INTRODUCTION TO BIORISK MANAGEMENT

STANDARD OPERATING PROCEDURES

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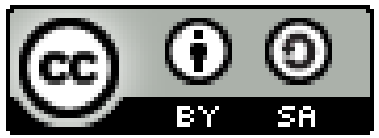
LICENSE



INTRODUCTION

This lecture has been designed and developed to introduce you to the **concept of the Standard Operating Procedure (SOP).**

LEARNING OBJECTIVES

The objectives of this lecture are:

1. To introduce you to the **concept** of SOP.
2. To introduce you to the **process of development of an SOP.**
3. To provide **guidance** on development of your own specific **SOP.**

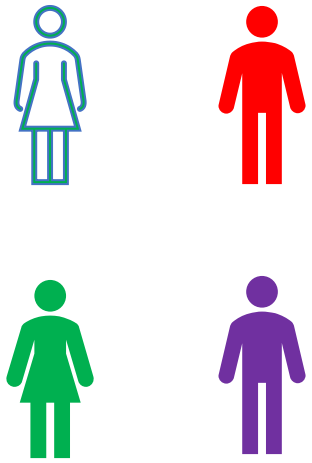
LEARNING OUTCOMES

Upon completion of this module you should demonstrate the ability to:

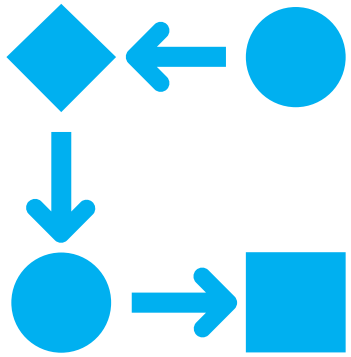
1. Describe the **function** of an SOP.
2. Describe the procedure of design, development, implementation and improvement of an SOP.
3. **Design and develop** a basic Standard Operating Procedure **(SOP).**

GOAL OF AN SOP

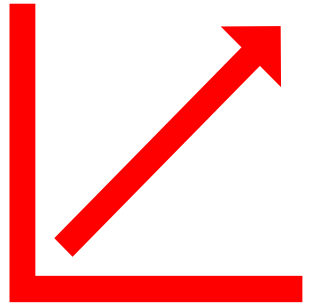
- Reproducibility.
- Ensures that different individuals performing the same procedure obtain a similar result.



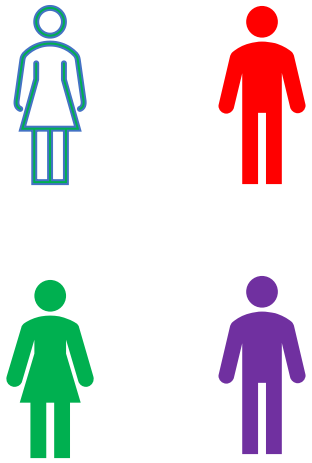
Different Laboratory Workers



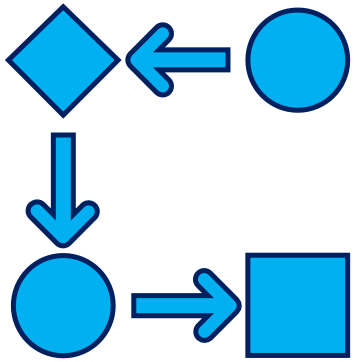
Same Process
SOP



Same Result



Different Laboratory Workers



Same Process
SOP

Different results!

