



ISO: Achieve the world's best practice

ISO (International Organization for Standardization) is a network of national standards institutes from 146 countries working in partnership with international organizations, governments, industry, business and consumer representatives. It is an essential bridge between public and private sectors. ISO standards make a positive difference, not just to engineers and manufacturers, but to the service industry and society as a whole.

Implementation made easy

Making the decision to become registered to ISO9001: 2000 is often a very simple one, as the benefits are well documented. A more difficult task is putting the documentation together and successfully completing an implementation plan.

There is no single blueprint for implementing ISO9001: 2000. Every plan is as unique as the company, which implements it. However, there are common steps that will allow you to balance the often-conflicting requirements and prepare you for a successful quality program.

Simplicity begins here

Although it might seem daunting, putting an ISO9001:2000 program in place is easier than you think. If these standards are new for your company, a Spectrum Quality Advisor can take the guesswork out of establishing your requirements, especially if you have a deadline.

- 1. Regard the implementation as a project:** Your first step is to appoint a team project manager and key players you can rely on. A well-orchestrated plan includes support from senior and department managers, good communications at all levels and ownership of the quality system.
- 2. Understand the process approach:** Successful ISO implementation begins with ordering the ISO9001: 2000, ISO9000: 2000, and ISO 9004: 2000 family of standards. When you review these materials, pay close attention to the requirements and processes and activities described. In each business stage, you need to systematically identify and manage these processes and their interaction within a quality management system. The advantage is the ongoing control over the linkage between individual processes within your entire system, their combination and interaction.
- 3. GAP Assessment:** This process allows an organization to determine the difference between current practice and those that should be in place when the company conforms to new quality management standards. In the early stages, a gap assessment should also focus on compliance to your established procedures and outline the steps to improvement, proper resource allocation, effective communication of objectives and responsibilities, personnel competency and training, and the company's ability to manage to change.
- 4. Assemble a solid team:** Choosing the right team members takes time, commitment and skill. Team members should be ready to act, implement change, experienced in business organization,



detail-driven, holistic, big picture thinkers and good communicators. Remember to balance all positions with appropriate skills to maximize outcomes.

5. **Documentation:** Everyone on your team must have a clear understanding of what documentation needs to be created, identifying the needs and expectations of your customers as they form the basis for many of your processes and procedures. This includes the documents needed by your company to ensure the effective planning, operation and control of your processes: quality plans, policies, standard operating procedures, work instructions, drawings, flowcharts, workmanship standards, product specifications, record keeping, etc.

Four levels of Documentation:

