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Review Article

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Practical approaches in the Creation and Revision of Standard Operating Procedures

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Abstract

The procedure for Standard Operating Procedures creation a applies to an organization's entire staff and to all circumstances where the need to create or modify a Standard Operating Procedure is identified [1]. The standard proposed here is currently being applied to Gentium Healthcare

Key words: *Practical; Creation; SOPs*

Abbreviations

Controlled Document

A document that has been created or modified through a controlled documentation process. Such a document cannot be modified without going through a documented process of revision. A controlled document will have a version number, an approval signature and be dated. In most cases it also must undergo review and authorisation [2].

Delegate

A person delegated specific but appropriate Quality Assurance (QA) tasks related to Standard Operating Procedure creation [3].

Document controller

A person responsible for the distribution and maintenance of Standard Operating Procedures [3].

Document reviewer

A person delegated the task of reviewing Standard Operating Procedures by Quality Assurance, the organization, or the document's primary investigator [4].

Standard Operating Procedure (SOP)

Detailed, written instructions created to regulate the performance of a specific Function [5].

Introduction

A Standard Operating Procedure is set of a detailed, written instructions that outlines the way a specific task or function should be performed. Standard Operating Procedures should be developed for any and all tasks or procedures that require regulation in order to assure the product or service is delivered to the organization's standard. A Standard Operating Procedure is a controlled document created through a controlled documentation process. It cannot be modified without going through a documented process of

approval [2]. The purpose of this article is to document best practices for creating and implementing Standard Operating Procedures (SOPs) [1].

Materials and Methods or Experimental Procedures

(See Appendix I: Standard review cycle of Standard Operating Procedures)

The following is a detailed set of procedures any organization can follow to guide the creation and revision of Standard Operating Procedures.

Initiating the creation of a new Standard Operating Procedures or revision of an existing Standard Operating Procedure [1]

- Any staff member may identify the need for a new Standard Operating Procedure or the need for revisioning an existing document [3].

When the need for a new/revised Standard Operating Procedure is identified:

- The revision or new Standard Operating Procedure will be written by a staff member with relevant expertise and experience. Additional advice may be sought from external advisors when necessary.
- The contents of any new or revised Standard Operating Procedure will be reviewed against any guidelines or regulations pertaining to the task in question. Feedback from the Marketing Authorization Holder will be considered.
- All Standard Operating Procedures are subject to approval by the Board of Directors (BOD) and/or the Managing Director before being implemented.
- Upon approval of a revised Standard Operating Procedure, the superseded Standard Operating Procedure will be archived, and the newest version shared by E-mail to all team members on the mailing list; only the current version will be made available to employees.
- The organization is responsible for communicating revisions or new Standard Operating Procedures to the affected employees
- If a new Standard Operating Procedure is made, it will also be shared by e-mail to all team members and any necessary trainings arranged for by the employee managers.
- If appropriate, a new Document ID or version number will be assigned to the new or revised Standard Operating Procedure.
- Upon release of the Standard Operating Procedure, the procedure's effectiveness should be assessed to ensure it meets the identified need.
- All Standard Operating Procedures must be reviewed at least every 2 years.

Organizations are to:

- Ensure that the below procedures for creating/revision Standard Operating Procedures are used for all new Standard Operating Procedures
- Maintain a Document Register of approved Standard Operating Procedures that includes at least the Document ID, version number, approval date, effective date, and review before date.
- Maintain a hardcopy or electronic folder containing all approved Standard Operating Procedures with signature blocks completed.

Preparation of a new Standard Operating Procedure or revision of an existing Standard Operating Procedure [6]

The document author/reviewer will:

- For a new Standard Operating Procedure, prepare a draft following standard Operating Procedure sections, which may include:
    1. Purpose
    2. Scope
    3. Background
    4. Definitions & Abbreviations
    5. Procedure
    6. References
    7. Appendices
- Use sub-section numbering (e.g. 6.1, 6.2, 6.3, etc.) where applicable, to keep the document clear and organized.
- Make appropriate changes to the version number and date when revising existing Standard Operating Procedures.
- State the document's history in the front page of every updated Standard Operating Procedure, including the description of any changes, the change number, the effectiveness, effective period for previous versions, and the controller of the document.
- Distribute the drafted new, or revised Standard Operating Procedure to stakeholders for review, and incorporate relevant comments before planning for further review (if required).
- Arrange for approval of the final Standard Operating Procedure [7]

Approval and Authorisation of the Standard Operating Procedure

Prior to the release of a Standard Operating Procedure, it should be approved by the relevant department head or delegate. This approver will then fill out each Standard Operating Procedure's signature blocks (either the hard copy or electronic version) to signify their approval of the document [2].

Assigning "Effective" and "Review" Dates to a Standard Operating Procedure

A Standard Operating Procedure is considered effective once the new/updated material has been communicated to the relevant staff and they have undergone the necessary trainings in the updated Standard Operating Procedure's material. Managers are responsible for securing training logs and training consents from all staff affected by the new Standard Operating Procedures before the document's set effective date and before commencement of operations. The Quality Assurance Manager will be responsible for providing the Marketing Authorization Holder with the list of employees involved in any patient-centred programs (such as Patient Support or Patient Oriented Programs) and ensuring the availability of all training logs for audit at any time [2].

