

ADAPTATION OF INTERNATIONAL STANDARD

ISO 9001

Fourth edition 2008-11-15

Quality Management Systems — Requirements

Systemes de management de la qualite — Exigences

**ANNEX B INCLUDES INTERPRETATIVE CHANGES
BETWEEN ISO 9001:2000 AND ISO 9001:2008**



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BRS Annex A (informative) Not included as this is an Adaptation Strictly for ROWO use, in the Official Document is the Correspondence between ISO 9001:2008 and ISO 14001:2004

BRS Annex B (informative); Table B1 BRS Summarizes the Clarifications with Comments of ISO 9001:2008

Bibliography

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing the International Standards is carried out through ISO technical committees. Each member body interested in a subject and 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. International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2. The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO is not to be held responsible for identifying any or all such patent rights. ISO 9001 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 2, Quality systems.

This fourth edition cancels and replaces the third edition (ISO 9001:2000), which has been amended to clarify points in the text and to enhance compatibility with ISO 14001:2004 in the official standard. Details of the changes between the third edition and this fourth edition are given in the official international standard in Annex B.

This document is not an official document as it contains explanations and clarifications not inclusive to the official International Standards. This document is not for distribution outside the channels of application as herein determined.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by:

- a) its organizational environment, changes in that environment, and the risks associated with that environment,
- b) its varying needs,
- c) its particular objectives,
- d) the products it provides,
- e) the processes it employs,
- f) its size and organizational structure.

It is not the intent of the official International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this Adaptation of the International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This adaptation of the official International Standard may be applied by internal and external parties, including conformity assessment bodies with the intent to certify, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 are taken into consideration during the development of the official International Standard.

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0.2 Process approach

the official 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.

For an organization to function effectively, it has to 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. Often the output from one process directly forms the input to the next.

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”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and meeting requirements,
- b) the need to consider processes in terms of added value
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs.

Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of the official International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

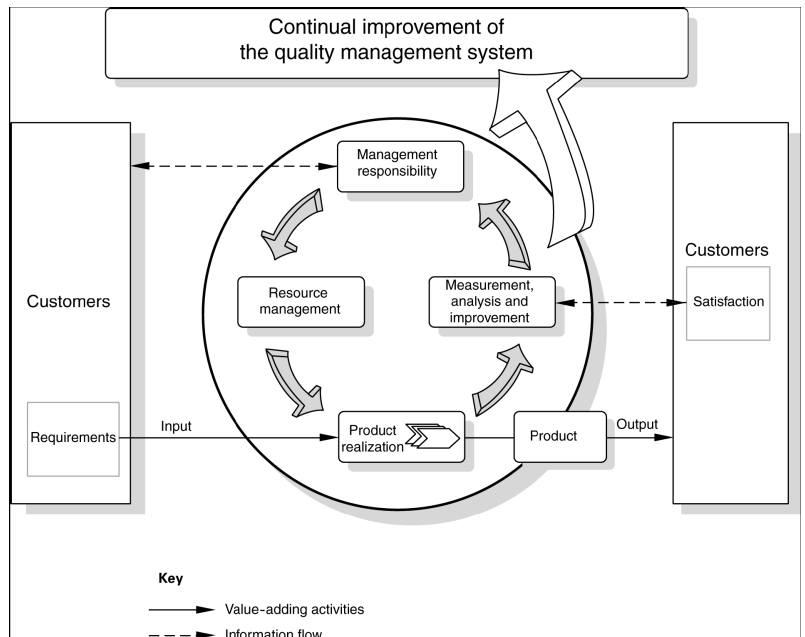


Figure 1 — Model of a process-based quality management system

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0.3 Relationship with ISO 9004

ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

At the time of publication of the official 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

During the development of the official 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 in an official version of the Standard shows the correspondence between ISO 9001:2008 and ISO 14001:2004.

The official International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, the official International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of the official International Standard.

Quality management systems — Requirements

1 Scope

1.1 General

The official International Standard specifies requirements for a quality management system where an organization

- 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.

NOTE 1 in the official International Standard, the term “product” only applies to

- a) product intended for, or required by, a customer,
- b) any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

1.2 Application

The requirements of the official International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of the official International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to the official 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.

2 Normative references

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 9000:2005, Quality management systems — Fundamentals and vocabulary

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 apply. Throughout the text of the official International Standard, wherever the term “product” occurs, it can also mean “service”.

