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1. PURPOSE

The purpose of this procedure is to describe the process by which Quality Management System (QMS) documents are originated, approved, revised, and retired. Periodic review of documents is also included.

2. SCOPE

This SOP applies to all CLS QMS approved, controlled documents.

3. RESPONSIBILITIES

Author is responsible for the initiation of a new document or update of an existing document.

Reviewer is responsible with reviewing the changes made by the author and identify improvements.

Approver is responsible for the final approval of the document.

Document Control is responsible for the flow of the document with the master index.

4. PROCEDURE

4.1 Overview

Section 4 outlines the key processes for the management of documentation as follows:

Section 4.2 General requirements of documentation

Section 4.3 Creating a new document.

Section 4.4 Updating an existing document.

Section 4.5 Retiring a document

Section 4.6 Periodic Review of Documents

4.2 General

4.2.1 General guidelines for preparing QMS documents:

- Documents must be written in a clear, logical, stepwise fashion.
- The responsible role must be identified for all action steps.
- The use of Process Flow Diagrams or similar is to provide clear and unambiguous information is encouraged.
- Where acronyms are used these must be explained at the first point of use and the acronym used thereafter.

4.2.2 Document Control maintains a document index containing, at a minimum, the following information regarding SOPs and other QMS documents:

- Document title
- Document number (unique to the document)
- Document version number
- The process/functional area to which the document belongs
- The document effective date
- The document periodic review date.

4.2.3 Documents are tracked using prefixes per Table 1

Documentation Type	Documentation Number Format
Policy	POL
Procedure	SOP
Form	FOR

Table 1: Description of Documentation Type for Naming Purposes

4.2.4 Documents are version controlled with the first version of a document being version 1. Subsequent versions will increase in increments of 1.

4.2.5 SOPs are written in the format outlined in the CLS document template FOR-2.

4.2.6 Forms are written in the format outlined in the CLS document template FOR-3.

4.2.7 The life of a document includes the following status:

- Draft
- Effective
- Superseded
- Void

4.3 Creating a New Document Process Flow

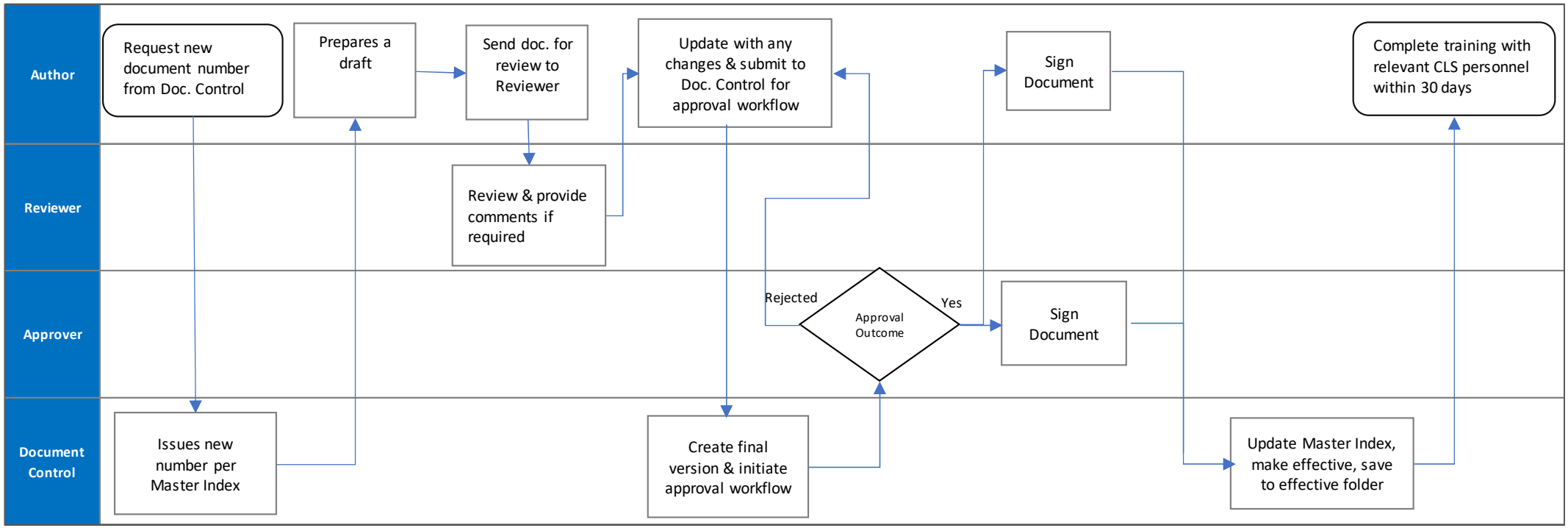


Figure 1 outlines the process flow to create a new document.

