Whitepaper Collection

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ISO 9001

An Overview



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Abstract
The scope of this paper specifies the idea and requirements for a quality management system created by the International Organization for Standardization (ISO).
This international quality standard has been a major contributor to the evolution of the quality management system. It is a baseline set of tenets that compels companies to document what has made them successful, to live to that documentation and to internally audit their quality management system for compliance. ISO has become the foundation for may quality management systems and, because of its world wide acceptance, has given many companies the incentive to develop a basic quality management system where other activities have failed in the past.

Modification History

Version	Date	Author	Description of Changes
0.1	01.03.2004	Alexander Gola	Initial Release
0.2	12.04.2004	Alexander Gola	Enhancements, Changes
0.3	17.04.2004	Alexander Gola	Chapter "Process Identification"
1.0	17.04.2004	Alexander Gola	First Release
1.1	07.01.2005	Alexander Gola	Layout Changes
1.2	18.01.2005	Alexander Gola	Enhancements, Chapter "Trademarks"
1.3	18.10.2005	Alexander Gola	Publishing informations
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1 ISO 9001

For a broad spectrum of commercial and personal lines of insurance, ISO provides analytical and decision-support products and services, including statistical, actuarial, underwriting and claims information.

1.1 History

The International Organization for Standardization (ISO) was founded in 1946 to develop a common set of manufacturing, trade and communications standards. It is based in Geneva, Switzerland.
ISO promotes standards to facilitate international trade. The American Standards Institute (ANSI) is the United States representative to ISO. ISO has a full time staff plus technical committees, subcommittees, working groups and ad hoc groups. ISO receives input from governments, industry and other interested parties. ISO develops and promotes but does not implement or enforce international standards.

1.2 Philosophy And Concepts

Quality systems or quality programs in one form or another have existed since the beginning of factories. Companies developed and implemented a quality system that worked for them. Although there was an abundance of literature on quality system elements, quality tools and statistical techniques, a standard did not exist until 1987. In that year, an ISO technical committee developed and published the ISO 9000 series of standards that define the minimum requirements for an adequate quality system.

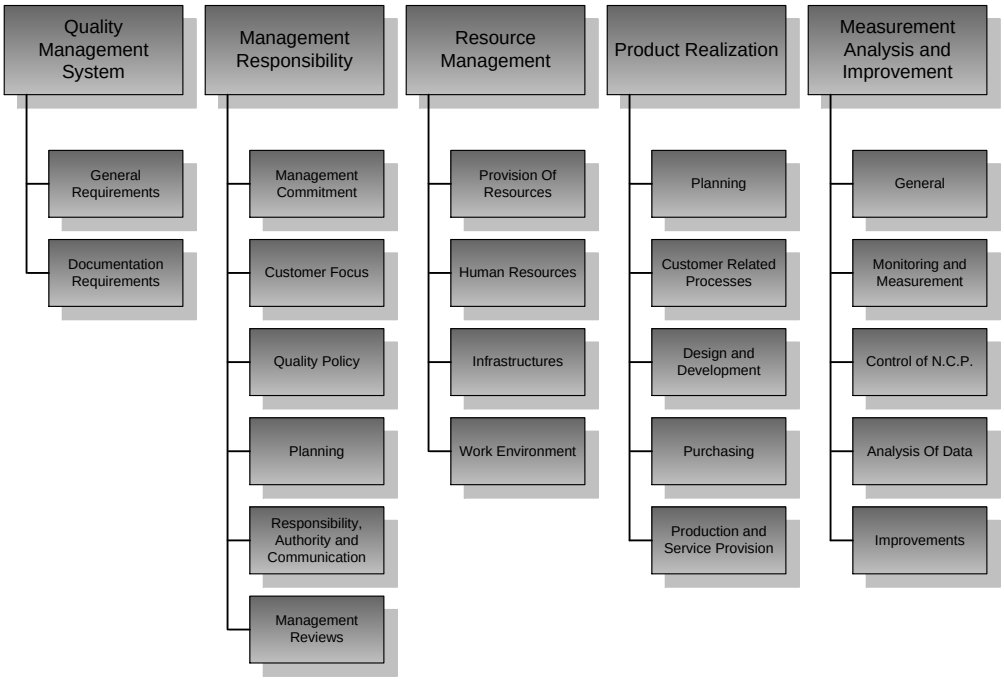


Figure 1 Philosophy Of ISO

For an ISO registration a company must be audited to determine if the company is actually doing what it has documented. Companies use first-party audits to evaluate their own performance. Second-party audits are conducted by a customer on a supplier. Audits conducted by completely separate companies, with no personal stake in the audited company, are labeled third- party audits. Auditors in a third-party audit are usually registrars that audit to international standards such as the ISO 9000 series.

1.3 Series Of Standards

The original ISO series, issued in 1987, was revised and reissued in 1994 and again in 2000.
The external quality management systems requirements, ISO 9001, contain specific elements that a company quality system must contain for compliance and subsequent certification. The standards do not specify how a company is required to implement the essential elements. The requirements are generic and broadly suited to any industrial or economic activity.
ISO standards are not intended to enforce a worldwide uniform quality management systems method. Companies are encouraged to adopt the standard best suited to their needs and then adapt a quality management system that complies with the essential ISO elements but which is also consistent with the individual requirements of each company. A flexible quality system is intended to conform to the company processes and not to force company to change its basic production methods.

There are three basic ISO quality standards groups. These are defined as:

- Primary Standards for external quality systems in response to customer requirements and/or internal quality system used by management as an independent control tool (also known as Conformance Standards)
- Secondary Standards to provide guidance in the selection and applicability of primary standards (also known as Guidance Standards)
- Support Standards to provide technological support in the development of a quality system. Support standards are generally issued under the ISO10000 Series and not under the ISO 9000 numbering system.

