ISO 9000
An Overview
Introduction

The Purpose of this Presentation is to Provide an **Overview of ISO 9000** and What It Means to Everyone at Company X
ISO 9000

- The Ultimate **Goal** of ISO 9000 is to Provide **CONSISTENT PROCESSES**
- Documented Systems Provide For Consistency
- **RESPONSIBILITIES** Defined
- Periodic **Internal & External Audits** Ensure Systems Are Working
ISO 9000 Origin & Scope Of Application

- International Organization for Standardization
- TC 176 - Meets in Geneva, Switzerland
  - TC = Technical Committee
- Europe Wide
  - Must Be Registered to Sell In Europe
- Japan is Accepting
- US Military Switching From MIL-Q-9858A
ISO 9000 Documents

- **ISO 9000-1**
  - Quality Management and Quality Assurance Standards - Guidelines for Selection and Use

- **ISO 9001**
  - Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Servicing

- **ISO 9002**
  - Quality Systems - Model for Quality Assurance in Production, Installation and Servicing

- **ISO 9003**
  - Quality Systems - Model for Quality Assurance in Final Inspection and Test

- **ISO 9004**
  - Quality Management and Quality System Elements - Guidelines
ISO 9001 Sections

- 4.1 Management Responsibility
- 4.2 Quality System
- 4.3 Contract Review
- 4.4 Design Control
- 4.5 Document & Data Control
- 4.6 Purchasing
- 4.7 Control of Customer Supplier Product
- 4.8 Product Identification & Traceability
- 4.9 Process Control
- 4.10 Inspection and Testing
- 4.11 Control of Inspection, Measuring and Test Equipment
- 4.12 Inspection and Test Status
- 4.13 Control of Non-Conforming Product
- 4.14 Corrective and Preventative Action
- 4.15 Handling, Storage, Packaging, Preservation & Delivery
- 4.16 Control of Quality Records
- 4.17 Internal Quality Audits
- 4.18 Training
- 4.19 Servicing
- 4.20 Statistical Techniques
Responsibility

Circle (or Cycle) Of Responsibility

- Quality In Hands Of 'Operator' or Artesian
- Statistics & Data Analysis
- Information Age
- Industrialisation

1800's → 1930's → 1960's → 1990's → 1970's → Information Age

Company X (York, PA)
Documentation

- Organisation Charts
- Procedures
  - Flow Charts
  - Process Sheets
  - Process Routers
  - Work Instructions
- Forms
- Tags
- Prints
- Specifications
- GES Specs
- SPC Data
- Inspection & Test Results
Myths vs. Truths

- This Is **NOT** An Effort To **CHANGE** The Way You Do Things Now
- Documentation Is Meant To Be **Easily Changed**
- The **Less** Documentation, The **Better**
Basic Rules

.Comparator Your Job & Documentation

- **SAY** What You Do
  - Documentation
- **DO** What You **Say** You Do
  - Actions

- **If It’s Not WRITTEN** Down, It **DIDN’T** Happen
Real Life
What ISO 9000 Means To You

✨ You **MUST**:  
• Know Your **Job Duties**  
• Know What **Training Your Job Requires**  
• Be Able To Tell **About How You Were Trained**  
• Know **What Documentation Involves YOU!**  
• Know **How To Find Out What The ‘Latest’ Version Is**  
• Know **What The Documentation Says**  
• Know **How The Documentation Applies To YOU!**  
• Know **What The INTENT of the Documentation**
Quality Policy

✧ You MUST Know **What** The **Company X** Quality Policy **Is**

And

✧ You WILL Be Asked **What** The Quality Policy **Means** To **YOU**!
Things To Be Alert For

✦ Container Labelling
✦ Documents - Watch for “Headers”
  • Title
  • Date
  • Signature or Initials
  • Originating Department or Group
✦ Calibration Labels
  • Measurement and Test Equipment
  • Assembly Equipment (e.g.: Torquing Tools)