The New ISO 9000 Standard: Evolution or Revolution?

Robert B. Austenfeld, Jr.

(Received on October 11, 2001)

1. Introduction

The purpose of this paper is to describe the new ISO 9000 standard for quality management, especially in terms of how it differs from its predecessor. The new standard was approved by the International Organization for Standardization (ISO) on December 13, 2000 and replaces the 1994 ISO 9000 standard. This paper is organized as follows:

1. Introduction
2. Some Background
3. Why the Change?
4. The New ISO 9000 Family of Standards
5. The Major Changes
6. Clauses 0–3 (Introduction, Scope, Normative Reference, and Terms and Definitions)
7. Clauses 4–8 (the System, Management, Resources, the Product, and Measurement)
8. Why the New Standard Will Result in Better Organizations
9. Conclusions.

2. Some Background

Considered one of its most successful and certainly one of its best known standards, the ISO 9000 family is the product of the International Organization for

Standardization (ISO)[1]. Headquartered in Geneva Switzerland, ISO is a non-profit organization made up of the national standards bodies of some 140 countries. It was established in 1947. Here is its mission taken from its Web page:

> The mission of ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity. (ISO home page, 2001, under *About ISO* and *Introduction*)

To accomplish its work ISO has established some 2,850 technical committees, subcommittees, and working groups made up of experts in a particular group's area of concern. For example, the ISO 9000 standards were prepared by Subcommittee SC 2 (Quality Systems) of Technical Committee ISO/TC 176 (Quality Management and Quality Assurance). The America member to the ISO is the American National Standards Institute (ANSI) and the Japanese member is the Japanese Industrial Standards Committee (JISC). The American Society for Quality (ASQ) has the expertise and primary interest in quality standards. Therefore, it administers, for ANSI, the U.S. Technical Advisory Group (TAG) that provides American input to the quality standards.

The genesis of the ISO 9000 standards can be traced back as far as 1959 when the U.S. government issued MIL-Q-9858, a military specification that set forth requirements for a quality program. Over the next eight years several other standards were issued that covered inspection and calibration requirements and the evaluation of a contractor's quality/inspection/calibration systems. One of the first non-military standards was American National Standards Institute/American

1) As explained on its Web site, the reason the International Organization for Standardization's short name is ISO instead of IOS is because it has chosen ISO, not an acronym, but as word derived from the Greek "isos" meaning equal (ISO home page (2001) under *About ISO* and *Introduction*)

Society for Quality Control[2)] (ANSI/ASQC) C1-1968 *Specification of General Requirements for a Quality Program*. Since then a number of different standards have been developed by various countries. In addition to MIL-Q-9858 and C1-1968, some of the more important ones as far as laying the groundwork for the ISO 9000 standards are:

- Britain's BS 5750 *Quality Systems*, BS 5179 *Guide to the Operation and Evaluation of Quality Assurance Systems*, and BS 4891 *A Guide to Quality Assurance*
- Canada's Z 299 series
- France's AFNOR NFX 50-110 and 111
- Germany's DIN 55-355
- The Netherlands's NEN 2646 (Stephens, 1994).

Wilson (1996) aptly cites the situation at the beginning of the 1980s:

> By the early 1980s, it had become quite apparent that a common basis for quality system interpretation and application was needed to assure success in the global marketplace. With a common baseline, it was obvious that the likelihood of achieving attendant commonality of results would be greatly enhanced. The global economy was clearly driving both industries and nations to the point of requiring a universal quality baseline. (p. 37)

The problem was how to get all the countries concerned to agree on such a common baseline; especially when some of those countries already had quite well developed standards themselves. Would such countries really consider adopting an international standard? Fortunately this was not to be a problem, probably due to the strength of ISO's long-standing reputation for being able to develop inter-

2) A few years ago the American Society for Quality Control (ASQC) changed it name to the American Society for Quality (ASQ) to get away from the idea that quality was the responsibility of some particular part of the organization usually called the Quality Control Department.

nationally acceptable standards. In 1979 ISO established ISO/TC 176, which, as mentioned, is the technical committee responsible for developing the ISO 9000 standards.

