ISO 9001:2015 Overview, Introduction and Clauses 0.0 to 3.0

[This short lesson discusses the pre-matter in the standard such as the introduction comments and the scope.]

Learning Objectives:

Managers and auditors will be able to:

- recognize the 10-clause high level structure (HLS) and the benefits to the users
- explain the benefits to users
- list the management system principles and the changes
- grasp how the process approach and the Plan-Do-Check-Act (PDCA), cycle are connected
- identify notable word additions in ISO 9000:2015 Quality management system – Fundamentals and vocabulary

Synopsis: (note clause numbers are in parentheses)

The ISO 9001:2015 standard has most of the same requirements as the ISO 9001:2008 version. Many of the requirements in ISO 9001:2008 have been **reworded and are less prescriptive**. This gives organizations seeking certification more flexibility and is meant to be more valuable in supporting the goals and objectives of the organization. The major additional requirements include: defining the organization's context (4.1); understanding interested parties' expectations (4.2); determining risks and opportunities (6.1); determining organizational knowledge (7.1.6); and controlling all of the organization's inputs (8.4). Some new terms such as documented information have been introduced.

The ISO 9001:2015 Quality Management System Standard follows universal high level structure and common text from a document called Annex SL. It has 10 clauses and contains text common to all Management System Standards (such as, ISO 14001 etc.).

The review format for this class is to present the requirements and rationale supported by explanation, discussion and examples. **New requirements and important points are marked with bold text**. A checklist has been provided (see Class Links) that you can use to make notes and later use to conduct an audit or to implement the new requirements.

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ISO 9001 High Level Structure (HLS)

ISO 9001:2015 has 10 clauses. The 10 clauses represent the common HLS for all management system standards. **Clauses 4-10 contain "shall" requirements.**

- 1. Scope (i.e. area or boundaries)
- 2. Normative references (i.e. necessary additional documents)
- 3. Terms and definitions
- 4. Context of the organization (i.e. an organizational profile)
- 5. Leadership
- 6. Planning
- 7. Support
- 8. Operation
- 9. Performance evaluation
- 10. Improvement

Annex A (Clarification of new structure, terminology and concepts) Annex B (Other quality related standards) Bibliography

There was no particular plan regarding how the 10 clauses were organized, but it still **follows the PDCA cycle.** Some sub-clauses of the HLS are required while others are added by individual ISO groups that are developing a standard. Typically, clause 8 is very specific to the area covered by the standard such as quality (ISO 9001), business continuity (ISO 27001), and environmental management (ISO 14001).

As a model, it could resemble the figure on the next page showing the quality management system (QMS) processes.

ISO 9001 High Level Structure (HLS) -Continued



As a model, it could resemble the figure below showing the quality management system (QMS) processes.

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

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ISO 9001 High Level Structure (HLS) -*Continued*



Compared to quality award criteria

The QMS structure is new, but resembles other national quality award structures such as the American Malcolm Baldrige National Quality Award (MBNQA).

ISO 9001:2015 QMS Clause Titles	MBNQA Criteria for performance excellence
4.1 Organization and its context	Organization profile
• 5 Leadership	Leadership
5.1.2 Customer focus	Customer focus
• 6 Planning	Strategic planning
• 7.1 Resources	Workforce focus
• 8 Operation	Operation focus
9 Performance evaluation	Measurement, analysis and knowledge management
• 10 Improvement	• Results

The criteria for ISO 9001:2015 and the MBNQA share many common

elements. Some of the common criteria are: organization profile/context; leadership; planning; customer focus; measurement analysis and knowledge management; operational focus; and results. The MBNQA criteria claims to be less structured and very flexible, but many notes have been added to the criteria to provide additional guidance. The ISO 9001 Quality Management System (QMS) is structured and perhaps provides a more systematic and guided approach to improving performance and meeting objectives.

The performance focus for ISO 9001:2015 goes beyond improving the

effectiveness of the QMS. Improvement actions are still limited to the scope of the QMS, but meeting organizational objectives relative to the QMS elements is included. This means that it is okay for an organization to have an objective to improve the QMS efficiency, such reducing defects, but perhaps not improving the efficiency of accounting department reporting, if that accounting process is not part of the QMS scope.

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ISO 9001 Common Text



Auditing clauses 4, 5, 6, 7, 9 and 10 will be the same or similar for all management system standards. The **clauses contain common text** from a document titled Annex SL. (See explanation below) The intent is for all management system standards to contain the same common text for similar clauses such as document control, corrective action, control of resources, and so on. The common text and high level structure will make it **easier to audit and implement** various management systems such as quality, safety and environmental. Like cupcakes, audit clauses have the same structure and some common ingredients, but can vary in details.

Auditors and managers should note, the different management system standards will **contain the same common text**, **but the individual standard groups** such as quality or environmental **were allowed to add text**. The added text may provide an explanation or provide additional requirements.

Sidebar: Annex SL common structure and text Annex SL is controlled by a high level International Organization for Standardization committee. The annex is available to the public, but submerged in an ISO directive (ISO/IEC Directive, Part 1 Consolidated ISO Supplement). Annex SL provides the basis for a generic management system by providing guidance for high level structure and common text. The objective was to make implementing multiple management system standards much easier and eliminate redundancy.

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ISO 9001 Standard Introduction



The ISO 9001 introduction includes explanations, but no requirements to be audited against. In this class, we will provide a brief outline of the introduction since it does not contain requirements. However, the introduction is educational and we recommend that you read and study its content.

0.1 General

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 that need to be addressed (new)
- the ability of the organization to demonstrate conformity to specified quality management system requirements by QMS certification or 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.

Though the standard does not list the high level structure and common text as a benefit in clause 0.1, it 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

The 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 assure customer requirements are met. These include: process approach, risk-based thinking, PDCA and more flexible open-ended requirements. This has caused some descent in some of the compliance sectors that favor more prescriptive verifiable controls.

