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Useful Aids to Implementing ISO 9001:2008

Many companies implement ISO 9001 without using all the available tools. As a result, some companies may not fully optimize their implementation. This issue could be manifested as confusion over terms, misunderstanding about requirements, and perplexity concerning intention.

ISO, the International Organization for Standardization, based in Geneva Switzerland issues thousands of standards, but we limit our scope to ISO 9001:2008[1] and its immediate "family". This includes ISO 9000:2005 and ISO 9004:2000[2]. ISO 9001 is a general industry standard for quality management, but ISO also issues industry specific standards, as shown in Table 1. Many of these standards, such as ISO 13485 for medical devices, are based on ISO 9001 and can also utilize these available tools.

Table 1 Industry Standards Available from ISO

Industry	Standard
Automotive	ISO/TS 16949:2002
Education	IWA 2:2007
Energy	PC 242, ISO 50001
Food safety	ISO 22000:2005
Information security	ISO/IEC 27001:2005
Health care	IWA 1:2005
Local government	IWA 4:2005
Medical devices	ISO 13485:2003
Petroleum and gas	ISO 29001:2003
Ship recycling	ISO/PAS 30000:2008
Supply chain security	ISO 28000:2007

In addition to the information discussed below, ISO also issues standards related to specific activities that may arises in a quality management system. Table 2 lists these supporting documents.

Vocabulary

One of the most discussed issues is vocabulary. Often, people don't realize that some terms have technical meanings, and that often the technical meanings do not match the colloquial language. As in any profession, there are "terms of art". This also holds true in quality management.

[1] ISO 9001:2008/Cor 1:2009, Technical Corrigendum 1 to ISO 9001:2008, became available on July 15, 2009.
[2] ISO 9004:2009, Managing for the sustained success of an organization – A quality management approach, replaces ISO 9004:2000 and has a target publication date 0g Aug. 31, 2009.

Two pairs of terms illustrate the problem. Working with clients and in training sessions, we often encounter confusion about the meanings of *corrective action* and *preventive action*[3]. In dealing with the disposition of nonconforming material, we often see confusion in applying *repair* or *rework*[4]. Again, these are technical terms with defined meanings.

Table 2 Supporting ISO Documents

Document	Title
ISO 10001:2007	Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations
ISO 10002:2004	Quality management – Customer satisfaction – Guidelines for complaints handling in organizations
ISO 10003:2007	Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations
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	Measurement management systems – 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 10015:1999	Quality management -- Guidelines for training
ISO/TR 10017:2003	Guidance on statistical techniques for ISO 9001:2000
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

In dealing with the language of quality management, the best place to start is ISO 9000:2005, *Quality management systems - Fundamentals and vocabulary*. Consider this document as the master dictionary for your quality system implementation. As you work on implementation and improvement, be sure you understand the meaning of terms. Look them up!

Unlike a conventional dictionary, the terms are grouped by concept, not just listed alphabetically. The concept approach also employs concept diagrams that offer insight into the terms and their relationship to other terms. In addition, the terms are usually accompanied by Notes that offer further clarification and examples.

The second important document for vocabulary is one of the ISO guidance documents, which are explained below. The *Guidance on the Terminology used in ISO 9001 and ISO 9004*[5] tells us that the definitions in ISO 9000:2005 have normative status, which takes precedence over their common dictionary definitions. The definitions of terms in this guidance document are selected from the Concise Oxford Dictionary.

[3] *Corrective action* is action to eliminate the cause of a detected nonconformity
Preventive action is action to eliminate the cause of a potential nonconformity
[4] *Rework* is action on a nonconforming product to make it conform to the requirements
Repair is action on a nonconforming product to make it acceptable for the intended use
[5] See the link to guidance documents below

In Clause 1.1.b, ISO 9001:2008 added the underlined portion, "applicable statutory and regulatory[6] requirements", raising the question of how these differ. The terms are defined in the Guidance document and clearly illustrate the difference. In the US this is the difference between laws enacted by Congress and regulations issued by the Executive Branch.

Guidance Documents

One of the most valuable resources is the set of guidance documents available on the ISO website.[7] Table 3 lists the title of the available documents; we describe each one below.

