

Who Assisted Development of This Standard

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for whom a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Strategic Decision

The adoption of a quality management system ought to be a strategic decision for an organization. A robust quality management system can help an organization to improve its overall performance and forms an integral component of sustainable development initiatives. The design and implementation of an organization's quality management system is influenced by the context of the organization and the changes in that context, particularly with respect to:

- a) Its specific objectives;
- b) The risks associated with its context and objectives;
- c) The needs and expectations of its customers and other relevant interested parties;
- d) The products and services it provides;
- e) The complexity of processes it employs and their interactions;
- f) The competence of persons within or working on behalf of the organization;
- g) Its size and organizational structure.

What are the primary changes in the new version of ISO 9001:2015?

- a) The adoption of the HLS as set out in Annex SL of ISO Directives Part 1.
- b) An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach.
- c) Fewer prescribed requirements.
- d) Less emphasis on documents.
- e) Improved applicability for services.
- f) A requirement to define the boundaries of the QMS.
- g) Increased emphasis on organizational context.
- h) Increased leadership requirements.
- i) Greater emphasis on achieving desired outcomes to improve customer satisfaction.

Who is going to be impacted by these changes?

- Organizations certified and/or using ISO 9001:2008.
- Accreditation Bodies (ABs) & Certification Bodies (CBs).
- Training bodies and consultants.

What is Annex SL?

The clause sequence of ISO 9001:2008 has been changed to be consistent with “Annex SL”.

This new harmonized approach allows for the addition of discipline-specific (in this case quality-specific) text.

Compatibility with other management system standards

This International Standard has adopted the “high-level structure” (i.e. clause sequence, common text and common terminology) developed by ISO to improve alignment among its International Standards for management systems. An explanation of some of the key elements of the “high level structure” and some of the key changes introduced in this International Standard is provided in Annex A.

What Is “Risk-based thinking”?

Risk is the effect of uncertainty on an expected result and the concept of risk-based thinking has always been implicit in ISO 9001.

This International Standard makes risk-based thinking more explicit and incorporates it in requirements for the establishment, implementation, maintenance and continual improvement of the quality management system.

The concept of preventive action is expressed through a risk-based approach to formulating quality management system requirements. 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 titled ‘Preventive action’.

“Risk-based thinking” therefore means considering risk qualitatively (and, depending on the organization’s context, quantitatively) when defining the rigor and degree of formality needed to plan and control the quality management system, as well as its component processes and activities.

Organizations can choose to develop a more extensive risk-based approach than is required by this International Standard, and ISO 31000 provides guidelines on formal risk management which can be appropriate in certain organizational contexts.

Not all the processes of the quality management system represent the same level of risk in terms of the organization’s ability to meet its objectives, and the consequences of process, product, service or system nonconformities are not the same for all organizations.

For some organizations, the consequences of delivering nonconforming products and services can result in minor inconvenience to the customer; for others, the consequences can be far-reaching and fatal.

The risk-based approach to drafting this International Standard has facilitated some reduction in prescriptive requirements and their replacement by performance-based requirements.

Although risks and opportunities have to be determined and addressed, there is no requirement for formal risk management or a documented risk management process.

What Is Meant By Organizational Context?

There are two new clauses relating to the context of the organization, 4.1 Understanding the organization and its context and 4.2 Understanding the needs and expectations of interested parties. Together these clauses require the organization to determine the issues and requirements that can impact on the planning of the quality management system.

The titles of clauses 4.1 and 4.2 provide for alignment with other management system standards. They do not imply extension of quality management system requirements beyond the Scope (Clause 1) of this International Standard.

The context of an organization can include internal factors such as organizational culture, and external factors such as the socio-economic conditions under which it operates; consequently all the requirements of this International Standard are generic but the ways in which they are applied can differ from one organization to another. Accordingly, it is not the intent of this International Standard to imply the need for uniformity in the structure of different quality management systems, or uniformity of documentation to align to the clause structure of this International Standard, or to impose specific terminology to be used within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, to assess the organization's ability to consistently meet customer, statutory and regulatory requirements applicable to the products and services it provides, the organizations own requirements and its aim to enhance customer satisfaction.

