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How to write standard operating procedures: values and a practical guide

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Abstract

Standard operating procedure (SOP) is detailed, written step-by-step instructions for achieving uniformity while performing specific tasks to minimize variations of repeated tasks and plays a key role in the implementation of a quality management system. It is a document that describes the procedures that will be followed to accomplish various tasks. The procedures are organic documents and best-written SOPs fail if they are not followed. Poorly written, unavailable, and inadequate SOPs hamper working processes and lead to non-compliance in the implementation of quality management systems. A well-crafted SOP offers clear direction and instruction that minimizes deviations at different times using different personnel. The SOPs should be user-friendly and describes the processes in the sequential manner in which they are intended to occur and thus leading to a logical flow of events. In this article, SOP writing is summarised in seven steps, namely (i) Preparing, (ii) Reviewing, (iii) Updating, (iv) Maintaining, (v) Distributing, (vi) Archiving, and (vii) Training.

Keywords: Standard Operating Procedures (SOP), Quality Management System (QMS), SOP Preparation, SOP Guidance

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1. Introduction

Standard operating procedures are defined by writers with slight variations and use a variety of terms to describe them. (1, 2) The International Council for Harmonisation defines the standard operating procedure as "detailed, written instructions to achieve uniformity in the performance of a specific function." (3) The U.S Environmental Protection Agency defined it as “a set of written instructions that document a routine or repetitive activity followed by an organisation.” (4) Other authors defined it as a written formal document that describes how an individual or organisation performs a task and documents the performance of that task. (2, 5) The standard operating procedure is a component of a quality management system (QMS) which helps to cultivate transparent functions, implement error prevention measures, facilitate corrective actions, transfer knowledge and skills, (1) and is linked to intrinsic motivation – a requirement for creativity, however, resulted in controversy. (6) It is one of the process documents that provide guidance and instructions to the user on what to do and what is expected of them, (2) and is needed for the consistent operation of a given process. (7) Procedures are a good quality marker for an organisation, and if not expressed in writing, it is highly unlikely that responsible personnel have a clear idea of what is expected. (8) It also indicates compliance with organisational and governmental regulations and requirements. (4, 9)

A user-friendly SOP describes the processes in the sequence in which they are supposed to occur and leads to a logical flow of events. Short, clear, logical, and doable instructions are essential for implementation. (5, 10) Too much flexibility in standard operating procedures could make them ineffective and lead to violations. (5) In addition, lack of procures, contradictory procedures, obsolete procedures, incomplete procedures, overly detailed procedures, and procedures that are not followed are the pitfalls that an organisation should be cautious about in developing procedures. (2)

The SOPs must be written in a language that is clear and understood, preferably in the native language, but it should not be a barrier to others during an audit or any other action. It should specify who is responsible for what regulations to be followed. Thus, it outlines what to do, how to do it, when to do it, whom to do it, why to do and how to document the executed tasks. The signatures are crucial since they identify individuals who prepared, reviewed, revised, or approved the instructions and took ownership of the writing. (2, 4, 5)

A standard operating procedure is considered to be a living document that can be continually amendable. It will change when an internal and external change in an organisation arises. It should be reviewed, and ideally, the review should be performed every one to two years. However, amendments can be made when necessary. Access to SOPs must be restricted to prevent unauthorized distribution, and updating must be properly managed. (2, 4, 5, 11-13)

When experts write SOPs, various issues may raise regarding the use of SOPs, how much detail should it be, and how it will be implemented in an organisation. The article is conceptual in nature and summarizes information from the literature to provide guidance and tools to experts on concepts of how to write SOPs and their life cycles.

2. General formatting of SOPs

Standard operating procedures should be organised to ensure ease and efficiency in use and be specific to an organisation. In the process of developing SOPs, there is no single standard format to be followed. Internal formatting varies from organisation to organisation and with the type of SOPs being written. Where necessary, it might be required to break the information included in the SOPs into a series of logical steps to avoid a long list of narrations. Whether a process is critical, how frequently the SOP is followed, the number of people who will use the SOPs, and whether or not routine training is provided will all affect how much detail is provided in the SOPs. The general format of SOPs is discussed as follows. (1, 4, 8, 12)

Header***:*** It is the title page or cover page of SOP that identifies the activity in question, and it contains a title that identifies the procedure, SOP number, page numbers with the total number of pages (page x of y), issue date and/or revision date, approval date, next review date, name of the organisation, division, and/or branch to which the SOP applies, author, approver, reviewer, and signatures and signature dates of those individuals who prepared, reviewed, and approved the SOP. In addition, organisations can add supersede status, the logo of an organisation, etc. on the title page of the procedure. For SOPs maintained on a computerized database, electronic signatures are acceptable. The header of the SOPs should be repeated on each page of the SOPs.