Reference	ISO Quality Series	Type
ISO 9000:2000	Quality Management Systems – Fundamentals and vocabulary • Specifies the terminology for quality management systems.	Support
ISO 9001:2000	Quality Management Systems – Requirements • Specifies the outline requirements which exhibits where an organization must evidence a focus on customer service and demonstrate its ability to provide products that meet customer and applicable regulatory requirements.	Primary
ISO 9004:2000	Quality Management System – Guidelines for performance improvements • This is not a Conformance Standard. It is an internal quality management standard. Its elements are not intended for external quality assurance systems. The aim of this standard is to monitor the effectiveness and efficiency of the quality management system, focusing on overall performance, improvement and customer satisfaction.	Secondary
ISO 10005	Quality Management – Guidelines for quality plans	Support
ISO 10007	Quality Management – Guidelines for configuration management	Support
ISO 10011	Quality Management – Guidelines for configuration management • Part I: Auditing • Part II: Qualification criteria for quality system auditors	Support
ISO 10012	Quality Management – Quality assurance requirements for measuring equipment • Part I: Management of measuring equipment	Support
ISO 10013	• Quality Management – Guidelines for development quality manuals	Support
ISO 19011	Quality Management – Guidelines for auditing quality and environmental management systems	Support

Table 1 Series Of Standards

The ISO 9000 Standards have also been aligned with ISO 14001:1996 the environmental management standard.
All included standards are intended to assure that a company has at least a minimum adequate management and quality system in place. These generic standards provide quality management guidance as well as quality assurance guidance and requirements that apply to all types and sizes of companies.

1.4 Process Identification

ISO 9001 requires that all processes be identified, controlled, analyzed, audited and reviewed. This means, a company must create a list of processes that includes all the aforementioned management processes, the required realization process and any additional processes specific to the company operations.

1.4.1 Anatomy Of A Process

A process is an activity and cannot exist with an objective; a process exists to accomplish something.
More accurately, a process is an activity that converts a thing into something else. The standard vocabulary guidance document defines a "process" as a "set of interrelated or interacting activities which transforms inputs into outputs".

1.4.2 Management Processes

Using the definitions from the process-related clauses of the ISO 9001 standard, the following basic requirements for a process approach can be defined:

- all processes must be identified, including subcontracted processes
- the sequence and interaction of processes must be determined
- inputs and outputs of processes must be identified
- responsible authorities for each process must be identified to find the process owners
- the control methods for each process, as well as the measurement criteria, must be defined
- objectives for each process must be defined
- resources and information must be made available to support the processes
- each process must be monitored and measured

- actions must be taken on the results of monitoring and measurement, which generally constitute reaction plans for negative results and continual improvement plans for positive results

The following figure shows a typical relationship between the described management processes and the required realization processes.

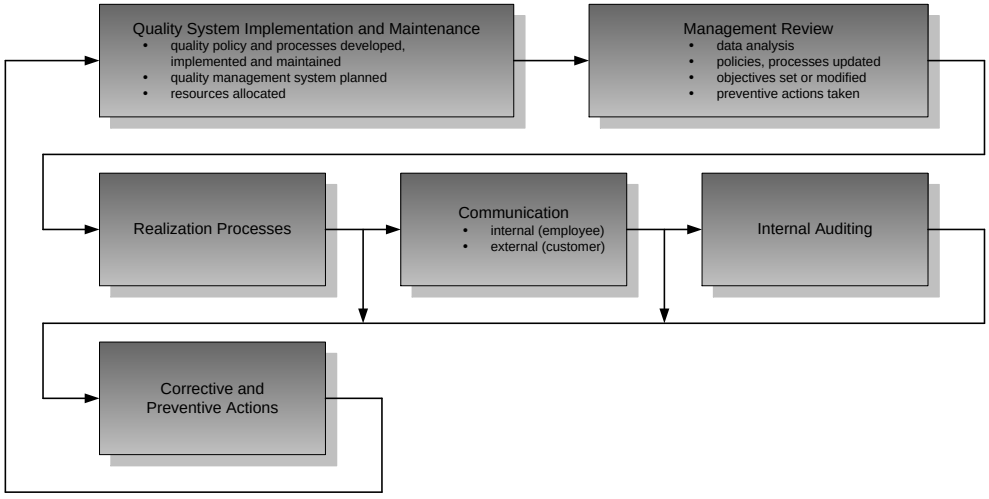


Figure 2 Management Processes

Identification of subcontracted processes is sometimes difficult, because many companies utilize subcontractors for various activities and most of these activities are not what ISO 9001 is concerned with. A good rule of thumb in determining which subcontracted processes to control is determining if the process in question falls under the companies scope of business or, more accurately, scope of ISO 9001 registration.
Once a company has identified its subcontracted processes, it must list them in the same way as internal processes.

1.4.3 Realization Processes

Realization processes are the activities a company conduct to produce its products or supply its services (or both). For this it is essential that these processes are designed to deliver outputs that are aligned to the needs of customers and stakeholders.

The specific process results and the related business processes are described in the table below or see the spreadsheet "ISO Process Identification".