Organizational knowledge

Clause 7.1.5 Organizational knowledge addresses the need to determine and maintain the knowledge obtained by the organization, including by its personnel, to ensure that it can achieve conformity of products and services.

The process for considering and controlling past, existing and additional knowledge needs to take account of the organization's context, including its size and complexity, the risks and opportunities it needs to address, and the need for accessibility of knowledge. The balance between knowledge held by competent people and knowledge made available by other means is at the discretion of the organization, provided that conformity of products and services can be achieved.

Control of externally provided products and services

Clause 8.4 Control of externally provided products and services addresses all forms of external provision, whether it is by purchasing from a supplier, through an arrangement with an associate company, through the outsourcing of processes and functions of the organization or by any other means.

The organization is required to take a risk-based approach to determine the type and extent of controls appropriate to particular external providers and externally provided products and services.

What Is Process Approach?

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system. This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Clause 4.4 of this International Standard includes specific requirements considered essential to the adoption of a process approach.

The process approach applies systematic definition and management of processes and their interactions so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using a “Plan-Do-Check-Act” (PDCA)

methodology (see 0.4) with an overall focus on “Risk- based thinking” aimed at preventing undesirable outcomes (see 0.5).

When used within a quality management system, the process approach ensures:

- a) Understanding and consistently meeting requirements;
- b) Consideration of processes in terms of added value;
- c) The achievement of effective process performance;
- d) Improvement of processes based on evaluation of data and information.

What Is Plan-Do-Check-Act Cycle?

The methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes and to the quality management system as a whole. The clauses of this International Standard broadly follow the PDCA cycle which can be briefly described as follows:

Plan: establish the objectives of the system and its component processes, and the resources needed to deliver results in accordance with customers’ requirements and the organization’s policies.

Do: implement what was planned.

Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives and requirements, and report the results.

Act: take actions to improve process performance, as necessary.

What Are The New Primary Clauses?

Clause 4 - Understanding the context of the organization, its quality management system and processes

Clause 5 - Leadership, policy and responsibilities (Clause 5)

Clause 6 - Processes for planning and consideration of risks and opportunities (Clause 6)

Clause 7 - Processes for support, including resources, people and information (Clause 7)

Clause 8 - Operational processes related to customers and products and services (Clause 8)

Clause 9 – Processes for performance evaluation (Clause 9)

Clause 10 - Processes for improvement (Clause 10).

Is There Any New Terminology?

All of the definitions previously defined in ISO 9000 have been moved to the ISO 9001 Standard under Clause 3.

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

The consequent changes in the structure and terminology do not need to be reflected in the documentation of an organization’s quality management system.

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 (for example: using 'records', 'documentation', 'protocols', etc. rather than "documented information"; or 'supplier', 'partner', vendor etc. rather than 'external provider').

What's The Difference Between Products vs. Products and Services?

ISO 9001:2008 used the term "product" to include all output categories. This International Standard uses "products and services". The term "products and services" includes 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, the terms "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. The organization needs to take into account where, for example, a tangible product has some associated intangible service or an intangible service has some associated tangible product.

Exclusions vs. Not used (See Annex A.4 for clarification of applicability)

This International Standard no longer makes specific reference to 'exclusions' when determining the applicability of its requirements to the organization's quality management system. However, it is recognized that an organization might need to review the applicability of requirements due to the size 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.

Where a requirement can be applied within the scope of its quality management system, the organization cannot decide that it is not applicable. Where a requirement cannot be applied (for example where the relevant process is not carried out) the organization can determine that the requirement is not applicable. However, this non-applicability cannot be allowed to result in failure to achieve conformity of products and services or to meet the organization's aim to enhance customer satisfaction.

Difference Between Documentation, Records vs. 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, the terms "documented procedure" and "record" have both been replaced throughout the requirements text by "documented information".

Where ISO 9001:2008 would have referred to documented procedures (e.g. to define, control or support a process) this is now expressed as a requirement to maintain documented information.

