ISO 9001:2015

How to manage the transition successfully ....

MANAGING TRANSITION

90 08 ⇨ 15

Transform

time for change

ISO ON THE MOVE & CREATING WAVES :

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International Certification Services Pvt. Ltd.

ISO 9001 WORLDS MOST POPULAR AND ADOPTED MODERN MANAGEMENT SYSTEM

You all our partners from he industry, government and public sector industry may be aware that ISO has been revising their international management systems as part of evaluation of the Management system and Quality.

ISO has successfully revised and launched few management system mid Sept. 2015 under ISO schedule review to make the standard user friendly, generic and focusing business risk and opportunities. The new management system recently launched are :

➢ ISO 9001 : 2015
➢ ISO 14001 : 2015

ISO adopted annexes SL, High Level structure with identical core text and common terms and definition two years back. All present future management system are being aligned with the requirements of the annexure SL.

Both the above revised management standards have ten clauses instead of old QMS – ISO 9001: 2008 eight clauses. The new management system will be based on seven management system in place of old eight management principles by redefining these management principles..

Salient features of the revised ISO 9001:2015 standards provide freedom to have tailored made, organization management system in context of their organization. Leadership has to play bigger role in effective development, implementation and management of the system. Management shall focus the customer and know their business, risks and opportunities thus replacing and removing preventive action. Requirements of documentation information give independence to define their own documentation and records to control their processes and activities to achieve appropriate quality of the goods and services to meet the customer / consumer needs. Similarly "Continual Improvement" of the old standard replaced with the "improvement" of appropriate to the organization. The exclusion has been removed and organization freedom to focus all the new 10 clauses of the standard and can align with the standard requirements accordingly. The time line to transit old to new standard given as three years starting from the date of launching of the new / revised standard. The old standard ISO 9001: 2008 and ISO 14001:2004 will expire mid 2018.

We are bringing this special issue of Quality Mantra to benefit the organization in understanding the requirements of the revised management system. We have also planned number of Awareness, Internal Auditor, Transition and Lead Auditor training and qualification program starting from Nov. 2015.

I take the opportunity to thank all our valued customers, business associates and partners and wish you and your family Happy and Prosperous Diwali Festival of Lights and Wisdom

COMPILED BY: DR. SUNDAR KATARIA AND V. MURALIDHAR

ISO FDIS 9001:2015 – EXCLUSIONS

PREAMBLE

ISO FDIS 9001:2015 has been released on 9th July 2015 and will be open for ballot.

As a committed CAB, it is our pleasure to bring out salient points for all to know.

In the ISO DIS 9001:2014 "Exclusions" was not used in the standard. However, it was mentioned in Annex A (A.5)

ISO 9001:2015 FDIS Exclusions to Scope:

We have had ISO 9001:2015 FDIS now for a couple of days, and we are busy trying to reconcile the FDIS, Annex SL and also what we would describe as a few myths. The subject of "exclusions" is something, at this present moment in time; we are ready to put on the latter pile.

Does ISO 9001: 2015 FDIS Permit Exclusions In The Same Way As ISO 9001: 2008 ?

Based on our interpretation, we would say that this is more "yes" than "no". Initially we were concerned that the rum-ours of "no permissible exclusions" were going to be true – and many people are still maintaining that it is true, but we don't think it is.

In ISO 9001:2008, the statement relating to permissible exclusions is defined with clause 1.2 Application of Scope. It is quite clear. Exclusions are permitted; they are limited to clause 7, must be justified and can only apply where the requirement doesn't affect the company's ability to meet its output requirements. Therefore, when we saw the copy of ISO 9001:2015 we went straight to section 1 (Scope) to see if there was an equivalent statement – there wasn't! Quite the reverse in fact, instead there was the following statement "All the requirements of this international standard are generic and are intended to be applicable to any organization, regardless of its type or size, products or services"

Nothing about exclusions! So what about FDIS clause 8.3 Design and Development? This clause is pretty similar to clause 7.3 of ISO 9001:2008 – no major changes – what about a company that has no design function? A warehouse for example? Surely a company that has no design function wouldn't be forced to develop contrived "design" procedures for the purpose of ticking a box? It was our understanding that ISO 9001:2015 was looking to move further away from that approach?

After a while our concerns were alleviated; however, whilst the clarification regarding applicability (or exclusions) is not defined in Section 1 (Scope), it is defined somewhere else, and when you read it carefully it leaves us not too far away from where ISO 9001:2008 is on the matter. Our assumption is that those people who maintain the position of "no exclusions in ISO 9001:2015 FDIS" have possibly simply checked Section 1 (Scope) and nowhere else.

Context of the Organizations:

The guidance relating to applicability of requirements (and non-applicability, exclusions in other words) has moved. It is no longer mentioned in the Scope. It is outlined in Section 4.3 Determining the Scope of the Quality Management System. In that section we receive the following advice;
"The organizations shall apply all the requirements of this international standard if they are applicable within the determined scope of the quality management system …. and provide justification for any requirement of this international standard that the organisation determines is not applicable to the scope of its quality management system"

Now that, we would argue, is pretty close to where we were on the topic of exclusions in ISO 9001:2008. The matter of applicability is addressed (i.e. not all requirement will be applicable to every organisation) and where a requirement is not applicable, it has to be consistent with the defined scope and justified by the organisation. The only material differences, so far as we can tell, is that the requirement has moved and the actual word "exclusions" is no longer used.

So, to summaries, in our opinion, we are pretty much where we were. So panic over. Alas!!!

COMPILED BY: DR. SUNDAR KATARIA & V. MURALIDHAR
ISO FDIS 9001: 2015

Quick Summary of changes on FDIS ISO 9001:2015

The idea is to understand the intent, and added requirements in FDIS. This is just an overview of each clause.

- Clause 4.1: Structured way to introduce company , and basis for audit
- Clause 4.2: Interested parties identified, and needs recorded. For sustained success it is important to move towards these compliances
- Clause 4.3: Clarity in scope, applicability (exclusions) and boundaries of QMS
- Clause 4.4: Approach to completeness of documentation, as well consideration to risk.

- Clause 5.1: Integrating QMS and business . Focus on strategic direction, risk assessment
- Clause 5.2: Specific focus on customer satisfaction , regulatory compliances
- Clause 5.3: Tasks defined , segregation possible & removal of dependency on single person

- Clause 6.1: Preparing for uncertainties and review with respective strategic direction
- Clause 6.2: Detailed methodology for objective tracking as process
- Clause 6.3: Assessing the impact before introducing changes in structured manner

- Clause 7.1.1- 7.1.5: Clarity on work env. Safety Related requirements & fitness for purpose for as more practical way.
- Clause 7.1.6: Operations related knowledge to be compiled as given in notes.
- Clause 7.2: No change.
- Clause 7.3: Awareness to nonconformities related to work, product added besides awareness to his own work.
- Clause 7.4: Clarity on communication, Internal/ external communication are specified.
- Clause 7.5: Compiled requirements related to documents, record control.