Main body***:*** This is the main text of the procedure where the details are stated. It is required to write the procedures in a format that clearly states the steps in order and use flowcharts to easily show the steps. Each SOP should include sections for background, purpose, scope, responsibilities of individuals, definitions of any terms or phrases, and procedures of the SOP. Furthermore, the conditions related to materials and equipment, safety considerations, document distribution, and revision history should also be indicated. Finally, list any cited or significant references and annexes used in the SOP. The SOP should be worded to be readily understandable by users.

3. Basic components of SOPs

Step-by-step instructions for performing tasks cannot be overstated. This ensures that personnel performs tasks correctly and consistently to achieve the desired quality outcome through uniform performance. (14) The SOPs should be written in a format that is tailored to the type of organisation and its unique requirements. (15) Depending on the need and context, organisations adapt different models to format their SOPs, though the basic components are similar. Written SOPs vary from single documents to multiple forms that include a combination of explanatory tools. If a section does not apply, indicate it with "N/A" or "None." Regardless of the format, the core components of SOPs include the following information. (15-17)

a) Header: This is the title page that identifies the activity in question and contains any relevant keywords. This should at least include the title, SOP number, date of creation or revision, signatures, and name and logo of the organisation, department, or team to which the SOP applies.

b) Purpose: a clear statement of the intent and objective(s) of the SOP and how it benefits the user and organisation. Describe the problems that the SOP will solve who the SOP is for, and where and how it will be used.

c) Scope: a statement describing the areas affected by the SOP, describes the limits of the document, and helps the reader understand the boundaries of the SOP. It defines the use and applicability of the SOP.

d) Background: a brief description of the activity to be performed and its results; the rationale for the SOP; and the operations affected by the procedure.

e) Responsibility: identifies the key persons responsible for a specific task as defined by the SOP. It outlines who performs the tasks and whom to contact if problems arise. It also outlines the person in charge of preparation, review, revision, and implementation. This helps to avoid confusion and keeps everyone accountable for their actions.

f) Definitions: an explanation of special terms, phrases, and abbreviations used within the SOP. It is helpful to include words, abbreviations, or acronyms you may have used in the document that may not be familiar to users.

g) Materials and equipment: a list of materials and equipment to be used when implementing the SOPs.

h) Safety: information regarding safety precautions applicable to the SOP. The SOP describes things that the employees need to avoid and perform the

operations in a safe environment. This protects users from potential dangers and keeps the organisation away from liabilities.

i) Procedure: It is the main body of the SOP and is a clear description of step-by-step instructions on how to perform tasks to achieve the intended purpose. The procedure includes all the necessary steps an employee must follow in an easily understood format and any additional information needed to complete the tasks. This section may include flowcharts that describe step-by-step instructions and diagrams related to the operations.

j) Document distribution: The distribution of the SOPs to which the responsible individuals, units, or departments act. It indicates and identifies to whom the SOP should be distributed to collect it easily when an amendment is made or the SOP is obsolete.

k) Document history: This is a revision history to ensure the users that the SOP is the latest one. The phrases "document history," "revision history," or "version control" can be used interchangeably. It also explains the history of change in detail and the reasons for change.

l) Reference**:** list of supporting documents, including other SOPs that are uniquely identified and used to prepare the SOPs.

m) Attachments**:** It includes forms, tables, checklists, diagrams, and/or worksheets that may be used as part of the procedures of the SOPs.

Writing Styles

Standard operating procedures should be written in a clear, concise, specific, step-by-step, easy-to-read format. The SOPs should be written to provide instructions for the completion of certain tasks and the information presented must be unambiguous, non-confusing, and not overly complicated. The active voice and present verb tense should be used. The procedure should not be wordy, redundant, or overly lengthy. The information should be conveyed in short, simple, clear, and explicit to remove any doubt as to what is required. It is also important to use workflows to illustrate the process being described and follow the style used or determined by the organisation, e.g., font type, font size, margins, and spacing. (4, 8, 9, 15) The language used in standard operating procedures should be adequate and allow for enough flexibility to execute the tasks regularly. Procedures are usually written in the third person. (4, 7, 17)

4. Writing SOPs

Preparing SOPs

Procedures are an essential component of a newly formed or existing organisation, small or big organisation, to properly function and execute its various services and activities. When the growth of an organisation increases, changes in the structure of an organisation, or any outside influence, the need for new SOPs or revisions to current SOPs will arise. This step will set off a sequence of steps in the life cycle of SOPs. The SOP should always be written from a purely practical perspective concerning those who will use it. (8, 14) The SOPs should be written by subject matter experts who perform the activity or use the processes, as they are the persons who have an understanding of what works and what does not. These persons who work in the field are best equipped to suggest workable and practical changes that need to be made in SOPs. In developing SOPs, a team approach can be used, particularly for multi-task procedures where the expertise of several people is essential, and this encourages buy-in from potential users. (4, 15)