Where ISO 9001:2008 would have referred to records this is now expressed as a requirement to retain documented information.

Quality management principles

Introduction

This document introduces the seven quality management principles on which the ISO portfolio of quality management system standards is based.

The principles were developed and updated by international experts of ISO/TC 176.

This annex provides a “statement” describing each principle and a “rationale” explaining why an organization should address the principle.

QMP 1 – Customer Focus

a) Statement - The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

b) Rationale - Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties on whom it depends. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of an organization.

QMP 2 – Leadership

a) Statement - Leaders at all levels establishes unity of purpose and direction and creates conditions in which people are engaged in achieving the quality objectives of the organization.

b) Rationale - Creation of unity of purpose, direction and engagement enable an organization to align its strategies, policies, processes and resources to achieve its objectives.

QMP 3 – Engagement of People

A) Statement - It is essential for the organization that all people are competent, empowered and engaged in delivering value. Competent, empowered and engaged people throughout the organization enhance its capability to create value.

b) Rationale - To manage an organization effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment and enhancement of skills and knowledge facilitate the engagement of people in achieving the objectives of the organization.

QMP 4 – Process Approach

a) Statement - Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

b) Rationale - The quality management system is composed of interrelated processes. Understanding how results are produced by this system, including all its processes, resources, controls and interactions, allows the organization to optimize its performance.

QMP 5 – Improvement

a) Statement - Successful organizations have an ongoing focus on improvement.

b) Rationale - Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.

QMP 6 – Evidence-based Decision Making

a) Statement - Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

b) Rationale - Decision-making can be a complex process, and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decisions made.

QMP 7 – Relationship Management

a) Statement - For sustained success, organizations manage their relationships with interested parties, such as suppliers.

b) Rationale - Interested parties influence the performance of an organization. Sustained success is more likely to be achieved when an organization manages relationships with its interested parties to optimize their impact on its performance. Relationship management with its supplier and partner network is often of particular importance.

9001:2015 DIS Quality management systems — Requirements

2 Normative references (Revised)

There are no normative references. This clause is included to **maintain** clause numbering alignment with other ISO management system standards,

4 Context of the organization (New)

4.1 Understanding the organization and its context (New)

The organization **SHALL determine** external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization **SHALL** monitor and **Review** the information about these external and internal issues.

NOTE 1 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional or local.

NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties (New)

Due to their impact or potential impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization **SHALL determine**:

a) the interested parties those are relevant to the quality management system;

b) the requirements of these interested parties that are relevant to the quality management system.

The organization **SHALL** monitor and **Review** the information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system (New)

The organization **SHALL determine** the boundaries and applicability of the quality management system to **establish** its scope.

When determining this scope, the organization **SHALL** consider:

- a) the external and internal issues referred to in 4.1;
- b) the requirements of relevant interested parties referred to in 4.2;
- c) the products and services of the organization.

Where a requirement of this International Standard within the determined scope can be applied, then it **SHALL** be applied by the organization.

If any requirement(s) of this International Standard cannot be applied, this **SHALL** not affect the organization's ability or responsibility to **ensure** conformity of products and services.

The scope **SHALL** be available and be **maintained** as documented information stating the:

- products and services covered by the quality management system;
- justification for any instance where a requirement of this International Standard cannot be applied.

4.4 Quality management system and its processes (Revised)

The organization **SHALL establish, implement, maintain** and **continually improve** a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization **SHALL determine** the processes needed for the quality management system and their application throughout the organization and **SHALL determine**:

- a) the inputs required and the outputs expected from these processes;
- c) the criteria, methods, including measurements and related performance indicators needed to **ensure** the effective operation, and control of these processes;
- e) the assignment of the responsibilities and authorities for these processes;
- f) the risks and opportunities in accordance with the requirements of 6.1, and **plan** and **implement** the appropriate actions to address them;
- g) the methods for monitoring, measuring, as appropriate, and evaluation of processes and, if needed, the changes to processes to **ensure** that they achieve intended results;

The organization **SHALL maintain** documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as **planned**.

