

Developing, Evaluating, and Validating Standard Operating Procedures

SAND2012-0246C

Student Guide





Developing, Evaluating, and Validating Standard Operating Procedures

Welcome & Intro Objections

Course Objectives

- Understand what an “SOP” is and how the document is used in biorisk management procedures
- Develop validated lab-level SOPs

Course Objectives, continued

S =	
O =	<ul style="list-style-type: none">• Explain what an SOP is and how it is used.
P =	<ul style="list-style-type: none">• Compare examples of SOPs used elsewhere and compare the effectiveness of each approach.
What	<ul style="list-style-type: none">• Write an SOP
When	<ul style="list-style-type: none">• Evaluate an SOP
How	<ul style="list-style-type: none">• Validate an SOP

How do you know if an SOP is working?

S
O
P
W
W
H



Developing Evaluating, and Validating Standard Operating Procedures

What is an SOP?

What is an SOP?

- S
- O
- P
- What does “SOP” stand for?
- What is an SOP?
- When do you need an SOP?
- How do you know if an SOP is working?



S =

O =

P =

What is an SOP?

When do you need an SOP?

How do you know if an SOP is working?



Developing Evaluating, 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.



How many different outcomes resulted from this simple SOP?

Why were there different results?

What is missing in this SOP?



Developing Evaluating, and Validating Standard Operating Procedures

What is an 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>



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What is an SOP?

Testing an SOP

- Did you understand the SOP?
- Could you physically do what the SOP asked?
- Was the outcome the intended outcome?
- Did different individuals achieve the same outcome?

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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Developing Evaluating, and Validating Standard Operating Procedures Writing an SOP

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.”



Developing Evaluating, and Validating Standard Operating Procedures

Writing an SOP

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



What is an example of a policy?

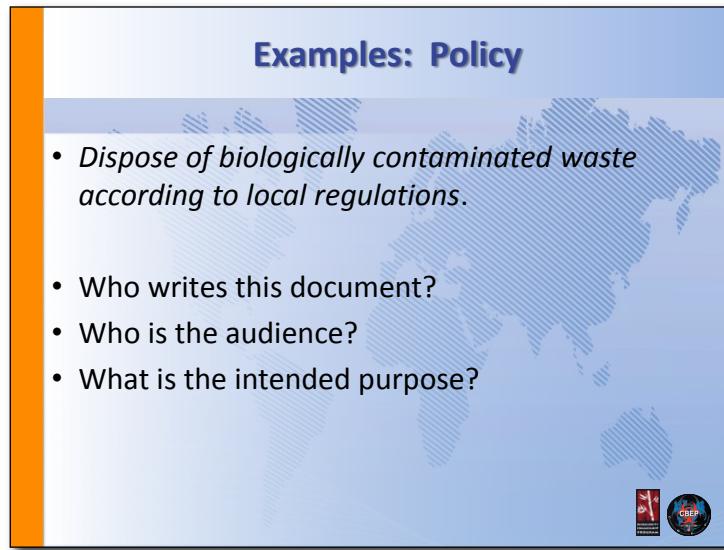
What is an example of a plan?

What is an example of a procedure?



Developing Evaluating, and Validating Standard Operating Procedures

Writing an SOP

A slide titled "Examples: Policy" with a blue world map background. It contains a bulleted list of policy examples and a small circular logo in the bottom right corner.

Examples: Policy

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

 CBEP

For a policy . . .

Who writes a policy?

Who is the audience?

What is the intended purpose?



Developing Standard Operating Procedures

Writing an SOP

Example: Program Plan

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

- Method of final decontamination and disposal
- Method of transport from point of generation to point of final decontamination and disposal
- Labeled waste containers
- Labeled (or colored) waste bags
- Training for all roles involved in waste disposal
- etc.
- *Along with the details required for each of the above to be in place and effective.*

Who writes this document?

Who is the audience?

What is the intended purpose?

 CBEP

Who writes this document?

Who is the audience?

What is the intended purpose?



Developing Standard Operating Procedures

Writing an SOP

Examples: Procedure

- *To dispose of contaminated laboratory waste, take the following actions:*
 - Step 1.
 - Step 2
 - Step 3, etc.
- Who writes this document?
- Who is the audience?
- What is the intended purpose



For a procedure . . .

Who writes a procedure?

Who is the audience?

What is the intended purpose?

Is the procedure that you brought with you a policy, a program plan, or a procedure? Or a combination?



Developing Standard Operating Procedures

Writing an SOP



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.



Developing Standard Operating Procedures

Writing an SOP

Conditions

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

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?

