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The ISO 9000 and 10000 Quality Documents - 1994 to 2004 Development and Application

PREFACE

This course is about quality standards; specifically about the development and application of the 9000 series quality standards and supporting documents produced by the International Standards Organization (ISO) in 1994 and 2000. The development of written, consensus standards for commercial products had begun in the latter part of the 19th century¹. The utility and benefits of these standards led, in the first part of the 20th century, to rapid increase in the number of standards produced and to acceptance of organizations and procedures for managing standards production. World Wars one and two clearly showed the need for international standardization.

The quality of products and services had always been an important aspect of standards, but had generally been addressed within the documents that focused on the particular products or services. By the middle of the 20th century the need for separate documents focusing on quality became essential. Various countries began to develop separate standards to address the quality of products. Differences, in terminology as well as in requirements, among the various national quality standards made for obvious difficulties in international commerce. Computer application, world-wide communications, and the increase in world-wide commerce prompted the need for comprehensive, international, quality standards.

BACKGROUND

ISO began in 1946 and is concerned with standards other than electrical (international electrical standards are produced by the International Electrotechnical Commission {IEC}). The object of ISO is to promote the development of standards in the world with a view to facilitating the international exchange of goods and services, and to develop mutual cooperation in areas of intellectual, scientific, technological, and economic activity. The technical work of ISO international standardization is carried out through its technical committees. In these committees, qualified representatives of industry, governmental bodies, international organizations, and research institutes are brought together to address international standardization concerns. Detailed work of the technical committees is performed by subcommittees and working groups.

Motivated by the increasing globalization of commerce and communications, ISO undertook the development of quality standards in the latter part of the 20th century. Technical Committee 176 of the ISO was formed in 1979 and was responsible for the development of these standards. TC 176 published a set of quality terms and definitions in 1986 (as ISO 8402:1986) and followed with publication of the following set of documents in 1987:

- ISO 9000:1987 - *Quality management and quality assurance standards – Guidelines for selection and use*
- ISO 9001:1987 - *Quality systems – Model for quality assurance in design/development, production, installation, and servicing*
- ISO 9002:1987 - *Quality systems – Model for quality assurance in production and installation*
- ISO 9003:1987 - *Quality systems – Model for quality assurance in final inspection and test*
- ISO 9004:1987 - *Quality management and quality system elements -- Guidelines*

These documents enabled organizations to develop quality systems that had a universal basis. A

system of internationally-recognized certification of acceptable quality programs also developed. This enabled world-wide acceptance of qualified quality programs. The benefits of a common quality base became increasingly apparent as more and more organizations accepted and used the ISO 9000 standards.

After the issue of the 1987 standards, work continued on the development of additional quality standards and additional guidance documents. In addition, work was underway on an update of the "model" standards as ISO rules provide that standards are to be updated approximately every five years. This work culminated in publication of new or revised documents in the 1990's.

¹ *To find out more about the history of standards, the standards development process, and the background of the International Standardization Organization see the Introduction to ISO 9000 Series course on PDHengineer.com.*

OBJECTIVES of THIS COURSE - What you can learn

This course is intended to give a review of how the ISO 900N:1987 Quality Standards progressed to the ISO 900N:1994 versions and then were transformed into ISO 9001:2000. Also the course describes how the complementary (guidance) documents were developed and coalesced into more compact versions. The course goes on to discuss the development of a quality system and to summarize experience with the ISO quality standards and future directions.

The course is arranged to be of value to both those who have developed or evaluated quality systems based on ISO 900N:1994 standards and their accompanying documents and those who began, or are planning to begin, the development or evaluation of quality systems using ISO 9001:2000 and its supporting documents. In order to fully understand and appreciate the ISO 9000:2000 quality documents, it is important to know something of the evolution process that the international quality standards have gone through.

For convenience, the course material is divided into five parts.

Part 1 - Definitions -presents some key quality terms and their definitions.

Part 2 - ISO Quality Documents in the 1990's - reviews ISO quality documents that were produced in the 1990's, includes application experience with the 1990's quality documents, and adds information about on-going work.

Part 3 - The ISO 9000:2000 Series - summarizes development of the series, comments on the documents.

Part 4 - Establishing A Quality System - considers the set-up of a sample quality system and provides observations.

Part 5 - On-going International Standards Activity - insight into experience with the current documents and on future directions.

Part 1: DEFINITIONS

Special or selected meanings are sometimes given to words when they are used in a quality context. Table 1 presents a few key terms and definitions that are important in understanding their use in this course.

