

Practical and Effective Standard Operating Procedure Development

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Agenda

- Procedure Outline
- SOP Template
- Test Run
- DCR/DCN
- Approval Process
- Training
- Annual or Biannual Review

Outline

- Floor Time
- Q&A During Observation
- Define Objective/Purpose
- Define Scope/Boundaries
- Capture All Materials & Equipment Required
- Go through Step by Step Procedure with “Best Technician or Installation Representative”
- Capture Details
- Allow Sufficient Time to “Get It Right”
- If an equipment procedure - draft during installation and start up for best results – Then Dry Run

Effective SOP Template

- PURPOSE - *Example*
 - The purpose of this Standard Operating Procedure is to describe the cleaning procedures, documentation, cleaning and sanitizing agents to be used, and required frequencies for disinfecting the production areas.
- SCOPE – To answer these questions
 - What does this SOP cover? How inclusive? Does it cover routine, emergency and non-routine cleaning procedures? Does it define materials and types of surfaces to be cleaned?

Template Continued - References

- Do we reference other facility or site SOPs within this SOP?
 - Include all SOPs that employees would need to be trained on in order to perform this procedure
 - Safety – Address PPE required for this procedure.
 - Equipment Operation
 - Cleaning Agent Preparation
 - Logbook Completion
 - Deviations/Out of Specification (OOS)

Template Continued - Responsibility

- Define Management Responsibility for this procedure.
- Define Responsibility of department performing the SOP
- Define any Laboratory Responsibilities
- Define Other Group Responsibilities e.g.; site committees, EH&S, Logistics, etc.

Template Continued - Definitions

- Definitions should provide detail of what and how it impacts this procedure
 - Three letter Acronyms
 - Active and Inactive Animal Laboratory Areas
 - Idle Animal Laboratory Areas
 - Disinfecting Cleaning Cycle
 - Area Classification
 - Sanitizing, Disinfecting, Sterilizing/Cleaning
 - Fixtures/Furniture/Equipment

Template Continued – Equipment & Materials

- List of equipment required to perform procedure
- List of materials required
- Assembly/Disassembly Requirements
- List of Job Aids/Illustrations
- Sequence of Use - Materials and Equipment

Template Continued – Procedure

- General Section – May include following:
 - Preparation of materials used in procedure for example type of water to be used if making up a disinfectant or cleaner
 - Time limits for certain actions to achieve specified results – sanitization hold time, disinfectant hold time, sterilization hold time, wash time, rinse time, etc.
 - Safety precautions
 - Animal exposure precautions

Template Continued – Procedure

- Step by step instruction
 - Headings with Sequential Actions to be taken
 - Action verbs to start each sequence
 - Expected results from each action
 - Documentation required for each step
 - Table References that may contain critical operating parameters, load diagrams, documentation requirements, frequency requirements, etc.

Revision History

- Section for Revision Number
- Effective Date of Document
- Signatures of Approval Designates
- Reason and SOP Sections Affected by Latest Revision
- Alternative Method is to Reference a Change Notification, Document Change Request or Document Change Notice

Test Run

- Draft of Procedure
- Go to floor and run it through with the “Best Technicians”
- Provide Opportunity for Q&A
- Revisions/Sequence Modifications/Missing Definitions
- Advantages
 - Real Time Application
 - User By-In of New Procedure
 - Begins Initial Training Process

CN/DCR/DCN

- A Formalized SOP-Driven Process for Initiating, Tracking and Controlling Changes to Site SOPs.
 - Change Notices (CN), Document Change Requests (DCR) and Document Change Notices (DCN) are usually assigned a number per an SOP that starts, documents what is changing and reasons for the changes.
 - Electronic Systems e.g; Documentum, Trackwise, etc. are now replacing some of these paper systems since e-sigs are sequential, time stamped and considered to be the same as an actual pen & ink signature

DCR Example

CC#	Change Owner (s):	Change Level (0, 1, 2a, 2b, 2c)	If Not 0 (CC# Required)
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Document Name(s) (#s) if known (if this is a <u>new</u> FORM, include associated SOP number for reference purposes)	
Title	
Author Recommended Approvers Required (include names/departments)	Author: Responsible Dept. Approver: Other Approvers:
Applicable Sites	SPECIFY:
Document Functional Area	
Product or Site Identifier	
Material Master # (Batch Records only)	NA

DCR Example Continued

Reason for Change	<input type="checkbox"/> Change Control <input type="checkbox"/> CAPA <input type="checkbox"/> Non Conformance <input type="checkbox"/> New Document <input type="checkbox"/> Obsolete <input type="checkbox"/> Periodic Review <input type="checkbox"/> Validation Use <input type="checkbox"/> Other
Is Revision Training Required?	
Target Effective Date	
Required Book Locations (New SOPs Only)	

NOTE: If a drawing is affected, follow applicable SOP prior to submitting Change Notice package to Documentation Department.

SUMMARY OF CHANGES	JUSTIFICATION

APPROVAL PROCESS

- Route Proofed Procedure with document and supervisor approval – follow process
- Approval Process Can Be Time Consuming
- Follow Approval Process and Monitor for Delays
 - If delay results from a minor revision work with the approver to keep the process moving

Training

- SOP Approval and Issuance
- Posting of SOP Book Locations
- Training of Personnel
- Documentation of Training
- Importance of Training for Maintenance of SOPs

SOP Review

- Standard Operating Procedure for Maintenance of Site SOPs
- Importance of Current SOPs During Audit Process
- Example

SOP Review Form

STANDARD OPERATING PROCEDURE AUDIT REVIEW

Standard Operating Procedure Title		SOP Number / Revision
SECTION I - To be completed by Quality Systems (Attach current copy of SOP)		
Date of Last Change or Review:		Manager or Department Responsible for Review:
Date Form Initiated:		Review Due Date:

SECTION II - To be completed by Manager (or delegate) responsible for the review.

A. Changes Required (check one)

No changes required. Document is current as is.

Make changes as listed (attach a list of changes or a draft of revisions to the SOP)

Obsolete (list reasons to obsolete document)

B. Manager (or delegate) signature and date: _____

Note: This form should be completed and returned to Quality Systems by the "Review Due Date" above.