Abacus Quality Training Services Inc. (AQTS Inc.)

DIFFERENCES BETWEEN ISO 9001:2008 AND ISO 9001:2000 EDITIONS AND IMPACT ON THE ORGANIZATIONS

IMPORTANT NOTE FOR THE READERS:

- Only the most significant differences are explained hereafter. Re-writings of parts of requirements based (with minor changes) on same words and with no added explanations have not been included.
- Differences hereafter detailed are referenced to articles and sub-articles of the standard. (No article numbering change has been included within 2008 amendment).
- Text in normal style refers to 2000 version while text with bold and italic style refers to 2008 modifications.
- Eventual "QCS comments" are supplement information that we feel necessary to add more understanding with regard to 2000 version. These comments are in no way an official interpretation of the new 2008 text. These are boxed below.
- **For a complete understanding of this document content it is Important to read it along with a copy of both ISO 9001: 2000 and ISO 9001: 2008 standards**

Introduction

0.1   General

2000 (1st paragraph,2nd sentence)
" … The design and implementation of an organization's quality management system is influenced by varying needs,…"

2008
" …The design and implementation of an organization's quality management system is influenced by: *its business environment, changes in that environment, or risks associated with that environment;* its varying needs …".

AQTS comments : this reinforce the initial concept already present in 2000 that the QMS must take in account the context in which the organization operates.

0.3   Relationship with ISO 9004

2000 (3rd paragraph)
" ISO 9004 gives guidance…, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness."

2008
" ISO 9004 gives guidance…, *particularly in managing for the sustainable success of an organization*."

AQTS comments : This modification is the result of a change in ISO 9004 scope. ISO 9004 is in a revision process with the edition of the revised standard foreseen in august 2009.

ISO 9001:2008 adds within the paragraph: "ISO 9004 is recommended as a guide for organizations whose top management *wishes to move beyond the requirements of ISO 9001 in pursuit of continual improvement of performance*."

1. Scope

1.1 General

ISO 9001:2008 adds in **a)** and **b)** "…and applicable *statutory and* regulatory requirements".

Moreover the NOTE has been revised to *NOTE 1* as follows:
" In this International Standard, the term "product" applies to the product intended for, or required by, a customer *or the product realization processes. This applies to any intended output resulting from product realization processes, including purchasing*."

AQTS comments : this confirms that all requirements related to final product applies also to intermediate product and product supplied by purchasing.

In addition a *NOTE 2* specifies:
" *Statutory and regulatory requirements may be expressed as legal requirements*."

4 Quality management system

4.1 General requirements

2000

" The organization shall

    a) identify the processes needed
    b) …
    …
    e) monitor, measure and analyse these processes, and

2008
" The organization shall

    a) *determine* the processes needed …
    b) …
    …
    e) monitor, measure (*where applicable*),and analyse these processes, and"

Last paragraph :

2000
" Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system".

2008

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

> AQTS comments : this gives better understanding to the 2000 already existing requirement and specifies elements to be developed as 2000 writing already implies.

About the NOTE :

2000

"Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement".

2008

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

Moreover NOTE 2 and NOTE 3 have been added.

" ***NOTE 2 : An outsourced process is identified as one being needed for the organization's quality management system but chosen to be performed by a party external to the organization***."

"***NOTE 3 : The type and nature of control to be applied to the outsourced process may 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 extent to which the control for the process is shared;***
   c) ***the capability of achieving the necessary control through the application of clause 7.4.***
Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements."

> AQTS comments : Notes 2 and 3 gives complete understanding to have about an outsourced process and its control.

4.2 Documentation requirements

4.2.1 General

Within ISO 9001:2008 NOTE 1 includes two additional 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***."

4.2.4   Control of documents

Within ISO 9001:2008 addition of a sentence (<u>precision that confirms what 2000 edition already implies</u>).

" ***Records shall remain legible, readily identifiable and retrievable***."