- Clause 8.1: Overall planning – From customer req. understanding - production, QA, till functional conformity
- Clause 8.2: No specific change, Understand customer, review before quote and acceptance stage, appropriate communication, and contingency planning
- Clause 8.3: Control over design stages to ensure failures & risks are taken care during design
- Clause 8.4: Service provides, supplier is selected, monitored for performance
- Clause 8.5: Production/ service provision is as defined , and requirements monitored , move to avoid human error added
- Post delivery activities refer to intended life,
- Preservation addresses care to be taken during manufacturing and delivery , now adds contamination control too
- Property of customer, and supplier/ service provider is also considered as part of requirement.
- Clause 8.6: No specific change, conventional inspection process for product release
- Clause 8.7: Addresses nonconforming products as defined by organization . The impact, disposal action are further clarified.

- Clause 9.1: Overall performance monitoring includes- customer perception & data analysis. Risk and opportunities added.
- Clause 9.2: structured way to internally assess processes is internal audit , no major change.
- Clause 9.3: Management review is to conform the processes performance, and objectives are being met . Consideration to risk, issues shall bring in quality & business focus together.

- Clause 10.1 :, why & what Types of improvements are clarified .
- Clause10.2: Deviations to be analyzed in systematic manner and avoid re ocurrance. Now includes preventive measures too, ref to consequences evident.
- Clause 10.3: Improvements to be obtained from reviews, performance results.Clause 10.1 :, why & what Types of improvements are clarified .
- Clause10.2: Deviations to be analyzed in systematic manner and avoid re ocurrance. Now includes preventive measures too, ref to consequences evident.
- Clause 10.3: Improvements to be obtained from reviews, performance results.

TRANSITION REQUIREMENTS OF NEW STANDARDS
ISO 9001 - QMS AND ISO 14001 - EMS

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As many of you would be aware, the new Standards of ISO 9001:2015 for QMS and ISO 14001:2015 for EMS have now been published. For all clients the transition period to implement the new requirements is 3 years from the date of publication of new Standard(s) i.e. 15th September 2015. After these 3 years i.e. 14th September 2018 all Certificates issued for ISO 9001:2008 version and ISO 14001: 2004 version, shall be deemed as expired. Hence all certified companies shall need to upgrade their systems as per the new 2015 versions of both QMS and EMS.

The revised standards are indeed nice and challenging for all organizations. However you will have to work for developing certain skills, ensuring more involvement of top management, risk based assessment and the most important is setting the context of organisation. In these Standards the Context is "KING" and shall be the back bone for the assessment of any organization. We at International Certification Services, are very keen that our valued clients properly understand the new requirements, so that they can smoothly transform to new system at an early date. In view of this, we have planned the following.

During next three months i.e. October / November / December 2015 we shall be upgrading all our Auditors for the new version. From 1st January 2016 ICS will start auditing considering the requirements of new Standards. If non-conformities are observed, ICS will raise two categories of NCs - one against old version and the other against new 2015 version. It will be optional for our certified clients to close or not-to-close the NCs against 2015 version. We opine that this would greatly help our prestigious clients to clearly understand what changes they need to introduce in actual working so as to fulfil the requirements of 2015 version. Upto 30th September 2017 these NCs against 2015 version shall be optional to close for continuation of certification

After this date all NCs against 2015 version shall be mandatory for closure.

For the financial benefit of our clients, ICS will try its best to complete during Surveillance / Re certification Audits the transition of existing certificate to new version. This would save our clients the charges of additional visits by ICS auditors to verify if the transition requirements are satisfactorily implemented for revising your Certificate as per the new Standard. However if any certified client fails to take advantage of the verification during Surveillance / Re certification Audit, then it may call for additional visit for transition. In other words, ICS will be trying to get the clients transited to 2015 versions in Surveillance / Re certification audit itself.

Our group Company M/s ICS Technologies will be conducting open forum training program for Transition in both QMS and EMS Standards, at confessionals rates for our existing clients. Exact dates of these program will be communicated shortly, so that you can depute your personnel for the same to improve their understanding about the new requirements. A small presentation is also attached herewith indicating key changes in these Standards.

Please feel free to revert if you need any clarifications / additional information on the subject. We shall deeply appreciate your pro-active interest and will be delighted to assist and guide our clientele.

ISO 9001:2015 "HOW TO MANAGE THE TRANSITION SUCCESSFULLY ...".

CLARIFICATION OF NEW STRUCTURE, TERMINOLOGY AND CONCEPTS

ANNEX A OF STANDARD

A.1 STRUCTURE AND TERMINOLOGY

The standard is based on Annex SL of the ISO Directives, a high-level structure (HLS) which standardizes sub-clause titles, core text, common terms and core definitions to enhance compatibility and alignment with other ISO management system standards.

The clause structure (i.e. clause sequence) and some of the terminology of this edition of this International Standard, in comparison with the previous edition (ISO 9001:2008), have been changed to improve alignment with other management systems standards.

There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using "records", "documentation" or "protocols" rather than "documented information"; or "supplier", "partner" or "vendor" rather than "external provider").

Table A.1 shows the major differences in terminology between this edition of this International Standard and the previous edition.
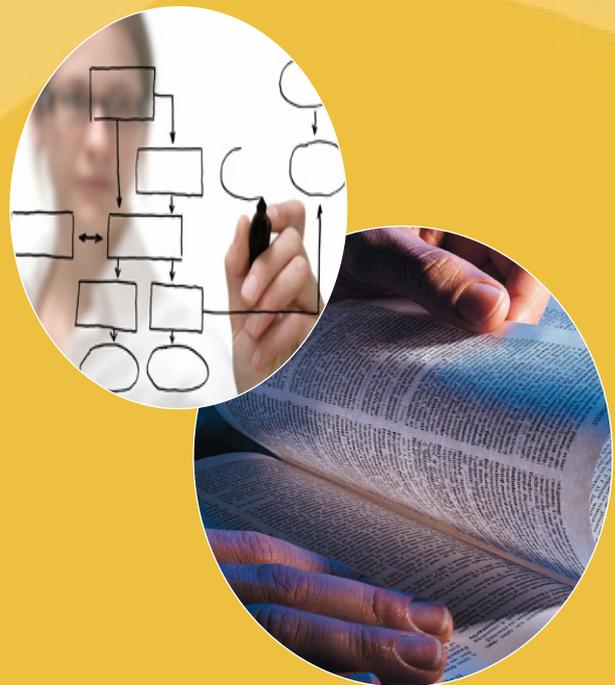
Table A.1 — Major Differences In Terminology Between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
PRODUCTS	Products and Services
EXCLUSIONS	Not Used (See Clause A.5 for clarification of applicability)
MANAGEMENT REPRESENTATIVE	Not Used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)
DOCUMENTATION, QUALITY MANUAL, DOCUMENTED PROCEDURES, RECORDS	Documented Information
WORK ENVIRONMENT	Environment for the Operation of Processes
MONITORING AND MEASURING EQUIPMENT	Monitoring and Measuring Resources
PURCHASED PRODUCT	Externally Provided Products and Services
SUPPLIER	External Provider

A.2 PRODUCTS AND SERVICES :

ISO 9001:2008 used the term "product" to include all output categories. This edition of this International
Standard uses "products and services". "Products and services" include all output categories (hardware, services, software and processed materials).

The specific inclusion of "services" is intended to highlight the differences between products and services in the application of some requirements. The characteristic of services is that at least part of the output is realized at the interface with the customer. This means, for example, that conformity to requirements cannot necessarily be confirmed before service delivery.
In most cases, products and services are used together. Most outputs that organizations provide to customers, or are supplied to them by external providers, include both products and services. For example, a tangible or intangible product can have some associated service or a service can have some associated tangible or intangible product.

