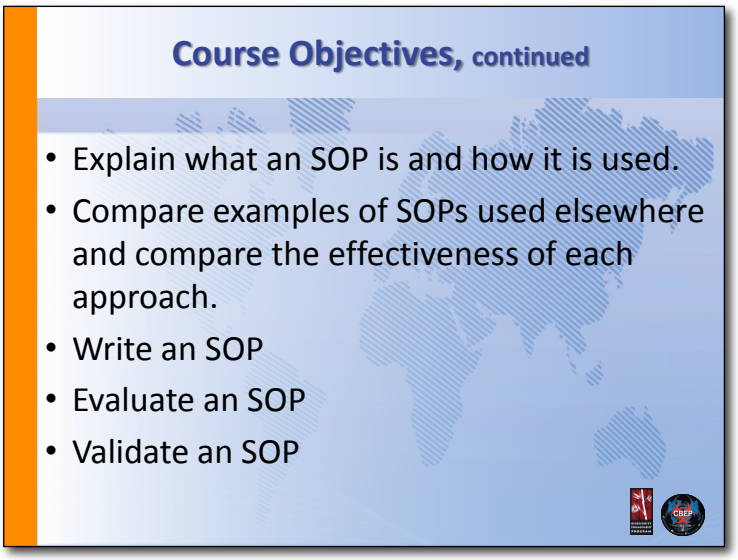
Slide 2



Background Information for Instructor

The slides on objectives should be self-explanatory. Refer to the design document for more information about the course design.

Slide 3



Welcome & Introductions

Background Information for Instructor

Review the course objectives, these can be read from the slide. Check for understanding and verify that these objectives are consistent with student expectations.

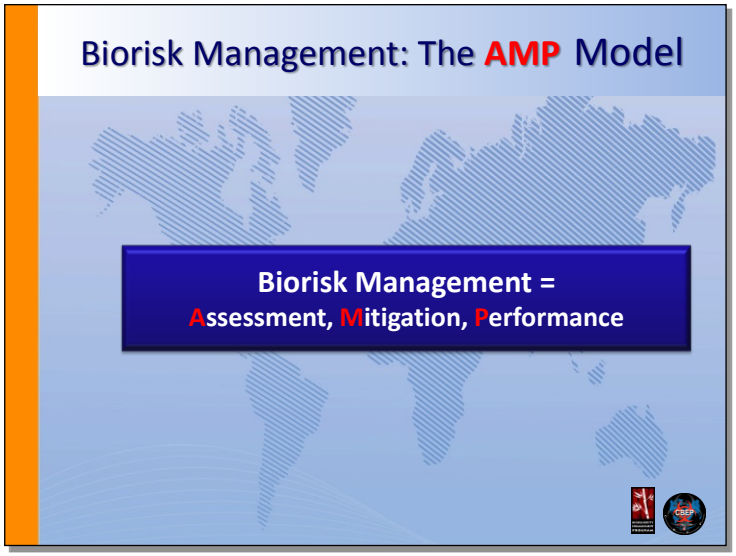
Capture any additional KNOW, FEEL, or DO or other learning goals

Capture any learning goals that will supplement course objectives and address any that are outside the scope of the course.

This course is flexible in nature. If there is a learning goal that is easily incorporated into the course, feel free to add it. Please note successful additions and consistently requested learning goals in the evaluation portion of this course and/or to GBRMC administrators.

Biorisk Management

Slide 5

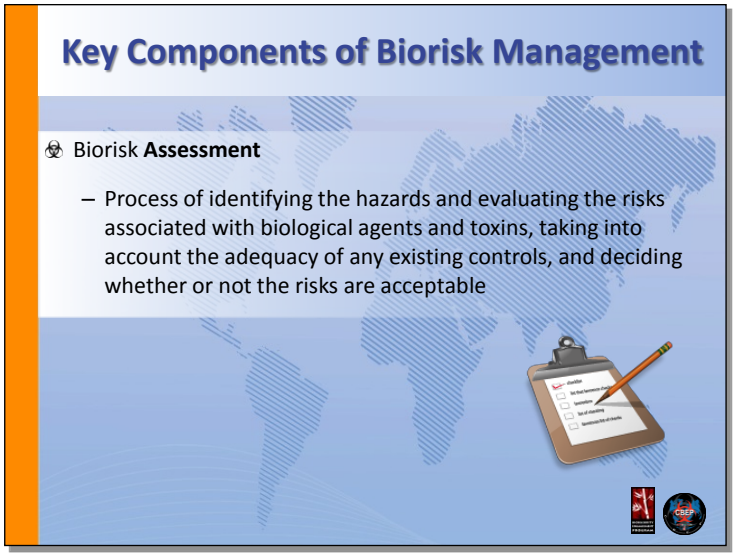


Background Information for Instructor

- Review the AMP model of Biorisk Management with the participants.
- The following three slides provide specific definitions for A, M, and P.

Biorisk Management

Slide 6



Background Information for Instructor

The instructor uses the following three slides: Biorisk Assessment; Biorisk Mitigation; and Performance to define key components of biorisk management

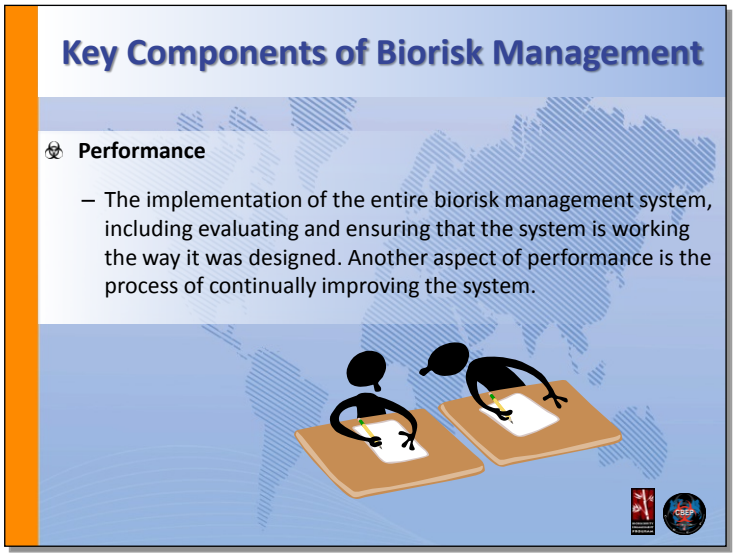
Slide 7

Biorisk Management

Background Information for Instructor

The instructor uses this slide and following slide (Performance) to define key components of biorisk management

Slide 8

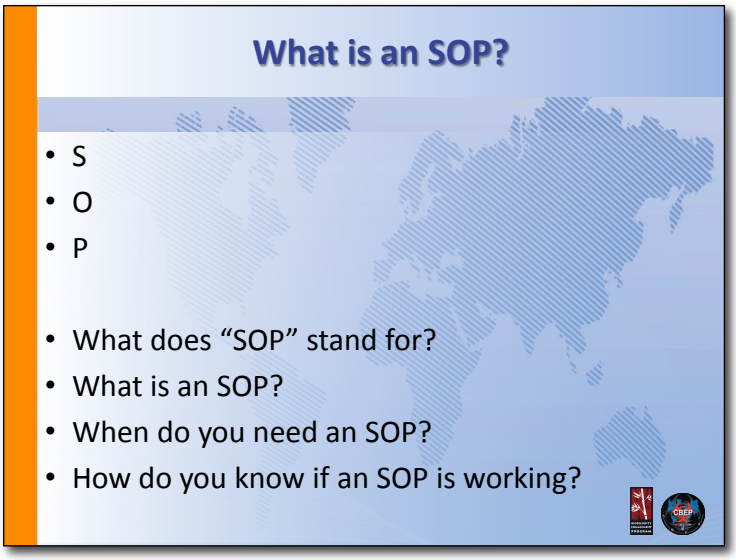


Background Information for Instructor

The instructor uses this slide to define key components of biorisk management

What is an SOP?

