ISO 9000:2015, Quality management systems

— Fundamentals and vocabulary

EST 2012

This document introduces **ISO 9000:2015, Quality Management Systems — Fundamentals and Vocabulary**, which provides the essential principles, concepts, and terminology that form the foundation for understanding and implementing quality management systems.

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Content (Quality Management Systems — Fundamentals And Vocabulary

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Audit

systematic, independent and documented process (3.4.1) for obtaining objective evidence (3.8.3) and evaluating it objectively to determine the extent to which the audit criteria (3.13.7) are fulfilled

Note 1 to entry: The fundamental elements of an audit include the determination (3.11.1) of the conformity (3.6.11) of an object (3.6.1) according to a procedure (3.4.5) carried out by personnel not being responsible for the object audited.
Note 2 to entry: An audit can be an internal audit (first party), or an external audit (second party or third party), and it can be a combined audit (3.13.2) or a joint audit (3.13.3).

Note 3 to entry: Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization (3.2.1) itself for management (3.3.3)review (3.11.2) and other internal purposes, and can form the basis for an organization's declaration of conformity. Independence can be demonstrated by the freedom from responsibility for the activity being audited.

Note 4 to entry: External audits include those generally called second and third-party audits. Second party audits are conducted by parties having an interest in the organization, such as customers (3.2.4), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations such as those providing certification/registration of conformity or governmental agencies.

Note 5 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition and Notes to entry have been modified to remove effect of circularity between audit criteria and audit evidence term entries, and Notes 3 and 4 to entry have been added.

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Audit Criteria

Audit criteria are used as a reference point and include policies, requirements, and other forms of documented information. They are compared against audit evidence to determine how well they are being met. Audit evidence is used to determine how well policies are being implemented and how well requirements are being followed.
See 9.2.2 of ISO ISO9001

Audit Evidence

Audit evidence includes records, factual statements, and other verifiable information that is related to the audit criteria being used. Audit criteria include policies, requirements, and other documented information.

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Audit findings

Audit findings result from a process that evaluates audit evidence and compares it against audit criteria. Audit findings can show that audit criteria are being met (conformity) or that they are not being met (nonconformity). They can also identify best practices or improvement opportunities.

Audit Program

An audit program (or programme) refers to a set of one or more audits that are planned and carried out within a specific time frame and are intended to achieve a specific audit purpose.
See 9.2.2 of ISO ISO9001

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Characteristic

A characteristic is a distinctive feature or property of something. Characteristics can be inherent or assigned and can be qualitative or quantitative. An inherent characteristic exists in something or is a permanent feature of something while an assigned characteristic is a feature that is attributed or attached to something.

See 8.3.5, 8.5.1 of ISO 9001

Competence

Competence means being able to apply knowledge and skill to achieve intended results. Being competent means having the knowledge and skill that you need and knowing how to apply it. Being competent means that you're qualified to do the job.

See 7.2, 7.5.1 of ISO 9001

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Complaint

In the context of ISO 9001, a complaint refers to an expression of dissatisfaction with a product or service and is filed by a customer and received by an organization. Whenever a customer lodges a complaint, a response is either explicitly or implicitly required.
See 8.2.1, 10.2.1 of ISO 9001

Concession

A concession is a special approval that is granted to release a nonconforming product or service for use or delivery. Concessions are usually restricted to a specific use and limited by time and quantity and tend to specify that nonconforming characteristics may not violate specified limits.
See 8.7.1, 8.7.2 of ISO 9001

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Conformity

Conformity is the "fulfillment of a requirement". To conform means to meet or comply with requirements and a requirement is a need, expectation, or obligation. There are many types of requirements including customer requirements, quality requirements, quality management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements, and regulatory requirements.