5 Leadership (New)

5.1 Leadership and commitment

5.1.1 Leadership and commitment for the quality management system (Revised)

Top management **SHALL demonstrate** leadership and commitment with respect to the quality management system by:

- a) taking **accountability** of the effectiveness of the quality management system;
- b) **ensuring** that the quality policy and quality objectives are **established** for the quality management system and are compatible with the strategic direction and the context of the organization;
- d) **ensuring** the **integration** of the quality management system requirements into the organization's business processes;
- e) **promoting** awareness of the process approach;
- g) **communicating** the importance of effective quality management and of conforming to the quality management system requirements;
- h) **ensuring** that the quality management system achieves its intended results;
- i) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- k) supporting other relevant management roles to **demonstrate** their leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this International Standard 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.

5.3 Organizational roles, responsibilities and authorities (New)

Top management **SHALL** assign the responsibility and authority for:

- a) **ensuring** that the quality management system conforms to the requirements of this International Standard;
- b) **ensuring** that the processes are delivering their intended outputs;

6 Planning for the quality management system

6.1 Actions to address risks and opportunities (New)

6.1.1 When **planning** for the quality management system, the organization **SHALL** consider the issues referred to in 4.1 and the requirements referred to in 4.2 and **determine** the risks and opportunities that need to be addressed to:

- a) **give** assurance that the quality management system can achieve its intended result(s);
- b) **prevent**, or reduce, undesired effects;
- c) **achieve** continual improvement.

6.1.2 The organization **SHALL plan**: (New)

- a) **actions** to address these risks and opportunities;
- b) how to: **integrate** and **implement** the actions into its quality management system processes (see 4.4); **evaluate** the effectiveness of these actions.

Actions taken to address risks and opportunities **SHALL** be proportionate to the potential impact on the conformity of products and services.

NOTE Options to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

6.2 Quality objectives and planning to achieve them (Revised)

6.2.1 The organization **SHALL establish** quality objectives at relevant functions, levels and processes.

The quality objectives **SHALL**:

- c) take **into account** applicable requirements;
- d) be **relevant** to conformity of products and services and the enhancement of customer satisfaction;
- e) be **monitored**;
- f) be **communicated**;
- g) be **updated** as appropriate.

The organization **SHALL** retain documented information on the quality objectives. (New)

6.2.2 When **planning** how to achieve its quality objectives, the organization **SHALL 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**.

6.3 Planning of changes

Where the organization **determines** the need for change to the quality management system (see 4.4) the change **SHALL** be carried out in a **planned** and systematic manner.

The organization **SHALL** consider:

- a) the purpose of the change and any of its potential consequences;
- b) the integrity of the quality management system;
- c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General (New)

The organization **SHALL** consider:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

7.1.5 Monitoring and measuring resources (New)

Where monitoring or measuring is used for evidence of conformity of products and services to specified requirements the organization **SHALL determine** the resources needed to **ensure** valid and reliable monitoring and measuring results.

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

- a) are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) are **maintained** to **ensure** their continued fitness for their purpose.

The organization **SHALL** retain appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources.

7.1.6 Organizational knowledge (New)

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

This knowledge **SHALL** be **maintained**, and made available to the extent necessary.

When addressing changing needs and trends, the organization **SHALL** consider its current knowledge and **determine** how to acquire or access the necessary additional knowledge.

NOTE 1 Organizational knowledge can include information such as intellectual property and lessons learned.

NOTE 2 To obtain the knowledge required, the organization can consider:

- a) internal sources (e.g. learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the organization);
- b) external sources (e.g. standards, academia, conferences, gathering knowledge with customers or providers).

7.3 Awareness (New)

Persons doing work under the organization's control **SHALL** be aware of:

- d) the implications of not conforming with the quality management system requirements.

7.4 Communication (New)

The organization **SHALL determine** the internal and external communications relevant to the quality management system including:

- a) on what it will **communicate**;
- b) when to **communicate**;
- c) with whom to **communicate**;
- d) how to **communicate**.

