

Date: January 14, 2004

Topic: Documentation Control and Record Keeping

How did you accomplish this topic during your implementation?

1. Anyone in the organization can be a document author.
2. There is a designated format or template for authors to utilize.
 - a. Format holds sections to contain the following:
 - o Table of Contents
 - o Revision History
 - o Scope, or what the document is related to
 - o Related documents, supporting forms
 - o Responsibilities
 - o Process steps/details
 - Any format is allowed: flowchart, text, bullets
 - Steps include inputs and outputs
 - o Instructions in template
 - o Table of Quality Records (ISO elements addressed)
3. Document Numbering
 - o Differentiate according to owning organization
 - o Contain unique identifiers, such as sequential numbering
 - o Revision Level
4. Master Document List Contains:
 - o Owner
 - o Document Number
 - o Title
5. Hierarchy
 - a. Use of the pyramid structure is recommended.
 - b. Top/down would then be structured with the manual at the top, procedures next, then work instructions and forms.
6. Document Review Process Consist of the Following:
 - a. Matrix for each type of document which list the reviewers/approvers (separate from process – working document)
 - b. Only key people are required for approval
 - c. Document control process lists the minimum approval as the department manager(s) of the organization(s) affected
 - d. Review documents / ongoing discussions with author and other reviewers (AFC uses desk review via an online tool, called AGILE, which maintains an action register of change requests.)
 - e. Approval
(AFC uses online tool, called AGILE, to electronic complete document approval.)
7. Quality Check
 - a. An employee has the following tasks:
 - o Maintain the Document Approval List
 - o Own the Document Control Process
 - o Update the Master Document List

Complete a quality check to verify the template followed, the document has the correct revision number

What resources/tools/vendors were used to accomplish this task?

AGILE is a document control tool that allows for online review and approval. The tool maintains a list of comments associated with a document during the review process.

Consultants were initially utilized to ensure that all necessary elements of the standard were addressed.

Was there any benchmarking activity?

No

What lead you to use this method?

N/a

What worked and what didn't work?

Decentralization was a challenge; essentially groups were managing their own documents and approval process. This caused many issues when processes spanned multiple groups; there were duplicate procedures with different steps for the same task.

What recommendations do you have for others attempting to use your method?

N/a

How did you measure the effectiveness of this method?

N/a