See ISO 9001 Standard - 4.3, 7.1.3, 7.1.4, 7.1.5.1, 7.1.6, 7.5.3.2, 8.1, 8.3.6, 8.5.2, 8.5.4, 8.5.6, 8.6, 8.7.1, 9.1.3, 9.3.2, ANNEX A.2, ANNEX A.5, ANNEX A.6, ANNEX A.7

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Context of the organization

An organization’s context is its business environment. It includes all of the internal and external factors and conditions that affect its products and services, have an influence on its QMS, and are relevant to its purpose and strategic direction. An organization’s external context includes all of the needs and expectations of interested parties, as well as its social, cultural, legal, technological, regulatory, and competitive environment. An organization’s internal context includes its values, culture, knowledge, and performance. ISO 9001 2015 expects you to consider your organization’s internal and external context when you define the scope of its QMS and when you plan it's design and development.

See 5.2.1 of ISO 9001

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Continual improvement

Continual improvement is a set of recurring activities that are carried out in order to enhance performance. Continual improvements can be achieved by carrying out audits, self-assessments, and management reviews. Continual improvements can also be realized by collecting data, analyzing information, setting objectives, and implementing corrective and preventive actions.

See ISO 9001 Standard clause 5.2.1, 7.1.1, 10.1, 10.3

Contract

A contract is a binding agreement between two or more parties.

See 8.2.1, 8.2.3.1 of ISO 9001

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Correction

A correction is any action that is taken to eliminate a nonconformity. However, corrections do not address root causes. When applied to products, corrections can include reworking products, reprocessing them, regrading them, assigning them to a different use, or simply destroying them.

See 8.7.1, 9.2.2, 10.1 of ISO 9001

Corrective action

Corrective actions are steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence. The corrective action process tries to make sure that existing nonconformities and potentially undesirable situations don't happen again.

See 9.2.2, 9.3.2, 10.1, 10.2.1, 10.2.2 of ISO 9001

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Customer

A customer is anyone who receives products or services (outputs) from a supplier. Customers can be either people or organizations and can be either external or internal to the supplier organization. Examples of customers include clients, consumers, users, guests, patients, purchasers, and beneficiaries.

See ISO 9001 Standard Clause - 4.2, 5.1.2, 5.3, 6.1.2, 7.1.6, 8.2.1, 8.2.2, 8.2.3.1, 8.3.2, 8.4.1, 8.4.2, 8.4.3, 8.5.3, 8.5.5, 8.6, 8.7.1, 9.1.2, 10.1,

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Customer satisfaction

Customer satisfaction is a perception. It's also a question of degree. It can vary from high satisfaction to low satisfaction. If customers believe that you've met their requirements, they experience high satisfaction. If they believe that you've not met their requirements, they experience low satisfaction. Since satisfaction is a perception, customers may not be satisfied even though you've met all contractual requirements. Just because you haven't received any complaints doesn't mean that customers are satisfied. There are many ways to monitor and measure customer satisfaction. You can use customer satisfaction and opinion surveys; you can collect product quality data (post delivery), track warranty claims, examine dealer reports, study customer compliments and criticisms, and analyze lost business opportunities.

See ISO 9001 Standard Clause - 4.3, 5.1.2, 6.2.1, 9.1.3, 9.3.2, 10.1, Annex 3

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Data

The term data is defined as any facts about an object.
See 9.1.3 of ISO 9001

Defect

A defect is a type of nonconformity. It occurs when a product or service fails to meet specified or intended use requirements.

Design and development

Design and development is a process (or a set of processes) that uses resources to transform general input requirements for an object into specific output requirements. An object is any entity that is either conceivable or perceivable. Objects can be real or imaginary and could be material or immaterial. Examples include products, services, systems, organizations, people, practices, procedures, processes, plans, ideas, documents, records, methods, tools, machines, technologies, techniques, and resources.
See 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6

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Determination

To determine means to find or to identify the value of a characteristic.

See ISO 9001 clause: 4.1, 4.2, 4.3, 4.4, 5.1.2, 6.1.1, 6.2.2, 6.3, 7.1.1, 7.1.2, 7.1.3, 7.1.4, 7.1.5.1, 7.1.5.2, 7.1.6, 7.2, 7.4, 7.5.1, 7.5.3.2, 8.1, 8.3.3, 8.3.4, 8.4.1, 8.4.2, 9.1.1, 9.1.2, 10.1, 10.2.1, 10.3

Documented information

The term documented information refers to information that must be controlled and maintained and its supporting medium.

