◈ Application Paper

A STUDY ON THE NEEDS FOR DOCUMENT IN QUALITY MANAGEMENT SYSTEM OF ISO 9001:2000

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ABSTRACT

This paper suggests the direction of documentation that enables the certified organizations to transform smoothly into newly revised ISO 9001:2000 Quality Management System. Documentation and control of records are major concerns not only to certified organizations but also to consultants and auditors of certification bodies. The revised standards ISO 9001:2000 requires a significantly reduced emphasis on the needs for documented procedures than the ISO 9001:1994 version of the standard. This paper describes documented procedures and records be kept as a minimum needed by organizations in accordance with the requirements of control of documents and records. This enables each individual organization to establish Quality Management System effectively and perform continual improvement activities.

1. INTRODUCTION

The ISO 9001:1994 requirements have been mostly incorporated into ISO 9001:2000. There have been varying degrees of simplification and rewording, as well as a significantly reduced emphasis on the needs for documented procedures. The revision also introduces some new requirements that may require considerable changes to the quality management systems (QMS) of certified organizations depending on whether or not the underlying quality management concepts have already been embraced. It is anticipated that smaller organizations will need to make an earlier start to address some of the new requirements: those are top management involvement, process approach to system, customer satisfaction monitoring (Voice of Customer), process measurement and management (Voice of Process) and continual improvement.

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ISO 9001 does not require a system of documents , however, in order to meet fulfillment to ISO 9001:2000 the organization must show a documented quality management system to provide objective evidence of the effectiveness of its processes and its quality management system. This may not necessarily depend on documented procedures or records, except where specifically mentioned in ISO 9001:2000. Also small organizations may demonstrate compliance without the need for extensive documentation. In order to remove the uncertainty and reduce the anxiety of those organizations that are preparing for new standard application, this paper is made to provide them a excellent interpretation of ISO 9001:2000.

2. BASIC REQUIREMENTS OF ISO 9001:2000

It should be emphasized that it is not obligatory to restructure documentation in accordance with the layout and sequence of the new standard, but it is still necessary to relate the elements of the QMS to the ISO 9001:2000 requirements by some means, such as a cross-reference matrix. Though not a requirement of the new standard, some organizations may find it useful to restructure their QMS, in order to manage their processes more effectively. All users should be aware that the underlying basic objective of the standard is for the organization to demonstrate its ability to consistently provide product that meets customer and regulatory requirements, and to enhance continuously customer satisfaction. It is also important point to be demonstrated during a compliance audit.

An organization that has implemented the standard should demonstrate that it:
- is aware of customer requirements, and transform them into product characteristics, as part of a product design and/or development process.
- is aware of the regulatory requirements in their relevant markets
- is able to provide a product which meets requirements on a consistent basis
- focuses on preventive action, rather than corrective action, problems shooting
- monitors customer satisfaction
- is continually improving the effectiveness of its QMS

This can be shown by: employee awareness of customer needs, positive customer satisfaction results, records of having consistently met customer requirements, improvement in results and reduction in defect levels or non-conformity, internally and externally .It is expected that an organization will adopt a Plan - Do - Check - Act (PDCA) approach to its processes, and will incorporate feedback obtained from process controls, product evaluations and indications of customer satisfaction to determine the need for greater or lesser control.
Within the context of clause 4.1 of ISO 9001:2000, this can be shown schematically as the following figure:

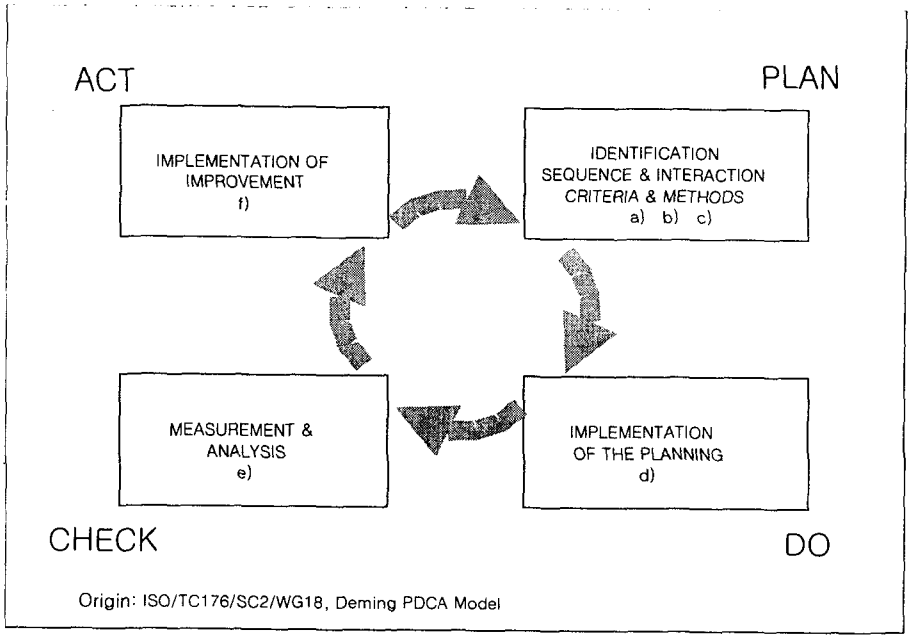


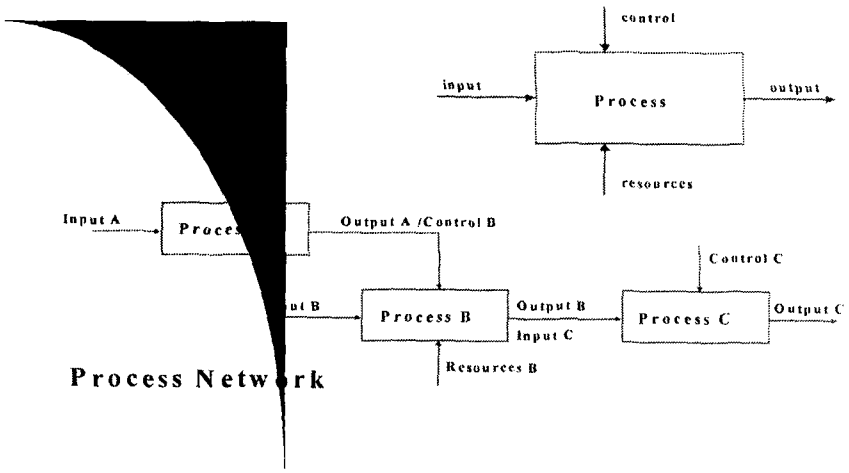
Figure 1. Management & Control of the Process

Some guidance is given below on how an organization may choose to address these requirements, though it must be stressed that these are only examples, and are not the only way to meet the requirements:

a) Identify the processes, needed for the quality management system, and its application throughout the organization.
- Identify the processes and the ownership of it, including those for outsourcing
- Define inputs and outputs for each process
- Define customers of the processes and their requirements

b) Determine the sequence and interaction of these processes.
- Draw overall flow charts of process
- Define interfaces between processes
- Declare processes where necessary

The following schematic representation gives an idea of how an organization may use process flow charts in order to understand better the interaction of the various process that make up the QMS.



c) Determine criteria and methods required to ensure that both the operation and control of these processes are effective
- Specify characteristics of intended and unintended results
- Specify methods for measuring, monitoring and analysis of criteria
- Consider economical issues (cost, time, waste, etc.)
- Define methods for data gathering

d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
- Allocate resources for each process
- Establish communication channels
- Provide external and internal information
- Get feedback
- Collect data and records

e) Measure, monitor and analyze these processes
- Measure processes in detail and monitor their performance
- Analyze gathered information (using Statistical techniques)
- Evaluate analysis results

f) Implement action necessary to achieve planned results and continual improvement of these processes
- Implement corrective and preventive action (Improve the process)
- Verify implementation and effectiveness of corrective and preventive action

In these circumstances, the organization should include such processes in the scope of its QMS and make it clear in its Quality Manual and any other publicly available documents that the QMS covers the *management* of these outsourced or subcontracted activities for which the organization retains overall responsibility.