4.4 Updating an Existing Document

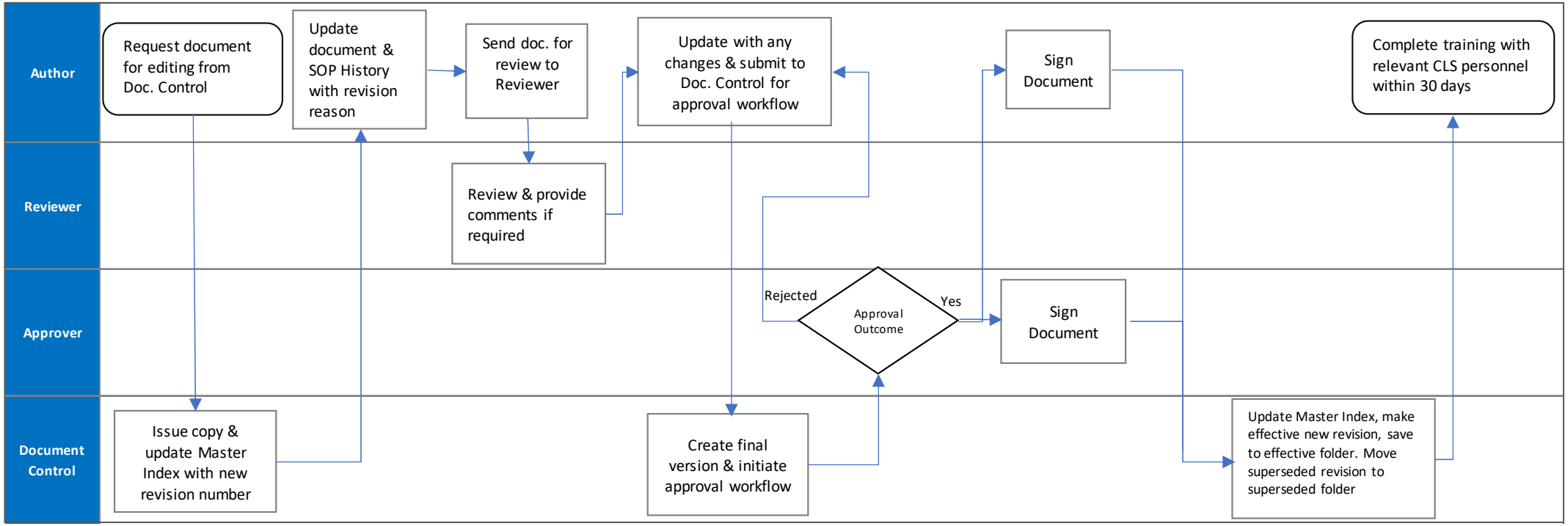


Figure 2 outlines the process flow when there is a requirement to update a document.