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0.2 Quality management principles



This international standard is based on the quality management principles described in ISO 9000:2015. The quality management principles have been modified to better align with an organization's needs. 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.

The quality management principles for a quality management system (QMS) are:



- 1. customer focus
- 2. leadership
- 3. engagement of people
- 4. process approach
- 5. improvement
- 6. evidence-based decision making
- 7. relationship management

The main changes to the quality management principles are:

- involvement of people is now "engagement of people." The concept has not changed.
- the system approach (previously # 5) has been combined with process approach. The concept has not changed.
- improvement has replaced "continual improvement" in that all kinds of improvement are essential to maintain organizational performance. The concept has not changed.
- evidence based decision making replaced factual approach to decision making. The statement is stronger and more focused. The concept has not changed.
- relationship management has replaced mutually beneficial supplier relationships. The principle is much broader to include all interested parties and is more comprehensive.

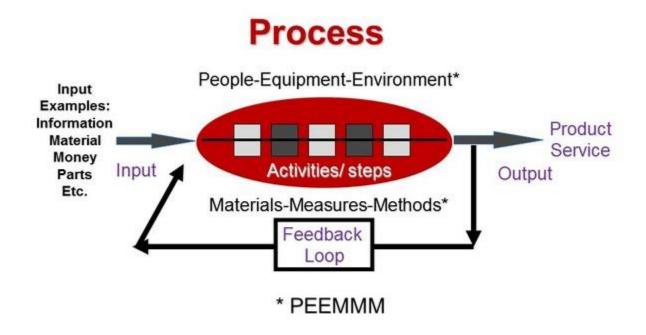
The ISO 9001 standard embodies the quality management principles.

0.3 Process approach



0.3.1 General

The **process approach enables organizations to control the interactions** among the processes of their system, so intended results can be achieved in accordance with the quality policy and strategic direction of the organization.



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 quality management system 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 that are 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 quality management system fulfill its promise of true quality management.**

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

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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 quality management system. Does one know that their system is suitable and effective simply because it meets the requirements of ISO 9001? That may be one measure 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 quality management system 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? It is only by understanding what risks exist in processes (manufacturing or service) that an organization can 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 short cut to your destination.

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0.4 Relationship with other management system standards

Annex B provides details of International Standards on quality management and quality management systems 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.

There can be two types of management system standards. There are **requirement standards**, such as ISO 9001 and ISO 14001, that use the word shall to indicate requirements that can be audited against for certification purposes. Most other standards are **guideline standards**, such as ISO 9004 and ISO 19001, that use the word should or may to indicate guidance for users of the standard.

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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 applies 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.

Sidebar: 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. If interested, click here for the discussion.

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**.

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3 Terms and definitions



The ISO 9000:2015 has approximately 62 new word definitions compared to the 2005 version. The design of this class includes hyperlinks to the definitions of words as needed to explain requirements of the quality management international standard. You don't need the ISO 9000 standard for this class but it is recommend for users.

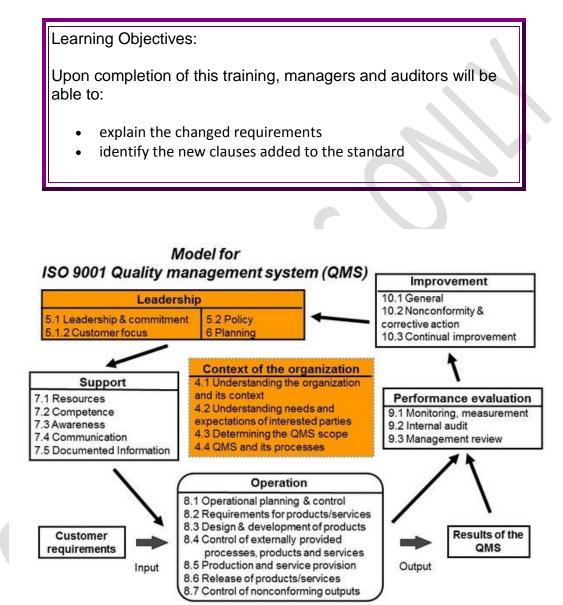
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Congratulations!

System and Leadership Requirements, Clauses 4-6

[This medium length lesson discusses the overall management system and leadership 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. These clauses include new requirements for understanding the context of the organization, establishing links to interested parties, demonstrating leadership, and identification of risks and opportunities.

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 marked with bold** text. A checklist has been provided (see Class Links) that you can use to make notes and later use to conduct an audit or to implement the new requirements.

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4.0 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 to use to address both external and external factors. Another common term for this is a profile, as in determine the organization's 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 their phones to business people, teenagers?
- Is 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 quality management system suitable for its purpose.

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4.1 Understanding the organization and its contextcontinued

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, economics at all levels
- company values, culture, knowledge, performance

4.1 Understanding the organization and its contextcontinued

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

Important issue	Who would	What information could be
	monitor	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 council 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/succession planning, progression through "job grades"
Changes in regulations/codes	Risk & Quality Department	Control of external documents from regulators, Monitor sector news

Monitoring important issues

4.1 Understanding the organization and its contextcontinued

4.1 Explanation and discussion

Stakeholders (an interested party) are those that influence the organization's work. The organization is already in contact with these stakeholders such as:

Possible Stakeholders		
Regulators	Trade/professional associations	
Government agencies	Property owners	
Trade unions	Sponsors	
Board of directors	Business partners	
Investors	Lenders/banks	

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 the 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.

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.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

Okay, now organizations must name interested parties and monitor them. How many do they need to monitor?

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4.2 Explanation and discussion

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

- the 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
- the organization could also voluntarily subscribe to policies of social responsibility, codes of ethics, anti-bribery, and 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 them. An environmental group might be interested in the conduct of an oil company, but that oil company is not bound to meet the needs of that particular interested party.

