

# Writing of standard operating procedures

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# WHAT IS SOP?

Standard operating procedures are a set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness.

**SOP** is a set of written instructions that document a routine or repetitive activity.

**SOPs**: Detailed written instructions to achieve uniformity of the performance of a specific function.

# WHY WRITE SOPs?

To provide people with all the information necessary to perform a job properly (i.e. a training tool)

To ensure that the procedures are performed correctly and consistently

To ensure compliance with guidelines.

# WHY WRITE SOPs?

To serve as a checklist for auditors

To serve as an explanation of steps in a process so they can be reviewed in accident investigations.

To serve as a historical record of the how, why and when of steps in an existing process occurred

# WHY WRITE SOPs?

To Ensure Safety

Maximize operational and production requirements

# WHY WRITE SOPs?

Most regulatory and accrediting agencies require that those who perform procedures have the education, experience and training to do so.

# WHY WRITE SOPs?

SOPs are the foundation of training!



# REGULATORY REQUIREMENTS

Good Laboratory Practice

21 CFR 58.81(a)

A testing facility shall have standard operating procedures in writing setting forth laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study.

# REGULATORY REQUIREMENTS

Strive to create a culture of  
compliance

# IMPORTANT POINTS

SOP is not a Policy

A policy tells you **WHAT** you will do,

SOP tells you **HOW** you will do it!

# WRITING “GOOD” SOPs

Accurate

Up to Date

Easy To Understand and Follow

Accomplishes the purpose for which it is written

# SUGGESTED FORMAT

**PURPOSE**

**SCOPE**

**RESPONSIBILITY**

**REFERENCES**

**DEFINITIONS**

**PROCEDURE**

**ATTACHMENTS**

**REVISION HISTORY**

# TITLE

This must describe in sufficient detail the focus of the SOP so that anyone can tell from the title the content of the SOP when searching a list of SOPs

This More Important Than You Think!

## PURPOSE

### What You Want To Accomplish

This often will duplicate the title of the SOP

Title: Writing, Review and Approval of Standard Operating Procedures

The Purpose of this procedure is to define the process used to write, review and approve standard operating procedures of the Quality Assurance Unit

# SCOPE

The scope defines the area to which the SOP applies

This procedure applies to all policies and procedures used by the Quality Assurance Unit



# RESPONSIBILITY

This states who has responsibility for training and execution of the SOP:

It is the responsibility of the Quality Assurance Manager or designee to assure that all Quality Assurance Specialists are trained on and comply with this standard operating procedure

# RESPONSIBILITY

You may want to include other statements in the responsibility section as suggested by your accrediting body.

You must state this in your SOP on SOPs

# REFERENCES

List all references that serve as the basis for the SOP

Do not list regulations, text books, standards, or articles, etc. without reference to sections or page numbers!

# DEFINITIONS

List all definitions that are essential to an understanding of the SOP including all acronyms

# SOME GUIDELINES

Use words such as:

Shall

Must

Will

When more than one person carries out an activity

Do not use

Should

May

# SOME GUIDELINES

Begin each activity with an active verb such as:

Analyze

Begin

Check

Delete

Enter

Start

Store

Submit

When only one person carries out an activity

# SOME GUIDELINES

Do not begin a step with a conditional phrase such led by When, After, If

Avoid Jargon and Abbreviations Unless Defined

Avoid Complexity

# PROCEDURE

## 6.0 Procedure

### 6.1 Writing a new document

6.1.1 Any staff member shall submit a written draft to the Quality Manager for consideration

6.1.2 The Manager shall discuss the submitted draft with the submitting staff member to make any changes necessary prior to circulating a draft for review.



# PROCEDURE

- 6.1.3 The Manager or designee shall circulate the draft to all appropriate staff for review and comment.
- 6.1.4 Each reviewer shall make changes and comments in red ink on the draft if necessary, initial and date any changes, and send the draft to the next available reviewer.
- 6.1.5 The last reviewer shall return the draft to the Manager for review and comment.

# ATTACHMENTS

Any forms, logs or other documents that are essential to the execution of the SOP and mentioned in the SOP shall be attached to the SOP

# REVISION HISTORY

This will include a detailed list of what changed in the revision.

It is extremely important to know what changed and when it was done

(Inspections, Accidents, Attorneys)

SOP Title	Concise but descriptive enough
SOP No.	Allocate no, review and approve
Prepared by	Identifies personnel
Prepared for	List of organisation / project
Version	Allocate when SOP is approved Increases incrementally by hundredths ( e.g. 1.1, 1.2 ....) for minor changes Major revision designated by next whole number ( version 2.0. 3.0. ....)

Revision history log

Records version number, revision date, author, brief summary of the changes

Approved by

Authorized personnel

Acknowledgement

List of other personnel

Table of content

quick reference, locate information

(SOP title, No., Purpose, scope, etc)

Purpose

Provide background information on the procedure

## Scope

Agencies and jurisdiction to which SOP will apply

Identifies those personnel who should be familiar with its content

## Definitions

Unfamiliar content

Provide references

## Procedure outline

describes when and how procedure done including troubleshooting

Principle, Materials and reagents, flow charts /tables /charts, step by step Interpretation,reference

# A standard operating procedure (SOP)

- a set of step by step instructions for carrying out a specific technique.
- focuses in documenting monitoring techniques.
- Provide quality assurance
- It should clear, concise with enough detail
- Helps users with basic understanding with limited experience can reproduce

# Advantages of SOPs

- Provide step by step instructions on a specific procedure with minimum variability.
- ensures procedures performed consistently and in compliance with guidelines.
- protect health and safety of personnel
- facilitate training
- Serves as a record, helps in modification
- promote quality
- encourage improvements and work evaluation



THANK YOU