A.3 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

Sub-clause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties. However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction. There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.

A.4 RISK-BASED THINKING

The concept of risk-based thinking has been implicit in previous editions of this International Standard,
e.g. through requirements for planning, review and improvement. This International Standard specifies requirements for the organization to understand its context (see 4.1) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4) and will assist in determining the extent of documented information.
One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or sub-clause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements.

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information and organizational responsibilities. Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations. Under the requirements of 6.1, the organization is responsible for its application of risk based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

A.5 APPLICABILITY

This International Standard does not refer to "exclusions" in relation to the applicability of its requirements to the organization's quality management system. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

The requirements for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

A.6 DOCUMENTED INFORMATION

As part of the alignment with other management system standards, a common clause on "documented information" has been adopted without significant change or addition (see 7.5). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, "documented information" is used for all document requirements.

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".

Where ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention.

A requirement to "maintain" documented information does not exclude the possibility that the organization might also need to "retain" that same documented information for a particular purpose, e.g. to retain previous versions of it. Where this International Standard refers to "information" rather than "documented information" (e.g. in 4.1: "The organization shall monitor and review the information about these external and internal issues"),

there is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

A.7 ORGANIZATIONAL KNOWLEDGE

In 7.1.6, this International Standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure the operation of its processes and that it can achieve conformity of products and services.

Requirements regarding organizational knowledge were introduced for the purpose of:

A) safeguarding the organization from loss of knowledge, e.g.

➢ Through Staff Turnover;
➢ Failure To Capture And Share Information;

B) encouraging the organization to acquire knowledge, e.g.

➢ Learning From Experience;
➢ Monitoring;
➢ Bench Marking.

A.8 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

All forms of externally provided processes, products and services are addressed in 8.4, e.g. whether through:

A) Purchasing From A Supplier.

B) An Arrangement With An Associate Company.

C) Outsourcing Processes To An External Provider.

Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization. The controls required for external provision can vary widely depending on the nature of the processes, products and services. The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided processes, products and services

UNDERSTANDING THE ISO 9001:2015

The Standards 9001:2008 / 2015 both essentially cover the same topics. However, there are some important differences, which are discussed as under:-

Structure of the standard

The biggest difference between the old and the new standard is the structure.

ISO 9001 2008 had five main sections (4 to 8) and

ISO 9001 2015 now has seven (4 to 10).

ISO 9001:2015 SECTION CHANGES

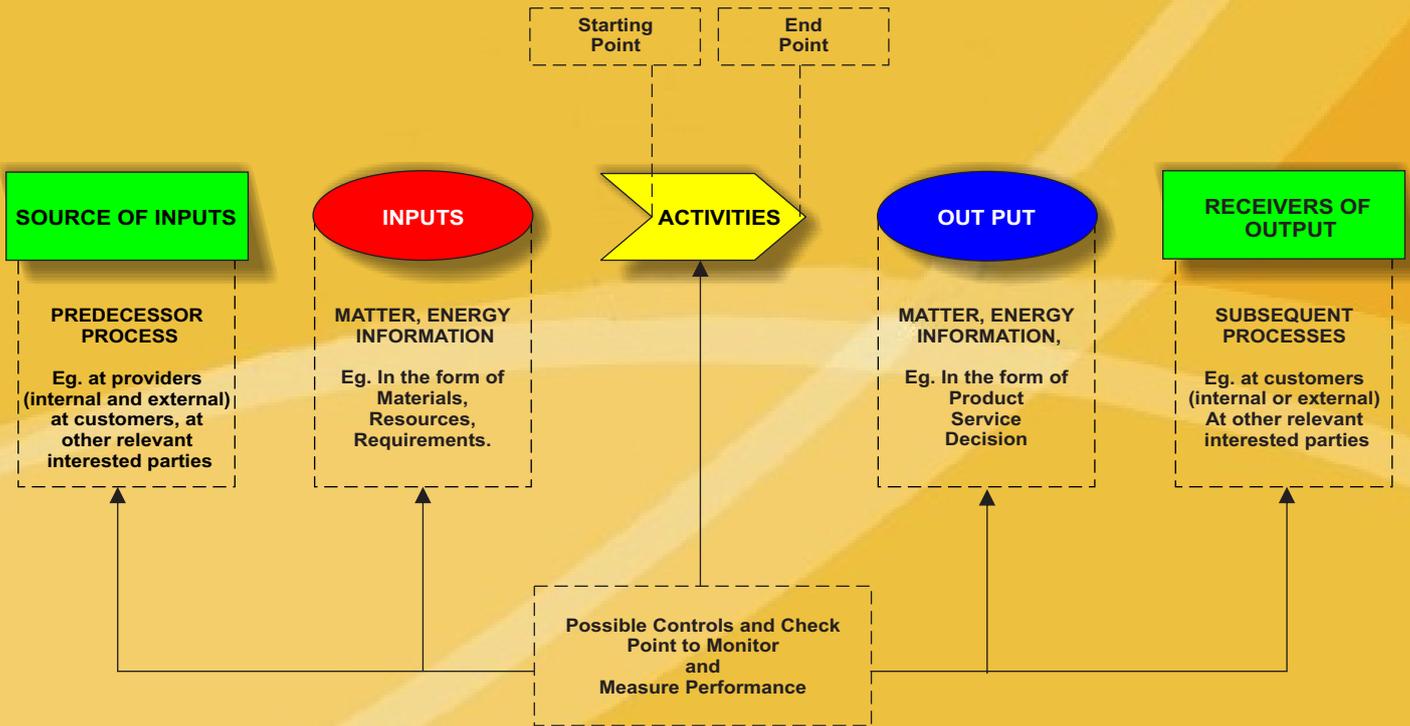| Section No.	Current Standard Sections	Proposed Standard Sections
Section 1:	Scope	Scope
Section 2:	Normative Reference	Normative References
Section 3:	Terms and Definitions	Terms and Definitions
Section 4:	General Requirements	Context of the Organization
Section 5:	Management Responsibility	Leadership
Section 6:	Resource Management	Planning
Section 7:	Product Realization	Support
Section 8:	Measurement, Analysis and Improvement	Operation
Section 9:		Performance Evaluation
Section 10:		Improvement

This is because the new edition uses the new Annex SL template. According to ISO, all future management system standards will use this new layout and share the same basic requirements. As a result, all new Management System Standards will have the same basic look and feel.