With an organization in place, ISO sought official recognition among its members that the work for a set of quality system standards should go forward and, in the early 1980s, the following position was reached: "A set of voluntary quality system standards needed to be developed by the ISO membership for international interpretation and application" (Wilson, 1996, p. 38). In March of 1987, the first set of the ISO 9000 standards were issued. In November 1987 these standards were adopted by the European Committee for Standardization (CEN), the organization that promotes regional standardization within Europe. With that, the standards were rapidly disseminated and adopted worldwide. A March 1992 ISO newsletter listed 45 countries with "identical" adoptions and three countries (China, Jamaica, and Venezuela) with "equivalent" adoptions (Stephens, 1994). In 1994, the standards were refined and reissued. Attesting to the success of the ISO 9000 standard is the latest official ISO figures showing that as of December 31, 2000, "... at least 408,631 ISO 9000 certificates[3)] had been awarded in 158 countries world wide. This is an increase of 64,988 ISO 9000 certificates over the end of December 1999, when the total stood at 343,643 for 150 countries" (The ISO Survey of ISO 9000 and ISO 14000 Certificates, available as a PDF file from the ISO home page, 2001, under *ISO 9000*).

3. Why the Change?

Why the change? I suppose one answer is that it had been six years since the last version was published, but there is much more to it than that. Young (1999), closely involved with ISO/TC 176, explained some of the reasons in a tutorial at

3) To become certified, an organization must be audited to the standard by an impartial and accredited third-party auditor.

an ASQ conference. According to Young, the 1994 ISO 9000 standard emphasized the contractual nature of the relationship between the provider of the product or service and the consumer. In fact, a close reading of the scope of the old standard would suggest this: "This [standard] specifies quality-system requirements for use where a supplier's capability to design and supply conforming product needs to be demonstrated" (ANSI/ISO/ASQC Q9001–1994, p. 1). Note that this scope statement stresses the organization's "capability" not what it actually produces. This means a company's certification to ISO 9000 could lead the customer to believe they are assured of getting a quality product or service when all the certification actually did was say that the capability existed; whether it results in a good product or service was something else. In other words, is the company truly committed to providing quality products or just getting the certification? Unfortunately, for too many it was the latter. The new standard, as we shall see, now goes far beyond the mere certification of a capability by its emphasis on having a comprehensive quality management system that truly focuses on customer requirements and, even, promotes continuous improvement.

Another reason for the change can be traced to the gradual evolution of the quality profession in terms of which principles and practices are emphasized. There has been a recent shift from what might be called merely being sure the product "met specification" (quality control/assurance) versus a more proactive approach that seeks to transform the entire organization into one that seeks to not only meet customer needs but anticipate those needs and continuously improve its processes and products. The "old" approach was called quality control or, a little better, quality assurance. The "new" approach is called quality management (or, sometimes, total quality management [TQM]). Figure 1, from Young (1999), shows the difference between these two approaches in terms of what is emphasized. As can be seen from Figure 1, the emphasis was on control, individual product/production functions, meeting the contractual requirements, and passing

Quality Assurance (ISO 9000:1994)	Quality Management (TQM)*
control/authorization procedures	employee support/empowerment
preventative/corrective actions	continuous improvement
product/production functions	cross-functional activities
contractual compliance	satisfaction of customers needs
conformance to specification	superior product features/performance
internal and third-party audits	self-assessments/benchmarking

Figure 1. Emphasis placed on principles/practices (from Young, 1999).
*Now this can be equated with ISO 9000:2000.

audits. Now it is on freeing up employee potential, continuous improvement, all functions working together, and self-initiated assessments and improvements.

