

The Quick Guide to Writing Standard Operating Procedures (SOPs)

Table of Contents

The Quick Guide to Writing Standard Operating Procedures (SOPs)	1-10
What is a Standard Operating Procedure?	1
Common Use Cases	2
Why Write a Standard Operating Procedure?	2
The Most Important Things To Keep In Mind When Writing SOPs	3
Where Do I Start And What Are The Main Steps?	3
What Do I Do With SOPs Once They Are Approved?	5
5 Things To Remember When Writing SOPs	7
The Business Case For Writing Good SOPs	7
5 Expected Results From Implementing A Well-Defined SOP System/Knowledge Transfer System	8
The CCCs of SOPs	8
Automatically Generate SOP Job Aids And Training Materials in Minutes	9
Are You Ready To Get Started?	11

Appendix	12-15
Critical SOP Document Specifications	12
SOP Document Outline Structure	12
Purpose	12
Scope	13
General Requirements (Overall Task Description)	13
Responsibilities	13
Definitions	13
Materials And Equipment	14
Policy/Procedure(s)	14
Describe Each Task In Detail	14
Avoid Long Lists Of Steps!	14
Regulatory Review	15
Contingencies (Corrective Actions)	15
References	15
Attachments	15
Document History Table	15

The Quick Guide to Writing Standard Operating Procedures (SOPs)

- Does your growing company require better processes for implementing standards and controls?
- Are you spending too much time and money to bring your new employees up to speed?
- When your expert operators retire, will their replacements be able to continue the level of quality and production you expect?
- Can you verify that your employees are qualified to follow your established standards properly?

If you are like most operations managers, you need tools to help you rapidly create custom training and job aids so you can implement quality standards across your entire workforce and train new hires quickly.

Standard Operating Procedures (SOPs) maximize the speed with which new employees learn their duties and make sure they do their job in an effective and consistent way.

What Is A Standing Operating Procedure?

A standard operating procedure, or SOP, provides a set of step-by-step instructions compiled by experts at an organization to help workers implement complex routine operations.

SOPs can be written for processes that an individual or group perform in many situations:

- Manufacturing: Unloading raw materials, manufacturing products, shutting down an operation, repairing a faulty electrical circuit, etc.
- **Healthcare**: Working with patients in a hospital, processing pharmaceuticals, reporting accurate patient medical history data, etc.
- Consumer Goods: Producing consumer goods and services, tracking product development, supporting packaging and logistics, etc.
- **Services**: Working in food service, performing activities in a firehouse, and thousands of other workplace activities, etc.

Common Use Cases

Compliance

- Pharmaceutical manufacturers capture SOPs and generate checklists and job aids for clean rooms
- Hospitals capture Lab Protocols with supporting checklists and quick reference cards

Efficiency

- Manufacturers create work instructions for equipment set-up, operations, shut-down, and downtime maintenance protocols
- Logistic companies train remote control crane operators at ports

• Standardization And Consistency

- Government Agencies standardize training and support across multiple international locations
- Aluminum plants standardize SOPs and Work Instructions, fully integrated with SharePoint, at some of the largest international locations

Why Write A Standard Operating Procedure?

The aim of the SOP is to achieve efficiency, improve safety, produce quality output, and guarantee uniformity of performance. Essentially, the SOP improves standardization and efficiency, eliminates miscommunication, and minimizes risk of failure to comply with industry regulations.

There are many reasons to use SOPs in your organization, including:

- Improve safety and operational effectiveness;
- Streamline and preserve company processes and knowledge;
- Support regulatory compliance and evaluation;
- Enforce quality assurance;
- Create consistently formatted, easy to follow workflows.

The Most Important Things To Keep In Mind When Writing SOPs

The most important things to do when creating SOPs are:

- Make sure you keep your audience in mind, as well as your regulatory auditors;
- Define what the process, procedure or protocol is intended to accomplish;
- Specify the purpose, scope and general requirements to be met;
- List the specific procedure to be followed in the most efficient manner;
- Include terms and definitions unique to the SOP.

Where Do I Start And What Are The Main Steps?

1. Identify all subject matter experts that know the process well.

• Subject matter experts (SMEs) can be found throughout your organization, across multiple departments. Some processes are touched by multiple people along the way and it is important to get information from all of these employees when creating your SOP. The operations managers are often the best resource for identifying the experts in each area.

2. Gather any existing resources related to the process or procedure.

• Review all existing legacy SOPs for your target area. Many of these will be brief, requiring only minor revisions, but be prepared to replace some legacy SOPs, add additional procedural information to existing SOPs, and create new SOPs to fill gaps.