The basic concepts applicable to all Management System Standards are:-

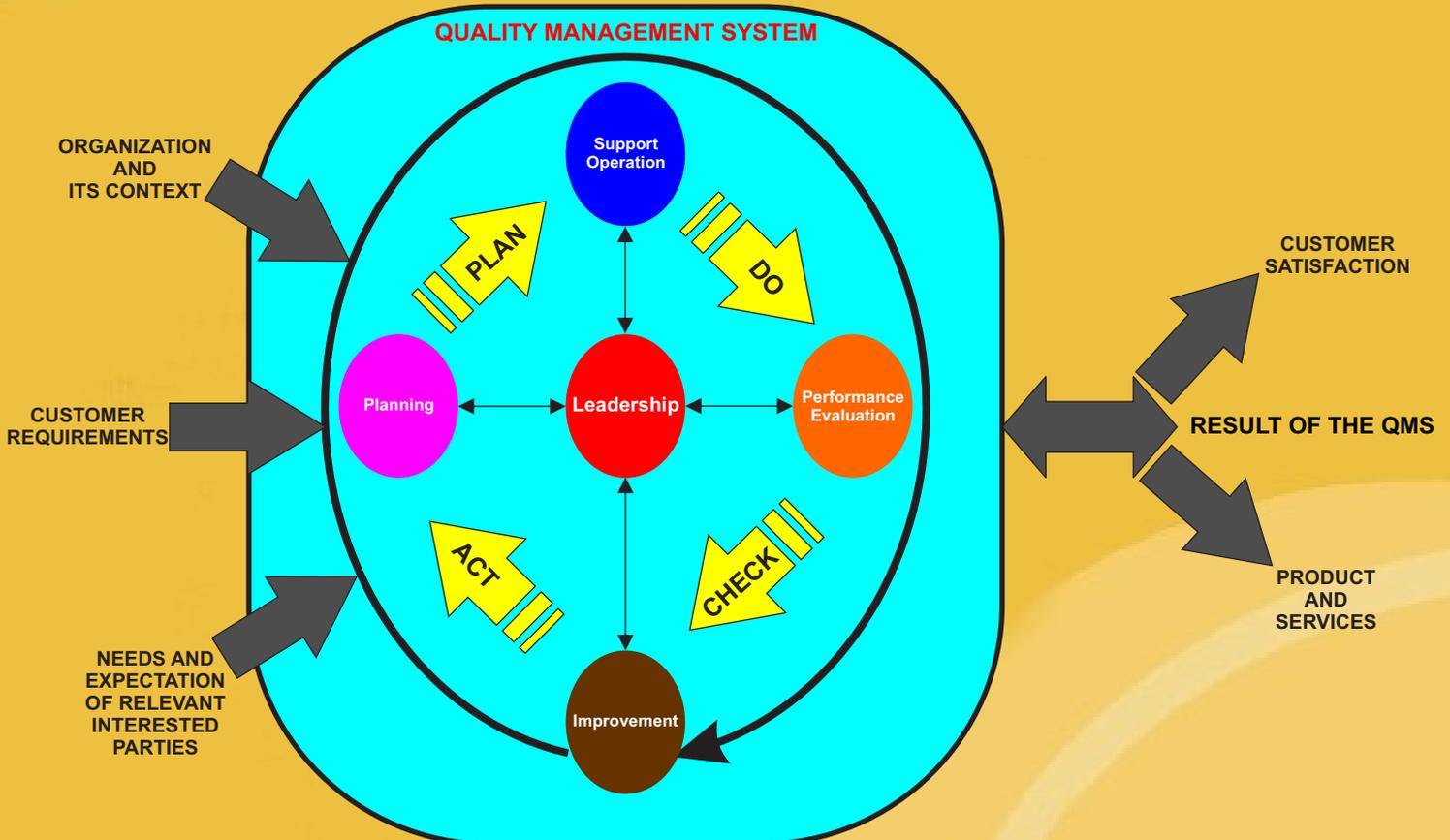| Management	Customer	Requirements	Policy
Procedure	Planning	Performance	Objective
Control	Monitoring	Measurement	Auditing
Decision Making	Corrective Action	Nonconformity	

Theses will have the same common requirements and are common to all management system standards. Therefore this will make it easier for organizations to implement multiple management system standards because they will all share the same basic requirements.

IS / ISO 9001: 2015

Starting Point — End Point

SOURCE OF INPUTS → **INPUTS** → **ACTIVITIES** → **OUT PUT** → **RECEIVERS OF OUTPUT**

PREDECESSOR PROCESS

Eg. at providers (internal and external) at customers, at other relevant interested parties

MATTER, ENERGY INFORMATION

Eg. In the form of Materials, Resources, Requirements.

MATTER, ENERGY INFORMATION,

Eg. In the form of Product Service Decision

SUBSEQUENT PROCESSES

Eg. at customers (internal or external) At other relevant interested parties

Possible Controls and Check Point to Monitor and Measure Performance

Schematic Representation of the Element of a Single Process

Plan - Do -Check - Act Cycle

QUALITY MANAGEMENT SYSTEM

ORGANIZATION AND ITS CONTEXT

CUSTOMER REQUIREMENTS

NEEDS AND EXPECTATION OF RELEVANT INTERESTED PARTIES

Support Operation

PLAN

DO

Planning

Leadership

Performance Evaluation

ACT

CHECK

Improvement

CUSTOMER SATISFACTION

RESULT OF THE QMS

PRODUCT AND SERVICES

Representation of The Structure of This International Standard In The PDCA Cycle

CONTEXT OF THE ORGANIZATION

Unlike the old standard, the new one expects you to understand your organization's context before you establish its QMS. When ISO 9001 2015 asks you to understand your organization's context it wants you to consider the external and internal issues that are relevant to its purpose and strategic direction and to think about the influence these issues could have on its QMS and the results it intends to achieve.

This means that you need to understand your organization's external environment, its culture, its values, its performance, and its interested parties before you develop its QMS. Why? Because your QMS will need to be able to manage all of these influences.
And once you understand all of this, you're expected to use this special insight to help you define the scope of your QMS and the challenges it must deal with. While this will certainly help ensure that organizations develop unique quality management systems that address their own needs and requirements, doing all of this could be quite a challenge for some organizations.

The context of the organization in the ISO 9001:2015 requires the organization to define influences of various elements on the organization and how they reflect on the QMS;

> **The Culture Of The Company**
> **Flow Of Processes Of And Information**
> **Objectives And Goals**
> **Complexity Of Products**

It also requires a reflection of the size of the organization, its markets, and how they define customers.

It is also uses the context as a way to detect risks and opportunities and how it affects the QMS.

ISO 9001:2015 in Detail: Documented Information
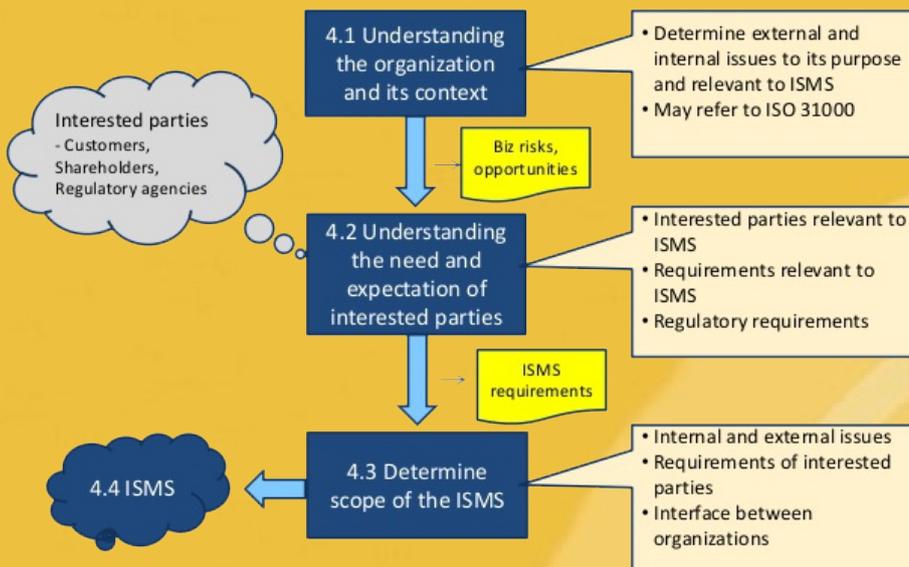
DOCUMENTED INFORMATION

The new ISO 9001 2015 standard has also eliminated the long standing distinction between documents and records. Now they are both referred to as "documented information".