4.3 Determining the scope of the quality management system (2008 version 4.1-General requirements)

Most of the requirements in this clause are similar to clause 4.1 of the 2008 version. The requirements are more descriptive (open-ended) versus prescriptive (closed 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, 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: manufacture, storage, safeguarding, delivery, maintenance, warranty, disposal, replacement; service: performance or delivery, products used, repeating service, qualification-certification, and so on.*)

There is no requirement for a record or retained documented information (DI) that a, b, and c were considered. 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, they **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 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 entire clauses that may be applicable or not applicable. Therefore any particular requirement within a clause could be not 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.

Remember there are more details in the checklist found in Class Links.

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4.4 Quality management system and its processes (2008 version 4.1-General requirements)



4.4.1

ISO 9001:2015 places a 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 for the QMS and their application throughout the organization. **The organization must (new requirements in bold):**

 $\boldsymbol{a})$ determine the inputs required and the outputs expected from these processes

b) determine the sequence and interaction 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 quality management system

The requirement to assign responsibilities and authorities for each process is a good addition to the new standard and is an auditable requirement. Now 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 will be verified during the audit.

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

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4.4.2 (2008 version 4.2.1d General requirements)



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

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 to verify outputs. © 2015 QualityWBT Center for Education, LLC ISO 9001 allows documented information to be in any medium or format. This includes paper, electronic documents and records on computer servers, hyper-text, etc.

The requirements are similar to the 2008 version except the requirements are openended. 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 vs Retained

There is no requirement for an organization to change its terminology from documents and records to documented information (DI). In fact, world organizations, governments and legal systems understand what it means to have a record but would not understand what retained DI means.

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5 Leadership (2008 version 5 Management Responsibility)



There is increased emphasis on leadership (new requirements in bolded text). The changes are at a high level, somewhat conceptual. Many of the leadership requirements can only be verified as part of an audit going from area to area.

The 2015 version goes beyond management commitment by requiring top management to demonstrate their leadership.

5.1.1 General

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

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

Reference to "business" in this ISO 9001:2015 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 to verify they have demonstrated leadership. According to Bloom's Revised 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.

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5.1.1 General - Continued



Some of the **key issues** are that b) the QMS be compatible with the organization's **strategic direction** and c) the **integration of QMS requirements** 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 measures (**metrics**) to assess achievement of objectives.

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 demonstrate their 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 this same clause requirements (a-j) during interviews.

Sidebar: One dimensional QMS

For example an auditor may observe that corrective actions are constantly delayed. This may mean that quality and the QMS are not a priority for top management.

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5.1.2 Customer focus (2008 5.2 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 an auditor goes 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. © 2015 QualityWBT Center for Education, LLC **Sidebar: Quality?** Quality for the customer is getting what you were expecting. Quality for the supplier is getting it right the first time. Quality Master Plan

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5.2 Policy (2008 5.3 Quality Policy)



The real change in this clause is that 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, but now the requirement is that the policy be available to stakeholders outside the organization as well.

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.

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 the organization's website.

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5.3 Organizational roles, responsibilities and authorities (2008: 5.5-Responsibility, authority and communication and 2008: 5.5.1-Responsibility and authority)

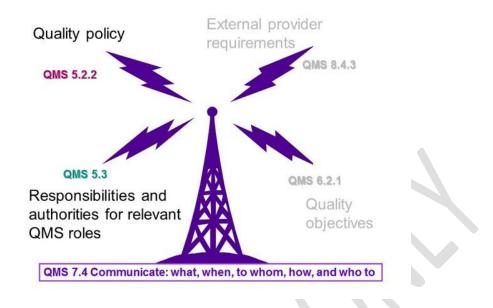
There is no clause titled management representative in the 2015 version, and the phrase "appoint a member of the organization's management" is no longer part of the clause. And, yes, there may be people responsible for elements of the QMS who are not a part of the organization's management. An example is a quality technician who is responsible for the calibration process.

Even though there is no management representative requirement, organizations do not need to change personnel titles. Although the term management representative no longer appears in the standard, the past responsibilities of that role remain, and can be distributed to anyone in the organization as they see fit. There could be an issue of no one taking overall ownership of the QMS and management of the QMS being disjointed and disorganized. This could relate to effective 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 requirements of this ISO 9001:2015 b) ensure the processes are delivering their intended outputs

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

Clause 5 includes 2 of the 5 citations in the standard to **communicate**. Auditors and managers need to **ensure there is communication and know the means** (clause 7.4).



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6.1 Actions to address risks and opportunities (2008: 5.4.2--Quality management system planning; 8.5.3-Preventive action)

6.1.1

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

This is new and replaces preventive action. The preventive action clause 8.5.3 in ISO 9001:2008 required organizations to determine potential nonconformities and their causes and evaluate the need for action to prevent those occurrences. In fact, this was essentially risk assessment. The organization needs to determine or identify risks and opportunities, assess their significance and take corresponding action relative to their importance (6.1.2). The 2008 version required organizations to analyze data in 8.4 and 8.5.1. Therefore, an organization may already meet many of the requirements and only ensure the more prescriptive requirements (above) are addressed. But also understand that per the requirements of Clause 4.4 f) above, risks must be addressed within business processes. There is no requirement to have a formal risk management program.

Risk-based thinking will be addressed in the Risk-based Thinking lesson.

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6.1.2 The organization shall plan (2008: 8.5.3-Preventive action)

The organization must plan actions to address risks and opportunities.

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

Opportunities can lead to improving effectiveness or efficiency, launching new products or services, opening new markets, adding new clients/customers, 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. The organization can evaluate the effectiveness of actions taken through monitoring and measurement, internal audit and management review.

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6.1.2 The organization shall plan - Continued

There is no requirement for formal risk assessment (ISO 31000 etc.) 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 have some kind of matrix ranking 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 not to quote a job that contains unfamiliar requirements or no longer offer the product or service.

