



# **ISO 9000**

## **Lesson 5 Documentation**

**Prepared for NASA  
by OPM and BDM Federal, Inc.**

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# Documentation



- **ISO 10013, “Guidelines for Developing Quality Manuals”**
- **Quality System Requirement 4.5 in ISO 9001**
- **Terms**
  - **Quality Manual**
  - **Procedures**
  - **Work Instructions**



# Documentation (concluded)

- **Three or Four Tiers**
  - **Quality Manual**
  - **Procedures**
  - **Work Instructions**
  - **Forms and Records**



# The Quality Manual

- **Explains How Compliance with the 20 Quality System Requirements Is to Be Accomplished**
- **Refers to Procedures and/or Work Instructions**
- **Must Explain Non-Inclusion of any Element**



# Quality Manual Purpose

- **Establishing and Communicating Policy, Procedures, and Requirements**
- **Implementing the Quality System**
- **Control of Practices and Facilitating Assurance**
- **Documented Bases for Audits**
- **Training Personnel in Quality System**
- **Presentation for External Purposes**
- **Demonstrating Compliance with Standards**



# Quality Manual Structure

- **No Required Structure**
- **Contents Should be:**
  - **Clear**
  - **Accurate**
  - **Complete**
  - **Stated Simply and Concisely**
- **May Only Reference Procedures or May Be a Compilation of Procedures**



# Developing Documentation

- **Perform “Gap” Analysis**
  - Determine What Documentation Exists, What Must Be Revised, and What Must Be Developed
  - Decide What Existing Documentation Applies to the ISO Standard
  - Obtain Data about Current System from Users
  - Determine Format and Structure for Intended Manual
  - Classify Existing Documentation with Intended Format and Structure
  - Avoid Excessive Volume by Referencing
  - Construct Manual
  - Final Review
  - Issue