According to ISO's definition, the term documented information refers to information that must be controlled and maintained. So, whenever ISO 9001 2015 uses the term documented information it implicitly expects to control and maintain that information and its supporting medium. However,

An annex to the new standard (A.6) further says that "Where ISO 9001:2008 would have referred to documented procedures ... this is now expressed as a requirement to maintain documented information", and "Where ISO 9001:2008 would have referred to records this is now expressed as a requirement to retain documented information".

So, whenever the new standard refers to documented information and it asks you to maintain this information, it's talking about what used to be referred to as procedures, and whenever it asks you to retain this information, it's talking about what used to be called records. So sometimes it must be maintained and sometimes it must be retained (contrary to what the official definition says).

So, while the definition of the term "documented information" abandons the distinction between documents (or documented procedures) and records, through the use of the words "maintain" and "retain" and because of what this means (according to Annex A) the main body of the standard actually restores this distinction.

In other words, while documents and records shall still play an important role as this documented information shall still be used as evidence of conformance.

In the new standard, a Quality Manual will not be required.

You do not need to scrap the Quality Manual. The new standard still requires documented information about:

➢ A Quality Policy
➢ The Scope of the QMS
➢ Information to support quality related processes

You can place these as other documented information, but if you already have a Quality Manual, these items should already be there. Remember you will have plenty of time to address this as the transition period for the implementation of 9001:2015 is 3 years ending 14-09-2018.
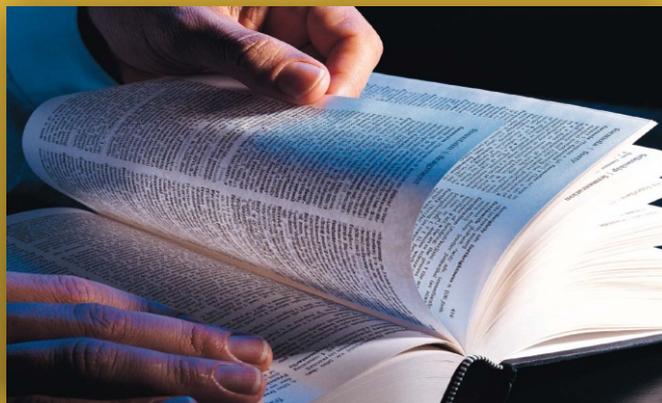
RISK-BASED THINKING

According to the new standard, "risk-based thinking has always been implicit in ISO 9001". According to this perspective, ISO 9001 has always been about anticipating and preventing mistakes, which is what risk-based thinking is all about. That's why we train people, why we plan our work, why we assign roles and responsibilities, why we validate and verify results, why we audit and review activities, and why we monitor, measure, and control processes. We do these things because we want to prevent mistakes. We do them because we're trying to manage risk. So, if we think of risk-based thinking in this way, it's always been an inherent part of ISO 9001. Before it was implicit; now it's explicit.

So what kind of thinking is risk-based thinking and how is it applied? What does the new standard expect organizations to do? The new standard expects organizations to identify and address the risks that could influence their ability to provide compliant products and services and to satisfy customers. It also expects them to identify and address the opportunities that could enhance their ability to provide compliant products and services and to satisfy customers.

The new ISO standard also expects organizations to identify the risks and opportunities that could influence the performance of their quality management systems or disrupt their operation and then it expects them to define actions to address these risks and opportunities. It then further expects them to figure out how they're going to make these actions part of their QMS processes and how they're going to implement, control, evaluate, and review the effectiveness of these actions and these processes.

While risk-based thinking is now an essential part of the new standard, it does not actually expect you to implement a formal risk management process nor does it expect you to document your risk-based approach.

MAKING RISK PART OF THE QUALITY MANAGEMENT PROCESS
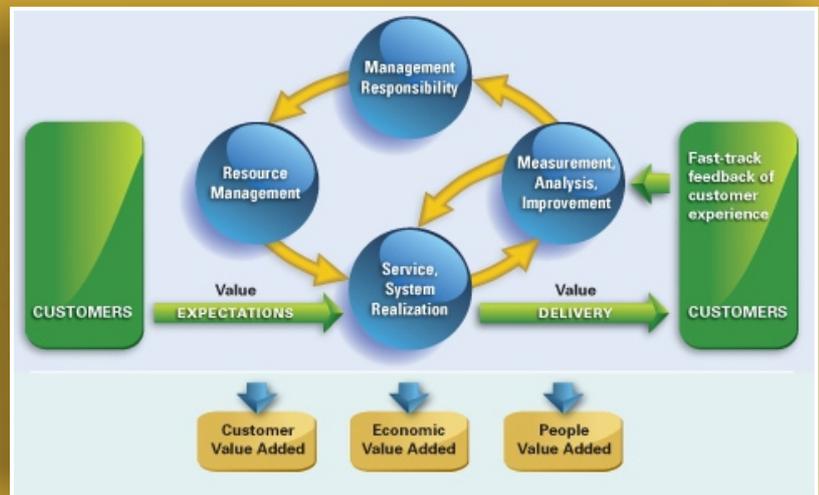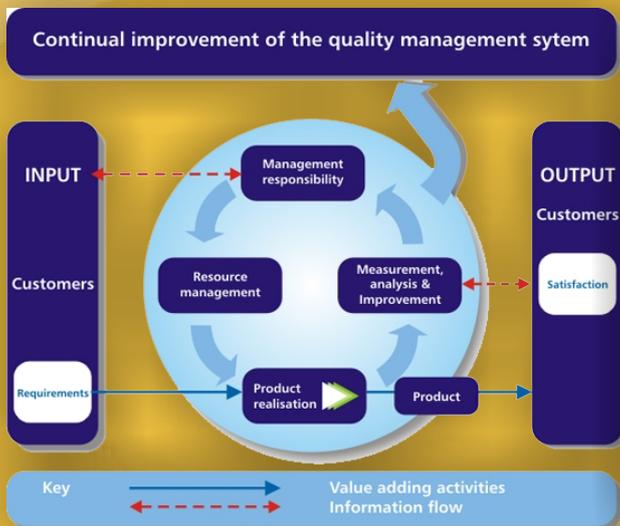
Preventing and correcting unwanted actions and outcomes have long been a part of ISO 9001, but it has been limited to specific elements of the quality management process. ISO 9001:2015 is about to change that.