Table 1 Quality Definitions – from ISO 9000:2000	
Quality	- degree to which a set of inherent characteristics fulfills requirements
Quality Management	- coordinated activities to direct and control an organization with respect to quality
Quality Control	- part of quality management focused on fulfilling quality requirements
Quality Assurance	- part of quality management focused on providing confidence that quality requirements will be fulfilled
Procedure	- a specified way to carry out an activity or process (can be documented or not)
Requirement	- need or expectation that is stated, generally applied, or obligatory
Product	- result of activities or processes (may be hardware, software, processed materials, or services)

In addition, in International quality standards, the word “ensure” is used in the sense of “make sure or certain” while “assure” is used in the sense of “to give confidence to oneself or others.”

In the quality standards, obligatory requirements are indicated by “shalls”, recommendations are indicated by “shoulds”

Part 2: ISO Quality Documents in the 1990's

ISSUES of the EARLY 1990's

In developing the 1980's documents, it became apparent that other aspects of the quality program needed definition and explanation. Accordingly, in the early 1990's, the following additional documents in the quality management series were issued:

- ISO 9000-3:1991 *Quality management and quality assurance standards - Part 3: Guidelines for the application of ISO 9001 to the development, supply, and maintenance of software*
- ISO 10011-1:1990 - *Guidelines for auditing quality systems - Auditing*
- ISO 10011-2:1991 – *Guidelines for auditing quality systems - Qualification criteria for quality system auditors*
- ISO 10011-3:1991 – *Guidelines for auditing quality systems - Management of audit programs.*
- ISO 9004-2:1991 - *Quality management and quality system elements - Part 2: Guidelines for services.*
- ISO 10012-1:1992 - *Quality requirements for measuring equipment - Part 1: Metrological confirmation for measuring system equipment*
- ISO 9004-3:1993 - *Quality management and quality systems - Part 3: Guidelines for processed materials*

- ISO 9004-4:1993 *Quality management and quality systems - Part 4: Guidelines for quality improvement*
- ISO 9000-2:1993 *Quality management and quality assurance standards - Part 2: Generic guidelines for the application of ISO 9001, ISO 9002, and ISO 9003*
- ISO 9000-4:1993 *Quality management and quality assurance standards - Part 4: Guide to dependability programme management*

In recognition of the proliferation and the importance of software, ISO 9000-3 was developed to address the special requirements of software which is different from most other products. The guidance of 9000-3 was structured to reflect the differences in software development and to assist in relating the quality models to the software development process.

It was also recognized that quality audits were an important feature of quality management and merited special attention. To strengthen the auditing process and to assist with the management of auditing, three separate standards were issued. As ISO had also assigned the 10000 block of numbers for TC 176 use, the audit standards received numbers in this category. ISO 10011-1:1991 provided guidance for the establishing, planning, executing, and documenting quality system audits. ISO 10011-2:1991 provided information on the selection and qualification of auditors – giving guidance on such things as education, training, experience, and maintenance of competence. A third document in this series, ISO 10011-3:1991 gave guidance on the management of the audit program; addressing such facets as planning & scheduling audits, evaluating auditor performance, confidentiality, and ethics.

Another document produced in 1991 was ISO 9004-2 which provided guidance on the special features of services. The concepts, principles, and quality system elements were applicable to all types of service and were appropriate for any size organization.

As one of the system requirements of the quality system models, inspection and testing results depended upon the accuracy of measuring and test equipment (M&TE). To bolster the dependability of M&TE, ISO 10012-1:1992 was issued. This standard prescribed requirements for M&TE management, confirmation, and use.

In 1993, two more documents providing guidelines for the quality model (where model refers to the configuration prescribed by ISO 9001, 9002, or 9003 requirements) standards were issued. These were ISO 9000-2 which presented generic guidelines for model application and ISO 9000-4 which supplied guidance for dependability program management. Also there were two documents added to the 9004 set. These were ISO 9004-3 which provided guidelines for processed materials and ISO 9004-4 which described guidelines for quality improvement.

DOCUMENTS ISSUED IN 1994

Concurrently with the preparation and issue of the early 1990's documents, TC 176 had been working on the development of an updated set of standards. And, in 1994, the second set of international quality standards was published. This set included:

- ISO 8402:1994 *Quality management and quality assurance - Vocabulary*
- ISO 9000-1:1994 *Quality management and quality assurance standards - Part 1: Guidelines for selection and use*
- ISO 9001:1994 *Quality systems - Model for quality assurance in design, development, production, installation, and servicing*
- ISO 9002: 1994 *Quality systems - Model for quality assurance in production, installation, and servicing*

- ISO 9003:1994 *Quality systems - Model for quality assurance in final inspection and test*
- ISO 9004-1:1994 *Quality management and quality system elements - Part 1: Guidelines*

ISO 8402:1994 continued with the same structure as ISO 8402:1987 had used. The text was presented in three languages; English, French, and Russian. The definitions themselves were presented together; there were three columns on each page and the terms and definitions in the three languages were presented side-by-side. There were more terms defined in 1994. Where there had been 22 terms defined in 1987, there were 67 defined in 1994. The definitions were not listed alphabetically, but were loosely grouped by similarity of application. An alphabetical index provided a degree of cross-reference.