To show how narrowly focused ISO 9000:1994 was, Young compared its 20 elements with the six criteria of the Canadian Awards for Excellence — Canada's national quality award — with these results (number of corresponding elements):

- Leadership 3
- Planning 2
- Customer Focus 1
- People Focus 1
- Process Management 14
- Supplier Focus 1

If we take these six criteria as representing the essential elements of a comprehensive TQM program, then it is apparent that the 1994 ISO 9000 standard fell short in all areas except process management; and this area applied only as it related to products and services.

Ketola and Roberts (2001) cite a survey conducted by ISO in 1997 to find out what changes were needed to ISO 9000. This is what it found:

Users complained that the 1994 version was cumbersome, functionally

> oriented, manufacturing-biased, and nonsystematic, and it failed to link methods for a unified business approach. Users also felt [the new standard] should have a process-oriented structure, be customer-focused, and be designed to promote continual improvement. (p. 6)

As a result of this feedback, it was decided that ISO 9000 required a complete rewrite that would change the emphasis from mere "quality assurance" to proactive, customer focused quality management. Accordingly, the new standard was developed with eight quality principles in mind. These principles are "derived from the collective experience and knowledge of the international experts who participate in ISO Technical Committee ISO/TC 176" (ISO home page, 2001, under *ISO 9000*). As expressed in the "fundamentals and vocabulary" part of the new standards, these principles "can be used by top management in order to lead the organization towards improved performance" (ANSI/ISO/ASQ Q9000–2000, p. ix). Although not called out explicitly in the new standard, it is obvious these principles form a basis for its requirements. These are the eight principles:

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

It is probably no accident that these principles are similar to the six criteria of Canada's national quality award[4)].

4) These principles are also very similar to the seven criteria for America's national quality award, the Malcolm Baldrige National Quality Award: leadership, strategic planning, customer and market focus, information and analysis, human resource focus, process management, and business results.

Having looked at some background and the rationale for changing the ISO 9000 standards, let's now see exactly what makes up this new family of standards.

4. The New ISO 9000 Family of Standards

Although the complete family of ISO 9000 standards consists of 13 standards and guidelines (see Appendix A), there are only four "core" standards. These are listed in Figure 2. Figure 3 (next page) shows the standards that made up the 1994 family which the 2000 version replaced.

Standards and Guidelines	Purpose
ISO 9000:2000 *Quality Management Systems —Fundamentals and Vocabulary*	Establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family which you need to avoid misunderstandings in their use.
ISO 9001:2000 *Quality Management Systems —Requirements*	This is the requirement standard you use to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction. It is now the only standard in the ISO 9000 family against which third-party certification can be carried out.
ISO 9004:2000 *Quality Management Systems —Guidelines for Performance Improvements*	This guideline standard provides guidance for continual improvement of your quality management system to benefit all parties through sustained customer satisfaction.
ISO 19011 *Guidelines on Quality and/or Environmental Management Systems Auditing* (currently under development)	Provides you with guidelines for verifying the system's ability to achieve defined quality objectives. You can use this standard internally or for auditing your suppliers.

Figure 2. The four core standards in the ISO 9000 family (from ISO home page, 2001, under *ISO 9000*).

Standards and Guidelines	Replaced by
ISO 9000-1 *Quality Management and Quality Assurance Standards — Guidelines for Selection and Use*	ISO 9000:2000
ISO 9001 *Quality systems — Model for Quality Assurance in Design, Development, Production, Installation, and Servicing*	ISO 9001:2000
ISO 9002 *Quality systems — Model for Quality Assurance in Production, Installation, and Servicing*	ISO 9001:2000
ISO 9003 *Quality systems — Model for Quality Assurance in Final Inspection and Test*	ISO 9001:2000
ISO 9004-1 *Quality Management and Quality System Elements — Guidelines*	ISO:9004:2000
ISO 8402 *Quality Management and Quality Assurance — Vocabulary*	ISO 9000:2000

Figure 3. The six 1994 standards replaced by the new ISO 9000 standards.

