ISO 9001:2015 Requirements from A to Z 16

Desk Reference

Note: The student textbook/Desk Reference contains the text content of the class without interactive exercises, activities, glossary links, images, examples, key points, tips, tests, EG bags, handouts, or summaries. The student textbook can be used for off-line refresher and future reference after the class. The desk reference should not be used in place of the web-based training program.

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Contents

Terminology and Definitions

Learning Objectives:

Upon completion of this training, managers and auditors will be able to:

- explain notable terms used in the standard
- locate where technical definitions found

Discussion: *The ANSI/ISO/ASQ Q9000-2015 Quality management systems - Fundamentals and vocabulary* (ISO 9000) standard defines selected terms and provides background information about quality fundamentals. **When dictionary definitions are not sufficient** to support the quality management standards, definitions are provided in ISO 9000 or in the quality management system requirements standard (normally clause 3).

ISO 9000 Terms and Definitions

We do not have the time to discuss every word definition, so we have picked some that we think are especially important or have some aspect that you need to be aware of.

Notable Organization Concepts

The word organization is used to indicate the **user of a standard**. The organization can be a manufacturer or service company, private or public, regulated or non-regulated, and small or large. The organization implements the management system and is audited by a certification body (CB).

In the United States, the term "stakeholder" has been used over the last two decades to reference individuals or groups that have a stake (something to lose or gain) in the outcome of a process or activity. Worldwide, the term 'stakeholder' does not translate well so the standard uses the term interested party to refer to those **interested in the performance or success of the organization**.

The term **infrastructure** is defined. The word "infrastructure" may be used when referencing an **organization's facilities, utilities, and equipment**.

Notable Terms Related to Conformity

The definition of the term nonconformity is non-fulfillment of a requirement. Nonconformities result in other actions (see diagram below that shows linkages to other terms). The term **correction** refers to responses to nonconformities that only alleviate the specified nonconformity. Other popular terms for correcting are containment action or remedial action. Correction must not be confused with corrective action or responses to identification of risks.

Important: Please note that auditors should seek evidence of conformity to requirements. There are two kinds of prevention. ***Corrective action*** requires an organization to prevent the problem from happening again (**reactive**) and there are actions to prevent potential risks (**proactive**).

Notable Terms Related to Process and Product

A **product is an output of an organization or the result of a process**. A product is normally something **tangible such as hardware, materials, or software.** Delivery of a product may result in a service.

A service is an **output of an organization** or process too but may be an intangible such as a like a medical treatment.

Product categories supported by the standard include:

Hardware	Hardware is tangible and its amount is a countable characteristic. It has physical form, you can see it and touch it; it may be produced by machines or assembled (nut and bolts, automobiles, I beams, refrigerators, computers, etc.).
Processed materials	Processed materials are tangible and their amount is a continuous characteristic (e.g. fuel and soft drinks). To produce them, they may undergo mixing, treatment, change of state or chemical reaction (chemicals, rubber, plastic, pharmaceuticals, food, etc.).
Software	Software consists of information (3.8.2) regardless of delivery medium (e.g. computer program, mobile phone app, instruction manual, dictionary content, musical composition copyright, driver's license). Delivered as code which gives instructions to hardware (ATM or cash machines) or other software.

Product is produced by a process while a service is a process. The technical definition for a **process** is that it is a set of interrelated or interacting activities that use **inputs to deliver an intended result**. Simply, a process is associated with some type of action or transformation such as stamping, rolling, designing or other actions that create value. In general, standard professionals associate inputs and outputs with a process and outcomes with a system.

Notable Terms Related to Audit

As standards evolve, such as the auditing and environmental standards, so does our need to understand the terminology used by the audit experts. The term **quality audit** is not in the current ISO 9000 vocabulary standard and has been replaced with the generic term, **audit**. There is little difference between the "quality audit," "environmental audit, "and "audit" definition.

The **audit** definition simply requires that audits determine the extent to which the audit criteria are fulfilled. The audit criteria may be determined on an audit-by-audit basis.

There is an audit **client**, who is the person who has authority to request the audit. **Audit evidence** is collected and then evaluated objectively. An auditor collects audit evidence to determine audit findings. The term **audit findings** refers to the conformity or nonconformity to the audit criteria as well as any opportunities for improvement. The output of the audit process is the audit conclusion. Based on the findings, an auditor may recommend or not recommend registration.

Notable Terms Related to Quality

The definition of **quality** is short but somewhat technical in nature and not as simple as we would like for everyday use. In this group of quality-related terms, there is a definition for **customer satisfaction**. Since customer satisfaction is one of the primary aims of the standard, it is important to define this term. The definition for **requirement** is very interesting because it goes beyond stated needs and expectations to include implied needs and expectations.

Notable Terms Related to Management

Probably one of the most prominent and challenging of audit terms in the standard is **effectiveness**. Several clauses in the standard require effective application, implementation, processes, planning, operation, control, arrangements, and communication. Auditors will need to verify that *effectiveness* requirements are being met.

The term **system** is used frequently as in management system or system audit. A system is a collection of processes. There are some alternate definitions in the glossary to provide more background, but for conformity audits, only the ISO 9000 definitions apply. A **quality management system normally includes quality control, assurance, planning and improvement processes**. It is important to know how **quality control** and **quality assurance** are related. The concept of **quality planning** and issuing **quality plans** should be well understood.

The term for senior management, executives or high level management is **top management**. Top management is universally acceptable worldwide.

Notable Terms Related to Documentation

A **document** is information (meaningful data) and it's supporting medium (paper, electronic, film, and so on). A document can be a **record**, specification, procedure, drawing, report or a standard. Set or collection of records or specifications can be called *documentation.* A procedure is a particular type of document that states a way to carry out an activity or process (determines how it will be done). A record is another type of document that **states results** or evidence of **activities performed** (determines what was done).

Overall, the information required to control and maintain the **organization** is called **documented information**. The use of the term *documented information* provides move flexibility in our modern era instead of the use of terms such as *documented procedures* or creation of *manuals*.

Notable terms to apply

a. Review

According to the dictionary, *reviewing* is an act of inspecting or examining. Reviewing is looking over or examining with the intent to amend or improve. However, from the ISO 9001 view, **review** includes **determining suitability, adequacy, or effectiveness** of the **object** (entity or item) to achieve established objectives. For a certified management system (MS) that uses the ISO 9000 vocabulary, review is much more than studying material again. When auditing the requirement to *review*, an auditor may ask how suitability, adequacy or effectiveness was determined.

b. Verification and validation

Standards require verification of products and activities to ensure control. It is part of the PDCA model. For example: The ISO 9001 uses the words verification and validation many times. Most **verifications** and **validations** are integrated into design, manufacturing or service delivery processes and are performed by operators, inspectors, technicians, engineers or those performing the service. Verification methods include inspection, independent or alternate calculations, independent test services, simulations, modeling, prototype testing and **product/service audit**.

Validation methods include testing the functionality of the product and/or delivery of the service for its intended use. Once validated, users can be **confident that the product or service will perform as expected or promised.**

For some products, **validation is the next logical step after verification** such as checking pump specifications and then turning it on to validate the rated capacity. In other cases, **product quality is easily verified,** but because of the nature of its use, such as the lunar vehicle used on the Moon, validation is challenging. In other cases, **product quality can only be validated** through destructive testing such as performance of liquid absorbents. Cost versus risk are important factors for determining verifying and validating methods. Outsourcing and globalization of businesses have made verification and validation important tactical methods to assure product quality and safety before use by the customer.

Auditors can verify processes and products/services. Verification audits may verify and validate: inspection methods, delivery of services, compliance with contracts, critical product or service characteristics, or process/product performance.

c. Risk

The word risk is used in the standard and there is a specific clause about actions to address risk. The idea of **implementing controls such as QMS controls, is to mitigate risk** of undesirable outcomes. Therefore, it is in our best interest to better understand risk. **Risk** is normally **quantified relative to negative consequences or outcomes** such as the possibility of loss, injury, disadvantage, or destruction and the degree of probability or amount of such loss, injury, disadvantage, or destruction. The ISO Guide 73 (Risk management Vocabulary) describes **risk as the combination of the probability of an event and its consequence.**

Inherently, there is risk associated with all products/services and processes. It is a matter of quantifying (estimating) the risk and determining what amount of risk that is acceptable for you or your organization (so call it risk appetite). Just like there is variability in all processes, it is a matter of quantifying the variability and determining what amount is acceptable. **If the risk is unacceptable, action must be taken** remove it, avoid it, or mitigate (minimize) it.

d. Opportunity

The standard includes requirements for the organization to determine opportunities that need to be addressed. There has been some confusion regarding what is meant by opportunities. The vocabulary standard (ISO 9000) is silent regarding opportunities which means it is generally believed the dictionary definition is acceptable and no technical definition is needed. The dictionary definition of **opportunity** uses descriptive words such as "**combination of circumstances... favorable** for a particular activity" and "**advantageous circumstances**" and "condition **favoring advancement** or progress." Also, there is a note in ISO 9001 clause 6.1.2 that provides some guidance (see sidebar).

Sidebar: NOTE 2 Opportunities can lead to the adoption of **new** practices, launching **new** products, opening **new** markets, addressing **new** clients, building partnerships, using **new** technology and other desirable and viable possibilities to address the organization’s or its customers’ needs.

It is clear that an opportunity is not business as usual. It is something special and does not happen every day.

Comments Studying word definitions (lexicology) can be very insightful. The definitions contained in the standard are somewhat technical but will prove useful during an audit. Knowing the words will result in a sharper focus and **better understanding when determining conformance to requirements**. Using the correct words will **improve communications** between you and the organization representatives.

Sector specific terms are normally included in clause 3 of a requirements standard. Clause 3 word definitions will be discussed in order as we discuss each clause in a step-by-step fashion.

Analysis of the Requirements for ISO 9001 Standard Clauses 0.0-3.0

[This lesson is medium length and discusses the introduction clauses of the standard, and has a test at the end that you must pass to continue.]

Learning Objectives: Upon completion of this training, managers and auditors will be able to:

- determine the intent and requirements for each element
- apply knowledge to audit for conformity to requirements
- explain the benefits to users
- list the management system principles
- paraphrase the key concepts of the process approach, risk-based thinking and the **Plan-Do-Check-Act (PDCA) cycle**

The next series of lessons and activities are very important for understanding the intent of the requirements and for successful completion of this class. The material in the following lessons is paraphrased for instructional purposes. Only the actual language of the standard is the language that is to be used in a conformance audit. **The ISO 9001:2015 (ASQ/ANSI/ISO 9001:2015 Quality management systems - Requirements)** standard is the **source document** and should be referenced regarding the need for interpretation of requirements. During the class, you may want to follow along the discussion with your copy of the standard, or our technically-correct and downloadable **checklist**, both provided as part of this class (note that the checklist starts with clause 4, the requirements). Our checklist marks requirements that were new to the 2015 version. You may open your standard and turn to the introduction to start this lesson.

0.0 Introduction

0.1 General

Discussion: This is the big-picture clause. It does not contain any auditable requirements but there is valuable information that will affect the quality management system (QMS).

Adoption of ISO 9001 standard should be a **strategic decision of the organization**. The word strategic is used to represent the fact that top management will need to be involved in its implementation and on-going application.

The design and implementation of the organization's QMS is influenced by:

Needs
Objectives
Products provided
Processes employed
Size and structure of the organization
Business environment, risks, and changes

The standard is intended to be **used internally and/or by organizations external** to the user organization such as an auditing organization (certification organization or customer). External organizations can use the standard to assess the user organization's ability to meet customer, statutory, and regulatory requirements.

Potential benefits of implementing this standard include:

- the ability of an organization **to consistently provide products and services that meet** customer and applicable statutory and regulatory **requirements**
- facilitating opportunities to **enhance customer satisfaction**
- identification of organization **risks and opportunities** needing to be addressed (new)
- the ability of the organization to **demonstrate conformity** to specified QMS requirements by QMS certification or by other means

The standard is **not intended**:

- to require organizations to **align their documentation to the clause structure** of this international standard
- to require organizations to **use the specific terminology** of this international standard such as "documented information" to replace "documents" and "records" or "control of externally-provided process", "products and services" to replace the "purchasing department" title.
- to establish absolute requirements for quality performance
- to require or guarantee optimal quality outcomes

This version of the 9001 standard has a high level structure that is common with other management system standards such as ISO 14001, the environmental management system standard. Management system standards designed around the same clause structure will make integrating with other management standards easier and possibly provide more stability and fewer clause numbering changes in the future.

Auditors should not force management systems standards lingo on auditee organizations. For example: "Documented information" to replace "documents and records" or "control of external providers" to replace "purchasing."

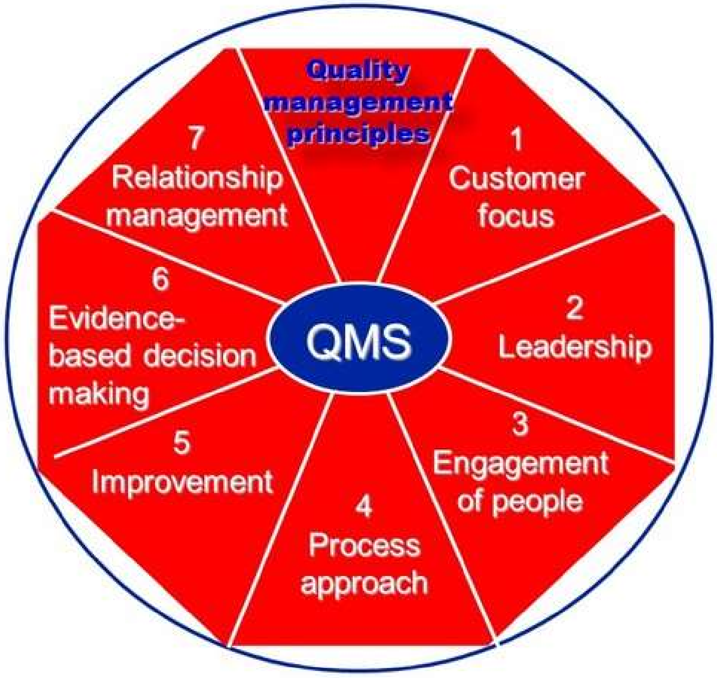
The standard content and design incorporates the following:

- the **process approach** embodying **PDCA cycle**
- use of **risk-based thinking** to determine the factors possibly causing its processes and its QMS to **deviate from planned results (objectives)**
- the concept that organizations should improve
- use of the word “shall” indicating a requirement

ISO 9001 was originally designed to be a baseline standard for assurance of quality. Over the last decade, the controls have expanded to include more progressive techniques to assure customer requirements are met. These include: process approach, risk-based thinking, the PDCA cycle, and more flexible, open-ended requirements. This has caused complaints in some of the compliance sectors that favor more prescriptive verifiable controls.

0.2 Quality Management Principles

This International Standard to ISO 9001 is based on the quality management principles described in ISO 9000:2015. The quality management principles are very important, but **cannot be the reference for a nonconformity**. The principles are conceptual in nature and should be **implemented at the highest levels** in an organization and permeate the processes and operations as well.


Quality management principles
QMS
1 Customer focus
2 Leadership
3 Engagement of people
4 Process approach
5 Improvement
6 Evidence-based decision making
7 Relationship management

The quality management principles for a QMS are:

1. **Customer focus:** Organizations depend on their customers and, therefore, should understand current and future customer needs, meet customer requirements, and strive to exceed customer expectations.
2. **Leadership:** Leaders establish unity of purpose and direction for the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
3. **Engagement of people:** People at all levels are the essence of an organization and their full engagement enables their abilities to be used for the organization's benefit.
4. **Process approach:** A desired result is achieved more efficiently when related resources and activities are managed as a process. The collection of processes form a system to be managed using management system standards.
5. **Improvement:** Improvement should be a permanent objective of the organization.
6. **Evidence-based decision making:** Effective decisions are based on analysis data and information.
7. **Relationship management:** An organization and its suppliers, and other interested parties, are interdependent and, a mutually beneficial relationship enhances the ability of all to create value.

The **ISO 9001 standard embodies the quality management principles**.
Quality management principles may be incorporated into an organization's vision or policy.

0.3 Process approach

0.3.1 General

The standard is based upon the use of the process approach. The standard promotes the adoption of a **process approach** when developing, implementing and improving the QMS.

The *process approach* embodies the following four principles;

- To function effectively, an organization must **identify and manage numerous linked activities.**
- A **process** is an activity (using resources, inputs) that is **managed to deliver intended results (outputs).** For example: transforming inputs into outputs.
- Outputs from one process often **provide inputs to the next process.**
- Multiple processes create a **system of processes.**

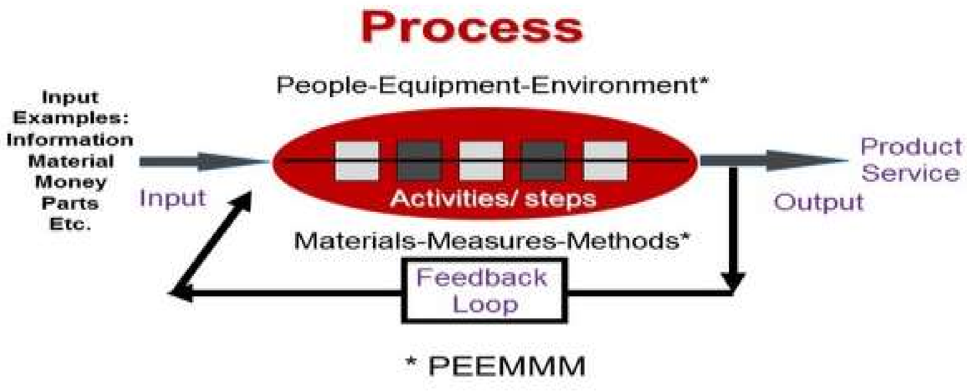
The aim **of the process approach is to enhance customer satisfaction** by meeting customer requirements.

The systematic identification and management of processes employed and their interactions are referred to as the *process approach*. The process approach strings activities together resulting in a desired outcome such as a product or service.

Simply, an organization`s management system is **more effective** if structured using the process approach as opposed to an element or departmental approach. A process represents action. The processes are normally collected under a **system** (clause 4) or subsystems to a bigger system.

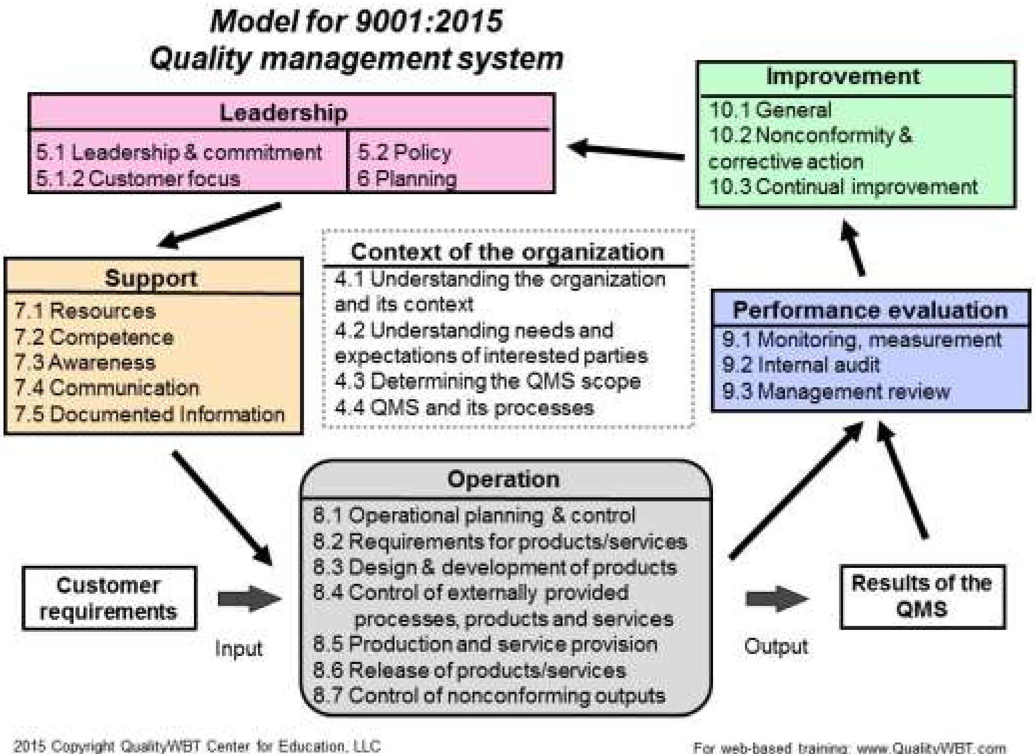
Management of the processes and the system as a whole can be achieved using the PDCA cycle with an overall focus on **risk-based thinking** aimed at taking advantage of **opportunities** and **preventing undesirable** results.