3. Identify who needs to review and approve SOPs.

• Make sure the SOPs are consistent with your company's policies and are supported by your work instructions.

4. Collect key information regarding your SOP*.

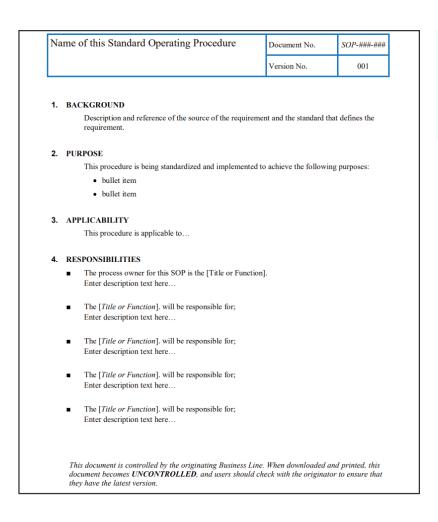
- The purpose, scope, general requirements, terms and definitions, and roles and responsibilities for each SOP need to be clearly defined.
- Including the most specific information you can in each procedure step, including images, charts, related documents, and expected outputs, will improve the quality of your SOP.

5. Decide where the SOP process lives.

- Decide how the SOPs will be organized, stored, reviewed, and approved.
- It is important to retain revision history and document control throughout the process of defining the official/final SOP.

6. Create your SOPs with a consistent structure, format, and look and feel.

- This will help with regulatory audits and reduce the risk of non-compliance.
- Using a predefined SOP template with standard output formats will save you considerable time and cost
- Successful SOP systems need to be consistent, concurrent, and compliant.



SOP Example

A well-structured SOP has a format that is easily followed and provides consistency across the organization.

7. Follow a well defined review and approval workflow for all SOPs.

- Identify the technical specialist in each department to review your SOP content.
- Identify appropriate operations managers, quality assurance specialists, and maintenance engineers to approve the final version of each SOP.

What Do I Do With SOPs Once They Are Approved?

- 8. Train your employees on your SOPs. SOPs are worthless if they aren't understood and utilized.
 - Training your employees on new and revised SOPs is critical to the success of your program.
 - Training materials need to made available in the most appropriate format for easy access by employees, including SOP job aids, checklists, PowerPoint slides and online training.
 - Develop methods to track and record employee SOP comprehension prior to having them implement the SOP.

INSTRUCTIONS FOR TURNING CAPPER ON AND OFF:

To turn the capper on make sure there are no containers in the capper or on the capper conveyor.

To Turn the Capper On:



No Containers are in the capper or on the capper conveyor.

Move the main power switch to the on position by turning it clockwise.



The ON position is straight up on the switch.

Verify that the air pressure on the gauge is showing a minimum of 80 lbs psi.



The capper requires a minimum of 80 psi to operate. Normal air pressure would usually be in the 100-120 psi range.

Check to be sure the RED round E-stop button is pulled out.



Notice the round E-Stop button at the very top of the panel.

Verify that all doors on all sides of the capping machine are in the closed position and all door contacts are made.



October 13 LH 3 Resina Capper

Quick Reference Card Example

Quick Reference Cards can be used to train employees to follow standard operating procedures, step-by-step.

- 9. SOPs need to be consistently disseminated across the organization. Put the approved SOPs in a place that is accessible to employees when and where they need it at their job site.
 - SOPs need to be made available in multiple formats, both digital and print.
 - Appropriate SOPs for each job/role need to be conveniently organized in a searchable indexed format

10. Revise and reiterate.

- Your system must allow for regular review with appropriate revisions for all critical SOPs.
- SOPs should not be set in stone. They should be updated and improved continuously as new efficiencies, tools, and systems arise. Look at it as a living, breathing document that will evolve over time.

*PCES TIP



Using a well-defined SOP template will facilitate implementation of your standards and drastically reduce your effort.

5 Things To Remember When Writing SOPs

- Be Concise: SOPs can become much too long and detailed to be helpful.
- Chunk Them: Do not try to put everything into a single SOP. Create multiple SOPs as needed.
- Use Common Language: Make sure your SOP will be easily understood by your target audience.
- Emphasize the What: The SOP states what is to be done—the Work Instruction states how it is to be done.
- Revise and Revise: Make sure your SOP review and approval system allows for easy updates and revisions over time.



*PCES TIP

Talk to multiple departments when writing SOPs to make sure that all angles are covered.

