

Principles and Standard Requirements for Quality Management System



Quality management system

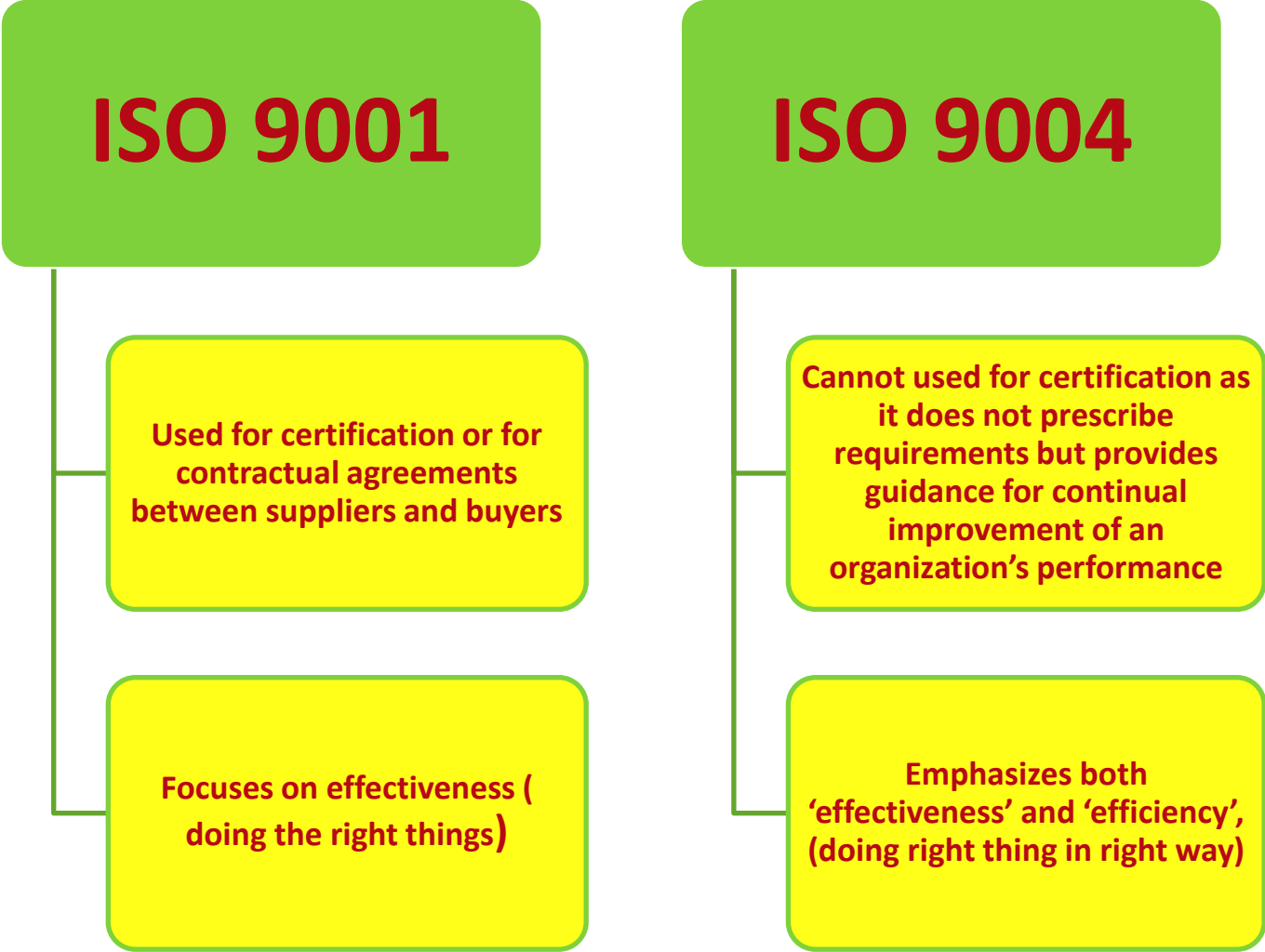
Increased international trade in 1980s created a need for development of universal standards of quality to enable one to objectively document quality practices around world.

ISO 9000 standards were first published in 1987 and subsequently revised in 1994 and 2000. Standards are reviewed every five years to ensure that they are current and satisfy needs of users.

- **ISO 9000** is a starting point for understanding the standards, as it defines the fundamental terms used in the ISO 9000 'family', or set of standards relating to quality management.
- **ISO 9001** specifies requirements for QMS to ensure that products fulfill customer requirements as well as applicable regulatory requirements; it also aims to enhance customer satisfaction.
- **ISO 9004** provides guidance on continual improvement of QMS so that needs and expectations of all interested parties (customers and end-users directors and staff in organization; owners/investors, suppliers) are met.