The figure below gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring feedback loop, which are necessary for control, are specific to each process and will vary depending on the related risks.


Process
People-Equipment-Environment*
Input Examples: Information Material Money Parts Etc.
Input
Activities/ steps
Product
Service
Output
Materials-Measures-Methods*
Feedback Loop
* PEEMMM

The standard “promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system” (clause 0.3.1). This means that the very architecture of a QMS should be constructed around the key business processes of the organization and not the requirements of ISO 9001. When creating a system, begin by determining key processes (through flowcharts, **SIPOC diagrams** or other means) and then create appropriate management controls based on the requirements of the ISO 9001, customers, regulators, and risk-based thinking. **Only by considering key business processes and the objectives for their outputs can a QMS fulfill its promise of true quality management.**

0.3.2 Plan-Do-Check-Act Cycle As a model, it could resemble the figure below showing the QMS processes.


Model for 9001:2015
Quality management system
Leadership
5.1 Leadership & commitment
5.1.2 Customer focus
5.2 Policy
6 Planning
Improvement
10.1 General
10.2 Nonconformity & corrective action
10.3 Continual improvement
Support
7.1 Resources
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented Information
Context of the organization
4.1 Understanding the organization and its context
4.2 Understanding needs and expectations of interested parties
4.3 Determining the QMS scope
4.4 QMS and its processes
Performance evaluation
9.1 Monitoring, measurement
9.2 Internal audit
9.3 Management review
Operation
8.1 Operational planning & control
8.2 Requirements for products/services
8.3 Design & development of products
8.4 Control of externally provided processes, products and services
8.5 Production and service provision
8.6 Release of products/services
8.7 Control of nonconforming outputs
Customer requirements
Input
Output
Results of the QMS

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In the model, context of the organization relates to overall system actions, planning would relate to leadership and support, doing is in operations, checking takes place under performance evaluation, and finally, acting on the evaluation results would be where improvement takes place.

The QMS **requirements start in clause 4** and continue to the end of the standard (clause 10).

0.3.3 Risk-based thinking The **concept of risk-based thinking has been implied in previous editions** of this international standard including, for example: 1) carrying out preventive action to eliminate potential nonconformities; and 2) analyzing occurring nonconformities and taking action to prevent recurrence. Also, consider the age-old requirement in the management review clause that the organization assess “the suitability and effectiveness” of their QMS. Does management know that their system is suitable and effective simply because it meets the requirements of ISO 9001? That may be one measurement, but “suitability and effectiveness” means much more. It means how well the system identifies and manages risks to product and service quality and customer satisfaction.

An organization needs to plan and implement actions to address risks and opportunities (clause 6.1). Addressing both **risks** and **opportunities** establishes a basis for increasing the effectiveness of the QMS, achieving improved results, and avoiding negative effects.

Risk-based thinking is the key to creating a suitable and effective QMS where there is an absence of ISO 9001 requirements. For example, ISO 9001 might require that organizations implement suitable product inspections at appropriate points during manufacturing. What does that mean? How does an organization do that properly? Only by understanding what risks exist in processes (manufacturing or service) can an organization implement appropriate controls. Risk-based thinking helps us decide where controls are needed and how simple or sophisticated those controls need to be.

Opportunities can arise as a result of a situation favorable to achieving an intended result. For example: a set of circumstances allowing the organization to attract new customers, develop new products and services, reduce waste, or improve productivity. An opportunity is not the opposite of risk. Perhaps it is like the difference between being able to stay on the plotted course versus finding a shortcut to your destination.

0.4 Relationship with other management system standards

This International Standard applies the framework developed by ISO to **improve alignment among its International Standards for management systems** (see clause A.1). A document titled Annex SL outlines a high level structure (framework) and common text to be used in all management system standards.

Annex B provides details of International Standards on quality management and QMSs developed by ISO/TC 176.

A matrix showing the correlation between the clauses of this edition of this international standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: **www.iso.org/tc176** or as a handout below.

a. Industry sector derivative standards

The **relationship between ISO 9001 and sector-specific derivative standards has not changed.** Some industry sectors have reaffirmed their requirements (no changes) and others have made significant changes.

Users of specific sector derivative standards should contact the organization that is responsible for that sector for their status. For example, for:

- IAFT 16949 refer to the IATF
- TL 9000 refer to the QuEST Forum
- AS 9000/ EN 9100 refer to the IAQG

b. ISO 9004: *Managing for the sustained success of an organization - A quality management approach*

The ISO 9001 and ISO 9004 standards have been designed to complement each other, but can also be used independently.

ISO 9001 specifies requirements for a QMS that can be used for internal application, for certification, or for contractual purposes. It **focuses on the effectiveness of the QMS** in meeting customer requirements.

ISO 9004 goes beyond the ISO 9001 requirements standard and gives guidance on improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to pursue more advanced methods and techniques for improvement of performance. It is not a guideline for implementing ISO 9001 and is not intended for certification or contractual use.

1 Scope

An organization would use the ISO 9001 standard when it wants to demonstrate conformity to a formal QMS, aim to enhance customer satisfaction, and/or assure conformity to customer and applicable statutory and regulatory requirements.

All the requirements of the standard are generic and are intended to be applicable to any organization regardless of its type or size or the products and services it provides.

An important note is the terms “product” or “service” only apply to products and services intended for, or required by, a **customer**. This information may be helpful in discussions regarding disposables, recyclables, sludge, and secondary or spin-off products.

Question? Does this mean that internal, “back office” processes may not be subject to QMS controls because they are not provided to a customer? I’m not too clear on this.

2 Normative references

Normative references are indispensable for the implementation and application of the QMS standard. The only normative reference listed is the ISO 9000:2015, Quality management systems — Fundamentals and vocabulary standard.

It is recommended that all users of the ISO 9001:2015 purchase or have available the ISO 9000:2015 vocabulary standard.

3 Terms and definitions

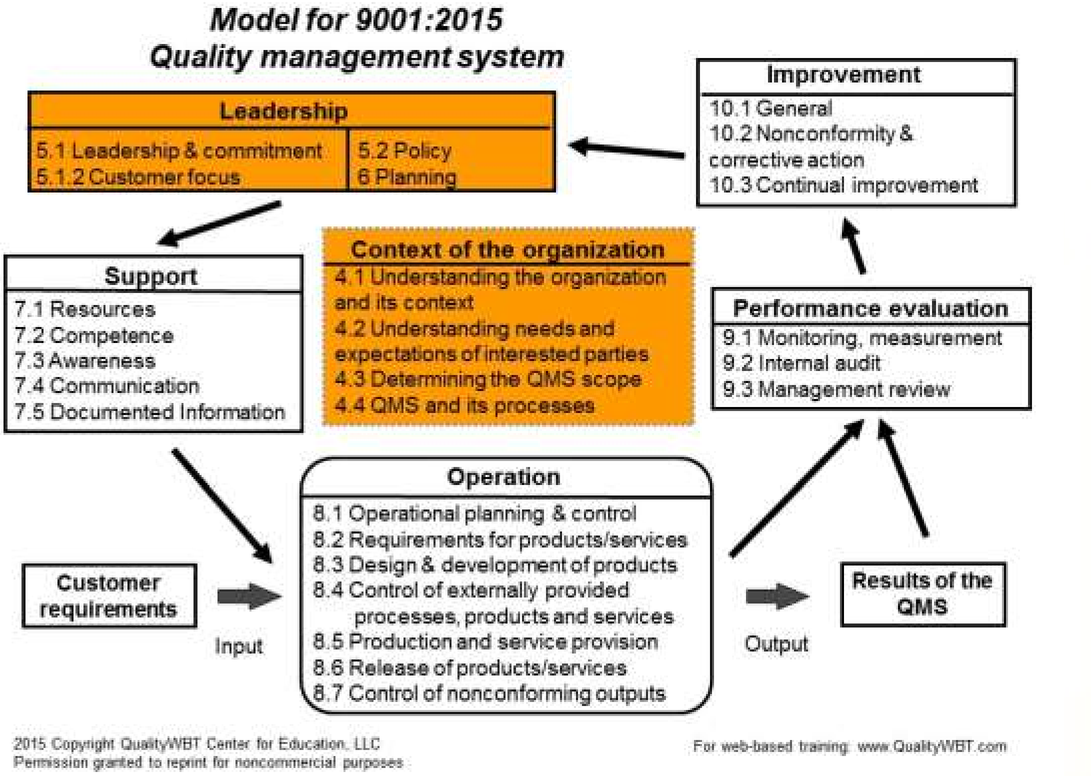
No new terms and definitions are listed in the standard. The design of this class includes hyperlinks to the definitions of words as needed to explain requirements of the quality management international standard. The ISO 9000 standard is not required for this class; however, it is recommended for users.

The next lesson discusses the actual requirements.

Analysis of the Requirements for ISO 9001 Clauses 4-6

Learning Objectives – Upon completion of this training, managers and auditors will be able to:

- determine the intent and requirements for each element
- apply knowledge to audit for conformity to requirements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Please note that we will be discussing clauses 4, 5 and 6, see orange blocks

Synopsis: Clauses 4, 5, and 6 represent the system requirements and planning/leadership aspects of the PDCA cycle. You may consider these areas as administrative. An auditor will **look for many of the system-leadership-planning requirements to be demonstrated** as part of the overall audit.

The review format for this class is to present the requirements and rationale supported by explanation, discussion, and examples. **Important phrases are shown in bold text**.

4 Context of the organization

4.1 Understanding the organization and its context

The standard states the organization must determine external and internal issues relevant to the organization's purpose and strategic direction and that affect its ability to achieve intended results.

The word “context” is used instead of “organizational environment” because it is intended to address both internal and external factors. Another common word for this is "profile."

The first requirement of the standard is to ask organizations to examine and understand the fundamentals of what business they are in, such as:

- the products/services they provide
- the customers for those products/services
- the competitive landscape
- the ability to raise capital and sell their products

What is the organization’s purpose? What business is it in? What market(s) will it pursue? For example:

- Is a mobile phone manufacturer in the business of building hardware or providing telecommunications services?
- Will that mobile phone maker market its phones to business people or teenagers?
- Are mobile telecommunications regulated by the government?

Only after the organization frames itself in terms of why it exists and what markets it serves can it properly design and implement a QMS suitable for its purpose.

Monitor and review information about these issues for consideration.

Issues can include positive and negative factors or conditions.

Consider issues arising from:

- legal, technological, competitive, market, cultural, social and economic factors at all levels
- company values, culture, knowledge, and performance

Organizations can list important issues that need monitoring. For an example, see the table below that shows important issues as well as who would do the monitoring and what kinds of information would be collected.

Monitoring important issues

Important issue	Who would monitor	What information could be monitored
Local pool of available workers	HR department	Local unemployment rate, graduating classes at local colleges and training centers
Local zoning and tax policies	Financial department	City government resolutions, annual budgets
Availability of technology	Engineering department	Trade publications, trade shows
Marketplace	Marketing department	Consumer Price Index, consumer buying trends, introduction of competing products
Worker skills, training	HR department	Retirements and succession planning, progression through job grades
Changes in regulations/codes	Risk and quality departments	External documents from regulators, sector news

4.1 Explanation and discussion

Stakeholders (**interested parties**) are those that influence the organization’s work. The organization is already in contact with these stakeholders such as those shown in the following:

Possible Stakeholders	
Regulators	Trade/professional associations
Government agencies	Property owners
Trade unions	Sponsors
Board of directors	Business partners
Investors	Banks and other lenders

This list of persons/organizations represents sources where the organization or an **auditor would expect to find external issues.** The reason for identifying stakeholders is to **provide an input into risk assessment (clause 6.1).**

Documentation, which will show that stakeholders have been considered, can be part of the risk assessment addressed in clause 6.1.

4.2 Understanding the needs and expectations of interested parties

Determine the interested parties relevant to the QMS and the requirements of those parties.

Monitor and review the information about these parties and their relevant requirements.

Consider the following examples:

- direct customers
- end users
- suppliers, distributors retailers or others involved in the supply chain
- regulators and others

Organizations must name interested parties and monitor them, but how many they need to monitor now needs to be discussed.

4.2 Explanation and discussion

Organizations and stakeholders have a **relationship that includes needs and expectations** of each other.

- A board of directors expects the company to make a profit.
- A regulator expects compliance with regulations.
- An organization may expect its trade association to lobby on its behalf.
- An organization expects its suppliers to deliver a quality product on time.
- Engineers are expected to use design standards.
- An organization could also voluntarily subscribe to policies of social responsibility, codes of ethics, and policies that prevent bribery or the appearance of bribery or that promote employee welfare.
- The **number of stakeholders reflects the complexity of the business/organization**. The output of this process is an input to the risk assessment (clause 6.1) and is documented there.
- **The key is to understand relevant** requirements for product/service quality and customer satisfaction. Although ISO 9001 requires that an organization understand the needs and expectations of **relevant interested parties**, organizations are not required to be bound by these expectations. An environmental group might be interested in the conduct of an oil company, but an oil company is not required to meet the needs of that particular interested party.

4.3 Determining the scope of the quality management system

The requirements are more descriptive (open-ended) versus prescriptive (close-ended). Note, *italic* text is not in the standard.

When determining this scope, **the organization must consider:**
a) the external and internal issues referred to in 4.1 *(strengths, weaknesses, opportunities and threats)*
b) the requirements of relevant interested parties referred to in 4.2 *(relationships: employees, unions, board of directors, customers, suppliers, shareholders, media, local community, government officials, financial organizations, special interest groups and so on)*
c) the products and services of the organization *(products: manufacturing, storage, safeguarding, delivery, maintenance, warranty, disposal, replacement; service: performance or delivery, products used, repeated service, qualification-certification and so on.)*

There is no requirement for a record or retained **documented information (DI)**. As an auditor, you may seek documentation that a, b and c were considered or interview a person who is responsible for review and approval of the scope and then ask about a, b and c. There is no “if appropriate” qualification for this requirement. This means an organization cannot select which are appropriate, and it **must consider each of those three requirements when determining the scope**. If it makes more sense to you, use the word “factors.” As in the picture, the organization must establish boundaries.

No quality manual is required. However, **the scope must be maintained as DI.** The scope must include justification for **requirements that cannot be applied and/or are determined to be not applicable.** All requirements are assumed to be applicable to an organization’s QMS unless identified as not applicable. Note that the standard refers to individual requirements, and not to entire clauses that may or may not be applicable. Therefore, any particular requirement within a clause might not be applicable.

Conformity to ISO 9001:2015 **may** be claimed only if the requirements determined as not being applicable do not affect the organization’s ability or responsibility to ensure the conformity of its products/services and enhancement of customer satisfaction. You should note this is ISO 9001 **guidance using the word "may"** instead of shall.

Sidebar: Code “Maintained DI” is the code for a document that must be under document control. Also, “retained DI” is the code for keeping a record.

4.4 Quality management system and its processes

4.4.1 no title

ISO 9001:2015 puts major emphasis on processes. Auditors need a strong grasp of the dynamics and a fundamental understanding of what constitutes a **process**.

The organization must determine the **processes needed** (such as: ordering, designing, providing, reviewing) for the QMS and their application throughout the organization. **The organization must do the following:**

a) determine **the inputs required and the outputs** expected from these processes

b) determine the **sequence and interaction** (how processes are connected) of these processes

c) determine and **apply the criteria and methods** (including monitoring, measurements and related performance indicators) needed to ensure the **effective operation and control** of these processes

d) determine the **resources** needed for these processes and ensure their availability

e) **assign the responsibilities and authorities for these processes**

f) **address the risks and opportunities** as determined in accordance with the requirements of 6.1

g) evaluate these processes and **implement any changes** needed to ensure that these processes achieve their intended results

h) **improve** the processes and the QMS

The requirement to assign responsibilities and authorities for each process shows accountability and is an auditable requirement. The organization needs performance indicators such as **metrics** to measure and monitor performance.

Verify the interaction of processes was determined in some manner. Many of the requirements in this clause will be verified during the audit.

Sidebar: Process list This is a great a-h list to keep with you when each process is implemented, evaluated or audited.

4.4.2 no title

To the extent necessary the organization must maintain DI (controlled documents such as procedures) **to support operations and its processes.**

> Note: Prior versions of the standard used the phrase to "control operations" instead of "support operations." Support has a broader meaning.

To the extent necessary the organization must retain DI (records) **to have confidence that the processes are being carried out as planned.**

This is the catch-all clause for auditors to cite if an organization does not have sufficient documents (plans) to control a process or necessary records or data to verify outputs.

ISO 9001 allows documented information to be in any medium or format. This includes paper, electronic documents and records on computer servers, or hypertext.

No specific procedures, or plans are required by the standard.

Sidebar: Support versus control comment
Standards establish rules (controls) to lower risk to assure outputs. Organizations must maintain DI that controls operations and its processes as well as support them.

Sidebar: Maintained versus retained
There is no requirement for an organization to change its terminology from "documents and records" to DI. In fact, international organizations, governments and legal systems understand what it means to have a record but would not understand what retained DI means.

5 Leadership

There is an emphasis on leadership in the standard. The requirements are high level and are somewhat conceptual. Many of the leadership requirements can only be verified as part of an audit going from by area to area.

5.1.1 General

The standard states that **top management** must **demonstrate their leadership** and commitment with respect to the QMS by doing the following:

a) taking **accountability for the effectiveness** of the QMS
b) ensuring that the **quality policy and quality objectives** are established for the QMS and **are compatible with the strategic direction and the context** of the organization
c) ensuring the integration of the QMS requirements into the organization’s business processes

(Note that reference to “business” can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence, whether the organization is public, private, for profit or not-for-profit.)

d) promoting the use of the process approach and risk-based thinking
e) **ensuring that the resources** needed for the QMS are available
f) **communicating** the importance of effective quality management and of conforming to the QMS requirements
g) ensuring that the QMS **achieves its intended results**
h) engaging, directing and supporting persons to contribute to the effectiveness of the QMS
i) promoting **improvement**
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

There must be evidence for applying a-j in the above list that top management has demonstrated leadership. According to *Revised Bloom’s Taxonomy*, the word “demonstrate” is linked to applying and actions such as implementing, carrying out, using, and executing. This is a higher level than being able to understand or remember by identifying, explaining, describing or listing.

Some of the **key issues** are that b) the QMS be compatible with the organization’s **strategic direction** and c) **QMS requirements** are to be integrated into the business processes. This supports the process approach using elements/clauses of the standard. The organization needs to be able to communicate its intended results. Perhaps it has key performance indices or other measurements (**metrics**) to assess achievement of objectives.

Top management may **communicate the importance of an effective QMS and conforming to requirements** by may distribute memos, intra organization news, make presentations, conduct one-on-one talks, etc. to get out the message.