ISO 9000-1:1994 was an update to make its guidelines relate to the new standards that were being issued and to achieve better agreement with ISO 9000-2:1993. As ISO 9000-1 was serving as a roadmap for the 9000 series of documents, 9000-1:1994 was expanded to include additional guidance. This increased guidance was needed to provide understanding and effective application of the ISO 900N:1994 quality standards.

The ISO 900N:1994 standards – ISO 9001:1994, 9002:1994, and 9003:1994 – were similar to their ancestors of 1987. However, the system requirements of ISO 9002:1994 and 9003:1994 were made more stringent. ISO 9002:1994 was essentially the same as ISO 9001:1994 except for the lack of the design control requirement. ISO 9003:1994 required that only 16 of the system requirements be developed, but some of the requirements were more stringent. The ISO quality system requirements prescribed in ISO 9001:1994 are listed in Table 2 in the left column. The center columns show the number of the system requirement and its application level (relative stringency) in each of the models. Note that the requirements for ISO 9002 are the same as those in ISO 9001 except for design control. The numbers of the elements in each of the 1994 standards were made the same to reduce confusion. Some of the recommendations in earlier guidance documents were made mandatory and were now included in the ISO 900N:1994 standards. As an example of the increased stringency, in ISO 9001:1987 there were 111 “shalls” while in ISO 9001:1994 there were 138 “shalls”. And whereas the 1987 version had seven pages, the 1994 version had eleven pages.

ISO 9004:1987 had presented guidelines on the quality elements in general terms. More guidance was in order and ISO 9004-2:1991 gave guidelines on the application of quality elements for services, ISO 9004-3:1991 on processed materials, and ISO 9004-4:1991 on quality improvement. ISO 9004-1:1994 then came into better agreement with these earlier guidance documents and updated its material to agree with the ISO 900N:1994 quality standards.

A world-wide system of registry and certification had been set up to formally recognize compliance with ISO quality standards. ISO does not do the certification; that is left to independent third-parties. Certification is not mandatory. It is possible for an organization to establish a quality program for themselves and to self-declare that they are in compliance. However, customers using their product may wish to perform audits to satisfy themselves that compliance exists.

Selection of a model, then, involved choosing ISO 9001 if engaged in a full range of production activity or ISO 9002 if production activity did not include design and development. For those where conformance to specified requirements was to be assured by the supplier only at final inspection and test, ISO 9003 could be used. For those performing service functions, any of the models could be used depending upon the organization’s activities. It was up to the organization to show compliance with the requirements that applied to their business.

Table 2
Quality System Requirements - Cross Reference List

ISO 900N system requirement	ISO numbers				MIL-Q-9858A system requirement
	clause	ISO 9001	ISO 9002	ISO 9003	
Management responsibility	4.1	X	X	Y	Organization
Quality system	4.2	X	X	Y	Quality planning
Contract review	4.3	X	X	X	Contractual intent, requirements
Design control	4.4	X	---	---	Drawings, documents, changes
Documentation and data control	4.5	X	X	X	Work instructions
Purchasing	4.6	X	X	---	Control of purchases
Control of customer-supplied product	4.7	X	X	X	Government property
Product identification	4.8	X	X	Y	Materials and material control
Process control	4.9	X	X	---	Production processing & fabrication
Inspection and testing	4.10	X	X	Y	Inspection and testing
Control of inspection, measuring, & test equipment	4.11	X	X	X	Measuring and testing equipment
Inspection and test status	4.12	X	X	X	Indication of inspection status
Control of nonconforming product	4.13	X	X	Y	Nonconforming material
Corrective and preventive action	4.14	X	X	Y	Corrective action
Handling, storage, packaging, preservation, and delivery	4.15	X	X	X	Handling, storage, and delivery
Control of quality records	4.16	X	X	Y	Records
Internal quality audits	4.17	X	X	Y	Government inspection
Training	4.18	X	X	Y	----
Servicing	4.19	X	X	---	----
Statistical techniques	4.20	X	X	Y	Statistical quality control and analysis
Quality economics					Costs related to quality
Product safety					----
Marketing					----
Key X – full requirement Y – less stringent than ISO 9001 & ISO 9002 ---- element not present					