4 Quality Management System

4.1 General Requirements

The organization is to establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of the official International Standard.

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The organization needs to:

- a) Determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) Determine the sequence and interaction of these processes,
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) Monitor, measure where applicable, and analyze these processes, and
- f) Implement actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by the organization in accordance with the requirements of the official International Standard.

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization is to ensure control over such processes. The type and extent of control to be applied to these outsourced processes needs be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

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.

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 7.4.

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation is to include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures and records required by the official International Standard, and
- d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term "documented procedure" appears within the official International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

NOTE 3 the documentation can be in any form or type of medium.

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4.2.2 Quality Manual

The organization is to establish and maintain a quality manual that includes

- a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of Documents

Documents required by the quality management system are controlled. Records are a special type of document and needs be controlled according to the requirements given in 4.2.4.

A documented procedure needs be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- 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
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system needs be controlled.

The organization is to establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records need to remain legible, readily identifiable and retrievable.

5 Management Responsibilities

5.1 Management Commitment

Top management needs to provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources.

5.2 Customer Focus

Top management is to ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

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5.3 Quality Policy

Top management is to ensure that the quality policy

- a) is appropriate to the purpose of the organization,
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality Objectives

Top management is to ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives needs be measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning

Top management ensures that:

- a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management ensures that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management Representative

Top management appoints a member of the organization's management who, irrespective of other responsibilities, needs to have responsibility and authority that includes;

- a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) Reporting to top management on the performance of the quality management system and needs for improvement,
- c) Ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal Communication

Top management ensures that the appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

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5.6 Management Review

5.6.1 General

Top management reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews need be maintained (see 4.2.4).

5.6.2 Review Input

The input to management review needs to include information on:

- a) results of audits,
- b) customer feedback,
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the quality management system, and
- g) recommendations for improvement.

5.6.3 Review Output

The output from the management review needs to include any decisions and actions related to:

- a) improvement of the effectiveness of the quality management system and its processes,
- b) improvement of product related to customer requirements, and
- c) resource needs.

6 Resource Management

6.1 Provision of Resources

The organization is to determine and provide the resources needed to:

- a) Implement and maintain the quality management system and continually improve its effectiveness, and
- b) Enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements need be competent on the basis of appropriate education, training, skills and experience.

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

The organization shall

- a) determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable, provide training or take other actions to achieve the necessary competence,

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- c) evaluate the effectiveness of the actions taken,
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

6.3 Infrastructure

The organization determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a) buildings, workspace and associated utilities,
- b) process equipment (both hardware and software), and
- c) supporting services (such as transport, communication or information systems).

6.4 Work Environment

The organization determines and manages the work environment needed to achieve 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).

7 Product Realizations

7.1 Planning of Product Realization

The organization plans and develops the processes needed for product realization. Planning of product realization need be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization determines the following, as appropriate:

- a) quality objectives and requirements for the product;
- 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;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning need be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

The organization determines:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) requirements not stated by the customer but necessary for specified or intended use, where known,
- c) statutory and regulatory requirements applicable to the product, and
- d) any additional requirements considered necessary by the organization.

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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

The organization reviews the requirements related to the product and services. This review needs be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) to ensure that:

- a) Product requirements are defined,
- b) Contract or order requirements differing from those previously expressed are resolved, and
- c) The organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review needs be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements needs be confirmed by the organization before acceptance

Where product requirements are changed, the organization ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.3 Customer Communication

The organization determines and implements effective arrangements for communicating with customers in relation to

- a) product information,
- b) enquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints.

7.3 Design and Development

7.3.1 Design and Development Planning

The organization plans and controls the design and development of product.

During the design and development planning, the organization needs to determine:

- a) the design and development stages,
- b) the review, verification and validation that are appropriate to each design and development stage, and
- c) the responsibilities and authorities for design and development.

The organization manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output needs be updated, as appropriate, as the design and development progresses.

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

Inputs relating to product requirements needs be determined and records maintained (see 4.2.4). These inputs includes:

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- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

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

7.3.3 Design and Development Outputs

The outputs of design and development needs be in a form suitable for verification against the design and development input and needs be approved prior to release.

Design and development outputs shall

- a) meet the input requirements for design and development,
- b) provide appropriate information for purchasing, production and service provision,
- c) contain or reference product acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use.