Perhaps the biggest change in terms of overall structure was the consolidation of the three requirements documents of the 1994 standards (ISO 9001, ISO 9002, and ISO 9003) into a single requirements document, ISO 9001:2000. Before the standard used depended on the extent of your organization's involvement with the product. If you didn't do design and development, then you were audited to ISO 9002; if you only did final inspection and testing, ISO 9003. Now these distinction have been dropped and all organizations will be audited to ISO 9001:2000. Where there are exceptions to the requirements because an organization doesn't do certain things — e.g., design and development — the new standard provides for this.

ISO 9000-1 contained fundamental concepts and guidance for selecting the right standard (9001, 9002, or 9003). Since there is now only one requirements standard, ISO 9001:2000, there is no longer a need to provide "selection" guidance. The other information contained in ISO 9000-1 has been revised and is now part of ISO 9000:2000 Qu*ality Management Systems — Fundamentals and*

Vocabulary.

ISO 9004-1 provided extensive additional guidance on how to implement the requirements of the 1994 standards. It has now been replaced by ISO 9004:2000. However, ISO 9004:2000 is a little different in that its emphasis is on telling managers how they can go beyond the minimum requirements (ISO 9001:2000) to make their organizations more and more customer responsive.

Finally, ISO 8402 was the definitions standard. It has been replaced by ISO 9000:2000 which attempts to define all the words/concepts associated with a quality management system. Just as ISO 8402 by reference was made part of ISO 9001, ISO 9002, and ISO 9003 of the 1994 standards, ISO 9000:2000 is part of ISO 9001:2000.

The fourth standard/guideline listed in Figure 2, ISO 19011 *Guidelines on Quality and/or Environmental Management Systems Auditing*, is currently under development and is expected to be published in 2002. It will replace six auditing guideline documents, three associated with ISO 9000 and three associated with ISO 14000 (the environmental management system standard)[5].

Summarizing, before there were three requirements documents, two guideline documents, and a vocabulary document. Now there is a single requirements document (ISO 9001:2000), a fundamentals and vocabulary document (ISO 9000:2000), and a guideline document (ISO 9004:2000). Rounding out the new family is an auditing guidelines document which will provide a uniform approach for auditing both the quality and environmental management systems. We will now begin taking a closer look at the new standards by first considering the major changes.

5) The three associated with ISO 9000 are: ISO 110011-1, ISO 110011-2 and ISO 110011-3; the three associated with ISO 14001 are: ISO 14010, ISO 14011 and ISO 14012. The new guidelines will provide a uniform approach for auditing both the quality management and environmental management systems of organizations and facilitate the auditing of both systems at the same time — potentially a great benefit to organizations.

5. The Major Changes

Introduction. Before discussing specific major changes to the standard it is worth considering the overall change in how the standard is now viewed versus the way it was viewed before. Before, as mentioned, it was viewed more from a contractual point of view. That is, "what does the contract say" and is our quality system adequate to meet those contractual requirements. Now the standard is viewed in a much broader way. As discussed in section 3 above, the standard has gone from a "quality assurance" perspective to a "quality management" perspective. And what, exactly, does it mean to have a "quality management" perspective? It means to no longer be seeking to do only what is minimally required and simply reacting to problems, but to become proactive; that is, doing such things as establishing and monitoring objectives, systematically gathering data and using it to continuously improve your processes and product, anticipating customer requirements, and ensuring everyone in the organization understand where they fit into the big picture and the importance of their work to that overall effort. For those familiar with the work of Dr. W. Edwards Deming, one could say the new standard very much advocates operating according to his famous 14 Points (see Appendix B).