Top management must **support other relevant management roles.** This part of the clause (j) is a broad, open-ended requirement. If top management is demonstrating leadership, how is it supporting others in management to also demonstrate leadership? This requirement may **relate to the culture of the organization.** Is the culture that the QMS and quality are a management priority? One approach is to verify other managers are conforming to these same clause requirements (a-j) during auditee interviews.

Sidebar: One-dimensional QMS
An auditor may observe, for example, that corrective actions are constantly delayed. This may mean that quality and the QMS are not a priority for top management.

5.1.2 Customer focus

The standard states that top management must **demonstrate leadership and commitment with respect to customer focus** by ensuring:

a) customer **requirements** and applicable statutory and regulatory requirements are determined, **understood and consistently met**

b) the **risks and opportunities** that can affect conformity of products and services and the ability to enhance customer satisfaction are **determined and addressed**

c) the focus on **enhancing customer satisfaction is maintained**

Here again, top management must demonstrate leadership. Besides customer requirements being determined and met, they also must be understood and consistently met. As auditors go from process to process they should determine if requirements are properly deployed throughout the processes of the organization and understood and met by everyone working in those processes.

The risk and opportunities thread is included in this clause.

Sidebar: Quality for the customer is getting what you were expecting. Quality for the supplier is getting it right the first time. (taken from the **Quality Master Plan**)

5.2 Policy

5.2.1 Developing the quality policy

Clause 5.2.1 states that top management will ensure there is a quality policy. The requirement standard states that the policy shall:
a) **be appropriate for the organization** purpose, context and strategic direction.
b) **provide a framework for setting quality objectives**
c) **include** a commitment to satisfy requirements
d) **include** a commitment to **continual improvement** of the QMS

As an auditor, **verify the policy includes** a commitment to satisfy requirements and continual improvement.

However, there is no specific guidance for how it should be worded or structured.

Sidebar: Audit evidence If the wording of the policy is such that it is irrelevant, un-checkable, or that when audited the evidence showed that it has not been effectively implemented or maintained, then there will be a nonconformity against the requirements of clause 5.2.1.

5.2.2 Communicating the quality policy

The quality policy must be **available to relevant interested parties, as appropriate.** In the past, the quality policy had to be communicated and available to all employees within the organization. Now, the requirement has been extended for the policy to be available to stakeholders outside the organization. The policy is also required to be communicated, understood, and applied within the organization.

This requirement is open-ended. An auditor may ask:

- Who has access to the quality policy?
- Is the quality policy available to interested parties? Which ones? How do you determine which are relevant?
- When is it appropriate to make the quality policy available to interested parties?

There is no requirement for a procedure or planned arrangements. However, since the quality policy is required to be **maintained as DI**, a person may be assigned responsibility for the policy and its distribution. There may be a checklist or policy for determining the distribution of the quality policy to **relevant interested parties**. One way to make sure that the policy is available to external stakeholders is to post it on your organization’s website.

5.3 Organizational roles, responsibilities and authorities

In the past, many organizations have used the title of *management representative* for the person in charge of the QMS. As an auditor, you may still see organizations that assign a management representative to manage the QMS. The standard does not require persons assigned QMS responsibilities to be a member of the organization’s management. Yes, there may be people responsible for elements of the QMS who are not a part of the organization’s management. An example might be a senior quality technician who is responsible for the calibration process. Top management shall ensure that **QMS responsibilities and authorities for relevant roles are assigned, communicated and understood** within the organization.

If no one is taking overall ownership of the QMS, management of the QMS could be disjointed and disorganized. This could relate to ineffective leadership. The site leader may become the de facto management representative.

Top management must **assign the responsibility and authority to:**
a) ensure the QMS conforms to the ISO 9001:2015 requirements
b) ensure the processes are delivering their intended outputs
c) **reporting** on the **performance** of the QMS and on **opportunities for improvement**, in particular to top management
d) ensuring the **promotion of customer focus** throughout the organization
e) ensuring that the **integrity of the quality management system** is maintained when changes to the quality management system are planned and implemented

The clause is linked to the process output results. Another thread promoted throughout the standard is on results and metrics to measure results.

Clauses 5.2 and 5.3 include 2 of the 5 citations in the standard to **communicate**. Auditors and managers need to **ensure roles are assigned, communicated and understood within the organization** (see clause 7.4 for communication process).

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 no title

When planning the QMS, the organization **must consider the issues identified** in clauses 4.1 and 4.2 and determine the **risks** and **opportunities** that need to be addressed regarding:

a) assuring that the **QMS can achieve its intended result**(s) 4.4.1
b) enhancing **desirable effects**
c) preventing or **reducing undesirable effects**
d) achieving improvement

The organization needs to determine or identify risks and opportunities, assess their significance and take appropriate action relative to their importance (6.1.2). An **auditor may be asked to identify risks** as part of their normal duties.

Also understand, however, that per the requirements of clause 4.4.1, risks must be addressed within business processes. There is no requirement to have a formal risk management program such as described in the ISO 31000 Risk management system standard.

6.1.2 The organization shall plan

The organization must plan actions to address risks and opportunities.

Organizations can **accept, avoid or take action to mitigate (diminish) the risk**. Mitigating the risk can include: eliminating the risk source, changing the likelihood or consequences, transferring the risk, or sharing the risk.

Opportunities can lead to improving effectiveness or efficiency, launching new products or services, opening new markets, adding new clients/customers, and building partnerships that add value, and so on.

A plan needs to be available in some form or media. It is also important to realize **opportunity** is not the opposite of **risk**.

The organization's **plan must include how to integrate actions into its QMS** processes and implement them (see 4.4).

The organization's **plan must include how to evaluate the effectiveness** of these actions.

Planning is about **anticipating positive and negative scenarios and putting appropriate controls in place**. Planning establishes the steps/actions necessary, resource needs and controls to address process/organization risks and opportunities. The organization can evaluate the effectiveness of actions taken through monitoring, measurement, internal audit, and management review.

There is no requirement for formal risk assessment (covered in ISO 31000 and others), but subjective risk-based thinking should be a part of all decision making. It is beneficial to use a team for risk assessment.

The **actions taken to address risks and opportunities must be proportionate to the potential impact** on the conformity of products and services.

Many organizations already use some kind of matrix that ranks risks or use the failure modes and effects analysis (FMEA) approach to assess the level of risk. Actions to address risk can include:

Avoid the risk

- Stopping the practice, process or activity. An example might be to not quote a job that contains unfamiliar requirements or no longer offer the product or service.

Accept the risk

- Accepting a risk to pursue an opportunity (For example, engaging a foreign partner may be necessary to secure a new customer or market.)
- Accepting the risk by informed decision or agreement. As a result of the risk assessment, it could be determined that the risks are not significant enough or will not occur with sufficiently high frequency to be worth mitigating. Product inspection and testing is an example of choosing to accept the inherent risks in a manufacturing process.

Mitigate/treat the risk

- Eliminating the risk source – Find the cause of risk and eliminate it. Error proofing is a good example.
- Changing the likelihood – It may be that more mistakes are made if the service transactions or machine speeds are too fast. Slowing things down might be a way to reduce the number of defects.
- Changing the consequences – Qualifying several suppliers for same raw materials can reduce the risk of shortages and other purchasing issues.
- Sharing the risk – Purchasing insurance is an example of having another party taking on some of your risk. Outsourcing product manufacturing or service delivery can also be a strategy for sharing risk.

6.2 Quality objectives and planning to achieve them

6.2.1 no title

The organization must establish quality **objectives at relevant functions, levels and processes** needed for the QMS. This requirement is just a good business practice. Auditors should ask about objectives as they conduct their interviews with managers and supervisors. Use the following list to verify conformance.

The standard states the quality **objectives must be**:

a) consistent with the quality policy (what is the policy?)
b) measurable (how is the objective measured?)
c) able to take into account applicable requirements (does it relate to requirements, which ones?)
d) relevant to conformity of products and services and to enhance customer satisfaction (does it improve conformity of the product or service and enhance customer satisfaction? how?)
e) monitored (how is it monitored? frequency?)

f) communicated (who, what and when are objectives communicated?)
g) updated as appropriate (have objectives been modified/change? how?)

In particular, the auditee should be able to **explain how the objectives relate to conformity of products and/or services and how they relate to enhancing customer satisfaction**. A nonconformity here would help the organization stay focused on the QMS and not let objectives drift into other areas of importance at the expense of quality. To address the requirement to monitor the objectives, it would be best if organizations understand how to establish good metrics to achieve desired results.

The organization must **maintain DI on the quality objectives.**

The standard requires objectives to be documented. This means the publication of the objectives must be under document control. The **organization may determine the level of control but certainly they must be retrievable and current.** Auditors and managers should to refer to clause 7.5 for DI requirements.

Sidebar: Appendix A1 of ISO 9001:2015 Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures" and "quality manual" or "quality plan," the 2015 revision of this international standard defines requirements to "maintain documented information."

Sidebar: SMART Goals A good practice is for goals to be SMART Goals, that is, Specific, Measurable, Accountable, Realistic, Time bound. Goals may be:
S – Specific (Let's reduce scrap on one specific production line.)
M – Measurable (We would like to reduce that scrap by 10%.)
A – Accountable (Define who is responsible to achieve this scrap reduction.)
R – Realistic (A 10% scrap reduction is realistic, but 90% might not be.)
T – Time bound (We would like to achieve this goal by December 31st.)

6.2.2 no title

The standard states that **when planning how to achieve its quality objectives** the organization **must determine:**

a) **what will be done**
b) **what resources** will be required
c) **who** will be responsible
d) **when** it will be completed
e) **how the results will be evaluated**

The requirements here (a to e) are similar to any project plan. This makes sense.

6.3 Planning of changes

Where the organization determines the need for change to the QMS (see clause 4.4), the change must be **carried out in a planned and systematic manner.**

The organization **must consider**:

a) the **purpose** of the changes and their **potential consequences**
b) the **integrity of the QMS**
c) the availability of **resources**
d) the allocation or reallocation of **responsibilities** and authorities

Plan what you do and do what you plan. This is just good business. The organization will need to provide evidence to demonstrate it is meeting this requirement.

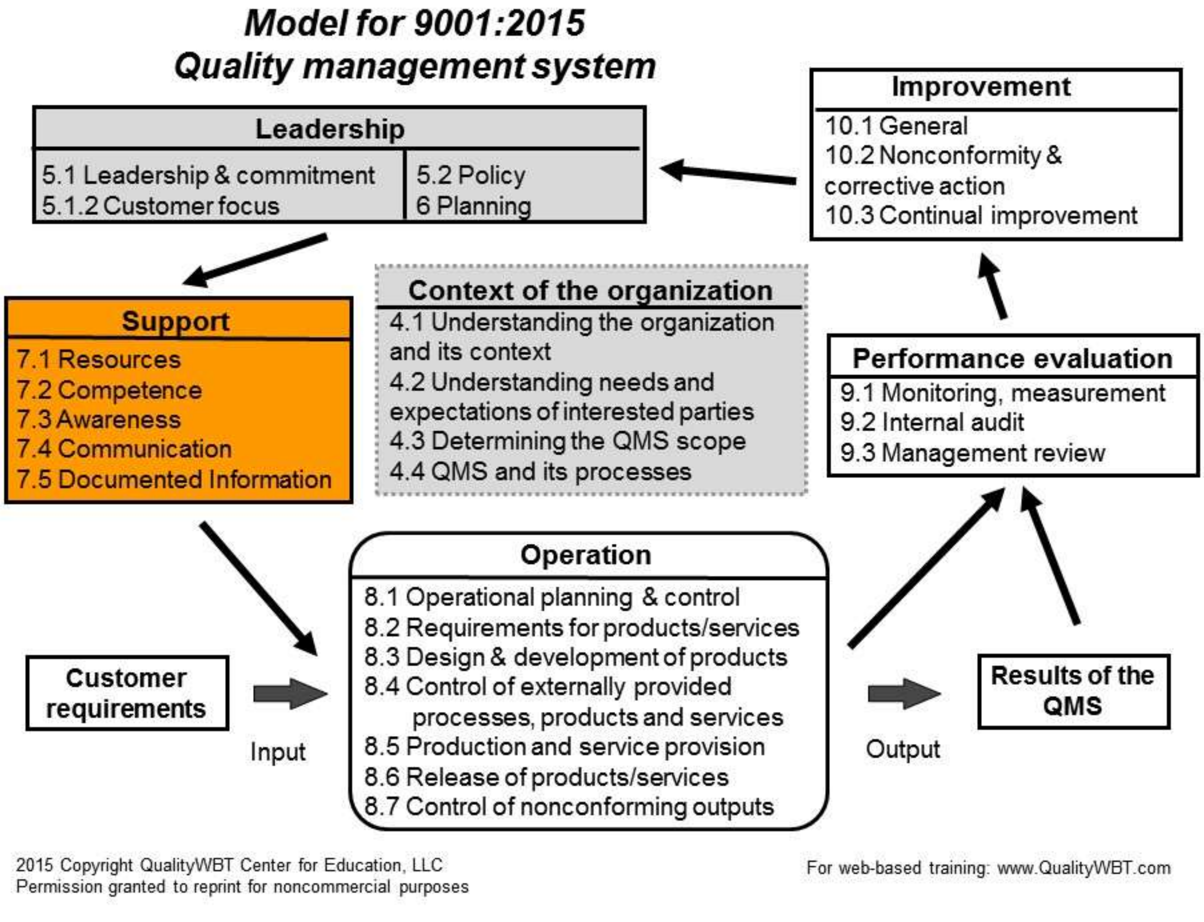
Analysis of the Requirements for ISO 9001 Clause 7

[This lesson is medium-length and discusses the QMS support requirements. A test you must pass to continue is at the end.]

Learning Objectives:

Upon completion of this training, managers and auditors will be able to:

- determine the intent and requirements for each element
- apply knowledge to audit for conformity to requirements



Model for 9001:2015
Quality management system
Leadership
5.1 Leadership & commitment
5.1.2 Customer focus
5.2 Policy
6 Planning
Improvement
10.1 General
10.2 Nonconformity & corrective action
10.3 Continual improvement
Support
7.1 Resources
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented Information
Context of the organization
4.1 Understanding the organization and its context
4.2 Understanding needs and expectations of interested parties
4.3 Determining the QMS scope
4.4 QMS and its processes
Performance evaluation
9.1 Monitoring, measurement
9.2 Internal audit
9.3 Management review
Operation
8.1 Operational planning & control
8.2 Requirements for products/services
8.3 Design & development of products
8.4 Control of externally provided processes, products and services
8.5 Production and service provision
8.6 Release of products/services
8.7 Control of nonconforming outputs
Customer requirements
Input
Output
Results of the QMS

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Please note that we will be discussing clause 7, see orange block.

Synopsis:

Clause 7 contains the system support requirements. Many of the requirements are open-ended. There is a new clause 7.1.6, Organizational knowledge, and clause 7.4, Communication, has significant changes compared to ISO 9001:2008. Clause 7.5, Documented information (DI), combines document and record control requirements.

The review format for this class is to present the requirements and rationale supported by explanation, discussion and examples. New requirements and important phrases are in bold type.

7 Support

7.1 Resources

7.1.1 General

The organization must determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS. When determining the resources needed, the organization must consider to following:

a) the **capabilities of and constraints on existing internal resources**

b) what needs to be **obtained from external providers**

> **Based on economics, strengths, weaknesses, opportunities and risks,** you must make choices when considering the resources you will need for a project, process or new venture.
>
> The requirements make sense. **First, an organization must fully utilize its internal resources to avoid unnecessary costs and/or clearly identify where additional resources may be needed to support existing competencies and constraints.** An organization may choose to add employees and facilities or hire or rent external resources. The decision will be based on the nature of the need such as whether it is short or long-term, the risks associated with outsourcing or remaining in-house, the level of internal knowledge/competencies and so forth.
>
> There is no requirement for a plan or a record or any kind of DI. An **auditor may ask the auditee how the organization goes about considering the resource needs and then review any available documentation.** For an auditor, a place to start is when a change has occurred or a new project requiring resources is undertaken. An organization may have some kind of checklist or flowchart and minutes from meetings to verify if a and b from clause 7.1.1 were considered. Without some kind of documentation, evidence from interviews will need to be corroborated.

Clause 7.1.1 b requires that a review of resources be undertaken to determine if additional outsourced resources are required. There is a relationship with clause 8.4, Control of externally provided processes, products and services, whereby those resources are then managed. **The intent of clause 7.1.1 b is at a higher decision-making level than clause 8.4, Control of external providers.** Does the organization need to purchase certain services instead of doing it internally? Does the organization need certain components or parts to be supplied externally?

The resources relate to both QMS and operational needs. Resources may include:

- time
- capital
- information
- personnel
- facilities
- equipment
- materials
- energy and other utilities
- knowledge and/or skills

Under clause 7.1, Resources, we continue with people, infrastructure, environment, monitoring and measuring, and organizational knowledge resources.

7.1.2 People

The organization must determine and provide the persons necessary for the effective **implementation of its QMS** and for the **operation and control of its processes.**

This clause is a broad overall system requirement for the organization to determine (identify), and provide persons needed. The **organization must determine (identify) people (labor) needs** of areas affecting the QMS. For example, this could be done during the annual budgeting process.

If QMS controls are not being constantly applied due to lack of resources, auditors can issue a nonconformity citing this clause.

7.1.3 Infrastructure

There is an overall requirement to **determine, provide, and maintain an infrastructure** needed to operate its processes and to ensure conformity to product requirements. The infrastructure may include **workspace, equipment, software, information, and support services.** Workspace may be buildings, office space, workstations. Equipment may be just about anything needed to complete a task or to communicate. Hardware is equipment such as a computer and its attachments. Software is a program on some type of hardware. People also need to be provided with support services as part of the infrastructure. Information may be data or plans. Support services could be pest control, electricity, waste disposal, potable water, fire alarm testing, transportation and security.

7.1.4 Environment for the operation of processes

There is a broad overall requirement to **determine and maintain an environment** to achieve conformity to product requirements and operate its processes.

The environment includes human and physical factors. **Human factors** are people's involvement and social behaviors, safety attitudes and habits (rules, use of equipment), meeting psychological needs (exercise programs, stress-reduction, burnout prevention, smoking cessation programs, etc.), and **ergonomics.**

Physical factors are noise, cleanliness, vibrations, air quality, light, temperature, humidity, hygiene, and so on.

The standard is very vague regarding the extent the organization must identify and manage the environment. Most organizations do this (manage the environment) to some degree. Organizations may have employee programs for self-improvement, programs to boost morale, and increase motivation, or they may accept suggestions for improvement of the workplace, and so on. The organization must determine and provide the persons necessary for the effective **implementation of its QMS** and for the **operation and control of its processes**.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization must **determine and provide the resources needed to ensure valid and reliable results** when monitoring or measuring is used to verify the conformity of products and services to requirements. This is the Check part of the Plan-Do-Check-Act Cycle. Organizations check their processes and products against criteria.

The organization must ensure that the **resources provided**:

a) are **suitable** for the specific type of monitoring and measurement activities being undertaken;

b) are **maintained** to ensure their continuing fitness for their purpose.

The organization must **retain appropriate as evidence** of fitness for purpose of the monitoring and measurement resources (equipment, devices, software, etc.).

Sidebar: Software controls
If software controls (user and machine) are not addressed by an organization, this could pose a large risk. Software is an integral part of processes in today's world. Software support and development may be 10% or more of personnel resources and perhaps more of budgets. Many machines and devices are dependent on software. When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application should be confirmed. Confirmation should be undertaken prior to initial use and reconfirmed as necessary.

Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment accuracy and repeatability must be maintained.

