

STANDARD OPERATING PROCEDURE

Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity.

BENEFITS OF SOP

- To perform a job properly.
- To ensure that production operations are performed consistently.
- To ensure that processes continue uninterrupted and are completed on a prescribed schedule.
- To ensure that no failures occur in manufacturing and other processes for which the SOP was written.
- To ensure that approved procedures are followed in compliance with company and government regulations.
- To serve as a training document for teaching users about the process.
- To serve as a checklist for co-workers who observe job performance to reinforce proper performance.
- To serve as a checklist for auditors.
- To serve as an historical record for the changeover.
- To serve as an explanation in review of accident investigations.

SOP PROCESS

1. SOP preparation
2. SOP review and approval
3. Frequency of revisions and reviews
4. Implementing SOP
5. Management of SOP

Typical Structure of SOP

The content of a Standard-Operation-Procedure should include the following minimum

- | | |
|----------------------------|---------------------------------------|
| • Title page | • Responsibilities & accountabilities |
| • Hester's Logo | • Procedure |
| • Header with title of SOP | • Footer |
| • Department Name | Approving Signatures |
| • Effective date | ✓ Prepared by |
| • Revision date | ✓ Checked by |
| • Review date | ✓ Approved by |
| • Page No | • Stamp |
| • Regulatory basis | ✓ Controlled Copy/Master Copy |
| • Reference documents | ✓ QA Stamp |
| • Purpose | |
| • Scope | |

SOP WRITING STYLE

- SOPs shall be written in a concise, step by step, easy to read and follow format.
- Information should not be complicated.
- The active voice and present verb tense should be used.
- Should be simple and short.
- Move from one step to another step in logical manner.
- Highlight exception. Use a symbol to flag that this is an exception and how to handle it.
- Routine procedures that are short and require few decisions can be written using simple steps format.
- Long procedures consisting of more than 10 steps, with few decisions should be written along with graphical format or hierarchical steps.
- Procedures that require many decisions should be written along with flow chart.
- Requirement for document identification and control, accountability and traceability responsibility must be included with every SOP; this can be achieved by providing consistent format.
- Highlight warning. Again, warn users that caution must be used in this scenario. Warning must stand out; use a larger font or a warning icon.
- Reduce the word count where possible without altering the meaning of the text.
- Introduce acronyms without explaining what it means.
- Don't use the word "may", "if possible" as it implies that the user can do something under conditions. Instead, be positive and tell them what to do.

GENERAL FORMAT FOR SOP

SOP Number: Procedures must be easily identified by giving unique number and version number. This identification number of the SOP supports accountability of the document throughout the facility and over time as it changes.

Title: The title should be descriptive. The title should use directive language to declare what is being done to what.

Department: The company name and pagination (e.g. page 4 of 7) must appear on every page.

Date: Date of preparation.

Revision number: Number of revisions done.

Effective date: Date when the SOP will be in operation/ implementation.

Objective: The purpose or objective of the procedure should restate and expand well written title. Expand or qualify the directive language used in the title (e.g. to describe the operation procedure of compression machine)

Scope: The scope should provide limits to the use of procedure. The scope shall be written in such a way that it answers following questions....

- Are there certain samples that are appropriate to test by this method?
- Do these operations apply only to certain equipment or certain departments?
- Is there a limit to the capacity, volume, or throughout of the procedure?
- State to what areas this procedure does apply and does not apply?

Responsibility: Who is responsible for performing the work described? Who is responsible for implementing the procedure?

Material equipment: What is needed to perform the test? It should be specific.

Procedure: Describe the procedure in a step by step, chronological manner. Use active verbs and direct statements.

Procedure includes:

- Preliminary test
- Safety consideration
- Chronological instruction
- Calculation

Reporting: What is going to happen next?

Abbreviation: Details of abbreviations included in SOP.

Reference document: Written by Edited by.... Authorizes by....

REVIEW AND APPROVAL:

All SOPs shall have space for signature of initiator (the person who has written the SOP) Reviewer (The persons who has reviewed the SOP) and approver (Quality Assurance Head of the organization).

IMPLEMENTING SOP:

SOP is implemented to train or retrain the user. The trainer should share the reason why SOP must be performed correctly. They should explain how each and every step in SOP should be performed and assure them that this will increase the quality of the product.

MANAGEMENT OF SOP:

Record should be there for issue and distribution of SOP.

- It is the responsibility of the process owner to
- Ensure the SOPs are current.
- Eliminate obsolete SOP's
- Ensures it meets quality requirements and are user friendly.
- Manages change controls
- Distribute SOP's
- Continuously improves the system.
- Measures system performance and periodically reports to management.
- Ensures new or changed SOPs are valid only after changes have occurred.