Volume 3 • Issue 2 • 2021

Review Article

Journal of Biotechnology and Immunology

Standard Operating Procedures for Change Control in Healthcare Organizations

Mohamed Refaat[1]*, Marwan ElBagoury[2] and Amy Hutchinson[3]

[1]*Gentium Healthcare, Cairo, Egypt*

[2]*University of South Wales, School of Law, Accounting and Finance, Pontypridd, Wales*

[3]*McMaster University, Hamilton, Canada*

***Corresponding Author:** Mohamed Refaat, Gentium Healthcare, Cairo, Egypt.

Received: July 02, 2021; **Published:** October 04, 2021

Abstract

A Standard Operating Procedure (SOP) is a set of detailed, written instructions that outlines how a specific task should be performed [1]. A Standard Operating Procedure is important to any and all organization's with defined procedures that must be carried out consistently, including educational institutions, health care organizations, governments, etc. Due to the importance of Standard Operating Procedures to an organization's routine functions, these documents cannot be modified without going through a specific process called Change Control [1]. The aim of change control is to ensure that if a previously accepted Standard Operating Procedure is changed, then.

- The change has been reviewed and approved by all authorized individuals
- All employees are aware of the change
- The change process can be appropriately tracked

Change control is important for documents (and by extension the procedures they detail) that are vital to an organization's functioning and thus should be handled with appropriate care. This paper defines change control best practices for the revision and approval of Standard Operating Procedures and controlled documents

Key words: *SOPs; Change Control; Healthcare organizations*

Abbreviations

Controller: The Document Control/Quality Assurance employee who will be responsible for drafting, reviewing, updating, distribution and retaining the Standard Operating Procedures/documents according to Good Document Management practices [2]. In essence, they are responsible for a document's configuration management.

Configuration Item: Section of a Standard Operating Procedure that outlines a specific procedure or step in a procedure

Configuration Management/Document Control: The group and processes responsible for the Document Control activities specified in this document [3].

Introduction

These procedures should apply to all an organization's Standard Operating Procedures and controlled documents. These procedures are currently being applied to Gentium Healthcare [4].

Change management is the process of handling proposed changes to controlled documents (i.e. overseeing change control measures) [5]. Change control focuses on making sure that everyone affected by the document can participate in changes made to it, that everyone is aware of changes, and that there is an audit trail from the issue that instigated the change, to the people involved and affected by the change, to the final document. Documents should be reviewed regularly to kept up to date and well-suited to the workplace, and thus change control is set into motion. New legislation or external factors may lead to the need for more frequent changes which will be held to the same change control processes outlined below.

Proper change control requires defining the:

- Level of authority required to change each Configuration Item (CI)
- Methods of handling proposals for creating/revising CIs

Change control procedure typically includes:

- Identifying reason for change
- Investigating the impact (costs, timescales, risks, etc.) of the proposed change
- Reviewing proposed change (i.e. accept or reject)
- Making changes to the document as agreed upon by reviewers
- Releasing changes and alerting employees

Changes proposed in the first step of change control are reviewed by a nominated Change Review Board (CRB), which has the authority to accept or reject changes. It is important for the CRB to utilize a broad, long-term view and assessment of the system in order to make effective changes.

Some examples of this broader viewpoint include:

- Whether the number and extent of proposed changes indicate that operational requirements are changing, and thus the current system is unlikely to meet future requirements cost-effectively
- Whether a group of low-level changes can be more cost-effectively implemented through a re-write of a higher-level module; or are symptomatic of a fault in the design and can be rectified by re-designing and re-writing the CI; or can be delayed for more cost-effective implementation within a batch of additional future changes

Procedures

Document Change Control

In order to document the reason for a proposed change, a Problem Report Form (see Appendix A) or Change Control Form (see Appendix B) can be used. Both forms lead to proposed changes in procedure, and can be interchangeable [6]. These two types of report forms are: A Problem Report Form (Appendix A) used to report programs, and a Change Control Form (Appendix B), used to record proposed enhancements. Both forms lead to changes in the procedure and are interchangeable [6].

Identify need for document to be changed

A form can be submitted by any member of a related department to identify the need for change.

Identification of the enhancement [7]

If the need to enhance a document (e.g. a change required for a functional specification) is identified by an employee, then Section A of the Change Control Form should be completed and submitted to the Controller. The Controller will give the change control form a unique reference number and log its details for future purposes. They should maintain a file of all such forms they receive and retain a copy of each form in that file for future audit purposes.

The Controller will then arrange for a review of the issue in the form, to identify if the presented issue is a user error or represents the need for a full enhancement.

Investigation and Review [8]

The investigation will be performed by the Controller, or another suitably knowledgeable individual. The investigator will record the results of the investigation in Section B of the Change Control Form. The suggested action can include no action if the investigator sees fit.

Upon investigation, all parties with a legitimate interest in the document should review the results. These reviewers may or informally consist of designated or delegated representatives or be formally constituted into a Change Review Board (CRB). The Reviewers will indicate whether the recommended action arising from the investigation should be implemented or rejected.