The measuring and monitoring equipment must be **maintained in a proper environment.** Test and calibration equipment and standards should be properly stored to safeguard from wrong adjustments, from damage or deterioration that would invalidate the calibration status and subsequent measurement results. Some organizations have calibration laboratories and closely monitor the environment.

The equipment must be calibrated and **checked against national or international standards** when they exist. When there are no national or international standards, the **basis for calibration or verification must be retained as documented information.** For homegrown tests (developed internally), the organization will need to develop their own methods to calibrate the equipment.

When measuring and monitoring equipment are **found to be unfit for its intended purpose, appropriate action must be taken** concerning the measuring resources and product affected. The validity of previous measurement results may be adversely affected.

The calibration **status of equipment must be known** to the user of the equipment. Historically, this has been a sticker with the next calibration due date indicated on the sticker. Any other methods of calibration status notification are acceptable as long as they work. Some may be color coding, access, and so on.

7.1.6 Organizational knowledge

The organization must determine the knowledge necessary for the operation of its processes and to achieve conformity of products/services.

The knowledge must be maintained and be made available to the extent necessary.

When addressing changing needs and trends, consider current knowledge and determine how to acquire/access any additional knowledge and required updates.

NOTE - This knowledge is specific to an organization and gained by experience. The information is used and shared to achieve objectives.

Organizational knowledge can be based on:

- internal sources such as lessons learned, undocumented knowledge and experience, the results of product/process improvements and other sources
- external sources such as standards, academia, conferences, external consultants, trainers and others

7.1.6 Explanation and Discussion

Annex A7 explains that requirements in this clause were introduced for the purpose of:

- safeguarding the current knowledge base from the effects of staff turnover and failure to capture and share information
- acquiring necessary knowledge through mentoring, benchmarking and experience

Top management should assess how the organization's current knowledge base is identified and protected. Also, top management should consider how to obtain the knowledge required to meet the needs and objectives of the organization.

Many issues or factors need to be considered when determining how to identify, maintain and protect knowledge by:

- learning from events such as failures, near misses and successes
- capturing and recording the knowledge and experience of the people doing the work
- gathering and recording knowledge from customers, suppliers and partners
- knowing where knowledge can be obtained when needed (for example, trade and professional organizations such as ASME and ASQ)

During the development of ISO 9001:2015, the need for and application of clause 7.1.6, Organizational knowledge, in a QMS was discussed at considerable length. If an organization is successfully operating today, the necessary knowledge already exists. The emphasis should be on learning from mistakes/successes and on gathering knowledge gained and maintained by employees through experience. What is the cost of reinventing the wheel and/or having employees leave the organization with their valuable experience? This is an opportunity to apply risk-based thinking.

7.2 Competence

The organization must **determine the necessary competency** of personnel **performing work under its control that affects performance and effectiveness** of the QMS. Competence denotes having acquired (and using) one's formal education, training, skills, and experience. This is an overall system requirement to ensure the organization takes responsibility for competency of people. When people are selected for a position, **consideration should be given to individual education, training, skills, and experience** necessary to carry out the duties of the position. Most organizations have position requirements or a position description that includes individual requirements such as years of formal education and prior work experience.

Ensuring persons are competent **may require training**. If so, it may be appropriate to evaluate its effectiveness. **Other actions** other than training may be necessary to meet competency needs such as the mentoring or the reassigning currently employed persons, or hiring or contracting competent persons. It may be necessary for an individual to seek formal education, certain work experience or skill.

Transcript of live instructor discussion:

What's the difference between **education** and **training**? If you go to college are you being educated or trained? What's the difference between training and **experience**? What's the difference between **skills** and experience? The more experience you have, do you have more skills? Not always.

Education is usually formal, usually focuses on the big picture and how the big chunks fit together. Training has to do with the doing, the how, the mechanics. Sometimes, we need education before we can successfully do training. We sometimes need to know the big picture in order to understand that what we do needs to be done, and sometimes not.

Skill is the easiest of the four to understand. Either you have it or you don't. Take the example of shooting baskets. If you can shoot ten baskets in a row you have the skill. If you can't, you don't. Skill is often closely associated with experience; although that's not a universal truth.

There's an awfully strong linkage between experience and skill. Have you heard the axiom "That person hasn't had ten years of experience, he has had one year of experience ten times?" So, the linkage between skill and experience is usually there, but not always.

I'd like to define experience as those things that you see, touch, feel, experience and do that allows you to make better decisions in the future. If you are not able to do things better and make better decisions in the future, then it's not experience. It's just tenure and time on the job. Would you want your brain surgeon to be experienced? To be able to look at your brain and say, "You know what, it doesn't look right. Let me have another look at that?" And, you only get that with experience. – End of Transcript

The method to identify actions needed to achieve the necessary competence may be input from managers or from annual performance reviews. When considering training programs, management should give thought to the type and extent of skills, experience, and education of the personnel involved. The organization must **retain documented information (records)** to verify that training or other actions were conducted. Auditors may check for auditor training and/or determination of training for **all personnel performing work under the organization's control that affects performance and effectiveness of the QMS (7.2a)**.

Where applicable, the organization must **evaluate the effectiveness of the training provided**. Accrediting associations such as IACET (International Association for Continuing Education and Training) stipulate that training is effective if the learning objectives were achieved. Where applicable, the organization must have evidence that training effectiveness is evaluated. The **same is true of other actions to ensure**

competency. Other actions may be a reorganization, changing roles, changing the job, mentoring, changing the technology, and so on.

Effectiveness can be evaluated by a pass mark in an examination at the end of a course, satisfactory attendance of the course with a completed survey, a practical test at the end, on-the-job training assessment, observe acceptable workmanship over a number of hours on a machine, or a combination of these.

Evidence of action to ensure competence can be in the form of certificates with authorized CEUs awarded, the supervisor's signature, annual reports, performance data, and so on.

Sidebar: When should you determine the effectiveness of training?
There is no particular guidance for determining effectiveness *where applicable*.

Some considerations are:
1) Is the training organization accredited?
2) Is the course accredited/certified?
3) Is it new or routine?
4) Are the trainers internal or external?
5) Is there a lack of formal assessment tools?
6) What are the informal or formal methods?
7) What is the criticality of the application of what was learned?

7.3 Awareness

Person doing work under the organization’s control must **be are aware of the quality policy, the quality objectives, their individual contribution, and consequences of not conforming** to the QMS requirements.

a) the quality policy: The clause only requires individual to be aware of the quality policy. However, clause 5.2.2 b requires the quality policy to be communicated, understood and applied throughout the organization. As an auditor, avoid the obvious leading question, "Are you aware there is a quality policy?" A simple answer of yes would verify conformity to the requirement. Instead, an auditor might ask is quality important to the organization? This is also an ideal time to **verify conformance to clause 5.2.2 b.**

b) relevant quality objectives: This requirement only requires a person to state that they are aware of quality objectives. **Clause 6.2.1 f requires objectives to be communicated**. An auditor could explore that aspect during interviews. An auditor may ask an individual how his/her job contributes to the achievement of quality objectives. Some individuals in the labor force may not relate to the word objective, but could identify with target or goal.

c) their **contribution to the effectiveness of the QMS, including the benefits** of improved performance: Verification of this requirement is straightforward. Do people know how they contribute to the quality or the quality system? Do they know how doing it right helps improve the organization?

d) the **implications of not conforming** with the QMS requirements: What happens when things are not done right? What are the consequences? Is it a big deal?

This gives an auditor a **great list of questions that should be asked during interviews.**

7.4 Communication

The organization must determine the internal and external communications relevant to the QMS including:

a) what will be communicated
b) when to communicate
c) with whom to communicate
d) how to communicate
e) who does the communication

Explanation and Discussion

Some communication issues to consider:

Internal communication is very important. Many **problems** related to an organization's QMS can often be **traced back to poor communication**.

- Top management needs to **establish processes** encouraging communication at all levels.
- Information should be **clear and understandable and adapted for its intended audience**. Assess the effectiveness of the QMS through the management review and customer feedback. Communicate those results.
- Plant-wide meetings, chat, and **e**bulletin boards to communicate key performance indicators may be considered.

The requirement for **external communication in a QMS will be new to many people**. The organization needs to determine under what circumstances external communication would be appropriate--that is, what aspects of product or service quality would prompt external communications and who would be told.

Examples could include:

- We need to know who would handle the request for the quality policy from a consumer advocacy group such as Greenpeace.
- In the event of a product recall, we would need to have a plan in place to understand the regulatory requirements for reporting and know which bodies would need to be notified. We need a communication strategy to govern what announcement would be put on the company website and who would contact the local news media and other interested parties.

- In the event of a public complaint by a customer, we need the communication plan to have guidelines around whether or not the company would respond and how it would do so.

This requirement might be easily overlooked by many organizations.

7.5 Documented Information

The only required DI to be maintained in ISO 9001:2015 are the scope, objectives and policy (no documented procedures). The organization determines what other DI must be maintained to support the operation of its processes (clause 4.4.2a). The standard requires retained DI (record) at least 19 specific times. The organization is responsible for determining DI that must be retained to have confidence the processes are carried out as planned (clause 4.4.2b).

> Note: No quality manual is required; however, some regulatory bodies and customers may still require a quality manual. Organizations may also use different terms such as business manual, operations manual or service manual.

The organization’s QMS must include: a) DI required by this International Standard and, b) DI determined by the organization as being necessary for the effectiveness of the QMS. Plan what you do and do what you plan.

The **extent of the DI required is dependent** on the organization; the size, type, complexity and interaction of processes; and the competence of personnel. One would expect that smaller organizations and organizations with highly proficient personnel would need fewer documents whereas high tech or complex operations and those with a lack of proficiency would require more. DI can be on any medium such as paper, magnetic, electronic, photographic, master example.

In general, people need to know what they are supposed to do, the plan part of the Plan-Do-Check-Act Cycle. The plan may be in a procedure or flowchart or an outline or check sheet, etc. Some plans may be classified as maintained DI that must be controlled.

It is not up to auditors to specify the QMS documentation structure or the DI needed to adequately control the system. Auditors will need to know the DI the organization decided it needs to maintain and manage the QMS.

7.5.2 Creating and updating

The phrase “creating and updating” applies to DI. Historically, organizations have used descriptive titles such as "control of documents and records." The idea of combining document and record controls can seem awkward, but it is important to consider each specific requirement. The standard requires **"appropriate" controls** for identifying, formatting and reviewing when creating and updating DI. This is a very **open-ended requirement** and gives the organization plenty of flexibility.

An organization must ensure appropriate **identification, description, format, media, review and approval** are maintained. DI could be in the form of a procedure, manual or form. Later, data may be added to a form to show the results of an activity or process; thereby creating a record or retained DI.

Documents can be easily created and updated electronically using available software. With intranets (internal networks) and/or the cloud, **some documents can be updated in real time and always be current.** Records (retained DI) should not be changed, but corrected only when appropriate.

> Note: DI must be appropriately reviewed and approved for **suitability and adequacy.**
>
> Note: There is no requirement for a master list or distribution list, but auditors expect a facsimile to ensure adequate control.

7.5.3 Control of documented information

7.5.3.1 no title

No documented procedure for control of DI (documents and records) is required. However, from a control standpoint, some kind of plan is needed (plan what you do, do what you plan). For very small organizations, the plan may be that Paul updates the operations manual and Rachel updates the customer service manual. For most organizations, however, the situation will be more complicated and require a formal plan such as a procedure, flowchart, checklist, or software procedure controls.

DI required by the QMS and by ISO 9001 standard must be controlled to ensure it is:

a) available (when and where needed) and suitable for use
b) adequately protected (for example, from loss of confidentiality, improper use or loss of integrity)

The requirement to adequately protect DI is very important given electronic storage and distribution issues. Auditors will need to verify documents are adequately protected considering such issues as control, privacy, security, redundancy, and regular data backup. Software allows documents to be easily controlled (controlled access and permissions) and distributed using a pull system (users must go and get the document).

Suitable relates to adapted to a use or purpose. This is very important but seldom sited as a nonconformity. This would only be an issue if plans were created for the wrong reason such as meeting ISO 9001 requirements instead of the need to control a process.

7.5.3.2 no title

When **DI is controlled**, an organization must address the following activities as applicable:

a) distribution, access, retrieval and use *(who: gets it, can view it, can get to it, and can apply it)*
b) storage and preservation, including preservation of legibility *(where is it, is it safe)*
c) control of changes *(who can update or modify it, how are versions controlled and known)*
d) retention and disposition *(how long do you keep it and what do you do with it when it is obsolete)*

Access can imply a decision regarding permission to view only the DI or permission and authority to view and change the DI.

Historically, most of the requirements such as retention and disposition are **applied to control of retained DI** (records). However, the **same requirements apply to maintained DI** such as procedures or other plans that need to be controlled and maintained **when applicable**. An organization may apply all of the requirements to documents and records or an organization may simply reference the “as applicable” phrase to avoid certain requirements such as determining retention time and disposition of procedures and other plans. Most procedures or other plans are retained as long as they are useful or until they are replaced. In some cases, it may be important to retain plans for traceability due to product or service criticality, legal or risk reasons.

DI of an external origin that is necessary for planning and operation of the QMS must be identified and controlled. Depending on the organization's relationship with their customers or suppliers and third parties (i.e. governments, certification bodies), organizations may keep or have access to external DI (documents or records). It could be DI such as specifications, methods, data, or regulations. Where applicable, the organization must conform to the requirements of clause 7.5.3.2 for external DI.

DI **retained as evidence of conformity** shall be protected **from unintended alterations.** This requirement was specifically added to clarify records control issues. The purpose was to ensure organizations do not misinterpret clause 7.5.2, Creating and updating, to mean that records can be modified. Records should never be changed; only corrected if necessary.

When the standard requires **retained DI (record)**, there must be retained DI (record). If retained DI is not accessible or available to an auditor to examine, there could be a nonconformity. If retained DI is incomplete or data is missing, there could be a nonconformity.

See clause 7.5.3.2, Checklist, for list of required retained DI (records).

Sidebar: Are the standard writers daft?
The use of the term "documented information" is the international standard writers trying to keep current with technology and how it is changing how we do things. True, they may not get it right every time. Be assured that no matter the wordsmithing, to have control there must be a Plan-Do-Check-Act Cycle. There must be 1) a predetermined method (plan) for a process or activity, 2) a way for management to verify people are following (do) the

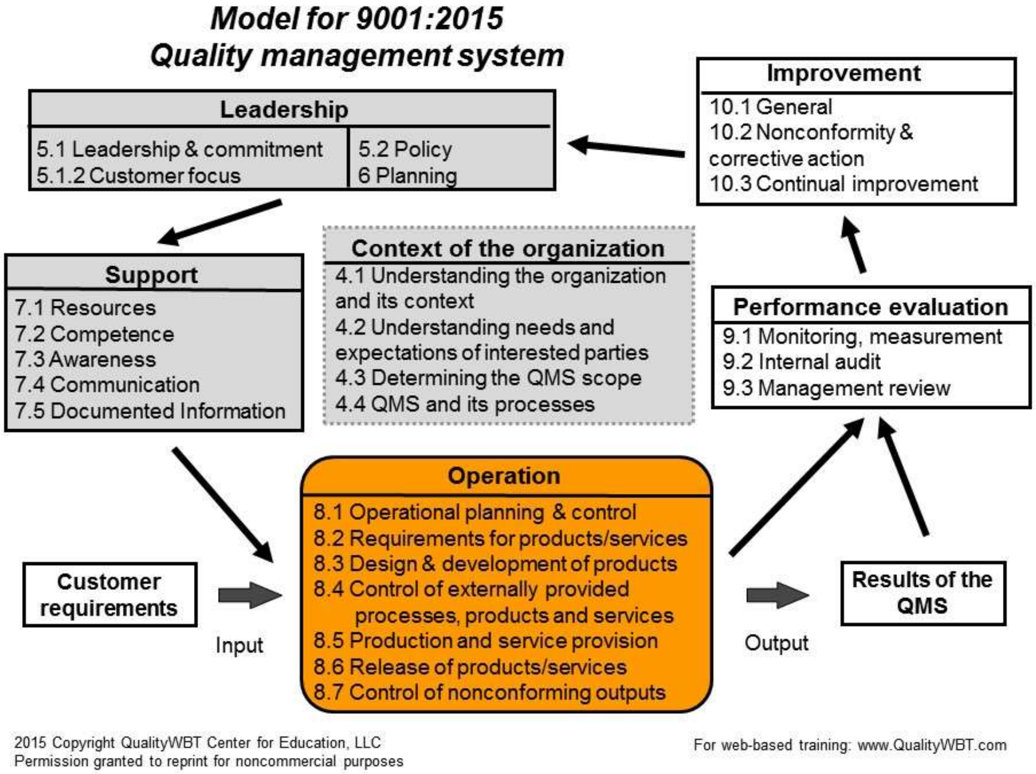
predetermined method, 3) criteria for the output (check), and 4) action (act) when the criteria are not met.

Analysis of the Requirements for ISO 9001 Clauses 8.0-8.4

[This lesson is medium-length and discusses the QMS operation requirements.]

Learning Objectives – Upon completion of this training, managers and auditors will be able to:

- determine the intent and requirements for each element
- apply knowledge to audit for conformity to requirements



Model for 9001:2015
Quality management system
Leadership
5.1 Leadership & commitment
5.1.2 Customer focus
5.2 Policy
6 Planning
Improvement
10.1 General
10.2 Nonconformity & corrective action
10.3 Continual improvement
Support
7.1 Resources
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented Information
Context of the organization
4.1 Understanding the organization and its context
4.2 Understanding needs and expectations of interested parties
4.3 Determining the QMS scope
4.4 QMS and its processes
Performance evaluation
9.1 Monitoring, measurement
9.2 Internal audit
9.3 Management review
Operation
8.1 Operational planning & control
8.2 Requirements for products/services
8.3 Design & development of products
8.4 Control of externally provided processes, products and services
8.5 Production and service provision
8.6 Release of products/services
8.7 Control of nonconforming outputs
Customer requirements
Input
Output
Results of the QMS
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Please note that we will be discussing clause 8, see orange block.

Synopsis:

Clause 8 provides the **controls for the core organization processes** that provide products and services. Many subclauses of clause 8 have familiar names such as planning, design, production, release of products/services and control of nonconforming outputs. Clause **8.2 Requirements for products/services is mostly about customer requirements**, but product/service requirements can come from sources other than a customer. Hence, the word “customer” is not in the title of the clause. A similar situation exists for clause **8.4**. Clause **8.4 Control of externally provided products and services**

is mainly about purchasing products and services for operations. The new name reflects an expanded focus of the controls for all external providers; not just organizations identified as suppliers.

A checklist has been provided (see Class Links) that can be used to make notes and later used to conduct an audit or to implement the new requirements.

8 Operation

8.1 Operational planning and control

The standard states that the organization must plan, implement and control the processes (see clause 4.4) needed for:

meeting the product and service requirements

implementing the actions determined in Clause 6, Planning

The organization must plan. The organization may document its plan in any form or medium as evidence that they have planned. Examples may be a flowchart, quality plan, outline, procedure, process description, or any other means that shows the processes and subprocesses required to achieve the product or service.

The standard states that the organization must **plan, implement, and control the processes needed by:**

a) determining requirements for the product and services
b) establishing criteria for the processes and for the acceptance of products and services
c) determining the resources needed to achieve conformity to product and service requirements
d) implementing control of the processes in accordance with the criteria
e) determining and keeping documented information (retaining records) to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements

An auditor will need the outputs of clause 6 (actions to address risk and opportunities, establish quality objectives) to verify that actions related to product and services are addressed. Clause 6 has some redundancy; especially clause 6.2.2. This is nothing major. The standard uses the word "demonstrate" again which implies a higher level of required conformity.