Stakeholder	Needs and Expectations	Success Measures	Factors Critical to success	Outputs	Business Processes
Owner	A financial return that meets target	Profitability	Productivity	A unit cost that is less than the selling price	Business Development
			Adapting to change	Strategic plan that takes account of market changes	Strategic Planning and Review
			Cash flow	Revenue exceeds expenditure	Financial Management
		Sales	Attracting customers	Qualified sales leads	Service Sales
			Understanding customer needs and expectations	Growth in the number of customers	Service Sales
			Keeping ahead of the competition	Continual improvement in service quality	Strategic Planning and Review
Employees	Job security	Staff turnover	Management style	a environment in which the workforce are motivated	Human Resource Management
	Good pay and benefits	Average pay for industry			
		Staff grievance			
	Good working environment	Accident levels	Management commitment	a safety record lower than average for the industry	Materials Management
					Human Resource Management
		Absenteeism	Management style	a sickness record lower than average for the industry	Human Resource Management
	Recognition of contribution	Participation in improvement teams	Management style	a motivated workforce	Human Resource Management
Customers	Effective warranty exchange service	Cycle time	Process efficency	Rapid cellular phone accessory exchange	Service Delivery
			Capable equipment and facilities	Equipment available when required	Materials Management
			Capacity	Enough personnel to handle the demand	Human Resource Management
		Product condition	Safe storage and handling facilities	Exchanged items of the correct type as received from the customer	Service Delivery
	Effective fault analysis service	Diagnostic integrity	Competent diagnostic skills	a opinion on customer property	Human Resource Management
					Service Delivery
	Effective product repair service	Product conformity	Competent repair skills	Faulty product restored to an acceptable condition	Human Resource Management
			Capable equipment and facilities	Equipment available when required	Materials Management
	Effective stock management service	Response to stock demand	Inventory control	a stock management and logistics service that responds the customer	Service Delivery
	Effective scrap material processing service	Material disposability	Available disposable streams	Scrap material channeled into the groups for disposal	Service Delivery
	Account reporting	On-time delivery of payment reports	Payment data collection	Accurate payment reports submitted on time	Service Delivery
	Compliance with ISO 9001	System effectiveness	Management commitment	Processes designed to deliver stakeholder satisfaction	Business Development
				Processes delivering stakeholder satisfaction	Strategic Planning and Review
Society	Environmental responsibility	Environmental impact	Plant design	Minimal environmental impact	Materials Management
	Disclosure of information	Disclosure response return rate	Communication skills	Public concern resolution	Human Resource Management
Suppliers	Mutually beneficial relationships	Negative feedback	Communication skills	Supplier concern resolution	Human Resource Management
Government	Compliance with regulations	Legal deviations	Management commitment	Process validation report	Business Development
				Internal audit report	Process Improvement

Table 2 Realization Processes

When properly implemented, the final result of the described process identification is that all founded and included processes changed to a vertical presence.

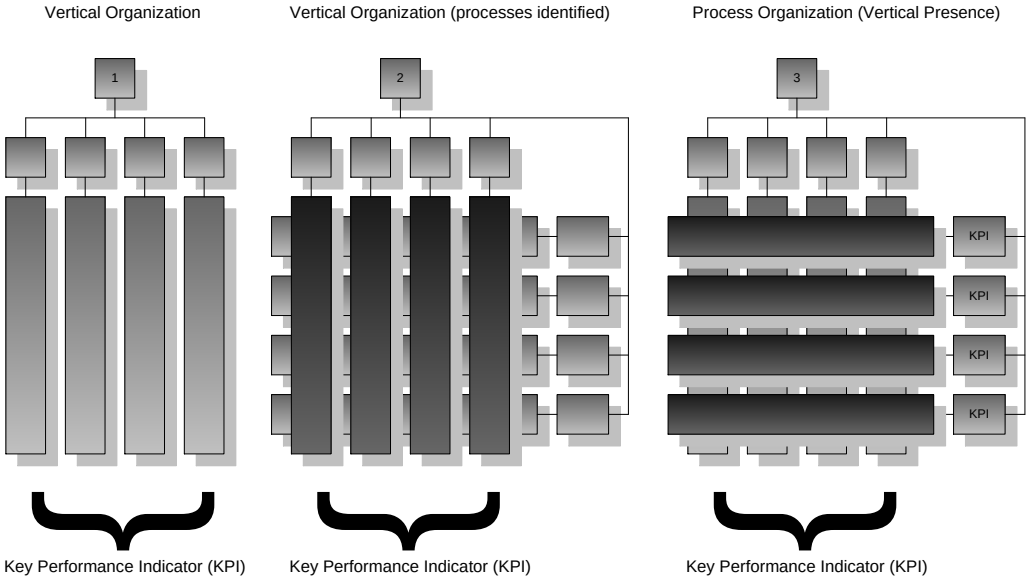


Figure 3 Process Result

This will improve the company effectiveness and brings a better performance for the involved departments and procedures.

1.5 Requirements

The standard completely follows the Plan-Do-Check-Act Cycle.

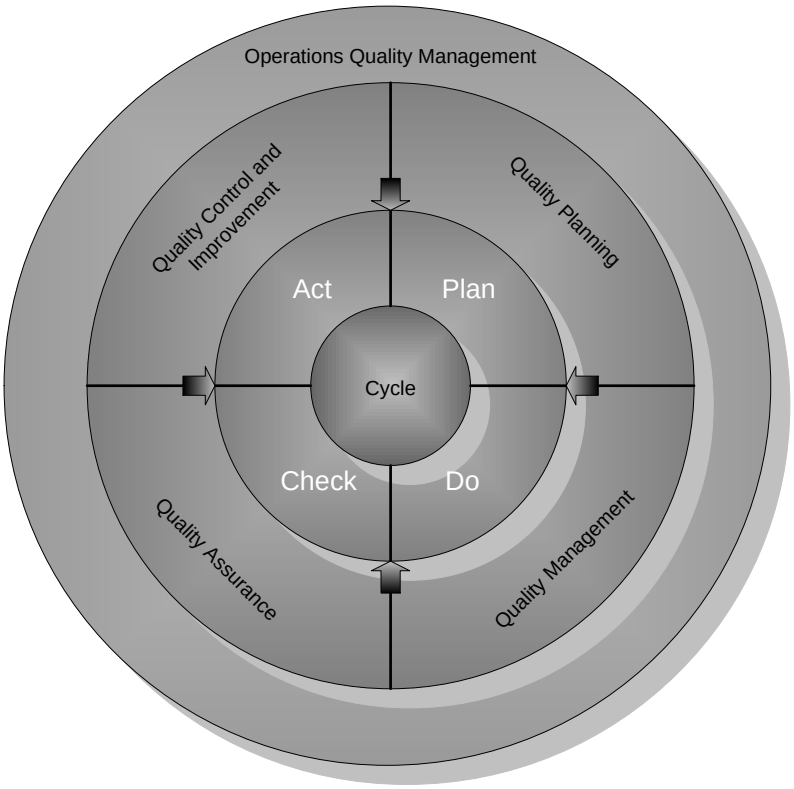


Figure 4 Plan-Do-Check-Act Cycle

ISO use for these five elements (clauses), the first element covers the general requirements and the remaining elements cover the specific requirements in a logical sequence.

