Document Control

Basics of Good Documentation

and

Document Control Systems

Steps to Building an Effective System

- Elements of Good Documentation
- How Much do I Need?
- Outline Your Document Control System
- Maintaining Documentation
  - Manual Filing/Word Processing Software
  - Manage in a Database
  - Document Control Software Packages
- Common Problems with Documentation

Annual Quality Survey Report

Identifies Document Control as the most difficult clause to implement...

And the most difficult clause to maintain.

Step 1 in Building an Effective System Is:

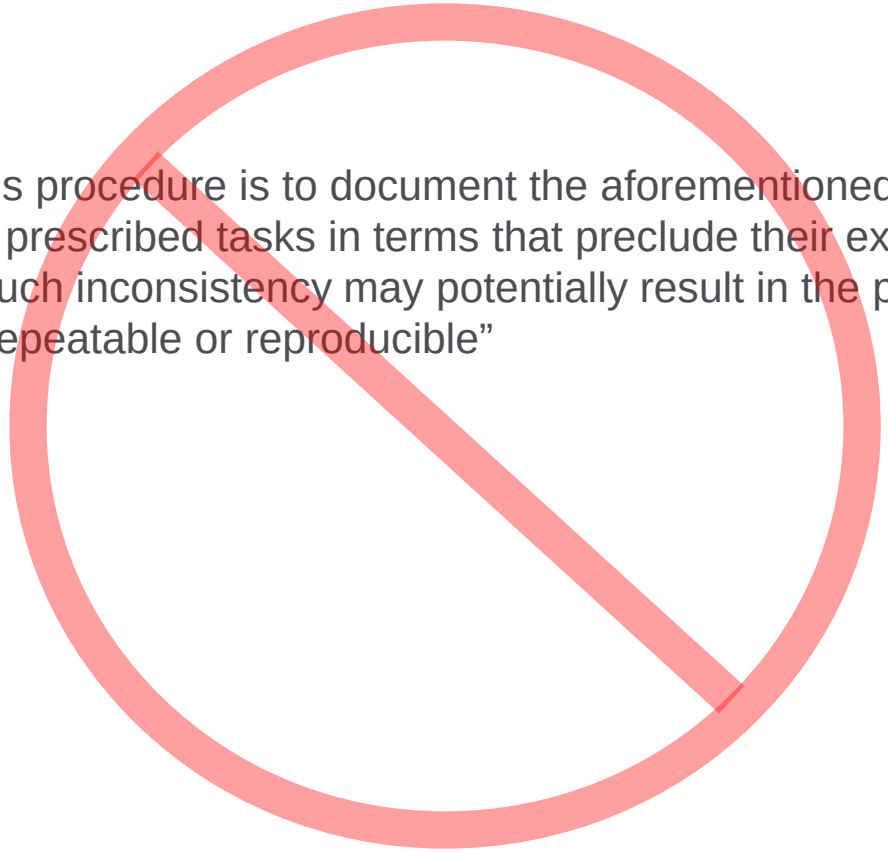
To Have Good Documentation!

Good Documentation is:

- ✓ Clear
- ✓ Concise
- ✓ User friendly

Avoid Drowning in Detail…..