It is to be expected that the organization will have process flow charts showing the interrelation between the key processes, and interfaces with sub-contractors, including a clear definition of roles and responsibilities, where applicable. These key processes should have clearly defined outputs with acceptance criteria and at least one associated measurement and in-process check. It is important that all the processes within the QMS, and that this is not limited only to product realization processes.
Organizations must be able to show that they are *managing* their processes using a PDCA approach, with the emphasis on achieving planned results.

3. DOCUMENTATION REQUIREMENTS

The fundamental objective of ISO 9001 is to achieve consistent products via a documented system, not to generate a bureaucratic system of documents. This documented QMS will typically include the policies, principal process descriptions, and any necessary detailed work instructions.
The intent of ISO 9001:2000 is to be less prescriptive in defining the specific documents that an organization must produce, and to use a more results-oriented approach. A number of documented procedures may still be necessary or desirable for routine execution of more complicated tasks, for introductory training of new staff, for problem solving or identifying areas for improvement, but this will depend on the nature and size of the organization, as well as the complexity of its processes.

ISO 9001:2000 allows the organization much more flexibility than ISO 9001:1994 to define where documented procedures are needed in order to manage its processes. Apart from the requirement for an organization to document its quality policy and quality objectives, and to prepare a Quality Manual, the new standard cites *only 6 specific instances* where a documented procedure is obligatory. These refer to clauses:

- 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.

During a compliance audit, however, it will still be necessary to provide evidence that the processes are being managed, but in many cases this could be in the form of data and records, without the need for documented procedures. This will facilitate a simplified approach to the QMS, with greater focus on demonstrable results as opposed to written procedures.
There are several requirements of ISO 9001:2000 where an organization could add value to its QMS and demonstrate conformity by the preparation of other documents, even though the standard does not specifically require them. Examples may include process maps, organization charts, internal communications, production schedules, approved supplier lists

and quality plans.

There must be a documented QMS covering all the applicable requirements of the standard. This has to include a quality manual which addresses, or at least makes a reference to where the system covers each element of ISO 9001:2000, and mentions the justification for any requirements of the standard that are considered not to be applicable. There should also be a process flow showing the interaction between the key processes. These key processes should normally have defined inputs, outputs, acceptance criteria and at least one associate measurement and in-process checkpoint.

3.1 Control of documents

The latest, approved version of all relevant documents should be available and be used at the right place and at the right time.
Documented procedures are not required for every clause in this standard. As above mentioned, the only written procedures specifically required by the standard are 6 specific clauses. Because the quality policy is a document, it must also be controlled according to the requirements of clause 4.2.3. Some organizations that may be revising their quality policy for the first time, in order to meet ISO 9001:2000 requirements will need to pay particular attention to this. The same applies to the quality objectives and the Quality Manual..
Other documents that may need to be controlled include:

- Plans and other planning outputs
- Forms and templates
- Written procedures necessary for the management of processes
- External documents such as standards, customer specifications and drawings
- Statutory and regulatory documents relating to the product
- Any other documents that are subject to revision, and which can have an impact on product quality or on the QMS
- Approved samples

It must be stressed that, according to ISO 9001:2000 clause 4.2 (Documentation requirements) documents may be in any form or type of medium, and the definition of document in ISO 9000:2000 clause 3.7.2 gives the following examples:

- paper (hard copy)
- computer file (soft copy)
- magnetic tape (back up)
- electronic or optical computer disc
- photograph
- master sample

A written procedure for document control. Verifications during the whole of the audit, relating to the management of processes, and the availability of appropriate documents that

are approved, and in their correct state of revision at the work place.