ISO 9001 and ISO 9004 make 'consistent pair' of standards that relate modern quality management to the processes and activities of an organization and emphasize promotion of continual improvement and achievement of customer satisfaction.



Quality Management System (QMS) Principles

- 1. Eight quality management principles on which QMS standards of ISO 9000:2000 and ISO 9000:2008 series are based.**
- 2. Principles can be used by senior management as framework to guide their organizations towards improved performance.**
- 3. Derived from collective experience and knowledge of international experts who participate in ISO Technical Committee ISO/TC 176, Quality management and quality assurance, responsible for developing and maintaining ISO 9000 standards.**
- 4. Quality management principles are defined in ISO 9000:2005, Quality management systems Fundamentals and vocabulary and in ISO 9004:2000, Quality management systems Guidelines for performance improvements.**

Principle 1: Customer focus: Organizations depend on their customers and therefore should understand current and future needs of customer.

Key benefits

Increased revenue and market share obtained through flexible and fast responses to market opportunities

Increased effectiveness in use of organization's resources to enhance customer satisfaction

Improved customer loyalty leading to repeat business

Researching and understanding customer needs and expectations

Ensuring that objectives of organization are linked to customer needs and expectations

Communicating customer needs and expectations throughout organization

Measuring customer satisfaction and acting on results

Systematically managing customer relationships

Ensuring balanced approach between satisfying customers and interested parties (owners, employees, suppliers, financiers)

Applying the principle of customer focus typically leads to

Principle 2: Leadership: Leaders establish unity of purpose and direction of organization. Create and maintain internal environment in which people can fully involve in achieving organization's objectives.

Key benefits

People will understand and be motivated towards the organization's goals and objectives

Activities are evaluated, aligned and implemented in a unified way

Mis-communication between levels of an organization will be minimized

**Considering needs of all interested parties
(customers, owners, employees, suppliers,
financiers, local communities and society)**

**Establishing a clear vision
of organization's future**

**Setting challenging goals
and targets**

**Creating and
sustaining shared
values, fairness
and ethical role
models at all levels
of organization**

**Establishing
trust and
eliminating
fear**

**Inspiring,
encouraging and
recognizing
people's
contributions**

**Providing people
with required
resources, training
and freedom to act
with responsibility
and accountability**

Applying the principle of leadership typically leads to

Principle 3: Involvement of people: People at all levels are essence of an organization and their full involvement enables their abilities to be used for organization's benefit.

Key benefits

Motivated, committed and involved people within the organization

Innovation and creativity in furthering organization's objectives

People being accountable for their own performance

People eager to participate in and contribute to continual improvement

People understanding the importance of their contribution and role in the organization

People identifying constraints to their performance

People accepting ownership of problems and responsibility for solving

People evaluating their performance against their personal goals and objectives

People actively seeking opportunities to enhance their competence, knowledge and experience

People freely sharing knowledge and experience

People openly discussing problems and issues

Applying the principle of involvement of people typically leads to

Principle 4: Process Approach: It is a management strategy. When managers use process approach (they manage the processes that make up their organization, interaction between these processes and inputs and outputs that tie these processes together.

Key benefits

Lower costs and shorter cycle times through effective use of resources

Improved, consistent and predictable results

Focused and prioritized improvement opportunities

Systematically defining the activities necessary to obtain a desired result

Establishing clear responsibility and accountability for managing key activities

Analyzing and measuring of the capability of key activities

Identifying interfaces of key activities within and between functions of organization

Focusing on factors (resources, methods, and materials) that will improve key activities of organization

Evaluating risks, consequences and impacts of activities on customers, suppliers and other interested parties

Applying the principle of process approach typically leads to.....

Principle 5: System approach to management: Relates to identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

Key benefits

Integration and alignment of processes that will best achieve desired results

Ability to focus effort on the key processes

Providing confidence to interested parties as to consistency, effectiveness and efficiency of organization

Structuring a system to achieve the organization's objectives in the most effective and efficient way

Understanding the interdependencies between the processes of system

Structured approaches that harmonize and integrate processes

Providing better understanding of roles and responsibility necessary for achieving common objectives

Understanding organizational capabilities and establishing resource constraints prior to action

Targeting and defining how specific activities within a system should operate

Continually improving the system through measurement and evaluation

Applying the principle of system approach to management typically leads to.....