The Business Case For Writing Good SOPs

Communicating the value of an SOP system to your colleagues and boss is an important step in SOP process implementation. Top benefits that show the value of SOP development and implementation include:

- Avoid knowledge loss when employee turnover occurs
- Save time and money
- Increase efficiency



*PCES TIP

Focus on the impact to the company bottom line/ROI to measure the impact of SOP development.

5 Expected Results From Implementing A Well-Defined SOP System/ Knowledge Transfer System

SOP implementation will ensure end-users are able to:

1. Do the right thing at the right time.

Improved Effectiveness: the degree to which the right procedure is successfully processed in the workflow—is this the right step at the right time?

2. Do the right thing in an efficient manner.

Improved Efficiency: the degree to which each procedure is completed correctly—is this step being done well?

3. Do the right thing just once.

Reduced Rework: Get it right the first time—reduce the cost and time required to fix or repair product that should have been completed correctly.

4. Use the SOP to focus your attention.

Improved Focus: the degree to which each employee is focused on an SOP they can follow without distraction.

5. Only do that which is necessary.

Work Elimination: by creating and revising SOPs based on operational experience, many steps can be eliminated, combined, or restructured.

The CCCs of SOPs

Compliance Liability

• Any regulated company in sectors like pharmaceuticals, energy, medical, and food processing needs to stay in compliance with industry standards in order to have operations assure required quality levels.

Consistency And Standardization

• Every company desires consistent policies and procedures to improve operational performance across departments. This is especially critical for mergers and acquisitions looking for a single corporate standard.

• Concurrence, Version Control, One Master Doc To Rule Them All

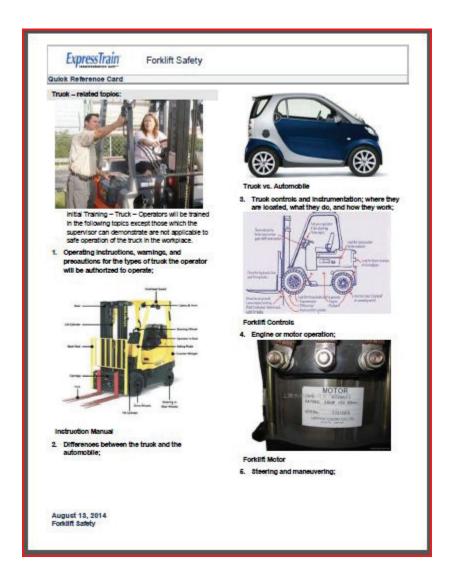
• Keeping standards concurrent is critical to keeping the organization up to speed on the latest (sometimes revised) policies and procedures. Having outdated SOPs can lead to citations and failed audits resulting in significant fines.

Automatically Generate SOP Job Aids And Training Materials in Minutes

Our Express Train Software allows you to enter your SOPs into a *single-source* and automatically create SOPs and job aids and training materials such as checklists, work instructions, and reference cards.

ExpressTrain allows you to enter your content in Microsoft Word templates that:

- Define the proper procedures for equipment setup, startup, operations, shutdown and maintenance protocols.
- Include specific steps in each procedure and elaborate on the most costly, dangerous and/or frequently used tasks.
- Include images, graphics, tables, even videos to help the operator better understand how best to proceed.
- And, enter knowledge-check questions to verify understanding.



Job Aid Example

Job aids based on SOP content can be made available to users in a format that is easy to follow.

Once you enter the content you need, you can automatically generate all your SOP job aids and training materials in minutes, including:

- Work Instructions and User Manuals;
- Job Aids including Checklists and Quick Reference Cards;
- Supervisor Task Qualification Checklists;
- PowerPoint presentations with Leader and Participant Guides;
- Web-based Training and online Quizzes.

Are You Ready To Get Started?

Now that you know what an SOP is and why it's so important, there are three things to keep top-of-mind as you get started.

- 1. Everyone in the organization must see and understand the big picture. If you want people to work together as a productive team they must all have the ultimate goal in mind or they may work at cross purposes.
- 2. People will tolerate the directives of leadership, but they will ultimately act on their own. If the end users and operators do not know what to do, they will make up their own minds about what is best.
- 3. By appealing to the highest level of thinking in your people, you will get the highest level of action, commitment and alignment. This is often overlooked.

If you have questions, want a demo, or would like to talk to an expert to see if ExpressTrain is right for you, email Peter Rizza at <u>prizza@princetoncenter.com</u> or call +1-609-737-8098.

