



# Doc Control and EMPs



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## Documentation and Doc Control

- The ISO EMS Standards:
  - ISO 14001 Section 4.4.4 (Documentation)
  - ISO 14001 Section 4.4.5 (Documentation Control)
- Other Standards
  - Quality
  - FDA
  - Responsible Care




### 4.4.4 Environmental Management System Documentation

- The organization shall establish and maintain information, in paper or electronic form, to
  - Describe the core elements of the management system and their interaction
  - Provide direction to related documentation




### 4.4.5 Document Control

- The organization shall establish and maintain procedures for controlling all documents required by this International Standard to ensure that:
  - They can be located;
  - They are periodically reviewed, revised as necessary and approved for adequacy by authorized personnel;




### 4.4.5 Document Control (continued)

- The current versions of relevant documents are available at all locations where operations essential to the effective functioning of the environmental management system are performed;
- Obsolete documents are promptly removed from all points of issue and points of use, or otherwise assured against unintended use; and
- Any obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified.



### 4.4.5 Document Control (continued)

- Documentation shall be legible, dated (with dates of revision) and readily identifiable, maintained in an orderly manner and retained for a specified period. Procedures and responsibilities shall be established and maintained concerning the creation and modification of the various types of documents.



## Documentation Basics

- Make docs clear, concise and user-friendly
- Use short sentences starting with verbs
- Use present tense.
- Make it clear who is performing the task
- Format docs to make them easy to read: Use headings and white space



## Do You Have the Right Amount of Documentation?

- Too Much:
  - Overlap and repetition
  - Work instruction written for virtually everything
- Too Little:
  - Ask yourself this question: "If 2 trained employees were to perform this task, would they do it the same way?" If the answer is "Maybe not", a work instruction is appropriate
- Just Right:
  - You have SOPs and work instructions to cover key processes



## Outline your Doc Control System

- Clarify your terminology
  - Procedure: describes the process
  - Work Instructions: tell how to perform the process
  - Attachment: Information attached to the procedure for clarification
- Determine what to control:
  - Procedures
  - Work instructions
  - Forms
  - Attachments
  - External documentation
  - Prints
  - Drawings
  - Routers/travelers



## Determine Where to Keep Your Docs

- Planning your infrastructure:
  - ISO gives you the specifics
  - You prepare your own blueprint
  - You choose your document control system
    - A simple word processing program
    - An existing database program
    - A packaged document control software



## What Will Be Best For Your Company?

- Consider the following when choosing a system for your company:
  - Company size
  - Computer setup and availability
  - Number of different processes performed
  - Rate of change for your processes or documents



## You May Need More Than One System

- If documents are different enough, it may be best to have two distinct systems. For example, one for quality system documents, and one for health and safety documents



## Hardcopy vs. Electronic

- This is a fundamental question that companies grapple with as they conceive of their EMS systems.
- Primary consideration: how do we assure that all available and used documents are current, correct and recoverable?



## Hardcopy System

- Prepare and keep master list
- Copy or print hard copies marked "CONTROLLED"
- Distribute in 3-ring binders
  - Master indicates the procedures and work instructions that need to be in each binder
  - Distribute binders only to the areas where they are relevant



## Electronic Systems

- Set up a database to hold procedures and Work Instructions
- Organize it using a "chapter system" with a chapter for each clause of the standard
- Write procedures and WIs into the system
- Give employees appropriate levels of "access"
  - System administrator
  - Author
  - Editor
  - Approver
  - Read only



## Electronic Systems (continued)

- Docs may be viewed online or printed
- Control printed docs with a "sunset clause:" use date stamp feature in your system to automatically place the date on docs when they are printed. Docs are only valid on the day they are printed.
- Keep a master list for any distributed hard copies
- Identify controlled hard copies



## Document Control Coordinator

- Designate one person responsible for the following:
  - Keep master list up to date
  - Make revisions to documents
  - Distribute revised documents
  - Collect and destroy outdated documents



## Use Change Request Forms

- Changes must be approved before they are implemented
- Indicate changes by displaying the revision number
- Determine a method to keep staff aware of revisions (e.g., memo or routine training)



#### 4.3.4 Environmental Management Programs

- The organization shall establish and maintain (a) program(s) for achieving its objectives and targets. It shall include:
  - Designation of responsibility for achieving objectives and targets at each relevant function and level of organization;
  - The means and time-frame by which they are to be achieved
- We saw examples of this presented by Steve Dark, Millipore Jaffrey



#### Let's Take a Look at Some Examples

- Nypro of Clinton, MA was an EMS peer mentoring host in 2002. They created a "cadillac" version of an EMS, and have made it available through TURI.
- Special thanks to Mr. Al Descoteaux of Nypro