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

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development needs be performed in accordance with planned arrangements (see 7.3.1)

- a) to evaluate the ability of the results of design and development to meet requirements, and
- b) to identify any problems and propose necessary actions.

Participants in such reviews are representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions needs be maintained (see 4.2.4).

7.3.5 Design and Development Verification

Verification needs be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions needs be maintained (see 4.2.4).

7.3.6 Design and Development Validation

Design and development validation needs be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. A record of the results of validation and any necessary actions is to be maintained (see 4.2.4).

7.3.7 Control of Design and Development Changes

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes needs to include evaluation of the effect of the changes on constituent parts and product already delivered. A record of the results of the review of changes and any necessary actions is to be maintained (see 4.2.4).

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7.4 Purchasing

7.4.1 Purchasing Process

The organization needs to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product are dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation needs be established.

Records of the results of evaluations and any necessary actions arising from the evaluation needs be maintained (see 4.2.4).

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including, where appropriate:

- a) Requirements for approval of product, procedures, processes and equipment,
- b) Requirements for qualification of personnel, and
- c) Quality management system requirements.

The organization ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

The organization establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization states the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

The organization plans and carries out production and service provision under controlled conditions.

Controlled conditions includes, as applicable;

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring equipment,
- e) the implementation of monitoring and measurement, and
- f) the implementation of product release, delivery and post-delivery activities.

7.5.2 Validation of Processes for Production and Service Provision

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

Validation is to demonstrate the ability of these processes to achieve planned results.

The organization establishes the arrangements for these processes including, as applicable,

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- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,
- d) requirements for records (see 4.2.4), and
- e) revalidation.

7.5.3 Identification and Traceability

Where appropriate, the organization identifies the product by suitable means throughout product realization.

The organization identifies the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization controls the unique identification of the product and maintains records (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.4 Customer Property

The organization exercises (due) care with customer property while it is under the organization's control or being used by the organization. The organization identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization reports this to the customer and maintains records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

7.5.5 Preservation of Product

The organization preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes the identification, handling, packaging, storage and protection. Preservation equally applies to the constituent parts of a product.

7.6 Control of Monitoring and Measuring Equipment

The organization determines the monitoring and measurement to be undertaken, and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization establishes the processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

- a) be calibrated or verified, or both, 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 needs be recorded (see 4.2.4);
- b) be adjusted or re-adjusted as necessary;
- c) have identification in order to determine its calibration status;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization takes appropriate action on the equipment and any product affected.

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Records of the results of calibration and verification needs be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application needs be confirmed. This undertaken needs to occur prior to initial use and reconfirmed as necessary.

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.

8 Measurements, Analysis and Improvement

8.1 General

The organization plans and implements the monitoring, measurement, analysis and improvement processes needed to;

- a) Demonstrate conformity to product requirements,
- b) Ensure conformity of the quality management system, and
- c) Continually improve the effectiveness of the quality management system.

This includes the determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, the organization monitors data and information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information needs be determined and implemented.

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 and dealer reports.

8.2.2 Internal Audit

The organization conducts internal audits at planned intervals to determine whether the quality management system

- a) conforms to the planned arrangements (see 7.1), to the requirements of the official International Standard and to the quality management system requirements established by the organization, and
- b) is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined.

The selection of auditors and conduct of audits need to ensure objectivity and impartiality of the auditing protocol. Auditors are not to audit their own work, maintaining objectivity and impartiality.

An explicit documented procedure is established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results needs be maintained (see 4.2.4).

The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

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Follow-up activities need to include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011 for guidance.

8.2.3 Monitoring and Measurement of Processes

The organization applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action needs be taken, as appropriate.

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.

8.2.4 Monitoring and Measurement of Product

The organization monitors and measures the characteristics of the product to verify that product requirements have been met. This need be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria needs be maintained.

Records need to indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer cannot 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 organization ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. An explicit documented procedure needs be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

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

- a) Taking action to eliminate the detected nonconformity;
- b) Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) Taking action to preclude its original intended use or application;
- d) Taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

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

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

8.4 Analysis of Data

The organization determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This needs to include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data needs to provide information relating to

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- a) customer satisfaction (see 8.2.1),
- b) conformity to product requirements (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

The organization continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective, and preventive actions, and management review.