Principle 6: Continual improvement: It is a set of activities that an organization periodically carries out in order to enhance its ability to meet requirements.

Key benefits

Performance advantage through improved organizational capabilities

Alignment of improvement activities at all levels to an organization's strategic intent

Flexibility to react quickly to opportunities

Employing consistent organization-wide approach to continual improvement of organization's performance

Providing people with training in the methods and tools of continual improvement

Making continual improvement of products, processes and systems an objective for every individual in organization

Establishing goals to guide and measures to track continual improvement

Recognizing and acknowledging improvements

Applying the principle of continual improvement typically leads to.....

Principle 7: Factual approach to decision making: **Effective decisions are based on the analysis of data and information**

Key benefits

Informed decisions

An increased ability to demonstrate the effectiveness of past decisions through reference to factual records

Increased ability to review, challenge and change opinions and decisions

Ensuring that data and information are sufficiently accurate and reliable

Making data accessible to those who need it

Analyzing data and information using valid methods

Making decisions and taking action based on factual analysis, balanced with experience and intuition

Applying the principle of factual approach to decision making typically leads to

Principle 8: Mutually beneficial supplier relationships: An organization and its suppliers are interdependent and mutually beneficial relationship enhances ability of both to create value.

Key benefits

Increased ability to create value for both parties

Flexibility and speed of joint responses to changing market or customer needs and expectations

Optimization of costs and resources

Establishing relationships that balance short-term gains with long-term considerations

Pooling of expertise and resources with partners

Identifying and selecting key suppliers

Clear and open communication

Sharing information and future plans

Establishing joint development and improvement activities

Inspiring, encouraging and recognizing improvements and achievements by suppliers

Applying principles of mutually beneficial supplier relationships typically leads to....



Standard Requirements For Quality Management System (QMS) – ISO 9001:2000

ISO 9000 consists of set of standards and a certification process for companies. By receiving ISO 9000 certification, companies demonstrate that they have met the standards specified by ISO. In many industries, ISO certification has become a requirement for doing business. In December 2000 the first major changes to ISO 9000 were made, introducing three new standards.....

ISO 9000:2000–QMS: Fundamentals and Standards

- **The ISO 9000:2000 set provides terminology and definitions used in standards.**
- **Starting point for understanding system of standards.**
- **This standard describes concepts of a quality management system (QMS) and defines fundamental terms used in ISO 9000 family.**
- **The standard also includes eight quality management principles which were used to develop ISO 9001 and ISO 9004.**
- **This standard replaces ISO 8402:1994 and ISO 9000-1:1994**

ISO 9001:2000–QMS: Standard Requirements

- **This standard used for certification of organization's QMS.**
- **Used to demonstrate conformity of quality management systems to meet customer requirements.**
- **This standard specifies requirements for QMS, whereby an organization needs to assess and demonstrate its ability to provide products that meet customer and applicable regulatory requirements and thereby; enhance customer satisfaction.**
- **This standard replaces ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994.**

ISO 9004:2000–QMS: Guidelines for performance

- ISO 9004:2000 provides guidelines for establishing QMS.
- **Focuses not only on meeting customer requirements but also on improving performance.**
- This standard provides guidance for continual improvement and can be used for performance improvement of an organization.
- While ISO 9001 aims to give quality assurance to manufacturing processes for products and to enhance customer satisfaction, ISO 9004 takes in broader perspective of quality management and gives guidance for future improvement.
- This standard replaces ISO 9004-1:1994.
- Guidelines for self-assessment have been included in Annexure A of ISO 9004:2000.
- This annex provides simple, easy-to-use approach to determine relative degree of maturity of an organization's QMS and identify main areas for improvement.



**ISO 9001:2000–QMS: Standard
Requirements for Application in a Dairy
Plant**

Step-1 Evaluate the organization's need/goals for implementing a QMS

- Need for implementing QMS may arise from repeated customer complaints, frequent warranty returns, delayed deliveries, high inventories, frequent production hold-ups and high level of rework or rejection of products/services.**
- One should identify goals which one would like to achieve through a QMS such as customer satisfaction, increased market share, improved communications and morale in the organization, greater efficiency and profitability, etc.**
- Another objective in implementing a QMS may be demonstration of compliance through third party certification, which may be requested by an important client.**