5.5   Responsibility, authority and communication

5.5.2   Management representative

<u>2000</u>
" Top management shall appoint a member of management who,…"

<u>2008</u>
" Top management shall appoint a member *of the organization's management* who,…"

AQTS comments : he is well an individual member of the organization !

6.2   Human resources

6.2.1   General

<u>2000</u>
" Personnel performing work affecting product quality shall be competent on the basis of …"

<u>2008</u>
" Personnel performing work *affecting conformity to product requirements* shall be competent on the basis of …"

Within ISO 9001:2008 a NOTE has been added.

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

AQTS comments : All personnel affecting directly or indirectly the conformity to product requirements is concerned as in 2000 edition "Personnel performing work affecting

<u>product quality</u>" already includes all personnel and not only the one working directly on the product.

6.2.2   Competence, training and awareness ("Competence, awareness and training" in the 2000 edition)

<u>2000</u>
" The organization shall

      a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) … "

<u>2008</u>

"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,*

AQTS comments : Already in 2000 edition "evaluate the effectiveness of actions taken" implies <u>de facto</u> the verification that training (or other actions) has enable concerned persons to achieve <u>necessary</u> competences (ref. to point a) above) thanks to training (or other actions).Text of edition 2008 only confirms this understanding i.e.: training effectiveness = <u>necessary</u> competences achieved.

6.3 Work environment

Within 2008 edition a NOTE has been added.

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

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

<u>2000</u>

" The organization shall determine

a) …

b) …

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

d) any additional requirements determined by the organization."

<u>2008</u>

"The organization shall determine

a) …

b) …

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

d) any additional requirements *considered necessary* by the organization".

Moreover within 2008 edition a NOTE has been added.

" *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*."

> AQTS comments : The NOTE gives an expected explanation on understanding of "post-delivery activities". This confirms what organizations should have considered in this matter since 2000 edition.

7.3   Design and development

7.3.1   Design and development planning

Within edition 2008 edition a NOTE has been added.

" *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   Design and development

7.3.3   Design and development outputs

Within edition 2008 edition a NOTE has been added.

" *NOTE : Information for production and service provision can include details for the presentation of product.*"

7.5   Production and service provision

7.5.2   Validation of processes for production and service provision

2000
" 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 deficiencies become apparent only after the product is in use or the service has been delivered."

2008
" The organization shall validate 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*."

> AQTS comments : Helpful re-writing what concerns the understanding of processes for which a validation is expected as a result of this requirement.

7.5.3   Identification and traceability

<u>2000</u>
" The organization shall identify the product status with respect to monitoring and measurement requirements."
<u>2008</u>
" The organization shall identify the product status with respect to monitoring and measurement requirements ***throughout product realization***."

> AQTS comments : Confirms that product status identification must be maintained through all realization stages.

7.6   Control of monitoring and measuring *equipment* ("devices" in 2000 edition)

Within 2008 edition the wording "devices" has been replaced by the wording " ***equipment***".

Moreover the NOTE has been modified as follows:

<u>2000</u>
" NOTE : See ISO 10012-1 and 10012-2 for guidance."

<u>2008</u>
" ***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***."

> AQTS comments :
> - Precision what concerns verification of computer software ability when used for monitoring and measuring.
> - No more reference to ISO 10012.

8.2   Monitoring and measurement

8.2.1   Customer satisfaction

Within 2008 edition a NOTE has been added.

" ***NOTE : Monitoring customer perception may 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***."

> AQTS comments : These are only examples. This is not a list of the only possible means which have to be used.

8.2.3 Monitoring and measurement of processes

Within 2008 edition a NOTE has been added.

" *NOTE : When determining suitable methods, it is advisable that the organization considers 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

2000 (2nd paragraph)
" Records shall indicate the person(s) authorizing release of product (see 4.2.4)."

2008 (2nd paragraph)
" Records shall indicate the person(s) authorizing release of product *for delivery to the customer* (see 4.2.4)."

2. <u>CONCLUSION</u>

ISO 9001:2008 is an amendment without any new or complementary requirement, the reading of which will give a better understanding of requirements for users.

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