3.2 Control of records

Table 1. Minimum Required Records in ISO 9001:2000

Clause	Record required
5.6.1	Management reviews
6.2.2 (e)	Education, training, skills and experience
7.1 (d)	Evidence that the realization processes and resulting products meet requirements
7.2.2	Results of the review of requirements relating to the product and actions arising from the review
7.3.2	Design and development inputs
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 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)	Standards used for calibration or verification of measuring equipment where no international or national measurement standards exist
7.6 (a)	Validity of previous results when measuring equipment is found not to conform with its requirements
7.6 (f)	Results of calibration and verification of measuring equipment
8.2.2	Internal audit results
8.2.4	Evidence of product conformity with the acceptance criteria and indication of the authority responsible for the release of the product
8.3	Nature of the product nonconformities and any subsequent actions taken, including concessions obtained
8.5.2	Results of corrective action
8.5.3	Results of preventive action

A documented procedure for control of records should be shown. Verifications during the whole of the audit, relating to obtaining evidence that what was planned has actually been done. It may also be necessary for the organization to maintain other records, in order to demonstrate compliance with the standard, even though these are not specifically mentioned in ISO 9001:2000.

The specific records will be different depending on its size and complexity. ISO 9001:2000 requires that the following records be kept *as a minimum*:

4. COMPLIANCE AUDIT APPROACH

With the reduced emphasis on documentation, a change in auditing approach will be required. The focus will move towards establishing that employees hold a common view of the organization's *process*, that these processes are under control and are achieving the desired results. This may require a certain amount of documentation, such as records, meeting minutes, reports, etc. in order to provide the necessary evidence, but in general, the effective operation of the QMS as shown in measurements and results will be of greater importance than the mere presence of written procedures or documents. Of course, many organizations may find it useful to maintain most of their current written procedures in order to manage their processes effectively, even though these may not be specifically required by the standard.

There has in the past been a perception that ISO9000 certification audits have focused primarily on strict compliance to the standards *documentation requirements*. The year 2000 edition, however, is expected to promote a greater element of assessment of the *effectiveness* of the QMS in achieving the organizations objectives, and in products that conform to customer and applicable statutory or regulatory requirements. Auditors will verify the organizations use of a PDCA concept to compare results with quality objectives, relate these results to the needs of the marketplace, and to promote improvements in the effectiveness of the QMS.

The auditor will identify a minor nonconformity where specific requirements of the standard are not being applied consistently in process activities. A minor nonconformity may also be raised where measurements and results show that requirements or objectives are not being met, or where adverse trends are observed, with no preventive and/or corrective actions to address the situation.

Major non-conformities will be raised for the absence of, or the failure to implement and maintain, one or more of the clauses of ISO 9001:2000, or a situation which, on the basis of available objective evidence, raises doubt as to the ability of the organization to provide conforming product.

5. CONCLUSION

While the interpretations within this paper are not officially endorsed by ISO, they have been produced with input from a range of references, and are intended for use by all stakeholder in the implementation of the ISO 9001:2000: certification bodies; certified organizations; consultants. By offering a common understanding of the principles and requirements, there should be reduced confusion, and possible tension, between the related body concerned in determining what constitutes compliance to the requirements and whether or not it has been achieved.

As such, the following outcomes are expected by reference to this paper:

- Ability to focus on the priority issues in upgrading to ISO 9001:2000.
- Reduced time in identifying and addressing the new requirements
- Streamlined documentation through understanding of the key points

When using this paper, it is intended that the reader will have reference to the ISO 9001:2000, ISO 9004:2000 and ISO 9000:2000.

REFERENCES

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(Replaces ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994)
[4] ISO 9001:1994 Quality systems Model for quality assurance in design, development, production, installation and servicing
[5] ISO 9004:2000 Quality management systems Guidelines for performance improvements
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Howie Ng, HKQAA, Raymond Cheung, PSB
[7] The official ISO Website, at www.iso.ch which includes:
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- Frequently Asked Questions and Answers
- ISO 9001:2000 Documentation requirements
- The Process Approach
[8] ISO/TC 176 N 484 The Eight Quality Management Principles