If the recommendations are rejected, then the Controller will file the completed Change Control Form for future reference. If the recommendations are accepted and a decision is made to implement the change then the process moves on to the next stage: Change document.

Change Document

Record Document Change [9]

All amendments to the Standard Operating Procedure should be tracked in the Change Control Form. Changes or updates to a Standard Operating Procedure are documented in a Change Control Document to serve as a record of the change control process, from beginning to end. In the Change Control Form the author will state the document's previous language followed by the revised language along with appropriate rationales and references. The author and all signatories for the Standard Operating Procedure will sign this document to show acceptance of the change. The form will be kept in the Standard Operating Procedure manual for the year the change or update occurred.

Update Document [10]

The author will review the Change Control Form, and apply the requested changes. The newest version of the document will be stored as a separate version in the configuration management (CM) library that stores documents. The change to the document should be identified in the change history of the document (as outlined on page 1), and by marking-up the text.

Review Document Change [11]

The author will double-check that the change has been applied consistently and correctly to all relevant documents that may be affected by the procedural change resulting from this process. Where beneficial, a separate individual (known as the Reviewer) should also check the revised document to ensure that there is no contradiction. If it appears that the impact of the change on the whole system could be significant, full review of all other related documentation will be done. The reviewer completes the Change Control Form and signs it off when the review of relevant secondary documentation is complete.

Release Change [12]

The Controller schedules the change so that it is included in a controlled release of the revised document. The release may occur in a matter of hours if the change is urgent, or it may not occur for weeks.

Document History will be stated in the front page of every updated Standard Operating Procedure and include a description of change, the change no., the effectiveness, the old version's effective period, and the name of the controller. The controller will record the details of the release are recorded on the Change Control Form before singing the Change Control Form to indicate the change is complete. When the Change Control Form is complete, it will be reviewed and archived by the Quality Assurance Manager (QA) and Managing Director.

Change Control Revision Period

Each Standard Operating Procedure will be reviewed for updates every 2 years. Each version is consecutively numbered and dated as it is revised by changing the version number and date in the "header" section of the Standard Operating Procedure. The revised Standard Operating Procedure will be signed by the Board of Directors (BOD).

Employee managers are responsible for making sure that updated Standard Operating Procedures are communicated to their employees, through emails notifications or updated hard copies of manuals regularly and constantly available in the office. To ensure compliance to the procedure and the effective communication of 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 Manager and employee managers of the change.
- The Approver will double check that the change is communicated to both the Quality Assurance Manager and the employee Manager's.
- Employee Managers are responsible for securing employees' training logs and training consents and communicating them to the Quality Assurance Manager.
- The Quality Assurance Manager will double check that employee training consents are secured, and training logs are completed before archiving a copy the documents.
- The Quality Assurance Manager and the Managing director are responsible for notifying the Marketing Authorization Holder and making the training logs available for audit at any time.

Obsolete Documentation [3]

When new Standard Operating Procedures are released, obsolete versions will be kept in company records away from the operating environment. These documents are under the control of the Quality Assurance Manager and Managing director. Document Control/ Quality Assurance is responsible for gathering and removing obsolete items from regular use. Manuals shall be gathered and updated at this time to ensure they contain accurate details.

Document Control/Quality Assurance personnel shall retain an electronic copy of the document for Document Control purposes; this includes retaining electronic copies of previous editions. Documents shall have the item's unique number and revision on the front page and in the electronic file name. The electronic files that are retained in the "Documentation folder" shall be separated as "Current" and "Obsolete" to prevent improper use.

Corporate personnel will then sign a training log documenting their training on the content of the revised Standard Operating Procedure. Employee managers are responsible for securing training logs and consent from all staff involved in patient care for any new Standard Operating Procedures or any further relevant changes. This must be done before the set effective date for the new/revised Standard Operating Procedure and before commencement of operations. This is done to ensure patients/patient-related items are being handled with only best practice procedures. The Quality Assurance Manager will be responsible for providing the Marketing Authorization Holder with the list of employees involved in Patients Support Programs and ensuring the availability of all training logs for audit at any time.

Healthcare organizations should be committed to the retention of superseded Standard Operating Procedures, process documents or working procedures. Healthcare organizations should keep records of such documents to infinity with no limited time for retention. Healthcare organization Standard Operating Procedures will be made available at any time, kept, and archived in company files; destruction is forbidden to occur.

Results

Contractual Change Control

Organizations are required to communicate to clients any procedural change that will impact them before the change's implementation. Change control procedures are included in contracts with stakeholders to describe the process for identifying the need for change, investigating the impact of a change (configuration items to be changed, costs, timescales, risks, etc.), and reviewing changes (i.e. accept or reject). This is done to assure stakeholders that changes to vital procedures are handled appropriately.

The wording of a change control procedure that will be included in a contract should be carefully checked. The approval of a Legal Service should be sought to overview the process. The process for change control and configuration management of the contract document is similar to that for documents as described above.