Documented information can be in any format and on any medium and can come from any source.

Documented information includes information about the management system and related processes.

It also includes all the information that organizations need to operate and all the information that they use to document the results that they achieve (aka records).

See ISO 9001 Standard Clause 4.3, 4.4.2, 5.2.2, 6.2.1, 7.1.5.1, 7.1.5.2, 7.2, 7.5.1, 7.5.2, 7.5.3.1, 7.5.3.2, 8.1, 8.2.3.2, 8.2.4, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.5.1, 8.5.2, 8.5.3, 8.5.6, 8.6, 8.7.2, 9.1.1, 9.2.2, 9.3.3, 10.2.2

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Effectiveness

Effectiveness refers to the degree to which a planned effect is achieved. Planned activities are effective if these activities are actually carried out and planned results are effective if these results are actually achieved.

See ISO 9001 Standard Clauses 5.1.1, 6.1.2, 7.2, 7.3, 7.5.1, 8.4.2, 9.1.1, 9.1.3, 9.3.1, 9.3.2, 10.1, 10.2.1, 10.3

Feedback

The term feedback is used to refer to a comment or an opinion expressed about a product or service or an interest expressed in a product or a service. It may also be used to refer to the customer complaints-handling process itself.

See ISO 9001 Standard Clauses 8.2.1, 8.5.5, 9.1.2, 9.3.2

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Function

A function is a role that is performed by a unit of an organization.
See 6.2.1 of ISO 9001

Improvement

Improvement is a set of activities that organizations carry out in order to enhance performance (get better results). Improvement can be achieved by means of a single activity or by means of a recurring set of activities.
See ISO 9001 Standard Clauses 5.1.1, 5.3, 6.1.1, 7.1.6, 9.1.3, 9.3.2, 9.3.3, 10.1 of ISO 9001 Standard

Information

Information is “meaningful data”. While it's not entirely clear what the word “meaningful” is supposed to mean in this context, dictionaries tend to say that something is meaningful if it is significant, relevant, material, valid, or important.
See 4.1, 4.2, 7.1.3, 7.1.6, 8.2.1, 8.2.3.1, 8.3.3, 9.1.2, 9.1.3, 9.2.1, 9.3.2 of ISO 9001 Standard

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Information system

In the context of this ISO 9001 standard, an information system is a network of communication channels used within an organization.

Infrastructure

The term infrastructure refers to the entire system of facilities, equipment, and support services that organizations need in order to function.
According to ISO 9001, section 7.1.3, the term infrastructure can include buildings, equipment, utilities, and technologies (both hardware and software). See 7.1.3, 8.5.1 of ISO 9001

Innovation

Innovation is a process that results in a new or substantially changed object.
An object is any entity that is either conceivable or perceivable. Objects can be real or imaginary and could be material or immaterial. Examples include products, services, systems, organizations, people, practices, procedures, processes, plans, ideas, documents, records, methods, machines, tools, technologies, techniques, and resources. See 10.1 of ISO 9001 Standard

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Interested party

An interested party is anyone who can affect, be affected by, or believe that they are affected by a decision or activity. An interested party is a person, group, or organization that has an interest or a stake in a decision or activity.

See 4.2, 4.3, 5.2.2, 8.3.2, 9.3.2 of ISO 9001

Involvement

Involvement occurs when people share objectives and are actively engaged in and contribute to their achievement.

See 8.3.2 of ISO 9001 Standard

Knowledge

Knowledge is a collection of information and a justified belief that this information is true with a high level of certainty.

