Changes in
ISO 9001:2008
from
ISO 9001:2000

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ISO-IAF Joint Plan

According to a joint announcement by the ISO (International Organization for Standardization) and the IAF (International Accreditation Forum), the two organizations have agreed to an implementation plan for a smooth migration to ISO 9001:2008.

1) Certification of conformity to ISO 9001:2008 will only be issued after publication of ISO 9001:2008 (issued November 15, 2008) and after a routine surveillance audit or re-certification audit against ISO 9001:2008.

2) One year after publication of ISO 9001:2008, all certifications issued (new certifications and re-certifications) must be to ISO 9001:2008.

3) Two years after publication of ISO 9001:2008, existing ISO 9001:2000 certifications will not be valid.

This plan is possible, because ISO and IAF agreed that ISO 9001:2008 introduces no new requirements. The revised quality standard only introduces clarifications to the ISO 9001:2000 requirements, as well as, changes to improve consistency with ISO 14001:2004, the environmental standard.

ISO 9001:2008 Differences

The differences in ISO 9001:2008 vs. ISO 9001:2000 are described below. Deleted ISO 9001:2000 text is indicated by ~~strikethroughs~~. New ISO 9001:2008 text is <mark>highlighted</mark> and underlined. The underlining will allow readers to distinguish the new text, even if this paper is printed without color.

Most of the text in ISO 9001:2000 has not been affected by ISO 9001:2008. Text from the standard is shown in this paper as *Italics* to distinguish it from comments.

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ISO 9001:2008 - Introduction

0.1 General

In the Introduction, ISO 9001:2008 adds "organizational environment", "change", and "risk" to the list of factors that influence the design and implementation of a quality management system. The other changes to this text are minor revisions to the other factors, as well as, the use of a bulleted list.

> *The design and implementation of an organization's quality management system is influenced by*
>
> *- its organizational environment, change in that environment, and the risks associated with that environment,*
> *- its varying needs,*
> *- its particular objectives,*
> *- the products it provides provided,*
> *- the processes it employs employed, and*
> *- its the size and organizational structure of the organization.*

Later in section 0.1, ISO 9001:2008 changes "regulatory" to "statutory and regulatory" and clarifies that the customer, statutory, and regulatory requirements are those applicable to the product.

> *This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory, and regulatory requirements applicable to the product, and the organization's own requirements.*

0.2 Process Approach

In the Process Approach section, ISO 9001:2008 switches from having to "identify" linked activities to "determine" linked activities. The section clarifies that a Process can be an activity or set of activities.

> *For an organization to function effectively, it has to identify determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process.*

Also in this section, the definition of the Process Approach has been clarified by adding "to produce the desired outcome" to the text below:

> *The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".*

0.3 Relationship with ISO 9004

The planned revision to ISO 9004:2000 is expected in 2009 with extensive changes, including a new clause structure that no longer matches that of ISO 9001.

ISO 9001:2008 Differences

As a result, ISO 9001:2008 no longer refers to the two standards as having, "similar structures in order to assist their application as a consistent pair." The title of the revamped ISO 9004 is expected to be, "Managing for the Sustained Success of an Organization - A Quality Management Approach".

> *The present editions of ISO 9001 and ISO 9004 ~~have been developed as a consistent pair of~~ are quality management system standards which have been designed to complement each other, but can also be used independently. ~~Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.~~*

ISO 9001:2008 adds a Note about the upcoming revision to ISO 9004.

> *NOTE: At the time of the publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory, or contractual use.*

0.4 Compatibility with Other Management Systems
The change at this section is to refer to ISO 14001:2004 instead of ISO 14001:1996, and to refer to the appendix that compares the clauses of ISO 9001:2008 to the clauses of ISO 14001:2004.

> *~~This International Standard has been aligned with ISO 14001:1996 in order~~ During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.*

ISO 9001:2008 - Scope

1. Scope
1.1 General
This section still explains that ISO 9001 specifies requirements for a quality management system. It refers to the product as meeting customer and applicable "regulatory" requirements, as well as, enhancing customer satisfaction by assuring conformity to customer and applicable "regulatory" requirements. ISO 9001:2008 has expanded the uses of "regulatory" to "statutory and regulatory".