EXPERIENCE WITH the 1994 STANDARDS

With the issuance of ISO's 1994 quality standards, the utilization of the ISO quality program continued to expand. Advantages of having many groups committed to the program included –

- a reduction in the amount of external auditing required
- ease in showing or verifying quality qualification for products
- improvement in communications on quality matters

There was a corresponding increase in the ease of obtaining certification and in the number of registrars. As a result, many more groups developed quality programs based upon the ISO quality standards. These groups included not only industrial and commercial companies, but also schools, legal offices, and others. Groups with large and international procurement activities such as the U. S. Department of Defense (DoD) were especially interested in the ISO quality standards. DoD had been relying upon MIL-Q-9858A, Quality Program Requirements (Military Specification), as its principal quality document. In the right-hand column of Table 2, the quality system requirements of MIL-Q-9858A are listed. Their correspondence with the system requirements of ISO 9001:1994 is quite good. In addition, there were all of the supporting (guidance) documents available with the ISO program. Accordingly, effective 1 October 1996 MIL-Q-9858A and MIL-Q-45208A, Inspection System Requirements, were cancelled. DoD contracts awarded after that date cited ISO quality standards. In support of this decision, DoD developed further guidance related to its specific requirements in MIL-HDBK-9000. Special applications of the ISO quality standards were developed by the U. S. Federal Aviation Administration and the Federal Food & Drug Administration. The U. S. Auto industry developed QS 9000, basically the ISO 9000 standards, but with additions unique to the auto makers and their suppliers.

On the international scene, the ISO quality standards were accepted by ANSI, the Standards Council of Canada, the European Community, and many other countries. The European Committee for Standardization (CEN/CENELEC) adopted the ISO 9000 series as EN ISO 9000. And NATO developed AQAP (Allied Quality Assurance Publications), essentially the ISO quality standards.

ON-GOING WORK in the 1990's

Based upon the wide acceptance of the ISO 9000:1994 documents, their utility in application, and the continuing globalization of commerce, ISO TC 176 proceeded with development work on new quality standards and revisions. Additional standards produced in the 1990's included –

- ⊕ ISO 10005:1995 *Quality Management - Guidelines for quality plans*
- ⊕ ISO 10007:1995 *Quality Management - Guidelines for configuration management*
- ⊕ ISO 10013:1995 *Guidelines for developing quality manuals*
- ⊕ ISO 10012-2:1997, *Quality assurance requirements for measuring equipment - Part 2: Control of the measurement process.*

By the latter part of the 1990's decade then, twenty quality documents had been issued in the ISO quality family. They had presented the requirements for quality systems, provided application guidance, and offered guidelines for the development of quality systems by a variety of organizations. These were standards that could be adapted to produce quality programs for industrial activities such as design, manufacturing, testing, and installation as well as services such as medical facilities, legal firms, educational institutions, and offices. ISO's generic product categories of hardware, software, processed materials, and services were well suited to

encompassing the scope of human activity.

However, in the course of quality standards development, it was noted that –

- ∇ a broad familiarity had been developed with the international quality standards and their elements and requirements
- ∇ as an organization had to adapt a selected model to its particular operation and activity, there was not much utility in having multiple models
- ∇ with the numerous documents containing guidance, in preparing a quality program it was necessary to refer to and coordinate with many various documents
- ∇ application and maintenance of a quality program is a dynamic process; new products, new equipment, new technology, and new methods are continually appearing – these require changes and upgrades in the program
- ∇ management evaluations, internal audits, and customer comments also lead to upgrades in a quality program
- ∇ while the need for program adaptation and modification was always a part of quality program management, such continual improvement was not emphasized as an equal to program development and application.

Accordingly, work on the next revision of the quality standards took a new tack. ISO/TC 176 set out four strategic goals for the 9000 and 10000 series of documents. These goals were -

1. universal acceptance
2. current compatibility
3. forward compatibility
4. forward flexibility

Universal acceptance was achieved in that there was world-wide use of the ISO 9000 and 10000 documents and the quality program prescribed by these documents was widely applicable and adaptable.

Current compatibility existed through the use of common clause numbering and structure. Supplements do not change or conflict with the parent documents.

Forward compatibility provided that revisions would be minor, narrow in scope, and would continue the basic thrust of the requirements. This provision was important in assuring that a user's quality program would not need to be completely redone for a new issue of the standards, but would only require adjustments and revision where appropriate.