INSTRUCTIONAL DOCUMENT

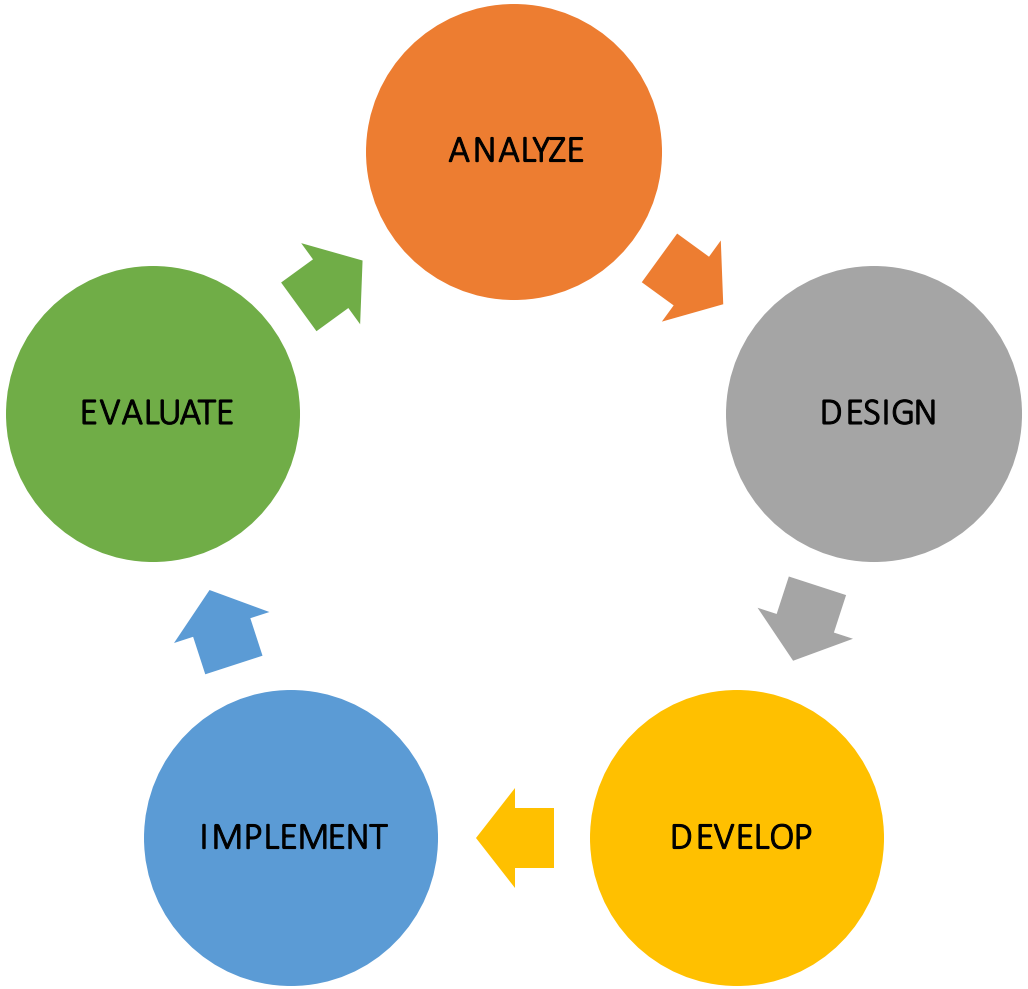
- Reader **centered.**
- **Engages** the end users during the developmental process.

INSTRUCTIONAL DOCUMENT

- Instructional documents teach a **reader** to:
  - **Understand** a rule or principle.
  - **Envision** a process or workflow.
  - **Perform** a task.
  - **Use** a tool.

DEVELOPMENT OF AN SOP

SOP DEVELOPMENT



INSTRUCTIONAL DOCUMENT

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**

POLICY DOCUMENTS

EXAMPLE: Dispose of biological waste in compliance with national regulations.

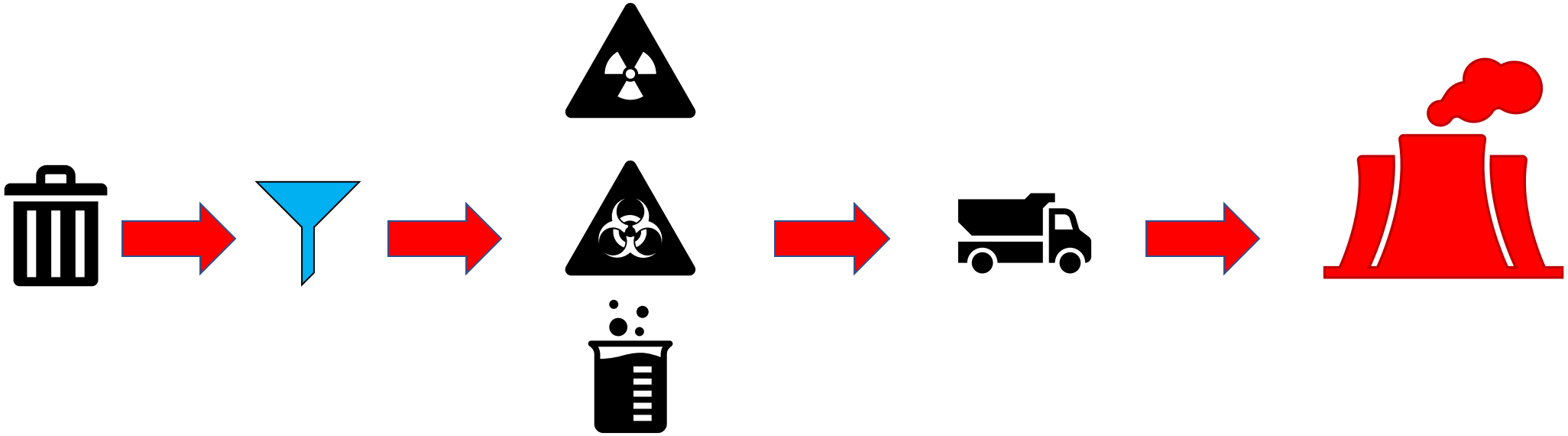
- Who writes this document?
- Who is the audience?
- What is the intended purpose?