Accept the risk

- Accepting a risk in order to pursue an opportunity 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 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– At a blackjack table, the consequences of losing can be reduced by making smaller bets.
- Sharing the risk– Purchasing insurance is an example, as another party is taking on some of your risk. Outsourcing product manufacturing or service delivery can also be a strategy for sharing risk.

The 2008 version preventive action clause requiring a documented procedure has been deleted in the 2015 version. However many of the actions and steps in 6.1.2 are the same as in 2008: clause 8.5.3 Preventive Action.

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6.2 Quality objectives and planning to achieve them (2008: 5.4.1?Quality objectives)



6.2.1 (no title)

The standard states the quality objectives must be (new requirements in bold text):

- a) consistent with the quality policy
- b) measurable
- c) able to take into account applicable requirements
- d) relevant to conformity of products and services and to enhance customer satisfaction
- e) monitored
- f) communicated
- g) updated as appropriate

There are new requirements for this clause, but most organizations are already doing most of what is required. 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 their objectives drift into other areas of importance at the expense of quality Also, 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 to 7.5 for documented information requirements.

Sidebar: Appendix A1 of ISO 9001:2015

Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition 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, Measureable, Accountable, Realistic, Timeframe. . Goals may be: S – Specific (let's reduce scrap on one specific production line) M – Measureable (we would like to reduce that scrap by 10%)

A - Accountable (Define who is responsible to achieve this scrap reduction)

R – Realistic (10% scrap reduction is realistic, 90% might not be)
 T – Timeframe (we would like to achieve this goal by December 31st)

6.2 Quality objectives and planning to achieve them - *continued*

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 new requirements here (a-e) are similar to any project plan. It makes sense.

6.3 Planning of changes (2008: 5.4.2?Quality management system planning)

Where the organization determines the need for change to the QMS (see 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

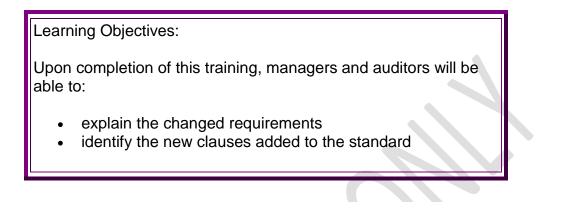
Plan what you do and do what you plan. This is just good business. The organization will need to provide evidence to demonstrate they are meeting this requirement.

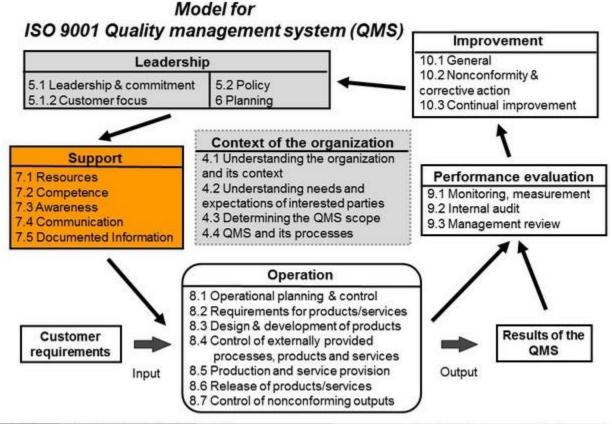


Congratulations!

Support Requirements, Clause 7

[This medium length lesson discusses the overall management system and leadership requirements. At the end is test you must pass to continue.]





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

Synopsis:

Clause 7 is the system support requirements. **Most of the requirements are similar to the ISO 9001:2008 except they have been reworded and are more 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 records control.** Most of the DI requirements are similar to the ISO 9001:2008 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 marked with bold** text. A checklist has been provided (see Class Links) that you can use to make notes and later use to conduct an audit or to implement the new requirements.

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7 Support



7.1 Resources

7.1.1 General (2008 6.1 Provision of resources)

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 resourcesb) what needs to be obtained from external providers

Exercise:

If you were to go camping in your motor home, what would be your internal and external resource needs? Assume you own a fully equipped camper.

The very **important point of this exercise is that you have choices. Based on economics, strengths, weaknesses, opportunities and risks,** you must make choices when considering the resources you will need for a project or process or new venture. Do you drive the camper or hire someone to do it? Do you use your extra propane tank hooked to your grill or purchase a new one or risk running out of propane until you can get it refilled on the road. Are the coolers you own the right size or do you need new coolers for the trip. If you must hire a chauffeur, the venture may be too costly.

The new 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 seek external resources for hire or rent. The decision will be based on the nature of the need such as being short or long-term, the risks associated with outsourcing or remaining inhouse, the level of internal knowledge/competencies, etc.

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7.1.1 General - continued



There is no requirement for a plan or a record or any kind of Documented Information. An **auditor may ask the auditee how they go about considering the resource needs and review any available documentation.** For an auditor, a place to start is when a change has occurred or a new project requiring resources was 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 (external provider controls), 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 or doing it internally? Does the organization need certain components or parts to be supplied externally?

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

- time,
- capital,
- information,
- personnel,

- facilities,
- equipment,
- knowledge and skills

7.1.2 People (2008: 6.2 Human resources)

Either no change or very minor changes

7.1.3 Infrastructure (2008: 6.3 Infrastructure)

Either no change or very minor changes.

7.1.4 Environment for the operation of processes (2008: 6.4

Work environment)

Either no change or very minor changes.

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7.1.5 Monitoring and measuring resources(2008: 7.6 Control of monitoring and measuring equipment)



There is **change in terminology** in this clause. Over the last two versions we have switched from **equipment to devices and now measurement resources.** Measurement resources is all inclusive and will include things like capturing guest comments.

One potential concern is the **removal/deletion of the software verification/confirmation clause**. One could assume it is implicit in the existing requirements, but it could be overlooked by an auditor or management.