Additionally, it's a good idea to engage someone with experience in quality management to liaise with relevant people who are knowledgeable in the subject matter of the required SOPs. The SOPs will also be signed off on by the head of the organisation, the quality manager, or possibly the sectional head. The SOPs must be reviewed for both technical and usability considerations before being approved. (5)

5. Reviewing SOPs

Reviewing and commenting on new or existing versions of current SOPs

Approved SOPs will be reviewed to determine whether new SOPs or revisions to existing SOPs are needed. (8) The SOPs should be reviewed and validated by one or more individuals with appropriate training and experience in the process. Before the SOPs are finalized, it is immensely important to circulate a draft SOP or revision SOP for review and actual testing by someone other than the original writer. (4, 8, 9, 15) As the SOPs are "living" documents, comments and/or suggestions to improve or change the SOP may arise. The SOP review or revision will be required if the organisation changes in its working environment, legal and technological changes such as changes in structure, mergers, process re-engineering efforts, internal restructuring, staff changes, optimization of processes, the introduction of new technology, and if new guidelines or regulations are introduced, or if existing ones are amended. All comments will be documented and filed in archives by the responsible person. (4, 5, 8)

The subject matter experts are encouraged to carefully review the developed SOP and to address any concerns regarding format, language, practicality, the sufficiency of details, procedural issues, and supporting documents attached to the SOP. (5) For existing SOPs, there should be a document history section where changes can be stated and controlled. If revised, revision dates should be stipulated as well as a corresponding date of approval or implementation date. If a new SOP is written, it will have a review date. Should a new version of the SOP be issued, new revision date and approval date will be noted, as well as a comment that the previous version is superseded.

Standard operating procedures should also be systematically reviewed periodically. A formal or authorized review can be performed every 1-2 years or more frequently, if necessary, because of urgently needed changes. The frequency of review should be

indicated in the quality management plan or procedure for document management and control. In addition, the plan or procedure should indicate who is responsible for ensuring that the SOPs are current. The exercise is to ensure that the procedures remain current and appropriate and to determine whether the SOP is even needed. Each SOP that has been reviewed should have the review date added to it. If SOP describes a process that is no longer followed, it should be withdrawn from the current file and archived. The review process should not be overly cumbersome to encourage timely review. (4, 5, 7, 8)

6. Approving SOPs

Authorizing Reviewed SOPs

The finalized SOP should be approved as described in the quality management plan or procedure for document management and control of an organisation. The approval of proposed SOPs and amendments shall be documented. Generally, the immediate supervisor, such as a section head, branch head, quality assurance officer, or head reviews and approves each SOP. A signature and date of approval indicate that the SOP has been reviewed and approved by the responsible person. The use of electronic signature, electronic maintenance, and submission for approval is acceptable considering national laws. (4, 7, 15)

Once SOPs have been authorized, they should be accessible to relevant employees and other responsible bodies following the document distribution modality. The SOPs shall come into effect on the date of issue. For proper implementation of SOPs, employees should be adequately trained and equipped with the necessary tools. The management should monitor compliance, enforce accountability, and track the outcomes. Non-compliance with SOPs must not be tolerated or overlooked as it undermines the efforts invested in the quality system and overall performance of the organisation. (4) The root causes of the non-compliance should be identified retrospectively as well as proactively, and appropriate countermeasures should be initiated to prevent recurrence. (5)

7. Updating SOPs

Gathering and incorporating comments and continuously informing end users

Standard operating procedures need to remain current to be useful. Whenever a procedure is changed, it should be updated and re-approved. If desired, modify only the pertinent section of SOPs and indicate the change date and revision number for that section in the document control section. Comments and suggestions for improving SOPs should be made continuously and should be saved in an allocated place until the review date of SOPs is reached. However, immediate updating of SOPs can also be done when there are major changes that require immediate implementation. (4, 7)

8. Revising SOPs

Revision of SOPs requires authorization. The SOPs need to be reviewed systematically periodically. Revision forms are an integral part of the process and should be performed every one to two years. If no revision is required after a review process, this should be indicated in the SOPs. The re-authorization of SOPs is required after amendments have been made. The quality manager must authorize the amendments. Amendment of SOPs can be done manually or electronically and be version controlled. Major changes should result in an immediate review and immediate re-authorization. (15)

9. Maintaining SOPs

Tracking and archiving of SOPs

The organisation should maintain a master list of all SOPs, and proper archiving is essential for the good administration of SOPs. The current SOPs should be kept up-to-date and accessible to personnel. All current and superseded versions of SOPs must also be available for audit. Maintaining SOPs in either electronic and/or signed hardcopy forms is crucial. The maintenance and backup of SOPs of amended versions cannot be stressed enough. There should be an allocated file where hardcopy and/or electronic versions of approved SOPs are maintained. This file or database should indicate the SOP number, version number, date of issuance, title, author, status, organisational division, branch, section, and any historical information regarding past versions. A working system for archiving electronic versions and/or hard copies should be maintained and secured. This area should have strict access control as unauthorized distribution of SOPs as well as unauthorized amendments should be avoided.