Slide 4



WRITE

S

O

P

on the flip chart

ASK*: What does “SOP” stand for?*

ANSWER: Standard Operating Procedure (write on flip chart)

Ask students to REFLECT individually on the following question/statement (using the lab procedure they brought in as a reference, if they wish):

What is a Standard Operating Procedure?

How do you know if an SOP is working?

What is an SOP?

Snowball Discussion

Ask students to share their individual reflections on both questions with others in their group.

Ask each group to work together to answer the questions as a group and write their answers on their flip chart.

Ask each group to share their answers with the class (to save time, ask one group to answer one question, etc., asking for additional comments from the other groups).

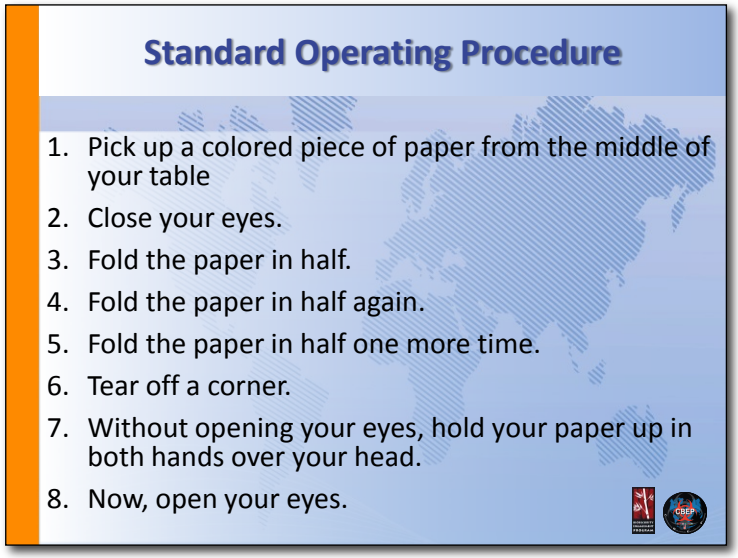
Ask the class to identify the common factors in the answers.

Capture common factors on a flip chart:

Example SOP

In order to see if we've thought about all the factors needed to define an SOP and to determine if it works, let's all follow a simple SOP.

Slide 7



What is an SOP?

Folding paper SOP

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. (Pause for a moment to make sure everyone has caught up)
7. Without opening your eyes, hold your paper up in both hands over your head.
8. Now, open your eyes.

Count how many different outcomes resulted. Post representatives of each different outcome on a blank flipchart.

Why do we have different results from the same SOP?

Capture on a flip chart:

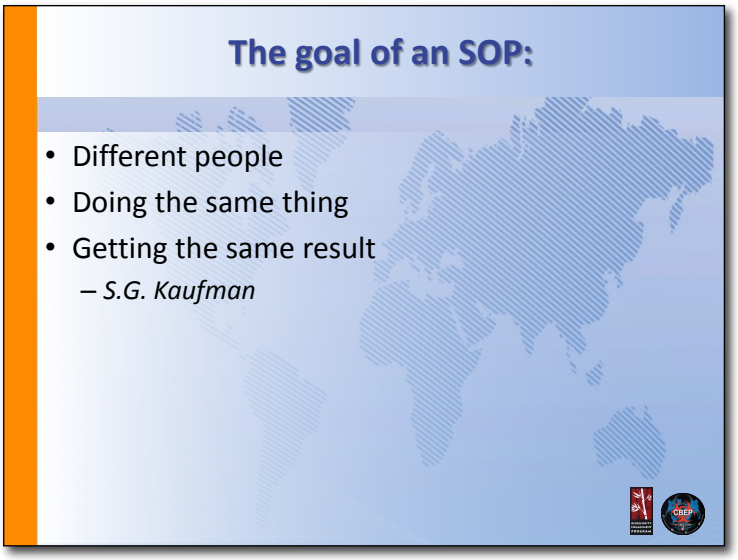
What features of our definitions from before are missing?

What if this SOP involved keeping a biological agent contained?

What if it was VERY IMPORTANT that this procedure did not result in a piece of paper with a hole in the middle? What failed?

What is an SOP?

Slide 5

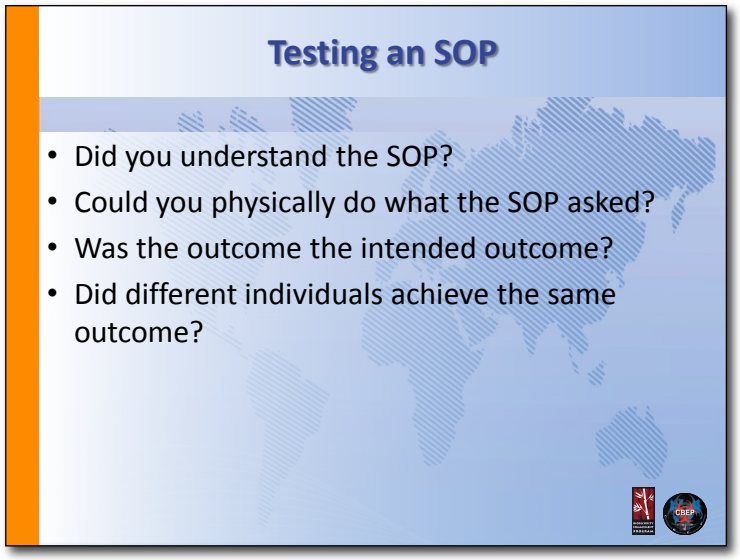


Lecture

The goal of an SOP involves three things: people, steps, and outcome. To craft an effective SOP, you must pay careful attention to all three. Do you have the right (trained, experienced, etc.) people? Do you know the right steps (and are the resources in place to allow those steps to take place)? And have you identified a clear outcome? Do you know what you want at the end?

What is an SOP?

Slide 6



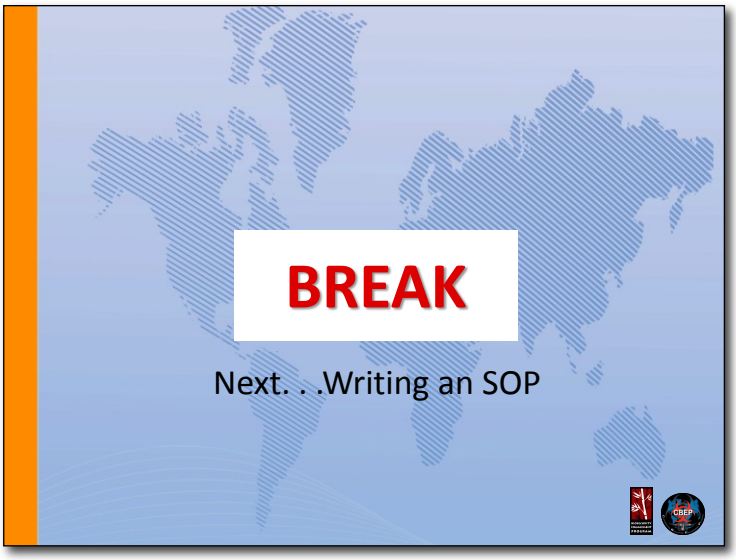
Lecture: Here is a quick check on whether an SOP is on target:

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 individuals achieve the same outcome?