8.5.2 Corrective Action

The organization takes action to eliminate the CAUSES of nonconformities in order to prevent recurrence. Corrective actions needs to be appropriate to the effects of the nonconformities encountered.

An explicit documented procedure needs to be established to define requirements for and includes:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the CAUSES of nonconformities,
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing action needed,
- e) Records of the results of action taken (see 4.2.4), and
- f) Reviewing the effectiveness of the corrective action taken.

8.5.3 Preventive Action (Preventive Measures)

The organization needs to determine action to eliminate the CAUSES of potential nonconformities in order to prevent their occurrence. Preventive measure / action needs to be appropriate to the effects of the potential problems.

An explicit documented procedure needs to be established to define requirements for;

- a) Explicitly determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of the identifiable potential nonconformities,
- c) Determining and implementing action needed to prevent the nonconformity,
- d) Records of results of action / measure taken (see 4.2.4), and
- e) Reviewing the effectiveness of the preventive measure / action taken.

Annex A (informative)

Interrelationship between ISO 9001:2008 and ISO 14001:2004, you need to see the official standard of your region as expressed in Table A1 and Table A2



Annex B (informative)

Table of Interpretative Changes between ISO 9001:2000 and ISO 9001:2008

(After reasonable time, in excess of two years, this Annex B in this Adaptation we will vacate)

Summary: There is no requirement of action that client-organizations need to take other than updating documents by stating ISO 9001:2008, after reading the contents that follows. Please obtain a separate document expressing the table BRS A1 that follows.

Legend: Read BRS, GOB or ISO comments in *italics*.

ISO 9001 and based on the final draft of the 2008 version to be publish. Pending formal approval of converting the final draft to the official version expected in November of this year 2008. According to a June 17th press release from the International Organization for Standardization (ISO) in reference to this finalized adaptation of the official standard, *“The proposed ISO 9001:2008 does not introduce additional requirements compared to the last edition in 2000 and does not change the intent of ISO 9001:2000. No new requirements have been added, the revision of the standard 2008 is purely clarifications to the requirements.*

While many of the clarifications are only rearrangements of existing text and punctuation, others involve additional notes and text. It is possible that a previous misunderstanding of a requirement by non-BRS client-organizations and BRS assessment – auditors. While we recommend that client-organizations management reviews ISO 9001:2008 once published, and read to ensure that their quality management system effectively addresses the clarified requirements. Afterward changing the reference from ISO 9001:2000 to ISO 9001:2008 internal audits and management reviews need to reference ISO 9001:2008.

Vocabulary Adjustments

There are several words and phrases that have been changed throughout ISO 9001 2008:

- References to “regulatory requirements” have been changed to “statutory and regulatory requirements.” This can be seen in sections .0.1, 1.1 a) and b) and 1.2. In addition, a note was added to section 1.1 explaining that statutory and regulatory requirements can also be called legal requirements. Client-organizations should keep in mind that statutory and regulatory requirements may come from the location in which the product is created or from the country in which it is sold, or both. *This is something that we have address since the 2000 version of ISO 9001, ISO 14001, ISO 22000 and other standards to which we grant a CoR.*

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- References to “measuring devices” have been changed to “measuring equipment.” This can be seen in sections 7.5.1 d) and 7.6. *This is a non-change and we prefer using the term measuring device as it address a broader view.*
- References to “product quality” have been changed to “conformity to product requirements” in section 6.2.1 and 6.2.2 a). In addition, a note has been added to 6.2.1 stating that this new phrase can be affected “by personnel performing any task within the quality management system.”
- The word “identify” has been replaced with “determine” in sections 0.2 and 4.1.
- A significant number of clarifications are shown in the form of notes.

Table BRS B1

ISO 9001:2008 Section with Direct Comments

BRS Relevant Comments

Section 0.1

New text has been added clarifying that a business environment, or risks associated with that environment, influences a quality management system. Section 0.4 still states that this standard does not include requirements specific to risk management. It is left to each organization to determine the best approach for their management system. When addressing statutory and regulatory requirements, the words “applicable to the product” have been added.

In BRS, as part of AVA we do not separate and add billing if a client is at risk of a very obvious issue. We may not document as a requirement in protecting our client and thus we may reference a statement of this nature as a comment.

