Preparation of Standard Operating Procedures #B-06

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By

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Guidance for the Creation of Standard Operating Procedures:

Scope: Any organization. This is the target user or audience to which the document will apply.

Purpose: To outline the steps for creating a Standard Operating Procedure (SOP). A "Standard Operating Procedure" is a set of written instructions or guidance documenting a routine behavior (typically within an organization). This guidance includes:

1. **The goal of an SOP**
   a. **Standardization**
   b. **Simplification**
   c. **Clarification**
   d. **Consistent application of policy**
   e. **Delegation of duties where appropriate by expertise**
2. **The value of an SOP**
   a. **Reduction in the cost of time, labor, and money**
   b. **Preventing abuse**
   c. **Streamlining audits**
3. **The structure and format an SOP**
4. **The contents of an SOP**
   a. **The Title Page**
   b. **The Table of Contents (if necessary)**
   c. **The Purpose**
      i. **Including scope**
   d. **The Procedures (or body text)**
   e. **The associated complicating factors for an SOP**
      i. **Anything that may cause issues with the policy or may require manual review.**
   f. **Quality Control**
   g. **References**
      i. **Copies of any relevant documents, statutes, SOPs, graphs, pictures, etc.**
5. **The relevant regulatory information for an SOP**
   a. **Legal requirements for or responsibilities of the company**
   b. **Specialization or licensing restrictions for users**
6. **The review process for an SOP**
   a. **How often the SOP should be reviewed**
   b. **Who should review the SOP**
   c. **How challenges to the SOP are handled**
   d. **How the changelog for the SOP is written**
   e. **How records of the SOP (and related documents) are maintained**

Goal: The goal of a good SOP is to standardize, simplify, clarify, and delegate tasks and to guide users.

1. Primarily, an SOP should standardize the ways users approach a task or policy. The ideal SOP will:
   a. Provide a detailed set of instructions for performing a task.
   b. Ensure every relevant user has the same understanding of a task.
   c. Help an organization achieve consistent application of a policy across its users.
2. An effective SOP should simplify these instructions as much as possible while maintaining any necessary accuracy.
   a. The fewer steps there are to a task, the less likely it is to be carried out differently each time.
   b. Everyone who falls within the scope of an SOP should be able to read it and understand what it wants them to do.
3. SOPs should also clarify any obvious sources of confusion or any foreseeable problems so relevant users will have fewer questions when approaching the topic.
   a. Most niche cases for any problem will come back every once in a while. It's important to identify these outliers and include them where possible in the SOP.
4. Once a task has been standardized and simplified, the intention behind many SOPs is to automatically and easily delegate tasks to a specific set of users.
   a. This improves efficiency at every level, since users will have a more streamlined understanding of their role and how to perform any relevant tasks.
5. Lastly, an SOP exists to guide its users through a sensible and smooth approach to solving a problem.
   a. Including examples can help users understand the relevance of the procedure.
   b. Pictures detailing any step-by-step processes can make learning or using software easier.
   c. Sometimes, a complicated topic can be a lot easier to explain with an analogy. A mechanic doesn't need users to understand how their car works so long as they know how to use the gas, breaks, transmission, and steering wheel.

Value: A good SOP is worth the company's weight in gold because it saves money, time, *and* effort.

1. SOPs naturally reduce a company's costs by preventing mistakes, waste, audits, and abuse.
   a. Standardizing user behavior reduces the risk of errors both because it makes learning easier, and also because it gives users a source of knowledge they can quickly reference.
   b. Decisions and behaviors that don't constantly need to be double-checked will free up valuable time and energy by users and every person above them in the organization.
   c. Having a firm set of SOPs in place will reduce the likelihood that someone violates the law (accidentally or otherwise), which can mean fewer fines, legal bills, or even lawsuits.
   d. Making sure a rule is put in place on paper can keep employees from taking advantage of the company, and it will aid in identifying abuse as it happens.
2. These policies help to ensure time isn't wasted where it isn't needed by properly delegating authority and by properly communicating expectations, needs, and institutional knowledge.
   a. When a user's tasks and authority are appropriate for their level of expertise and position, their time can be spent more efficiently on what they know how to do.

    b. Because all of this information is communicated openly and clearly to every relevant person at any level of the organization, less time is needed to answer routine questions.

    c. Many organizations have special knowledge or skills that are critical to the day-to-day operations, and SOPs will help preserve this information regardless of any major personnel changes.

        i. This includes training and onboarding new users to the organization, which is made significantly faster and cheaper with a comprehensive set of SOPs.