- Element 4 - Quality Management System
- Element 5 - Management Responsibility
- Element 6 - Resource Management
- Element 7 - Product Realization
- Element 8 - Measurement, Analysis and Improvement

1.5.1 Quality Management System

1.5.1.1 General Requirements

A quality management system must be established, documented, implemented and maintained. Its effectiveness must be continually improved in accordance with the requirements of ISO 9001.
To implement the system, an organization must:

- Identify processes needed for the quality management system (and their application throughout the organization)
- Determine process sequence and interaction
- Determine criteria and methods for process operation and control
- Ensure resources and supporting information are available
- Monitor, measure and analyze these processes
- Implement actions to achieve planned results and continual process improvement

These processes have to be managed in accordance with ISO 9001 requirements. Any outsourced processes that affect product conformity must be identified and controlled.

1.5.1.2 Documentation Requirements

General

The quality management system documentation shall at least include the quality policy and quality objectives, quality manual and all the documented procedures required by ISO9001.

- Documented statements of a quality policy and quality objectives
- A quality manual
- Procedures required by the standard
- Documents needed by the organization (for effective planning, operation and control of its processes)
- Records required by the standard (maintained in accordance with clause "Quality Management System/Documentation Requirements/Control Of Records")

The extent of the quality management system documentation is dependent on the

- Size of the organization and type of activities
- Complexity of processes and their interactions
- Competence of personnel

Quality Manual

A quality manual must be established and maintained with
- Scope of the quality management system
- Details and justification for any exclusions
- Procedures or references to the procedures
- Description of interaction between processes

This is a controlled document.

Control Of Documents

Documents required by the quality management system must be controlled. Records are a special type of document and must be controlled as required by clause "Quality Management System/Documentation Requirements/Control Of Records".
A documented procedure must be established to
- Approve documents for adequacy prior to issue
- Review, update as necessary and re-approve documents
- Identify the changes and current document revision status
- Make relevant documents available at points of use
- Ensure the documents remain legible and readily identifiable
- Identify and control distribution of any external documents
- Prevent obsolete documents from unintended use
- Apply suitable identification if obsolete documents are retained

When obsolete documents are to be retained for any purpose they should be suitably identified to prevent unintended use.

Control Of Records

Records must be established and maintained as evidence of conformance to requirements and to demonstrate the effective operation of the quality management system. Records must remain legible, readily identifiable and retrievable.
A documented procedure must be established for the control of records, including
- Identification
- Storage
- Protection
- Retrieval
- Retention
- Disposition

The retention times must be stored.

1.5.2 Management Responsibility

1.5.2.1 Management Commitment

Top management must provide evidence of its commitment to develop and implement the quality management system, as well as, continually improve its effectiveness by

- Expressing the importance of meeting requirements
- Establishing the quality policy and quality objectives
- Conducting management reviews
- Ensuring the availability of necessary resources

1.5.2.2 Customer Focus

Top management must ensure customer requirements are determined and met in order to improve customer satisfaction.

1.5.2.3 Quality Policy

Top management must ensure the quality policy is

- Appropriate to the purpose of the organization
- Focused on meeting requirements and continual improvement
- Used as a framework for quality objectives
- Communicated and understood at appropriate levels
- Reviewed for continuing suitability

The Quality Policy itself should be periodically reviewed to ensure its continuing suitability.

1.5.2.4 Planning

Quality Objectives

Top management must ensure quality objectives, including those needed to meet product requirements, are established at the relevant functions and levels within the organization. Quality objectives must be measurable and consistent with the quality policy.

Quality Management System Planning

Top management must ensure that planning for the quality management system:

- Meets the general requirements (clause "Quality Management System/Documentation Requirements/General"), as well as, quality objectives (clause "Management Responsibility/Planning/Quality Objectives")
- Maintains the system integrity when changes are planned and implemented

1.5.2.5 Responsibility, Authority And Communication

Responsibility And Authority

Top management must ensure responsibilities and authorities are defined and communicated within the organization. This does not necessarily mean that job descriptions or organization charts are mandatory – just as long as people know what the limits of their duties are.

Management Representative

Top management must appoint a member of management who, irrespective of other duties, has the responsibility and authority to

- Ensure the needed processes are established, implemented and maintained
- Report to top management on quality management system performance
- Report to top management on any need for improvement
- Ensuring the promotion of awareness of customer requirements

The responsibility of a management representative may include liaison with external parties on matters pertaining to the quality management system.

Internal Communication

Top management must ensure the appropriate communication processes are established and carried out within the organization regarding the effectiveness of the system.

1.5.2.6 Management Review

General

Top management must review the quality management system at planned intervals to

- Ensure a suitable, adequate, and effective system
- Assess possible opportunities for improvement
- Evaluate the need for any changes to the system
- Consider the need for changes to the quality policy and objectives

Review Inputs

Inputs for management review must include information on

- Results of audits
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- Follow-up actions from earlier reviews
- Changes that could affect the quality system
- Recommendations for improvement

Review Outputs

Outputs from the management review must include any decisions and actions related to

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

1.5.3 Resource Management

1.5.3.1 Provision Of Resources

The organization must determine and provide the resources necessary to
- Implement and maintain the quality management system
- Continually improve the effectiveness of the system
- Enhance customer satisfaction by meeting customer requirements

1.5.3.2 Human Resources

General

People performing work affecting product quality must be competent based on the appropriate education, training, skills and experience.

Competence, Awareness And Training

The organization must
- Determine the competency needs for personnel
- Provide training (or take other actions) to satisfy these needs
- Evaluate the effectiveness of the actions taken
- Inform employees of the relevance and importance of their activities
- Ensure they know their contribution to achieving quality objectives
- Maintain education, training, skill, and experience records

Infrastructure

The organization must determine, provide and maintain the necessary infrastructure to achieve product conformity. Infrastructure includes, as applicable
- Buildings, workspace and associated utilities
- Process equipment (both hardware and software)
- Supporting services (such as transport and communication)

Work Environment

The organization must determine and manage the work environment needed to achieve product conformity. This could include such areas where heat, weatherproofing, high noise levels for instance plays a part of the process.

