

New Methodology for Value Added Auditing

Sandford Liebesman, Ph.D.
Quality Management Systems Consultant ·
Morristown, NJ 07960
973-898-0082
sandfordl@msn.com

KEY WORDS

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SUMMARY

This paper describes the use of Quality Management Principles as Themes in auditing ISO 9001:2000 and TL 9000 Release 3.0. ISO 9001:2000 [2000a] was revised to provide a quality management system model based on a process orientation. Since TL 9000, release 3.0 is based on ISO 9001:2000 it provides auditors with a unique opportunity for adding value to the quality management systems (QMS) they audit. The results will be improved product quality and reliability leading to greater customer satisfaction. In this paper I describe the new structure of ISO TL 9000 and discuss the use of the eight quality principles as themes to help improve the auditee's products/services and processes. The end result should be improved customer satisfaction.

INTRODUCTION

In December 2000 ISO 9001:2000 was revised and re-published as a single standard ISO 9001:2000. It was developed based on eight quality management principles. These principles also apply to the adders of TL 9000 (QuEST 2000a) and provide an opportunity for auditors to add value by using them as themes during an audit. In the next sections I describe the new structure of TL 9000, Release 3.0, discuss the quality management principles and describe how each can be used as a theme during the auditing process.

THE NEW STRUCTURE OF ISO TL 9000

The new structure of TL 9000, Release 3.0 is based on ISO 9001:2000. The new structure is a major change from that of the Release 2.5 which is based on ISO 9001:1994. In ISO 9001:1994 (ISO 1994), the requirements consisted of 20 elements based on a manufacturing model dating back to standards developed in the 1970's. The new structure is aimed at continual improvement and consists of four major processes:

- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement

Management Responsibility

Management responsibility provides a framework for top management to develop an effective QMS and make commitments to the organization's stakeholders. This process contains requirements covering the following:

- management commitment,
- customer focus,
- quality policy,
- planning,
- responsibility, authority and communication, and

- management review.

Management review is an important step in the improvement loop defined later in the standard.

Resource Management

Resource management covers human resources, infrastructure and the work environment. One interesting aspect of human resources is the requirement to determine the competency requirements of personnel in the organization and to provide the necessary training to ensure competency. The resources needed to effectively operate an organization and enhance customer satisfaction are identified in this section.

Product Realization

Product realization covers the activities needed to design, develop, produce and support products and services. The largest number of requirements from ISO 9001:1994 (ISO 1994) is included here.

The following activities are defined:

- planning of product realization,
- customer related processes,
- design and development,
- purchasing,
- product and service provision, and
- control of monitoring and measuring devices.

Measurement, Analysis & Improvement

This process starts with the requirement to gather and analyze data, and ends with a requirement to improve the products and services and the quality management processes used in their realization. The heart of the improvement requirements is the “improvement loop,” which requires the organization to cycle back through the other major processes with the goal of continual improvement.

The following activities are defined:

- monitoring and measuring,
- control of nonconforming product,
- analysis of data, and
- improvement.

General Requirements of a Quality Management System

A fifth section of the standard describes the general requirements of the quality management system (QMS). In this section, there is an overall view of how an effective QMS should be organized. The following are defined:

- process focus,
- a system of processes,
- control of “outsourced” processes
- documentation requirements, and
- use of records to provide evidence of compliance.

QUALITY MANAGEMENT PRINCIPLES

The developers of ISO 9001 also felt that the revision was an opportunity to define a philosophy of quality which would be universally understood. The result was a set of eight quality management principles which forms the

basis of a superior QMS. These quality management principles are described in ISO 9000:2000 (ISO 2000b) and in a pamphlet published by ISO (ISO 2001). They are:

- Customer focus
- Leadership
- Continual improvement
- Involvement of people
- Factual approach to decision making
- Mutually beneficial supplier relationships
- Process approach
- System approach to management

One opportunity for the auditor is to provide an understanding of the quality management principles to the auditee organization and to create a mindset that views quality on a higher plane.