If software controls (user and machine) are not addressed by an organization, it could pose a large risk. Software is an integral part of our processes in today's world. Software support and development may be 10% or more of personnel resources and perhaps more of the budget. Many machines and devices are dependent on software. The 2008 version stated: "When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall © 2015 QualityWBT Center for Education, LLC be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary."

The 2008 note states: "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."

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7.1.6 Organizational knowledge

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

The knowledge shall 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; gained by experience; and 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, etc.
- external sources, such as standards, academia, conferences, external consultants/trainers, etc.

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 learning from 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:

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

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7.1.6 Explanation and discussioncontinued

Remember our camper example, in that case we would need to determine which knowledge would be required to achieve a successful family vacation in the Rocky Mountains. Examples include:

- how to drive a large vehicle, and navigate using only side mirrors
- how to shift gears and drive in mountainous terrain
- how to maintain and empty the sanitation system
- how to use a propane-powered refrigerator
- how to purge the water system and stow it for the return trip

Which members of the family would need to have this knowledge? Should only mom or dad know how to do these things, or would it be important for the children to have some of this knowledge too?

During the development of ISO 9001:2015, the **need** and application for this clause (7.1.6 Organizational knowledge) in a QMS was discussed at considerable length. If an organization is successfully operating today, having the necessary knowledge already exists. The emphasis should be on learning from mistakes/successes and gathering knowledge maintained by employees as experience. What is the cost of reinventing the

wheel and/or employees leaving the organization with valuable experience? This is an opportunity to apply risk-based thinking.

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7.2 Competence (2008: 6.2.1 General; 6.2.2 Competence, training and awareness)

The only minor change is an organization must **retain DI (keep records) of competence** compared to specific records of training, education and experience. Job descriptions may include competency needs for each position/job. An auditor can follow up by asking to be shown the records of evidence of competence for select positions such as inspector, quality manager, purchasing manager, and auditor.

Training and competency may be accomplished as two steps. First, a person is trained, and then after a period of time on the job, the person is assessed for competency. This is an **evaluation of how well they were able to apply what they learned from their training.** Competency can be assessed directly, by observing the person or indirectly, by review of their output and performance results. Competency can be judged by someone that is considered an authority on the subject. An authority may be the person who originally performed the training, or by someone else, such as a quality inspector or department leader. **Records should show the basis by which they were deemed competent** and who conducted the assessment.

Sidebar: Know it, teach it

Note that some trainers are not experts of the subject matter but can teach, and there are subject matter experts that are not good teachers.

7.3 Awareness (2008: 6.2.2d Competence, training and awareness)

There are no substantive requirement changes in this clause. However, this clause has a great list of issues an auditor should ask during interviews. (see checklist).

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7.4 Communication (2008: 5.5.3 Internal 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

7.4 Explanation and Discussion

- 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 must be clear and understandable and adapted for its intended people. Assess the effectiveness of the QMS through the management review and customer feedback, and communicate those results.
- Plant-wide meetings and bulletin boards to communicate key performance indicators may be considered.

The requirement for **external communication in a quality management system 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, Greenpeace, etc.
- In the event of a product recall, there would need to be a plan in place to understand the regulatory requirements for reporting, and which bodies would

need to be notified. A communication strategy should be in place to govern what announcement would be put on the company website, and who would contact the local news media, etc.

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

This might be new for most organizations on the ISO 9001 side.

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7.5 Documented information (DI)

7.5.1 General (2008: 4.2.1 c and d, General)

The only required DI to be maintained in the ISO 9001:2015 standard 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 (4.4.2a).** The standard requires retained DI at least 19 specific times. The organization is responsible for determining of DI that **must retained to have confidence the processes are carried out as planned (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.

7.5.2 Creating and updating (2008: 4.2.3 Control of documents and 4.2.4 Control of records)

The phrase "creating and updating" is more descriptive than control of documents and records. The idea of combining documents and records control can seem awkward. However, it is important to consider each specific requirement. The standard uses the term "appropriate." This is a very open-ended requirement and gives the organization plenty of flexibility.

An organization must that ensure appropriate identification, description, **format**, **media**, review and approval are maintained. Such requirements are very generic. DI

could be in the form of a procedure, a manual or a 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: Approval of documents for adequacy prior to release is not required. Now DI must be appropriately reviewed and approved for **suitability** and adequacy.

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7.5.3 Control of documented information (2008: 4.2.3 Control of documents and 4.2.4 Control of records)



7.5.3.1 (no title)

Unlike with the 2008 version, the new standard does not require a documented procedure for control of documents and records. From a control standpoint, some kind of plan is required (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. However, for most organizations the situation will be more complicated and require a formal plan (procedure, flowchart, checklist, etc.).

DI required by the QMS and by ISO 9001:2015 must be controlled to ensure they are:

a) available (when and where they are needed) and suitable for their use,

b) **adequately protected** (example, from loss of confidentiality, improper use or loss of integrity)

The requirement to adequately protect documented information has been added and is appropriate 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).

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7.5.3 Control of documented information *-continued*



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.
- b) storage and preservation, including preservation of legibility.
- c) control of changes (for example, version control).
- d) retention and disposition.

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

Most of the requirements in this section come from the ISO 9001:2008 clauses for document and records control. Historically, most of the requirements such as retention and disposition applied to control of records. Now, the same requirements apply to maintained DI, such as procedures or other plans that need be controlled and maintained. An organization may apply all 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.

The ISO 9001:2015 added that DI of an external origin must be controlled. The 2008 version required the distribution be controlled. Dropping the word distribution requires the organization to address all aspects of external DI control.

DI retained as evidence of conformity shall be protected from unintended alterations.

The 2008 version required records to be protected, but did not specify from what they should be protected (such as unintended alterations). This requirement was specifically added to the 2015 version of the standard to clarify records control issues. The purpose was to ensure organizations don't misinterpret clause 7.5.2, Creating and updating, to mean that records can be modified. Records should never be changed, only corrected if necessary.