1.5.4 Product Realization

1.5.4.1 Planning Of Product Realization

The processes needed for product realization must be planned and developed by the organization. The planning must be consistent with other requirements of the quality management system and be documented in a suitable form for the organization. The planning must also determine, as appropriate, the

- Quality objectives and product requirements
- Need for processes, documents and resources
- Verification, validation, monitoring, inspection and test activities
- Criteria for product acceptance
- Records as evidence the processes and resulting product meet requirements

1.5.4.2 Customer Related Processes

Determination Of Requirements Related To The Product

The organization must determine customer requirements

- Specified for the product (including delivery and post-delivery activities)
- Not specified for the product (but needed for specified or intended use, where known)

The organization must also determine:

- Statutory and regulatory requirements related to the product
- Additional requirements determined by the organization

Review Of Requirements Related To The Product

The organization must review the product requirements before committing to supply the product to the customer in order to

- Ensure product requirements are defined
- Resolve differences between order and tender
- Resolve any requirements differing from those previously expressed
- Ensure its ability to meet the requirements

The results of the review, and any subsequent follow-up actions, must be maintained. When the requirements are not documented, they must be confirmed before acceptance.
If product requirements are changed, the organization must ensure relevant documents are amended and relevant personnel are made aware of the changed requirements.

Customer Communication

The organization must determine and implement effective arrangements for communicating with customers on

- Product information
- Inquiries, contracts or order handling (including amendments)
- Customer feedback (including customer complaints)

1.5.4.3 Design And Development

Design And Development Planning

The organization must plan and control the product design and development. This planning must determine the

- Stages of design and development
- Appropriate review, verification and validation activities for each stage
- Responsibility and authority for design and development

The interfaces between the different involved groups must be managed to ensure effective communication and the clear assignment of responsibility. The planning output must be updated, as appropriate, during design and development.

Design And Development Inputs

Product requirement inputs must be determined and records maintained. The inputs must include

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Applicable information derived from similar designs
- Requirements essential for design and development

These inputs must be reviewed for adequacy. Any incomplete, ambiguous, or conflicting requirements must be resolved.

Design And Development Outputs

The outputs of the design and development process must be documented to enable verification against the inputs to the process. The outputs must

- Meet design and development input requirements
- Provide information for purchasing, production and service
- Contain or reference product acceptance criteria
- Define essential characteristics for safe and proper use
- Be approved before their release

Design And Development Review

Systematic reviews of design and development must be performed at suitable stages in accordance with planned arrangements (clause "Product Realization/Design And Development/Design And Development Planning") to

- Evaluate the ability of the results to meet requirements
- Identify problems and propose any necessary actions

The reviews must include representatives of the functions concerned with the stage being reviewed. The results of reviews and subsequent follow-up actions must be maintained.

Design And Development Verification

Design and development verification must be performed in accordance with planned arrangements (clause "Product Realization/Design And Development/Design And Development Planning") to ensure the output meets the design and development input requirements. The results of the verification and subsequent follow-up actions must be maintained.

Design And Development Validation

Validation must be performed in accordance with planned arrangements (clause "Product Realization/Design And Development/Design And Development Planning") to confirm the resulting product is capable of meeting the requirements for its specified application or intended use, where known. When practical, the validation must be completed before delivery or implementation of the product. The results of the validation and subsequent follow-up actions must be maintained.

Control Of Design And Development Changes

Design and development changes must be identified and records maintained. The changes must be reviewed, verified, and validated (as appropriate) and approved before implementation. Changes must be evaluated in terms of their effect on constituent parts and products already delivered. The results of the change review and subsequent follow-up actions must be maintained.

1.5.4.4 Purchasing

Purchasing Process

The organization must ensure that purchased product conforms to its specified purchase requirements. The type and extent of control applied to the supplier and purchased product depends upon the effect of the product on the subsequent realization processes or the final product.
The organization must evaluate and select suppliers based on their ability to supply product in accordance with the requirements. The criteria for selection, evaluation and re-evaluation must be established. The results of the evaluations and subsequent follow-up actions must be maintained.

Purchasing Information

Purchasing information must contain information describing the product to be purchased, including the requirements for

- Approval of product, procedures, processes and equipment
- Qualification of personnel

(also include quality management system requirements in the purchasing information)
The organization must ensure the adequacy of the specified requirements before communicating the information to the supplier.

Verification Of Purchased Products

The organization must establish and implement the inspection or other necessary activities for ensuring the purchased products meet the specified purchase requirements.
If the organization or its customer proposes to verify the product at the supplier location, the intended verification arrangements and method of product release must be stated in the purchasing information.

1.5.4.5 Production And Service Provision

Control Of Production And Service Provision

The organization must plan and carry out production and service provision under controlled conditions to include, as applicable

- Availability of product characteristics information
- Availability of work instructions, as necessary
- Use of suitable equipment
- Availability and use of monitoring and measuring devices
- Implementation of monitoring and measurement activities
- Implementation of release, delivery and post-delivery activities

Validation Of Processes For Production And Service Provision

The organization must validate any production or service provision where subsequent monitoring or measurement cannot verify the output. This validation includes processes where deficiencies may become apparent only after product use or service delivery. The validation must demonstrate the ability of processes to achieve the planned results.
The organization must establish validation arrangements including, as applicable

- Criteria for process review and approval
- Approval of equipment
- Qualification of personnel
- Use of defined methods and procedures
- Requirements for records
- Re-validation

Identification And Traceability

The organization must identify, where appropriate, the product by suitable means during product realization. The product status must be identified with respect to monitoring and measurement requirements. The unique product identification, where traceability is a requirement, must be recorded.

Customer Property

The organization must exercise care with any customer property while it is under the control of, or being used by, the organization. Customer property provided for use or incorporation into the product, must be identified, verified, protected and safeguarded.
Any lost, damaged or unsuitable property must be recorded and reported to the customer. The property may include intellectual property, for example, information provided in confidence.