Although opinions are sure to differ, I believe most would agree these are the major changes to ISO 9000:

- A process-oriented structure
- A general emphasis on processes
- Simpler, straight-forward language
- Documentation deemphasized
- Top management's responsibilities emphasized
- The use of quality objectives at all levels required
- An effective means of internal and customer communications required

- Worded to be more broadly applicable
- Continuous improvement a requirement
- Customer satisfaction now important

A process-oriented structure. Figure 4, from the new standard, shows a model of a process-based quality management system. This model is based on the structure of the new standard shown in Figure 5[6]. Figure 6 shows how the 1994 standard was structured with its 20 elements which were more or less randomly organized. The new standard stresses by its very organization the key ingredients of a superior quality management system (Figure 4): good management, ensuring adequate resources are available, detailed attention to product realization,

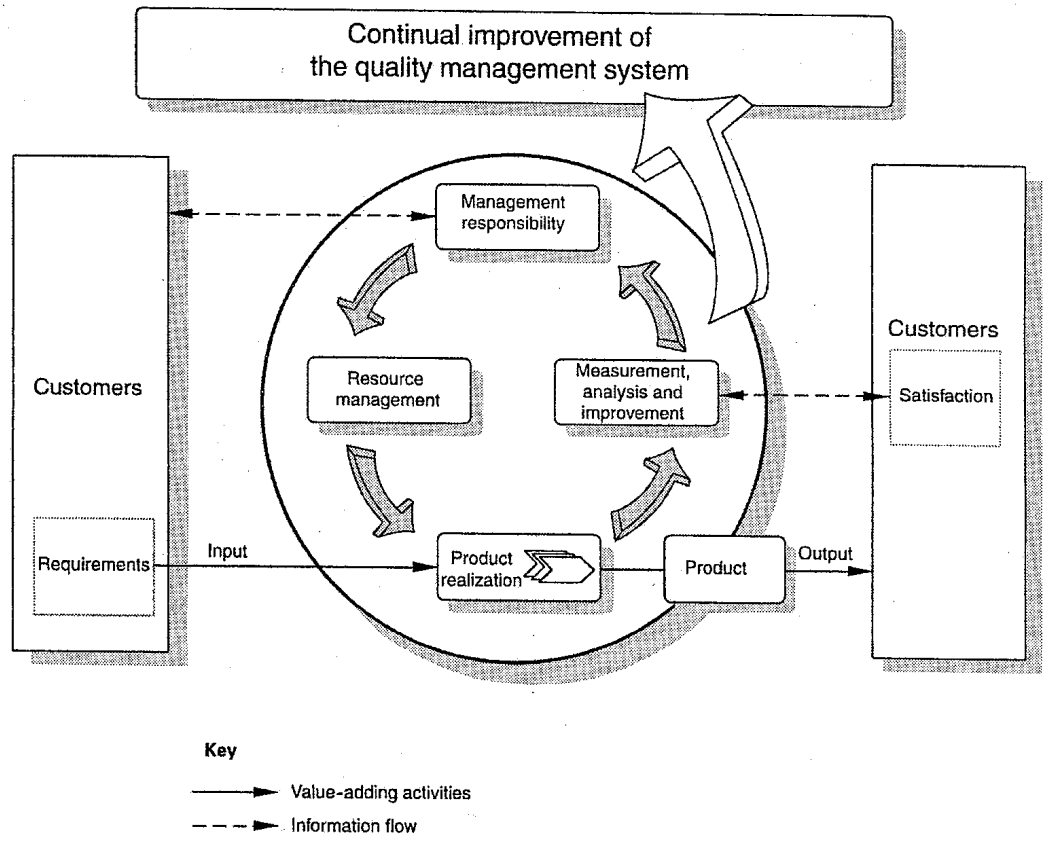

Figure 4. Model of a process-based quality management system (from ISO 9001:2000, p. x).

6) Figure 5 shows those parts of the new standard where the requirements are set forth. The standard also includes an Introduction, and clauses 1 (Scope), 2 (Normative Reference), and 3 (Terms and Definitions).

4 Quality Management System			
5 Management Responsibility	6 Resource Management	7 Product Realization	8 Measurement, Analysis and Improvement

Figure 5. The five major clauses of ISO 9001:2000.