See checklist clause 7.5.3.2 for list of required retained DI (records)

Sidebar: Lost records

Be aware that ISO 9001:2015 does not require records of the validity of previous results when instruments are found to be out of calibration as in 2008 clause 7.6. Also, there is no requirement to keep a record of the results and preventive actions (2008: clause 8.5.3.d). Preventive action is now incorporated into risks and opportunities, but no records are required.

Sidebar: Are the standard writers daft?

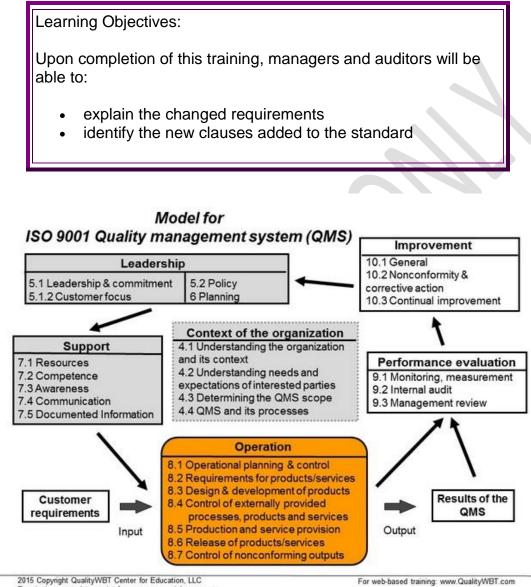
The international standard writers are trying to stay up with technology and how it is changing how we do things. True, they may not get it right every time. Be assured that no matter the wordsmithing, to have control, there must be PDCA. There must be 1) a predetermined method for a process or activity, 2) a way for management to verify people are following the predetermined method such as a record or observation, 3) a criteria for the output and 4) action when the criteria are not met.



Congratulations!

Operation, Clause 8

[This medium length lesson discusses the product or service operations of the organization.]



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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. There are **no major changes** in the operations clause (Product realization). However, there are many refinements and additional requirements; especially in the design clause, 8.3. There are two new clauses titled

Post-delivery activities and Control of changes (in Operations). The Purchasing clause has been renamed "**Control of externally provided products and services**." The new name helped expand the focus of the controls to all external providers; not just organizations identified as suppliers.

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 marked with bold text.** A checklist has been provided (see Class Links) that you can use to make notes and later use to conduct an audit or to implement the new requirements.

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8 Operation (2008: 7 Product realization)



8.1 Operational planning and control(2008: 7.1 Planning and product realization)

The organization must implement the actions determined in clause 6 (Planning), 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 DI (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 to verify that actions related to product and services are addressed. There is some redundancy with clause 6; especially clause 6.2.2. Nothing major here. The standard uses the word demonstrate again which implies a higher level of required conformity.

Another change is that 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 the organizations may utilize external providers (suppliers of services or products), the organization must ensure that **outsourced processes are controlled (8.4).** This is linked to the control of external providers clause 8.4 (purchasing). This appears to be a redundant requirement for most organizations in that proper implementation of clause 8.4 would satisfy the requirement in 8.1. In the 2008 version, organizations were required to take responsibility for outsourced processes, but the 2015 version requires control of outsourced processes per clause 8.4.

Sidebar: Outsourcing

Outsourcing controls should be the purchasing function's responsibility. Prior versions of ISO 9001 presented outsourcing controls in different parts of the standard. This was confusing to many organizations.

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8.2 Requirements for products and services



8.2.1 Customer communication (2008: 7.2.3 Customer communication)

New requirements are that communication with the customer must include: d) the handling or controlling of customer property e) establishing specific requirements for contingency actions, when relevant

This brings control of customer supplied property into the contract and specification of requirements. This is where it should be.

The potential need for contingency plans is consistent with risk-based thinking. There could be contingency plans for any of the requirements such as product substitutions, delays in delivery of a product or service, changes in supplier processes.

8.2.2 Determining the requirements for products and

services (2008: 7.2.1 Determination of requirements related to product)

Either no change or very minor changes (See checklist)

Sidebar: Able to meet the claims determined to offer

Note there is specific wording now 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 (2008: 7.2.2 Review of requirements related to product) Either no change or very minor changes (See checklist)

8.2.4 Changes to requirements for products and

services (2008: 7.2.2 Review of requirements related to product) Either no change or very minor changes (See checklist)

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8.3 Design and development of products and services (2008 7.3 Design and development)



The 9001:2015 version of the design clause has many refinements that incorporate riskbased thinking, considering interested parties and focusing on meeting requirements. The new 8.3.4 Design and development controls clause replaces clauses 7.3.4, 7.3.5, 7.3.6 (See checklist). The new version has removed all requirements for specific plans such as planned arrangements, but kept requirements for retained DI (records).

8.3.1 General

The basic structure (approach) is the same as it has always been.

Process plan	8.3.2 Design and development planning
Inputs	8.3.3 Design and development inputs
Process controls	8.3.4 Design and development controls
Outputs	8.3.5 Design and development outputs
Control changes	8.3.6 Design and development changes

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

This is a new requirement, but it was implied in the 2008 version. Otherwise, how could an organization conduct design activities? An auditor should ask about the overall processes and verify they are established, implemented and maintained.