AUDITING USING THE QUALITY MANAGEMENT PRINCIPLES

In the paper, I will discuss each of the principles, provide an overview of how they can be used as themes in a TL 9000 audit and identify the “adders” that apply to each theme. As an example, let us look at “customer focus”

Customer Focus

ISO 9001:1994 had in its scope the aim of “achieving customer satisfaction by preventing nonconformity at all stages from design through to servicing” (ISO 1994, p1). This has been broadened in ISO 9001:2000 to include management responsibilities to communicate with the customers, monitoring and measuring customer satisfaction and developing improvements related to customer requirements.

There is an important role required of top management with respect to the customer. The importance of meeting customer requirements must be communicated to the staff. Also, there is a new requirement to monitor customer satisfaction information. This information should tie into the continual improvement requirement.

The following is a list of requirements in ISO 9001:2000 and TL 9000 relating to customer focus:

- Top Management: Customer Focus (ISO 5.2)
 - Customer Relationship Development (TL 5.2.C.1)
 - Customer Communication Procedures (TL 5.2.C.2 and TL 5.2.C.2 Note 1)
 - Customer Input to the planning process (TL 5.4.2.C.2)
- Management Rep: Promote awareness of customer requirements (ISO 5.5.2c)
- Resources to enhance customer satisfaction (ISO 6.1b)
- Customer related processes (ISO 7.2)
 - Determine product/service requirements specified and “not stated” (ISO 7.2.1b)
 - Requirements specified for delivery and post-delivery activities (ISO 7.2.1a)
 - Review of product/service requirements (ISO 7.2.2)
 - (TL 7.2.2.C Notes 1 and 2)
 - Communicate with the customer including complaint handling (ISO 7.2.3)
 - Notification about problems (TL 7.2.3.C.1)
 - Problem severity (TL 7.2.3.C.2 and 7.2.3.C.2 Note 1)
 - Problem escalation (TL 7.2.3.C.3)
 - Customer Feedback (TL 7.2.3.C.4)
 - Organization’s Recall Process (TL 7.2.3.H.1)

- Control of production and service provision, implementation of release, delivery and post delivery activities (ISO 7.5.1f)
 - Organization's support program (TL 7.5.1.C.1)
 - Service resources (TL 7.5.1.C.2)
 - Emergency service (TL 7.5.1.HS.1)
 - Installation plan (TL 7.5.1.HS.2)
 - Patching procedure (TL 7.5.1.S.1)
 - Patch documentation (TL 7.5.1.S.2)
 - Replication (TL 7.5.1.S.3)
 - Software used in service delivery (TL 7.5.1.V.1)
 - Tool changes (TL 7.5.1.V.2)
- Handling of customer property (ISO 7.5.4)
 - Control of customer supplied documents and data (TL 4.2.3.C.1)
- Monitor and measure customer satisfaction information (ISO 8.2.1)
 - Customer Satisfaction Data (TL 8.2.1.C.1)
- Analysis of customer satisfaction data (ISO 8.4a)
 - Trend analysis of nonconforming product (TL 8.4.C.1)
 - Field performance data (TL 8.4.H.1)
 - Service performance data (TL 8.4.V.1)
- Customer feedback: an input to management review (ISO 5.6.2b)
- Improvements related to customer requirements: an output from management review (ISO 5.6.3b)

Leadership

Top management's commitment to the QMS has been greatly expanded by the requirements of ISO 9001:2000. The role centers on fulfilling customer requirements, communicating with customers and staff, and planning and assuring the continual improvement of the QMS.

A major issue for top management is assuring that objectives are measurable. This is a very important part of the continual improvement process. The objectives must not only be measurable, but they must tie into the quality policy. A "framework" must be developed for establishing and reviewing objectives.