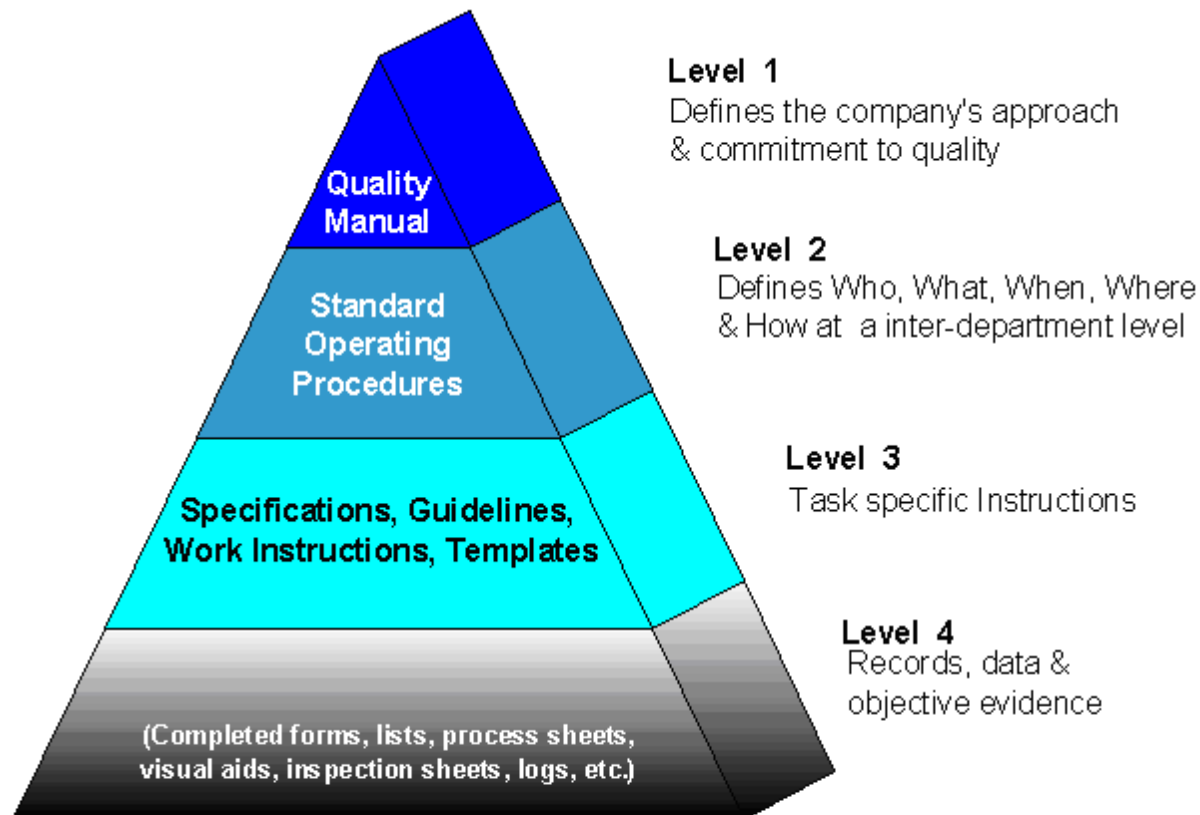


Figure # 1. Quality Management System Documentation Structure

- i) **Quality Policy & Manual** – An overview your company’s commitment to applying quality policies which maintain the quality of your products / services and meeting the quality system requirements. These policies commit to describing your system’s scope and exclusions, organization and responsibilities, management commitments, as well as sequence, interaction of processes and documented procedures.



- ii) **Procedures** – Each procedure addresses the who, what, when, where, why, and how the process is implemented at an interdepartmental level. These aspects include: Control of Documents, Control of Records, Internal Audit, Control of Nonconforming Product, Corrective Action, Preventative Action.
- iii) **Work Instructions** – Describes specific tasks and details and how to perform them.
- iv) **Other Records and Documents** – Forms, logs, tags, labels, databases, and other documents that require the recording of evidence / data to show your compliance with the standard ISO requirements. Mandatory records depend on each called out ISO 9001 clause.
 - 1. Management Review (ISO 5.6.1)
 - 2. Education, training, skills and experience (ISO 6.2.2 e)
 - 3. Evidence that realization processes and resulting product meet requirements (ISO 7.1 d)
 - 4. Results and actions arising from the review of requirements relating to product (ISO 7.2.2)
 - 5. Design and development inputs (ISO 7.3.2)
 - 6. Results and any actions from design and Development reviews (ISO 7.3.4)
 - 7. Results and any actions from design and Development verification (ISO 7.3.5)
 - 8. Results and any actions from design and Development validation (ISO 7.3.6)
 - 9. Results and any actions from design and Development Changes (ISO 7.3.4)
 - 10. Results and any actions from supplier evaluations (ISO 7.4.1)
 - 11. Records for validation of processes where the process output cannot be verified by subsequent monitoring or measurement (ISO 7.5.2)
 - 12. Unique identification of product, where traceability is a requirement (ISO 7.5.3)
 - 13. Customer property that is lost, damaged, or otherwise found unsuitable for use (ISO 7.5.4)
 - 14. Standards used for calibration or verification of measuring equipment where no international or national measurement standards exist (ISO 7.6 a)
 - 15. Assessment of the validity of previous measuring results when measuring equipment is found not to conform with its requirements (ISO 7.6)
 - 16. Results of calibration and verification of measuring equipment and software (ISO 7.6)
 - 17. Internal Audit results (ISO 7.2.2)
 - 18. Evidence of product conformity with the acceptance criteria. Identification of the authority responsible for the release of product (ISO 8.2.4)
 - 19. Description of product nonconformities and any subsequent actions taken, including concessions obtained (ISO 8.3)
 - 20. Results of Corrective action (ISO 8.5.2)
 - 21. Results of Preventive actions (ISO 8.5.3)



Implementation Time Scale

The amount of time and planning it takes to implement an ISO 9001 system averages 6 to 18 months. This timeline depends on how sound your plan is according to your flow of business, the number of new or revised documents needed, the amount of existing or new records, the commitment from management and staff to meet a deadline, and the number of systems to implement.

Plan for at least six months of implementation or practice to allow sufficient time to collect enough records and verify your system is working. You can expect to start data analysis within two to three months. Remember that registrars want to see at least three months of system operation before conducting a third-party audit. This operating period should also include an entire internal audit cycle and a management review.

Key Clauses of ISO

Quality Management System (section 4): The documented methods of how an organization directs and controls quality.