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8.3.2 Design and development planning(2008: 7.3.1 Design and development planning)



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 DI 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 (2008: 7.3.2 Design

and development inputs) Either no change or very minor changes (See checklist)

8.3.4 Design and development controls (2008: 7.3.4 Design & devt. review; 7.3.5 Design & devt. verification; 7.3.6 Design & devt. validation) Either no change or very minor changes (See checklist)

8.3.5 Design and development outputs (2008: 7.3.3 Design

and development outputs) Either no change or very minor changes (See checklist)

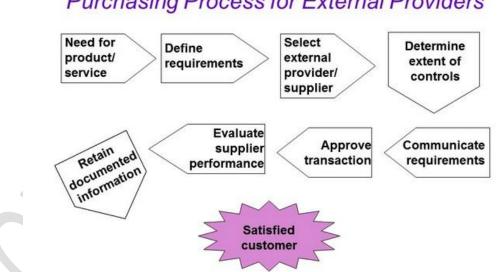
8.3.6 Design and development changes (2008: 7.3.7 Control

of design and development changes) Either no change or very minor changes (See checklist)

8.4 Control of externally provided products and services (2008; 7.4 Purchasing)

8.4.1 General (2008: 7.4.1 Purchasing process)

In general, there are only minor changes in requirements but the **concept of external** providers has been introduced. The scope of this clause has been expanded to include external providers beyond what we normally call suppliers.



Purchasing Process for External Providers

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 © 2015 QualityWBT Center for Education, LLC

- organizations that provide internal service needs such as equipment maintenance
- organizations providing materials for a product or delivery of a service

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 specified requirements.

An auditor should verify organizations are monitoring performance. In the past, organizations had to verify products and services met requirements and that suppliers were evaluated, but they were not required to monitor performance. The new added requirement 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.

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8.4.2 Type and extent of control (2008: 7.4.1 Purchasing process, 7.4.3 Verification of purchased product)



b) The organization must 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 be 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.

The organization must 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.

For 1), This is an extension of the risk-based thinking. For 2) The organization must periodically verify the controls are effective. For example: This could be a review of product inspection records or an audit every three to five years.

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8.4.3 Information for external providers(2008: 7.4.2 Purchasing information)

This is the last of the communication requirements.

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, and
 - 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

The additional requirements (in bold) are activities many organization already are doing but perhaps not communicating. There is no requirement for maintained or retained DI (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).

8.5 Production and service provision (2008: 7.5 Production and service provision)



8.5.1 Control of production and service provision (2008: 7.5.1 Control of

product and service provision and 7.5.2) Either no change or very minor changes (See checklist)

Sidebar: 7.5.2 is now located in 8.5.1f

Note that the requirement of the organization needing to validate special processes did not go away, it was relocated to 8.5.1f.

8.5.2 Identification and traceability (2008: 7.5.3

Identification and traceability) Either no change or very minor changes (See checklist)

8.5.3 Property belonging to customers or external

providers (2008: 7.5.4 Customer property) The only significant change is **expanding the scope of this clause to include external providers**. Either no change or very minor changes to requirements. (See checklist)

Please continue to the next screen. Nothing very interesting here. 😎

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8.5.4 Preservation (2008: 7.5.5 Preservation of product)



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

The word product was deleted from the title so that both product and service preservation can be included. This allows **preservation to include identification**, **handling**, **contamination control**, **packaging**, **storage**, **transmission or transportation**, **and protection** (in a note in the standard). The control is the same, but the scope of the clause has been extended.

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 necessary 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.

A service example from the ISO community is preservation of a bank transaction (electronic or physical). In some cases, the difference for the need to preserve a service versus retaining documented information (a record) may be confusing. A record of the service can verify it was performed. Retaining the record would fall under documented information controls.

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.

8.5.5 Post-delivery activities (2008: 7.5.1 Control of production and service provision)

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 9001:2015 standard has added a list of things an organization must consider. The new 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 DI 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?"

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8.5.6 Control of changes (2008: 7.3.7 Control of design and development changes)

Ideally, when operations/production makes changes to a process, it should be reviewed according to the design changes clause, but this was not a 2008 requirement.

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?

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 DI 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 DI (record). Was there a review? Was the change authorized? Were there follow-up actions?

8.6 Release of products and services (2008: 8.2.4 Monitoring and measuring of product, 7.4.3 Verification of purchased product

Either no change or very minor changes (See checklist).

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8.7 Control of nonconforming outputs (2008: 8.3 Control of nonconforming product)



8.7.1 (no title)

The standard specifies how the organization must deal with nonconforming outputs. The organization must deal with nonconforming outputs in one or more of the following ways:

a) correction, which can include rework, repair, blend, re-grade

b) segregation, 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, but were not specifically referenced in the 2008 version as a response to nonconforming outputs. Holding products would be temporary until the organization determined their disposition. Scrapping, dumping or disposal of nonconforming product is not mentioned in the 2015 or the 2008 versions, but the 2008 version was more open-ended to allow action to eliminate the nonconformity and/or take appropriate action.

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 the nonconformity so they can adjust their process or schedule to accommodate the nonconforming product or service. For a service, the nonconformity could happen before the service 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.

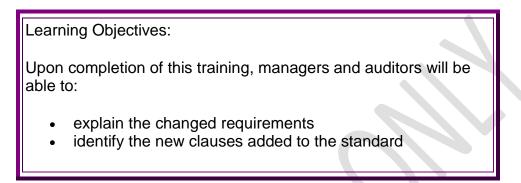
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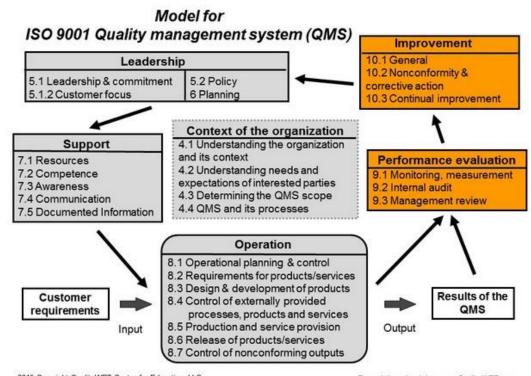


Congratulations!

Evaluation and Improvement, Clauses 9 and 10

[This medium length lesson discusses analyzing data and the resulting improvement of the organization. At the end is a test you must pass to continue.]





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Please note that we will be discussing clauses 9 and 10, see orange blocks.