Preservation Of Product

The organization must preserve the product conformity to customer requirements during internal processing and delivery to the intended destination. The preservation must also apply to constituent parts of the product and includes

- Identification
- Handling
- Packaging
- Storage
- Protection

Control Of Monitoring And Measuring Devices

The organization must determine the monitoring and measurements to be made, and the required devices, to provide evidence of product conformity. The monitoring and measuring devices must be used and controlled to ensure that measurement capability is consistent with monitoring and measurement requirements.
Where necessary to ensure valid results:

- Calibrate or verify the devices at specified intervals or prior to use
- Calibrate them to national or international standards (or record other basis)
- Adjust or re-adjust as necessary
- Identify for calibration status to be determined
- Safeguard them from improper adjustments
- Protect them from damage and deterioration

The validity of prior results must be assessed and recorded if the device is found to not conform to requirements. Records of the calibration and verification results must be maintained.
The ability of software used for monitoring and measuring must be confirmed for the intended application before its initial use (and reconfirmed as necessary).

1.5.5 Measurement, Analysis And Improvement

1.5.5.1 General

The organization must plan and implement the monitoring, measurement, analysis and improvement processes needed to

- Demonstrate product conformity
- Ensure conformity of the system
- Continually improve effectiveness

The planning must determine the need for, and use of, applicable methods, including statistical techniques, as well as, the extent of their use.

1.5.5.2 Monitoring And Measurement

Customer Satisfaction

The organization must monitor information on customer perception as to whether the organization is meeting requirements (as one of the performance measurements of the quality management system). The methods for obtaining and using this information must be defined.

Internal Audits

The organization must conduct periodic internal audits to determine if the quality management system

- conforms to planned arrangements
- conforms to requirements of ISO 9001
- is effectively implemented and maintained

The organization must

- Plan the audit program
- Consider the status and importance of the audited areas
- Consider the results of prior audits
- Define the audit criteria, scope, frequency and methods
- Select and use impartial and objective auditors (not audit their own work)

An audit program shall be planned taking into consideration the status and importance of the process and areas to be audited as well as the results of previous audits.
The audit criteria, the scope, the frequency and methods shall be defined.

Departements	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Principal Office	P			P			A	P			A	
Agricultural College		P										
City College			P		A		A					
Technical College	A				P				A			
Purchasing				A		P			A			P
Kitchen	A			A			P					
Chemical Laboratory		A							P			
Documents / Records			A			A				P		
Auditing		A				A					P	
Food Store					A							P

Key P = Audits scheduled on the basis of IMPORTANCE only
A = Additional audits taking into account the STATUS and IMPORTANCE

Table 3 Audit Planning

Also a documented procedure must address responsibilities and requirements for

- Planning and conducting audits
- Reporting results and maintaining records

Management must ensure actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up actions must verify implementation of the action and report the results. Refer to ISO 10011 for additional audit guidance.
For an example of audit planning see the spreadsheet "ISO Audit Planning".

Monitoring And Measurement Of Processes

The organization must apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods must confirm the continuing ability of each process to satisfy its intended purpose. When the planned results are not achieved, correction and corrective action must be taken (as appropriate) to ensure product conformity.

Monitoring And Measurement Of Product

The organization must monitor and measure product characteristics to verify product requirements are being met. The monitoring and measuring must be carried out at the appropriate stages of product realization in accordance with planned arrangements.
Evidence of conformity to the acceptance criteria must be documented. The person responsible for authorizing product release must be recorded. Product release and service delivery can not proceed until all planned arrangements (clause "Product Realization/Planning Of Product Realization") have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, the customer.

1.5.5.3 Control Of Nonconforming Products

The organization must ensure any nonconforming product is identified and controlled to prevent its unintended use or delivery. These activities and related responsibilities and authorities must be defined in a documented procedure.
The organization must deal with the nonconforming product by

- Taking action to eliminate the detected nonconformity
- Authorizing its use, release, or acceptance by concession
- Taking action to preclude its original intended use or application

Records of the nature of the nonconformity, and any subsequent actions, (including any concessions), must be maintained. When the nonconformity is corrected, it must be re-verified to show conformity. When nonconforming product is detected after delivery or use has started, the organization must take action appropriate to the effects or potential effects, of the nonconformity.

1.5.5.4 Analysis Of Data

The organization must determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system, as well as, evaluate where continual improvement of the effectiveness of the quality management system can be made. The analysis must include data generated by monitoring and measuring activities and from other relevant sources. The organization must analyze this data to provide information on

- Customer satisfaction
- Conformity to product requirements
- Characteristics and trends of processes and products (including opportunities for preventive action)
- Suppliers

1.5.5.5 Improvement

Continual Improvement

The organization must continually improve the effectiveness of the quality management system through

- Quality policies
- Quality objectives
- Audit results
- Analysis of data
- Corrective and preventive actions
- Management reviews