Management Responsibility (section 5): As leaders of the company, managers have made a commitment to the quality management system. They are required to identify all the relevant business policies and procedures, allocate resources to ensure implementation, maintenance and continual improvement of the quality management system.

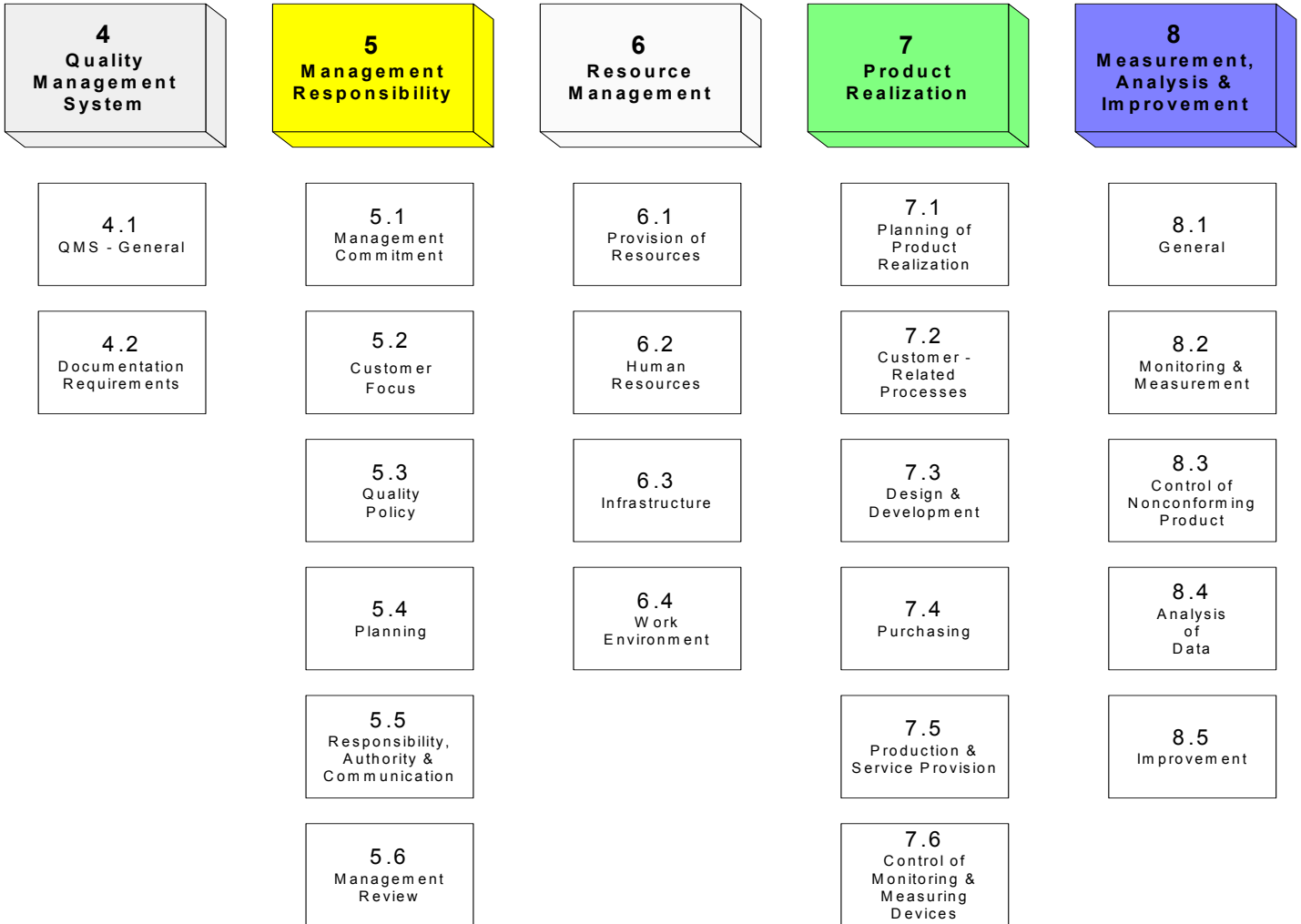
Resource Management (section 6): The day-to-day management of quality and effectiveness relies on using the appropriate resources for each task. These include competent staff with relevant knowledge, skills, training, the correct tools, equipment and supportive services.

Product Realization (section 7): Covers the steps in your operation to provide your products and services. These steps include: determining and matching customer requirements, development, design, sales, purchasing, production / operations, delivery controls, etc.

Measurement, Analysis and Improvement (section 8): To achieve success in business, measurements and analysis help to improve your company's performance, organization and compliance. Statistical techniques should be used where necessary.