Instructor - walk the students through each of these questions relative to the paper-folding SOP

What is an SOP?

Slide 10



Take a Break (10-15 minutes)

Time Check

You should be approximately __ hour into the lesson. You have X hours, Y minutes of lesson remaining.

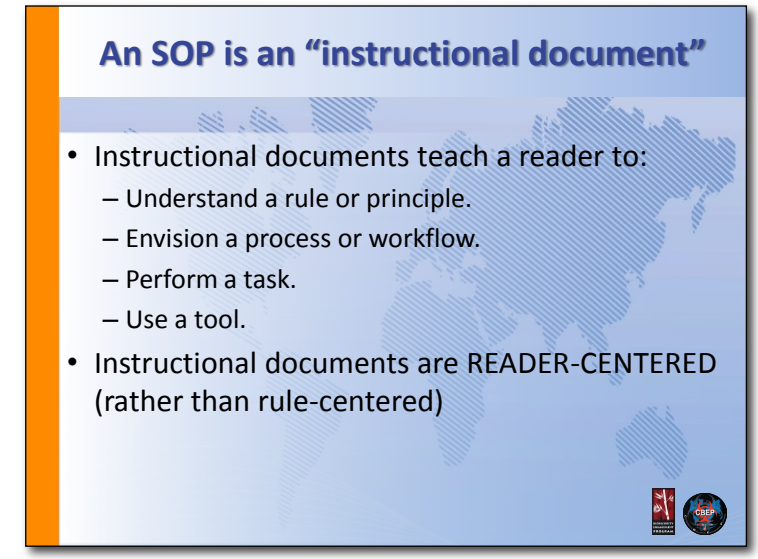
Transition to Writing an SOP Error! Reference source not found.

Writing an SOP

This lesson will emphasize the following key points:

- SOPs are (generally) designed to achieve a single, or small, outcome – for example, correctly disposing of laboratory waste (e.g., what should I do with this contaminated glove?)
- There are many acceptable ways to write an SOP; however, there are key components that comprise an effective SOP.
- Pre-designed SOP templates can be used for developing biorisk management SOPs.

Slide 11



Lecture:

An SOP is not a novel, a scientific paper or a report. Remember that a successful SOP is focused on the people (readers/users), the steps, and the outcome. It is not simply "putting something into writing" but rather serving as a job-aid to support policies, programs, training, etc.

Writing an SOP

Slide 12

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

Lecture:

Each of these will be discussed in detail.

Slide 13

Examples: Policy

- *Dispose of biologically contaminated waste according to local regulations*.
- Who writes this document?
- Who is the audience?
- What is the intended purpose?

Writing an SOP

Plenary Discussion

Question(s) to consider:

- Who writes this document?
- Who is the audience for this document?
- What is the intended purpose?

Directions for Instructor:

- Ask students to respond in plenary discussion
- Capture their answers on a flipchart prepared as described below

Capture on a flip chart:

Prepare a flip chart with a table similar to the following:

Document	Author	Audience	Purpose
Policy			
Program Plan			
SOP			

Writing an SOP

Expected Responses

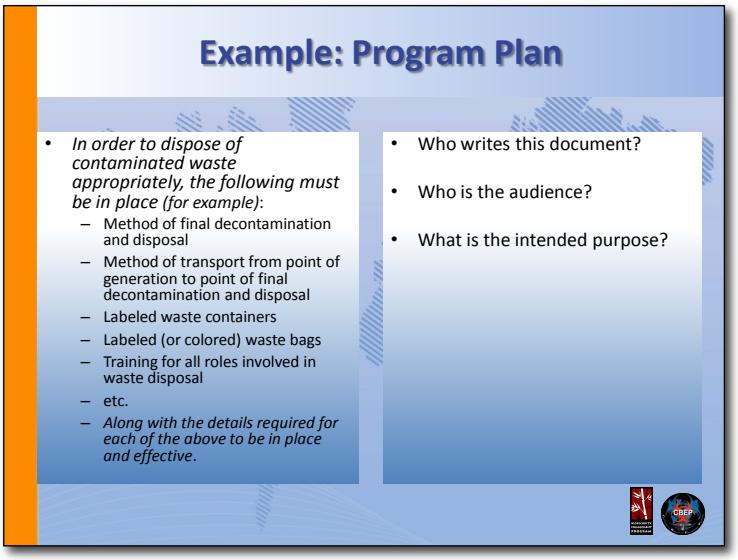
- Author: usually management, although it is good to have a variety of stakeholders involved. The bottom line is that a policy should be signed by management – the higher up the better
- Audience: The internal audience is the entire organization; externally, interested/affected parties (defined differently for different types of policies)
- Purpose: Describes the organization's commitment as well as defining expectations for the work force.

New Responses from Students:

Slide 14

Writing an SOP

Slide 15



Writing an SOP

Plenary Discussion

Question(s) to consider:

- Who writes this document?
- Who is the audience for this document?
- What is the intended purpose?

Directions for Instructor:

- Ask students to respond in plenary discussion
- Capture their answers on a flipchart prepared as described below

Capture on a flip chart:

Prepare a flip chart with a table similar to the following:

Document	Author	Audience	Purpose
Policy			
Program Plan			
SOP			

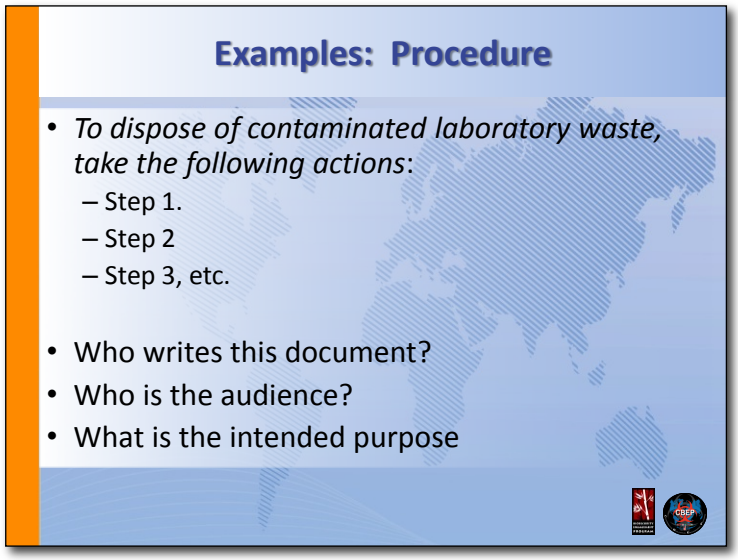
Writing an SOP

Expected Responses

- Author: often biorisk management advisors (BRMA) in conjunction with other operational managers: EH&S, security, facilities, occupational health, etc.
- Audience: Top management, operations groups, lab management & workforce, auditors and other outside authorities
- Purpose: Document and catalog the components and workings of the organization; to serve as the foundational reference for the program; to describe, in general, the tasks & actions to be carried out to accomplish the program and meet the expectations of the policy..

New Responses from Students:

Slide 16



Writing an SOP

Plenary Discussion

Question(s) to consider:

- Who writes this document?
- Who is the audience for this document?
- What is the intended purpose?