Step-2 Obtain information about ISO 9000 family

- **Persons identified for initiating development of ISO 9000 QMS need to understand requirements of ISO 9001:2000 as read with ISO 9000:2000 and ISO 9004:2000.**
- **Supporting information (quality management principles, frequently asked questions (FAQs), guidance on clause 1.2 (application) of ISO 9001:2000, guidance on documentation requirements of ISO 9001:2000 and other brochures are available free of charge on ISO web site at <http://www.iso.org>)**

Step-3 Appoint a consultant, if necessary

- **If within the organization, one does not have adequate competence to develop a QMS, one may appoint a consultant.**
- **Check his/her background; knowledge about product realization processes of organization and experience in helping other organizations to achieve their stated goals including certification.**
- **Appoint a consultant only for training of key staff (carry out further training and development of system).**

Step-4 Awareness and training

- **Awareness about QMS requirements should be raised amongst all personnel performing activities that affect quality.**
- **Plan for how to develop Quality Manuals, on how to identify and implement improvement processes and on how to audit compliance with QMS etc.**
- **The Institute of Quality Assurance (IQA), the American Society for Quality (ASQ) and International Auditor and Training Certification Association (IATCA) can provide lists of training organizations.**

Step-5 Gap analysis

- Gaps between existing quality management system and QMS requirements of ISO 9001 need to be evaluated.
- Preparations should be made how to bridge these gaps, including by planning for any additional resources required.
- Gap analysis may be carried out through self-assessment/external consultant.

Step-6 Product realization processes: review clause 7 of ISO 9001: 2000

- Relating to 'Product realization' to determine how requirements apply or do not apply to company's QMS.
- Processes covered by this clause include **customer-related processes, design and development, purchasing, production and service provision and control of measuring and monitoring devices.**

Step-7 Staffing

- **Organization should decide responsibilities of persons who will be involved in developing and documenting QMS, including appointment of management representative who will oversee implementation of QMS.**

Step-8 Plan a time frame

- **Complete plan should be prepared to close gaps identified in step 5 to develop QMS processes.**
- **Plan should include activities to be performed, resources required, responsibilities and an estimated completion time for each activity.**
- **Total time required for each phase (planning, documentation, implementation and evaluation) depends on extent of gaps in existing QMS.**

Step-9 Draft a quality manual

- **Include how QMS applies to products, processes, locations and departments of organization.**
- **Exclude any requirement with justification for doing so as decided in step 6 above**
- **Refer to or include: documented procedures for QMS**
- **Describe interaction between processes of QMS, e.g. interaction between product realization processes and other management, measurement and improvement processes**
- **Draft quality policy and quality objectives for organization.**
 - The staff concerned should review Quality Manual and the documented procedures so that their comments and suggestions can be taken into account before the Quality Manual and procedures are approved for issue and use**

Step-10 Carry out internal audits

- **During phase of implementation of some three to six months after the documentation has been written, trained auditors should carry out one/two internal audits covering all activities for QMS and concerned management should take corrective action on audit findings without delay.**
- **Wherever required, manuals, procedures and objectives should be revised.**
- **After each internal audit, top management should review effectiveness of system and provide necessary resources for corrective actions and improvements.**

Step-11 Apply for certification

- If the company decides to obtain third party certification, it can make an application for certification to an accredited certification body.
- Certification audit process is explained in step 7.

Step-12 Conduct periodic evaluations

- After certification, organization should periodically conduct internal audits to review effectiveness of QMS and see how it can be 'continually improved'.
- Organization should evaluate periodically if purpose and goals (step 1) for which QMS was developed are being achieved, including its continual improvement.



Step-13 Certification

- How to select a certification body organizations that desire to obtain a certificate need to submit an application to certification body of their choice.
- Issues to consider when selecting certification body include **whether nature of accreditation of certification body is acceptable in market to which the organization wants to export; market image of certification body; quotations for certification and audit fees etc.**