ISO-9001:2000 QMS



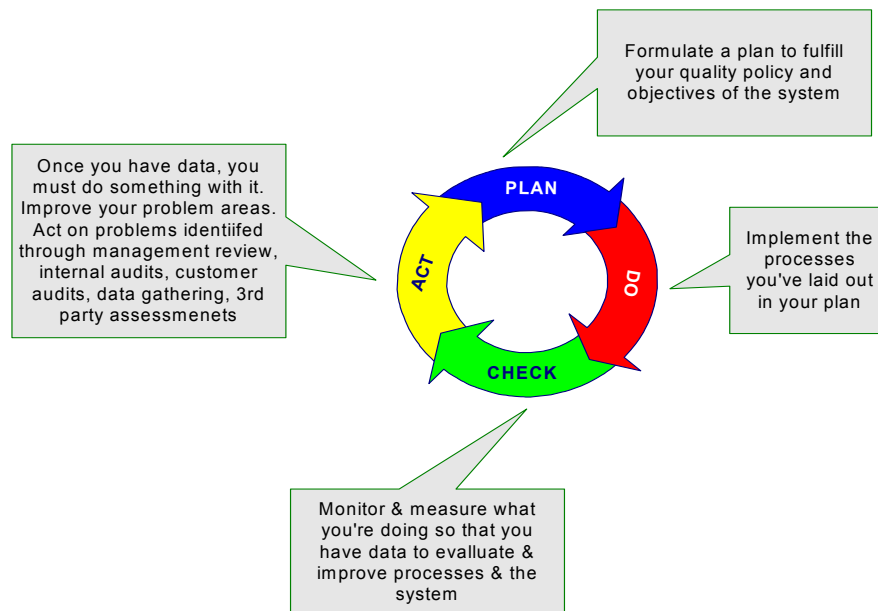


Key Concepts of ISO 9001:2000

Management Systems can direct and control your company with regards to quality. Together with Spectrum Quality Advisors, you can create an ISO 9001:2000 quality system that meets the standards, manages your processes and resources; monitors the operations; measures product and identifies where improvements are needed.

If your organization has not used a process approach in the past, you will need to pay particular attention to the definition of processes, the sequence and their interaction as it is described in your quality policy manual, procedures and records.

Continual Improvement – Defined as “Recurring activity to increase the ability to fulfill requirements”, this important step is a continual process using: audit findings / conclusions, data analysis, management reviews, performance objectives and other means. The data analysis help identify what needs corrective or preventative action, which will leads to achieving continual improvement.



PDCA Process Approach – ISO 9001: 2000 uses the concept of the PLAN-DO-CHECK-ACT model, which is designed for improvement in your business. This cycle is critical to understand the new standard and its requirements.

PLAN: This is a critical stage, and ISO 9001:2000 has planning requirements and suggestions in nearly every section. But the basic concept is simple—formulate a plan to fulfill your quality policy and the objectives or goals of your system.

DO: This concept means to implement the processes you’ve laid out in your plan and quality manual.



CHECK: This level monitors and measures what you're doing to confirm data, evaluates compliance and performance towards achieving your goals.

ACT: Once you have data and you have identified the problems, improvement and action implementation begins. You can improve your processes through the use of your management reviews, internal audits, quality objectives and data analysis.

ISO Quality Management Principles

ISO 9001 is based on 8 principles and the key concept of continual improvement (PLAN-DO-CHECK-ACT). Continual improvement is a recurring activity to increase your ability to fulfill requirements, in your quality systems this is accomplished by implementing corrective and preventative actions identified through the following:

- Establishing objectives (goals)
- Finding opportunities for improvement
- Acting on audit findings/conclusions
- Analysis of data, management review
- Other information

The eight principles are the basis on which you build quality system, they are the morals and values which need to be adopted by your company to make it successful.

1. **Customer Focus:** Understand and meet customer needs and expectations.
2. **Leadership:** Provide unity, direction and the internal company environment necessary to meet business goals.
3. **Involvement and People:** use the skills and expertise of the organization to meet business goals.
4. **Process Approach:** Manage resources and activities as a process.
5. **System Approach to Management:** Coordinate your process activities to enable your company to operate effectively and efficiently.
6. **Continual Improvement:** Make continual improvement one of the permanent objectives of your company.
7. **Factual Approach to Decision Making:** Ensure your company uses data generated from measurement and learning activities to make decisions.
8. **Mutually Beneficial Supplier Relationships:** Use partnership arrangements to enhance value added relationships for both buyer and seller.