

Part 4: Quality management system

- General concept is to:
 - Say what you do and do what you say (PDCA)
- Documentation requirements
 - Write down the important things
 - Get organized to achieve quality
 - Make directions available to users
 - Keep directions up-to-date (as long as needed)
 - Identify needed records and maintain them

Part 5: Management responsibility

- Provide vision and commitment to quality
- Plan to achieve quality
 - Establish quality objectives
 - Keep the quality management system current
- Define duties and responsibilities
 - Define and communicate responsibilities and authorities
 - Put someone in charge of the quality program
 - Communicate within the organization
- Monitor the operations
 - Periodically, to ensure suitability, adequacy and effectiveness of quality management system
 - Inputs from both internal and external sources
 - Outputs to cover QMS, product, and resources
 - Keep records

Part 6: Resource management

- Determine and provide resources for:
 - Implementing and maintaining the QMS (including improving effectiveness)
 - Enhancing customer satisfaction
- Allow people to excel in their work
 - Determine competencies and provide training
 - Give them the tools and equipment to do the job
 - Determine and manage the work environment

Part 7: Product realization

- Define the process steps before doing it
 - Product specifications
 - Processes, instructions, and resources to make it
 - Quality control (test and inspection) needed
 - Records to prove it to outsiders
 - Called “quality, production, or run plans”

- Know what the customer wants
 - Determine all the requirements
 - Make sure you can do it (contract review)
 - Keep the customer in the loop
- Design for quality
 - Create a design plan
 - Define the design input (requirements)
 - Capture the design in useful documents
 - Periodically review the design process
 - Verify that you did what you promised
 - Validate the design to see if it really works
 - Control changes to the design
- Use good stuff from your suppliers
 - Know what you want
 - Check out your suppliers and monitor them
 - Verify you received what you ordered
- Control your production and service
 - Make it under controlled conditions
 - Validate processes that can’t be measured
 - Match the job to the specs and show the status
 - Keep track of what you make (if required)
 - Don’t break your customer’s stuff
 - Keep it good as it proceeds through production and delivery
- Check the work with good equipment
 - Identify information needed for monitoring (process) and measuring (conformity)
 - Identify the devices needed for both
 - Control monitoring and measuring processes
 - Make sure measuring equipment is good

Part 8: Measurement, analysis and improvement

- Develop ways to measure QC, QA, QM
- Monitor your customer’s perception of your quality
- Audit your quality management system
- Monitor your internal processes
- Measure the product characteristics
- Don’t accidentally ship or use bad stuff
- Properly dispose of bad stuff
- Collect information and analyze it
- Continually improve the QMS effectiveness