Section 0.2

When defining a process, text has been changed to include a “set of activities” instead of just a single activity. *In BRS we have constantly used the term activities referring to components of processes.*

The words “to produce the desired outcome” have been added to the explanation of the process approach. This is part of an on-going effort to stress the importance of meeting an expected outcome or goal.

We have applied this concept since start-up of BRS.

More information on this can be provided by the conformity assessment body and its respective accreditation GOB in alignment with other accreditation platforms or entities.

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Section 1.1

The note defining “product” has been enlarged. It now also includes “any intended output resulting from the product realization processes.” According to TC 176 in drafting this document, this change was meant to help with outsourcing and to clarify that “Output Matters.”

We at BRS graciously refer to the “trees and the forest”, as we need to decide on the forest (and not necessarily the tree) – at times also refer to vertical and horizontal.

When performing a process assessment – audit, the assessors review the outputs of the steps within the integrated processes that produce the final product or service. They look at how the sum of activities provide acceptable ‘product’ to internal customers for the next process in the product realization process. It is also important to remember that data and other information can also be "output".

Section 2

The section was revised to show that when a document is referenced in the standard (e.g. 19011), it is referring to the most current version of the document unless otherwise specified.

No comment

Section 3

No effect

No comment

Section 4.1

In e), the words “where applicable” have been added to the requirement to measure.

ISO 9001 has a lot of new text regarding outsourced processes. Companies should carefully review it and determine if they conform to the clarified requirements.

In BRS we consider outsourcing and the impact that this may bear over the product or service and its processes. When and if, at the least, we verify the effectiveness of the control that the organization bears over these outsource and its impact to the process.

The last sentence in the last paragraph prior to the notes has been revised. It now says “The type and extent of control to be applied to these outsourced processes needs be defined within the quality management system.” This clarification may require some companies to expand on their documentation of their outsourced processes. Note 3 contain more information on this requirement.

Note 1 has been revised. The word “should” has been removed, and new processes have been added. It now says “Processes needed for the quality management system

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referred to above include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.” This clarifies the extensive scope of processes covered by these requirements.

Two new notes have been added. Note 2 states “An outsourced process is identified as one needed for the organization's quality management system but chosen to be performed by a party external to the organization.”

Note 3 states “Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customers, 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 7.4.”

The notes make clear that a process cannot be excluded from an organization's management system simply because it is an outsourced process. ISO previously published “Introduction and Support Package Guidance on 'Outsourced Processes”” (Document: ISO/TC 176/SC 2/N 630R2). This document contains further information on outsourced processes and can be found at this webpage:

http://www.iso.org/iso/iso_catalogue/management_standards/iso_9000_iso_14000/more_resources_9000/guidance_on_outsourced_processes.htm

ISO/TC 176/SC 2/N 630R2 contains very useful information, including this statement “An outsourced process can be performed by a supplier that is totally independent from the organization, or which is part of the same parent organization (e.g. a separate department or division that is not subject to the same quality management system). It may be provided within the physical premises or work environment of the organization, at an independent site, or in some other manner.”

Many companies outsource one or more of their processes (i.e. calibration). Note 3 c) connects these requirements for

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outsourced processes with those of 7.4. These clarifications should cause organizations to carefully review the scope of their supplier management programs, and to look for areas for improvement.

Section 4.2.1

A change in wording has been made to clarify that records are needed both as ISO 9001 requires, and as determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

For us this is an old adagio, as we focus not on the quality of its paper but on the quality of its procedures in addressing the organization's processes.

Sentences were also added to Note 1 to state that “a single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.”

Section 4.2.3 f)

The phrase “documents of external origin” has been modified to include “determined by the organization to be necessary for the planning and operation of the quality management system.” This clarifies which external documents must be controlled within the quality management system.

This is helpful to our client-organizations so as to why documents of external origins are relevant to the organization's activities and processes.

Section 4.2.4

The text in this section has been rearranged, and it now states that records needs be controlled.

Nothing new as we require, and have required, control of records [as determined by (1) law, (2) contractual agreement and (3) the organization itself].

Section 5.5.2

The requirements for the management representative have been clarified. The words “the organization’s” have been added to the first sentence which now says “Top management appoints a member of the organization's management who, irrespective of other responsibilities, have responsibility and authority that includes...”

