Standard

Operating Procedure

-0002 WRITING PROGRAMMATIC STANDARD OPERATING PROCEDURES

Table of Contents

1. Document Control	1
2. Procedures	1
2.1. Purpose & Applicability	2
2.2. Definitions	2
2.3. Summary of Method	3
2.4. Personnel Qualifications & Responsibilities	
2.5. Equipment & Supplies	
2.6. Procedural Steps	6
2.6.1. Writing SOPs	
2.6.2. Revising SOPs	
2.7. Data & Records Management	
2.8. References	
3. Quality Control & Assurance	9
4 Appendix	1 ^

0002 PAGE 1 OF 10

1. Document Control

Number	Division	Author	Date	Pages
#0002	C&T	K. Heller	10/13/21	12

Revision	Date	Reviewer	Division	Description of Change(s)
01				
02				



NOTE

The *Document Control* section of any SOP is critical to good record keeping—in SOP drafts, this information should go into a header.

Remember when writing to:

- Review policies
 - in Data & Records Management
 - in Quality Control & Assurance
- Review steps
 - in Procedural Steps > Writing SOPs
 - in Procedural Steps > Revising SOPs

2. Procedures



NOTE

Through the document, concision and clarity will help readers understand quickly.

Remember when you write to:

- Be clear
 - use simple terms and language; avoid jargon
 - use directives and avoid the passive voice
- Be concise
 - · use short sentences; avoid complex statements
 - use bulleted items and lists; avoid lengthy paragraphs

2.1. Purpose & Applicability

The purpose of this document is to provide employees with a rubric for thoroughly documenting their work processes. Developing and using standard operating procedures documents is critically important to the establishment and maintenance of quality standards as well as ensuring consistent output across the whole organization.

Use this document as both a guide and a template for writing administrative or programmatic SOPs.

(For a guide to writing Technical SOPs, please see -001 / Writing Technical Standard Operating Procedures²)



NOTE

In the *Purpose & Applicability* section, clearly and briefly state the intended: use of the process or work, and conditions under which the process is followed.

Remember when you write to:

- · Stay on topic
 - keep explanations short yet descriptive
 - · keep text within the scope of the section, document, and process described

2.2. Definitions

	Shortened version of company name, ' Inc."
Paligo (CCMS)	Paligo is a brand name for a Component Content Management System, or CCMS, based on the DocBook5 standard, which is characterized by it's management of text and image content at a topic level rather than document or page level
Release ()	In the context of''s document control, it is synonymous with "publish" for use by company employees
Standard Operating Procedure (SOP)	An official set of step-by-step instructions compiled by an organization to help workers carry out routine operations
Terminology (terms)	Special words, names, or phrases associated with or used within a specific field such as an industry or profession

0002 PAGE 3 OF 10



NOTE

In this *Definitions* section, clearly and succinctly define uncommon or shortened words and terminology used within the text of the SOP.

Remember when writing:

Define all

- · all acronyms and abbreviations
- all industry-specific terminology
- · all company-specific terminology
- · all words, phrases, or names not commonly understood by the general public
- · all words with multiple or conflicting meanings

2.3. Summary of Method



NOTE

In the *Summary of Method* section, state an abbreviated version of what is contained in the remainder of the SOP document.

Remember when writing to:

Touch upon

- Personnel Qualifications & Responsibilities
- · Data & Records Management
- Quality Control & Assurance
- · Process Steps
- Equipment & Supplies (if needed)

This SOP details 's procedures for writing, styling, numbering, reviewing, storing, and revising SOP documents, to ensure quality output across various business processes. This procedure for writing SOPs serves several functions, and requires the execution of a series of processes.

Functions:

- 1. Establish quality controls for processes
- 2. Serve as a reference tool for employees
- 3. Help management evaluate processes
- 4. Provide a historical record of procedures implemented

Requirements

SOP authors must be individuals experienced in the process they describe

- Completed SOPs must be reviewed by appropriate peers and reviewed and approved by management prior to their release
- SOPs must meet the standard format for styling, information required, and numbering
- Semi-annual review is required to ensure that the procedure is relevant and up-to-date
- 's archival system must be used to ensure that records are kept and only current SOPs are available for employee use

2.4. Personnel Qualifications & Responsibilities



NOTE

In the *Personnel Qualifications & Responsibilities* section, detail special qualifications users should have.