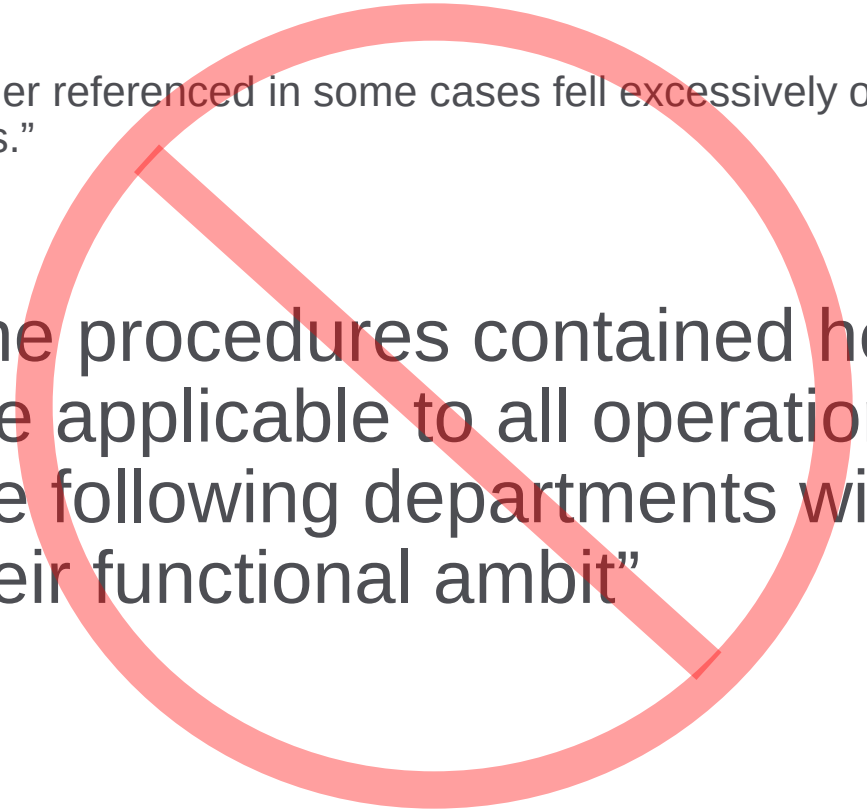
"The purpose of this procedure is to document the aforementioned activities, herin after referred to as the prescribed tasks in terms that preclude their execution in an inconsistent manner, wherin such inconsistency may potentially result in the prescribed tasks delivering a result that is not repeatable or reproducible"



And poorly written procedures

Why use ten words when one will do?

The items hereinunder referenced in some cases fell excessively outside normal parameters."



"The procedures contained herin are applicable to all operations in the following departments within their functional ambit"

Make procedures user friendly

- ✓ Use short sentences starting with a verb.
- ✓ Avoid using the passive voice. Make it clear who is performing the task.
- ✓ Use white space for easy reading.

Step 2: Have the Right Amount of Documentation

But how much documentation do I need?

Ask yourself:

Will it really Impact Customer Requirements?

Avoid Creating too much:

- Work instructions written for virtually everything
- Overlap and repetition - Including a process in more than one work instruction.

Or…

Too little:

- Lack of work instructions where the process affects the quality of the product.
- Employees have their own way of performing processes
- There is variation in the process because it is not well documented

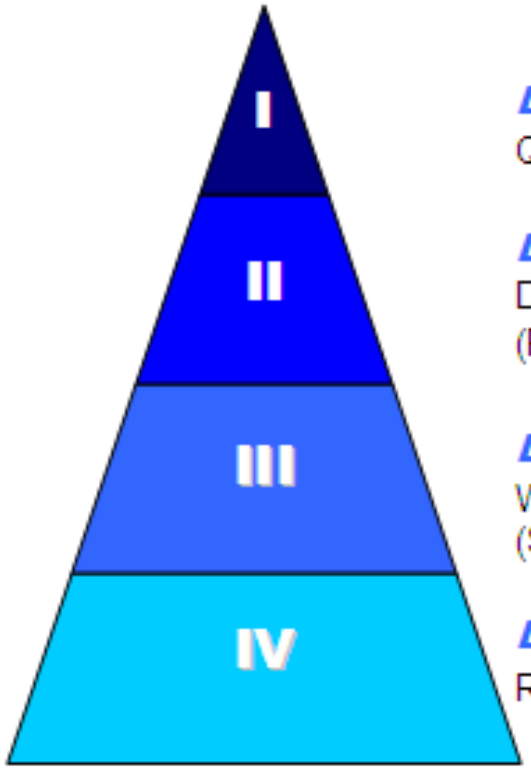
Documentation: The right amount

- ✓ Remember that the goal here is *consistency* for your processes.
- ✓ If two trained employees were to perform this task, would they do it the same way?

If the answer to this is "Maybe not" a work instruction is appropriate.

Step 3: Outline Your Document Control System

Outline document control system



Level I
Quality Manual (QM-001)

Level II
Documented Procedures (P-xxx-001)
(Referenced in the Quality Manual)

Level III
Work Instructions (WI-xxx-001)
(Specific to your Organization)

Level IV
Records & Forms (F-xxx-001)

Clarify Your Terminology:

Procedure: *Describes the process.*

Work Instructions: *Tells how to perform the process.*

Attachment: *Information attached to the procedure to help clarify the procedure.*

Forms, Tables, etc.: *Places to record the results of tests, audits, etc.*

Procedures describe an overall process such as "Purchasing", where as work instructions would describe a more detailed portion of the procedure such as "Completing a PO" or "Ordering supplies".