The following is a list of requirements relating to leadership:

- Top management: provide evidence of commitment including the importance of fulfilling requirements and provision of resources (ISO 5.1)
- Determine customer requirements and enhance customer satisfaction (5.2)
- Ensure that the quality policy includes commitment to meet requirements & continual improvement (ISO 5.3)
- Top management's role in quality planning including the establishment of measurable quality objectives (ISO 5.4)
 - Targets for Quality Objectives (TL 5.4.1.C.1)
 - Long- and Short-Term Quality Planning (TL 5.4.2.C.1)
 - TL 5.4.2.C.1-NOTE 1: Top management should demonstrate their active involvement in long- and short term quality planning.
 - Customer Input (TL 5.4.2.C.2)
 - Supplier Input (TL 5.4.2.C.3)
- Responsibility, authority and communication (ISO 5.5)
 - Appoint the management representative (ISO 5.5.2)
 - Communicate the state of effectiveness of the QMS (ISO 5.5.3)
 - Organization Performance Feedback (TL 5.5.3.C.1)

- Management review of the QMS (ISO 5.6)
- Top management's role in continual improvement (ISO 8.5.1)

Continual Improvement

A key addition to ISO 9001:2000 is the requirement to improve the effectiveness of the QMS through the use of the "Improvement Loop." The improvement loop consists of the following requirements identified in ISO clause 8.5.1: quality policy (ISO 5.3), quality objectives (ISO 5.4.1), audit results (ISO 8.2.2), analysis of data (ISO 8.4), corrective and preventive actions (ISO 8.5.2 and ISO 8.5.3) and management review (ISO 5.6).

Continual improvement is at the heart of the auditor's value added. Does the organization use all of the tools at its disposal to improve over time? The internal auditor should carefully review the management review process and determine whether there is evidence that the improvement loop is working to improve the organization's products and processes.

The following is a list of other requirements relating to continual improvement:

- Planning to Continually improve the QMS effectiveness and the individual processes as described in ISO 4.1f and ISO 5.4.2
 - Long- and Short-Term Quality Planning (TL 5.4.2.C.1)
 - TL 5.4.2.C.1-NOTE 1: Top management should demonstrate their active involvement in long- and short term quality planning.
 - Customer Input (TL 5.4.2.C.2)
 - Supplier Input (TL 5.4.2.C.3)
- Management representative reports to top management on the performance of the QMS and the need for its improvement (ISO 5.5.2b)
- Provide resources to continually improve the QMS effectiveness (ISO 6.1a)
- Plan and implement the improvement processes (ISO 8.1)
 - Plan and implement the monitoring, measurement, analysis and improvement processes needed to continually improve the effectiveness of the QMS (ISO 8.1c)
- Improvement (ISO 8.5)
 - Quality Improvement program (TL 8.5.1.C.1 & Note 2)
 - Employee participation (TL 8.5.1.C.2)
 - Corrective action notes (TL 8.5.2 Notes 1,2&3)
 - Problem resolution (TL 8.5.2.S.1)

Involvement of People

Involvement of people revolves around assuring the competency of the staff. The key requirements are focused on the effectiveness of training, awareness of individual contributions and an effective work environment.

Competence has to do with the long-term improvement in the capability of the organization to perform effectively. The auditor must review how the organization determines its needs and how it fulfills them by increasing the capabilities of its employees. It may be difficult to assess the effectiveness of the training given to the staff.

The following is a list of requirements related to involvement of people:

- Individual competency based on education, training, skills & experience (ISO 6.2.1, ISO 6.2.2, ISO 7.4.2b, ISO 7.5.2b)
 - Internal course development (TL 6.2.2.C.1)

- Quality improvement concepts (TL 6.2.2.C.2)
- Training requirements and awareness (TL 6.2.2.C.3)
- ESD training (TL 6.2.2.C.4)
- Advanced quality training (TL 6.2.2.C.5)
- Training content (TL 6.2.2.C.6)
- Operator qualification (TL 6.2.2.HV.1)
- Determine, provide and maintain the infrastructure (ISO 6.3)
- Determine and manage the work environment (ISO 6.4)
 - Work area (ISO 6.4.C.1)
- Assure awareness of requirements changes (ISO 7.2.2)

Factual Approach to Decision Making

The use of information in decision making starts with the requirement for identification of measurable quality objectives for products/services and processes and includes the requirement that the objectives be consistent with the quality policy. In order to determine how well the organization satisfies the objectives, data is gathered, analyzed and the results assessed against the objectives.