7.5.2 Creating and updating (New)

When creating and updating documented information the organization **SHALL ensure** appropriate:

- a) identification and description (e.g. a title, date, author, or reference number);
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) **Review** and approval for suitability and adequacy.

7.5.3 Control of documented Information (Revised)

7.5.3.1 Documented information required by the quality management system and by this International Standard **SHALL** be controlled to **ensure**:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

8 Operation

8.1 Operational planning and control (New)

The organization **SHALL control** planned changes and **Review** the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

8.2 Determination of requirements for products and services

8.2.1 Customer communication (New)

The organization **SHALL establish** the processes for communicating with customers in relation to:

- e) specific requirements for contingency actions, when relevant.

8.2.3 Review of requirements related to products and services (New)

NOTE Requirements can also include those arising from relevant interested parties.

8.3 Design and development of products and services (Revised/New)

8.3.1 General

Where the detailed requirements of the organization's products and services are not already **established** or not **defined** by the customer or by other interested parties, such that they are adequate for subsequent production or

service provision, the organization **SHALL establish, implement and maintain** a design and development process.

NOTE 2 For services, design and development planning can address the whole service delivery process. The organization can therefore choose to consider the requirements of clauses 8.3 and 8.5 together.

8.3.2 Design and development planning (Revised/New)

In determining the stages and controls for design and development, the organization **SHALL** consider:

- a) the nature, duration and complexity of the design and development activities;
- b) requirements that specify particular process stages, including applicable design and development reviews;
- e) the need to control interfaces between individuals and parties involved in the design and development process;
- f) the need for involvement of customer and user groups in the design and development process;
- g) the necessary documented information to confirm that design and development requirements have been met.

8.3.3 Design and development Inputs (New)

The organization **SHALL** determine:

- c) standards or codes of practice that the organization has committed to **implement**;
- d) internal and external resource needs for the design and development of products and services;
- e) the potential consequences of failure due to the nature of the products and services;
- f) the level of control expected of the design and development process by customers and other relevant interested parties.

8.3.4 Design and development controls (Revised)

CONSLIDATED DESIGN REVIEW, VERIFICATION & VALIDATION (BUT REDUCING REQUIREMENTS)

8.3.6 Design and development changes

REDUCED THE REQUIREMENTS AND ELMINATED THE NEED TO RE-REVIEW, VERIFY AND VALIDATE.

8.4 Control of externally provided products and services (Revised)

8.4.1 General

The organization **SHALL** apply the specified requirements for the control of externally provided products and services when:

- a) products and services are provided by external providers for incorporation into the organization's own products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process or part of a process is provided by an external provider as a result of a decision by the organization to outsource a process or function.

8.4.2 Type and extent of control of external provision (Revised)

In determining the type and extent of controls to be applied to the external provision of processes, products and services, the organization **SHALL** take into consideration:

b) the perceived effectiveness of the controls applied by the external provider.

Processes or functions of the organization which have been outsourced to an external provider remain within the scope of the organization's quality management system; accordingly, the organization **SHALL** consider a) and b) above and **define** both the controls it intends to apply to the external provider and those it intends to apply to the resulting process output.

8.4.3 Information for external providers (New)

The organization **SHALL communicate** to external providers applicable requirements for the following:

a) the products and services to be provided or the processes to be performed on behalf of the organization;

b) approval or release of products and services, methods, processes or equipment;

c) competence of personnel, including necessary qualification;

d) their interactions with the organization's quality management system;

8.5 Production and service provision

8.5.1 Control of production and service provision (Revised)

Controlled conditions **SHALL** include, as applicable:

a) the availability of documented information that **defines** the characteristics of the products and services;

b) the availability of documented information that **defines** the activities to be performed and the results to be achieved;

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

d) the use, and control of suitable infrastructure and process environment;

f) the competence and, where applicable, required qualification of persons;

8.5.3 Property belonging to customers or external providers (Revised)

When property of the customer or external provider is incorrectly used.....the organization **SHALL** report this to the customer or external provider.

NOTE Customer property can include material, components, tools and equipment, customer premises, intellectual property and personal data.