Step-14 Prepare for assessment

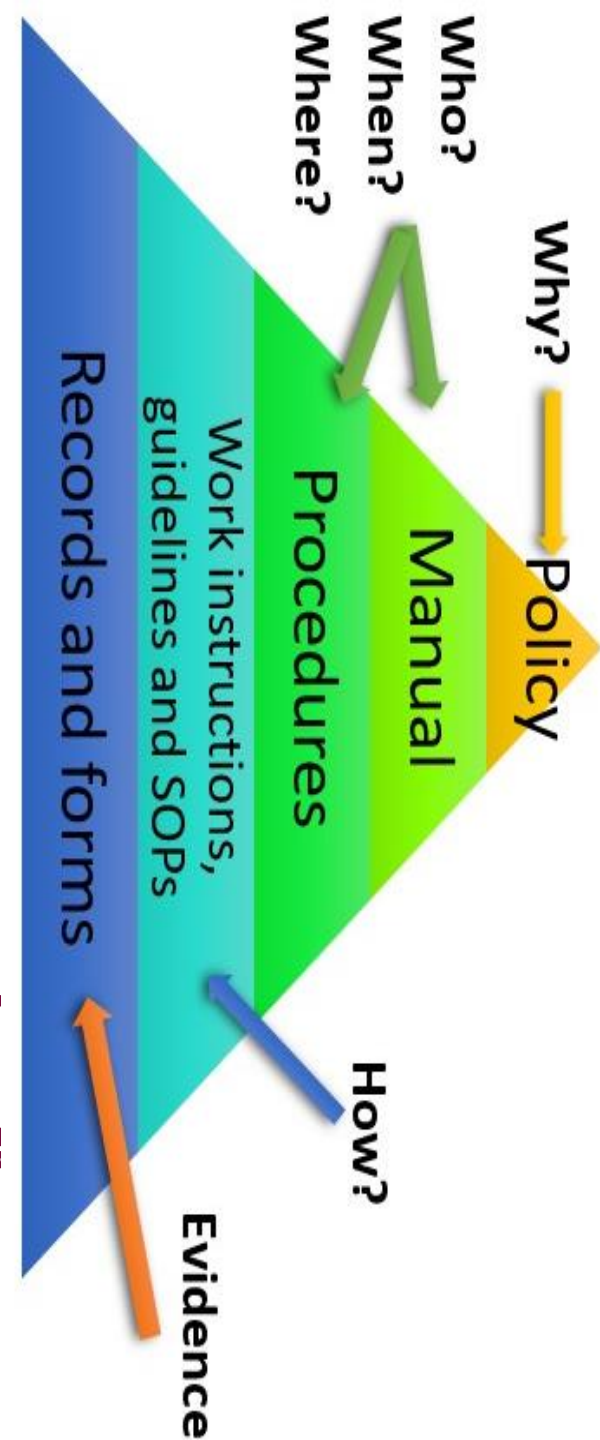
- **First requirement under ISO 9001:2000 is to define the organization's processes that affect quality, so that the first step is that the auditor from certification body meets with organization's management to gain an understanding of its processes.**

Step-15 Preparing for assessment

- **Auditor conveys any gaps (non-conformity) found in documents to organization for necessary actions and re-submission of documents.**
- **Certification body also examines, the justification included in Quality Manual for not including certain product realization processes (e.g. if company does not design product, it can exclude requirements of Clause 7.3 of ISO 9001, but this would need to be explained in Manual).**

Step-16 Auditing

- After completion of document review audit, auditors undertake second part of audit process at organization's location at a mutually agreed time and date.
- Audit at location begins with an 'opening meeting'.
- During this meeting, auditors explain to management how audit will be conducted and when and how the findings will be conveyed to management.
- Collect evidence of conformity/ non-conformity through observation of activities, examination of procedures/ records, observations of conditions of house-keeping through interviews with concerned managers/ personnel of organization etc.



Step-17 Non-conformity

- Evidence collected by auditors is compared with audit criteria and audit findings including non-conformity, if any, are clarified and reported to management at end of site audit in formal meeting with management called 'closing meeting'.
- **'Major' NC** indicates that company has failed to implement any one part or full QMS; any specific department of company has failed to implement QMS as applicable to department
- **'Minor' non-conformity** means an isolated incident of failure to comply with defined process.
- An 'observation' indicates that if situation as found during audit is not addressed it may lead to 'NC' in future.
- During major nonconformity, recommendation for certification is deferred until corrective action on the same is verified through follow-up audit.

Step-18 Award of the ISO 9000 certificate

- Certification body issues a certificate to organization, based upon recommendations of Lead Auditor and independent review of these recommendations.



Step-19 Surveillance audits

- **Certificate is initially awarded for period of 3 years.**
- **During this time, periodic surveillance audits (once or twice a year) are carried out by certification body on mutually agreed dates.**
- **An audit plan for three years indicating scope of audit in each surveillance audit is transmitted to organization in advance by certification body.**
- **These audits are planned in such a manner that all aspects of QMS are audited over a period of three years.**
- **Re-certification audit is carried out after 3 years using steps 2-5 above.**
- **During period of certification, certification body may examine records relating to quality complaints made by customers either directly to organization or to certification body, to check if organization is taking appropriate action to eliminate the cause of such complaints.**
- **Certification body also examines any misleading use of the logo of the certification body or incorrect references to certification.**