At issue is the analysis and use of data. The data should be available and used for measuring and improving processes, product quality and reliability, and customer satisfaction. Many organizations gather data, but do not have an effective means of using the data for improvement. One especially difficult set of data to gather and effectively use is customer satisfaction data.

The following is a list of requirements relating to factual approach to decision making:

- Documented quality objectives (ISO 4.2.1a)
- Ensure quality objectives are measurable and consistent with quality policy (ISO 5.4.1)
 - Quality policy shall provide a framework for establishing and reviewing quality objectives (ISO 5.3c)
 - Targets for Quality Objectives (TL 5.4.1.C.1)
 - Planning to satisfy quality objectives (ISO 5.4.2a)
- Management review: Assess the need for changes to the quality objectives (ISO 5.6.1)
- Product planning: Determine the quality objectives and requirements for the product (ISO 7.1a)
- Plan and implement the monitoring, measurement, analysis and improvement processes (ISO 8.1)
- Monitoring and measurement (ISO 8.2)
 - Customer Satisfaction data (TL 8.2.1.C.1)
 - Internal audit (ISO 8.2.2)
 - Monitoring and measurement of process (ISO 8.2.3)
 - Process measurement (TL 8.2.3.C.1)
 - Monitoring and measurement of product (ISO 8.2.4)
 - Inspection & test documentation (TL 8.2.4.HV.1)
 - Inspection & test records (TL 8.2.4.HV.2)
 - Periodic retesting (TL 8.2.4.H.1)
 - Content of testing (TL 8.2.4.H.2 and Note 1)
 - Frequency of testing (TL 8.2.4.H.3)
 - Testing of repair and return product (TL 8.2.4.H.4)
 - Test documentation (TL 8.2.4.S.1)
- Control of nonconforming product (ISO 8.3)
- Analysis of data (ISO 8.4)
 - Trend analysis of nonconforming product (TL 8.4.C.1)
 - Field performance data (TL 8.4.H.1)

- Service performance data (TL 8.4.V.1)
- The organization's measurement responsibilities (TL 9000 Measurement Handbook 3.5.3a-j) (QuEST 2001b)

Mutually Beneficial Supplier Requirements

The supplier management requirements have been simplified in ISO 9001:2000. It should be noted that control of outsourced processes is considered differently from management of suppliers and processes outsourced must be identified in the QMS.

The following is a list of requirements relating to mutually beneficial supplier requirements:

- Supplier input to the planning process (TL 5.4.2.C.3)
- Purchasing (ISO 7.4) including:
 - Control of suppliers and purchased products depend on the effect of these purchased products on subsequent product realization or the final product. (ISO 7.4.1)
 - Purchasing procedure (7.4.1.C.1 and Note 1)
 - Process required for the selection, evaluation and re-evaluation of suppliers (ISO 7.4.1)
 - Purchasing information including ensuring the adequacy of purchase requirements prior to communication to suppliers (ISO 7.4.2)
 - Verification of purchased products (ISO 7.4.3)
- Use of data analysis to provide information for use in improvement of suppliers (ISO 8.4d)
- Control of outsourced processes (ISO 4.1)

Process Approach

The elements of a process are inputs, outputs, controls and resources. A process consists of the activities that convert the inputs into outputs using the resources and constrained by the controls. The major structural change to ISO 9001 was the creation of the four super-processes and the requirement to identify all processes used in the QMS. It is required to monitor, measure, analyze and improve all processes.

A fundamental issue for the auditor is to determine the organization's understanding of the elements of a process. In addition, there is a requirement to identify the methods of managing outsourced processes. This is a key in today's environment where many organizations are transitioning to contract manufacturing.

It should be noted that there are only six processes that are required to be documented in ISO 9001:2000. These are control of documents, control of records, internal audit, control of nonconforming product, corrective action and preventive action. A challenge to auditors is: "How do you audit a process that is not documented?" One solution is to interview a number of users of the process and look for consistency. A second method, which may be combined with the first, is to review the records for accuracy and satisfaction of the requirements.

