



# 2.7 Document Control

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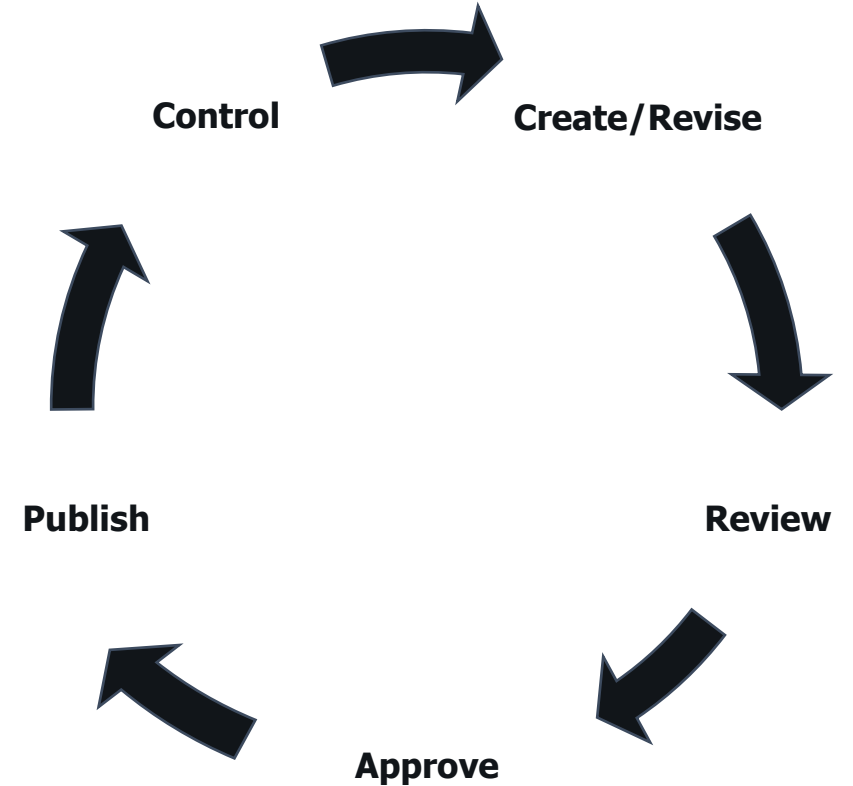
# What Is Document Control And Why Is It Important?

## ■ Document Control

– In simple terms, it is a Process of Applying Document Management Standards.

## ■ What is the Intent of a Document Control System

- A Systematic Approach creates Standardization
- Enhances Compliance Effectiveness
- Improves Quality
- Regulates Security
- Fosters Increase in Efficiencies



# Auditing Document Control

- The Requirements

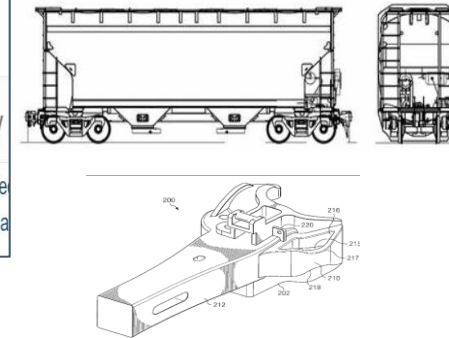
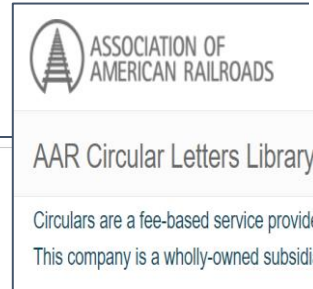
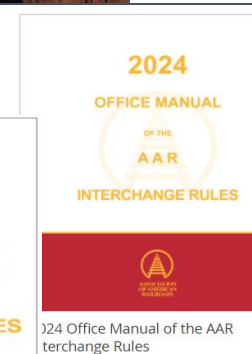
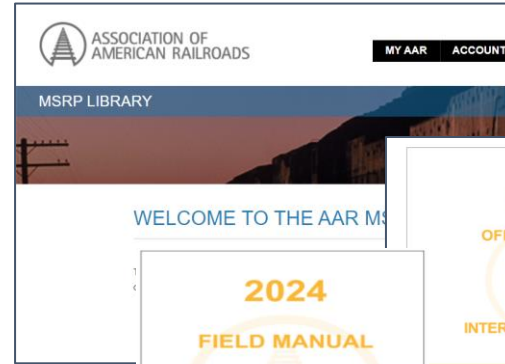
# 2.7 Document Control

- **2.7.1** The *facility shall* establish and maintain documented procedures to control all documents affecting quality, including, to the extent applicable, documents of external origin such as standards and customer drawings.