> *a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and*
>
> *b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.*

The Note at this General section used to say the term "product" applied only to the product intended for, or required by, a customer. ISO 9001:2008 has expanded Product to include any intended output resulting from the product realization processes.

> *NOTE ==1==: In this International Standard, the term "product" ==only== applies ~~only~~ to*
> *- ==a== ~~the~~ product intended for, or required by, a customer,*
> *- ==any intended output resulting from the product realization processes.==*

A second Note has been added to explain that "statutory and regulatory" requirements can be expressed as "legal" requirements.

> *==NOTE 2: Statutory and regulatory requirements can be expressed as legal requirements.==*

1.2 Application
ISO 9001:2000 stated that a requirement exclusion cannot affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements. ISO 9001:2008 replaces "regulatory" with "statutory and regulatory".

> *Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable ==statutory and== regulatory requirements.*

ISO 9001:2008 – Normative Reference

2. Normative Reference
Although the text at this section has been significantly reduced (the deleted text is not shown), the key change is to refer to ISO 9000:2005 instead of the old ISO 9000:2000.

> *==The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies==.*
>
> *ISO 9000:~~2000~~==2005==, Quality management systems - Fundamentals and vocabulary*

ISO 9001:2008 – Terms and Definition

3. Terms and Definitions
The change at this section was to no longer explain the supply chain terms, including that "supplier" replaced "subcontractor" and "organization" replaced "supplier". The explanation was needed for the transition from ISO 9001:1994 to ISO 9001:2000, but not now. The only text remaining is shown below:

> *For the purposes of this ==document== ~~International Standard~~, the terms and definitions given in ISO 9000 apply.*
>
> *Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".*

ISO 9001:2008 - Clause 4

4. Quality Management System

4.1 General Requirements

In 4.1, General Requirements, sub-clause (a), the word "Identify" has been replaced with "Determine".

> *a) ~~Identify~~ <mark>Determine</mark> the processes needed for the quality management system and their application throughout the organization (see 1.2),*

Although similar, the words "Identify" and "Determine" have slightly different meanings. To identify is to recognize or establish something as being a particular thing. To determine is to apply reason and reach a decision. To determine the processes implies more analysis and judgment than merely identifying them.

> *e) monitor, measure <mark>where applicable</mark>, and analyze these processes, and ...*

Processes are monitored, but may not need to be measured. Therefore, the requirement change above indicates processes are only measured where applicable.

Later in clause 4.1, regarding outsourcing:

> *Where an organization chooses to outsource any process that affects product conformity ~~with~~ <mark>to</mark> requirements, the organization shall ensure control over such processes. ~~Control of such~~ <mark>The type and extent of control to be applied to these</mark> outsourced processes shall be ~~identified~~ <mark>defined</mark> within the quality management system.*

This addition clarifies that specific controls are to be defined and applied, not just identified. See the new Note 3 below for an explanation of the type and extent of controls for an outsourced process.

The current Note under clause 4.1 has been expanded and two new Notes have been added:

> *NOTE <mark>1</mark>: Processes needed for the quality management system referred to above ~~should~~ include processes for management activities, provision of resources, product realization, ~~and~~ measurement, <mark>analysis, and improvement</mark>.*

The text above expands from "measurement" to "measurement, analysis, and improvement" to match the title for clause 8. And, by deleting "should", it clearly states that these processes are included.

The new Note below provides an explanation of what is considered an outsourced process.

> <mark>*NOTE 2: An outsourced process is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.*</mark>

ISO 9001:2008 Differences

The new Note below identifies the factors influencing the control of an outsourced process.

> *NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory, and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as*
>
> *a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,*
>
> *b) the degree to which the control for the process is shared;*
>
> *c) the capability of achieving the necessary control through the application of clause 7.4.*

Outsourcing a process to another organization typically involves the purchase of those services. As a result, the requirements of clause 7.4, including the controls mentioned in 7.4.1, apply equally to the supplier selected to perform the outsourced process.

4.2 Documentation Requirements
4.2.1 General
The changes in this section are basically just a restructuring of the sub-clauses c), d), and e).