8.5.5 Post-delivery activities (New)

As applicable, the organization **SHALL** meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization **SHALL** consider:

- a) the risks associated with the products and services;
- b) the nature, use and intended lifetime of the products and services;
- c) customer feedback;
- d) statutory and regulatory requirements.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes (New)

The organization **SHALL** Review and control unplanned changes essential for production or service provision to the extent necessary to **ensure** continuing conformity with specified requirements.

The organization **SHALL** retain documented information describing the results of the Review of changes, the personnel authorizing the change, and any necessary actions.

8.7 Control of nonconforming process outputs, products and services (Revised)

The organization **SHALL** ensure process outputs, products and services that do not conform to requirements are identified and controlled to prevent their unintended use or delivery.

As applicable, the organization **SHALL** deal with nonconforming process outputs, products and services in one or more of the following ways:

- a) correction;
- b) segregation, containment, return or suspension of provision of products and services;
- c) informing the customer;
- d) obtaining authorization for:
 - use “as-is”;
 - release, continuation or re-provision of the products and services;
 - acceptance under concession.

The organization **SHALL** retain documented information of actions taken on nonconforming process outputs, products and services, including on any concessions obtained and on the person or authority that made the decision regarding dealing with the nonconformity.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation (Revised)

9.1.1 General

The organization **SHALL 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 organization **SHALL evaluate** the quality performance and the effectiveness of the quality management system.

9.1.3 Analysis and evaluation (Revised)

The organization **SHALL analyze and evaluate** appropriate data and information arising from monitoring, measurement and other sources.

The output of analysis and evaluation **SHALL** be used to:

- a) **demonstrate** conformity of products and services to requirements;
- b) assess and enhance customer satisfaction;
- c) **ensure** conformity and effectiveness of the quality management system;
- d) **demonstrate** that **planning** has been successfully **implemented**;
- e) assess the performance of processes;
- f) assess the performance of external provider(s);
- g) **determine** the need or opportunities for improvements within the quality management system.

The results of analysis and evaluation **SHALL** also be used to provide inputs to management **Review**.

9.3 Management Review

9.3.1 The management **Review SHALL** be **planned** and carried out taking into consideration:

- c) information on the quality performance, including trends and indicators for:
 - 1) nonconformities and corrective actions;
 - 2) monitoring and measurement results;
 - 3) audit results;
 - 4) customer satisfaction;
 - 5) issues concerning external providers and other relevant interested parties;
 - 6) adequacy of resources required for **maintaining** an effective quality management system;
 - 7) process performance and conformity of products and services;

d) the effectiveness of actions taken to address risks and opportunities (see clause 6.1);

10 Improvement

10.1 General (New)

This **SHALL** include, as appropriate:

- a) improving processes to prevent nonconformities;
- b) improving products and services to meet known and predicted requirements;
- c) improving quality management system results.

NOTE Improvement can be effected reactively (e.g. corrective action), incrementally (e.g. continual improvement), by step change (e.g. breakthrough), creatively (e.g. innovation) or by re-organization (e.g. transformation).

TRANSITION GOING FORWARD

What will this change mean?

For any organization the degree of change necessary will be dependent upon the maturity and effectiveness of the current management system, organizational structure and practices, etc.

Note: You may want to consider an impact analysis or gap assessment to identify realistic resource and time implications.

How long do I have to make the transition?

In October 2013, the International Accreditation Forum (IAF) and the ISO Committee on Conformity Assessment (CASCO) have agreed to a three year transition period from the publication date of ISO 9001:2015. So this would mean you have until September 15, 2018.

Will my current certification still be valid?

The short answer is yes. However, ISO 9001:2008 certifications will no longer be valid after three years from publication of ISO 9001:2015. E.g., this means September 15, 2018.

The expiry date of certifications to ISO 9001:2008 issued during the transition period needs to correspond to the end of the three year transition period.

My organization is currently using ISO 9001:2008, what actions should I be taking?