## How to Audit?

- SOP – Standard Operating Procedures
- WI – Work instructions
- FO - Forms
- AAR MSRPs
- AAR Field Manual
- Circular Letters & Equipment Advisory
- 49 eCFR CHAPTER II
- Customer Drawings
- Supplier Drawings



SOP TITLE	
<b>Control Information</b>	
Subject or Title: Process Control	Procedure Number: SOP-XXX-XX
Procedure Department:	Procedure Owner:
<b>Approvals</b>	
Approval Date:	
Approval Date:	
Approval Date:	
Distribution: Operations	

WORK INSTRUCTION TITLE				
<b>Control Information</b>				
Subject or Title:		Work Instruction Number: WI-XXX-XXX		
Work Instruction Department:		Work Instruction Owner (Manager):		
Departments Affected:				
<b>Approvals</b>	<b>Initial issue</b>	<b>Revision #1</b>	<b>Revision #2</b>	<b>Revision #3</b>
Distribution:				
Purpose/Scope		Reference Documents		Required Tools & Equipment

# 2.7 Document Control

- **2.7.1.1** The *facility shall* complete and maintain a *Quality Assurance Program Evaluation (QAPE) Checklist* identifying the corresponding line item from the *facility's* Quality Assurance Manual and/or procedures that address each requirement in the current Specification M-1003.

## How to Audit?

- Quality Manual (prior to and on-site)
- Completed QAPE (prior to and on-site)
- Request for Review, the Applicable documents for Identifying and corresponding with line item. Examples below
  - Standard Operation Procedures
  - Work Instructions
  - Applicable Forms
  - Dates | Revision
  - Material Certs

		Manual		Audit		Facility Roadmap / Auditor Objective Evidence
Paragraph	Element	Yes	No	Yes	No	
		2.1	Objective of Quality Assurance Program	✓		
2.2	Applicability and Scope	✓		✓		
2.3	Quality Assurance Program and Manual Requirements	✓		✓		
2.4	Management Responsibility	✓		✓		
2.5	Production, Inspection, and Test Planning	✓		✓		
2.6	Corrective and Preventive Actions	✓		✓		
2.7	Document Control	✓		✓		
2.8	Measuring and Testing Equipment	✓		✓		
2.9	Purchasing/Subcontracting	✓		✓		
2.10	Incoming Inspection	✓		✓		
2.11	In-Process Inspection	✓		✓		
2.12	Final Inspection	✓		✓		
2.13	Inspection Status	✓		✓		
2.14	Identification and Traceability	✓		✓		
2.15	Process Control	✓		✓		
2.16	Preservation, Packaging and Shipping	✓		✓		
2.17	Quality Records	✓		✓		
2.18	Nonconformance Control	✓		✓		
2.19	Quality Assurance Program Review and Manual Revision	✓		✓		
2.20	Statistical Methods	✓		✓		
2.21	Internal Quality Audits	✓		✓		
2.22	Training	✓		✓		
2.23	Contract Review	✓		✓		
2.24	Design Control	✓		✓		

### Example of a Facility's Roadmap vs. Auditor's Objective Evidence

Facility Roadmap						
Paragraph	Element	Manual		Audit		Facility Roadmap / Auditor Objective Evidence
		Yes	No	Yes	No	
2.10.1	Does the facility inspect, test, and identify incoming items as required by the inspection and test plans?	X				See Inspection Test Procedure MSW-008 rev.2 for incoming inspection detailing process steps in 2.5 - Production, Inspection, and Test Planning
2.10.2	Does the facility check the evidence provided by subcontractors and suppliers as a means of verifying quality per the requirements of paragraph 2.10.1?	X				See Quality System Manual section 2.10, para. 3.2 states all incoming materials received from subcontractors and suppliers will be verified for quantity, quality, and shipping damage
2.10.3	Does the facility hold incoming items until the required inspection and tests are completed or the necessary inspection and test reports are received and verified (except when items are released under positive recall)?	X				See Incoming Inspection Procedure 2.10, Rev. 7 Dated 06/25/2021 for materials that require Material Test Reports (MTRs) for steel plates also color codes for on-hold and approved for release

# 2.7 Document Control

- 2.7.2 The facility **shall** establish and maintain a master list or equivalent document-control procedure identifying the current revision status of documents.
- 2.7.3 Authorized personnel shall review documents and approve them for adequacy prior to use.