The quality manager or any designated person for document control is responsible for maintaining a file listing all current SOPs used within the organisation. This list may also be used when audits are being considered or when questions are raised as to practices being followed within the organisation.

Electronic storage and retrieval mechanisms are easier to access than a hard-copy format. For a user, electronic access should be restricted to read-only mode, thereby preventing unauthorized changes to the document.

10. Controlling SOPs

Each organisation must develop an identification system based on a numbering scheme to systematically identify and mark thier SOPs. This system must be detailed in the organisation's document management and control SOP. Each page of the SOP should have a control documentation notation. A short title and identification number can serve as a reference designation. The revision number and date are very useful in identifying the SOP in use when reviewing historical data and are critical when the need for evidentiary records is involved and when the activity is being reviewed. When the number of pages is indicated, the user can quickly check if the SOP is complete. Generally, this type of document control notation is located in the upper right-hand corner of each document page following the title page. (11, 12)

11. Distributing SOPs

Distribution and retrieving of old SOPs

When a new SOP is prepared, amended, and re-authorized, it must be distributed to the relevant employees or responsible bodies. Considering the policy of an organisation, distribution can be inside as well as outside of the organisation. Distribution should be limited to relevant employees only. Collecting obsolete SOPs that have been distributed, both internally and externally, should be carried out concurrently when the distribution of an updated SOP is performed. Superseded SOPs must be archived, and the new SOPs must be filed in the applicable files.

All personnel involved in the tasks and required to comply with relevant SOPs shall be issued with copies of the most current SOPs and must be required to undertake their activities following the SOPs. To protect confidentiality, the distribution must be authorized by the responsible person in the organisation.

Moreover, individuals who received SOPs shall not photocopy the SOPs or distribute the SOPs to personnel outside the organisation without permission sought from the appropriate organ. When a personnel leaves an organisation, she or he must immediately return the SOPs to the responsible person.

Archiving obsolete SOPs

As mentioned before, an archiving system needs to be in place. Previous versions and superseded SOPs can be filed. The designated person is generally responsible for maintaining a file listing of all current and obsolete SOPs used within the organisation. (4) Only current procedures should be used in an organisation. The quality management plan or SOP for document management and control of an organisation should state where and how outdated versions are to be maintained or archived in a manner to prevent their continued use, as well as to be available for historical data review. Electronic storage and retrieval mechanisms are usually easier to access than hard-copy document formats.

Destruction of obsolete SOPs

The obsolete SOPs should be retained for some time (time should be specified) for reference purposes. Copies of superseded SOPs that have been distributed, both internally and externally, should be collected and destroyed by the responsible person after the issue of new and revised SOPs.

12. Training on SOPs

Training and training forms are an important part of the quality management system of an organisation. The quality of a process is as good as the trained employees on each SOP. Although some employees might think that their creative abilities are limited by SOPs, (5) training should be of such a nature that this view is discouraged. Training on SOPs should take time, and each of the employees should ensure that they understand what is expected of them. The employees should be provided with a training log to date and sign (i.e. ideally, the training log should be attached to the training SOP) which ideally should be attached to each of the specific SOPs. (1, 4)

Procedures are a critical part of QMS and require proper personnel training to be effectively implemented. Implementation of procedures is only as good as the people who are trained to implement them. This implies the wheel needs not to be reinvented every time instructions are given, but rather to spend time on improving current processes.

13. Conclusions

A standard operating procedure is a detailed, written instruction to achieve uniformity in performing a specific task and forms a crucial part of the quality management system of an organisation. It should ideally be written by trained subject matter employees who work in a particular field and understand what works best and what does not. The SOP should be written clearly and understandable manner and should provide unambiguous instructions. When developing an SOP, proper time should be spent. Furthermore, cross-referencing where applicable across SOPs indicates good operational QMS. Writing a procedure in your interest without seeking advice from others is no longer acceptable, especially if it covers several departments.

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Authors' contributions

The authors meet the ICMJE criteria for co-authorship, providing substantial intellectual contributions to the manuscript. KGB conceived the idea, conducted the review and analysis, and wrote the manuscript. SSN, WGA, AGG and SGA reviewed the manuscript. All authors approved the final manuscript and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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