According to the deputy task group leader of the international team responsible for amending the current version of ISO 9001, this requirement does not necessarily mean that this role must be filled by a full time employee. A contracted person is acceptable if they are involved in on-going management of the system. It would not be acceptable if the management representative was just involved during the management review.

There is no change just to clarify that it is top management who has to appoint someone relevant to the organization's activities and processes to bear the responsibility for the management system. This means that it could be one person, a panel, or even an outsider as long as it bears responsibility within the organization which includes addressing 6.2.2 such as profile and responsibilities. This QMR¹ role, if an outsourced, needs be continuous and not ad hoc.

Section 6.2

The order of the words in the title of 6.2.2 has been changed to “Competence, training and awareness.”

6.2.2 b) has been changed to “where applicable, provide training or take other actions to achieve the necessary competence.”

For us it been known all along, further it brings “competence” at the forefront (same as ISO 14001). It is also known to us that training is not a “cure all” action. So we challenge client-organizations to think beyond merely training as a “catch all” to raise competence.

Section 6.3

Examples of supporting services, described in c), have been expanded to include information systems. Companies which have not considered all of their supporting services within the context of the requirements of 6.3 Infrastructure need to review how they meet these requirements.

Ann old adagio for us is that we consider IT as an integral part of the processes and activities. Another service that we consider in assessments is the role of physical security.

Section 6.4

A note has been added to clarify what is meant by work environment. It says “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).” Companies which have taken a more narrow approach to this requirement need to revisit how they address the requirements of 6.4

We have taken a broader view of work environment to include as far as surrounding environments, soil and land. We consider issues regarding protection of communities as much as protection of consumers.

¹ Quality Management Representative

Section 7.1

The word “measurement” has been added to c). Companies which have excluded measurement from their planning processes need to include it.

This is a mere clarification, as any competent assessment – auditor would have and still considers measurability as integral part of planning realization.

Section 7.2.1

The word “related” has been changed to “applicable” in c). This was meant to remove ambiguity relating to non-product requirements which can be termed “related to the product.”

No surprise for us here, assessment – auditor competence is highly relevant in this issue.

The word “determined” has been changed to “considered necessary” in d).

Post-delivery we have consider through many other interactions including customer focus, customer satisfaction, and other actions that we consider in protection of client-organizations.

A note has been added which states “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.” Companies which have not considered all of their post-delivery activities within the context of the requirements of 7.2.1 need to review how they meet these requirements.

Section 7.3.1

A note has been added to clarify that although design and development review, verification and validation have distinct purposes, they may be conducted and recorded separately or in any combination, as suitable for the product and the organization.

We known this all along, that verification and validation can be mutually inclusive or exclusive.

Section 7.3.3

A note has been added saying “Information for production and service provision can include details for the preservation of product.” Companies which have not considered this aspect of design and development outputs may wish to include it.

For us is an old adagio that packaging, bottling, storage, and any other means to preserve the product (or service) is relevant part that needs be consider during designing stages.

Section 7.5.1

The requirement in f) was changed to clarify that this requirement is related to the product.

No new issue, self explanatory.

Section 7.5.2

The first paragraph of 7.5.2 has been reworded. The meaning has not been revised.

Self – explanatory.

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Section 7.5.3

The second paragraph has been revised to clarify that this requirement applies “throughout product realization.” If a company previously believed that this requirement was more limited, for example to final product, then its process for identifying product status would need to be expanded.

The third paragraph has been revised to include the phrase “maintain records.”

Section 7.5.4

The last sentence has been revised to clarify that it is the organization’s responsibility to report to the customer “if any customer property is lost, damaged or otherwise found to be unsuitable for use.”

The note giving examples of customer property has been expanded to include “personal data.” Organizations dealing with customer’s personal data should seriously consider how they apply the requirements in 7.5.4.

Section 7.5.5

This section has been modified to clarify that preserving the conformity of the product means preserving conformity to requirements.

The words “as applicable” have been added to the second sentence.

Section 7.6

“In a), the words “be calibrated or verified” have been hanged to “be calibrated or verified or both.”

“See 4.2.4” was added to a) to clarify that the information that is being recorded is to be maintained as a record.

The text in c) now states “have identification in order to determine its calibration status.”

The records requirement is now a separate paragraph and clarifies that the requirement applies to more than a single paragraph within 7.6.

This is for us is part of the criticality of scope.

Note: At times BRS ROWO becomes grumpy when scope is poorly determined.