> *c) documented procedures and records required by this International Standard, and*
>
> *d) documents, including records, needed determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. ,and*
>
> *e) records required by this International Standard (see 4.2.4).*

You can see that adding "records" to sub-clause (c) allowed sub-clause (e) to be dropped. Sub-clause (d) has been expanded to include the necessary records.

The first Note for clause 4.2.1 has added two more sentences:

> *A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.*

An example for the first sentence would be satisfying the requirements for documented procedures in 8.5.2, Corrective Action, and 8.5.3, Preventive Action, through one combined Corrective and Preventive Action procedure. An example for the second sentence would be splitting the required procedure for the Control of Documents into two separate documented procedures.

4.2.2 Quality Manual
No changes in ISO 9001:2008.

4.2.3 Control of Documents
The opening sentence of this clause in ISO 9001:2008 still states that documents required by the quality management system are to be controlled. The only revision to clause 4.2.3 is shown below:

> *f) to ensure that documents of external origin ==determined by the organization to be necessary for the planning and operation of the quality management system== are identified and their distribution controlled, and*

The change in sub-clause (f) clarifies that not all external documents have to be identified and controlled; only those needed for the planning and operation of the quality management system.

4.2.4 Control of Records
The opening sentence for clause 4.2.4 has expanded from records being "maintained" to having them "controlled". Maintaining records would simply keep them in good condition. Controlling the records means to regulate their use.

> *Records ~~shall be~~ established ~~and maintained~~ to provide evidence of conformity to requirements and of the effective operation of the quality management system ==shall be controlled==.*
>
> *~~Records shall remain legible, readily identifiable and retrievable.~~*
>
> *==The organization shall establish== a documented procedure ~~shall be established~~ to define the controls needed for the identification, storage, protection, retrieval, retention ~~time~~, and disposition of records.*
>
> *==Records shall remain legible, readily identifiable, and retrievable.==*

The requirement for a documented Record Control procedure has been rewritten, but the content is basically the same. It is now a separate paragraph for emphasis and moved up in the section.

Note that "retention time" has been reduced to "retention". And, you can see that records must still remain legible, readily identifiable, and retrievable. This requirement is now a separate paragraph and moved to the end of clause 4.2.4.

ISO 9001:2008 - Clause 5

5. Management Responsibility
5.1 Management Commitment
5.2 Customer Focus
5.3 Quality Policy
5.4 Planning
No changes in ISO 9001:2008 for clauses 5.1 through 5.4.

5.5 Responsibility, Authority, and Communication
5.5.1 Responsibility and Authority
No changes in ISO 9001:2008.

5.5.2 Management Representative
Most organizations already appoint a Management Representative that is a member of their own management team. The change below clarifies that requirement.

> *Top management shall appoint a member of ==the organization's== management who, irrespective of other responsibilities, shall have responsibility and authority that includes:*

Some companies in the past have outsourced the Management Representative role to someone in a different organization, or even to their consultant. This text change may be aimed at that practice.

5.5.3 Internal Communication
No changes in ISO 9001:2008.

5.6 Management Review
No changes in ISO 9001:2008.

ISO 9001:2008 - Clause 6

6. Resource Management
6.1 Provision of Resources
No changes in ISO 9001:2008.

6.2 Human Resources
6.2.1 General
The revision below changes from work affecting "product quality" to work affecting "conformity to product requirements". Since quality is the degree to which a set of inherent characteristics fulfils requirements, then product quality would be the degree of conformity to product requirements.

> *Personnel performing work affecting ==conformity== to product ~~quality~~ ==requirements== shall be competent on the basis of appropriate education, training, skills and experience.*

The revision above should not be viewed as a new requirement. Anyone performing, verifying, or managing work within the scope of the quality management system, including supporting services, can affect conformity to product requirements. A new Note has been added to 6.2.1 to explain this point.

> *==NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.==*

6.2.2 Competence, ==**Training, and**== Awareness~~, and Training~~

This clause title has been changed from "Competence, Awareness, and Training" to "Competence, Training, and Awareness". Awareness comes from some form of training and should be last in the title. And, that is also the sequence of the requirements as listed within clause 6.2.2.