As an organization, ISO has already addressed the notion of a more global risk management approach to businesses in its ISO 31000 standard, which provides an organizational-level risk management approach. ISO 31000 deals with crucial risk management concepts like:
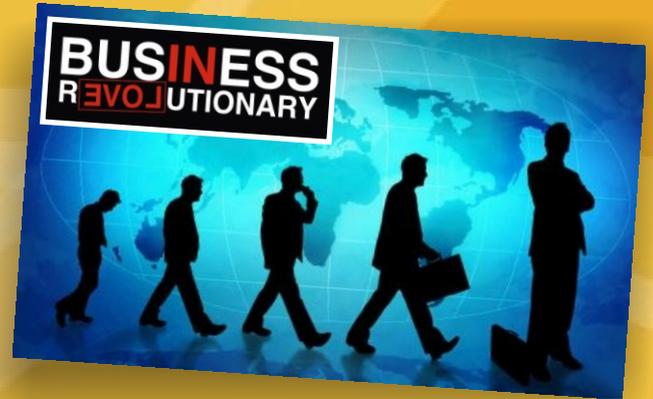
➤ Avoiding activities associated with a given risk

➤ When to or not to accept risk when taking advantage of a key opportunity

➤ Acceptable ways to remove a risk source entirely

Another example of ISO's move into risk management is ISO 9004, which addresses many aspects of risk management such as including the needs and expectation of interested parties and risk's impact on strategy and innovation.

ISO 9001:2015: REVOLUTIONARY OR EVOLUTIONARY ?

The ISO 9001:2015 revision expands the more limited view of trying to find the "root cause" of a problem, then fix it and keep it from happening again. Instead, it elevates the idea of risk management into higher priority. It examines system-wide risks that can be concerns of a broader base that the organization may serve. This can include not only customers, but other "stakeholders" as well including employees, vendors, communities in which the company operates, unions, regulators and beyond. It also asks the company to balance the likelihood versus the impact of these potential events.* (So for instance the impact of a meteor strike is enormous, but the likelihood very small.)

But is the notion of charging a quality management system with the responsibility of anticipating and responding to organizational such a major reach? Perhaps not if you view ISO 9001 previous involvement with risk management in specific areas of the standard, since clauses dealing with subjects ranging from human resources to purchasing seem to address it. (See the table below for some "indirect" examples of risk management included in the current ISO 9001:2008 revision.)

ISO 9001:2008 clauses	Comments
5.6. Management review	Review should include an assessment of improvement opportunities and needs for changes in the quality management organization. One of the conditions of this review is to analyze changes that could affect the quality management system
6.2 Human Resources	By meeting the requirements to ensure the necessary competence, you can manage the risks associated with human resources.
6.3 Infrastructure	The provision and maintenance of infrastructure (i.e. buildings, equipment, information environment) needed to achieve conformity to product requirements, would manage the risks associated with the control of infrastructure
7.2.2 Review of requirements related to the product	The requirement to review contract prior to its signing, including determining the organization's ability to fulfill certain requirements, significantly reduces the risk of default on contractual obligations in the future
7.3.7 Control of design and development changes	It is necessary to evaluate the effect of the changes on constituent parts and product already delivered.
7.4 Purchasing	Definition of criteria for evaluating vendors and their systematic evaluation reduces risks of the vulnerability of organizations associated with the activity of suppliers and partners
7.5. Production and service provision	Provision of controlled conditions for production (i.e., availability of necessary information, instructions, equipment, measurement and testing, etc.) significantly reduces the risk of release of nonconforming products.
8.2.1 Customer satisfaction	Monitoring information relating to customer perception as to whether the organization has met their requirements is an important element for the identification of risks associated customer dissatisfaction, and hence the risk to the reputation / image of the organization and, consequently, declining market share
8.2.2 Internal audit	Internal audits help to identify operational risks
8.5.3 Preventive action	The organization shall determine actions to eliminate causes of potential non-conformance in order to prevent their occurrence, i.e. to conduct risk assessment.

The new ISO 9001-2015 revision focuses on risk management at the organizational level. While this may seem a departure from a strict quality management focus, there is ample focus within the existing standard on controlling risk to justify an expanded focus. Above are just some of the clauses that in effect mandate risk management, albeit for specific activities. The new revision in its current draft form appears to expand these more tactical risk management elements into a more programmatic view.

HOW ISO 9001:2015 WILL ASK YOU TO MANAGE YOUR RISK

Interestingly, the current working draft of ISO 9001:2015 no longer even mentions the specific term preventive action (although this may of course change as the standard develops into a final form). This may be the first clue on how the revision aims to take risk management to a higher level by assuming that a management system (and in this case a quality management system or QMS) is designed as a whole to prevent unwanted outcomes - and that this function of isolating potential risks is really also implicitly preventing them. In the draft, clause 4.1 requires your company to identify risks and ways to address them so that the QMS can deliver upon its objectives.

Clause 6.1 does require a "traditional" prevention or reduction of unwanted outcomes, but more in a more global sense and at a higher priority level. The clause also asks the organization to consider opportunities, since many risks contain both "opportunities" and "threats." Essentially ISO 9001:2015 will likely ask organizations to do the common sense (but not commonly executed) task of asking and answering key questions such as:

➢ How will the organization identify potential threats?

➢ What are they ways to prevent, or reduce, undesired effects?

➢ How will the organization ensure that it can achieve its intended outcomes?

➢ Who will be responsible for ensuring that this process works correctly?

➢ When and how will the risk management actions be triggered?

➢ What are the priorities and cost impacts of each threat?

➢ Where could these threats come from, and who are all of the potential players that could help identify and deal with these risks?

➢ How can such a system for dealing with these risks be evaluated, tested and kept up to date to ensure it will work when needed ?

In effect, 9001:2015 risk management asks the organization to establish an end-to-end process for risk management and then to execute that process consistently, carefully and widely. And while the process for creating and applying risk management may never be overly specific because of the need to apply in so many different situations, ISO has already provided a fairly rich reference set in this area including:

➢ ANSI/ASSE Z690.1-2011 Vocabulary for Risk Management (U.S. Adoption of ISO Guide 73:2009),

➢ ANSI/ASSE Z690.2-2011 Risk Management Principles and Guidelines (U.S. Adoption of IEC/ISO 31000:2009)

➢ ANSI/ASSE Z690.3-2011 Risk Assessment Techniques (U.S. Adoption of IEC/ISO 31010:2009

HOW RISK MANAGEMENT IN ISO 9001:2015 MAY CHANGE QUALITY MANAGEMENT

In a sense, quality management has always been about ensuring the output of a group meets a consistent, acceptable level. But this new emphasis on higher level risk impact may put quality management representatives (including organizational quality personnel, consultants and auditors) in the position of managing higher level business risks.

And where other planning is present (as perhaps in the case of larger organizations), that role may also include reconciling or integrating those other management systems around the risks identified through the new ISO 9001:2015 risk management process. (This may be even beyond current responsibilities for integrating multiple standards into areas of strategic business planning.) At whatever level the quality representatives operate, the increased emphasis upon higher level risk management may necessitate a broader perspective, increased organizational knowledge, and expanded skill sets. This may be in opposition to others who see the role of quality management shrinking and being "subsumed" by other departments or functions such as engineering, human resources or financial management.

For example, the growing dependence upon global suppliers and outsourcing of management functions, may shift the responsibility for assessment and accountability in these functions to the quality representative, since the risks associated with these functions could be one of the keys to creating and managing risk under ISO 9001:2015.

QUESTIONS THAT REMAIN ABOUT IMPLEMENTING ISO 9001:2015 RISK MANAGEMENT

The objectives of injecting more risk management into ISO 9001 may be aimed at addressing a variety of management needs such as:

- ➤ Moving to more of a data-driven decision process that increases objectivity
- ➤ Being able to more accurately prioritize risks and allocate resources to mitigating them more successfully
- ➤ Being truly preventative with respect to those risks that have the potential for greatest harm
- ➤ Capturing, retaining and transferring organizational knowledge regarding risk mitigation as employees and managers change
- ➤ Broadening the knowledge base regarding risk and creating communication and trust among those who are involved

However, because of the major shift that this approach entails, and because the revision is still very much a work in process, there are major questions and concerns regarding ISO 9001:2015 risk management as proposed including

- ➤ Will the inclusion of risk management make ISO 9001 (2015) more confusing and less likely to be applied and audited correctly either by the certification body or the registered organization?