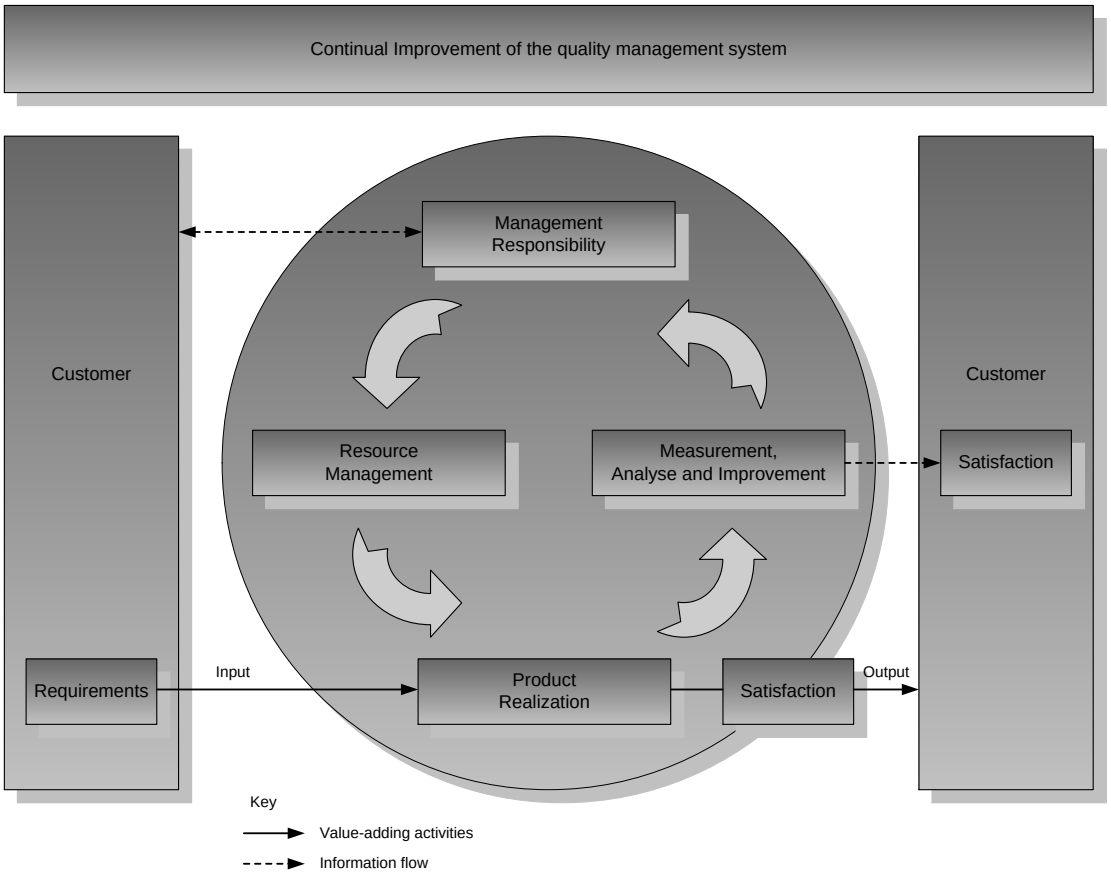


Figure 5 Continual Improvement

Corrective Action

The organization must take corrective action to eliminate the cause of the nonconformity and prevent recurrence. Corrective action must be appropriate to effects of the problem.
The documented procedure for corrective action must define requirements for

- Reviewing nonconformities (including customer complaints)
- Determining the causes of nonconformities
- Evaluating the need for actions to prevent recurrence
- Determining and implementing the needed action
- Records of the results of the action taken
- Reviewing the corrective action taken

Preventive Action

The organization must determine the action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions must be appropriate to the anticipated effects of the potential problem.
The documented procedure for preventive action must define requirements for

- Determining potential nonconformities and their causes
- Evaluating the need for actions to prevent occurrence
- Determining and implementing the needed action
- Records of the results of the action taken
- Reviewing the preventive action taken

1.6 Implementation Of ISO

Successful companies have well trained and competent employees. They know how to perform their jobs efficiently and effectively. However, employees may not have the necessary knowledge and skills for new assignments.
Training develops knowledge, skills and behaviors to meet business requirements. A well defined training process makes an important contribution by helping an organization improve its capabilities and achieve its business objectives.
To make the proper investment for human resources, carry out the training process in these five stages:

- Define the training needs
- Select a delivery method
- Select a training provider
- Take the training
- Evaluate the training effectiveness

1.6.1 Training Needs Definition

Begin the training process by analyzing the skills required for current and planned business activities. Then determine the competence level of personnel assigned to, or already performing, these tasks. Gaps between the required competence and the current skill level can then be used to define your training needs.
Training may be the best solution to closing competence gaps, but don't overlook other possible actions. For example, consider changing processes, improving procedures, rotating jobs, outsourcing or recruiting fully trained people.

1.6.2 Delivery Method

Before designing and planning the training, identify any constraints faced by the organization. Consider the impact of schedule demands, personnel availability and financial limitations. These constraints may influence the choice of training methods and providers.
Selecting the best training method depends on objectives, resources and constraints. Methods may include public courses, on-site courses, apprenticeships, on-the-job coaching and distance learning.
The company may decide to internally develop and deliver the training, particularly to address unique organizational techniques. However, an external training provider is often the best solution for many training needs.

The types of training they offer might include:

1.6.2.1 Public Courses

A public training course is one that takes place in an "open" setting and is available to employees from any organization. These classes typically take place in larger cities and provide a convenient and low cost way to send a small number of employees to be trained.
By attending a public class, students will be away from any office distractions and able to fully focus on the course material. In addition, they should benefit from the exposure to people from other organizations.

1.6.2.2 On-Site Courses

An "on-site" training course is one held at a location provided by the organization and is typically open only to employees. Training students at this facility eliminates their travel expenses and their additional travel time away from the workplace.
On-site classes can be tailored to meet the unique requirements and ensure confidentiality. Training the employees together promotes teamwork and allows everyone to hear the same message for consistency. When there five or more students, an on-site class typically offers substantial savings over a public class (since it is offered at a fixed price instead of individual student fees). On-site training is convenient and stretches limited training budgets. The training provider may even offer a "train-the-trainer" option, so your own employees can become qualified to deliver a course.

1.6.2.3 Distance Learning

Another training option is distance learning, for example, e-Learning on the Internet. Students can enroll in synchronous (scheduled) courses or asynchronous (self-paced) courses. Both methods are cost effective since travel isn't involved. In the case of self-paced courses, students may prefer to take the course on their home computer.
Of course, distance learning doesn't have direct interaction with instructors and students as in traditional courses. This limitation may actually be an advantage for some students, since they may be more likely to ask questions and participate in Internet forums than in a classroom environment.

1.6.3 Training Provider

Based on training needs and the evaluation of training methods, the company may decide to acquire the training solution from outside the organization.

1.6.3.1 Identification Of Training Providers

If the course is needed for student certification, ensure it is a properly accredited course. Searching the Internet may identify possible training solutions for further evaluation. Also listen to suggestions from co-workers and friends at other companies who may have had similar needs.

1.6.3.2 Evaluation Of Training Providers

If the company is unfamiliar with a training provider, determine how long they been in business. See if the provider is dealing with a stable and respected organization. Check with references before making a decision.
It is important for the training provider to offer a broad curriculum and have extensive experience so they can satisfy the needs with an integrated set of comprehensive courses.