POLICY DOCUMENTS

EXAMPLE: Dispose of biological waste in compliance with national regulations.

- Who writes this document? Biorisk manager in consultation with laboratory workers and management.
- Who is the audience? Laboratory workers and external contractor.
- What is the intended purpose? Ensure the safe disposal of biological waste in compliance with national regulations.

PROGRAM PLAN



PROGRAM PLAN

The following must be in place:

- Procedure for **collection** of waste.
- Procedure for **segregation** of waste.
- Procedure for **tansport** of waste.
- Procedure for the **decontamination and neutraliztion** of waste.
- Labels and signage.
- Training.
- PPEs.

SOP: SECTIONS

Conditions

Context

Actions

Documentation

CONDITIONS

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

CONDITIONS

- **Who** should use the SOP? Laboratory workers.
- **When** should it be used? During disposal of laboratory waste.
- **Why** should the SOP be used? To ensure the safe disposal of biological waste.
- **Where** should it be used? Containment facility, transport and disposal facility.

CONTEXT

- Basic process:
  - Input + Actions = Output
- Input
- Output
- Preparation: assumed readiness before implemntation of the SOP.

CONTEXT

The following measures exist:

- Trained personnel.
- Competent personnel.
- Facilities for storage.
- Facilities for segregation.
- Facilities for transport.
- Facilities for decontamination.

ACTIONS

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

ACTIONS

Steps	Action	Checklist
1	Place all the waste from the facility into the designated containers	
2	Label the containers with the designated label(s).	
3	Transfer the containers to the staging area.	
4	Inform the shipper when 50% of the staging area has been occupied.	
5	Transfer the containers onto the transport vehicle.	
6	Secure the containers	
7	Transport to the designated facility.	

DOCUMENTATION

- Cross-references: guidelines and best practices.
- Regulatory sources: national laws on disposal of biological waste.

IMPLEMENTATION: TESTING SOP

- Comprehension: do you understand the SOP? If no, why?
- Implementation: Could you physically do what the SOP asked? If no, why?
- **Reproducibility:** Was the outcome the intended outcome? If no, why?
- **Consistency:** Did different individuals achieve the same outcome? If no, why?

VALIDATION

Behavioral Observation Data (BOD)

- A **question about an observed behavior** that can be answered “yes” or “no”.
- Example: Does X don his biosafety suit in compliance with the SOP: YES or NO
- Useful in validating SOPs

BEHAVIOURAL OBSERVATION DATA

Useful for checking and validating SOPs

Objective assessment.

Observers will also improve.

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

BEHAVIOURAL OBSERVATION DATA

Involve personnel who will be observed when developing BOD questionnaire.

Consistency.

Self-audit: provides a more realistic overview.

APPROVAL OF SOP

The SOP must be **approved**, and the process of approval must be documented.

This may involve a consultative session between the biorisk managers and the key stakeholders.

