

SOPs

and the Technical Writer



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Standard operating procedures (SOPs) are sequences of steps for workers to follow to complete tasks. Owing to industry standards and government regulations, SOPs are increasingly in demand. The pharmaceutical sector is a case in point: Companies are expected to conform to GxP (good practices in manufacturing, testing, and other areas). A big part of GxP is the standardization and documentation of production tasks. The ISO 9000 conventions used in other industries have similar requirements. SOPs are typically required for activities such as operating or calibrating a machine, backing up data, testing samples, and requesting approvals of changes in systems.

In a standards-conscious environment, SOPs are supposed to be maintained and followed faithfully, so that they reflect the truth about critical activities. SOPs should be held to a high standard of accuracy and managed so that only current versions are available. The U.S. Food and Drug Administration has been pressing for auditing and control of procedures, not only in manufacturing, but also in support systems such as computer applications. In practice, pharmaceutical companies are complying gradually by creating both SOPs and document management systems.

These circumstances present opportunities for technical writers. I have found that SOP skills are in demand in the health research and pharmaceutical industries, particularly in the area of electronic data systems. SOP writing is not a career, but expertise in it has helped me get work. If you are seeking employment, familiarity with SOPs may enhance your cover letter or job interview.

This article aims to set you on the right track—and help you avoid some mistakes—if you are responsible for producing SOPs or would like to be. I assume that you are a technical writer with analytical and document management skills. You're going to need them.

What SOPs Are (and Are Not)

The phrase “standard operating procedure” is often misinterpreted as signifying either an unregulated habitual practice or a statement of goals or requirements. Here's my take on its meaning, using synonyms:

- “Standard” means *required* or *mandatory*; also *defined*.
- “Operating” means *routine* or *repeated*; also *normal*.

- “Procedure” means *steps* or *sequence*; also *instructions*.

You could say that “SOP” is equivalent to “required routine steps” without going wrong.

SOPs are not fundamentally different in content from other procedural documents, such as instruction manuals, but they are distinctive in format, and they generally exist in coordinated sets that demand rigorous management. The writer of SOPs plays a critical role in an organization, because he or she is defining the activities of the organization itself.

An SOP is a multipurpose object intended to do the following:

- Document (record) a practice, for research and review purposes
- Support compliance with requirements stated elsewhere
- Control process quality to meet standards and produce predictable results
- Train personnel by informing them and by enabling them to conform to instructions
- Coordinate one procedure with others

It is equally important to know what an SOP shouldn't do. First, an SOP should not make policy statements. A policy expresses purposes; a procedure prescribes actions. Unfortunately, some organizations fail to understand this distinction. For example, many SOPs include wording such as “The engineering department should keep the maintenance department informed of all design changes.” This sort of advice is actually a policy. It does not belong in an SOP because it is not a procedure. SOPs that are filled with policy statements but lack steps that people can execute will not be followed. Also, policies

may change without necessarily affecting procedures.

Second, SOPs cannot take the place of effective management. Managers should be happy to know that they are needed, in spite of SOPs, to organize and direct staff and respond to non-routine circumstances.

Third, SOPs should not contain too many facts. Facts often change, and SOPs containing facts tend to become obsolete quickly. Consider, for example, an SOP containing a list of contact names and telephone numbers, perhaps for emergency notification. The names and numbers will probably change often. Instead of including this information in your SOPs, insert references to data sources such as directories, inventories, or specifications.

Finally, SOPs are not complete, all-encompassing instructions. An SOP defines one or more roles to be filled by qualified personnel, and it always presumes that the worker has some background knowledge and skills. The SOP cannot explain everything a worker needs to know or do.

Structure of an SOP

It's fairly obvious that standardization should be applied to SOPs. They should contain required elements organized within a fixed structure. There is no universal standard for SOP structure; what follows is a suggested form.

Front Matter

An SOP should have a title, document number, effective date, version, document approval and ownership information, applicability information, and cross-references. Organizations that have document management systems may define these items as metadata and store them in a database.

Purpose

Summarize what the SOP's steps accomplish.

Scope

Delineate the applicability of the SOP, preferably in simple language. Scoping requires joint deliberation by the subject matter experts (SMEs) and the technical

writer, who should know how each SOP fits into the overall collection.

Definitions

Translate all acronyms and define specialized terms that cannot be found in the organization's glossary.