Organizations must control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. For an auditor, this might materialize as a project plan and follow up (make good) when the project is completed.

Since organizations may use external providers (suppliers of services or products), the organization must ensure that **outsourced** processes are controlled. This is linked to the control of external providers (clause 8.4, Purchasing). An auditor may ask management if they outsource any processes, products or services. Next, ask how they are controlled. If they answer that purchasing is responsible for ensuring outsourced processes are controlled, there could be a nonconformity.

Sidebar: Outsourcing Normally, outsourcing controls should be managed by the purchasing function. However, operations should ensure it is done properly.

It is still said, from time to time, that the organization retains documented information (records) to satisfy the auditor. Closer to the truth is that organizations retain documented information (records) to manage their businesses. A business cannot operate on hearsay. It must be able to verify important activities from time to time.

8.2 Requirements for products and services

8.2.1 Customer communication

Most organizations have an order-taking or a contracts department. Orders may come in by telephone (verbal), by fax, post, email, internet shopping cart, etc. Even when there is an order department it is not unusual for occasional orders to be taken by field sales, marketing, operations, and development.

Organizations must first determine their method of communication (the **best channels**). If organizations don't keep their customers informed, then they may not receive what they were expecting which could result in **customer dissatisfaction and complaints**.

The standard states that the communication with customers must include *(instructor comments in italics):*

a) **providing information** (meaningful facts about an object [data]) relating to products and services *(This may be called a product or service specification.)*

b) **handling enquiries**, contracts or orders, including changes *(What processes, procedures or methods need to be shared?)*

c) obtaining **customer feedback** relating to products and services, including customer **complaints** *(Feedback of this nature is probably an organization’s most valuable source of strengths and weaknesses.)*

d) **handling** or **controlling customer property** *(Organizations must protect other peoples’ property that they control.)*

e) **establishing** specific requirements for **contingency actions**, when relevant *(Expect the unexpected.)*

The potential need for **contingency plans is consistent with risk-based thinking** (What if things don't go as planned?). There could be contingency plans for any of the requirements such as product substitutions, delays in delivery of a product or service, and/or changes in supplier processes.

8.2.2 Determining the requirements for products and services

The standard states that when determining the requirements for the products and services to be offered to customers, the organization must ensure that:

a) the **requirements for the products and services are defined**, including:

1) any applicable statutory and regulatory requirements

2) those considered necessary by the organization

b) the organization can **meet the claims** for the products and services it offers

Sidebar: Able to meet promised claims
Note: There is specific wording that the organization must be able to meet its own claims. This is in addition to being able to meet what the customer wants. As an auditor, you could ask for the marketing literature to see what the organization is promising.

8.2.3 Review of the requirements for products and services

8.2.3.1 (no title)

The standard states that the organization must **ensure that it has the ability to meet the requirements** for products and services to be offered to customers. The organization must conduct a **review before committing** to supply products and services to a customer, to include: *(instructor comments in italics)*

a) **requirements specified by the customer** including the requirements for delivery and post-delivery activities:

1) *Requirements examples include: color, size, weight, time, qualifications, features, materials, options, etc.*

2) Delivery *examples include: time, conditions, markings, damage-free, etc.*
3) *Post-delivery examples include: technical service, refills, actions under warranty provisions, contractual obligations such as maintenance services, other services such as recycling or final disposal.*

b) requirements **not stated by the customer, but necessary** for the specified or intended use, when known *(Not stated but necessary examples may be: traceability, clean, damage free, safe, accessible, etc.)*

c) requirements **specified by the organization** *(Organization specified examples include: internal specifications, methods, techniques, etc.)*

d) **statutory and regulatory** requirements applicable to the products and services *(Governmental requirements may include: safe, marked, notice, caution, warning, etc.)*

e) contract or order requirements **differing from those previously expressed**

Sidebar: Don't promise what you don't have
Before accepting the order or making an agreement, the organization must review all requirements. There can be one review or several reviews depending on the purpose of the review. The review can be a face-to-face meeting, exchanging emails, following a checklist, or whatever fits the situation. There must be retained documented information (a record) of the review and actions taken as a result of the review.

The standard states that the organization must ensure that contract or order requirements differing from those previously defined are **resolved**. The **customer's requirements must be confirmed** by the organization before acceptance **when the customer does not provide a documented statement of their requirements** *(such as an order, purchase order, specification, etc.)*. Note: In some situations, such as Internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information such as catalogs.

8.2.3.2 (no title)

The standard states that the organization must **retain documented information (keep records),** as applicable:

a) on the **results of the review**

b) on any new requirements for the products and services

Sidebar: Review records may vary in form and medium
For record-keeping purposes, an organization may require that order entry personnel initial and date the order as a record, another organization may require the completion of a checklist and signature, another may require that a box on a computer screen be checked to indicate the electronic record was verified, etc.

8.2.4 Changes to requirements for products and services

The standard states that the organization must ensure that relevant **documented information is amended**, and that relevant **persons are made aware** of the changed requirements, when the requirements for products and services are changed.

When **orders are changed** or modified (different from previously agreed-upon) all relevant **documented information must be changed** and all **relevant people must be informed** (made aware of the change). Most of the time, organizations follow a well-thought-out process for the initial order but handle changes informally. Businesses put a strong emphasis on getting the order and closing the deal. Sometimes order changes are not given the proper priority and can lead to customer complaints or the possibility of losing the next order.

Sidebar: Change orders can result in improvement
If customer requirements change, there needs to be a change order. However, consider how many change orders are a result of not getting it right the first time. Some organizations may want to monitor the cause of change orders to determine if there is an opportunity for improvement.

8.3 Design and Development of Products and Services

Sidebar: Instructor comments regarding applicability
This clause may not apply to some organizations because they do not design and develop products or services. Here are some examples when design should be included in the organization's QMS:

- if the customer requires (contract) design/development of a product, process or service
- if the organization designs the product or service that is provided to the customer
- if the organization believes that design and development play a key role in the quality management system

8.3.1 General

The standard states that the organization must establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

The design and development clause is like a mini standard all on its own. It covers everything from inputs to the design process to the design output. It even has its own documented information change control requirements.

8.3.2 Design and development planning

The design and development clause is organized into a plan it, do it, check it, and improve it format. First, there must be a plan that determines the design stages, the review-verification-validation activities, and the plan-and- update responsibilities and authorities. Communication between groups must be managed to ensure it is effective. Once there is a plan, there can be design inputs.

The standard states that the organization must determine project stages and controls for design and development. The organization must consider the following:

a) the nature, duration and complexity of the design and development activities
b) the required process stages, including applicable design and development reviews
c) the required design and development verification and validation activities
d) the responsibilities and authorities involved in the design and development process
e) the internal and external resource needs for the design and development of products and services
f) the need to control interfaces between persons involved in the design and development process
g) the need for involvement of customers and users in the design and development process
h) the requirements for subsequent provision of products and services
i) the level of control expected for the design and development process by customers and other relevant interested parties
j) the documented information needed to demonstrate that design and development requirements have been met

Some of the above requirements (in bold font) have been added to clarify the intent of the design and development planning controls and to incorporate consideration of interested party needs and expectations.

8.3.3 Design and development inputs

When determining requirements products and services to be designed, the organization must consider:

- **functional and performance** requirements
- information from previous similar design and development activities
- **statutory and regulatory** requirements
- standards or codes of practice implemented by the organization
- potential consequences of failure

The inputs must be adequate, complete and unambiguous. Conflicts must be resolved. There must be evidence, retained documented information, regarding design and development inputs.

The design and development group may get inputs from sales or marketing (new product or service), order entry (special order) or operations (production requirements, issues, and interfaces). Ideas for new projects may also come from within the design group.

Very little is said about the actual 'do' part of design because that varies from organization to organization. It is up to the design group to decide what documented information will be needed to complete the design. Typically, there are established methods for design of certain types of equipment or protocols (standard practices) for development methods.

You may evaluate the controls within design to see if they are working as intended. You (as the auditor) may ask about the qualifications for designers and then check personal records to verify educational and experience requirements are being met.

8.3.4 Design and development controls

Creating the design may be in the form of blue prints, models, specifications, drawings, pictures or CAD files.

The standard states that the organization must apply **controls** to the design and development process to ensure that:

a) the **results to be achieved are defined**
b) **reviews are conducted** to evaluate the ability of the results of design and development to meet requirements
c) **verification** activities are conducted to ensure that the design and development outputs meet the input requirements
d) **validation** activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use
e) any **necessary actions are taken on problems** determined during the reviews, or verification and validation activities
f) documented information of these activities is **retained**

An auditor can ask about objectives or goals. There may be milestones to **assess progress**. There may be certain design functions or features that must be achieved. An auditor must verify that reviews are taking place.

Verification is similar to a product or service inspection. The organization must collect evidence that outputs meet requirements. **Validation is more about demonstration of performance claims.** The organization may have verified all the calculations and assumptions, but does the product or service actually perform as intended? For example: Does the stove heat up to 400F in 10 minutes, does the printer print 20 pages per minute, can containers be loaded in 27 minutes, and so on.

Based on the review results, does the **organization follow through**? An auditor can ask to see evidence of the reviews and where actions may be recorded such as publication of minutes. There must be retained documented information to support control requirements.

Design and development reviews, verification, and validation each have distinct purposes. They can be conducted separately or in any combination as is suitable for the products and services of the organization.

An auditor will need to verify that controls are applied checking project files, notebooks, and various records called for in the design and development plans (see 8.3.2).

Verification and Validation

Designs can be verified by several means to include:

- Alternate calculations
- Comparing to similar proven designs
- Prototype testing and other tests
- Verification of the same calculations by an independent body
- Review of design documents prior to release

There must be validation activities.

Designs must be validated. Validation deals with ensuring the product meets user needs and requirements. This may be a field test or a performance test during use in the actual intended environment. Validation **results and necessary actions should be retained (recorded).** Whenever practical, design validation should be conducted prior to the delivery or implementation of the product/service. Validation activities must be performed according to plans (see **8.3.2**).

8.3.5 Design and development outputs

The standard states that the organization must ensure that design and development outputs:

a) **meet** the input **requirements**
b) are **adequate for the subsequent processes** for the provision of products and services
c) **include or reference monitoring and measuring requirements**, as appropriate, and **acceptance criteria**
d) **specify the characteristics** of the products and services that are essential for their intended purpose and their safe and proper provision

The organization must **retain documented information** on design and development outputs.

Design outputs should be in a form that will **allow comparing design outputs with design input** requirements. Design **outputs must meet design input** requirements.

Appropriate design output **information must be provided to purchasing, production, servicing and other functions controlling externally provided products and services** (see b above). Many organizations already have some type of transition or hand-off plan to the operations group. This is an important step to ensure successful project startup.

8.3.6 Design and development changes

The standard states that the organization must identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization must retain documented information on:
a) design and development changes
b) the results of reviews
c) the authorization of the changes
d) the actions taken to prevent adverse impacts

This is classic document and records control of design changes and their approval, results of review, and risk-based thinking. Again, the organization should think through potential consequences of changes. Another important point is the control of the design and development document information does not end when the design is first implemented. Design controls should stay in place as long as the design is in use.

Auditors may check drawings or specifications to ensure changes are properly controlled and recorded.

8.4 Control of externally provided processes, products and services

8.4.1 General

The standard states the organization must ensure that **externally provided** processes, products and services conform to requirements. The organization must determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization’s own products and services
b) products and services are provided directly to the customer**(s)** by external providers on behalf of the organization
c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization

The scope of this clause includes suppliers as well as other external providers to the organization.

External providers could include:

- customers providing a product or service
- organizations providing products or services directly to customers
- a third party providing testing and verification services for incoming material
- organizations providing internal service needs such as equipment maintenance
- organizations providing materials for a product or delivery of a service

Note: This clause applies to external providers. **Providers** of products, services and processes may be internal or external.

The standard states that the organization must determine and apply criteria for the **evaluation, selection, monitoring of performance, and re-evaluation of external providers,** based on their ability to provide processes or products and services in accordance with requirements. The organization must **retain documented information** of these activities and any necessary actions arising from the evaluations.

An auditor should verify organizations are monitoring performance. **Monitoring performance goes beyond verifying if products and services met requirements and that suppliers were evaluated**. Monitoring performance is important because, for some organizations, there was a disconnect between the purchasing function and the department that verified incoming product. Now, monitoring performance is the responsibility of the function that is responsible for external providers.

8.4.2 Type and extent of control

The standard states that the organization must ensure that externally-provided processes, products and services **do not adversely affect the organization's ability to consistently deliver conforming products and services** to its customers.

The organization must: a) ensure that **externally provided processes remain within the control** of its quality management system **b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output.**

This requirement could cover the type or level of verification activities or specific process/system controls. For example, external provider controls could be a QMS certification or financial background check and resulting output controls may be first-article inspection, tests by an independent laboratory, or specification limits or targets.

c) take into consideration:

1) the potential impact of the externally-provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements
2) the effectiveness of the controls applied by the external provider

No. 1 above is an extension of the **risk-based thinking**. No. 2, the organization must periodically **verify the controls are effective**. This, for example, could be a review of product inspection records or an audit every three to five years.

d) **determine the verification or other activities** necessary to ensure that the externally-provided processes, products and services meet requirements

Sidebar: Plan what you do, do what you plan
During the interview, the auditor was told about how the organization evaluated and **controlled** their suppliers. The organization showed the auditor their approved supplier list and purchasing plan for each raw material. The auditor was impressed. Before leaving the purchasing department, the auditor asked to see the last ten purchase orders for a specified raw material. The auditor was surprised to see that five of the last ten purchase orders were from suppliers neither listed as approved, nor audited or qualified. When asked, the purchasing agent said those were **spot purchases.** The auditor determined that *spot* purchases were not included in their plan and there could be unlimited spot purchases.

8.4.3 Information for external providers

This is the last of the "communication" requirements.

The standard states that the organization must ensure the **adequacy of requirements prior to their communication to the external provider**.

The standard states that the organization must **communicate to external providers its requirements** for:
a) the **processes, products and services** to be provided
b) the **approval of**:

1) products and services
2) methods, processes and equipment
3) the release of products and services

c) **competence**, including any required qualification of persons
d) the **external providers' interactions** with the organization
e) **control and monitoring of the external providers' performance** to be applied by the organization
f) **verification or validation activities** that the organization or its customer intends to perform at the external providers' premises

There is no requirement for maintained or retained documented information (a plan or record). Auditors will need to collect evidence that the **information is communicated**. A purchase order may contain information such as how product will be released and how the organization will monitor external providers such as an audit (onsite or remote).

The objective is to provide sufficient information in the purchasing documents such that suppliers understand exactly what they need to provide. The organization must provide audit evidence that they ensure that the purchasing information is adequate **prior to communicating it to the supplier**. Examples of audit evidence could be a signature associated with criteria, a completed checksheet, initials and date on purchasing forms, and so on.

Verification activities This is the only place in the standard that requires assurance (inspection or other means) that the **purchased product or service meets purchase requirements**. Many organizations have receiving and inspection departments that formally check and verify incoming parts and materials.

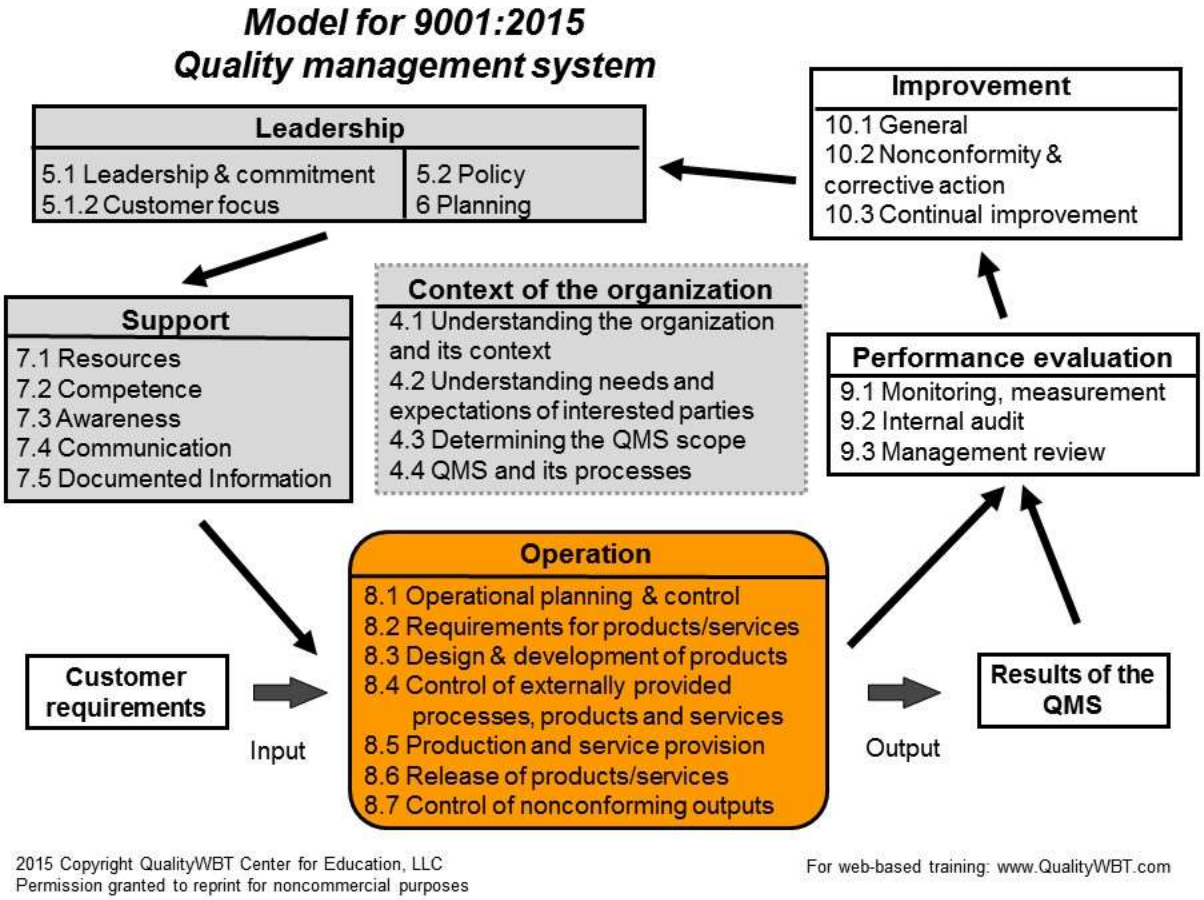
When products are verified at the supplier's premises (if source inspection controls are appropriate for ensuring conformity of the purchased product), the organization should communicate the arrangements for verification and the basis for release of product in the purchasing documents.

Analysis of the Requirements for ISO 9001 Clauses 8.5-8.7

[This medium-length lesson discusses the core operations of the organization. A test you must pass to continue is at the end.]

Learning Objectives – Upon completion of this training, managers and auditors will be able to:

- determine the intent and requirements for each element
- apply knowledge to audit for conformity to requirements


Model for 9001:2015
Quality management system
Leadership
5.1 Leadership & commitment
5.1.2 Customer focus
5.2 Policy
6 Planning
Improvement
10.1 General
10.2 Nonconformity & corrective action
10.3 Continual improvement
Support
7.1 Resources
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented Information
Context of the organization
4.1 Understanding the organization and its context
4.2 Understanding needs and expectations of interested parties
4.3 Determining the QMS scope
4.4 QMS and its processes
Performance evaluation
9.1 Monitoring, measurement
9.2 Internal audit
9.3 Management review
Operation
8.1 Operational planning & control
8.2 Requirements for products/services
8.3 Design & development of products
8.4 Control of externally provided processes, products and services
8.5 Production and service provision
8.6 Release of products/services
8.7 Control of nonconforming outputs
Customer requirements
Input
Output
Results of the QMS

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Please note that we will be continuing our discussion of clause 8, see orange block.