See 4.1, 7.1.6, Annex A.7 of ISO 9001 Standard

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Management

The term management refers to all the activities that are used to coordinate, direct, and control organizations. These activities include developing policies, setting objectives, and establishing processes to achieve these objectives.
In this context, the term management does not refer to people. It refers to what managers do.
See 9.2.2 of ISO 9001

Measurement

Measurement is a process that is used to determine a value. In most cases this value will be a quantity. Measuring equipment Measuring equipment includes all the things needed to carry out a measurement process. Accordingly, measuring equipment includes instruments and apparatuses as well as all the associated software, standards, and reference materials.
See 4.4.1, 7.1.5.1, 7.1.5.2, 8.3.5, 8.5.1, 8.5.2, 9.1.1, 9.1.3, 9.3.2 of ISO 9001

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Management system

A management system is a set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved.

These elements include structures, programs, procedures, practices, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.

There are many types of management systems. Some of these include quality management systems, environmental management systems, financial management systems, information security management systems, business continuity management systems, emergency management systems, disaster management systems, food safety management systems, risk management systems, and occupational health and safety management systems.

The scope or focus of a management system could be restricted to a specific function or section of an organization or it could include the entire organization. It could even include a function that cuts across several organizations.

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Monitoring

To monitor means to determine the status of an activity, process, or system at different stages or at different times. In order to determine status, you need to supervise and to continually check and critically observe the activity, process, or system that is being monitored.

See 4.4.1, 7.1.5.1, 8.3.5, 8.4.1, 8.4.3, 8.5.1, 8.5.2, 9.1.1, 9.1.2, 9.1.3, 9.3.2 of ISO 9001 Standard

Nonconformity

Nonconformity is a nonfulfillment or failure to meet a requirement.
A requirement is a need, expectation, or obligation. It can be stated or implied by an organization or interested parties.

See 8.7.1, 8.7.2, 9.3.2, 10.2.1, 10.2.2 of ISO 9001 Standard

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Object

An object is any entity that is either conceivable or perceivable. Objects can be real or imaginary and could be material or immaterial. Examples include products, services, systems, organizations, people, practices, procedures, processes, plans, ideas, documents, records, methods, tools, machines, technologies, techniques, and resources.

Objective

An objective is a result you intend to achieve. Objectives can be strategic, tactical, or operational and can apply to an organization as a whole or to a system, process, project, product, or service. Objectives may also be referred to as targets, aims, goals, or intended outcomes. Quality objectives are generally based on or derived from an organization's quality policy and must be consistent with it.

See 7.1.6 of ISO 9001 Standard

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Objective audit evidence

Objective audit evidence is information that is verifiable and generally consists of records and other statements of fact that are relevant to the audit criteria being used.

Objective evidence

Objective evidence is data that shows or proves that something exists or is true. Objective evidence can be collected by performing observations, measurements, tests, or using other suitable methods.

Organization

An organization can be a single person or a group that achieves its objectives by using its own functions, responsibilities, authorities, and relationships. It can be a company, corporation, enterprise, firm, partnership, charity, association, or institution and can be either incorporated or unincorporated and be either privately or publicly owned. It can also be an operating unit that is part of a larger entity. See 4.1, 4.2, 4.3, 4.4, 5.1.1, 6.1.1, 6.1.2, 6.2.1, 6.2.2, 6.3, 7.1.1, 7.1.2, 7.1.3, 7.1.4, 7.1.5, 7.1.6, 7.2, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3, 8.1, 8.2.2, 8.2.3, 8.2.4 of ISO 9001 Standard

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Output

An output is the result of a process. Outputs can be either tangible or intangible. The output from one process is often the input for another process.
ISO 9001 lists four generic output categories: services, software, hardware, and processed materials. Outputs often combine several of these categories. For example, an automobile (an output) combines hardware (e.g. tires), software (e.g. engine control algorithms), and processed materials (e.g. lubricants).
See 4.4.1, 5.3, 8.1, 8.3.4, 8.3.5, 8.4.2, 8.5.1, 8.5.2, 8.5.4, 8.7.1, 9.3.3, 10.3 of ISO 9001

Outsource

When an organization makes an arrangement with an outside organization to perform part of a function or process, it is referred to as outsourcing.
To outsource means to ask an external organization to perform part of a function or process normally done in-house. While an outsourced organization is beyond the scope of your QMS, the outsourced process or function itself falls within your scope. See 8.1of ISO 9001 Standard

