

**TECHNICAL  
COMMUNICATORS  
AND  
ISO 9000  
IMPLEMENTATION**

# ISO 9000 IMPLEMENTATION STRUCTURE

**STEERING  
COMMITTEE**

**PROJECT  
TEAM**

**SUBJECT MATTER EXPERTS**



# WHEN WRITERS SHOULD BE INVOLVED

- Ideally, a person knowledgeable in communication techniques should be on the ISO Steering Committee.
- As a minimum, the Project Team should have a senior communications representative.
- Continuously involved in the ongoing maintenance of ISO registration.

# WHEN WRITERS ARE USUALLY INVOLVED

- When management realizes the present documentation doesn't meet the ISO requirements.
- After it's discovered there is one year's work to be done and three months left before the ISO audit.

# PROMOTING ISO 9000 WITHIN THE COMPANY

# INTERNAL PROMOTION

- Why must we promote ISO internally?
  - get employee buy-in to the initiative
  - culture changes involve everyone

# METHODS OF INTERNAL PROMOTION

- Employee newsletter articles
- Poster campaigns
- 'Coffee klatches' with management

# METHODS OF INTERNAL PROMOTION

WHAT IDEAS DO YOU HAVE FOR  
INTERNAL PROMOTION OF ISO  
9000?

# ISO 9000 DOCUMENTATION STRATEGY

# WHAT'S THE BIG DEAL WITH DOCUMENTATION?

- The single most important aspect of ISO 9000.
- The foundation on which a robust Quality System is built.

# WHAT'S THE BIG DEAL WITH DOCUMENTATION?

- Documentation of the output verifies the validity of the process from which it came.
- The basis on which your registration audit is built.

# QUALITY DOCUMENTATION DEFINED

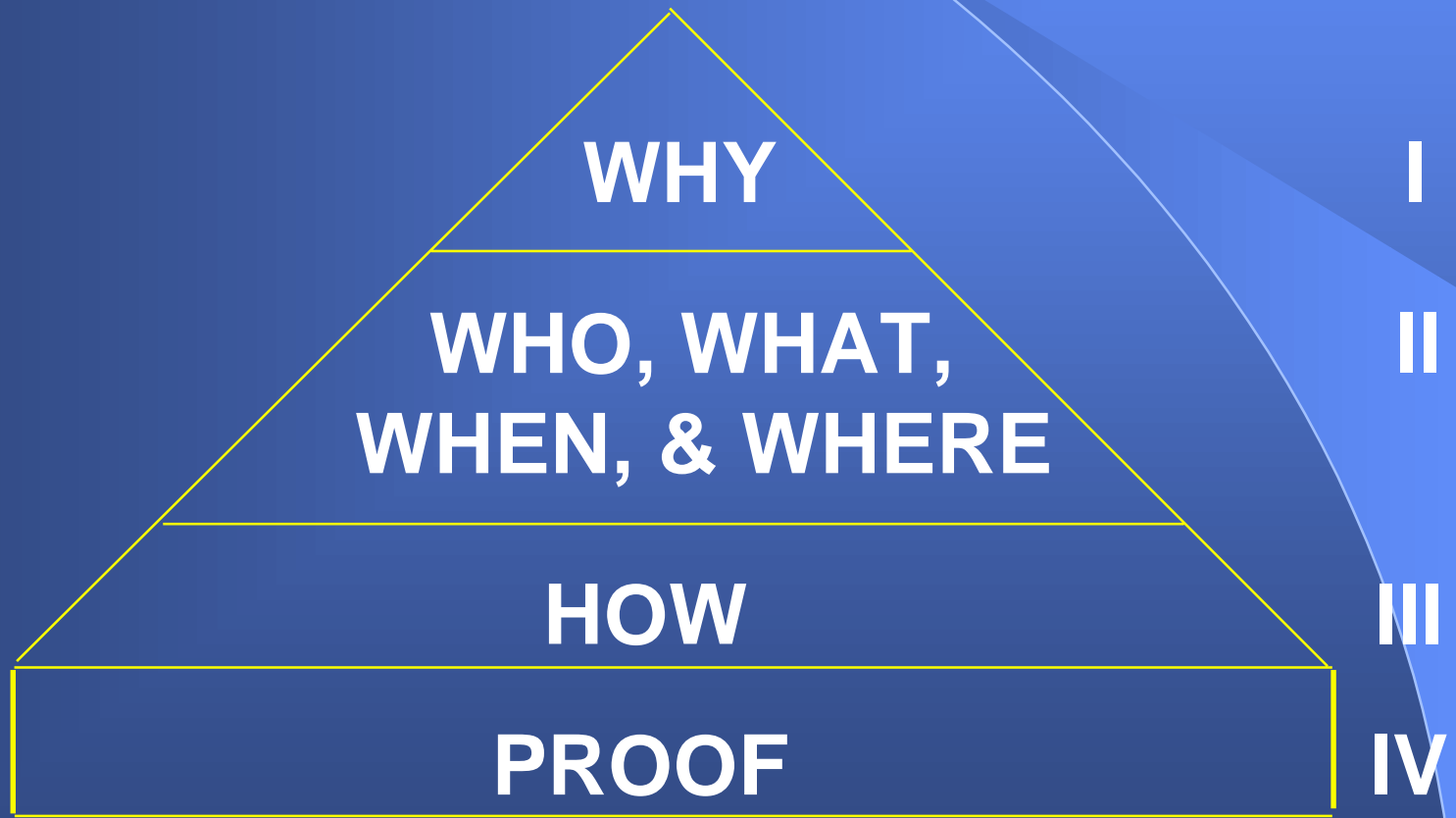
- Quality documentation can be defined as –