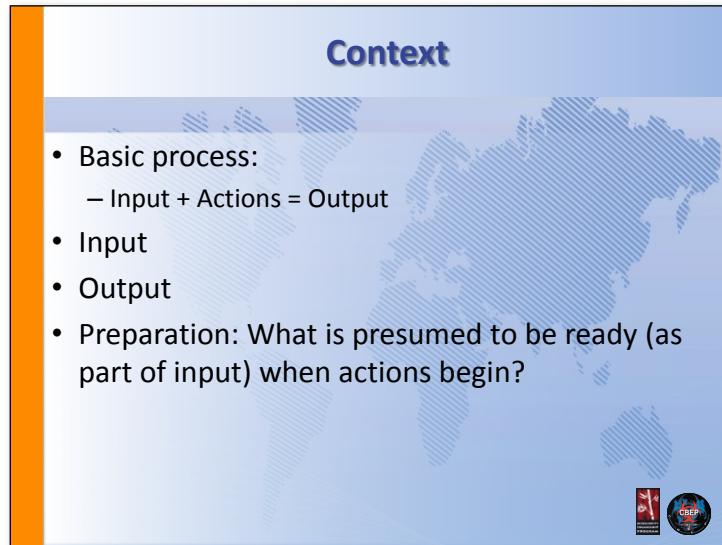
Why should the SOP be used?

Where should it be used?



Developing Standard Operating Procedures

Writing an SOP

A slide titled "Context" with a world map background. It contains a bulleted list of concepts related to standard operating procedures. The slide is framed by a blue border and has a vertical orange bar on the left. Logos for the International Society for Standardization of Laboratory and Clinical Tests (ISOLAB) and the Clinical Laboratory Standardization (CLSI) are visible at the bottom right.

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

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?



Developing Standard Operating Procedures

Writing an SOP

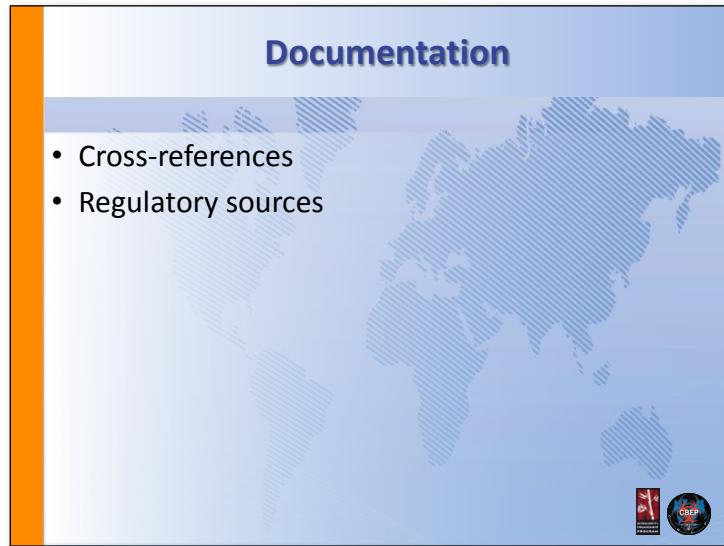
Actions

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)?



Developing Standard Operating Procedures

Writing an SOP



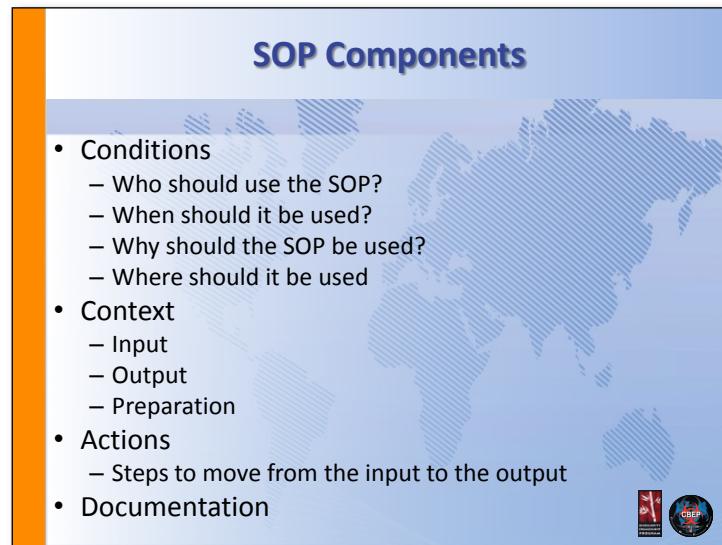
What kind of cross-references can you think of that would be commonly used in SOPs?

What are typical regulatory sources that might be referred to in biorisk management SOPs?



Developing Standard Operating Procedures

Writing an SOP

A slide titled "SOP Components" with a world map background. It lists five components: Conditions, Context, Actions, and Documentation, each with sub-points. A small circular logo is in the bottom right corner.

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
 - Output
 - Preparation
- Actions
 - Steps to move from the input to the output
- Documentation

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?



Developing Standard Operating Procedures

Writing an SOP

Write your own 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.