Author: The author for a given SOP depends on the expertise or skills needed for the task. The person most suited to answering questions about a task is generally who should write the guide for it. However, a technical writer is often employed to write the majority of an organization's SOPs because it's more efficient to have one person translate the tasks at every level into a consistent database.

1. A technical writer may be preferable for an organization's SOPs if:
    a. The organization is larger and has a more comprehensive knowledge base that needs translated across many different disciplines for many different users *or* to many new employees as they're onboarded.
    b. The organization requires a great deal of interdisciplinary communication, where the consistent language across many SOPs may save time and energy as they're frequently referenced by users.
2. Relying on subject matter experts may be preferable for an organization's SOPs if:
    a. The subject matter is particularly dense and the required knowledge cannot be easily translated through a writer.
    b. The skills required are extremely technical and require a level of precision that cannot be reached without firsthand expertise.
    c. The organization is sufficiently small that a great deal of consistency isn't necessary between SOPs.
    d. An organization's users are unlikely to have their workflow made significantly more efficient by having thorough SOPs.
        i. This may be the case for organizations in which the tasks are very simple and have relatively few risks associated with most tasks.

Content and Structure: Generally, an SOP will be formatted a little differently depending on the type of organization or the expertise in which the SOP is applicable. The overall structure will typically have:

1. A title, which may have:
    a. The organization name.
    b. The SOP name.
    c. The SOP's identification number.
    d. The date the SOP was last revised.
    e. The current revision number for the SOP .
    f. signatures by any individual responsible for the SOP's contents.
2. A table of contents, which is generally only needed for larger, more dense SOPs.
3. A purpose or general explanation of the SOP. This may contain:
    a. The definitions needed for the SOP.
    b. A justification for the SOP's value to the organization or the user.

4. The SOP policy itself, which details reproduceable, step-by-step instructions for performing a task. This may include:
    a. Any relevant technology or software that the user may need to be familiar with.
    b. Any rules (including organization rules, regulatory rules, or laws) that the user must adhere to in completion of the task.
5. The potential complications that could or would reasonably arise that might reduce the usability of the SOP.
    a. This will typically be a situation that demands manual review by someone with expert knowledge or organizational authority.
    b. This may also be legal or regulatory complications that can't be properly accounted for, like a rapidly changing technological landscape.
6. The methods of quality control employed for the task, if necessary.
    a. This may be needed for any task that, performed poorly, could pose significant financial, regulatory, or institutional risk to an individual or the organization.
    b. This may include required licensing by the organization or a user in order to perform a task.
    c. This will also include the ways that a user can reasonably be judged on their work with this task by supervisors so as to generate valuable, actionable feedback.
7. The references that are relevant to fully understanding the SOP's content. This may include:
    f. Other SOPs (reference any other SOP by name and document ID#)
    a. Regulations or laws
    b. Graphs, pictures, or similar visual content
    c. Print material such as books, magazines, or academic articles.

Legal or regulatory considerations: An organization may require special licensing in order to perform a given task, or it may require a specific user to have special licensing. This is critical to reference to ensure both that users don't perform tasks outside of their legal authority, but also to ensure the organization has done its due legal diligence to prevent misconduct.

Review: An organization needs a policy for reviewing, amending, and maintaining any given SOP. This will generally include:

1. Who must review the SOP.
2. How often an SOP must be reviewed.
3. How to document changes to or maintain a changelog for an SOP.
4. How challenges to the SOP are resolved.
5. How an updated SOP is transmitted to users.