Roles and Responsibilities

List roles that are appropriate for the SOP, such as "analyst," "installer," or "requester." Define each role in terms of who may fill it. For example, the installer may be "a member of the operations department." Briefly describe the responsibility associated with the role, if it is not obvious. Be aware that assigning a person to a role is a management function, so there should be some flexibility in case of absences.

Procedure

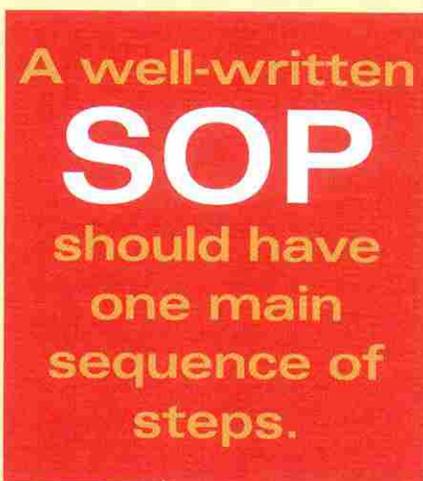
The procedure consists of activity steps assigned to roles. For a simple SOP, it's nice to have a table with three columns: Step Number, Role, and Activity. A simple SOP has the steps in a temporal sequence. Be flexible, however: In many environments it's all right to say "Perform this step as soon as possible." SOPs are not intended to eliminate all judgment and discretion.

Knowledge Management Provisions

Knowledge processing is a given in an environment requiring SOPs. For example, the SOP may specify documents to be signed (and then deposited somewhere) or records to be updated. These steps may or may not fit in the procedure section.

The Research Process

As a technical writer, you know how to locate and interview SMEs, take notes, analyze source documents, organize content, and write precisely. But if you have experience only with user documentation, you may find working on SOPs awkward at first, because the inputs you seek are not purely technical. Procedures often involve teamwork, organizational relations, and decision-making. There may be more than one way to perform a task, as you'll discover when consulting multiple SMEs. You may have to originate the written procedure and build a consensus around it.



A common misconception about SOPs is that you can document current practices by simply "writing down what you normally do." In fact, knowing how to do something and articulating what you know are two very different things. Your mission as a procedures analyst and writer is to lead an educational, introspective process—not merely to record what is obvious. Another myth is that "any knowledgeable person can write a procedure." In fact, it takes finely honed skills to refine differing accounts of activities into a harmonious set of SOPs.

Most SOPs are about cooperation among staff who have distinct responsibilities. The lack of an accurate departmental organization chart and/or responsibilities matrix should be taken as a warning that procedures may be difficult to define.

Authorship Issues

In sharing these ideas, I fantasize that you are in control of the process of creating SOPs. That may be too much to expect, but you should at least have some say in the information design. Following are some tips on writing SOPs.

Write a cookbook, not a contract. SOPs should facilitate operations, not merely discipline them. Write procedures for usability, with plain language, short sentences, imperative statements (courteously worded), and helpful headings.

A well-written SOP should have one main sequence of steps. Within a step, it is reasonable to have notes about a few contingencies or variations. Try to avoid complicated loop-backs and branches.

Don't specify every detail. Some activities are not suited to SOPs, including some management functions as well as personal techniques staff apply to their work. For example, a procedure for frying eggs probably need not say "Pick up knife #1. Make a 1-inch crack in the shell of egg #2." Instead, it can say "Crack the eggs into the pan." Let the workers manifest their skills. The purpose of the SOP is not to lock down all behavior, but to control the quality and compliance of important behavior.

Be careful about "structured" SOPs. Some procedures will inevitably refer to other procedures. However, try to keep this practice to a minimum. Avoid creating, for example, an overall process SOP that calls sub-process SOPs, which may call sub-sub-process SOPs. Don't make someone read three recipes to cook one dish.

Minimize cross-references. This is one of the tough problems in SOP development. A procedure does not exist in a vacuum, and workers want to know how it is related to policies and other procedures. But every cross-reference inserted into an SOP adds to the maintenance burden, which may fall on your shoulders.

Don't over-classify. I know of one department that decided to classify all of its activities as cases of abstract processes, such as "request," "change," "monitor," "configure," and "fix." Describing procedures in terms of high-level, universal ideas mystifies workers. Statements about "the request process," for instance, are generally unhelpful to a person engaged in a specific task.

Test your procedures. When the writer and the SMEs have reached consensus on an SOP, it often seems as though all the hard work has been done, and no one notices that the procedure is untried. There should at least be a walkthrough involving the personnel designated in the SOP.