Of course records are kept as the organization determines in response to the law, contractual agreement or the organization’s own imposition in regards to realization records.

For us we have consider information, copyrights, patents and others that relate to intellectual property as well as information relevant to the management system. This is more so in organization that retains medical, personal and other information that could be detrimental to our clients’ client. This is also wherein IT becomes a significant consideration.

This is a no change for us, as we assess the integrity in preserving the agreed requirements whether these are applicable because of the law or contractual agreement need be also in response to the nature of the product and consumers interest.

Indeed this is an old adagio for us as we known that some devices, apparatus and equipment are verified and calibrated and others are merely verified.

Recorded for the purpose of having a record available as evidence is no news to us.

Identification to determine the status of calibration (or verification) is nothing new to us.

“Configuration Management” is something that we have considered as part of combining machine and man and it many components

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The note has been revised to say “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.” If a company has not considered configuration management in this context before, it should investigate this application.

and we convey at times as “autonomation”.

Section 8.1

The text in a) has been changed to say “to demonstrate conformity to product requirements.” It previously said “conformity of the product.”

Self-explanatory

Section 8.2.1

A note has been added which gives examples of sources of customer perception. It says “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.”

Self – explanatory, but we need to understand that the examples are not limiting nor imposed requirements.

We may seek that client-organizations may expand their sources of field or customer perception as to gain accuracy.

Section 8.2.2

The requirement for records of the audits and their results has been split out and made into its own paragraph.

The first sentence of the last paragraph has been changed to “...ensure that any necessary correction and corrective actions are taken...” Previously, the text just said “...ensure that actions are taken...” This approach may be new to many organizations. These terms are defined in ISO 9000.

A record of audits as evidence is an old adagio.

The term correction is added followed by corrective action, something we known all along, specially the assessment professionals interacting with ISO 15161 and ISO 22000.

- We reiterate that correction is “Action to eliminate a detected nonconformity.” It is also referred by some as “containment.”
- Corrective action is “Action to eliminate the cause of a detected nonconformity or other undesirable situation.”

The note in this section now references ISO 19011 instead of the outdated ISO 10011 documents.

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Section 8.2.3

The last sentence was revised, which results in an expanded scope for this requirement. It previously said “When planned results are not achieved, correction and corrective action needs be taken, as appropriate, to ensure conformity of the product.”

The clause has been revised to delete the phrase “to ensure conformity of the product.” It now says “...correction and corrective action needs be taken, as appropriate.” Since the requirement is no longer tied solely to product conformity, appropriate actions may include those regarding the monitoring or measurement of the processes, or regarding the processes themselves.

A note has been added saying “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.”

Section 8.2.4

Two changes have been made in this section to clarify that when this section refers to release of product, it means release of product (or service) for delivery to the customer.

Section 8.3

The words “as applicable” have been added to the beginning of the sentence “The organization deals with nonconforming product by one or more of the following ways:”

Section 8.4

“See 7.2.1” has been changed to “see 8.2.4” in b).

“See 8.2.3 and 8.2.4” has been added to c).

“See 7.4” has been added to d).

Correction is an addition that we know all along see comments in 8.2.2 previously.

The clarification helps in understanding a process focus in addition to just merely a product specification focus.

Self-explanatory

Self-explanatory

Historically, from field obtained information, in BRS we have been one of the conformity assessment and certification bodies raising a significant number of RA against this clause. The clarification may help understand why BRS acted in this manner, but let's not limit to what this clause indicates.

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Section 8.5.2

The word “cause” has been replaced by “causes” in the first sentence. It may be a change for some companies to take appropriate actions when multiple causes are identified.

The text in f) has been revised to say “reviewing the effectiveness of the corrective action taken.”

Section 8.5.3

The text in e) has been revised to say “reviewing the effectiveness of the preventive action taken.”

The BIBLIOGRAPHY that follows carries more references than the previous versions of ISO 9001

We known this all along, that there may be causes and not one single cause.

The rest is self explanatory as in the case of “reviewing” (there is no need to state this as competent assessment – auditors can understand this is an objective in assuring that the action taken is effective).

“Reviewing” is self evident as there is no need to state this as competent assessment – auditors can understand this is an objective in assuring that the measure taken bears a high probability of effectiveness.

For BRS, need adding industry sector agreements, international trade agreements, regulatory, and statutory requirements.

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