Forward flexibility assured that the standards and supplements could be combined as needed to adapt to the needs of almost any potential application.

Part 3: The ISO 9000:2000 Series

DEVELOPMENT of the 2000 DOCUMENTS

Working Group 18 (WG 18) was established under TC176, Subcommittee 2 to develop the next revisions to ISO 9001 and ISO 9004. The criteria for these revisions included –

- ⊗ continue to be compatible with existing standards to facilitate understanding, minimize changes required, and simplify development of quality management systems

- ⊗ accommodate all sizes and types of businesses from all areas of industry
- ⊗ provide standards that related well to various types of processes and to other management systems
- ⊗ improve compatibility between ISO 9001 (the quality standard) and ISO 14001 (the environmental standard)
- ⊗ provide standards that were to-the-point and could be easily understood

A significant move by WG 18 was to employ the procedure for design control (as described in clause 4.4 of ISO 9001:1994) to the development of ISO 9001:2000. In this development process, the use of e-mail and computer technology enabled WG 18 to effectively handle thousands of comments that were received during the creation, verification (internal checks), and validation (external checks) processes. This ability to receive and process many comments, from organizations all over the world, helped assure that the standards had a broad base and were adaptable to many activities, particularly services.

The broad application and experience with the ISO 900N:1994 standards and the rest of the documents issued in the 1990's showed that (1) the users (organizations, registrars, customers) had become quite familiar with the international quality standards, and (2) benefit could be realized by consolidation of both the standards and the reference material. Work on revisions of the documents proceeded in the late 1990's and balloting on the new quality standard was completed in 2000.

This new standard, ISO 9001:2000, *Quality management systems - Requirements*, was issued in December 2000. It took the place of the three models in the previous standards. Structure of the text material was changed so that although all of all of the system requirements were still present, they appeared in a somewhat different arrangement. They were now grouped in categories of; the quality management system, management responsibility, quality resource management, product realization, and measurement, analysis, and improvement. One of the significant changes was that there was emphasis on the responsibilities and duties of top management; referring to the person or persons who manage an organization at the highest level. An Annex in the standard provided cross-reference, for the system requirements, between ISO 9001:2000 and ISO 9001:1994. Some of the recommendations that were made in the 1990's guidance documents were now included in ISO 9001:2000 and these became mandatory. However, because of the change in structure, it was possible to group more of the requirements. As a result, even though there were more requirements, the number of "shalls" was reduced from 138 in ISO 9001:1994 to 134 in ISO 9001:2000. But because of the increased content, the standard had more pages; 32 in the 2000 version as contrasted with 11 in the 1994 version.

Accompanying the new standard was a new version of the document explaining quality terms. This new version was ISO 9000:2000, *Quality management - Fundamentals and vocabulary*. At the beginning of the document, in Section 2, fundamentals of quality management systems were presented and described. This material coordinated and replaced the guidance formerly provided in ISO 9000-1 thru 4:1994. Quality terms and definitions were presented in Section 3; this now replaced ISO 8402:1994. More terms had been added; 81 terms were defined in the 2000 document whereas the 1994 document had defined 67 terms. In addition, ISO 9000:2000 had a different structure. The definitions were no longer presented in three languages; they were only in one language (English in the U. S.). Also the definitions were not listed alphabetically in the text (in the index they were), but were grouped into 10 categories which were -

Terms	1) quality	6) conformity
relating to:	2) management	7) documentation
	3) organization	8) examination
	4) process and product	9) audit
	5) characteristics	10) quality assurance for measurement processes

Annex A in the document presented the methodology used in development of the quality vocabulary. Knowledge of this methodology is helpful in making proper interpretation of the quality terms.

A second accompanying document, intended to be part of a consistent pair with ISO 9001:2000 was ISO 9004:2000, *Quality management systems - Guidelines for performance improvement*. 9001:2000 would prescribe requirements for quality systems, 9004:2000 would provide guidelines for their improvement. This pairing was an important step as it added emphasis to quality improvement. Quality is a dynamic characteristic. Product activities experience changes in personnel, resources, methods, and customer preferences. Assessments and evaluations of quality systems need to be ongoing, structured, and comprehensive. The results of internal audits frequently indicate quality system changes that, if effected, could be beneficial to both organizations and their customers. The structure of ISO 9004:2000 makes its application convenient. It shows the requirements (enclosed in blocks) from ISO 9001:2000 in the areas where the guidance for those requirements are described. Annexes present guidelines for self-improvement and for continual improvement of processes.