Synopsis:

Clauses 8.5-8.7 set out requirements for operations. These clauses address controls for operations, care of customer supplied property, traceability, preserving product, post-delivery, control of changes, release of products and services, and the handling of **nonconforming outputs**. Processes have inputs that result in outputs. A service may be a nonconforming output. The clauses cover basic controls for everyday operations.

8.5 Production and service provision

8.5.1 Control of production and service provision

This clause requires organizations to control their operations. Then there is a list of eight control requirements that must be included, as applicable. “As applicable” means the organization must decide which requirements will be included as part of their controls. This requirement is open-ended and there is no requirement for documented information regarding the applicability of each control. From a practical sense, if organizations don't control their operations, they will not be operating for very long.

For class instruction purposes, we will list each of the eight controls and discuss them one by one.

Controlled conditions must include, as applicable:

1) the availability of documented information that defines:
a) the characteristics of the products to be produced, and the services to be provided, or the activities to be performed
b) the results to be achieved

Discussion: Management must provide documented information that includes the acceptance criteria (characteristics of the product and/or services) for the processes. For example: When is the job/process done right? What are the product or service specifications? What is desired? What is a success for that process?

2) the availability and use of suitable monitoring and measuring resources and

3) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met.

Discussion: Resources (i.e., equipment) for measuring and monitoring can be about anything needed to gauge and make adjustments to the process. They may be anything from gas chromatographs to tire gauges. When the organization needs equipment to control (pass-fail) the process, they should have them, use them, and maintain them. Monitoring can include: process control charts, measuring tolerances, testing samples, trend charts, conducting process audits, etc. Measuring equipment is used to test a product, resulting in a pass/fail decision. Monitoring equipment is used to control a process and may result in an operate/do not operate decision.

Sidebar: Produces, work instructions, plans, etc.
The standard calls for documented information. The documentation may include procedures or work instructions when needed to support the operation of its processes (4.4.2). The need for work instructions or other documents may depend on the organization’s size, type, complexity, interactions, and competency of personnel. When it is important for an activity to be done a certain way every time to ensure quality, safety, and other objectives (such as economic) are met, the organization may decide to issue a

work instruction to improve the effectiveness or control of the process. Work instructions and other such documents are management control tools.

4) the use of suitable **infrastructure** and environment for the operation of processes

Discussion: Infrastructure issues may be more evident in isolated geographical area**s**. We frequently take infrastructure for granted. Operation environmental issues may be more important in harsh operational venues (such as steel making, underwater repairs in the ocean, and so on) or when strict environmental controls are required to avoid contamination.

5) the appointment of **competent** persons, including any required qualification

Discussion: Everyone must be competent and some employees may require a specific qualification or certification. Some may need a specific skill or knowledge. Perhaps grading lumber, verification of color, or verification of a smell.

6) the implementation of actions to prevent human error

Discussion: The wrong approach here can create a fearful environment. Some view all nonconformities a result of human error. Most aviation accident investigations conclude the accident was the result of human error. Human error has been cited as a primary cause or contributing factor in disasters and accidents. Human error means that something was done that was unintended or not desired; a deviation from intention, expectation or desirability. If there is a nonconformity, an organization's corrective action may include dismissal of an individual instead of changing the system or process.

A more positive approach is to employ risk-based thinking to identify the potential variability of human performance within the system and take action to avoid undesirable outcomes. Many organizations use error proofing to identify potential human errors as part of design and everyday operations.

According to ISO 9000, clause 3.10.3, the human factor is a characteristic of a person having an impact on an object under consideration. The characteristics can be physical, cognitive or social.

Sidebar: A reminder of an important Quality Management Principle
Engagement of people: Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization’s capability to create and deliver value.

Rationale: To manage an organization effectively and efficiently, **respecting and involving all people at all levels is important.** Recognition, empowerment, and enhancement of competence facilitate the engagement of people in achieving the organization’s quality objectives.

7) the implementation of release, delivery, and post-delivery activities

Discussion: To complete the product/service provision process, the organization must **include a release process, delivery process, and, when applicable, a post-delivery** process (such as installing or maintaining). The wording (such as release or post-delivery) may seem strange to some, but most organizations already have these processes in place. Normally, there is some type of final release step, such as an *It is okay to send to the warehouse” or “It is okay to ship to the customer”* (or both). In all cases for a product company, arrangements have been made to get the product to the customer. And finally, many organizations have some type of installation or technical service linked to the sale of the product. For a service organization, the release may come before the service is performed (i.e., a release that it is okay to perform the service). Or, if a service (see image below) is performed on a customer’s equipment, there may be a release prior to returning the equipment to the customer.

It is **important** to note that **delivery and post-delivery processes** are mentioned as part of the operations control clause. For a JIT (Just-In-Time) company, product may come off the line and be put on a truck or train without any storage. When service is provided, it is normally being delivered, but there may be post-delivery processes such as an annual review of policies or equipment maintenance requirements.

8) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement

Discussion: In the past, processes that needed validation were called special processes. When a process output (product) cannot be verified by subsequent measurement and monitoring, the **process must be validated**.

In simpler terms, if you cannot **check it before the customer receives it**, you must validate the process that produced it. Examples include cases where (a) the **characteristics of interest** do not exist until further downstream in the process; (b) a **method of measurement** does not exist or is destructive; or (c) results within the process **cannot be measured in later inspections** (prior to customer receipt).

Processes needing validation have been associated with those such as medical treatments, flying aircraft, metalworking, welding, nondestructive examination, and heat treating. These processes require the process itself to be validated, equipment approved, and operators qualified. For example, the process that produces a finished welded product must be validated even if expensive x-ray inspection devices are used to verify the weld. The weld strength cannot be measured unless the weld is broken (i.e., the product must be destroyed to verify it meets requirements).

If part of the service includes engaging the customer, such as training courses, then the process must be validated.

There may be a considerable number of opinions concerning the **identification of processes that need to be validated**. While some experts say all services must be validated, one must go back to the exact wording in ISO 9001 to determine what to do.

"Validate... where the resulting output cannot be verified by subsequent monitoring or measurement." ISO 9001, clause 8.5.1f).

Subsequent measurement and monitoring comes after the operation (product and service provision) but **before customer receipt**. For example, one cannot argue that welding does not need to be validated because we can go back 20 years later to see if the bridge is still standing, or that ability to measure the safe arrival of the airplane precludes the need to validate the air carrier process.

The validation process must verify that the process being validated can achieve planned (specified) results (objectives). **Validation is demonstrating (verifying) that the process can achieve planned results**. The organization must **arrange for validation** when applicable.

Sidebar – Validation may include the following:

- qualification, or registration of processes (demonstrate performance)
- qualification, or certification of equipment or people/operator license
- use of specified procedures or techniques or work practices
- determine record requirements (retained documented information)
- determine re-validation requirements

8.5.2 Identification and traceability

The standard states that the organization must use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization must identify the status of outputs with respect to monitoring and measurement requirements throughout the production and service provision.

The organization must control the unique identification of the outputs when traceability is a requirement, and must retain the documented information necessary to enable traceability.

Discussion: Product and service identification, traceability and status are three separate processes, but they must be compatible. If it is important to differentiate between similar products (parts, batches, lots, etc.) or services (treatment, project, transaction, etc.), there must be some type of **identification process**.

Once there is an identification process, **traceability may be required by the customer or a regulatory agency.** One form of traceability, called backward traceability, is to be able to match the finished item with the incoming parts and materials. This is very useful for failure analysis. Traceability calls for **identification** of the finished product by stamp or serial number. Those warranty cards you fill out when you purchase a new microwave ask for a serial number. This allows the organization to trace the sale back to the factory and date of production. In the food processing and pharmaceutical industries, the organization needs to be able to trace the distribution of the product, in case of recall. This is called forward traceability.

As an item or service progresses through the various process steps, an organization may need to know if it is **ready for the next operation**. For many processes, **organizations knowing the status of a product or service is important**. It helps organizations make good decisions, and, in many cases, it keeps the customer informed of production, performance, and delivery progress.

Knowing the status of a product during production is one of the earliest forms of quality control. It allows fellow workers to know the quality of something before they work on it. More importantly, it allows the customer to know the quality before the product is purchased.

Product identification, status, and traceability are concepts that have withstood the test of time. They are 'good business practices.'

When traceability is required, the organization must control the unique identification of the product and retain documented information (maintain records). This means that if there is other necessary information associated with traceability such as dates, time, and location those records must be maintained, too. **Auditors and organization management should verify that the organization is retaining documented information of all applicable information associated with product or service traceability controls.**

Some organizations use a **configuration management** process as a means by which identification and traceability are maintained.

8.5.3 Property belonging to customers or external providers

The standard states that the organization must exercise care with property belonging to customers or external providers while it is under the organization’s control or being used by the organization.

The organization must identify, verify, protect and safeguard customers’ or external providers’ property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization must report this to the customer or external provider and retain documented information on what has occurred.

Discussion: **Customer Property** is property provided by the customer that the customer owns. Customer property may be tangible (has physical form), **intellectual property** or personal data.

The organization must **exercise care in identifying, verifying, protecting and safeguarding** customer or external provider property (e.g. equipment) that has been received. If the customer or external provider property is lost, unsuitable, damaged upon receipt, or in storage, the **customer or external provider must be notified**. The organization must retain documented information (**keep records)** of lost, unsuitable, or damaged property.

Discussion: The standard includes a note that states a customer’s or external provider’s property can include material, components, tools and equipment, premises, intellectual property and personal data.

Retaining personal data as an example of customer or external provider property. If an organization is not controlling personal data (private information) under the requirements of this clause, there could be a nonconformity.

Data is defined as: 1) facts and/or statistics used for reference or analysis; 2) information based on facts; 3) facts about an object (ISO 9000). ISO 9000 continues by defining object as an entity, item or anything perceivable or conceivable. A bit of a brain exercise.

Personal is not defined in the ISO 9000 vocabulary standard nor ISO 9001 support documents. However, dictionary definitions suggest that personal relates to a particular person or individual. Therefore, if an organization has personal data under the organization's control or it is being used by the organization, the requirements of this clause apply. All organizations, especially service organizations, need to review this clarification to determine if there is a potential nonconformity. Examples personal data include medical, financial, individual profiles, and personal preference records.

8.5.4 Preservation

The standard states that the organization must preserve the **outputs** during production and **service** provision to the extent necessary to ensure conformity to requirements.

Any outputs necessary to ensure conformity to requirements must be preserved. The scope of the preservation clause is NOT limited to the product. This allows preservation to include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection (in a note in the standard).

For example, it may be necessary to preserve labels on material stored in a warehouse. The identification, integrity security of product may need to be preserved through all output stages of the operation. Depending on the nature of the operations, it may be necessary to take steps to preserve component parts needed for the final product.

A **service** is an intangible, and so has no physical form. For services, it may be necessary to preserve product, equipment or facilities used in the delivery of the service. The means to provide the service may need to be preserved (controlled/protected) such as access to the Internet, a transmission cable and/or security software. The result of a service may need to be preserved such as a finished, painted car.

Sidebar: Final product or service
Some auditors or managers may ask if this requirement is limited to final product or service delivery. Since output is any process and the requirement states the control

applies to outputs during production and service provision, it applies to all stages of product and service delivery that are necessary to ensure conformity to requirements.

The concept here is that if the organization provides a good product or service or service prep for the customer, they should take steps to ensure it stays good for the customer.

Many industry sectors issue specific handling, storage, packing, preservation, and delivery requirements beyond ISO 9001 requirements.

This clause may be very **difficult to audit** using the requirements approach because there are few requirements and the ones that exist are conceptual requirements. There is no requirement for a documented procedure or specific requirement for management control of this process. However, the general requirements in clause **8.1 and 8.5.1 would apply to** preservation. Auditors can audit the preservation process defined by the organization, degree of implementation, and achievement of desirable outcomes.

8.5.5 Post-delivery activities

The standard states that the organization must meet requirements for post-delivery activities associated with the products and services.

When determining the extent of post-delivery activities that are required, the organization must consider:

a) statutory and regulatory requirements
b) the potential undesirable consequences associated with its products and services
c) the nature, use and intended lifetime of its products and services
d) customer requirements and feedback

The requirements are consistent with risk-based thinking plus, recognition of potential product/service obsolescence issues, as well as customer feedback. There is no requirement for retained documented information so the organization has a lot of flexibility. An auditor may ask, “What issues/factors do you consider when planning the delivery process and any post-delivery services?”

8.5.6 Control of changes

Ideally, when there is a change to a product or service or the processes that create the outputs, the change should be reviewed before implementation.

For example: Is changing the room wall color okay?

- Has there been a review of the proposed change in wall color?
- Will the new color be suitable for the work environment?
- Will the new color show every little dirty spot and scratch?
- Is the paint lead-free?
- Have safety issues been addressed?

- Has the change been authorized and by whom?
- Will the color be objectionable to anyone in the workplace?

The standard states that:

1) The organization must review and control changes for production or service provision to the extent necessary to ensure continuing conformity with requirements.

2) The organization must retain documented information describing the results of the review of changes, the persons authorizing the change, and any necessary actions arising from the review.

Now, when in the operations area, auditors should ask if there have been changes to operations. Then follow up with verification that there is retained documented information (record). Was there a review? Was the change authorized? Were there follow-up actions?

Sidebar: Little changes - big problems One time I made a little change to the process. I increased the operating temperature by five degrees. It boosted production rates and there was no apparent change in product characteristics that we tested for. Six months later, customer complaints started coming in. The change in the process changed the performance of the product. The temperature went back to the design specifications.

8.6 Release of products and services

The standard states that the organization must implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer must not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization must retain documented information on the release of products and services. The documented information shall include:
a) evidence of conformity with the acceptance criteria;
b) traceability to the person(s) authorizing the release.

Discussion: The organization must **verify that product and service requirements are being met at appropriate stages** in accordance with **planned arrangements.** Planned arrangements may include testing, inspecting, analyzing, or observing specified characteristics. Outputs can be hardware (bolt, machine, and computer), processed materials (food, gasoline, and juice), software (computer program) and services such as banking, insurance, retail sales, so on.

There must be retained documented information (record) **that provides evidence of conformity and traceability to person authorizing the release of the product or service** for delivery to the customer. Product and services must **meet all requirements (planned arrangements) prior to release and delivery to the customer** unless otherwise approved by a relevant authority or by the customer (where applicable).

8.7 Control of nonconforming outputs

8.7.1 (no title)

The organization must ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Discussion: The idea is to prevent the bad stuff from getting to the customer or end user.

The organization must take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This must also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

Discussion: As an auditor, you need to determine if the dispositioning process is sensitive to the criticality of the effect of nonconformity on the organization (such as safety, scheduling of products or services, health, recalls, customer satisfaction and so on).

The standard specifies how the organization must deal with nonconforming outputs in one or more of the following ways:
a) correction which can include rework, repair, blend, or regrade
b) segregation by containment, return, or suspension provision (the act or process of providing) of products and services
c) informing the customer
d) obtaining authorization for acceptance under concession (such as use as-is, or a different application/use)

Segregation and containment are common initial responses to nonconformities. Holding products would be temporary until the organization determined their disposition. In some cases, scrapping, dumping or disposal of nonconforming product is the most economical or lowest-risk choice.

Another option is to inform the customer. The resulting actions expected depend on an organization's relationship (contractual or otherwise) with the customer. Perhaps informing the customer would result in their approval or perhaps the customer needs to know of the nonconformity so they can adjust their process or schedule to accommodate for the nonconforming product or service. For a service, the nonconformity could happen before the service delivery such as an airline flight cancellation or after a service such as a third-party certification of equipment to the wrong standard. There are times when an organization must inform the customer so that the customer can take action to mitigate the consequences. The standard states that conformity to the requirements must be verified when nonconforming outputs are corrected.

Discussion: If the product was, for example, reworked or blended with good product, it must be re-verified as meeting requirements.

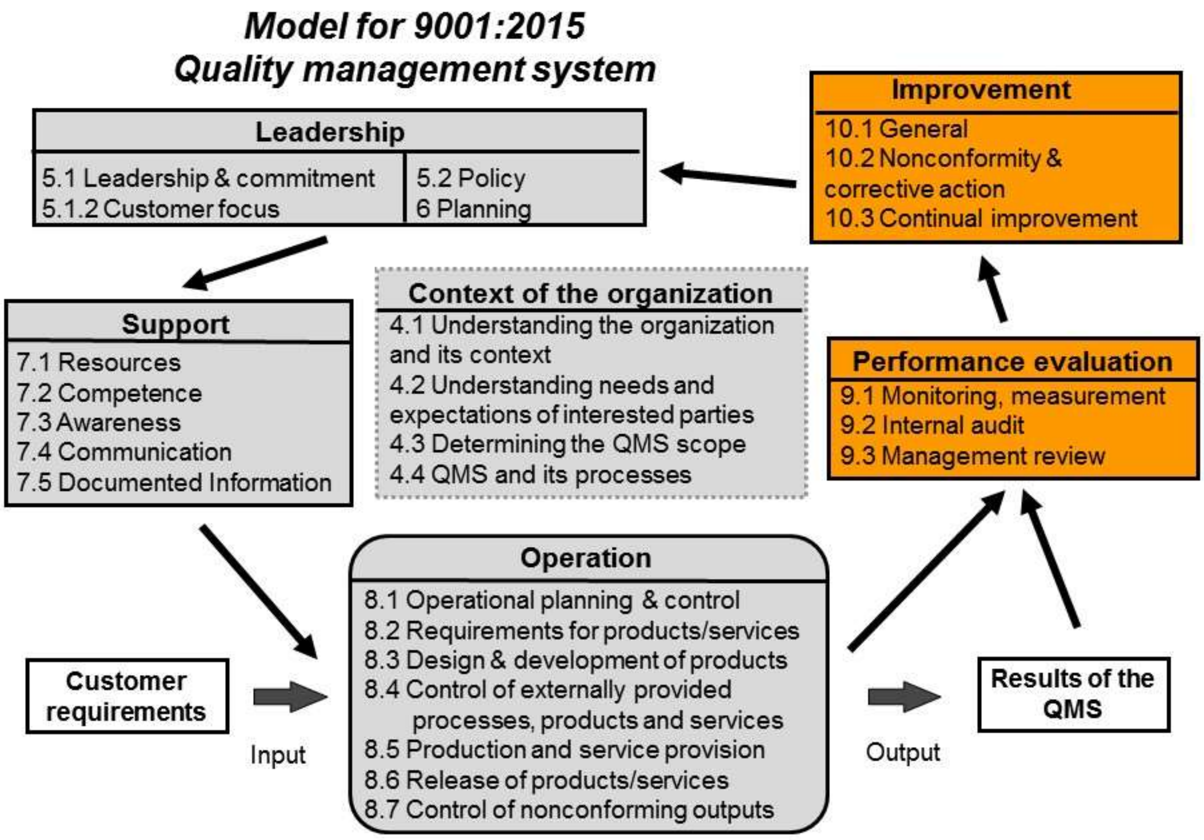
Analysis of the Requirements for ISO 9001 Clauses 9-10

[This medium-length lesson discusses the check and action part of the PDCA cycle. A test you must pass to continue is at the end.]

Learning Objectives:

Upon completion of this training, managers and auditors will be able to:

- determine the intent and requirements for each element
- apply knowledge to audit for conformity to requirements


Model for 9001:2015
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8.6 Release of products/services
8.7 Control of nonconforming outputs
Customer requirements
Input
Output
Results of the QMS

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Please note that we will be discussing clauses 9-10, see orange block.