The change in 6.2.1 from "product quality" to "product requirements" has been made to this sub-clause:

> *a) determine the necessary competence for personnel performing work affecting ==conformity to== product ~~quality~~ requirements,*

Use below of the phrase "where applicable" recognizes that training or other actions may not be necessary, since individuals may already have the necessary competence. And, since "these needs" could be taken out of context, the requirement has been revised to specifically mention competence.

> *b) ==where applicable==, provide training or take other actions to ~~satisfy these needs~~ ==achieve the necessary competence==,*

6.3 Infrastructure

The only change in 6.3 was to add "information systems" as an example of a supporting service.

> *c) supporting services (such as transport, ~~or~~ communication==, or information systems==).*

6.4 Work Environment

The only change in 6.4 was to add a Note to explain the term "work environment" by giving examples of work environment conditions for achieving conformity to product requirements.

> *==NOTE: The term "work environment" relates to those conditions under which work is performed including physical, environmental, and other factors (such as noise, temperature, humidity, lighting, or weather).==*

ISO 9001:2008 - Clause 7

7. Product Realization
7.1 Planning of Product Realization
The only significant change to the text of clause 7.1 is the addition of "measurement" as one of the required activities to be determined during the planning of product realization.

In planning product realization, the organization shall determine the following, as appropriate:
b) the need to establish processes, and documents, and to provide resources specific to the product;

c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

7.2 Customer-Related Processes
7.2.1 Determination of Requirements Related to the Product
The change below from "related" to "applicable" shifts from determining legal requirements that are merely associated with the product to those that are relevant and can be applied to the product.

The organization shall determine:

c) statutory and regulatory requirements related applicable to the product, and

---

Since the bulleted list for 7.2.1 begins with "The organization shall determine", the use of the word "determined" again in the entry below was not appropriate. The new text clarifies that the additional requirements "considered necessary" must be determined.

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d) any additional requirements determined considered necessary by the organization.

Organizations may not have considered the breadth of post-delivery activities as described by the new Note below.

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

7.2.2 Review of Requirements Related to the Product
7.2.3 Customer Communication
No changes in ISO 9001:2008.

7.3 Design and Development

7.3.1 Design and Development Planning

Clause 7.3.1.b continues to state that the organization must determine the review, verification, and validation appropriate for each design and development stage. The new Note below explains that although review, verification, and validation have distinct goals, they can be carried out separately or in any combination.

NOTE: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

7.3.2 Design and Development Inputs

This clause continues to require the design and development inputs to be determined and records to be maintained. It lists several types of requirements to be included. The revision below simply changes from "These inputs" to "The inputs".

~~These~~ The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and Development Outputs

The change below removes the unnecessary word, "provided". It also switches from "a form that enables verification" to "a form suitable for verification". To enable something is to make it possible. However, to be suitable means it is meant for use, or in this case, for verification.

The outputs of design and development shall be ~~provided~~ in a form ~~that enables~~ suitable for verification against the design and development input and shall be approved prior to release.

The change below was to simply remove the word "for".

b) provide appropriate information for purchasing, production, and ~~for~~ service provision,

The new Note below reminds the reader that clause 7, Production and Service Provision, includes sub-clause 7.5.5, Preservation of Product. Why do that? To indicate that the design output should consider product preservation, e.g., product packaging.

NOTE: Information for production and service provision can include details for the preservation of product.

7.3.4 Design and Development Review

7.3.5 Design and Development verification

7.3.6 Design and Development Validation

No changes in ISO 9001:2008 for clauses 7.3.4 through 7.3.6.

7.3.7 Control of Design and Development Changes

The two paragraphs in this section were merged into one paragraph. No text changes.

7.4 Purchasing
No changes in ISO 9001:2008.

7.5 Production and Service Provision
7.5.1 Control of Production and Service Provision
This clause continues to require planning and carrying out production and service provision under controlled conditions. However, two of the listed six conditions have been revised.

Later in the standard, the title of clause 7.6 has been changed to refer to the control of monitoring and measuring "equipment" instead of "devices", therefore, the terminology has been changed below:

> *d) the availability and use of monitoring and measuring ~~devices~~ ==equipment==,*

The change below simply clarifies that the implementation activities are those related to the "product".