Directions for Instructor:

- Ask students to respond in plenary discussion
- Capture their answers on a flipchart prepared as described below

Capture on a flip chart:

Prepare a flip chart with a table similar to the following:

Document	Author	Audience	Purpose
Policy			
Program Plan			
SOP			

Writing an SOP

Expected Responses

- Author: ideally SOPs should be written by those who use them; often the development is delegated to BRMA or other managers. If management writes the SOPs, they MUST be validated and tested by those who use them before being made final.
- Audience: Those who use them or whose procedures are impacted by them.
- Purpose: Details the specifics of an individual procedure/process – very locally specific.

New Responses from Students:

Ask students to REFLECT individually on the following question/statement:

Look at the procedure you brought with you. Is it a policy, program plan, or procedure? Or a combination of all the above? Is there at least a piece of the document that represents steps to accomplish a single outcome? If so, highlight that to use in the upcoming work (instructor – hand-out "extra" SOPs if the document will not work for the upcoming exercises, included in the appendix of this instructor guide).

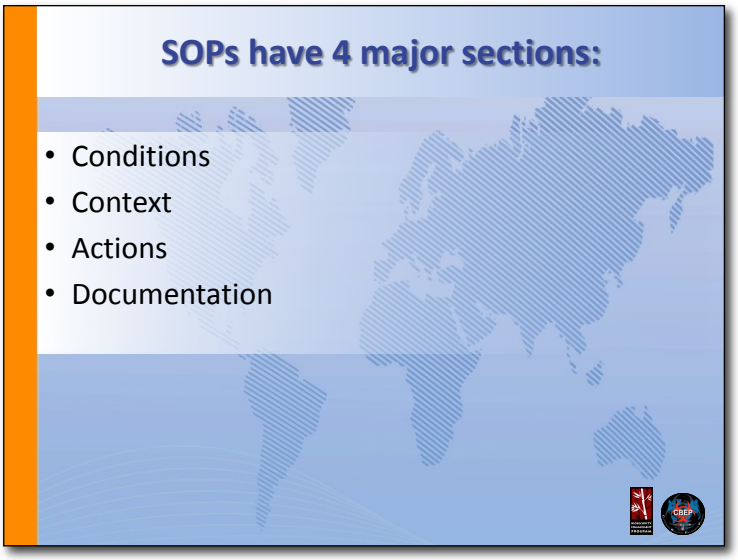
Page [#]

Direct participants to the Participant Workbook: SOP template

Instructor: see the appendix to this instructor guide for a copy of the template.

Writing an SOP

Slide 17

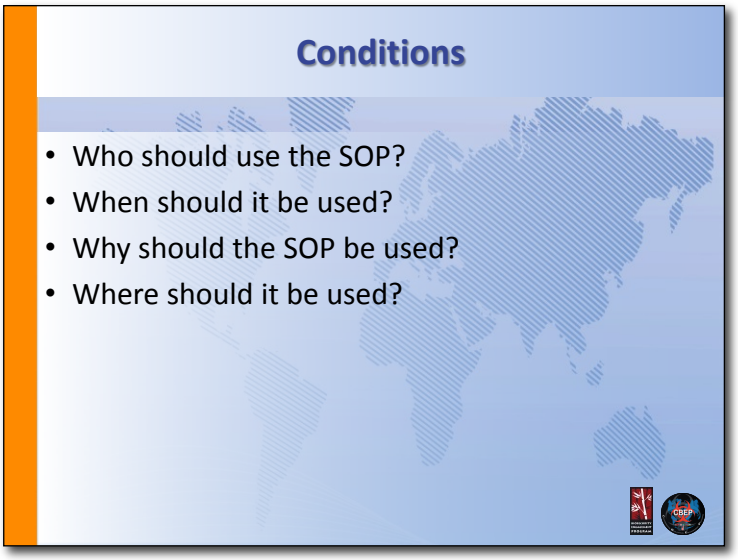


Lecture:

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

Writing an SOP

Slide 18



Lecture:

Who? Is it everyone in the lab? Only those trained in a certain procedure? Only those with a specific clearance (medical, security, etc.)? Only the supervisor or people with a specific title?

When? Is this a daily, weekly, monthly procedure? Should it be done only before or after certain other procedures? Etc.

Why? This is a harder question. Most SOPs are targeted towards getting consistent results (quality) or towards safety or security.

Where? Is there a specific place this SOP should/must be performed? On a certain piece of equipment? In a specific room? In the BSC?

Writing an SOP

Small group activity (10 minutes). [Instructor: this activity is OPTIONAL, depending on the time]

Activity Instructions (to students)

1. Consider the SOP conditions for entry into a laboratory where the organisms used could be transmitted by ingestion, direct contact, or via needle-stick or other percutaneous exposure (e.g., Biosafety Level 2 lab). [Instructor, you may wish to assign one question to each group]:
    a. Who should use the SOP?
    b. When should it be used?
    c. Why should the SOP be used?
    d. Where should it be used?

2. Write your answers in your workbook., but be prepared to share your answers with the class

You have 5 minutes to complete this activity

Directions for Instructor:

- Prepare flipchart as below:

BSL2 Entry SOP	
Who	
When	
Why	
Where	

- Ask the group assigned to each question to report out. Capture their responses in the correct section of the flipchart.

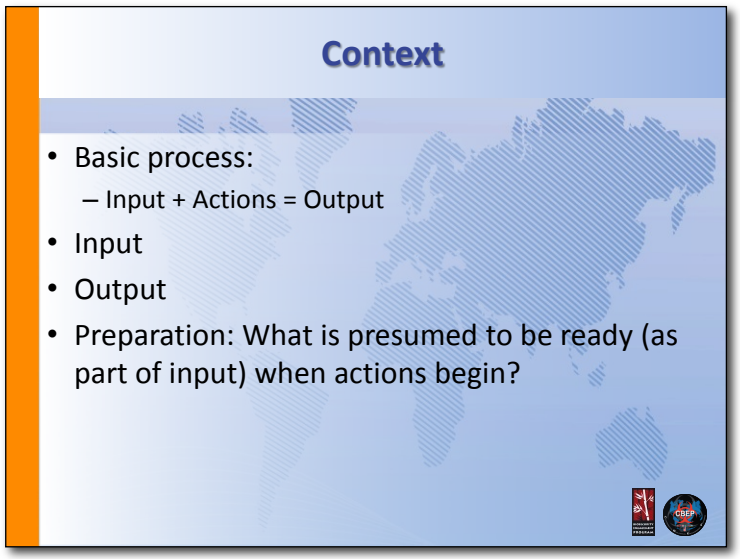
Writing an SOP

Expected Responses

BSL2 Entry SOP	
Who	xx
When	xx
Why	xx
Where	xx

New Responses from Students:

Slide 19



Writing an SOP

Lecture:

This section summarizes where the procedure falls into the larger procedures/program.