These basic documents, ISO 9000:2000, ISO 9001:2000, and ISO 9004:2000, were supplemented by other standards and technical reports. ISO 10006:2003, *Quality management systems - Guidelines for quality management in projects*, provides guidance on the application of quality principles and practices in projects. In this role it supplements guidance in ISO 9000:2000. It is intended that ISO 10006:2003 be applicable to projects of various sizes, duration, complexity, and kind of result. ISO 10007:2003, *Quality management systems - Guidelines for configuration management*, is intended to enhance understanding of configuration management, promote its use, and assist in its application. ISO 10012:2003, *Measurement management systems - Requirements for measurement processes and measuring equipment*, replaces the former standards ISO 10012-1:1992 and ISO 10012-2:1997. This new revision contains both requirements and guidance for measurement management. Compliance with its provisions will assist in meeting the control of monitoring and measuring devices requirements in ISO 9001:2000.

ISO/TR 10013:2001, *Guidelines for quality management system documentation*, is a Technical Report which cancels and replaces ISO 10013:1995. Technical Reports are documents that are informative in nature; they contain information that may be of help in following standards and do not have to be reviewed until their data is no longer valid or useful. The guidelines in this Technical Report are intended to assist with the preparation and maintenance of documentation for quality systems. A second Technical Report, ISO/TR 10014:1998, *Guidelines for managing the economics of quality*, supplies guidance on identifying, monitoring, evaluating, and improving the economics of quality. A third Technical Report, ISO 10017: 2003, *Guidelines on statistical techniques for ISO 9001:2000*, assists in identifying needs for statistical techniques and in their application in a quality management system.

Guidance for training planning and activities is provided in ISO 10015:1999, *Quality management - Guidelines for training*. This document supersedes ISO 9004-2:1991. Guidance for auditing is provided in ISO 19011:2002, *Guidelines for quality and/or environmental management systems*

auditing. This document cancels and replaces ISO 10011-1:1990, ISO 10011-2:1991, and ISO 10011-3:1991 and includes the topics covered by the replaced standards.

As of 2004, then, the ISO 9000 and 10000 quality standards series consists of documents that could be considered to be in two groups. The first of these groups would include -

ISO 9000:2000 - *Quality management systems - Fundamentals and vocabulary*

ISO 9001:2000 - *Quality management systems - Requirements*

ISO 9004:2000 - *Quality management systems - Guidelines for performance improvements*

ISO 10012:2003 - *Measurement management systems - Requirements for measurement processes and measuring equipment*

and would address fundamentals, vocabulary, quality requirements, performance improvement, and measurement requirements.

The second of these groups would include -

ISO 10006:2003 - *Quality management systems - Guidelines for quality management in projects*

ISO 10007:2003 - *Quality management systems - Guidelines for configuration management*

ISO 10013:2001 - *Guidelines for quality management system documentation*

ISO/TR 10014:1998 - *Guidelines for managing the economics of quality*

ISO 10015:1999 - *Guidelines for training*

ISO/ TR 10017:2003 - *Guidelines on statistical techniques for ISO 9001:2000*

ISO 19011:2002 - *Guidelines for quality and/or environmental management auditing*

where the documents in this group would present application guidelines for special uses, documentation, economics, training, statistical techniques, and auditing.

Part 4: Establishing A Quality System

THE QUALITY PROGRAM

In preparing a quality program, one would comply with the requirements of the ISO 9001:2000 standard as appropriate to the orientation and function of the organization. In deciding how to do this, the guidance provided in Section 2 of ISO 9000:2000 would be helpful. These standards describe what elements a quality system should include, but do not prescribe how individual organizations are to implement them. A basic requirement is that the system must be documented in one or more quality manuals. As the objectives and activities of different organizations vary, the focus and arrangement of their quality systems must be adapted to their particular objectives. On this basis, a smaller organization might be able to cover their operations with a few procedures and be able to put all of their documents into one manual while a larger, perhaps international organization, might require multiple manuals for their documentation. Assessment of customer satisfaction is also an essential factor in establishing the rationale for a suitable quality system.

ISO quality standards distinguish between quality system requirements and product requirements. The generic product categories for quality standards are hardware, software, processed materials, and services. Product requirements are addressed by product standards and technical specifications while quality requirements are generic to apply to all organizations and product categories. The ISO quality standards are written in terms of objectives to be met. The way that these objectives are met is left to the organizations that seek compliance.