4.5 Retiring a Document

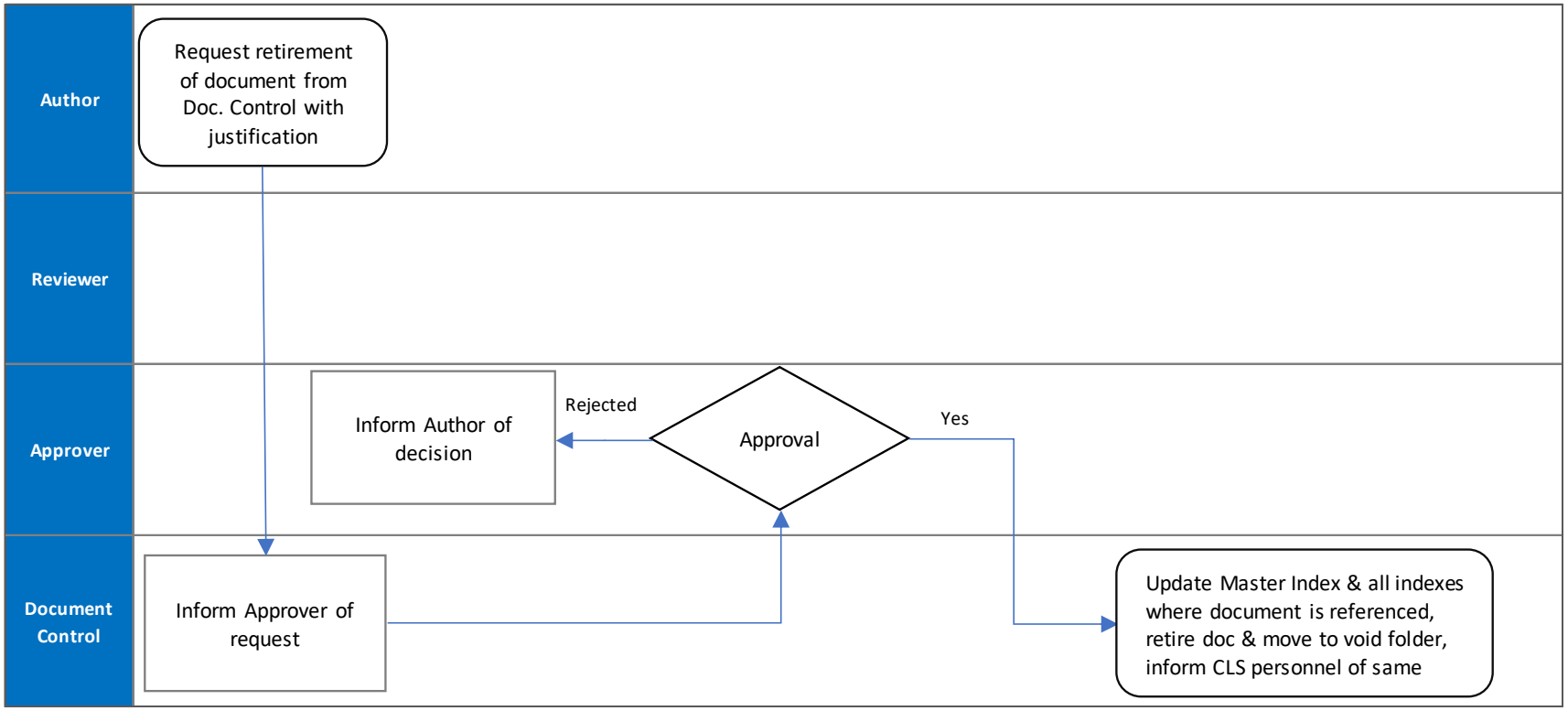


Figure 3 Outlines the process of Retiring a Document.

4.6 Periodic Review of Documents & Training Matrix

4.6.1 The following table is the periodic review and training required of controlled documents. A revision of a controlled document can be triggered either following a periodic review or outside the periodic review cycle if necessary.

Document Type	Minimum Review Frequency	Mandatory Training Required
SOP	Every 36 Months	30-day grace period
Form	Not Required	None required
Associated Instruction	Every 36 Months	None required
Policies	Every 36 Months	None required
Guideline	Every 36 Months	None required

4.6.2 The review date will be included and tracked in the Master Index by Document Control.

- It is the responsibility of each process owner to ensure that all controlled documents generated within their process remit are handled in accordance with this procedure, review of the master index on a regular basis is required to ensure their documents are within their review period. Review of the periodic review process will also be performed as part of SOP-6 Self-Evaluation, Management Review and Continuous Improvement.

5. ABBREVIATIONS AND DEFINITIONS

5.1 Abbreviations

Abbreviation	Description
QA	Quality Assurance
QMS	Quality Management System
QM	Quality Manual
SOP	Standard Operating Procedure
PDF	Portable Document Format
SP	SharePoint
WI	Work Instruction

5.2 Definitions

Term	Definition
Effective Date	The date on which a procedure is implemented and becomes available for use (after all relevant personnel have been trained).
Forms	Forms are documents used to record information and are always associated with a parent SOP, which describes their use. Electronic copies of Forms for use can be made available via SharePoint by Document Control.
Master Document	The original, signed copy of a document, made available on One drive.
Policy	A QMS document which describes the organisation's adopted or proposed course or principle of action. Policies are the 'what to' documents.
SOP	Standard Operating Procedure: A document which provides instructions on how policies are implemented and/or tasks are performed. Procedures (and Work Instructions) are the 'how to' documents.

Superseded document	A document which has been replaced by a newer version of the same document e.g., when version 5.0 of a document has been made effective, version 4.0 becomes a superseded version.
Version number	This is the number that indicates the version control of a document. It is included in the header of SOPs and possibly elsewhere for other documents. All QMS documents are version controlled.
Void	A document that has been removed from use.
Work Instruction (WI)	Associated with an SOP, WIs contain detailed, step-by step instructions on how to perform specific tasks.

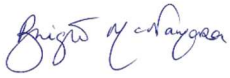
6. RELATED DOCUMENTS

Doc ID	Title
SOP-5	Employee Development Training
SOP-6	Self-Evaluation, Management Review and Continuous Improvement
FOR-2	SOP Template
FOR-3	Form Template

7. SOP HISTORY

Revision #	Reason for Revision
1	Original Version

8. DOCUMENT APPROVALS

Role	Name	Signature	Date
Author	Maria Ryan		12/07/2021
Approver	Brigid McNamara		12/07/2021