- Identify organizational gaps which need to be addressed to meet new requirements.
- Develop an implementation plan.
- Provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organization.
- Update the existing quality management system (QMS) to meet the revised requirements and provide verification of effectiveness.
- Where applicable, liaise with their Certification Body for transition arrangements.

NOTE: Users should be aware that at the Draft International Standard (DIS) stage technical changes may still occur, therefore it is recommended that, while preparation can be carried out at the DIS stage, significant changes should not be implemented until the Final Draft International Standard (FDIS) is issued and the technical content is finalized.

What actions will my Certification Body like take?

- Communicate with existing clients and share guidance on the transition process and arrangements for transition.
- Plan the timing of audit and certification activities for the revised standard.
- Plan the timing of certification decisions for upgrading certification documents.
- Encourage current and new users of ISO 9001:2008 to implement ISO 9001:2015 at an early stage, taking into account any changes that may occur during the DIS stage.
- Arrange audit schedules for existing client organizations.
- Train their auditors and verify the results to ensure the relevant level of competence is demonstrated.

What will my Certification Body (CB) be doing during this transition?

CBs should communicate their transition arrangements to their clients at the earliest opportunity.

It is recommended that this is done at the latter DIS or FDIS stage.

Will my Certification Body have a transition plan?

Yes. CBs are expected to develop a transition plan to address the following:

- Training and verification of competence of auditors and other staff.
- The CB's arrangements for communicating with its clients.
- The CB's arrangements for auditing conformance to the new standard. For example, will it be a single visit or a staged approach.
- How the CB will ensure clients' ongoing conformance to ISO 9001:2008 through the transition process.
- How the CB plans to use the results of any audits conducted against the FDIS.
- Action to be taken in respect of clients that have failed to complete the transition by three years after the publication of ISO 9001:2015. For example, the level of audit necessary for certification to be reinstated.

Certification Bodies are asked to ensure the following:

- a) All issues that require client action for compliance with the new requirements should be clearly identified and raised as documented findings.
- b) Only when all identified outstanding issues have been appropriately addressed and the effectiveness of the management system demonstrated, can auditors recommend certification to the published ISO 9001:2015 standard.
- c) Records should be available to demonstrate that all prior transition audit findings have been evaluated for corrective action and compliance before any recommendation for approval to ISO 9001:2015 can be made.
- d) The CB should ensure that the evaluation of a client's conformance to the new requirements during the transition phase does not interfere with the client's on-going conformance to ISO 9001:2008.
- e) Where evaluation activities have taken place at the FDIS, a review will be undertaken by the Decision Maker to ensure the validity of such activity is taken into account in the decision process.

ISO 9001:2008 to ISO/DIS 9001

Correlation Matrix

ISO 9001:2008		ISO/DIS 9001	
4	Quality management system	4	Quality management system
4.1	General requirements	4.4	Quality management system and its processes
4.2	Documentation requirements	7.5	Documented information
4.2.1	General	7.5.1	General
4.2.2	Quality manual	4.3	Determining the scope of the quality management system
		7.5.1	General
		4.4	Quality management system and its Processes
4.2.3	Control of documents	7.5.2	Creating and updating
		7.5.3	Control of documented Information
4.2.4	Control of records	7.5.2	Creating and updating
		7.5.3	Control of documented Information
5	Management responsibility	5	Leadership
5.1	Management commitment	5.1	Leadership and commitment
		5.1.1	Leadership and commitment for the quality management system
5.2	Customer focus	5.1.2	Customer focus
5.3	Quality policy	5.2	Quality policy
5.4	Planning	6	Planning for the quality management system
5.4.1	Quality objectives	6.2	Quality objectives and planning to achieve them
5.4.2	Quality management system planning	6	Planning for the quality management system
		6.1	Actions to address risks and opportunities
		6.3	Planning of changes
5.5	Responsibility, authority and communication	5	Leadership
5.5.1	Responsibility and authority	5.3	Organizational roles, responsibilities and authorities
5.5.2	Management representative		Title removed
		5.3	Organizational roles, responsibilities and authorities
5.5.3	Internal communication	7.4	Communication
5.6	Management review	9.3	Management review
5.6.1	General	9.3.1	Management review