> *f) the implementation of ==product== release, delivery, and post-delivery activities.*

7.5.2 Validation of Processes for Production and Service Provision
The revised text in this clause makes clear that any process output that can't be verified may result in deficiencies becoming known only after the product is in use or the service has been delivered.

> *The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. ~~This includes any processes where~~ ==and, as a consequence,== deficiencies become apparent only after the product is in use or the service has been delivered.*

7.5.3 Identification and Traceability
This clause continues to state that, where appropriate, the organization must identify the product by suitable means "throughout product realization". The text below refers to inspection and test status of the product, and some organizations may have thought it only applied to the final product. The revision below clarifies that identifying the product monitoring and measurement status applies throughout product realization, from received product to final product, including in-process product.

> *The organization shall identify the product status with respect to monitoring and measurement requirements ==throughout product realization==.*

By moving the "records" reference to the end of the sentence below, the meaning has expanded from recording the product identification, to keeping any type of record associated with product traceability.

> *Where traceability is a requirement, the organization shall control ~~and record~~ the unique identification of the product ==and maintain records== (see 4.2.4).*

7.5.4 Customer Property
The change below reads better, but hasn't changed the requirement to report customer property issues to the customer and keep records.

> *If any customer property is lost, damaged, or otherwise found to be unsuitable for use, ~~this shall be reported~~ <mark>the organization shall report this</mark> to the customer and ~~records maintained~~ <mark>maintain records</mark> (see 4.2.4).*

The existing Note in 7.5.4 has been revised to include "personal data" as an example of customer property, broadening its applicability to more organizations, especially service organizations.

> *NOTE: Customer property can include intellectual property <mark>and personal data</mark>.*

7.5.5 Preservation of product
If anyone was confused over the meaning of "conformity of product" in the current text, using "conformity to requirements" should be easier to understand in the new text.

> *The organization shall preserve the ~~conformity of~~ product during internal processing and delivery to the intended destination <mark>in order to maintain conformity to requirements</mark>.*

The current requirement that begins with, "This preservation shall include", doesn't give the flexibility to include, or not include, the identification, handling, packaging, storage, and protection of the product. The change below allows product preservation to be applied as applicable.

> *~~This~~ <mark>As applicable,</mark> preservation shall include identification, handling, packaging, storage, and protection. Preservation shall also apply to the constituent parts of a product.*

7.6 Control of Monitoring and Measuring ~~Devices~~ <mark>Equipment</mark>
The second clause title to change in ISO 9001:2008 is clause 7.6, where "devices" has been changed to "equipment". The term equipment was already used in several places in clause 7.6. The term "devices" has a broader scope and could include non-equipment types of tools. Equipment is the better choice for this calibration clause.

The changes to the clause below are to replace "devices" with "equipment" and to remove the reference to clause 7.2.1, Determination of Requirements Related to the Product.

> *The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring ~~devices~~ <mark>equipment</mark> needed to provide evidence of conformity of product to determined requirements ~~(see 7.2.1)~~.*

A minor change to 7.6 (a) is shown below. This requirement went from "calibrated or verified" to "calibrated or verified, or both", meaning a type of equipment might be calibrated and/or verified.

> *Where necessary to ensure valid results, measuring equipment shall:*
>
> *a) be calibrated or verified<mark>, or both,</mark> at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);*

ISO 9001:2008 Differences

The prior statement below, that measuring equipment must "be identified" sounded like the organization was to add identification. However, the measuring equipment may come with the identification already in place.

> *c) ~~be identified~~ <mark>have identification</mark> ~~to enable~~ <mark>in order to determine</mark> ~~the~~ <mark>its</mark> calibration status ~~to be determined~~;*

The text below was split from its old paragraph and made a standalone sentence for emphasis.

> *Records of the results of calibration and verification shall be maintained (see 4.2.4).*

Software development organizations may have been unsure how to "confirm", per clause 7.6, that software used for monitoring and measurement has the ability to satisfy the intended application.

A new Note was added to explain that confirmation of software would typically include verification and configuration management.

> <mark>*NOTE: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.*</mark>

The prior Note for clause 7.6 was dropped. It referred the reader to the ISO 10012-1 and ISO 10012-2 standards for guidance. Although these standards have been replaced with ISO 10012:2003, the reference was not retained.