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Performance

According to ISO, the term performance refers to a measurable result. It refers to the measurable results that activities, processes, products, services, systems and organization s are able to achieve. Whenever they perform well it means that acceptable results are being achieved and whenever they perform poorly, unacceptable results are achieved.
See 4.1, 4.4.1, 5.3, 7.2, 7.3, 8.3.3, 8.4.1, 8.4.3, 9.1.1, 9.1.3, 9.3.2, 10.1 of ISO 9001 Standard

Performance indicator

A performance indicator (metric) is a characteristic that is used to measure customer satisfaction and how well outputs are realized. See 4.4.1 of ISO 9001 Standard

Policy

A policy is a general commitment, direction, or intention and is formally stated by top management. A quality policy statement should express top management's commitment to the implementation and improvement of its quality management system and should allow managers to set quality objectives.

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Process

A process is a set of activities that are interrelated or that interact with one another. processes use resources to transform inputs into outputs.
processes are interconnected because the output from one process often becomes the input for another process. While processes usually transform inputs into outputs, this is not always the case. Sometimes inputs become outputs without transformation.

Organizational processes should be planned and carried out under controlled conditions. An effective process is one that realizes planned activities and achieves planned results.
See 4.4.1, 4.4.2, 5.1.1, 5.3, 6.1.2, 6.2.1, 7.1.2, 7.1.3, 7.1.4, 7.1.6, 7.5.1, 8.1, 8.3.1, 8.3.2, 8.3.4, 8.3.5, 8.4.1, 8.4.2, 8.4.3, 8.5.1, 9.2.2, 9.3.2 of ISO 9001 Standard

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Process approach

The process approach is a management strategy. When managers use a process approach, it means that they manage and control the processes that make up their organization, the interaction between these processes, and the inputs and outputs that tie these processes together.

See 5.1.1 of ISO 9001 Standard

Process-based quality management system

A process-based quality management system uses a process approach to manage and control how its quality policy is implemented and how its quality objectives are achieved. A process-based QMS is a network of interrelated and interconnected processes.

Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single integrated process-based QMS

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Product

A product is a tangible or intangible output that is the result of a process that does not include activities that are performed at the interface between the supplier (provider) and the customer.
Products can be tangible or intangible.
According to a note to this definition, there are three generic product categories: hardware, processed materials, and software.

Many products combine several of these categories. For example, an automobile (a product) combines hardware (e.g. tires), software (e.g. engine control algorithms), and processed materials (e.g. lubricants).

See 4.2, 4.3, 5.1.2, 6.1.2, 6.2.1, 7.1.3, 7.1.4, 7.1.5.1, 7.1.6, 7.5.1, 7.5.3.2, 8.1, 8.2.1, 8.2.2, 8.2.3.1, 8.2.3.2, 8.2.4, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.4.2, 8.4.3, 8.5.1, 8.5.2, 8.5.3, 8.5.5, 8.6, 8.7.1, 9.1.2, 9.1.3, 9.3.2, 10.1 of ISO 9001 Standard

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Provider

A provider is a person or an organization that supplies or provides products or services. Providers can be either internal or external to the organization. Internal providers supply products or services to people within their own organization while external providers supply products or services to other organizations.

See 7.1.1, 7.1.6, 8.4.1, 8.4.2, 8.4.3, 8.5.3, 9.1.3, 9.3.2 of ISO 9001 Standard

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Quality

The adjective quality applies to objects and refers to the degree to which a set of inherent characteristics fulfills a set of requirements.
An object is any entity that is either conceivable or perceivable and an inherent characteristic is a feature that exists in an object. The quality of an object can be determined by comparing a set of inherent characteristics against a set of requirements. If those characteristics meet all requirements, high or excellent quality is achieved but if those characteristics do not meet all requirements, a low or poor level of quality is achieved. So the quality of an object depends on a set of characteristics and a set of requirements and how well the former complies with the latter.