What Will You Control?

Procedures

Work Instructions

Forms

Attachments

External Docs:
Customer Drawings

Prints

Drawings

Routers/Traveler

Step 4:
Where will you keep your documents?

Planning Your Infrastructure

ISO gives you the specs

You prepare your own blue print

You may choose:

- A simple word processing program.
- An existing database program
- A packaged document control software.

What Will be Best for Your Company?

Choose a system for your company based on:

- Company size
- Computer set-up and availability
- Number of different processes performed
- Rate of change for your processes or documents

Your company may need more than one type of system.

For example:

- One for quality system documents, and
- One for engineering documents

These documents may be different enough to make it best to have two distinct systems.

Example Systems

Simple Hardcopy System

- The master electronic documents are stored in “Word”.
- A Master list is prepared and kept in “Excel”.
- Hard copies are copied on to paper that is marked “CONTROLLED”.

Simple Hardcopy System

- The hardcopies are distributed to 3-ring notebooks throughout the facility.
  - The master list indicates what procedures and work instructions need to be in each book.
  - Copies are kept to a minimum by only distributing relevant documents to each area.

Simple Hardcopy System

- One person is designated as the Document Control Coordinator.
- This person
  - keeps the master list up-to-date
  - Makes revisions to documents
  - Distributes revised documents
  - Collects the outdated documents

Simple Hardcopy System

- A “Change Request Form” is available for employees to initiate revisions to documents.
  - Changes must be approved before they are made.
  - Changes are indicated by using the revision tool in Word.
  - Staff must be aware of revisions.

Online System

- A Database is set-up to hold procedures and work instructions.
  - Lotus Notes
  - Packaged System
- This may be organized into a “Chapter System” with a chapter for each clause of the standard.

Online System

- Procedures and Work Instructions are written in or loaded into the system.
- Employees are given “Rights”
  - System Administrator
  - Author
  - Editor
  - Approver
  - Read Only

Online System

- Authors write the procedures or work instructions.
- The document is sent to the editor and approver for approval.
- When it is approved it is automatically moved into the “Quality Documents” and becomes available to all those with read rights.

Online System

- The documents may be viewed on the screen or printed.
- Printed documents are controlled by a “sunset clause”
  - The date printed appears on all printed documents. Documents are valid only for the day they are printed.

Online System

- Some hardcopy distribution may be necessary.
- A master list must be kept for distributed documents.
- Controlled hardcopies need to be identified.

Online System

- Revisions are made by the author, and must be reviewed and approved by the editor and approver.
- The author must determine if the changes affect any process that is being performed that day.

Engineering Prints

- A master list indicating the current revision of each print is maintained.
  - This is usually in the manufacturing software.

Engineering Prints

- A master file of the current print revisions is maintained.
  - Simple file cabinet system
  - An electronic CAD system

Engineering Prints

- If prints are distributed to each operation they must be controlled.
  - Operators verify against electronic master list.
  - Prints are copied and labeled with a job number.
  - The copy is good only for the job number.

Documents of External Origin

- These documents must be included in your document control system. For example:

  - Customer Prints
  - Industry Regulations
  - ISO Standards
  - References used for your documentation.

Documents of External Origin

- Control these by having a section on your master list for documents of external origin. Include:
  - Document Name
  - Current Revision
  - Document Location(s)
  - Document Number (Assigned by your company).

Common Problems with Document Control

Common Problems

- Employees writing documents do not understand the difference between a Procedure and a Work Instruction.
- Terminology has not been defined, and is not used in a consistent manner.
- Revisions take too long, documents are not kept current.

Common Problems

- There is no process for tracking changes or training on changes
- Inconsistent use of other documents such as:
  - forms
  - attachments
  - drawings
  - documents of external origin

Common Problems

- Approval
- Distribution
- Keeping distribution current

Common Problems

- ✘ Too many documents are distributed. The system cannot be maintained.

- ✘ Lack of control of documents of External Origin.

  - ✓ **Avoid these problems by planning ahead…**

And all the pieces will fall in place.