Synopsis:

Clause 9 addresses the analysis of data, collecting data via the internal audit program, and management review of management system outcomes. Clause 10 covers the controls for improvement of the organization. The **interested parties and risk-based thinking**

themes are integrated into the requirements. There is a strong emphasis on **monitoring metrics and improving performance** of the organization.

9 Performance evaluation

9.1 Monitoring, measurement, analysis, and evaluation

The standard states that the organization must determine:
a) what needs to be monitored and measured
b) the methods for monitoring, measurement, analysis, and evaluation, as applicable, to ensure valid results
c) when the monitoring and measuring shall be performed
d) when the results from monitoring and measurement shall be analyzed and evaluated

All organizations want valid results, but sometimes organizations use wrong metrics to assess progress towards their objectives. The organization must determine "when" the results will be analyzed. The organization must specify a time or period when results will be analyzed. An auditor can ask for a schedule or other means for determining when results are analyzed. This evaluation is important because organizations can be measuring the wrong metric or there could be a downturn in performance between measurement intervals.

The management system is made up of processes.

Which processes need to be monitored? How are we going to do it? Is it continuous or periodic? When do we start analyzing the data that was collected?

9.1.2 Customer satisfaction

The standard states that the organization must monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization must determine the methods for obtaining, monitoring, and reviewing this information.

Discussion: Customer satisfaction information must be monitored. Specifically, the **standard requires the measurement of customer perception** regarding meeting customer needs and expectations. For customer satisfaction, the customer's perception of the product or service is more important than any single metric such as on-time-delivery or defect free product. Customer perception is one of the key measures of quality management system (QMS) performance. The **methods** for gathering and using the information need to be thought out. The **customer's perception of satisfaction and dissatisfaction may be measured**. For example: Customer complaints are a measure of customer dissatisfaction; other measures, such as a survey or interview, may be needed to assess customer satisfaction.

9.1.3 Analysis and evaluation

The addition of the word “evaluation” to the title is important to note. Organizations must evaluate the data as well as analyze it. What can be concluded from the analysis of the data/information?

The standard states that the organization must analyze and evaluate appropriate data and information arising from monitoring and measurement.

There is no specific data, just appropriate data. Auditors need to verify that appropriate data analysis is taking place. There needs to be verifiable evidence. The organization determines the data that is appropriate.

The standard states that the results of analysis must be used to evaluate:

a) conformity of products and services
b) degree of customer satisfaction
c) the performance and effectiveness of the QMS
d) that planning has been implemented effectively
e) the effectiveness of actions taken to address risks and opportunities
f) the performance of external provider**(s)**
g) the need for improvements to the QMS

The emphasis on performance continues and there is a requirement to ensure that plans have been effectively implemented.

There is a note that mentions analysis can include statistical techniques. Statistical techniques can be very powerful, but not always the best tool.

S**tatistical techniques can include** statistical process control (SPC) methods, histograms, or sampling. Statistical methods are not required, but most organizations would, at a minimum, use elements of **descriptive statistics** techniques such as averaging and ranges.

Some examples of results that may be evaluated include:

- customer perception (9.1.2)
- performance of external (supplier) providers (8.4.1)
- process/service performance (8.5.1)
- product test results (8.5.1)
- effectiveness of actions from risk assessment (6.1.2b)
- audit results to confirm the effectiveness of the QMS (9.2.1)
- corrective action results (10.2.2)
- performance indicators for processes (4.4.1c)
- performance of the QMS (5.3c)
- status of quality objectives (6.2.2)

Organizations should monitor Key Performance Indicators (KPI). Management and auditors should be knowledgeable in determining the best metrics to monitor performance.

9.2 Internal Audit

9.2.1 (no title)

The standard states that the organization must conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1) the organization's own requirements for its quality management system
2) the requirements of this International Standard

b) is effectively implemented and maintained

Discussion: Audits must be conducted at planned intervals (scheduled) to determine if the QMS **conforms to** (are in compliance with) the organization's Quality Management System requirements, and the **requirements of ISO 9001**, and that implementation and ongoing maintenance of conformance to requirements be assessed.

The organization's own requirements would mean the documented information such as a manuals, procedures, plans, and work instructions. The internal quality auditors should audit against all organizational quality management system documents.

9.2.2 (no title)

The standard states that the organization must:

a) plan, establish, implement, and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements, and reporting which must take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits
b) define the audit criteria and scope for each audit
c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process
d) ensure that the results of the audits are reported to relevant management
e) take appropriate correction and corrective actions without undue delay
f) retain documented information as evidence of the implementation of the audit program and the audit results

Discussion: The audit program plan must consider factors such as **changes in area status, importance of processes, and results of prior audits** when scheduling audits. An organization could receive a nonconformity if they only schedule audits to cover the ISO 9001 clauses and do not consider area status, importance, and prior results.

Auditors must be **selected in ways that ensure impartiality and objectivity of the audit results**. Internal auditors must have some level of independence or no vested interest in the area being audited. Practicality and the nature of the organization must be considered when determining the level of independence to ensure impartiality and objectivity. A small organization providing low-risk products or services does not need the same level of independence as a large, complex organization that provides high-risk products or services (law firm versus nuclear power plant).

Management must take action without undue delay on audit **nonconformities**.

The follow-up actions must be verified and reported. The concept that many nonconformities require **correction** or **remedial action** is included in this clause. The requirement is: Results must be reported to relevant management and the organization must take appropriate correction and corrective actions without undue delay. Another way to phrase this requirement is: without undue delay, management should make necessary corrections (take remedial action) to eliminate the detected nonconformity and follow up by taking corrective action (when appropriate) to eliminate the cause of the nonconformity.

Auditors can **verify that corrections and/or corrective actions were taken without undue delay.** However, there is no requirement in this clause to verify the effectiveness of the action or corrective action as a result of the audit. The effectiveness of corrective actions should be addressed as part of the corrective action review (clause 10.2) and management review (clause 9.3).

The standard states that there must be retained documented information as evidence of the implementation of the audit program and the audit results. Auditors and management should verify that auditing records (retained documented information) include: 1) a record of the audit (proof that there was an audit); and 2) the audit results (such as **findings**).

9.3 Management review

9.3.1 General

The basic concept is the management needs to review the organization's performance and take necessary action to achieve its objectives.

The standard states that the reviews conducted must ensure the quality management system's continuing **suitability**, **adequacy**, **effectiveness**, and alignment with the **strategic** direction of the organization. For management to ensure alignment with the strategic direction, they would need to know what that direction is. The direction could be communicated through a strategic plan or perhaps in a policy statement or other means.

An auditor also needs to know the strategic direction (4.1, 5.1.1, 5.2.1) to assess this requirement. For example:

- If one strategy is to provide a product with value-added features that would increase product sales margins, there should be metrics to support that strategy.
- If the strategy is to provide a service with the lowest direct costs, there should be metrics to support that strategy.

Sidebar: Review to ensure:
suitable − Does it still fit its purpose?
adequate − Is it still sufficient?
effective − Does it still achieve the intended results?

9.3.2 Management review inputs

The standard states that when management reviews are carried out, the organization must take into consideration the following:

a) the status of actions from previous management reviews
b) changes in external and internal issues that are relevant to the QMS, including its strategic direction
c) information on performance, including trends in:

c1) customer satisfaction and feedback from relevant interested parties
c2) the extent to which quality objectives have been met
c3) process performance and conformity of products and services
c4) nonconformities and corrective actions
c5) monitoring and measurement results
c6) audit results
c7) the performance of external providers **(e.g. suppliers and others)**

9.3.3 Management review output

The standard states that the outputs of the management review must include decisions and actions related to:

a) opportunities for improvement
b) any need for changes to the QMS
c) resource needs

Need for improvement is open-ended to the extent that improvement may go beyond customer product/service requirements or the quality management system. Improvement may relate to internal and external issues.

Also, the requirement to include decision and actions of outputs related to changes in the quality management system is directly related to effectiveness, suitability, and adequacy. In one context, one might think all changes would be related to improvement, but that is not the case. Some changes are for maintenance, compliance with governmental requirements, or downsizing to support survival of the organization.

The organization must retain documented information as evidence of the results of management reviews. An auditor should ask for the documents that show reviews were conducted.

Sidebar: Frequency of reviews
Reviews must be conducted at planned intervals (9.3.1), but there is no requirement

regarding the frequency of the reviews. Typically, certification bodies expect, at a minimum, annual reviews. Depending on the organizational objectives, more frequent reviews may be justified. Since most organizations scrutinize their performance annually, quality management system reviews held less frequently than annually should be scrutinized.

10 Improvement

10.1 General

Regarding improvement, the standard includes three specific areas for meeting customer requirements and enhancing customer satisfaction.

Does the product need to be improved?
What can be done to prevent undesirable effects?
Are we responsive to customers?

The standard states that the organization determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

This requirement ensures an ongoing customer focus.

The standard states that opportunities for improvement must include:

a) improving products and services to meet requirements as well as to address future needs and expectations
b) correcting, preventing, or reducing undesired effects
c) improving the performance and effectiveness of the quality management system

This requirement has no qualification such as “as appropriate”. An auditor needs to verify that all three (a, b, and c) are taking place. Improvement can be reactive (e.g. corrective action), incremental (e.g. a relatively small individual improvement project), step-by-step change (e.g. a breakthrough, major project), creative (e.g. innovation), or by reorganization (e.g. transformation).

10.2 Nonconformity and corrective action

10.2.1 (no title)

The standard states that when a nonconformity occurs (including complaints), the organization must:

a) react to the nonconformity, and as applicable:

1) take action to control and correct the nonconformity
2) deal with the consequences

This requirement is somewhat redundant when compared with 8.7.1. Taking action to control, correct, and deal with the consequences are typical first steps when there is a nonconformity or complaint. However, this clarifies what was expected. Other terms associated with this requirement are **remedial action,** containment action, quick fix, and a **correction** step.

Consequences of nonconformity can include issues such as the customer's product quality, inefficiencies within the organization, and substitutions to provide immediate relief to a customer.

b) The standard states that the organization must evaluate the need for action to eliminate the cause(s) of the nonconformity so it does not recur or occur elsewhere, by:

1) reviewing and analyzing the nonconformity
2) determining the causes of the nonconformity
3) determining if similar nonconformities exist or could potentially occur

Many quality professionals link **corrective action** of a nonconformity with preventing it from recurring because it may happen again. The writers of Annex SL (common text) added the possibility that it could occur elsewhere.

Item 3) helps emphasize the importance of identifying systemic problems.

The corrective action steps continue with:

c) implement any needed action
d) review the effectiveness of any corrective action taken
e) update risks and opportunities determined during planning, if necessary
f) make changes to the quality management system, if necessary

As you may have noticed, the standard refers to changes in several places. One of the tests to determine if there was improvement is to verify there was change. Change the system or change the process. If there is no change, there is no improvement because you will be doing the same things over and over again.

Sidebar: Change
Albert Einstein quote. Insanity: doing the same thing over and over again and expecting different results.

An organization could state it has not been necessary to make changes. However, if they truly take corrective action, change would be necessary.

10.2.2 (no title)

The organization must retain documented information as evidence of the nature of the nonconformities and any actions taken, and the results of any corrective action.

10.3 Continual improvement

The standard states that the organization must continually improve the suitability, adequacy, and effectiveness of the quality management system.

The organization must consider the results of analysis and evaluation and the outputs from management review, to determine if there are needs or opportunities that must be addressed as part of continual improvement.

Discussion: As stated, the continual improvement clause ties back into opportunities (6.1) and management review (9.3). If the organization conforms to 6.1 and 9.3 requirements, an auditor could conclude, that they are likely to be compliant with 10.3.

Conclusion

This concludes the detailed review of the requirements. The ISO 9001:2015 has many open-ended requirements that gives the organization more flexibility so that they can avoid onerous, nonapplicable perspective requirements. It also requires the auditor to keep an open mind and ask the auditee how they have implemented the stated requirement. However, if the auditee has not properly prepared or implemented the requirements, they may find themselves without adequate evidence. Whereas if the requirements were closed-ended, the auditee only needed implement what was required in the standard. The open-ended requirements have shifted more responsibility to the auditee organization to implement and maintain an effective quality management system.

Open-ended questions are required for open-ended requirements. For example:

- How do you…
- Please explain...
- Can you show me...
- Why did you...

Risk-based Thinking Application

[This medium length lesson discusses how to risk-based thinking may be applied in a management system environment. At the end is a test you must pass to continue.]

Learning Objectives:

Upon completion of this training, managers and auditors will be able to:

- explain ISO 9001:2015 requirements related to risk-based thinking
- provide interpretive guidance
- apply quantitative and qualitative approaches to process risk
- assess risks using a simple qualitative approach to risk assessment

Synopsis:

ISO 9001:2015 requires risk-based thinking to replace preventive action and to advance quality management system (QMS) controls. This lesson discusses risk-based thinking and provides some guidance for its application. **Important phrases are marked with bold** text.

There are two common definitions for Risk:

Effect of uncertainty– (ISO 9000:2015 Clause 3.7.8)
Effect of uncertainty on objectives – (ISO 31000:2009 Clause 2.1)

Since both of these definitions are similar, either one will suffice for our consideration of risk-based thinking for your organization.

History

In the 2015 version of the standard, **risk-based thinking has replaced Preventive Action** (2008 clause 8.5.3). Preventive Action was meant to have an organization look into their crystal ball and predict what could go wrong before it had actually ever happened. Preventive Action was all about assessing a level of uncertainty associated with an adverse outcome and deciding whether or not some pre-emptive action was required to prevent that outcome. When you compare this to the definitions of risk above, it becomes clear that **Preventive Action was a form of risk-based thinking** all along.

ISO 9001 clause requirements related to risk-based thinking include:

5.1.2 Top management shall demonstrate leadership and commitment with respect to customer focus by **ensuring that**:

> b.) **risks & opportunities** that can affect conformity of products/services and the ability to enhance customer satisfaction are **determined and addressed**

4.4 The organization shall determine the processes needed for the QMS and their application throughout the organization and **shall determine:**

> f.) the **risks and opportunities** in accordance with 6.1 and plan and **implement the appropriate actions to address them**

Different types of risk within an organization

Risk assessment is required by the top leadership levels of an organization (in clause 5.1.2) and at the lower levels of designing or identifying key business processes (in clause 4.4). Therefore, we can consider at least the following three types of risks:

1. Organization
2. Product
3. Process

Type 1: Organization/enterprise level risks
These are risks to the company's business and strategic purpose. Examples include:

Regulatory environment
Market/competitors risk
Financial, access to capital Risk

A SWOT (Strength-Weakness-Opportunities-Threats) analysis is a good tool for looking at high-level, **strategic** risks.

Strengths People love our products We have strong supplier partners Strong Marketing Division We have great managers, engineers	**Weaknesses** Manufacturing is inefficient High turnover in key positions Too long to introduce new products Weak distribution in Europe
Opportunities Purchase a competitor Increase sales in Europe and Asia Purchase new High Speed equipment Introduce the next generation product	**Threats** Gov't sales of new spectrum New lower EMI requirements Downward pressure on prices Market shift to touchscreen tech. Lack of credit to upgrade capacity

Simple brainstorming can result in filling in the SWOT matrix.

It's important to consider the above based on the type of business you are in (the organization and its context, and the needs of interested parties). Many SWOT factors may related to external issues.

Type 2: Product/service risk
These are risks associated with the product or service that the organization provides to customers. These risks can be seen in light of the **legal/ethical obligations** associated with the product, and **risks of consumer acceptance** in the marketplace

Examples include:

- inherent product safety, such as flammable petroleum products
- early Failures, reliability, such as with an automobile during its warranty period
- safe operation of the product, such as instructions for use of a power saw.
- risks that a product doesn't function in the way customers want
- risks that a product isn't ascetically pleasing or user-friendly

Some may think of up sides and down sides of the product or service.

Type 3: Operational process risk
These are risks association with the day-to-day operation of the business.

Examples include:

- absenteeism of key employees
- unavailability of important materials or information
- unexpected quality disruptions resulting in rework or remakes
- breakdown of key equipment
- lack of supplier capacity, or late deliveries

Every organization has its **own method of operating, its own bottlenecks and critical processes and equipment.** Think of the key operations that are vital to achievement of daily/weekly/monthly objectives. For example: Breakdown of equipment may not be important if there is redundancy but if 3 lines feed into one piece of equipment, online or run time is very important. Many issues may be related to internal operations.

Risk-based thinking application

First, it is important that risk-based thinking has to **begin with top management**.

- clause 5.1.2b – risks to products/services and customer satisfaction have to be determined and addressed.
- clause 9.3.2e – circle back via the management review to assess the effectiveness of actions taken to address risks and opportunities.

Second, it is important that risk-based thinking be **embedded in the processes**

- clause 4.4 – determine risks and opportunities at the process level as processes are defined and then take appropriate actions to address
- clause 6.1 – consider organizational context (vision and strategy) and the needs of stakeholders to identify risks to the business and mitigate them.

Third, we know that operational controls are appropriate when they are derived by and proportional to risk. Just as clause 6.1.2 states **actions to address risk must be proportionate to the potential impact** on conformity of products and services.

Assessing Risk

There are a number of ways to assess risk. If you are interested in a comprehensive list of over 30 risk assessment techniques, you can consult ISO 31010:2009.

For this course, we will review the application of popular qualitative and quantitative approaches.

Risk Assessment – Quantitative

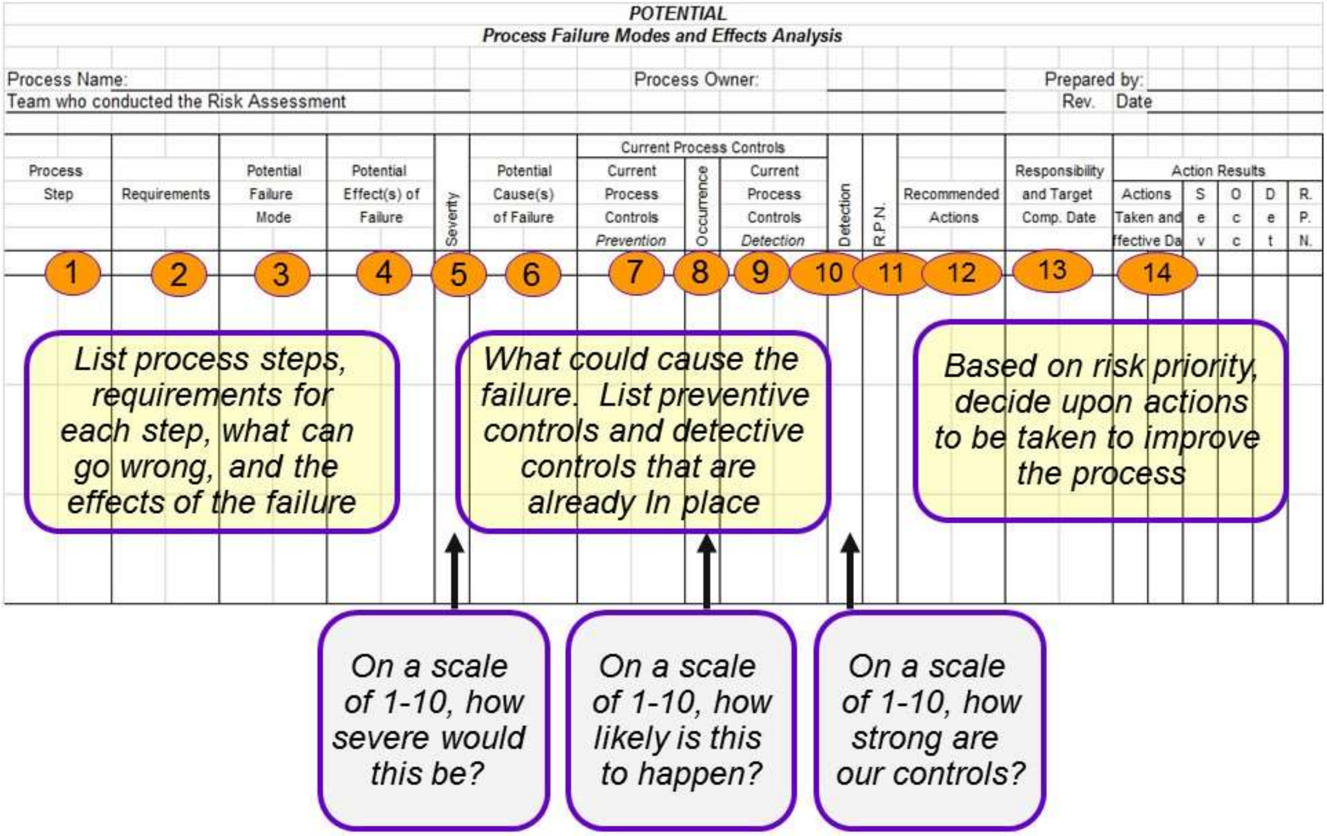
There are a number of methods to assessing risk quantitatively. In this class, we address two approaches:

- **Failure Modes and Effects Analysis** (FMEA) considers the “three dimensions” of risk, 1) severity, 2) probability of occurrence, and 3) effectiveness of detection, in order to quantitatively prioritize risks for attention. FMEA was originally used to evaluate the risks that products would not meet their design intent. For example, FMEAs were used with complex designs such as aircraft and automobiles. This tool however, can be used with any services and administrative processes.