*“Any documentation upon which you make a Quality decision”*

# DOCUMENTATION INVENTORY

- You must determine what you have before you can decide what you need!
- The big reality check.

# THE ISO 9000 DOCUMENT STRUCTURE



# LEVEL I DOCUMENTATION

- There is generally only one document in Level One: the Quality Manual.
  - Its purpose is to provide an overview of the Quality System and an entry point to its documentation.

# LEVEL II DOCUMENTATION

- This documentation contains the *What*, *Where*, *When*, and *Who* of the organization.
  - All members of the organization form the audience for this level of documentation.
- It describes the organization's processes.

# LEVEL III DOCUMENTATION

- These provide the *HOW* information for the Quality System.
  - All members of the organization form the audience for this level of documentation.

# LEVEL III DOCUMENTATION

- When is enough, enough?
  - Ask two simple questions.
  - Plot a matrix of the answers.

# DOCUMENT NEED MATRIX

QUESTION	YES	NO	COMMENT
1	✓		Nothing is required.
2		✓	

# DOCUMENT NEED MATRIX

QUESTION	YES	NO	COMMENT
1	✓		Nothing is required.
2		✓	
1	✓		Level III documentation is required.
2	✓		

# DOCUMENT NEED MATRIX

QUESTION	YES	NO	COMMENT
1	✓		Nothing is required.
2		✓	
1	✓		Level III documentation is required.
2	✓		
1		✓	Level III documentation and thorough training is required.
2	✓		

# DOCUMENT NEED MATRIX

QUESTION	YES	NO	COMMENT
1	✓		Nothing is required.
2		✓	
1	✓		Level III documentation is required.
2	✓		
1		✓	Level III documentation and thorough training is required.
2	✓		
1		✓	Why is the employee in that job?
2		✓	

# LEVEL IV DOCUMENTATION

- This level comprises the records of the organization.
  - All members of the organization and its customers make up the audience for this level of documentation.
  - These provide the transition between the controlled documents and Quality Records.
  - This level is made up of completed forms.

# HOW DO REGISTRARS AUDIT DOCUMENTATION?

- ISO 9000 Assessors read the company's Level I and II documentation **BEFORE** visiting the site.

# DOCUMENT CONTROL WITHIN ISO 9000

# WHY CONTROL DOCUMENTS?

- The ISO 9000 Quality Management standards specify:
  - all documents relating to the product and its marketing, design, manufacturing, and maintenance must be captured, controlled and properly distributed
  - personnel must have access to the latest version of a document and the document itself must reflect a true state of affairs

# WHY CONTROL DOCUMENTS?

- The ISO 9000 Quality Management standards also specifies:
  - any changes to the Quality System must be promptly documented and these changes must be efficiently registered, approved, distributed, and implemented
  - all obsolete documents must be promptly removed from the workplace, or be identified as such to prevent inadvertent use

# WHAT MUST BE CONTROLLED?

- Controlled documents include:
  - drawings
  - specifications
  - operational procedures
  - inspection, testing, and other work instructions
  - the Quality Manual and procedures
  - inspection and test reports and data
  - visual aids

# DOCUMENT CONTROL STRATEGIES

- Decentralized
  - usually each document generating function looks after control of the document
  - a common method in product-oriented quality systems
  - can lead to a multitude of control schemes
  - documents rarely follow the same format, style, etc.

# DOCUMENT CONTROL STRATEGIES

- Centralized

- functional area(s) retain control over documentation content
- common strategy of process-oriented quality systems
- control scheme is common throughout the whole organization
- centralized function ensures a common format, style, look, etc.

# THE ASACa EXPERIENCE

- Prior to first ISO assessment audit.
- Prior to our registration audit.
- The future for the Document Management Group.