Appendix

Critical SOP Document Specifications

The page header should include the name of the Organization, address and if possible the department or group. The header will then include the SOP Number, Title, Version Number, Page Number, and Effective Date. Often, the author's name of the SOP is in the header.

At the end of the SOP, indicate a section for documenting SOP reviews with space for reviewer's signature and date signed. If the SOP is to be archived or retired, add a line to document this purpose. The page footer should include the complete file name and path.

- Document Title
- Document Class (Policy, Procedure, Process, Directive, etc.)
- Document Number
- Revision Number Version
- Copyright
- Division
- Location
- Department
- Area
- Effective Date
- Author

SOP Document Outline Structure

Purpose

The purpose statement identifies the goal of the SOP. It answers the question of why the SOP is being written. For example, "The purpose of this Standard Operating Procedure (SOP) is to specify the processes used to manage SOPs". The Purpose statement needs to be detailed enough so that the intended user can recognize what the document covers.

- Explain the objective the SOP is intended to achieve.
- To provide individuals who perform operations with all the safety, health, environmental and

operational information required to perform a job properly.

• To ensure that operations are done consistently in order to maintain quality control of processes and products.

Scope

The scope of the SOP identifies who needs to follow the procedure and what the procedure covers. It should help the reader to identify what is (and what is not) covered in the procedure.

- Explain the objective the SOP is intended to achieve.
- Write a scope for the SOP, answering these questions: Which specific operations or tasks within an operation will be covered? Which are not covered?
- Who is the SOP written for?

General Requirements (Overall Task Description)

- Develop an overall task description.
- Include the number of people required for the task, their skill levels, the equipment and supplies required, any personal protective or safety equipment required, and a description of how the finished product or result should look.
- If you need to give some background information, or list any warnings or precautions before performing a procedure, this section is the place to list them. Warnings and cautions should be set out from the regular text by using bold, italics, underlining, or color (or combination).

Responsibilities

State the personnel, departments, groups, contractors, and/or subcontractors responsible for both performing and complying with the SOP. State the person or group responsible for assuring the appropriate personnel are trained on the SOP.

Definitions

Define terms and acronyms that people reading the SOP would not generally know and that would require clarification. If a definition is needed, and one exists in regulations, use the regulation definition.

Materials and Equipment

List all of the materials and equipment needed to complete the procedure. If the procedure is written for the operation of a specific piece of equipment, make sure the user's guide for the machine is listed in the References section, and that users have been trained to operate the equipment prior to performing the procedure.

Policy/Procedure(s)

- Explain the procedure in simple steps. Carefully think about how a procedure is performed from the very beginning.
- Draft the SOP in a flow diagram to help visualize the entire process. Describe specifically what to do, not how to do it.
- Then state who does each step and where it is recorded to be certain that whoever is performing the procedure can prove that they have done it.

Describe Each Task In Detail

In this section, include the following:

- Specific order in which activities are done
- Timing sequences and times allowed
- Materials or tools used and how they are used
- Safety or health considerations
- References to other associated SOPs

Avoid Long Lists Of Steps!

- A long list looks formidable, which makes the task daunting and tedious for many people who then don't want to perform the steps.
- A long list is difficult for your eyes to follow. You forget where you are on the list, which can lead to mistakes.
- A long list scares people and makes them nervous or anxious to "get it over with."
- A long list can hide steps that should be performed with caution.
- A long list is difficult for writers to write while ensuring that the sequence is clear.

The solution to SOPs that involve a long list of steps is to break up the steps into logical sections of about 10 steps per section, such as "Getting ready for the process," "Initial steps," "Final steps."

Regulatory Review

State how often the SOP is reviewed, and/or under what circumstances it is to be revised and indicate who is responsible for reviewing the SOP.

Contingencies (Corrective Actions)

- State what happens if the SOP cannot be followed and requires contingencies. Identify who needs to be notified of contingencies and what documentation is required.
- State what happens when an SOP is incorrectly followed. Include short-term and long-term corrective action measures and how to document the actions.

References

List related SOPs, any supporting documentation necessary to understand and correctly follow the procedure, and any applicable regulations and regulatory guidelines.

Attachments

List applicable forms that are required to be completed in the SOP. Attach any documents used in support of the SOP, e.g., flowcharts, work instructions, pictures or diagrams, forms and labels.

Document History Table

- A separate document should sufficiently detail changes made to an SOP, what parts were affected and when the changes become effective.
- Follow a uniform format for tracking SOP changes; indicate who made the revision, date of revision and the new version number.
- Properly archive an outgoing version and all existing copies to avoid unnecessary confusion.