1.6.3.3 Review Of Course Contents

It is important to review the course objectives, audience, topics and agenda. How it is packaged and delivered is equally important.
In addition to covering the appropriate subjects, in-depth courses should provide practical examples and exercises. For some courses, it may be important to engage students in case studies and role-play activities.
The course should provide adequate time for questions and as appropriate, share information on student performance. Quizzes may be used to monitor student progress. Knowledge may be judged through exams.
If the course includes an international standard as a reference, such as ISO 9001, make sure the course has been revised to reflect the latest version of the standard. The same holds true with industry schemes, such as, AS9100 for aerospace, ISO/TS 16949 for automotive, and TL 9000 for telecommunications.
For auditing courses, the ISO 19011 quality and environmental management system auditing guidance should be integrated into the course materials.
Online e-learning courses should be easy to review, register and launch. Other key features to consider might be discussion forums, note taking, screen prints, and pre- and post-assessments.

1.6.3.4 Evaluation Of Instructors

Many students consider instructors as important as the course content. However, some training providers may cut corners and select instructors for low fees and geographic proximity. Unfortunately, the class might be the first time the instructor has even seen the course materials.
The company wants a training provider that chooses instructors based on experience, certifications, expertise, and communication skills.
Students want instructors that have done what they teach.
The company must find out who will be the instructors and ask for their credentials. Talented instructors can explain complex subjects in an understandable way. Their classes are enjoyable and meet the learning objectives.

1.6.3.5 Evaluation Of Student Materials

Poor course materials can greatly diminish the value of a course. See if the training provider is willing to provide a copy of the materials (or a sample) for the evaluation.
The student materials should be easy to read. They should be formatted for quick retrieval of information. Presentation slide copies should be included, along with space for taking notes. However, the need for recording additional information should be minimal based on the slide details and associated course notes.
Slide copies and course notes should be prepared in a readable size and format. The supplied student books and handouts should become valuable references after class. If standards are an integral part of the course, copies should be provided for the students.
See if certificates are issued as proof of the training.

1.6.3.6 Consideration Of Training Costs

The company wants the best training solution, but cost is still a factor. The selected training provider should have competitive prices. However, be wary of the lowest cost provider. Training from these sources may be delivered by less qualified instructors, have inadequate content, and result in less value.
Public classes incur travel and living costs, as well as, possible job-related costs for time away from work. If the estimated travel costs for multiple students at a public class strain your budget, see if the course can be offered at your facility.

1.6.3.7 Curriculum Examination

Quite often, the training need is for a sequence of related courses. View the recommended course roadmap to see if the training provider has the appropriate curriculum.
For example, students pursuing internal auditor training may begin with a requirements course, followed by an internal auditor course. After gaining experience, they may return for a lead auditor course. Depending on their assignments, they may also be interested in a system documentation or implementation course.

1.6.3.8 Verification Of Training Support

Most training providers have an Internet presence. The company can view course descriptions, see class pricing and enroll online. Their web sites may even provide hotel information for public classes. Be aware that their capability and attitude is often a reflection on their training solutions. Assess their ability to provide information on class schedules, travel directions, and payment methods.

1.6.3.9 Consideration Of Learning Environment

Put a great course and instructor in a cramped, cold, poorly lighted room and learning suffers. Ask about the planned class location and layout.
The company must verify the number of students will be kept to a reasonable level for individual attention.

1.6.3.10 Verification Of Course Availability

If the desired training is not offered when and where the company needs it, then it does not meet the requirements. See if the training provider offers a wide choice of class dates and locations. Also verify the class will be held as planned. Do not make travel arrangements until you receive confirmation it has sufficient students.
If the company is interested in an on-site class, check on the availability of their instructors to meet your schedule. Asynchronous e-Learning classes are at your own pace. However, synchronous, scheduled classes should be available often enough to meet your needs. Training should be "just-in-time" so learning can be applied immediately to solidify the new knowledge.

1.6.4 Training

If the company selects a public class, the company will rely on the training provider to make the necessary arrangements and deliver the course. However, the company needs to make sure the students have received travel directions and any pre-course materials.
If the company hosts an on-site class, the organization must support the trainer and monitor the training. The company support may include briefing the trainer, arranging the room, providing the equipment, suggesting hotel accommodations and obtaining copies of the student roster and course evaluations.
If students enroll in an e-Learning course, the company will want to support that activity by making time available for them to take the online course without business interruptions. The company must also want to ensure the employee's computer has compatible software to access and run the on-line class.

1.6.5 Evaluation Of Training Effectiveness

It is important to evaluate the effectiveness of the training to ensure the objectives were met. In fact, it is a requirement in the ISO 9001:2000 quality standard.
Consider these six possible ways for judging the outcome:

Reaction: What was the reaction of the participants? This measure is an assessment of the student satisfaction as expressed on an evaluation form at the end of the class.

Retention: What learning has taken place? This measure can be determined through a pre-test and post-test to indicate how much information has been retained by the students. It shows what skills, knowledge, or attitudes have changed, and by how much.

Relevance: Have the participants applied what they learned? Students assess the relevance of the training through a follow-up evaluation conducted a few weeks after they return to their jobs.

Rating: Has their job performance improved? This rating summary of the participants is extracted from their performance appraisals while maintaining strict confidentiality of personal information.

Results: Did the application of the learning produce the desired results? This measure focuses on the business results achieved after the training has completed. You may be able to pinpoint the productivity gains and quality improvements resulting from the training.

Return: Did the monetary value of the results exceed the cost of the training? This measure of return on investment compares the monetary benefit of the training to its costs.

Wise use of some of these "6-Rs" may give the company new insights on how to satisfy your training needs and justify your investments.

Links



Since 1946, the "International Organization for Standardization" (ISO) is the world largest developer of standards. ISO is a network of standardization institutes of 148 countries with a central secretariat in Geneva, which coordinates the system. The principal activity is the development of technical standards, the complete work program ranges also from standards for traditional activities, such as agriculture and construction, through mechanical engineering, to medical devices and to the newest information technology developments.

Homepage: http://www.iso.org

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