- ### How to Audit?
- Review Procedure for Documents Control.
  - Throughout the audit when reviewing SOPs | Wis | Forms gather.
    - Unique Identifier
    - Revision Number or Letter, if used
    - Revision Date
    - Approver(s)
  - Master list (Hard copy of Electronic)
    - Ensure Information from Documents agrees with Master List

**Master Document Index**

**AAR Quality Assurance Program Documentation**

Department, Document Number, Title	Issue Date	Revision Number	Revision Date	Approved by
QA MP-01 - M-1003 Certification Management: Issuing QAC Ballot	2017-09-28	D	2023-06-27	MR
QA MP-02 - M-1003 Certification Management: Maintaining Approvals	2017-05-19	C	2021-07-08	MR
QA MP-03 - Procedure for Creating an Online Training Event (Configio)	2017-06-06	C	2021-07-08	MR
QA MP-04 - M-1003 Certification Management: New Applications	2017-06-22	E	2023-10-18	MR

SharePoint

**Company Name**

☆ Not following

+ New | Upload | Sync | Add shortcut to OneDrive | Pin to Quick access | Export to Excel | All Documents

Procedures & Forms

Name	Document Number	Revision Date	Approval
AAR Section J Element : 2.01 - Objectives of Quality Assurance Program (1)			
Element <b>Objectives of Quality Program.pdf</b>	SOP-QA-2.1.1	7/24/2023	J. Doe
AAR Section J Element : 2.02 - Applicability and Scope (1)			
Element <b>Applicability and Scope.pdf</b>	SOP-QA-2.2.1	7/24/2023	J. Doe
AAR Section J Element : 2.03 - QA Program and Manual Requirements (1)			
Element <b>Quality Assurance Manual.pdf</b>	SOP-QA-2.3.1	7/24/2023	J. Doe
AAR Section J Element : 2.04 - Management Responsibility (2)			
Element <b>Management Responsibility.pdf</b>	SOP-QA-2.4.1	7/24/2023	J. Doe
Form <b>Management Reviews M-1003.pdf</b>	FO-QA-2.4.1	7/24/2023	J. Doe





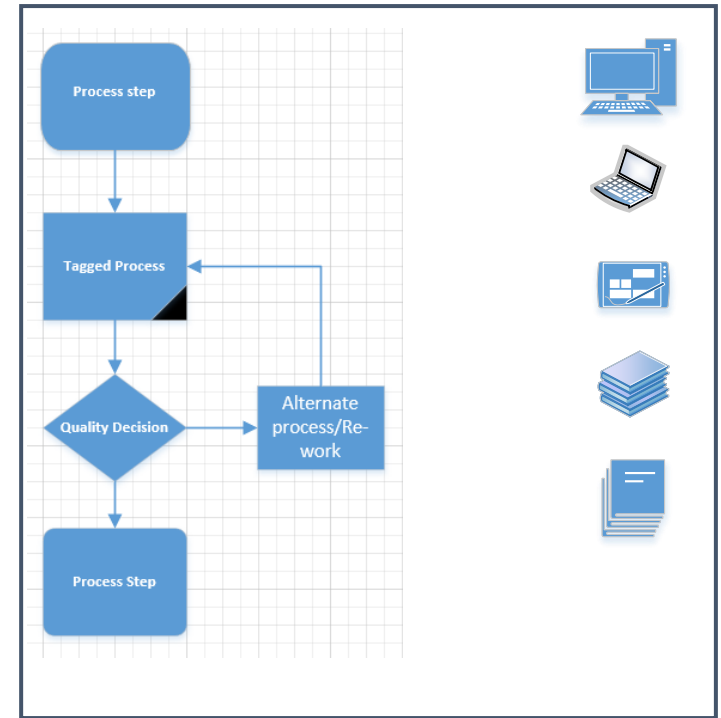
## 2.7 Document Control- continued

### 2.7.4 Established procedures **shall** ensure the following:

- 2.7.4.1 The applicable versions of documents must be available at all functional areas, including inspection and test points.
- 2.7.4.2 Applicable standards, internal procedures, and forms necessary to demonstrate compliance with this specification and any related technical requirements must be maintained in English, as well as the appropriate language for the user.

### How to Audit?

- Boots on the ground! Go & See!
- Processes (Track/Line, Work Cell and/or Office-Administrative Service being provided).
- Team Member's ability to access required document(s) to perform Task or Service.
- Can the Team member read/comprehend the requirements in document to perform Tasks?



