

A training presentation prepared by WATSON Dairy Consulting on the design, project management and implementation of ISO systems.

There are many options in the designing of a coding system and this is simply a guide to why you need one and how to go about deciding on the coding system critical to the control of documents

For guidance only

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# ISO 9000 & ISO 22000

## **IMPLEMENTATION STRUCTURE**

APPOINT STEERING COMMITTEE

#### **PROJECT TEAM**

SUBJECT MATTER EXPERTS

COMMUNICATION SKILLS ESSENTIAL

Appoint TEAM Select TEAM Leaders

Allocate AREAS



# Basics of ISO 9000

#### ISO 9000 does not address some issues which are the focus of:

### Total Quality Management (TQM)

Identify Prioritise training for MANAGERS and Supervisors

Leadership

**Team Building** 

#### COMMUNICATION

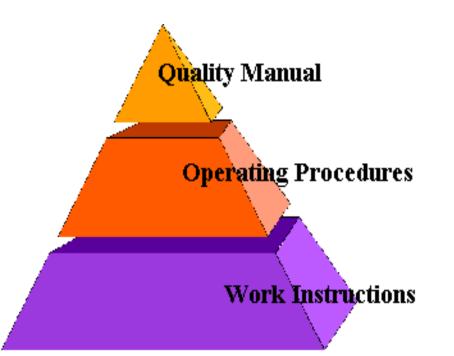
**Customer Service** 

Strategic Planning

# Basics of ISO 9000



## WHAT IS REQUIRED ?



describes the overall system and states the general policies and distribution of authority

define in **general** terms how the interdepartmental (cross-functional) flow of work is controlled.

define **specifically** how work is performed, step by step, within an individual department

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# DOCUMENTATION STRATEGY

**ISO 9000 Document control** 

### WHAT'S THE BIG DEAL WITH DOCUMENTATION?

Documentation of the output verifies the validity of the process from which it came

It forms the basis on which YOUR registration audit is built

The single most important aspect of ISO 9000

The foundation on which a robust Quality System is built.

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# QUALITY DOCUMENTATION DEFINED

### **Quality documentation can be defined as:**

"Any documentation upon which you make a Quality decision"



Next



# 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

•any changes to the Quality System must be prompty 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



#### Outline of the document control system

#### Terminology

Procedure: describes the process Work instructions: tells 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



# DOCUMENT CONTROL METHODS

### 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.

## 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.

Next



Setting up the document control system to be as easily manageable and as simple as possible is critical to the success of the quality management system

#### **Build effective documents.**

- Make them clear, concise, and user-friendly.
- Use short sentences starting with a command verb.
- Use present tense (e.g.: is, are). Make it clear who is performing
- the task.
- Format your documents to make them easy to read: use headings and white space

#### Have the right amount of documentation

- •Avoid too much Overlap and repetition
- •Avoid including a process in more than one work instruction
- •Avoid too little
- •The goal is consistency for your processes.
- •If two 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.
- •Avoid work instructions written for virtually everything
- •Just right
- •You have SOPs and work instructions to cover key processes.

#### The goal is consistency for your processes.

If two 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.

#### Avoid work instructions written for virtually everything

#### **Just right**

You have SOPs and work instructions to cover key processes.



#### Determine where to keep your documents Planning the infrastructure

Use the ISO standards and specifications

Prepare a blueprint for the system

Choosing YOUR document control system.

A simple word processing program or an existing database program or a packaged document control software

#### What will be best for YOUR company

Consider the following when deciding on a system

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 engineering documents



#### WHAT DO WE NEED IN A DOCUMENT CODE?

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#### TOTAL QUALITY MANAGEMENT

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