Quality management

coordinate quality. These activities include formulating a quality policy and setting quality objectives. They also include quality planning, quality control, quality assurance, and quality improvement.

See 5.1.1 of ISO 9001 Standard

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Quality management system

A quality management system (QMS) is a set of interrelated or interacting elements that organizations use to formulate quality policies and quality objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved. These elements include structures, programs, practices, procedures, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.

See 4.1, 4.2, 4.3, 4.4.1, 5.1.1, 5.2.1, 5.3, 6.1.1, 6.1.2, 6.2.1, 6.3, 7.1.1, 7.1.2, 7.2, 7.3, 7.4, 7.5.1, 7.5.3.1, 7.5.3.2, 8.4.2, 9.1.1, 9.1.3, 9.2.1, 9.3.1, 9.3.2, 9.3.3, 10.1, 10.2.1, 10.3 of ISO 9001 Standard

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Quality objective

A quality objective is a quality result that you intend to achieve. Quality objectives are based on or derived from an organization's quality policy and must be consistent with it. They are usually formulated at all relevant levels within the organization and for all relevant functions. The adjective quality applies to objects and refers to the degree to which a set of inherent characteristics fulfills a set of requirements; and an object is any entity that is either conceivable or perceivable. Therefore, a quality objective can be set for any kind of object.

See 5.1.1, 5.2.1, 6.2.1, 6.2.2, 7.3 , 9.3.2 of ISO 9001 Standard

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Quality policy

A quality policy should express top management's commitment to the quality management system (QMS) and should allow managers to set quality objectives.
It should be based on ISO's quality management principles and should be compatible with your organization's other policies and be consistent with its vision and mission. ISO's quality management principles ask you to focus on customers and interested parties, to provide leadership, to engage and involve people, to use a process approach, to encourage improvement, to use evidence to make decisions, and to manage corporate relationships.
See 5.1.1, 5.2.1, 5.2.2, 6.2.1 & 7.3 of ISO 9001 Standard

Regulatory requirement

A regulatory requirement is an obligation that is specified by an authority which gets its mandate from a legislative body.
See 4.2, 5.1.2, 8.2.2, 8.2.3.1, 8.3.3, 8.4.2, 8.5.5 of ISO 9001 Standard

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Release

To release means to grant permission to proceed to the next stage of a process. The term release is also used to refer to a version of software or documented information. See 8.4.3, 8.5.1, 8.6 of ISO 9001 Standard

Requirement

A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties.

A specified requirement is one that has been stated (in a document for example), whereas an implied requirement is a need, expectation, or obligation that is common practice or customary. There are many types of requirements.

Some of these include customer requirements, quality requirements, quality management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements, and regulatory requirements.

See 4.2, 4.3, 4.4.1, 5.1.1, 5.1.2, 5.2.1, 5.3, 6.1.1, 6.2.1, 7.1.5.1, 7.1.5.2, 7.3, 8.1, 8.2.1, 8.2.2, 8.2.3.1, 8.2.3.2, 8.2.4, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.4.2, 8.4.3, 8.5.2, 8.5.4, 8.5.5, 8.5.6, 8.6, 8.7.1, 9.2.1, 9.2.2, 10.1 of ISO 9001 Standard

ISO 9000:2015

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Review

A review is an activity. Its purpose is to figure out how well the thing being reviewed is capable of achieving established objectives.
Reviews ask the following question: is the subject (or object) of the review a suitable, adequate, effective, and efficient way of achieving established objectives? There are many kinds of reviews. Some of these include management reviews, design and development reviews, customer requirement reviews, nonconformity reviews, and peer reviews.

Risk-based thinking

Risk-based thinking refers to a coordinated set of activities and methods that organization s use to manage and control the many risks that affect its ability to achieve objectives.
Risk-based thinking replaces what the old standard used to call preventive action. While risk-based thinking is now an essential part of the new standard, it does not actually expect you to implement a formal risk management process nor does it expect you to document your organization's risk-based approach. See 5.1.1

ISO 9000:2015

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Risk

According to ISO 9000, risk is the “effect of uncertainty on an expected result” and an effect is a positive or negative deviation from what is expected. The following two paragraphs will explain what this means.