- ➤ How will ISO 9001:2015 risk concepts be harmonized and prioritized with those expressed in other standards such as ISO 31000 since they are to some extent unique?

- ➤ Correctly implementing organization-wide risk management will likely require more internal authority and access than many quality representatives currently hold; will the new standard including anything to help quality representatives gain this access and resources

- ➤ Risk management may be a more abstract concept than other elements of ISO 9001; will internal auditors, lead auditors and registrars be able to audit these concepts?

- ➤ Other more mature risk management systems include processes for Governance, Risk and Compliance (GRC) and Enterprise Risk Management (ERM) which are considered essential but are not yet included in ISO 9001:2015's risk management approach.

*Some "risk-based thinking" models also consider the potential frequency with which the threat can occur.

REQUIREMENTS AND EXCLUSIONS

Section 1.2 of ISO 9001 2008 says that organizations may exclude or ignore product realization requirements (section 7) if they cannot be applied and if doing so doesn't interfere with its ability or responsibility to meet customer and legal requirements. The new standard takes a similar approach but, instead, seems to apply this thinking to all requirements.

Section 4.3 of ISO 9001 2015 says "The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system". So once you've determined the scope of your QMS, ISO 9001 2015 says that every requirement must be applied within the boundaries defined by your statement of scope if it applies in your case.

However, while the new ISO 9001 2015 standard says that every requirement must be applied, section 4.3 and Annex A5 also says that any requirement may be excluded if it cannot be applied, if you can justify and explain why it can't be applied, and if excluding it does not undermine your ability or responsibility to ensure that products and services are in compliance.

So, the message is clear: if a requirement can be applied you can't just ignore it. You must apply it. And if you really can't apply it, you better be able to explain why not.

OBJECTS, OUTPUTS, PRODUCTS, AND SERVICES

The definition of the term "object" is new. The introduction of the term "object" to mean anything conceivable or perceivable and its use in various definitions (quality, design and development, innovation, review, traceability) seems to suggest that the new ISO 9001 standard can be applied to any object whatsoever. In theory at least, this greatly expands its scope.

What ISO 9000 2005 used to call a "product" the new standard now calls an "output". The two definitions are the same. Since the term "output" was not defined in 2005, this shift in terminology suggests that the process approach is now even more central to the new standard.

And to further complicate things, the old definition of "product" has now been split into three separate definitions for the terms output, product, and service. "Output" is the general concept since both "products" and "services" are now thought of as "outputs".

OTHER CLARIFICATIONS AND MODIFICATIONS

While the previous changes could be the most important ones, the new standard has also clarified some concepts and modified others. Some of these changes are listed below.

The old standard said that a "service" was a type of "product". Now, the phrase "products and services" is used throughout the new standard and the term "service" has received its own definition. This should help make it clear that ISO 9001 2015 applies not only to manufacturers but also to all types of service providers.

What used to be called "customer property" has been modified and greatly expanded to include products, services, and processes belonging to all types of external providers (including customers). The new standard now expects you to control externally provided products and services if they are included in your products or services or if they are provided directly to customers.

The old definition of "continual improvement" has changed. When ISO 9001 2008 asked you to make continual improvements it was asking you to improve your ability to fulfill requirements. Now, ISO 9001 2015 says it means enhancing performance (getting better results). This is an important shift.

According to the new standard, organizations must now identify, acquire, and share the "knowledge" that personnel need in order to support process operations and achieve conformity of products and services.

The old concept of "product realization" is gone. Most of the material in the old product realization section has been modified and moved to the new ISO 9001 2015 section on Operations.

The term "management representative" has been dropped. The management duties and responsibilities that were previously assigned to someone called a "management representative" may now be assigned either to one person or to many people.

"Preventive action" has also disappeared. It's been replaced by "risk-based-thinking", evidently because both approaches try to achieve the same thing. Both try to prevent future problems. Once you introduce risk-based thinking, you no longer need a separate clause on preventive action. It's redundant.

While the old standard asked you to use monitoring and measuring "equipment", the new standard refers to monitoring and measuring "resources". This is a more flexible approach to monitoring and measuring because it recognizes the fact that these activities can often be carried out without the use of equipment.

ISO 9001:2015 IN DETAIL: EXCLUSIONS AND REQUIREMENTS

What requirements can you exclude from your QMS under the new ISO 9001:2015 standard?

Section 1.2 of ISO 9001:2008 states an organization may exclude or ignore product realization requirements if they cannot be applied or if implementing them does not adversely affect its ability or responsibility to meet customer and legal requirements.

Section 4.3 of ISO 9001:2015 says --Where a requirement of this International Standard within the determined scope can be applied, then it shall be applied to the organization.-- This says that once the scope of the QMS is defined, every requirement must be applied within the boundaries defined by the statement of scope.

section 4.3 and Annex A5, however, states that any requirement may be excluded if it cannot be applied. The exclusion is justified by showing that compliance would undermine the performance of the product or service.

ISO 9001:2015 IN DETAIL: OBJECTS, OUTPUTS, PRODUCTS & SERVICES

Integrated-Standards.com has many tools to help you integrate ISO Standards in their existing format, which will be simplified with Annex SL.

The new ISO 9001:2015 standard defines an object as anything conceivable or perceivable that is used within the area of quality, design and development, innovation, review, and traceability. Objects can be material or immaterial. Examples of objects include

- Products,
- Services,
- Systems,
- Organizations,
- People,
- Practices,
- Procedures,
- Processes,
- Plans,
- Ideas,
- Documents,
- Records,
- Methods,
- Tools,
- Machines,
- Technologies,
- Techniques, And
- Resources.

The 2015 standard suggests that the new term can be applied to any object whatsoever thus expanding is scope and use. What the ISO 9000:2005 called a product, the new standard calls it an output. This change further emphasizes the process approach.

WHAT NEEDED CLARIFICATION FROM THE LAST REVISION ?

While the previous changes could be the most important ones, the new standard has also clarified some concepts. Some of these changes are listed below.

The ISO 9001:2008 standard stated a service was a type of product. Now, products and services is used throughout. The term service now has a distinct definition.

The concept of Customer Property is expanded to include products, services, and processes belonging to external providers

Customers are considered external providers.

➢ As a result the 9001:2015 standard requires control over externally provided products.

➢ Continual Improvement has changed to encompass enhancing performance.

➢ According to the new standard, organizations must now share knowledge between employees to achieve conformity. This put a greater burden on training and communication.

➢ Preventive action is now risk-based-thinking.

➢ The ISO 9001:2008 standard asked to use equipment to monitor and measure. The ISO 9001:2015 refers to monitoring and measuring resources.

Comparison Between Iso 9001:2015 And Iso 9001: 2008

➢ Table showing the major theme differences between the new and old standard

➢ Matrix showing the new ISO 9001:2015 standards clause compared to the existing ISO 9001:2008 standard clause.