Table 3 Introduction and Support Packages for ISO 9001:2008

Guidance on ISO 9001:2008 sub-clause 1.2 "Application"
Guidance on the documentation requirements of ISO 9001:2008
Guide to the Terminology used in ISO 9001 and ISO 9004
Guidance on the concept and use of the process approach for management systems
Guidance on "Outsourced processes"
Implementation guidance for ISO 9001:2008
Frequently Asked Questions (FAQs)

Application and Tailoring

Implementation of ISO 9001:2008 can differ from company to company. One of the features of ISO 9001 is the ability to tailor the standard. Clause 1.2 offers the capability to exclude requirements when they don't apply to the company and its products. The Quality Manual documents the exclusions, which must apply to Clause 7, including the justification.

The document *Guidance on ISO 9001:2008 sub-clause 1.2 "Application"* explains how to apply the exclusion and gives examples to help illustrate the concepts. Among the examples discussed and analyzed are:

- Customer property (intellectual property) controlled by a bank
- Exclusion of design and development by a contract manufacturer
- Regulators permit the exclusion of design development
- Outsourced design and development activities
- Traceability; Design of services
- Post delivery activities
- Validation of processes
- Monitoring and measuring devices.

Documentation Requirements

Guidance on the documentation requirements of ISO 9001:2008 explains the intent of the documentation system. As an overarching principle, the guidance document advises that ISO 9001 requires (and always has required) a "Documented quality management system", and not a "system of documents".

[6] *Regulatory* means required, permitted, or enacted by a rule or directive passed by an authority
Statutory means required, permitted, or enacted by a written law passed by a body having the power to make laws

[7] http://www.iso.org/iso/iso_catalogue/management_standards/iso_9000_iso_14000/iso_9001_2008.htm#support_package

The guidance document explains that Clause 4.2 outlines the documentation requirements, which are listed below. It discusses each requirement and provides guidance on how an organization can satisfy the documentation requirement.

- documented statements of a quality policy and quality objectives;
- a quality manual;
- documented procedures required by the standard – specifically for the following six activities
    - 4.2.3 Control of documents
    - 4.2.4 Control of records
    - 8.2.2 Internal audit
    - 8.3 Control of nonconforming product
    - 8.5.2 Corrective action
    - 8.5.3 Preventive action
- documents needed by the organization to ensure the effective planning, operation and control of its processes; and
- records required by this International Standard;
    - 5.6.1 Management reviews
    - 6.2.2 e) Education, training, skills, and experience
    - 7.1 d) Evidence that the realization processes and resulting product fulfill requirements
    - 7.2.2 Results of the review of requirements related to the product and actions arising from the review
    - 7.3.2 Design and development inputs relating to product requirements
    - 7.3.4 Results of design and development reviews and any necessary actions
    - 7.3.5 Results of design and development verification and any necessary actions
    - 7.3.6 Results of design and development validation and any necessary actions
    - 7.3.7 Results of the review of design and development changes and any necessary actions
    - 7.4.1 Results of supplier evaluations and any necessary actions arising from the evaluations
    - 7.5.2 d) As required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement
    - 7.5.3 The unique identification of the product, where traceability is a requirement
    - 7.5.4 Customer property that is lost, damaged or otherwise found to be unsuitable for use
    - 7.6 a) Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist
    - 7.6 Validity of the previous measuring results when the measuring equipment is found not to conform to requirements
    - 7.6 Results of calibration and verification of measuring equipment
    - 8.2.2 Internal audit results and follow-up actions
    - 8.2.4 Indication of the person(s) authorizing release of product
    - 8.3 Nature of the product nonconformities and any subsequent actions taken, including concessions obtained
    - 8.5.2 e) Results of corrective action

- 8.5.3 d) Results of preventive action

Terminology

The content of *Guidance on the Terminology used in ISO 9001 and ISO 9004* is discussed above as part of the discussion on vocabulary.

Outsourced Processes

One of the changes in ISO 9001:2008 is clarification of the role of outsourced processes in a quality management system. *Guidance on 'Outsourced processes'* helps clarify the intent and shows the linkage between Clause 4.2, where outsourced processes appear, and the purchasing controls in clause 7.4.