Table 3
Establishing a Quality System - Sample Checklist

step	description
1	Establish management (including top management) approval to proceed
2	Assemble team (including a management representative) to develop a plan of action
3	Have top management develop and establish a quality policy
4	Determine how the elements of ISO 9001:2000 apply in the organization
5	Select format and structure for the Quality Manual that is to be prepared
6	Assign responsibility for developing documents (policy and procedure sections) for the various quality elements that apply
7	Prepare documented positions for applicable quality system requirements. Explain any exclusions; follow established formats, assign numbers, and revision status
8	Review and approve positions on system requirements
9	Assemble the developed Quality Policy and positions on system requirements into the Quality Manual
10	Prepare such implementing procedures as are necessary to address quality activities; use consistent formats, provide definitions of special terms, add forms or references if applicable; develop work instructions if appropriate
11	Review and approve procedure and work instruction drafts
12	Add procedures and instructions to the Quality Manual or use additional Manuals as appropriate
13	Establish means for control of Quality Manual(s)
14	Issue Preliminary Manual(s) for a [limited] Trial Use period (select a Trial Use period appropriate to the organization's operation)
15	During Trial Use, assure that policies and procedures properly respond to the standards, are suitable for the processes, and are adequate
16	Make additions, corrections, and revisions to the policies and procedures if necessary
17	Issue Quality Manual(s) for use
18	Set up an [internal] audit plan and schedule
19	Use audit results and management evaluations as bases for quality improvements
20	Update positions, procedures, and instructions as appropriate; log as performance improvements

Table 3 presents a sample checklist for the development of a quality system. Again, this list must be tailored to correspond to the objectives, resources, and activities of the organization for which it is intended. Part of the preparation should include planning for the documentation that is to be prepared. The program description, procedures, work instructions, and other parts of the system documentation should have consistent formats, page numbering and total page indication, item (e.g. procedure) numbers and revision numbers, issue dates, and approval(s) as appropriate. Arrangement should be made for both controlled and uncontrolled copies of manual(s). Controlled copies are numbered, assigned to individuals, and checked (audited) periodically to ensure that they are in the proper place and are kept up to date. Uncontrolled copies are those that may be given to interested parties (e.g. customers) and are often not numbered or audited.

DOCUMENTATION RELATIONS and FEATURES

Primary requirements of the quality standard are that a quality system must be established, documented, and maintained. The documentation has a hierarchy; it can be considered in the form of a pyramid, see Figure 1.

At the top of the pyramid is the Quality Policy. This Policy is a statement, defined by the executive management of the organization, of the organization's basic objective. This statement should be easy to understand, relevant to the organization product(s), and be achievable. The Quality Policy should be prominently displayed and be known to, and understood by, all of the members of the organization. The quality system is to be developed and implemented to achieve the purpose(s) of the quality policy

Below the Quality Policy in the hierarchy is the description of the Quality Program. This Program should identify the scope of the quality system established (with reference to the quality standard followed) and provide information about the

organization. An organization chart showing the lines of authority and of communication may be helpful in describing the organization. The program description should provide detail about the system requirements that are addressed, as well as justification for any excluded. A Table of Contents is necessary and is a convenient way to effect control by adding information on the individual document numbers, revision numbers, and issue dates. New Tables of Content issued with each revision will show that the manuals are current.



Figure 1

Each section (that is subject to revision) is to bear evidence of revision status, approval, and date of issue. The extent and nature of changes should be indicated, if practicable. Other documents, such as Codes or Regulations, that are important to the products of this quality system should be referenced. Approval(s) of these sections should be by those with authority for implementing that aspect of the quality policy.

Below the Quality Program in the hierarchy of documentation are the Quality Procedures. These are the documents that prescribe the activities, methods, and resources used to effect the quality requirements. Considerable flexibility is available in the preparation of these procedures. As stated in ISO 9000:2000, Clause 2.7.2, "— Each organization determines the extent of documentation required and the media to be used. This depends on factors such as the type and size of the organization, the complexity and interaction of processes, the complexity of products, customer requirements, the applicable regulatory requirements, the demonstrated ability of personnel, and the extent to which it is necessary to demonstrate fulfillment of quality management system requirements."

A procedure is also to have – title, number, revision status, issue date, and approval(s). The text should indicate a purpose, any pertinent references, and the definitions of any special terms used in the process described. Flow diagrams may be of considerable help for the users and auditors of the process. Any internal forms that are to be used in the process should be included (as attachments) or referenced. Procedures are also to be controlled to ensure that the correct issues are being used. In the preparation of procedures, it is important that no more than necessary

detail be inserted. The amount of detail should be that which is necessary for control of the process consistent with the education, training, and experience of those who perform the quality activities involved.