The document author shall record the "Effective Date" and "Review Date" on page 1 of the Standard Operating Procedure. The Standard Operating Procedure 'Review Date' shall be 2 years from the Standard Operating Procedure's assigned "Effective Date", though earlier review dates may be necessary (such as in the event of legislative changes).

Results

Distribution of the New or Revised Standard Operating Procedure

All managers, team members, and employees will be notified of any new or revised Standard Operating Procedures. Employee managers are responsible for making sure that new/updated Standard Operating Procedures are communicated and available to their employees, by making hardcopy or electronic versions always available.

The master Standard Operating Procedure shall be securely filed and used only for making further controlled copies as necessary. Hard copies of the master Standard Operating Procedure will be placed in an accessible location for relevant staff and electronic copies should be provided only as locked PDFs [2]. To ensure effective communication of new/updated Standard Operating Procedures the following process is followed:

- The author of the new/updated Standard Operating Procedure is responsible for notifying the Quality Assurance and other managers of the changes made.
- The manager responsible for approving the document will ensure the changes are communicated to the Quality Assurance and other managers.
- Employee Managers are responsible for securing employees' training consents and logs and communicating them to the Quality Assurance Manager.
- THE Quality Assurance Manager will ensure training logs are complete and secure and archive a hard copy of the employee consents.
- The Quality Assurance Manager and Managing Director are responsible for notifying the Marketing Authorization Holder and making employee training logs available for audit at any time [8]

Discussion

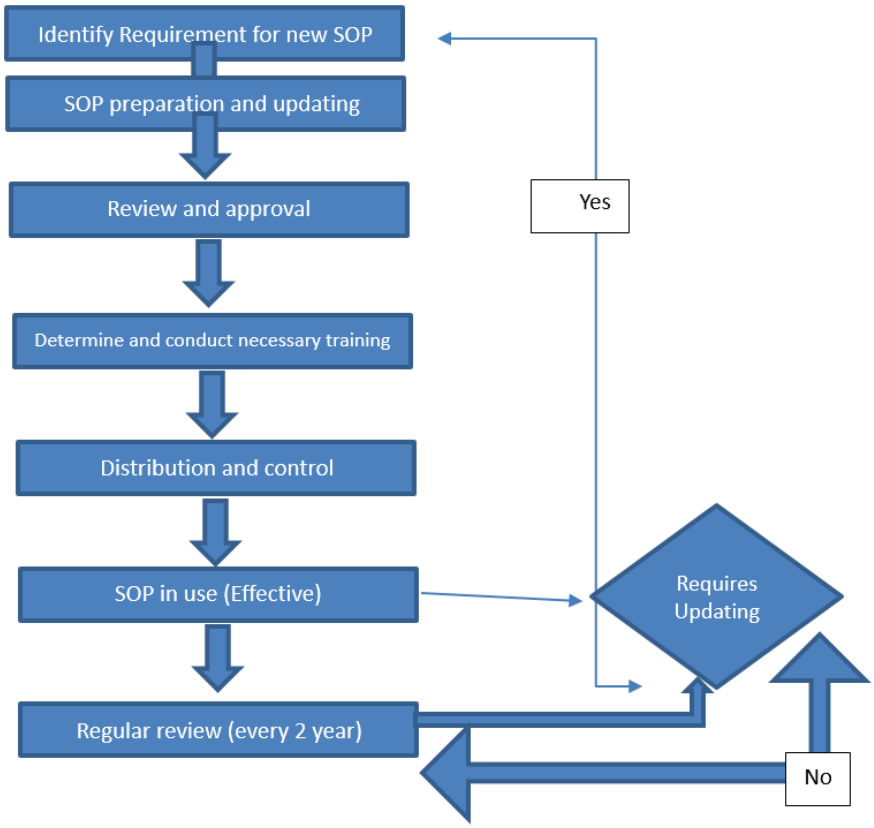
Recall of superseded Standard Operating Procedures [9]

When a Standard Operating Procedure is revised, the superseded master Standard Operating Procedure shall be filed securely as a record of previous procedures. Old revisions must be kept in company records and stored away from the operation environment in order to prevent confusion. Only one copy (either electronic or hard copy) of a superseded Standard Operating Procedure shall be kept, all others will be deleted or destroyed [2].

These old revisions are under the control of the Quality Assurance Manager and managing director [2]. The organization is committed to the retention of superseded Standard Operating Procedures. They will keep records of such documents to infinity with no limited time for retention to ensure full tracking of historically used Standard Operating Procedures. Current Standard Operating Procedures will be made available at any time, while superseded version will be kept and archived in company files; destruction is forbidden to occur [2].

Conclusion

Appendix 1 (FLOW CHART): Standard Operating Procedure Standard Review Cycle [10]



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