> *~~NOTE: See ISO 10012-1 and ISO 10012-2 for guidance.~~*

ISO 9001:2008 - Clause 8

8. Measurement, Analysis, and Improvement

8.1 General

The prior use of "conformity of the product" has been revised to "conformity to product requirements".

> *The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed*
>
> *a) to demonstrate conformity ~~of the~~ to product requirements,*

8.2 Monitoring

8.2.1 Customer Satisfaction

A new Note has been added to clause 8.2.1 to provide examples of monitoring customer perceptions.

> *NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.*

8.2.2 Internal Audit

The change below was to simply add the word "The" at the beginning of the sentence.

> *The ~~S~~selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.*

The requirement below was edited to emphasize the need for a documented procedure (by placing it first in the sentence). Also, "establishing records" has been moved ahead of "reporting results" in the list of topics to be defined in the procedure. Records are being captured throughout the audit and should be listed before the reporting of results.

> *A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.*
>
> *~~The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.~~*

The new sentence below highlights the need to maintain records of the audit and its results. The reference in the old text to 4.2.4 for record control was moved to this new sentence.

> *Records of the audits and their results shall be maintained (see 4.2.4).*

Expanding from "actions" to "any necessary corrections and corrective actions" reminds us that an immediate correction might be needed before determining the cause of the nonconformity and taking corrective action to prevent its recurrence. Clause 8.2.3 also refers to corrections and corrective actions.

> *The management responsible for the area being audited shall ensure that <mark>any necessary corrections and corrective</mark> actions are taken without undue delay to eliminate detected nonconformities and their causes.*

The reference in the Note below to the withdrawn ISO 10011, Guidelines for Auditing Quality Systems, has been replaced with a reference to ISO 19011, Guidelines for Quality and/or Environmental Management Systems Auditing.

> *NOTE: See ~~ISO 10011-1, ISO 10011-2 and ISO 10011-3~~ <mark>ISO 19011</mark> for guidance.*

8.2.3 Monitoring and Measurement of Processes

This clause requires applying suitable methods for monitoring and measuring processes to demonstrate their ability to achieve planned results. For some supporting processes, these results are only indirectly related to product conformity. Therefore, the reference to product conformity was moved from this paragraph to the new Note below.

> *When planned results are not achieved, correction and corrective action shall be taken, as appropriate~~, to ensure conformity of the product~~.*

What is a "suitable" method for monitoring and measuring processes? The Note below says to consider the type and extent of monitoring or measurement based on the impact of the process on conformity to product requirements and system effectiveness.

> *<mark>NOTE: When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system</mark>.*

8.2.4 Monitoring and Measurement of Product

> *The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). <mark>Evidence of conformity with the acceptance criteria shall be maintained.</mark>*

The requirement to maintain evidence of conformity with acceptance criteria has been moved from the paragraph below to the paragraph above. And, the release of product is not to the next in-process stage, but for delivery to the customer.

> *~~Evidence of conformity with the acceptance criteria shall be maintained~~. Records shall indicate the person(s) authorizing release of product <mark>for delivery to the customer</mark> (see 4.2.4).*

The requirement below has been edited to clarify that the release of product and delivery of service is to the customer.

The release of product release and delivery of service delivery to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of Nonconforming Product
The sentence below has been edited to begin with (instead of end with) the requirement for a documented procedure.

A documented procedure shall be established to define Tthe controls and related responsibilities and authorities for dealing with nonconforming product. shall be defined in a documented procedure.

The requirement below adds "where applicable", meaning where relevant and suitable, to deal with nonconforming product in one or more of the four ways listed.

Where applicable, Tthe organization shall deal with nonconforming product by one or more of the following ways:

The new entry below, in the list of ways to deal with nonconforming product, is edited text from the last sentence in clause 8.3 to become part of the list of ways to deal with nonconforming product.

d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

The deleted text below wasn't actually deleted, just moved from paragraph 3 to paragraph 4.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

The text below was moved from paragraph 4 to become paragraph 3. The requirement is nearer the list of ways for dealing with nonconforming product, which includes taking action to eliminate the detected nonconformity, e.g., rework. Therefore, the requirement for re-verification in that situation is nearby.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

The requirement in paragraph 4 below is from paragraph 3. No changes were made. Since it includes "subsequent actions", e.g., re-verification, it is appropriate for recordkeeping to be last in the section.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4)

The deleted text below was moved to entry (d) in the list of ways to deal with nonconforming product.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of Data
The analysis of data provides information on customer satisfaction, conformity to product requirements, characteristics and trends of processes and products, and suppliers. The changes below were to revise a reference (from 7.2.1 to 8.2.4) and to add new references (8.2.3, 8.2.4, and 7.4).