Basic process – often this will be a simple, high level flowchart of the process to provide a visual for readers in one glance

Input – starting state (e.g., blank piece of paper)

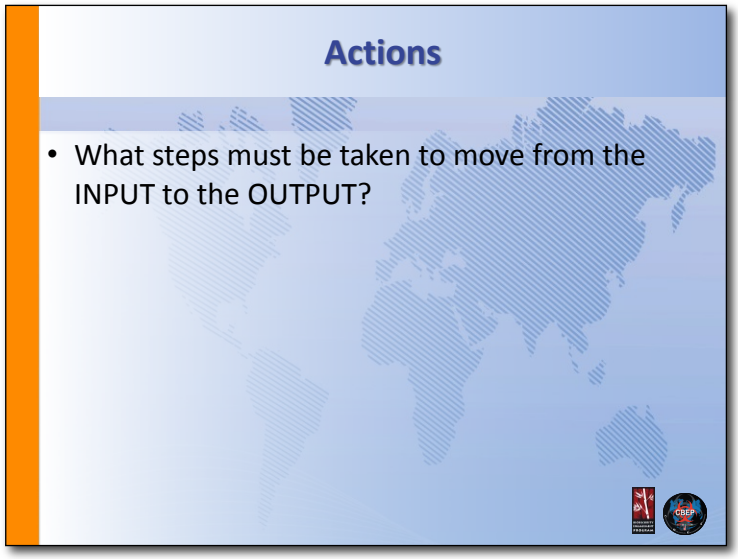
Output – the desired ending (e.g., a piece of paper with folds and holes in designated places)

Preparation – anything necessary to be in place before the SOP can successfully occur (e.g., colored paper stacked on the table)

Let's think of a laboratory example.

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? (sharps containers in place, etc.)

Slide 20



Writing an SOP

Lecture:

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)? As we saw in the paper folding exercise, SOP actions should be as simple, but as specific as possible.

Slide 21

Lecture:

Often SOPs will rely on each other or on other documents. For the most part, SOPs should not cross-reference to other SOPs in the actions section. BUT if other SOPs help define the conditions or the preparation needed or guide the reader to the next step, a cross-reference is quite useful.

The SOP reader should not need to read the regulations to successfully perform the SOP; however, it is good to reference any documents that influence the SOP. If that document changes, then a quick search of SOPs for that reference will help determine if changes to the SOP need to be made.

Writing an SOP

Slide 22

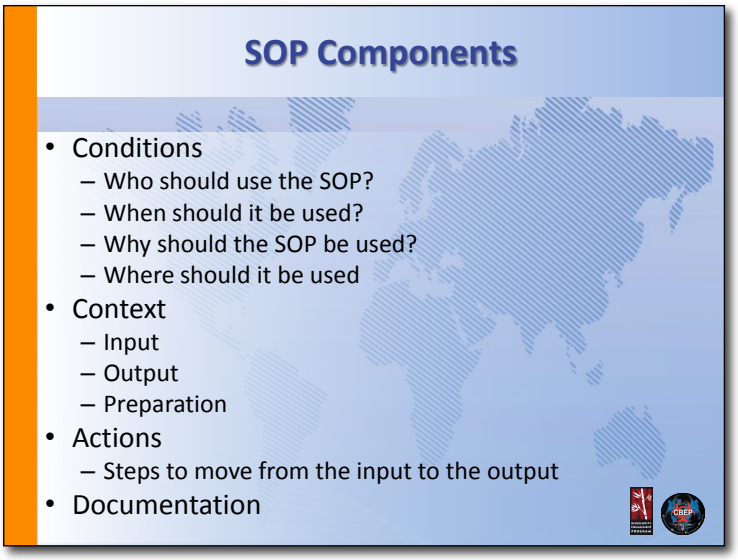
Take a Break (10 minutes)

Time Check

You should be approximately __ hour into the lesson. You have X hours, Y minutes of lesson remaining.

Writing an SOP

Slide 23



Page [#]

Direct participants to the Participant Workbook:

1. Look at the procedure you brought with you today.
2. Determine which pieces of the procedure fit into the different components on the template in the workbook.
3. Which pieces in the template are not included in your procedure?
4. Are there pieces in your procedure that don't fit into the template?
5. 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?

You have 10 minutes to complete this activity

Writing an SOP

Plenary Discussion (10 minutes)

Question(s) to consider: What did you find when you examined the procedure you brought with you? Did your procedure have all the pattern components (Conditions, Context, Action, Documentation)? Did your procedure have more? What was missing? What was extra?

Does your procedure have a clear input and output?

Directions for Instructor:

- This is just a discussion – there is no need to capture the results, unless you would prefer to.

Expected Responses

- There are no "right " answers here. In general, most procedures are missing components and have additional components that more properly belong in policy or program documents. The main point of this exercise is to streamline and focus on what is required for an effective procedure document.

New Responses from Students:

Writing an SOP

Slide 24

Using the M&M sorting template in your workbook (page X) and the materials provided at your table, complete the template for the input and output given.

Capture, as a group, on the flip chart a basic SOP.

Report out. Questions? Differences?

Writing an SOP

Small group activity (15 minutes).

Activity Instructions (to students)

1. Using the M&M sorting template in your workbook (page X) and the materials provided at your table, complete the template for the input and output given
2. Record your answers in your workbook but also designate one person to write a sticky note for EACH step in your procedure. [Instructor – it would be helpful here for each group to have different colored sticky notes.]

You have 10 minutes to complete this activity

Directions for Instructor:

- Prepare flipchart(s) – you may want to put conditions and context on one flipchart and use another flipchart to have students post the actions:

Conditions	
Who?	
When?	
Why?	
Where?	
Context	
Input	
Output	
Actions – ask students to post their steps	

- Continued on next page. . .

Writing an SOP

continued

- Collect the conditions and context info from groups (ask one for the who, another for the when, etc., always checking to see if the other groups have a different answer or different perspective). Write the answer on the flipchart.
- For the actions, ask the students to post their steps on a common flip chart. Don't let this take too long – the point is not getting a consensus procedure but rather that there are different ways to go from a common input to a common output.

Plenary Discussion (7-10 minutes)

Question(s) to consider:

How would this SOP change if:

- I told you that the procedure must be completed without any exposure (touching) of M&Ms and that you could not release any droplets or aerosols (no pouring)?
- What if I gave you this kind of equipment to sort (plastic spoon)? What if I gave you this (chopsticks?) What would need to change in your procedure?
- Lastly, what if one or more of the people who might be conducting the procedure were allergic to chocolate? How would you change the SOP?

Directions for Instructor:

- This is intended to be discussion only. If you want, you can capture the changes, if articulated clearly enough, in a different color on the SOP o the flipchart.
- After the discussion, ask students why it is important to identify this information up front?