Remember when writing to:

- Be specific
 - include prerequisite certifications and trainings
 - include practical knowledge, like software skills
 - include any individual roles or departments that are responsible for the activity described

Qualifications

Authors and reviewers of programmatic or administrative SOPs must:

- 1. Be currently employed by or their services retained by
- 2. Have deep knowledge of their field
- 3. Regularly perform the process(es) described
- 4. Be willing to take on the related responsibilities below

Responsibilities

Authors

- Authors of SOPs are responsible for describing process(es) in sufficient detail for another worker to follow and execute
- 2. Authors of SOPs are responsible for ensuring a peer review of the SOP is performed before its submission to management, use, or release
- 3. Authors of SOPs are responsible for following 's SOP preparation, numbering, retention, indexing, and revision rules and guidelines

Managers & Department Heads

- Managers or department heads are responsible for ensuring that all routine procedures in their area are documented using SOPs
- 2. Managers or department heads are responsible for approving:
 - a. All SOPs prior to their release for employee use

- b. All revisions to SOPs (see *Procedural Steps > Revising SOPs*)
- c. All discontinuation of SOP use and archiving of SOPs

All Employees

- 1. Workers are responsible to follow the process(es) according to the SOP, and identify to their manager when an SOP (or a component of that SOP) is not being followed
- 2. Workers are responsible for identifying the need for development or revision of an SOP and to convey that need to their manager or department head
- 3. Workers must read new or revised SOPs within five working days of release if the procedures are relevant to their position
- 4. Workers must read and document their understanding of applicable SOPs before executing the documented procedure for the first time

2.5. Equipment & Supplies



NOTE

In the *Equipment & Supplies* section, List any software, hardware, or other special equipment or supplies necessary to carry out the instructions in the procedural steps.

Remember when writing to:

- Avoid making assumptions
 - aim to list out all needed equipment and supplies, even if they seem obvious
- Computer with operating system capable of creating, zipping and sending files (hardware)
- G-Suite account or similar (software)
- · Draw.io, Visio, or other flowchart tool
- Google Drive, or other file-zipping tool
- · Gmail, Outlook, or other email platform
- Google Docs or Microsoft Word
- · Paligo (software)
- Programmatic SOP Template (document)

2.6. Procedural Steps



NOTE

In the *Procedural Steps* section(s) include only the steps necessary to executing the procedure—excess material can create a compliance risk.

Remember when writing to:

- Write "big to small"
 - start with major steps
 - then add minor steps
 - and individual actions
- Throughout where necessary, add clarifying elements like:
 - warnings
 - images
 - videos

2.6.1. Writing SOPs

Once the need for an SOP is established by a department manager, and an appropriate author is identified, the drafting process can begin.

1. Prepare the document

- a. Start with this document, # ____-0002, and/or a ____-provided <u>template</u> to outline your content
- **b.** Use either Microsoft Word or Google Docs to author the document
 - i. Use only the system-standard font
 - **ii.** Use only the standard formatting options (H1, H2, etc) to format titles, subtitles, or other headings
- **c.** Do *not* include a table of contents or cover page
- **d.** Include a header with the following information about the origin of the SOP:
 - i. Name of procedure
 - ii. Business Division
 - iii. Author's name
 - iv. Date effective
 - v. Page number and total number of pages

2. Author the content

- **a.** Describe processes in precise steps in enough detail to be followed accurately by a new worker
- **b.** Separate guidance and/or warnings from mandatory procedural steps
 - i. For procedural requirements:
 - A. Use simple directive statements and/or indicate "must" or "shall"
 - **B.** Eliminate language that leaves room for doubt about whether to perform an action, such as "should" or "may"
 - ii. For general guidance and warnings:

- insert into separate bullets, processes, or sections
- c. For programmatic/administrative SOPs, include the following sections at a minimum:
 - i. Purpose & Applicability
 - ii. Summary of Method
 - iii. Procedural Steps
 - iv. Quality Control & Assurance

3. Attach additional materials

- a. Insert applicable images and visual aids within procedural steps
- **b.** Attach, insert, or link any reference materials in the *References* section
- **c.** Include a process flowchart in the *Appendix* section

4. Prepare the draft submission

• Create a folder with the SOP document, all images, videos, charts, and other references

5. Perform a peer review

- a. Send the draft package to your working peer group and solicit feedback
- **b.** Integrate peer input before seeking approval

6. Seek managerial approval

- **a.** Submit the draft package to your manager or department head for approval
- **b.** Perform any subsequent requested edits
- c. Repeat steps 6a and 6b until SOP is approved

7. Submit approved SOP package for document control

- **a.** Zip approved SOP package
- b. Fill out <u>Document Control Form</u> to obtain a new document number
- c. Email zipped and approved SOP to Certification & Training

2.6.2. Revising SOPs

As soon as a qualified employee identifies that any portion of the SOP no longer accurately describes the procedure within, the revision process must begin, or the document must be designated as discontinued and archived.