An *outsourced process* is a process that the organization needs for its quality management system and is performed by an external party. This party could be another company, a corporate service, another division, *etc*.

The organization needs to ensure the outsourced process is conducted in accordance with ISO 9001:2008 and other requirements of the quality management system. This brings in the purchasing controls of 7.4. The service may not be purchased in the traditional sense of a monetary transaction. The guidance document explains that the controls in clause 4.2 and 7.4 apply. For example, a "no charge" service from a corporate head office requires documentation of supplier selection and, most importantly, control.

The guidance document addresses two important cases and gives guidance on the appropriate level of control. The cases are:

- The organization has the competence and ability to carry out a process, but chooses to outsource it (for commercial or other reasons).
- The organization does not have the competence to carry out the process itself, and chooses to outsource it.

Process Approach

The process approach was introduced into ISO 9001 with the year 2000 version of the standards. Prior versions used an element approach. The document *Guidance on the concept and use of the process approach for management systems* describes to process approach and offers an implementation paradigm.

1. Identification of processes of the organization
   1.1. Define the purpose of the organization
   1.2. Define the policies and objectives of the organization
   1.3. Determine the processes in the organization
   1.4. Determine the sequence of the processes
   1.5. Define process ownership
   1.6. Define process documentation
2. Planning of a process
   2.1. Define the activities within the process
   2.2. Define the monitoring and measurement requirements
   2.3. Define the resources needed

2.4. Verify the process and its activities against its planned objectives
3. Implementation and measurement of the process
4. Analysis of the process
5. Corrective action and improvement of the process

Implementation
This document, *Implementation guidance for ISO 9001:2008*, explains the process used to evaluate changes to the 2008 version. In particular, it explains the revision process and illustrates the impact *vs*. benefit analysis used to evaluate potential changes.

Frequently Asked Questions
The website also contains a set of FAQs, which are updated regularly. Check the website on a regular basis to see what new information may have been added.

Interpretations
In addition to the guidance documents, ISO maintains a web site[8] with "official interpretations" of ISO 9001. Currently, these interpretations only include ISO 9001:2000, but, because the changes to the 2008 version were limited, they are valuable.

Consider a common question. An organization needs a documented procedure for preventive action (8.5.3), and must keep records of the results of preventive action (8.5.3.d). One of the interpretation requests asks, "Does sub-clause 8.5.3 a) require organizations to demonstrate, with objective evidence in the form of records, that they have undertaken actions to determine the existence of 'potential nonconformities and their causes'?" The answer is "No".

Auditing Practices
The ISO 9001 Auditing Practices Group maintains a website[9] with guidance and information on auditing ISO 9001 quality management systems. It is an informal group of quality management system (QMS) experts, auditors, and practitioners drawn from the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the International Accreditation Forum (IAF).

The website, primarily aimed at QMS auditors, consultants, and quality practitioners, is an on-line source of papers and presentations on auditing a QMS and reflect the process based approach.

The website contains almost forty guidance documents with practical advice ranging from "How to audit top management processes" to "The role and value of the audit checklist".

Summary and Conclusion

[8] http://www.tc176.org/Interpre.asp
[9] http://isotc.iso.org/livelink/livelink/fetch/2000/2122/138402/138403/3541460/customview.html?func=ll&objId=3541460&objAction=browse&sort=name

Implementing a quality management system can be an involved task; the people responsible can use help to develop an effective and efficient implementation. The material described here can offer tremendous value.

Clearly, one of the most confusing issues is the use of technical terms. The two sources of definitions, ISO 9000 and the guidance document on terms, can help define the concepts and ensure understanding among stakeholders.

The guidance documents provide good insight and examples. One of the most important is the guidance document on applicability. Many organizations struggle with decisions on exclusions, justification, and documentation.

Interpretations provide additional information that is especially valuable, since it comes from practitioners. You could very well have the same question.

Lastly, the Auditing Practices Group provides a set of very powerful guidance documents that span the issues in auditing a QMS.