Developing, Evaluating, and Validating Standard Operating Procedures

Review and Wrap-Up

Testing an SOP

- Did you understand the SOP?
- Could you physically do what the SOP asked?
- Was the outcome the intended outcome?
- Did different individuals achieve the same outcome?

Was the SOP clear?

Could you execute the SOP?

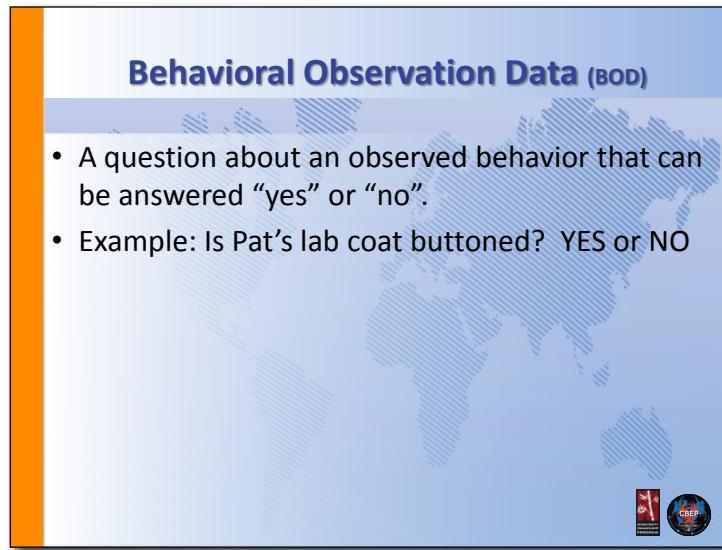
Did you reach the intended outcome?

Variations?



Developing, Evaluating, and Validating Standard Operating Procedures

Behavioral Observation Data

A slide titled "Behavioral Observation Data (BOD)" with a blue header and a world map background. It contains two bullet points: "A question about an observed behavior that can be answered "yes" or "no"." and "Example: Is Pat's lab coat buttoned? YES or NO".

Behavioral Observation Data (BOD)

- A question about an observed behavior that can be answered "yes" or "no".
- Example: Is Pat's lab coat buttoned? YES or NO

Examples:



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Behavioral Observation Data

BOD Activity

- Using the SOP template on page X of your workbook, 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.

How can BOD be applied to your SOP?





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Behavioral Observation Data

Standard Operating Procedure

Notes:



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Behavioral Observation Data

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.

How can BOD be applied to your SOP?





Developing, Evaluating, and Validating Standard Operating Procedures

Behavioral Observation Data

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.

Name some considerations of BOD:



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Behavioral Observation Data

A world map graphic with a blue and white striped background. The map is visible in the background of the slide content.

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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Behavioral Observation Data

Keeping SOPs current

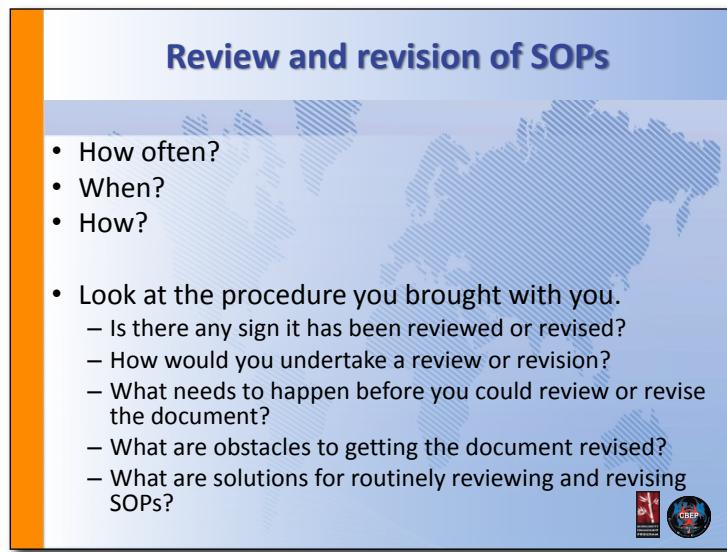
- What can happen, over time, to compliance with SOPs?
- How do you make sure that SOPs remain relevant?
- How do you increase the likelihood that SOPs will be followed?

Notes:



Developing, Evaluating, and Validating Standard Operating Procedures

Behavioral Observation Data

A slide titled "Review and revision of SOPs" with a world map background. It contains a bulleted list of questions and a small logo in the bottom right corner.

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?

 CBEP

How Often?

When?

How?

Review your SOP:



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Review

Review of SOPs

Review

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?





Action Plan

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

KNOW		FEEL		BE ABLE TO DO	
------	--	------	--	------------------	--

Your learning doesn't stop with this course. Use this space to think about what else you need to do or learn to put the information from this course 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?