1. Identify all necessary revisions

 Revisions such as typographical errors, formatting or grammatical errors can be submitted to the <u>Certification & Training Department</u> or document author without approval and shall be corrected and re-released immediately without issuing a revision number

2. Submit all revisions for approval to managers or department heads

- Revisions requiring management approval include:
 - i. The addition, removal, or change to procedural steps
 - ii. The addition of clarifications, images, addenda, or procedures
 - iii. The combining of two or more SOPs
- **3. Managers or department heads will then submit the approved revisions** to the document via their Paligo account, or email to <u>Certification & Training Department</u>
- 4. Revision numbers are issued upon approved revision release



IMPORTANT

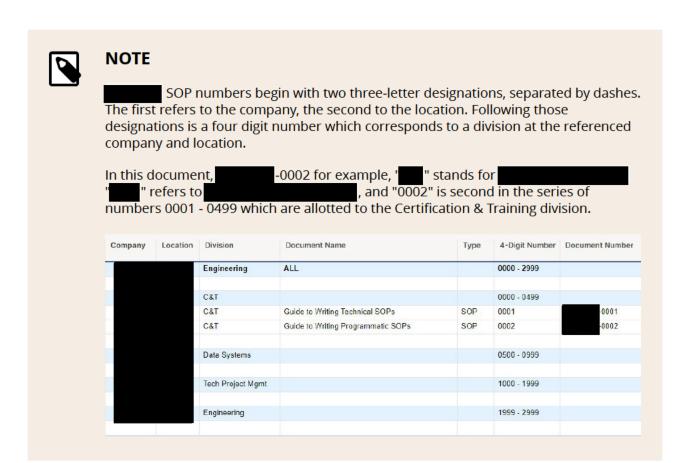
Revisions or versions may be reversed or reverted upon request by a department head

2.7. Data & Records Management

SOP Numbering & Retention

The Certification & Training Department will:

- 1. Manage the release of submitted SOPs
- 2. Maintain records of revisions to submitted SOPs
- 3. Assign final SOP numbers based on location, business division, subject matter, and number of existing versions
- 4. Manage Archive of SOPs



2.8. References

Citations & Documents

- 1. Office of Environmental Information (2007, April). *Guidance for Preparing Standard Operating Procedures (SOPs) EPA QA/G-6*. United States Environmental Protection Agency, epa.gov. https://www.epa.gov/sites/default/files/2015-06/documents/g6-final.pdf
- 2. Inc. (2021, October 13). Writing Technical Standard Operating Procedures (# -0001)
- Programmatic SOP Template v1.1

0002 PAGE 9 OF 10



NOTE

In the *References* section, include all in-text citations, applicable standards, regulatory information, and reference materials. Remember, when writing:

Use links

- · to reference lengthy materials
- to reference materials not owned or licensed by the company

Use content

- insert full images, charts, and graphics when possible
- insert full documents, sections or texts up to several pages

3. Quality Control & Assurance



NOTE

In the *Quality Control & Assurance* section, list steps and measures for the review and oversight of the process(es) described within the SOP.

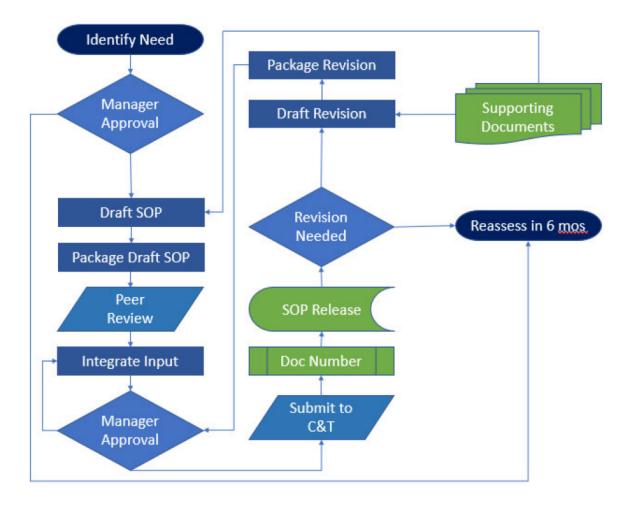
Remember when writing: Include verification and validation plans, and output testing metrics.

Include all

- plans for verification and/or validation of deliverables
- · metrics for output and/or results testing
- · methods and time frames for process review
- 1. Managers must review SOPs issued by their respective departments at a minimum of once every six months for relevance and accuracy.
- 2. Each year, managers must conduct and complete twice-annual departmental SOP reviews in the months of January and July.
- 3. All SOP revisions must be logged in their respective *Document Control* sections.
- 4. SOP reviews not requiring revisions must also be logged in their respective *Document Control* sections.

4. Appendix

Figure 1. SOP Writing Flowchart



This flowchart details the process for authoring and maintaining SOPs.



NOTE

In the *Appendix* section, insert or link to additional tools to help other perform the process detailed in the SOP procedures.

Remember when writing to:

- Optimize usability
 - include a process flowchart to aid visual learners
 - include checklists for faster implementation