Discussion

Document Change Control Steps

Step	Description
Change Request	The change request process is used to document the request for change, the reason for the change and the impact of the change. The process is also used to assign user roles: Revision Author, Review & Approve, and Training.
Create/edit	The create/edit process is initiated when the assigned Revision Author receives a workflow notice that they have been assigned to either create a new document or edit an existing document.
Review	Once the assigned task has been completed, the Revision Author checks in the document and starts the Review workflow which allows the assigned reviewers to collaborate on the edits to a document until all reviewers reach agreement.
Approve	The approve workflow is used to approve the document. GENTIUM HEALTHCARE supports both electronic signature and digital signature technologies.
Training	The system provides two methods. Employee review or Supervisor training. Both methods provide an audit trail of training provided.
Publishing	The final step in the process publishes a copy of the signed PDF version of the document in the "Documentation folder". If there is a prior version, it is automatically replaced with the most current approved version.
Archive	Document Control/Quality Assurance personnel archives the document as per predefined schedules.

Conclusion

A. Problem Report Form [13, 14]

Section A		
Project / Program	Give Program Name	Problem Reference Number
Location of Problem	Give Module, Screen or Report name	Program Version Number
Environment Details	Give details such as Operating System / Machine / Office / City / Country	

Problem Details Include indication of importance & any Business Deadlines Critical • High • Medium • Low •	Give details such as: Specification that defines how the system should operate, Step-by-step description of what happened and how to reproduce the problem, Location of any supporting evidence (e.g. report, screen print, log file). Tick if Continued Overleaf •
Problem Date	Give Date Problem Raised
Person Raising Problem	Give Name, Organization, and Contact Number
Section B	
Investigator of Problem	Print Name
Investigation Outcome	Suggested Action and details of other items affected
Suggested Priority Critical / High / Medium / Low	Give Schedule for Resolution
Release Number	
Signoff	Signature	Date
Reviewer	
Project Manager	

A. Problem Report Form [13, 14]

Section A		
Project	Change Number	
Controlled Item	Item Version	
Identification of Aspect to be Change	For Document give section number / page number	
Change Details Include indication of importance and urgency	Tick if Continued Overleaf •	
Requester of Change Print Name	Date Raised	
Section B		
Investigator of Change		
Impact, give details of other items affected		
Investigation Outcome Reject / Action at No Cost / Action at Cost	Suggested Priority High / Medium / Low	Date Investigated
Section C		
Implementer	Date Scheduled	
Section D		
Change Implemented	Signature	Date
Implementer		
Project Manager		

How to Use this Form [16] Change Requester completes ALL boxes in Section A and passes to Project Manager. Project Manager arranges investigation of request, depending on outcome request is rejected, or given a priority and cost, and with investigator completes Section B & C, form is then retained in project files. Once change is implemented Section D is signed-off.

References

1. Garcés Gómez, M. P. Guidance for Preparing Standard Operating Procedures (SOPs). In La organización del discurso; Iberoamericana Vervuert: Frankfurt a. M., Madrid, (2008); pp 155–158.
2. ISO 9001 Requires that you maintain control of documents - 9000 Store https://the9000store.com/articles/iso-9000-tips-document-control-requirements/ (accessed May 12, 2020).
3. QMS Tier 2 Document Control Procedure; (2014).
4. Manager, S. Q.; Monitor, E. How to Write Standard Operating Procedures (SOPs). (2011), No. November, 4–7.
5. History, D.; By, C.; Date, R.; Corke, K.; Haynes, S. Standard Operating Procedure : Change Control. (2019). 2–4.
6. OVERVIEW AND PHASE I IMPLEMENTATION GUIDANCE. (1992).
7. Software Change Request (SCR) Form Date Completed Initial Requirements Specification System Design Specification System Test Plan.
8. Saudi Aramco Suppliers Safety Management System.
9. Guidance Document for the Writing of Standard Operating Procedures (Taken from United States Environmental Protection Agency Guidance for Preparing Standard Operating Procedures (SOPs) EPA QA/G--6 [EPA/600/B--07/001 April 2007]).
10. Configuration Management vs Change Management | PM Study Circle https://pmstudycircle.com/2012/01/configuration-management-vs-change-management/ (accessed May 12, 2020).
11. Kelly, J.; Sadeghieh, T.; Adeli, K. Peer Review in Scientific Publications: Benefits, Critiques, & A Survival Guide. EJIFCC (2014). 25 (3), 227–243.
12. Watt, A. 4. Framework for Project Management. BCcampus August 14, 2014.
13. Kgatelopele Municipality https://kgatelopele.gov.za/files/Policies/IT Change Control Policy and procedures_KLM 2016-17.pdf?cv=1 (accessed May 12, 2020).

14. PROBLEM REPORT FORM.
15. Change Management Request Form https://www.pvamu.edu/its/wp-content/uploads/sites/46/change-management-request-form_fill.pdf (accessed May 12, 2020).
16. Project Change Request | IST Project Management Office | University of Waterloo https://uwaterloo.ca/ist-project-management-office/methodologies/project-management/execution/project-change-request (accessed May 12, 2020).