- **Consequence/Probability Matrix** is a simpler approach, which requires less detail and considers only Probability and Severity.

Failure Modes & Effects Analysis

This is not an FMEA how-to class, but simply to show some of the tools that can be used for risk-based thinking. A person using FMEA tool assesses risk using a form. The form guides users through the process. Below is an example form showing the columns that must be completed by the individual user or team. Teaming up to complete FMEA assessments is recommended.



POTENTIAL
Process Failure Modes and Effects Analysis

Process Name:
Process Owner:
Prepared by:
Team who conducted the Risk Assessment
Rev.
Date

Process Step	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Current Process Controls Prevention	Occurrence	Current Process Controls Detection	Detection	R.P.N.	Recommended Actions	Responsibility and Target Comp. Date	Actions Taken and ffective Da	Sev	Occ	Det	R.P.N.
1	2	3	4	5	6	7	8	9	10	11	12	13	14				

List process steps, requirements for each step, what can go wrong, and the effects of the failure

What could cause the failure. List preventive controls and detective controls that are already In place

Based on risk priority, decide upon actions to be taken to improve the process

On a scale of 1-10, how severe would this be?

On a scale of 1-10, how likely is this to happen?

On a scale of 1-10, how strong are our controls?

The form can be completed for a process or product/service. You can read left to right the steps taken to complete the form and address the risks. The approach is:

- determine **severity** - Steps 1-5
- determine **occurrence** - steps 6-8
- determine **detection** - steps 9-10
- risk level (**RPN**) - step 11
- **actions** to address risk- steps 12-14

An organization may consider creating an **FMEA for every process identified** in your quality management system. Processes will be defined in accordance with Clause 4.4 of ISO 9001:2015. Flow charts are the preferred approach.

An FMEA can be completed individually but perhaps most effectively accomplished with a small team. **Convene a small team** of those involved in the process, along with a customer and supplier of that process. List their names on FMEA and begin the analysis

The following briefly describes what belongs in each column of the FMEA. If you are unfamiliar with FMEA, please read through each step to better understand the process. If interested, formal FMEA courses are available, such as FMEA for Beginners.

1. Enter the name of the process step from the flow chart.

2. Describe the essential requirement(s) or purpose(s) of that step.

3. List those things that could happen (failure modes) to cause each requirement to not be met. Brainstorm failure modes – those things which could go wrong at that step in the process.

4. If the failure mode were to occur, describe the effect of the failure on the process and its customers. Consider both internal customers (the next process) and external customers.

5. On a scale of 1 to 10, **decide how severe** the failure mode would be. Ratings of 9-10 are typically reserved for risk to safety or life. Ratings of 6-8 describes a total failure of that process step. Scale ratings of 4-5 describes poor execution of the process step. Ratings of 2-3 is a nuisance, and 1 means there is no impact.

6. Describe what could cause the failure mode.

7. List what current controls are already in place in the process to prevent the cause which was identified in column 6.

8. On a scale of 1 to 10, **decide how likely the failure is to occur**. Consider the net effect of the cause of the failure and any offsetting preventive controls. Ratings of 9-10 means the failure is very frequent and could occur every day. Ratings of 6-8 means that the failure occurs once per week to once per month. Ratings of 4-5 means failure every two to 6 months. Scale ratings of 2-3 is a failure few times per year, and 1 means the preventive controls are so effective, that the failure mode can never occur.

9. Would we notice if the failure occurred before it was “too late?” Describe the process controls that would ensure we noticed the failure before it resulted in an adverse outcome for the customer.

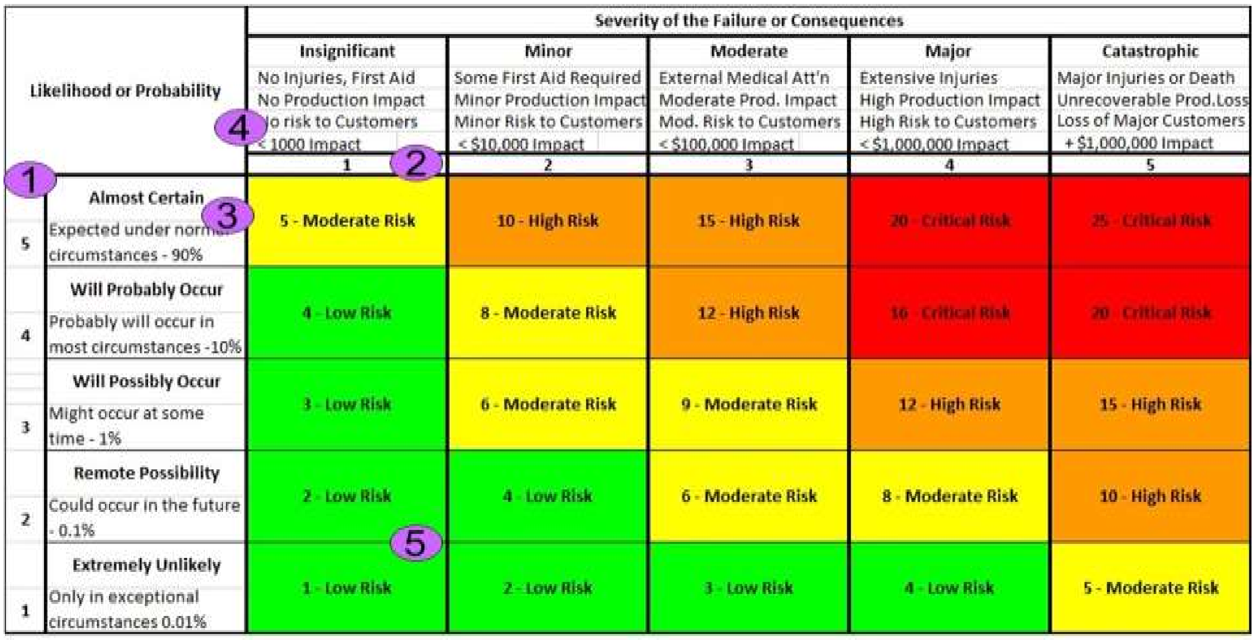
10. On a scale of 1 to 10, **decide the quality of our detection control**. Ratings of 9-10 means we would never notice the failure if it occurred. Ratings 6-8 means there is a very low probability we would notice and stop the failure. A rating of 4-5 describes a moderate chance that we would notice. Scale ratings of 2-3 is a very high chance of detecting the failure, and 1 means the nature of the failure is such that it could never escape detection.

11. RPN stands for Risk Priority Number. Multiply the three S (5)-O (8)-D (10) values together. For Example, 5 x 4 x 2 = 40. Once all of the risks are assessed and RPN numbers derived, **review the highest RPNs** (highest risk priorities) and assess the need for improvement actions.

12. As a team, **decide what recommended actions** to take to reduce the highest Risk Priority Number.

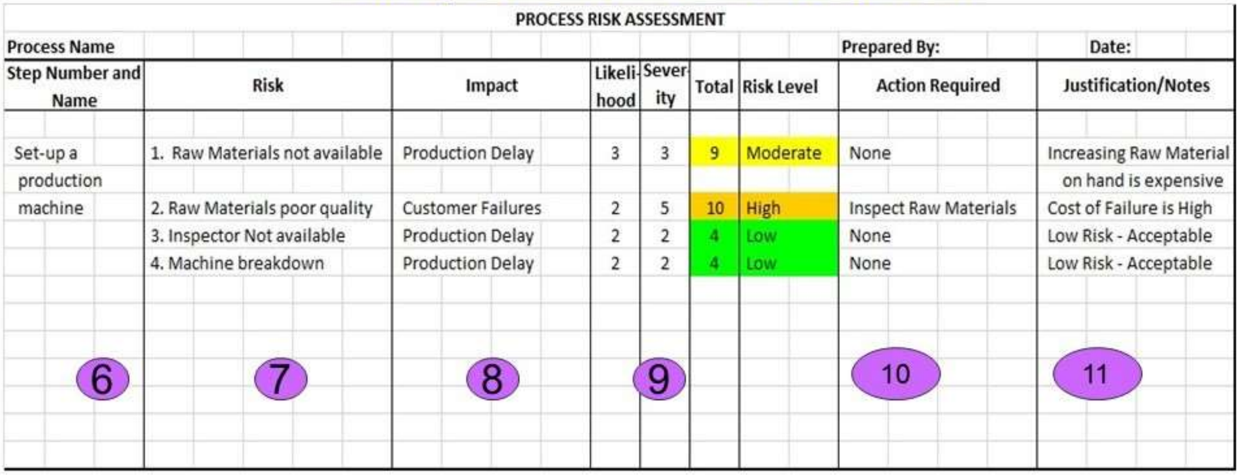
13. Assign responsibilities & due dates for each item.

14. After all actions are completed, list what was actually done, and then go back to recalculate S, O, D, and the new Risk Priority Number based on the process improvements that were made.



Likelihood or Probability		Severity of the Failure or Consequences				
		Insignificant No Injuries, First Aid No Production Impact No risk to Customers < 1000 Impact	Minor Some First Aid Required Minor Production Impact Minor Risk to Customers < $10,000 Impact	Moderate External Medical Att'n Moderate Prod. Impact Mod. Risk to Customers < $100,000 Impact	Major Extensive Injuries High Production Impact High Risk to Customers < $1,000,000 Impact	Catastrophic Major Injuries or Death Unrecoverable Prod.Loss Loss of Major Customers + $1,000,000 Impact
		1	2	3	4	5
5	Almost Certain Expected under normal circumstances - 90%	5 - Moderate Risk	10 - High Risk	15 - High Risk	20 - Critical Risk	25 - Critical Risk
4	Will Probably Occur Probably will occur in most circumstances -10%	4 - Low Risk	8 - Moderate Risk	12 - High Risk	16 - Critical Risk	20 - Critical Risk
3	Will Possibly Occur Might occur at some time - 1%	3 - Low Risk	6 - Moderate Risk	9 - Moderate Risk	12 - High Risk	15 - High Risk
2	Remote Possibility Could occur in the future - 0.1%	2 - Low Risk	4 - Low Risk	6 - Moderate Risk	8 - Moderate Risk	10 - High Risk
1	Extremely Unlikely Only in exceptional circumstances 0.01%	1 - Low Risk	2 - Low Risk	3 - Low Risk	4 - Low Risk	5 - Moderate Risk

Consequence Criteria Table - Worksheet



PROCESS RISK ASSESSMENT

Process Name							Prepared By:	Date:
Step Number and Name	Risk	Impact	Likelihood	Severity	Total	Risk Level	Action Required	Justification/Notes
Set-up a production machine	1. Raw Materials not available	Production Delay	3	3	9	Moderate	None	Increasing Raw Material on hand is expensive
	2. Raw Materials poor quality	Customer Failures	2	5	10	High	Inspect Raw Materials	Cost of Failure is High
	3. Inspector Not available	Production Delay	2	2	4	Low	None	Low Risk - Acceptable
	4. Machine breakdown	Production Delay	2	2	4	Low	None	Low Risk - Acceptable

Break time

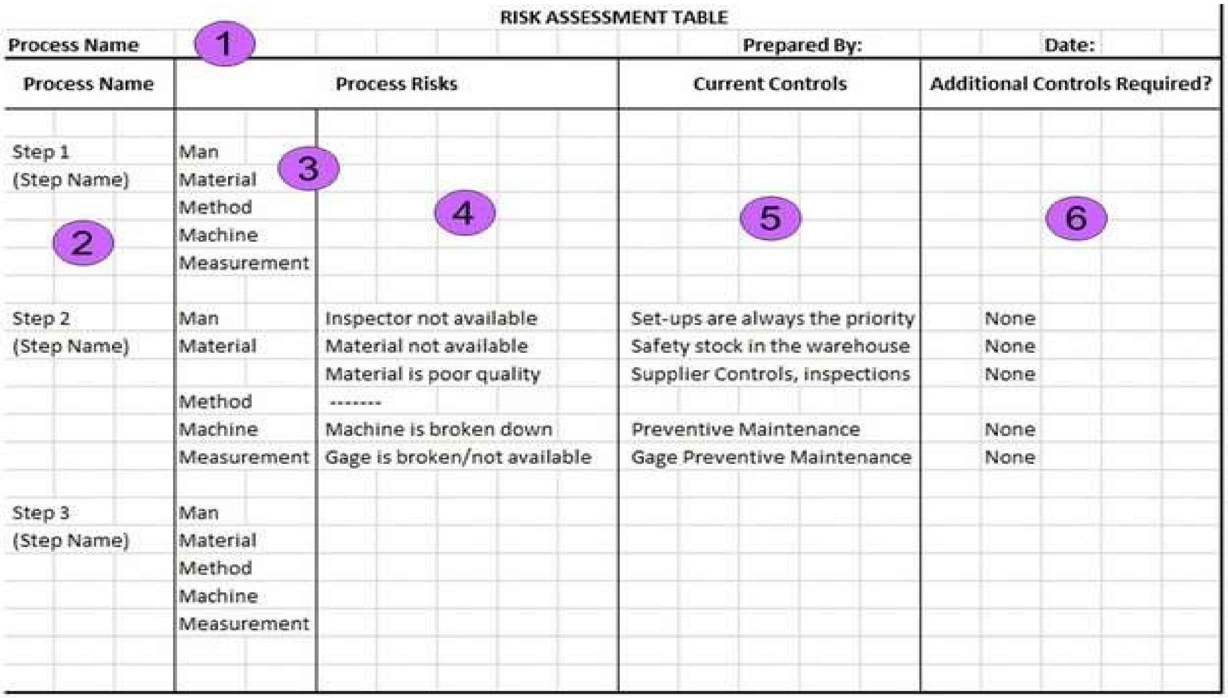
Before we view the qualitative tool for assessing risk, perhaps we can pause for a moment. **Assessment of identified risks is very important** in the decision process. The tools we are discussing are common tools you may observe/expect as a manager or auditor. However, **risk-based thinking is about the thinking**, not the forms or process for evaluating risks.

Risk-based thinking is an everyday mindset. It is taking time to assess your plans (your moves) to achieve your goals or objective. If you are running late for your dinner reservation, do you plan to exceed the speed limit to be on time or mitigate the risk by calling ahead that you will be late or change restaurants. Risk-based thinking is every day, but there are times when **formal assessment is required to best achieve your goals.**

Risk Assessment - Qualitative

Unlike the quantitative approach, which uses a numerical ranking to determine risk levels, a **qualitative approach is based more on "gut feel"** and does not follow a scoring guideline for determining where risk mitigation is required. Here, we present a "Risk Assessment Table" as a way of capturing the thoughts and decisions of the group performing the assessment.

This is the simplest approach, but the lack of numerical rankings to guide decision making can result in high inconsistency between groups performing the risk assessments.

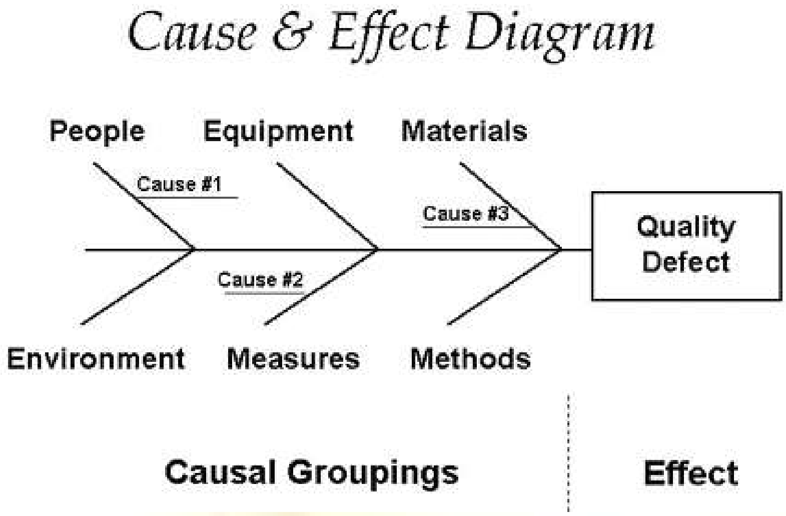


RISK ASSESSMENT TABLE

Process Name | Prepared By: | Date:

Process Name	Process Risks		Current Controls	Additional Controls Required?
Step 1 (Step Name)	Man Material Method Machine Measurement			
Step 2 (Step Name)	Man	Inspector not available	Set-ups are always the priority	None
	Material	Material not available	Safety stock in the warehouse	None
		Material is poor quality	Supplier Controls, inspections	None
	Method	-------		
	Machine	Machine is broken down	Preventive Maintenance	None
	Measurement	Gage is broken/not available	Gage Preventive Maintenance	None
Step 3 (Step Name)	Man Material Method Machine Measurement			

Examples of Operational Risks (Organized by the “5Ms & E” of the Ishikawa Diagram)



The CE diagram (Ishikawa) has been used to describe processes and causes of problems such as quality defects. In this case, we will use the causal groupings to identify risks and their impact on the Risk Assessment Table.

Summary and Conclusion

***Risk-based Thinking* is the single biggest breakthrough** in quality systems thinking since the *Process Approach* in 2000. This is because many organizations considered fulfilling the requirements of ISO 9001:2008 as a sufficient level of control and evidence that it had an effective quality management system. The fact is, ISO 9001 always awarded a great deal of discretion to organizations to define its own quality controls and determine the levels of those controls. It’s risk-based thinking that determines which discretionary controls are required and the appropriate level of those controls.

Risks should also be considered at different levels of the organization. There are risks at the organization/enterprise level, such as acquiring customers and suitable technology; but there are also risks at the process execution level, such as how to inspect a product or to cover for key employees when they are busy or absent. The **honest and diligent application of risk-based thinking at the process level will truly make the difference** between a moderate and highly effective quality management system.

Once the organization understands the context of the organization, and the needs and expectations of stakeholders, it can begin to consider what risks get in the way of achieving the organization’s strategic mission and fulfilling those stakeholder needs that are essential for its success. There are **many tools and techniques that can help guide an organization**. The two quantitative approaches introduced here, FMEA and the Consequence/Probability Matrix, along with the qualitative risk matrix to support brainstorming, are examples. Of course, there are many other examples of risk assessment tools and techniques, and you are encouraged to consult ISO 31010:2009 for more information.