Writing an SOP

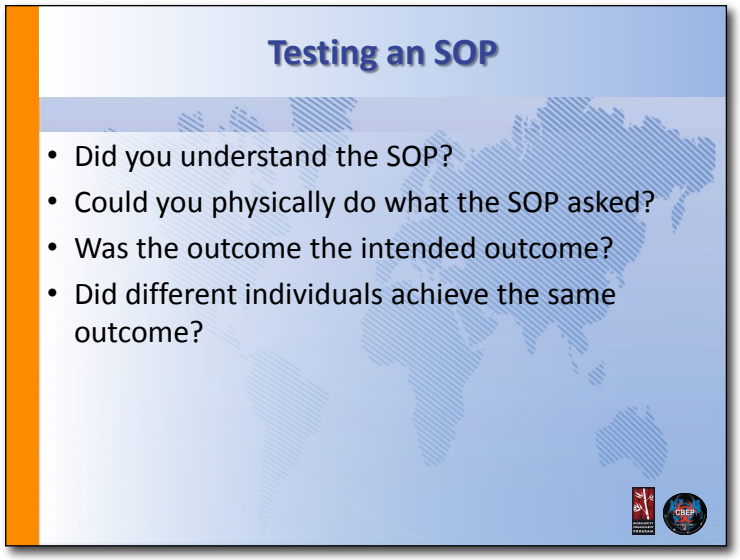
Expected Responses

- In response to not being able to touch or pour, the students will hopefully answer that they would need some sort of sorting equipment or PPE (e.g., gloves). Ask where/how that would be recorded in the SOP
- In response to the plastic spoon, students will likely decide to re-write the SOP action steps to use the spoon to sort. Remind them that the spoon should also be captured in both the where of the conditions and the preparation step in the context block.
- In response to the chopsticks, students will likely report that the user of the procedure must be capable of using chopsticks or be trained to use them. Ask them where that would be captured.
- In response to the chocolate allergy question, students will like want to exclude those workers from the procedure, assign them additional PPE, or have them cleared by occupational health prior to work. Ask how those will be addressed in the SOP
- Hopefully the students will answer that it is important to identify this information up front so that all factors influencing the SOP can be included in the SOP. A good follow-on question is whether safety procedures should be integrated into laboratory procedures or if they should be separate. The answer to this question, of course, is "it depends." In most cases, however, safety and security considerations should be integrated into the procedures so that they are not considered "add-ons" but are just part of "doing business." However, some safety and security procedures might be stand-alone. For example, waste disposal or testing an autoclave, etc.

New Responses from Students:

Writing an SOP

Slide 25



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Direct participants to the Participant Workbook

Testing an 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 individuals achieve the same outcome?

Lecture

One of the most common mistakes in writing SOPs is thinking that once you've written your procedure, you are done. The final steps in writing an SOP include testing the SOP to make sure it accomplishes the goal: Different people, doing the same thing, with the same result (and the desired output). These are questions to ask when an SOP is tested. Ideally, SOPs are tested by the users – but different users than those who wrote the SOP.

Writing an SOP

Ask students to REFLECT individually on the following question/statement (5 minutes):

Question to reflect on.

Using the procedure you brought with you, answer these questions. If you cannot answer "yes" to each question, what needs to happen to make the answer "yes"? (Instructor: get examples of "failures" and "solutions" from class).

Record your thoughts in your workbook (page X).

Instructor – ask two or three students (voluntarily) to report their observations and ask the students if they have any questions.

Take a 10 minute break.

Time Check

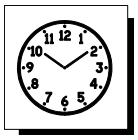
You should be approximately __ hour into the lesson. You have X hours, Y minutes of lesson remaining.

Transition to Behavioral Observation Data

Behavioral Observation Data

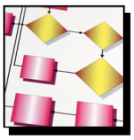
Goal

The purpose and goal of this module is introduce the concept of using behavioral observation data to determine if SOPs can be and are being followed



Time

[Enter the length of time needed to complete the module]



Overview

To consistently measure the ongoing effectiveness of an SOP, behavioral observation data metrics can be used.

SOPs must be reviewed periodically and revised as needed.

Ask: "An SOP is written to assure a given outcome which is, presumably, measurable. How do you assure that each person is performing the SOP in the same way?"

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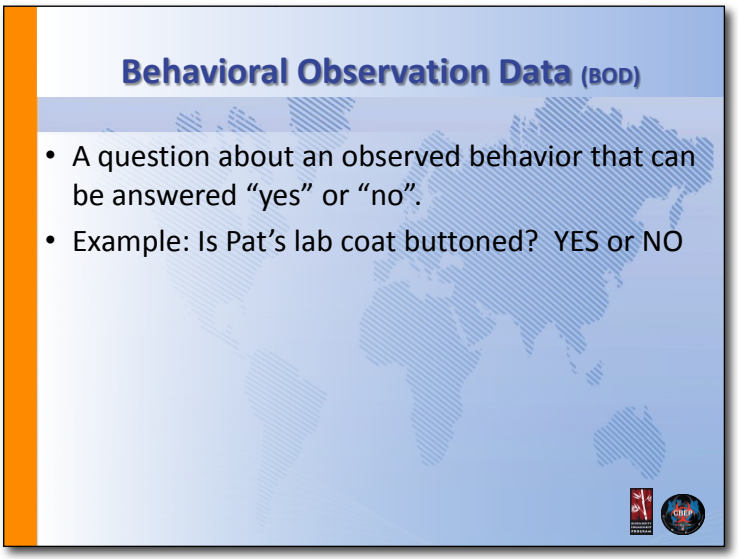

Behavioral Observation Data

Behavioral Observation Data (BOD)

One tool used in safety industry.

MUST not stand alone.

A question about an observed behavior that can be answered “yes” or “no”.

Example: Is Pat’s lab coat buttoned? YES or NO

In this case, the desired behavior/outcome is a buttoned lab coat (YES). The undesirable behavior is an unbuttoned lab coat (NO). If you wanted to measure the performance of lab coat buttoning for the entire lab, you could get a “% yes % no” and measure that across labs or time, etc.

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Behavioral Observation Data

Page [#]

Direct participants to the Participant Workbook.

This SOP should look familiar ☺ - except now there are some additional columns.

Column 1 (to the left) is the "old" SOP instructions. Column 2 is for you to make any changes to the original instructions and Column 3 is for you to write a BOD question that will validate proper completion of that step. Remember it should be able to be answered "yes" or "no".

Let's try together Step 1. "Close your eyes." Any trouble understanding or accomplishing that step? If so, re-write the instructions. More importantly, what is a BOD question to validate that the SOP is followed?

Page [#]

Direct participants to the Participant Workbook

Continue with the Paper Folding SOP.

Work in your small group to determine all the columns for the rest of the steps. Remember that you need to decide the output for your SOP (what the paper should look like when it is folded properly) BEFORE you begin (complete the appropriate section of the SOP).

(Allow about 10 minutes)

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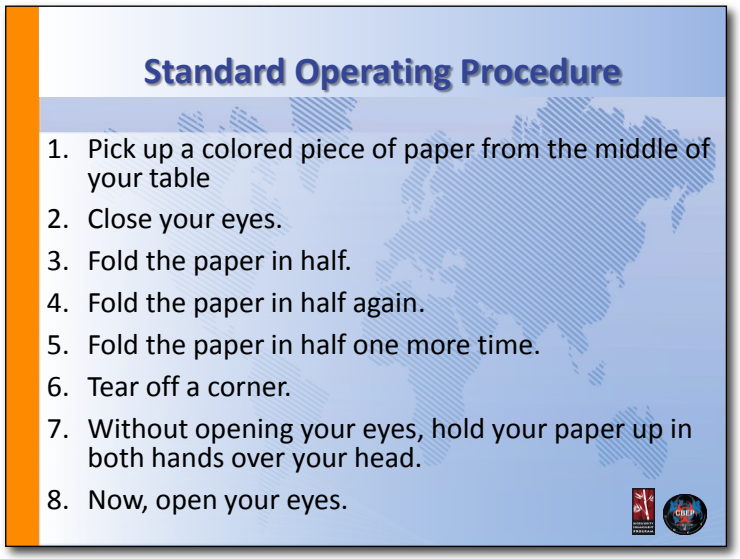

Behavioral Observation Data

Background Information for Instructor

This slide is to project while students are working on their new SOP plus BODs – there is nothing to address or speak to.

SOP Validation and BOD Metrics

1. Group 1 (etc.): Give a copy of your new SOP template to the instructor.
2. The instructor reads the new SOP to the remainder of the groups.
3. Meanwhile, Group 1 takes BOD observations for 4 of the group.