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 © 2015 QualityWBT Center for Education, LLC controls for improvement of the organization. There are no major changes to these clauses. The **interested parties and risk-based thinking themes have been integrated into the requirements.** There is a strong emphasis on **monitoring metrics and improving performance** of the organization.

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 marked with bold** text. A checklist has been provided (see Class Links) that you can use to make notes and later use to conduct an audit or to implement the new requirements.

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9 Performance evaluation



9.1 Monitoring, measurement, analysis and evaluation (2008: 8-Measurement analysis and improvement) 9.1.1 General (2008: 8.1 General)

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

The 9001:2015 version qualified the need to determine methods as to ensure valid results. Of course 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. Now, 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.

9.1.2 Customer satisfaction (2008: 8.2.1 Customer

satisfaction)

Either no change or very minor changes.

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9.1.3 Analysis and evaluation (2008: 8.4 Analysis of data)



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 the added requirement to ensure that plans have been effectively implemented. There is a **note that mentions analysis can include statistical techniques.** Note that the use of applicable methods, including statistical techniques **was a "shall' requirement in the 9001:2008** version. Statistical techniques can be very powerful but not the best tool in all cases. Most organizations will use descriptive statistics such as average, mean and mode, dispersion and standard deviation to analyze data.

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9.1.3 Analysis and evaluation -Continued

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.

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9.2 Internal audit (2008: 8.2.2 Internal audit)



Some useful refinements have been added to the internal audit clause. And yes, there is no requirement for a documented procedure. The ISO leadership are having discussions to remove the word "documented" from the definition of

an audit in ISO 9000 and the ISO 19011. We don't know what the future will bring, but for control purposes, all processes must have a predetermined method to perform the process. Plan what you do, do what you plan.

The standard states that the organization must **plan**, **establish**, **implement and maintain an audit program(s)** including the frequency, methods, **and responsibilities**, **planning requirements and reporting**.

The organization must conduct planning to manage the audit program. The planning outputs will vary from organization to organization. The audit program **plans need to include who has what responsibilities, the need for plans (such as an audit plan), and reporting needs such as individual audit reports and audit program reports.** Audit programs could include: compliance audits, management audits, process audits, project implementation audits, supplier audits and product audits.

As in the 2008 version, the requirements for the internal audit state that the audit is to provide information on the level of compliance and effectiveness of the quality management system (clause 9.2.1). It is important for internal auditors to understand that they do have an important role to play in auditing, not only for compliance, but for effectiveness as well.

The standard states that the organization must take into consideration the importance of the processes concerned, **changes affecting the organization** and the results of previous audits.

When there is a change in a process, the probability of a nonconformity is higher. Scheduling an audit after a change is made in a process or in personnel would be a good practice.

The 2015 version **does not require that follow-up activities be carried** out to verify the effectiveness of actions taken and that verification results be reported as does the 2008 version. However, this is covered in the 2015 version's clause 10.2 regarding corrective action.

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9.3 Management review (2008: 5.6 Management review)



There are several refinements to management's review or periodic checkup of the organization. The basic concept is the same: management needs to review the organization's performance and take necessary **action to achieve its objectives**.

9.3.1 General (2008: 5.6.1 General)

The standard states that the reviews conducted must ensure the QMS's continuing suitability, adequacy, effectiveness and **alignment with the strategic direction of the organization**. In order 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 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?

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9.3.2 Management review inputs (2008: 5.6.2 Review input)



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

d) the adequacy of resources

- e) the effectiveness of actions taken to address risks and opportunities (see 6.1)
- f) opportunities for improvement

There are several new criteria that need to be considered when conducting a management review. New criteria include adding internal/external changes and integrating the risk-based thinking theme. In keeping with the process approach (clause 4.4), management review must also review process performance. Many of the items link back to clause 9.1.3 Analysis and evaluation.

Looking at external issues is very important in today's global economy. External issues could be a new law, one less competitor, a drop in energy costs and so on.

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9.3.3 Management review outputs(2008:5.6.3 Review outputs)



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

The 2015 version **scope is greater** than the 2008 version of ISO 9001. The 2008 version specified improvement to products/services related to customer requirements or the QMS. The 2015 version leaves **improvement open-ended** to the extent that improvement may go beyond customer product/service requirements or the QMS. Improvement may relate to internal and external issues.

Also, the requirement to include decision and actions of outputs **related to changes** in the QMS was added. 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.

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10 Improvement (2008: 8.5 Improvement)



10.1 General (2008: 8.5.1 Continual improvement)

The 2008 version simply stated the organization was to continually improve the effectiveness of the QMS and listed several data and other inputs. The 2015 has added clarification and specifics.

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 QMS

There is **no qualification such as "as appropriate" for this requirement.** An auditor needs to verify that all three (a, b and c) are taking place. Improvement can be reactive (for example, corrective action), incremental (for example, a relatively small individual improvement project), step-by-step change (for example, a breakthrough, major project), creative (for example, innovation) or by reorganization (for example, transformation).

10.2 Nonconformity and corrective action(2008: 8.5.2 Corrective action)



10.2.1 (no title)

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

a) react to the nonconformity, and as applicable:

take action to control and correct it 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 in the 2008 version. 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) is new and helps emphasize the importance of identifying systemic problems.

- 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 QMS, 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.

Sidebar: Change Interesting: Change can take place without realizing improvement but improvement cannot be realized without change. JP

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

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10.2 Nonconformity and corrective action -*Continued*



10.2.2 (no title)

As with the 9001:2008 version, 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. The corrective action process may look like the animation in the class:

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10.3 Continual improvement (2008 8.5.1 Continual improvement)



Either no change or very minor changes.

The preventive action clause (ISO 9001:2008 Clause 8.5.3) has been eliminated in the 2015 version. In the past, the preventive action requirement has been confusing to many. The need to address potential nonconformities or undesirable situations is addressed when risks are assessed as part of clause 9001: Clause 6.1.

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Congratulations!

End of class