> *The analysis of data shall provide information relating to*
>
> *a) customer satisfaction (see 8.2.1)*
>
> *b) conformity to product requirements (see 7.2.1) (see 8.2.4),*
>
> *c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and*
>
> *d) suppliers (see 7.4).*

8.5 Improvement
8.5.1 Continual Improvement
No changes in ISO 9001:2008.

8.5.2 Corrective Action
The requirement below switched from "cause" to "causes" to match with "nonconformities" and to be consistent with a similar sentence in 8.5.3, Preventive Action.

> *The organization shall take action to eliminate the cause causes of nonconformities in order to prevent recurrence.*

ISO 9000:2005 defines "review" as an activity to determine the <u>effectiveness</u> of a subject to achieve established objectives. However, the "reviewing" in the requirement below was often interpreted as checking to see if an action was taken, instead of determining its effectiveness. It has been clarified.

> *f) reviewing the effectiveness of the corrective action taken.*

8.5.3 Preventive Action
As explained under 8.5.2, Corrective Action, the "reviewing" of the action has been clarified to include determining the effectiveness of the action.

> *e) reviewing the effectiveness of the preventive action taken.*

Annex A

Table A.1 in the Annex was revised to show the correspondence of ISO 9001:2008 clauses with ISO 14001:2004 (instead of ISO 14001:1996). Table A.2 shows the reverse correspondence, from ISO 14001:2004 clauses to ISO 9001:2008 clauses.

Annex B

The old Annex B, that showed the correspondence of ISO 9001:2000 and ISO 9001:1994 clauses, has been replaced since the clause structure of ISO 9001:2000 and ISO 9001:2008 are the same. The new Annex B (Table B.1) identifies the text changes from ISO 9001:2000 to ISO 9001:2008.

Bibliography

The Bibliography for ISO 9001:2008 has been updated to reflect new standards, new editions of standards, and withdrawn standards since the publication of ISO 9001:2000.

New Standards
ISO 10001:2007, Customer satisfaction - Guidelines for codes of conduct for organizations
ISO 10002:2004, Customer satisfaction - Guidelines for complaints handling in organizations
ISO 10003:2007, Customer satisfaction - Guidelines for dispute resolution external to organizations
ISO 10019:2005, Guidelines for the selection of quality management system consultants and use of their services
ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing
IEC 61160:2006, Design review
ISO 90003:2004, Software engineering - Guidelines for the application of ISO 9001:2000 to computer software

New Editions
ISO 9004:200x, Managing for the sustained success of an organization - A quality management approach
ISO 10005:2005, Quality management systems - Guidelines for quality plans
ISO 10006:2003, Quality management systems - Guidelines for quality management in projects
ISO 10007:2003, Quality management systems - Guidelines for configuration management
ISO 10012:2003, Requirements for measurement processes and measuring equipment
ISO/TR 10013:2001, Guidelines for quality management system documentation
ISO 10014:2006, Quality management - Guidelines for realizing financial and economic benefits
ISO/TR 10017:2003, Guidance on statistical techniques for ISO 9001:2000
ISO 14001:2004, Environmental management systems - Requirements with guidance for use
IEC 60300-1:2003, Dependability management - Part 1: Dependability management systems

Withdrawn Standards
ISO 9000-3:1997 (replaced by ISO 90003:2004)
ISO 10011-1: 1990 (replaced by ISO 19011:2002)
ISO 10011-2: 1991 (replaced by ISO 19011:2002)
ISO 10011-3:1991 (replaced by ISO 19011:2002)
ISO 10012-1:1992 (replaced by ISO 10012:2003)
ISO 10012-2:1997 (replaced by ISO 10012:2003)