Capture data on a flip chart:

Prepare flipchart:

	# BOD ?s	Yes	No	Y/N
Group 1				
Person 1				
Person 2				
Person 3				
avg				
Group 2				
Person 1, etc.				

(Insert photo of example)

1. Collect data from each group on prepared flipchart
2. Did BOD data predict output?

Repeat for each group (collect data from 2 groups minimum – repeat for the others as time allows).

Behavioral Observation Data

Ask: Who is responsible for getting an SOP "right"?

What needed to be "fixed"? What are options to assure that the BODs and ultimately the SOP outcomes are as intended?

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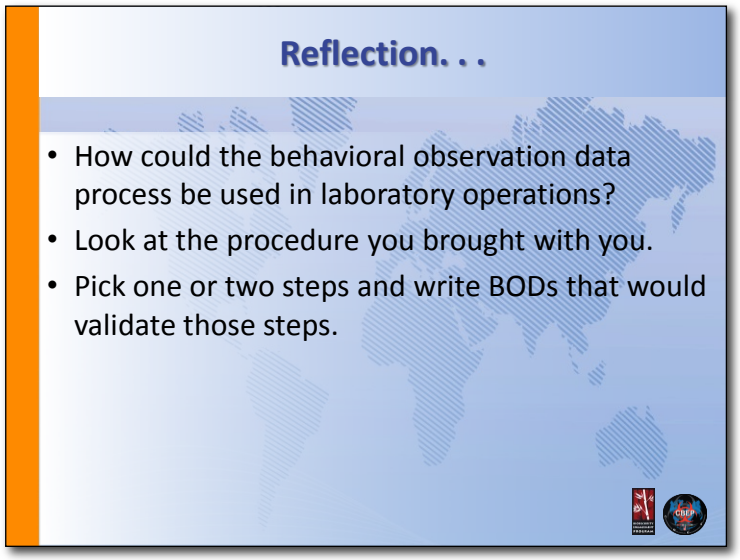

Ask students to REFLECT individually on the following question/statement:

Look at the procedure you brought with you. What BODs could be added to the procedure? What strategy for evaluating and validating existing procedures will you employ in your work setting?

Record your thoughts in your workbook.

Instructor – if time allows, solicit two or three thoughts from the group.

Behavioral Observation Data

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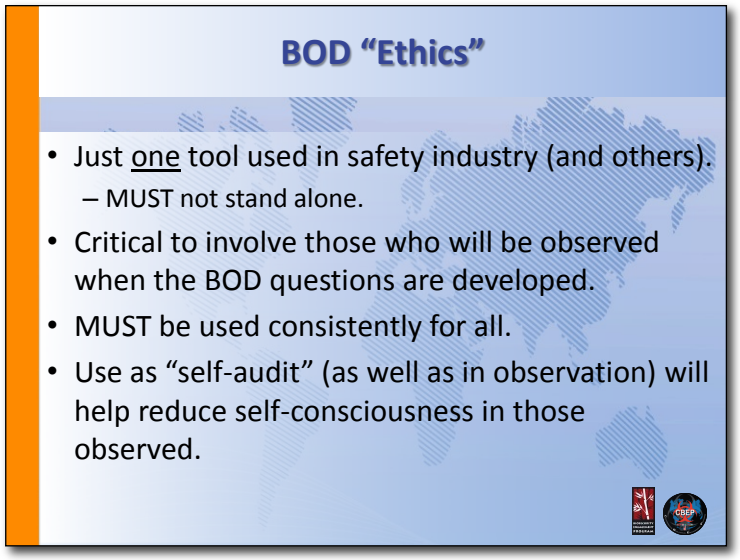

Lecture

Collecting BOD metrics can be a very powerful tool because it is SO simple . . .BUT because it focuses on individual behavior, it must be used very carefully and ethically. BOD metrics are a validated tool in the safety industry and is best used in concert with other tools, like physical audits and staff surveys (perceptual audits for safety climate, etc.). It is also imperative to get buy-in from those being observed – the best way to do this is to have the group to be observed help develop the BOD questions. BOD questions can be included as part of the SOP as a step-by-step validation that the procedure is on-track and/or can be used as a proficiency check during training and included as a checklist as an addendum to the procedure.

Behavioral Observation Data

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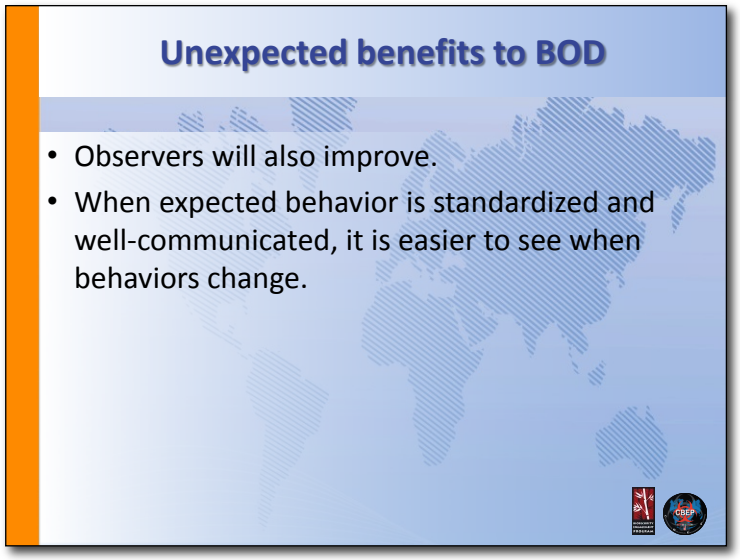

Lecture:

BOD observations support training not only in those being observed but in those observing. In fact some studies have shown that the observers ultimately improve their performance (of the observed procedures) more than those who are merely observed. This supports drawing the observers from the workforce rather than exclusively from the "outside". Also supports peer pressure to perform the procedure in line with the BODs because it is objective, rather than each person finding their own way.

Behavioral Observation Data

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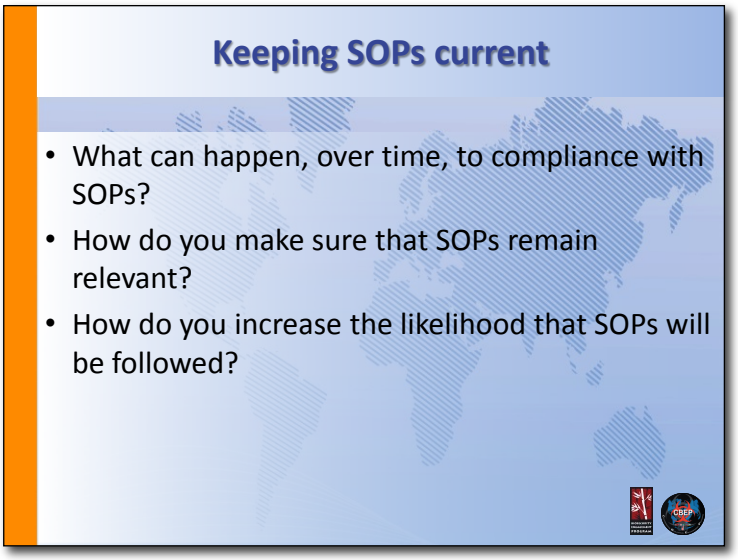

Behavioral Observation Data

Plenary Discussion

Question(s) to consider: What can happen over time to SOPs and the behavior that they outline? How do you make sure that SOPs remain relevant?

Directions for Instructor:

- Collect student responses and summarize on a flipchart.
- After collecting student responses, described behavioral evolution as listed below.