	ISO 9001:2008	ISO 9001:2015
THE STRUCTURE	Compare the old Structure	Preparing for Integrated Standards
CONTEXT	How the QMS relates internal issues to external issues	9001:2015 requires how an organization defines internal and external influences
DOCUMENTED INFORMATION	The documents are strictly defined	The new standard loosens the definition to "information" and the quality manual requirements
RISK BASED EMPHASIS	Risk was implicit in ISO 9001:2015	ISO 9001:2015 explicity expects risk assessment and avoidance
EXCLUSIONS & REQUIREMENTS	Excluding a standard requirement was specific to Product Realization	The new standard allows for a more general way to exclude specific requirements
OBJECTS, OUTPUTS, PRODUCTS AND SERVICES	Process Based Only	The process model is expanded to include anything that affects quality
CLARIFICATIONS		From implementing, and auditing within ISO 9001:2008, there were a number of issues that needed clarification

CLAUSE BY CLAUSE COMPARISON

ISO 9001: 2015	ISO 9001:2008	Discussion
4 Context of the organization	1.0 Scope	
4.1 Understanding the organization and its context	1.1 General	A new requirement - the organization must determine the external and internal context that affects the organization
4.2 Understanding the needs and expectations of interested parties	1.1 General	
4.3 Determining the scope of the quality management system	1.2 Application 4.2.2 Quality manual	The Quality Manual is no longer mandatory. The requirement remains for determining and documenting its scope.
4.4 Quality management system and its processes	4 Quality management system 4.1 General requirements	This requirements remains, the new cover risks, opportunities, and assigning authority for processes.
5 Leadership	5 Management responsibility	
5.1 Leadership and commitment	5.1 Management commitment	
5.1.1 Leadership and commitment for the quality management system	5.1Management commitment	The new version requires top management to become accountable for the QMS' effectiveness.
5.1.2 Customer focus	5.2 Customer focus	Virtually the same except the new version includes services (along with products) and also addresses government regulations.
5.2 Quality policy	5.3 Quality policy	
5.3 Organizational roles, responsibilities and authorities	5.5.1 Responsibility and authority 5.5.2 Management representative	The new version details the responsibilities, roles and authorities within the QMS.
6 Planning for the quality management system	5.4.2 Quality management system	

	planning	
6.1 Actions to address risks and opportunities	5.4.2 Quality management system planning 8.5.3 Preventive action	
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives	
6.3 Planning of changes	5.4.2 Quality management system planning	
7 Support	6 Resource management	
7.1 Resources	6 Resource management	
7.1.1 General	6.1 Provision of resources	
7.1.2 People	6.1 Provision of resources	
7.1.3 Infrastructure	6.3 Infrastructure	
7.1.4 Environment for the operation of processes	6.4 Work environment	The 2015 version focuses the provision of resources to monitor and measure. The organization must retain the evidence monitoring and measuring resources.
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment	
7.1.6 Organizational knowledge	New	**The organization must determine the knowledge necessary to run the processes and achieve conformity of products and services**
7.2 Competence	6.2.1 General 6.2.2 Competence, training and awareness	The old version covered both competence and awareness in the same clause. The new clause separates them.

CLAUSE BY CLAUSE COMPARISON

|		
7.3 Awareness	6.2.2 Competence, training and awareness	Separated for clarity and focus.
7.4 Communication	5.5.3 Internal communication	Internal and External communication responsibilities must be defined.
7.5 Documented information	4.2 Documentation requirements	
7.5.1 General	4.2.1 General	
7.5.2 Creating and updating	4.2.3 Control of documents 4.2.4 Control of records	Documents and records are now considered in the same category (i.e. documented information)
7.5.3 Control of documented Information	4.2.3 Control of documents 4.2.4 Control of records	
8 Operation	7 Product realization	
8.1 Operational planning and control	7.1 Planning of product realization	
8.2 Determination of requirements for products and services	7.2 Customer-related processes	The new version emphasizes documenting the treatment of customer property.
8.2.1 Customer communication	7.2.3 Customer communication	
8.2.2 Determination of requirements related to products and services	7.2.1 Determination of requirements related to the product	
8.2.3 Review of requirements related to the products and services	7.2.2 Review of requirements related to the product	
8.3 Design and development of products and services	7.3 Design and development	
8.3.1 General	**New**	
8.3.2 Design and development planning	7.3.1 Design and development planning	
8.3.3 Design and development Inputs	7.3.2 Design and development inputs	
8.3.4 Design and development controls	7.3.4 Design and development review	The new clause aggregates of the three

	7.3.5 Design and development verification 7.3.6 Design and development validation	2008 clauses, and emphasizes the nature, duration of design and development processes.
8.3.5 Design and development outputs	7.3.3 Design and development outputs	
8.3.6 Design and development changes	7.3.7 Control of design and development changes	
8.4 Control of externally provided products and services	7.4.1 Purchasing process	
8.4.1 General	7.4.1 Purchasing process	
8.4.2 Type and extent of control of external provision	7.4.1 Purchasing process 7.4.3 Verification of purchased product	
8.4.3 Information for external providers	7.4.2 Purchasing information	The 2015 version emphasizes monitoring and control of external providers.
8.5 Production and service provision	7.5 Production and service provision	
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision	
8.5.2 Identification and tractability	7.5.3 Identification and tractability	
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property	Describes extending requirement for property belonging to external providers (as well as customers).
8.5.4 Preservation	7.5.5 Preservation of product	
8.5.5 Post-delivery activities	7.5.1 Control of production and service provision	The new standard separates to a new clause.
8.5.6 Control of changes	7.3.7 Control of design and development changes	A new separate clause is used to highlight the importance of change

		control.
	8.2.4 Monitoring and measurement of processes 7.4.3 Verification of purchased product	
8.6 Release of products and services		
8.7 Control of nonconforming process outputs, products and services	8.3 Control of nonconforming product	
9 Performance evaluation	**New**	
9.1 Monitoring, measurement, analysis and evaluation	8 Measurement, analysis and improvement	
9.1.1 General	8.1 General	
9.1.2 Customer satisfaction	8.2.1 Customer satisfaction	
9.1.3 Analysis and evaluation	8.4 Analysis of data	
9.2 Internal audit	8.2.2 Internal audit	The new standard does not require a documented procedure
9.3 Management review	5.6 Management review	
10 Improvement	8.5 Improvement	
10.1 General	8.5.1 Continual improvement	
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product 8.5.2 Corrective action	
10.3 Continual Improvement	8.5.1 Continual improvement	The 2015 standard emphasizes the use of all available information for continually improving the Quality Management System

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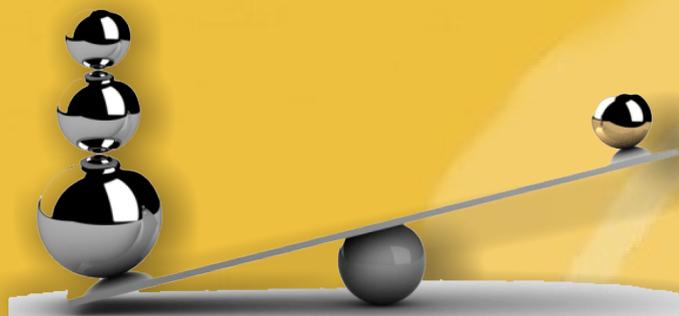
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