The following is a list of requirements relating to the process approach:

- Identify processes needed in the QMS, including their interactions, effectiveness, provision of resources and improvements.(ISO 4.1)
- Determine the justification for exclusions (ISO 4.2.2, ISO 1.2)
- Identify control of outsourced processes (ISO 4.1)
- Management Representative ensures that processes needed for the QMS are established, implemented & maintained (ISO 5.5.2a)
- Management review includes process performance as an input & actions to improve processes as an output (ISO 5.6.2c & ISO 5.6.3a)

- Monitor, measure, analyze and improve processes using objective measurements (ISO 4.1e, ISO 8.2.3)
 - Process measurement (TL 8.2.3.C.1)
- Analysis of data to provide information relating to characteristics and trends of processes (ISO 8.4c)

System Approach to Management

A QMS is a system of processes linked together to effectively manage the quality of products and services. The main requirement is to determine the sequence and interaction of these processes. Processes are defined throughout the product realization section of ISO 9001:2000. The standard requires that all processes of the QMS be identified and their sequence and interaction be determined.

A second major consideration is the issue of “exclusions.” These can only be done for requirements in Section 7 (Product Realization) of ISO 9001:2000. The auditor has a role in reviewing the suggested exclusions and determining whether they are justified.

The following is a list of requirements relating to the system approach:

- General requirements of a quality management system (ISO 4.1)
- Documentation requirements (ISO 4.2)
- Ensure planning of product realization is consistent with the requirements of the other processes of the QMS (ISO 7.1).
 - Life cycle model (TL 7.1.C.1)
 - New product introduction (TL 7.1.C.2 and Note 1)
 - Disaster recovery (TL 7.1.C.3)
 - End of life planning (TL 7.1.C.4)
 - Configuration management plan (TL 7.1.HS.1 and Note 1)
 - Estimation (TL 7.1.S.1 and Note 1)
 - Computer resources (TL 7.1.S.2)
 - Support software and tools management (TL 7.1.S.3)
 - Service delivery plan (TL 7.1.V.1)
- Management of customer-related processes (ISO 7.2),
- Design & development (ISO 7.3)
- Project Plan (TL 7.3.1.C.1 and Notes 1 & 2)
 - Requirements traceability (TL 7.3.1.C.2 and Note 1)
 - Test planning (TL 7.3.1.C.3 and Note 1)
 - Integration planning (TL 7.3.1.S.1)
 - Migration planning (TL 7.3.1.S.2)
 - Customer & supplier input (TL 7.3.2.C.1)
 - Design & development requirements (TL 7.3.2.C.2)
 - Content of requirements (7.3.2.H.1)
 - Identification of software requirements (TL 7.3.2.S.1)
 - Requirements allocation. (TL 7.3.2.S.2)
 - Software design & development output (7.3.3.S.1)
 - Service design & development output (7.3.3.V.1)
 - Release management (7.3.6.S.1)
 - Include customer or 3rd party inputs in validation (7.3.6.C Note 1)
 - Change management process (7.3.7.C.1)
 - Informing customers (7.3.7.C.2)
 - Problem resolution configuration management (7.3.7.HS.1)
 - Component changes (7.3.7.H.1)
- Purchasing processes (ISO 7.4)

- Production & service provision (ISO 7.5)
 - Operational changes (TL 7.5.2.HV.1)
 - Product identification (TL 7.5.3.HS.1)
 - Traceability for recall (TL 7.5.3.H.1)
 - Traceability of design changes (TL 7.5.3.H.2)
 - Anti-static protection (TL 7.5.5.C.1)
 - Packaging & labeling audit (TL 7.5.5.HS.1 and Note 1)
 - Deterioration (TL 7.5.5.H.1)
 - Software virus protection (TL 7.5.5.S.1)
- Monitoring & measuring devices (ISO 7.6)
 - Identified equipment (TL 7.6.H.1)
- Plan and implement monitoring, measurement, analysis and improvement processes (ISO 8.1)

CONCLUSIONS

It is clear that the auditor's job has grown in complexity. This leads to many opportunities for auditors to be value-added suppliers to the auditee organizations. The Quality Management Principles can be used as themes that transcend the basic elements of the standard. No longer can one audit element-by-element and be effective. In the new environment, these themes should be identified and continually improved within an organization. The auditor has a value added role in this effort.

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