In general, a procedure should be clear and definitive, complete in ensuring that requirements are met, and be suitable for use by the workers and auditors involved. Whereas the standards (addressing the third person) use “shall” for a mandatory requirement, a procedure would preferably use “will” or “must” for compliance with the same requirement as the procedures address the second person. In the procedures, it is recommended that active verbs (e.g. make, adjust, inspect) be used as this approach more directly informs the action party what is to be done. Procedures should be written so that they are clear, unambiguous, and easily understandable. Grammar and word usage should be correct. This becomes very important for users whose first language is not English. Misunderstandings or errors in translation can lead to quality problems.

Below the procedures in the documentation hierarchy are work instructions. These may need to be developed in the interest of maintaining quality, but detail not essential to the control of quality should be avoided. As provided in ISO/TR 10013:2001, Clause 4.6.1 – “The structure, format, and level of detail used in work instructions should be tailored to the needs of the organization’s personnel and depends on the complexity of the work, the methods used, training undertaken, and the skills and qualifications of such personnel.”

At the bottom of the documentation hierarchy are the quality records. These documents are to provide objective evidence that quality requirements for the products have been met. These records are to be legible, complete, responsive to the requirements, and available for review. This latter demand involves planning and implementing storage and recovery methods and equipment appropriate to the media used for the various records. These records provide -

- Γ verification of compliance with quality requirements
- Γ assistance in the investigation of failures
- Γ help with responses to questions or complaints
- Γ bases for process or method changes
- Γ substantiation of past performance
- Γ data that can be used for business improvement.

Part 5: Ongoing International Quality Standards Activity

EXPERIENCE WITH the 2000 STANDARDS

The 200X series of quality documents continued to be increasingly successful. After the issuance of the ISO 9001:2000 standard, the bodies involved in development, conformity assessment, and accreditation jointly agreed that there would be a three-year transition window, ending 15 December 2003. After this date, accreditation would be based on only the new standard. The transition has largely been accomplished. As of 2003, there were more than 500,000 organizations throughout the world that were accredited and some 750 certification and accreditation bodies.

The rearrangement and consolidation of quality documents for the 200X series was beneficial for many users. More organizations and those in new areas have now employed the standard. These groups included educational facilities, hospitals, transportation providers, legal offices, and even police departments. In addition, the number of variants by sector and product type is

increasing.

The criteria for preparation of the 2000 versions of ISO 9000 and 10000 documents were followed and the goals were achieved. New documents were compatible with previous versions. Regrouping of requirements made the text easier to understand and follow. The standards and guidelines related well to different types of businesses and organizations.

FUTURE DIRECTIONS

The ISO 9001:2000 standard has achieved a new level of stability. TC 176 has decided to not make any changes to the standard before the second quarter of 2008. This enables users to work with the same standard for an extended period of time and to focus on system improvement.

During this period of stability, there is increased focus on customer relations. A draft international standard, ISO/DIS 10018, *Complaints handling - Guidelines for organizations*, has been prepared and was balloted in 2003. This document is oriented to the effective handling of complaints and the information that can be obtained from the complaint process. It is intended to reflect the needs of both suppliers of products and receivers of them. When issued, the standard can be used in conjunction with ISO 9001:2000 and ISO 9004:2000 or it can be used independently of them.

ISO is also working on additional guidelines for the application of ISO 9001:2000 in the educational sector. ISO/IWA 2, *Quality management systems - Guidelines for the application of ISO 9001:2000 in education*, will include text that makes the requirements easier to understand and apply.

The ISO international quality standards have provided a good resource for anyone wishing to establish a quality system in their organization. Whether they wish to simply have a quality system to help them manage operations and improve business, to establish and self-declare a system that improves product quality and customer satisfaction, or to become certified (which requires verified compliance with ISO 9001:2000) to the international quality standards thereby achieving wide recognition of organization and product quality, the ISO quality standards and guidance documents are very useful

Resources for Additional Reading

- 1) Todorov, Branimir, ISO 9000 Required, Productivity Press, Portland, OR, 1996
- 2) ISO Standards Compendium, ISO Quality Management, 6th Edition, International Organization for Standardization, Geneva, Switzerland, 1996 *
- 3) Kanholm, Jack, ISO 9000:2000 New Requirements, 4th Edition, AQA Press, Pasadena, CA
- 4) Peach, Robert W. (Ed.), The ISO 9000 Handbook, 4th Edition, Irwin Professional Publishing, Fairfax, VA
- 5) ISO Standards Compendium, ISO Quality Management, 10th Edition, International Organization for Standardization, Geneva, Switzerland, 2003 *

*Obtained from Global Engineering, Englewood, CO