Standard Operation Procedures = Procedimiento Operativo Estándar (Spanish)

Work Instructions = 작업 지시 (Korean)

Customer Drawing 123 rev. 1 = ग्राहक ड्राइंग 123 संस्करण 1 (Hindi)

## 2.7 Document Control- continued

2.7.4 Established procedures **shall** ensure the following:

- 2.7.4.3 Invalid and/or obsolete documents are promptly removed from all points of issue or use or otherwise assured against unintended use.
- 2.7.4.4 Any obsolete documents retained for legal and/or reference purposes shall be suitably identified and assured against unintended use.

### How to Audit?

- Works in Conjunction with Boots on the ground.
- Select and record documents at point of use and Validate all the above to current Master list
  - Unique Identifier?
  - Revision level?
  - Approver(s)?
  - Handwritten notes?
- Legal document retention Procedure
  - How are they Ided?
  - How are they stored and protected from use? (Electronic or Hard copy)





# 2.7 Document Control- continued

2.7.5 When changes are made to documents, the facility **shall**:

- 2.7.5.1 Ensure that changes to documents are approved by authorized personnel.
- 2.7.5.2 Ensure that the changes are processed promptly at all specified locations.
- 2.7.5.3 Maintain a record of changes and, where practical, identify the nature of the changes.

## How to Audit?

- Approvers as designated by procedure?
- Approvals Dates? - Revision level?
- Distribution Location?
- When did change(s) go into effect?
  - If applicable, is there a documented clean point for Running change?
- Identify the nature of the change, why?

SOP TITLE

Subject or Title:		Procedure Number: SOP-XX-XX-XX			
Procedure Department:		Procedure Owner:			
Departments	Id				
Approver(s)	Title	Initial	Revision #1	Revision #2	Revision #3
		Approval Date:			
		Approval Date:			
		Approval Date:			
Distribution Locations:					

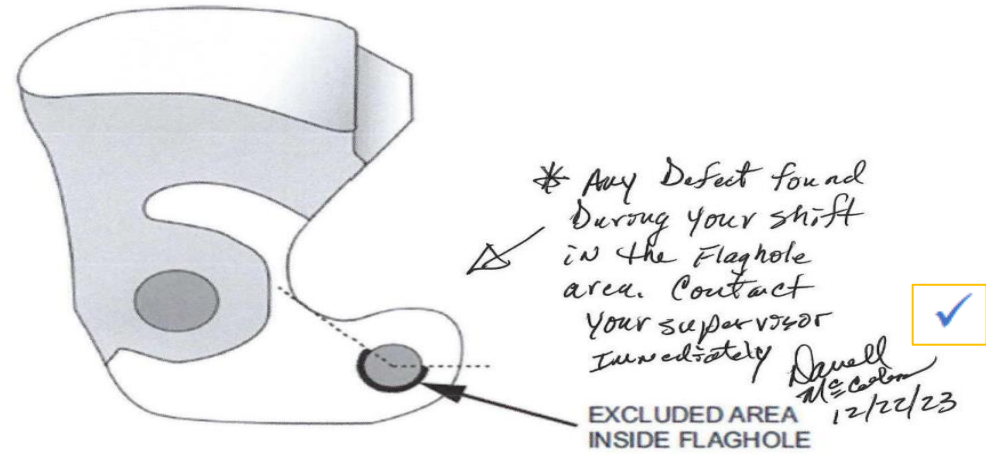
SOP TITLE

List of Effective Changes

Date	Section or Line	Description

# 2.7 Document Control- continued

- **2.7 Document Control- continued**
  - 2.7.6 Written notes on documents are acceptable provided they are made by authorized persons according to established procedures.
  - 2.7.7 The facility **shall** revise and reissue documents after a practical number of changes have been issued in accordance with established procedures.



## How to Audit?

- Review the content of the written note(s).
- Review the approver of the notes(s)?
- When was the notes written?
- Does meet Company's procedure, like affecting the Quality?
- How many revision does the established procedure allow?
- Does the document supersede another document?

- 3.1.10 Document sweeps shall occur to ensure uncontrollable documents are not available and current processes, specifications, and instructions are being followed.
- 3.1.11 Personal notes are acceptable provide they do not have a quality affecting criteria. ✓

### Control Information

Subject or Title:		Procedure Number: SOP-XXX-XXX			
Procedure Department:		Procedure Owner :			
Departments Affected					
Approvals		Initial Issue	Revision #1	Revision #2	Revision #3
			✓	✓	✓
Distribution:					

**Purpose:**  
**Scope:**  
**Key Definitions**







THANK YOU