Instructor – if time allows, draw the steps of "behavioral evolution" on a flip chart: (Ref – Sean Kaufman at Emory University in Atlanta)

Write: "New procedure" – ask how students feel when faced with a new procedure

Now ask, how the students feel once they've done the procedure successfully three or four times. Ask whether someone who has repeated a procedure three to four times really KNOWs (has mastered) the procedure. WRITE "Perceived Mastery" after new procedure.

Ask what often happens when someone thinks they know how to do a procedure but doesn't really.

Write "Incident" on the flipchart. What happens when an incident occurs? In general, people realize that they hadn't mastered the procedure and they go back to re-learn.(Draw an arrow back to new procedure)

Write "Mastery" on the flipchart and say eventually people will master the procedure, but what can happen over time once the procedure is mastered? (Wait for answers – hopefully you will get the answer (complacency or similar) that you are looking for.)

Write "Complacency" on the flipchart. And what can happen when even an expert gets complacent? Write "incident" on the flipchart.

How does normal human behavior relate to SOPs?

Behavioral Observation Data

Expected Responses

- SOPs become out-of-date: something changes (new equipment, new policies, etc.) and the SOP isn't changed
- People start doing things their own way or think they can do them without referring to the SOP
- Someone writes another conflicting SOP and no one knows which one to use, so they don't use either.
- There is an incident and instead of revising the current SOP, a brand new SOP is written without regard to what's been done before.

New Responses from Students:

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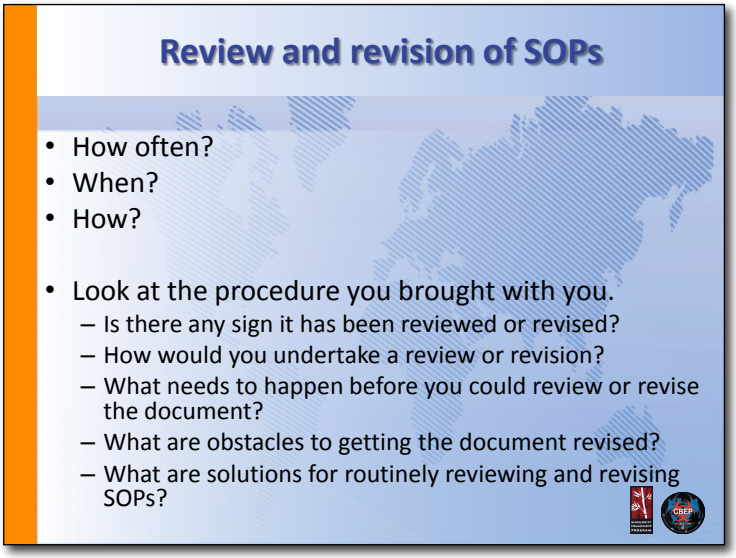

Behavioral Observation Data

Ask students to REFLECT individually on the following question/statement:

Look at the procedure you brought with you. Is there any sign that it has been reviewed or revised? How would you undertake a review or revision of this procedure? What needs to happen before you could conduct a review? Are there steps you can take?

Capture your thoughts in your workbook.

Instructor – if time allows, solicit some feedback on this exercise from the students if they wish to share.

Transition to Review

Review

Goal

The purpose and goal of this module is to recap the key messages of the course and to conduct a “What? So What? Now What?” review of the course and key messages.

Time

Allow 20 minutes to get through the Review section.

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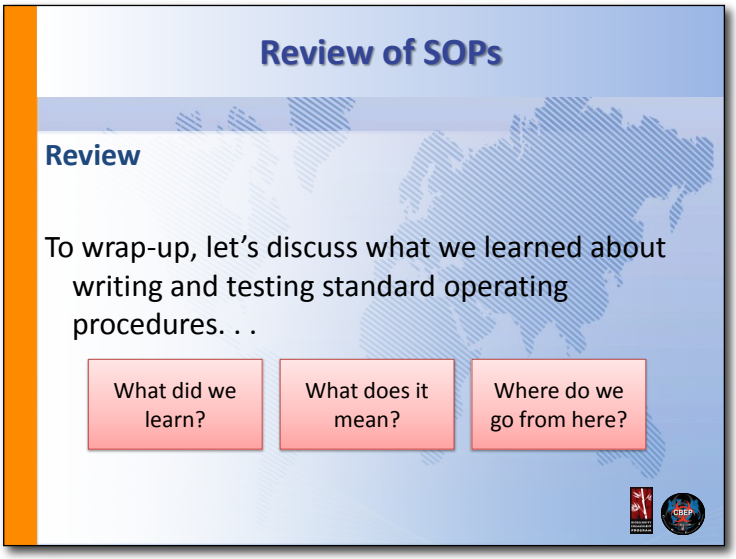


Review Key Messages

Include discussion on how activities/examples related to the Key Messages of the course and how the messages can be applied.

Review

Run the Key Message Recap (Cards) activity.

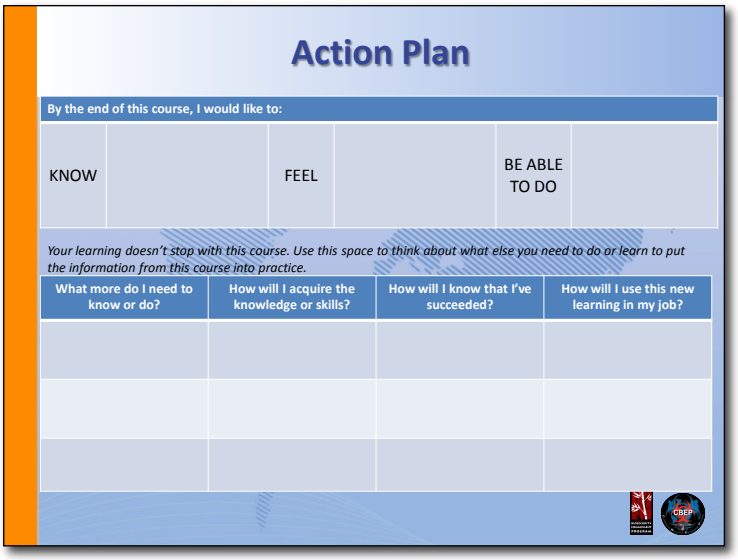
1. Have the class stand up and gather in a circle with plenty of room on the floor. Place a "start" and "finish" card on the floor with plenty of room linearly between them.
2. Pass around the "Debrief Deck" and ask each student to take one card.
3. Ask the students to look at each card and take a minute to think about WHAT concept that card represents (and an example) and also WHERE that concept occurred during the lesson.
4. Ask the student who thinks they have the first card to lay it down toward the "top" of the circle. (You may have to help resolve order – ask the circle what they think). When they lay the card down, ask them to read what the card says and either describe the concept or provide an example that illustrates the importance of the concept. Ask the other students to help fill in the concept, if needed.
5. Ask for the "next" concept. And repeat step #4 until all the cards and concepts have been laid down.

Run the Key Message Debrief activity.

1. Stay in the Recap circle.
2. Ask each student to name 1) the most valuable thing they learned during the lesson and 2) how they intend to use what they learned in their work.
3. As each student completes Step #2, hand them their certificate of completion and offer your congratulations.
4. Once every student completes #2 and has their certificate, ask the students to return to their seats.

Review

Slide 35



Ask students to spend a few minutes reviewing and completing their action plan.

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Review

Level 1 Evaluation

Ask students to complete the lesson evaluation and to put it in the evaluation box (alternately, give students instructions for completing the evaluation on-line).