This definition recognizes that all of us operate in an uncertain world. Whenever we try to achieve something, there’s always the chance that things will not go according to plan. Sometimes we get positive results and sometimes we get negative results and occasionally we get both. Because of this, we need to reduce uncertainty as much as possible. Uncertainty (or lack of certainty) is a state or condition that involves a deficiency of information and leads to inadequate or incomplete knowledge or understanding.

In the context of risk management, uncertainty exists whenever the knowledge or understanding of an event, consequence, or likelihood is inadequate or incomplete. While this definition argues that risk can be positive as well as negative, a note acknowledges that "the term risk is sometimes used when there is only the possibility of negative consequences".

See 4.4.1, 5.1.2, 6.1.1, 6.1.2, 9.1.3, 9.3.2, 10.2.1

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Service

A service is an intangible output and is the result of a process that includes at least one activity that is carried out at the interface between the supplier (provider) and the customer. Service provision can take many forms. Service can be provided to support an organization's own products (e.g. warranty service or the serving of meals). Conversely, it can be provided for a product supplied by a customer (e.g. a repair service or a delivery service). It can also involve the provision of an intangible thing to a customer (e.g. entertainment, ambience, transportation, or advice). See 4.2, 4.3, 5.1.2, 6.1.2, 6.2.1, 7.1.3, 7.1.4, 7.1.5.1, 7.1.6, 7.5.1, 7.5.3.2, 8.1, 8.2.1, 8.2.2, 8.2.3.1, 8.2.3.2, 8.2.4, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.4.2, 8.4.3, 8.5.1, 8.5.2, 8.5.3, 8.5.5, 8.6, 8.7.1, 9.1.2, 9.1.3, 9.3.2, 10.1

Statutory requirement

A statutory requirement is defined by a legislative body and is obligatory. Strategy A strategy is a plan for achieving an objective.

See 4.2, 5.1.2, 8.2.2, 8.2.3.1, 8.3.3, 8.4.2, 8.5.5 of ISO 9001 Standard

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Supplier

A supplier is a person or an organization that provides products or services. Suppliers can be either internal or external to an organization. Internal suppliers provide products or services to people within their own organization while external suppliers provide products or services to other organization s.
Examples of suppliers include organizations and people who produce, distribute, or market products, provide services, or publish information. While ISO still includes a definition for this term, the new ISO 9001 2015 standard no longer actually uses it. It prefers, instead, to use the term external provider.

System

A system is defined as a set of interrelated or interacting elements. A management system is one type of system. It is a set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved.

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Top management

The term top management normally refers to the people at the top of an organization. It refers to the people who provide resources and delegate authority and who coordinate, direct, and control organizations.

However, if the scope of a management system covers only part of an organization, then the term top management refers, instead, to the people who direct and control that part of the organization.

See 5.1.1, 5.1.2, 5.2.1, 5.3, 9.3.1

Traceability

Traceability is the ability to identify and trace the history, distribution, location, and application of products, parts, materials, and services.

A traceability system records and follows the trail as products, parts, materials, and services come from suppliers and are processed and ultimately distributed as final products and services.

See 7.1.5.2, 8.5.2, 8.6

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Validation

Validation is a process. It uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a validated status is established.

Validation can be carried out under realistic use conditions or within a simulated use environment. There are several ways to confirm that the requirements which define an intended use or application have been met. For example you could do tests, you could carry out alternative calculations, or you could examine documents before you issue them.

See 8.3.2, 8.3.4, 8.4.2, 8.4.3, 8.5.1

Verification

Verification is a process. It uses objective evidence to confirm that specified requirements have been met. Whenever specified requirements have been met, a verified status is achieved. There are many ways to verify that requirements have been met.

For example you could inspect something, you could do tests, you could carry out alternative calculations, or you could examine documents before you issue them.

See 7.1.5.2, 8.3.2, 8.3.4, 8.4.2, 8.4.3, 8.7.1

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