Keep page layout simple. Fill the page: Nobody needs a twenty-five-page SOP that is mostly white space because of huge margins and indents. You can avoid indents by using good heading styles with outline numbering.

Use consistent language. A glossary is very helpful when writing procedures. Start one of your own to ensure consistency among SOPs. Carry it with you, and refer to it during conferences with SMEs. In due course, you should make the glossary official.

Try to keep the glossary short. Don't define ordinary words such as "step" or "responsibility": doing so will cause arguments. Define only terms that require exactitude or are special to your environment.

Use diagrams sparingly. Only the simplest flowcharts are universally comprehensible. They are illustrations, not substitutes for text, because it is impossible to precisely define a procedural step using only a graphic representation.

Be wary of bulleted lists. I've seen documents so riddled with bullets that they are mortally wounded. Set a good example by using structural text elements consistently and with restraint. Bullets and numbering schemes are not always needed.

Know the differences between forms and SOPs. Some procedures require forms, which demand careful definition and treatment. A person executing an SOP must get a copy of the associated form and fill it in, producing a data document. Often, one form spawns many data documents. The form is managed together with the SOP collection, while the data documents are managed separately and differently. In the SOP, you must specify what to do with the data documents.

Management of SOPs

Generally, an SOP is a controlled document, in the sense that it requires signature approval. Revisions are numbered and approved as well. There should be a mechanism to ensure that only the latest approved version is in circulation. If your organization does not have a document management system, you may be responsible for these controls. Although document management is beyond the scope of this article, it is worth noting that the administration of more than a few SOPs inevitably requires

a database as well as physical storage. Don't forget about the time consumed by database maintenance.

As a creator of SOPs, your relation to management, and the management of SOPs themselves, are both areas of concern and challenge. A key task is to create a workflow, which promotes efficiency and helps pinpoint responsibility. If you have enough clout, establish and document the SOP workflow. After some time, make it into an SOP.

For project management, you may be asked for completion dates. In simple cases, researching and writing an SOP may take only a day or two, but approval and publication may take months, since SOPs are generally interdependent. The SOP should be considered essentially complete when a consensus draft exists.

Another important management issue is the ownership of SOPs. It's best if the manager closest to the activity owns the SOP, taking responsibility for its upkeep. Unfortunately, an SOP containing lists of items, names of groups, or technical instructions may become incorrect at any time. Consider, for example, an SOP about installing an application on a computer. There may be steps prescribing how the installation is requested and approved, plus detailed technical instructions. The latter will become obsolete as soon as there is a new release of the application, so the SOP should reference the technical instructions as a separate document. For example, a step in the SOP should instruct workers to obtain and follow the installation instructions for the application, which should be owned by the application development department. This structured approach to documentation, if not overdone, supports maintenance well.

Be mindful of the worst hazard to SOPs: organizational change. In procedures, you can't avoid naming departments or groups. When reorganization occurs, the responsibility boundaries change, and many SOPs may be invalidated simultaneously. Let me know if you can solve this problem in a practical way without requiring content management tools beyond the horizons of most employers.

One final management difficulty with

SOPs concerns how workers know which SOPs apply to their work. It's a manager's job to inform the staff about responsibilities. However, what is really needed is a huge matrix or network diagram connecting people, roles, and procedures. Keyword searches in your SOP database have some utility, but there is no readily available tool that maps SOPs automatically.

Professional Matters

If you're responsible for SOPs at your organization, you should define and defend your boundaries. As an analyst you have to listen hard to SMEs and work under management. But try not to let others become your editors. Insist, if you can, on full control of the appearance, style, and language of documents.

I also encourage you to get involved with training. One of the purposes of SOPs is to ensure quality, but an SOP is only as good as the people who follow it. A person is supposed to be qualified, by education and experience, to perform prescribed tasks. In a regulated environment, records of training may be required. A tracking system for training can be a challenging and costly adjunct to SOP development. You may be pressed into service to maintain it.

If your organization has any consciousness of knowledge management, you may wish to assert that SOPs encapsulate knowledge. Once upper management realizes that SOPs are knowledge assets, you may be on your way to a promotion to CPO (chief procedural officer)! It's nice to dream.

Conclusion

Few organizations excel in the creation, maintenance, and execution of procedures. It is commonly an area experiencing cycles of attention, progress, and neglect. There are many ways to innovate and succeed, and I hope this article has left you stimulated, or at least better prepared to develop SOPs. **❶**

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