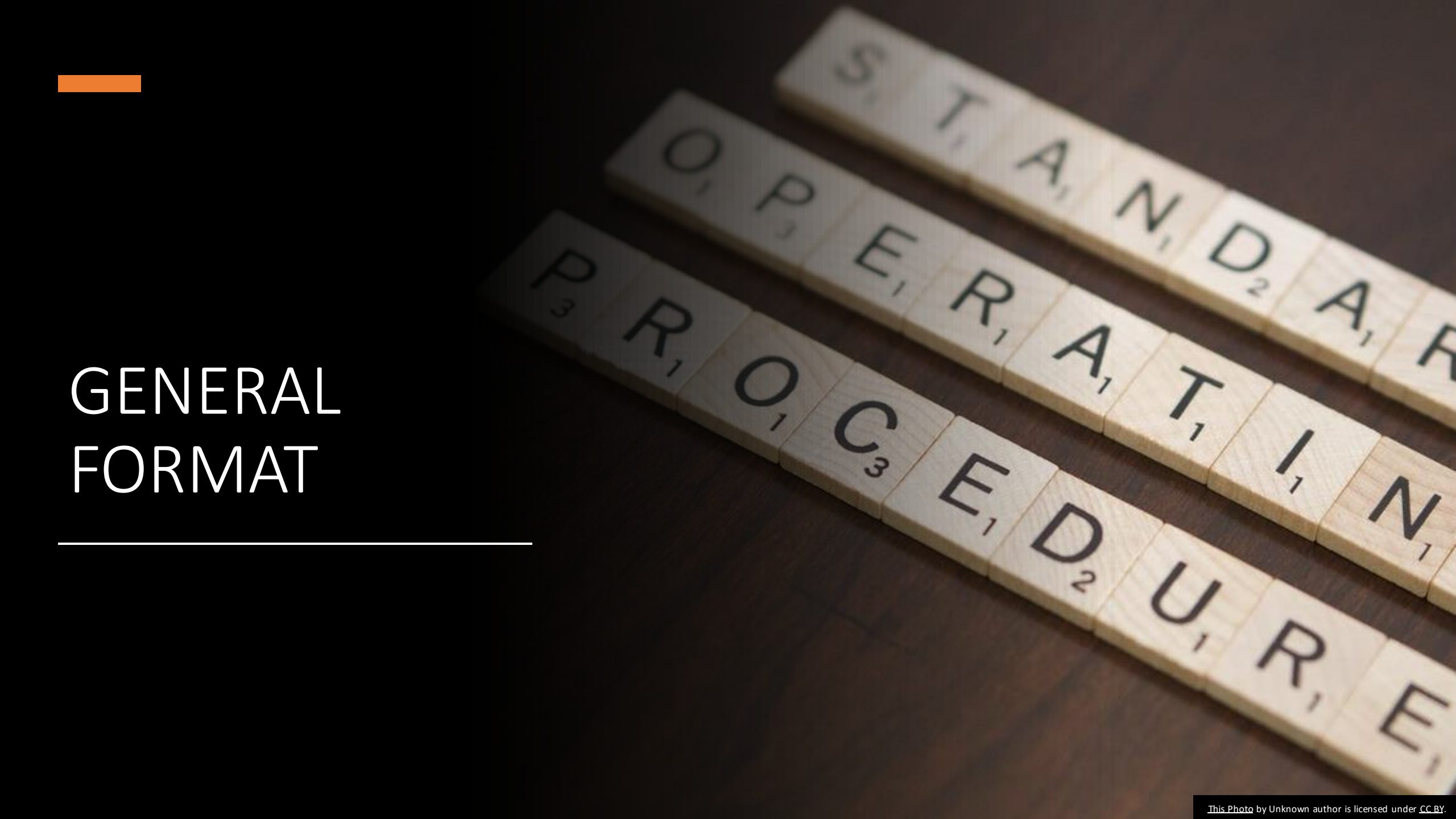
REVISION AND REVIEW OF SOP

- **How often** does an SOP have to be reviewed?
- **When** is there a need to review an SOP?
- **How will** the SOP be revised?

REVISION AND REVIEW OF SOP

- 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?

GENERAL FORMAT



TITLE PAGE	Title
TABLE OF CONTENTS	For SOPs with more than 3 pages.
DEFINITIONS	Definition of specific words or terms.
PURPOSE	The purpose of the SOP from a regulatory context.
PROCEDURES	The specific actions for implementation.
HEALTH AND SAFETY WARNINGS	Procedures which may pose a risk to health.
CAUTIONS	Concurrent SOPs.
INTERFERENCES	Concurrent SOPs.
QUALITY ASSURANCE AND QUALITY CONTROL	Scope within the QC/QA

TITLE PAGE	
REFERENCES	Guidelines, other SOPs which have been cited.
CONTACT LIST	Author(s) / Biorisk Manager
APPENDICES	Related SOPs (if any).
DISTRIBUTION	SOP Administrator decides on the number of copies.
ARCHIVING	Available for audits.

KEY MESSAGES: SOP

Instructional documents which ensure reproducibility.

Designed to achieve a single outcome.

Effective **SOP writing takes** key components into account.

Validation and evaluation of SOPs are critical to CQI.

THANK YOU