5.6.2	Review input	9.3.1	Management review
5.6.3	Review output	9.3.2	Management review
6	Resource management	7.1	Resources
6.1	Provision of resources	7.1.1	General
		7.1.2	People
6.2	Human resources		Title removed
		7.2	Competence
6.2.1	General	7.2	Competence
6.2.2	Competence, training and awareness	7.2	Competence
		7.3	Awareness
6.3	Infrastructure	7.1.3	Infrastructure
6.4	Work environment	7.1.4	Environment for the operation of processes
7	Product realization	8	Operation
7.1	Planning of product realization	8.1	Operational planning and control
7.2	Customer-related processes	8.2	Determination of requirements for products and services
7.2.1	Determination of requirements related to the product	8.2.2	Determination of requirements related to products and services
7.2.2	Review of requirements related to the product	8.2.3	Review of requirements related to the products and services
7.2.3	Customer communication	8.2.1	Customer communication
7.3	Design and development	8.5	Production and service provision
7.3.1	Design and development planning	8.3	Design and development of products and services
		8.3.1	General
		8.3.2	Design and development planning
7.3.2	Design and development inputs	8.3.3	Design and development Inputs
7.3.3	Design and development outputs	8.3.5	Design and development outputs
7.3.4	Design and development review	8.3.4	Design and development controls
7.3.5	Design and development verification	8.3.4	Design and development controls
7.3.6	Design and development validation	8.3.4	Design and development controls
7.3.7	Control of design and development changes	8.3.6	Design and development changes
7.4	Purchasing	8.4	Control of externally provided products and services
7.4.1	Purchasing process	8.4.1	General
		8.4.2	Type and extent of control of external provision
7.4.2	Purchasing information	8.4.3	Information for external providers
7.4.3	Verification of purchased product	8.6	Release of products and services
7.5	Production and service provision	8.5	Production and service provision
7.5.1	Control of production and service provision	8.5.1	Control of production and service provision

	8.5.5 Post-delivery activities
7.5.2 Validation of processes for production and service provision	8.5.1 Control of production and service provision
7.5.3 Identification and traceability	8.5.2 Identification and traceability
7.5.4 Customer property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of product	8.5.4 Preservation
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources
8.0 Measurement, analysis and improvement	9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Customer satisfaction	9.1.2 Customer satisfaction
8.2.2 Internal audit	9.2 Internal audit
8.2.3 Monitoring and measurement of processes	9.1.1 General
8.2.4 Monitoring and measurement of product	8.6 Release of products and services
8.3 Control of nonconforming product	8.7 Control of nonconforming process outputs, products and services
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	10 Improvement
8.5.1 Continual improvement	10.1 General 10.3 Continual Improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	Clause removed 6.1 Actions to address risks and opportunities (see 6.1.1, 6.1.2)

ISO/DIS 9001 to ISO 9001:2008

Correlation Matrix

ISO/DIS 9001		ISO 9001:2008	
4	Context of the organization	1.0	Scope
4.1	Understanding the organization and its context	1.1	General
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
4.4	Quality management system and its processes	4	Quality management system 4.1 General requirements
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	5.1	Management commitment
5.1.2	Customer focus	5.2	Customer focus
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
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	<u>Provision</u> of resources
7.1.3	Infrastructure	6.3	Infrastructure
7.1.4	Environment for the operation of processes	6.4	Work environment

7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment
7.1.6 Organizational knowledge	New
7.2 Competence	6.2.1 General 6.2.2 Competence, training and awareness
7.3 Awareness	6.2.2 Competence, training and awareness
7.4 Communication	5.5.3 Internal communication
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
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
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 7.3.5 Design and development verification 7.3.6 Design and development validation
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
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 traceability	7.5.3 Identification and traceability
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property
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
8.5.6 Control of changes	7.3.7 Control of design and development changes
8.6 Release of products and services	8.2.4 Monitoring and measurement of processes 7.4.3 Verification of purchased product
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
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