4.1 Management Responsibility	4.6 Purchasing	4.11 Control of Inspection, Measuring, and Test Equipment	4.16 Control of Quality Records
4.2 Quality System	4.7 Control of Customer Supplied Product	4.12 Inspection and Test Status	4.17 Internal Quality Audits
4.3 Contract Review	4.8 Product Identification and Traceability	4.13 Control of Nonconforming Product	4.18 Training
4.4 Design Control	4.9 Process Control	4.14 Corrective and Preventive Action	4.19 Servicing
4.5 Document and Data Control	4.10 Inspection and Testing	4.15 Handling, Storage, Packaging, Preservation, and Delivery	4.20 Statistical Techniques

Figure 6. The 20 elements of ISO 9001:1994.

verification that the system is producing what it should, and proactive continuous improvement.

A general emphasis on processes. Throughout the new standard there is reference to processes both related to the quality management system, such as those needed for effective management and provision of resources, and those related to product realization. In fact ISO 9000:2000, *Fundamentals and Vocabulary*, lists the process approach as one of the fundamentals of quality management systems

and defines the process approach as: "The systematic identification and management of the processes employed within an organization and particularly the interactions between such processes ..." (p. 2).

Simpler, straight-forward language. Figure 7 shows one, fairly dramatic, instance of this simplification for the "responsibility and authority" requirement. However, throughout the standard the language is less ambiguous and easier to understand.

ISO 9001:1994 ("before")	ISO 9001:2000 ("after")
4.1.2.1 Responsibility and authority. The responsibility, authority, and the interrelation of personnel who manage, perform, and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to: a) initiate action to prevent the occurrences of any nonconformities relating to product, process, and quality system; b) identify and record any problems relating to the product, process, and quality system; c) initiate, recommend, or provide solutions through designated channels; d) verify the implementation of solutions; e) control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.	5.5.1 Responsibility and authority. Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

Figure 7. A language simplification example.

Documentation deemphasized. A significant feature of the 1994 standard was the requirement to document essentially all your procedures. According to Cianfrani, et al. (2001) ISO 9001:1994 calls out the requirement for a documented procedure in 19 different places (p. 23). The new standard has only six mandatory requirements for documented procedures as follows:

- 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.

However, this doesn't mean these are the only places an organization should have documented procedures. Clause 4.2.1d of the new standard states that the documentation shall include: "documents needed by the organization to ensure the effective planning, operation and control of its processes." This means that management has to decide where and in what form documentation is needed. In some cases for small organizations and/or relatively simple operations, documentation beyond the minimum required might be satisfied by a few written procedures or, even, some sections in the quality manual (which is still required). For larger operations, extensive documentation might be needed. The general advice from the experts is that existing documentation, based on the 1994 standard, should probably be retained. Besides the quality manual, the new standard still requires that the quality policy, quality objectives, and, of course, records be documented.

Top management's responsibilities emphasized. As shown in Figure 5, Management Responsibility (clause 5) is one of the five main clauses of the new standard. Whereas before some of these responsibilities were couched in this rather stilted way "the supplier's management with executive responsibility shall...," now the straightforward "top management shall..." is used. And it is used much more extensively to show that, indeed, quality excellence depends on the commitment of top management. This is perhaps best illustrated by clause 5.1 Management Commitment:

Top management shall provide evidence of its commitment to the develop-

ment and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

The new standard goes on to elaborate on this requirement, especially what the quality policy should contain (5.3) and how management reviews should be conducted (5.6).

The use of quality objectives at all levels required. There was only passing reference to quality objectives in the 1994 standard under Quality Policy (4.1.1). The new standard now devotes a separate clause to this (5.4.1, Quality Objectives):

> Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1a)][7], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

Noteworthy about this requirement is that the objectives are to (1) be consistent with the policy, that is, flow down from the top; (2) be established at all relevant functions/levels, that is involve essentially everyone; and (3) be measurable. Too often objectives are more rhetoric than substance like "we will produce world-class products" or "we will strive for zero defects." These sort of objectives are meaningless. But, to say you will "reduce your reject rate by 10 percent over the next six months" *is* measurable and, hence, meaningful.

---

7) Clause 7.1a) requires the organization to determine the "quality objectives and requirements for the product."

An effective means of internal and customer communications required. In the 1994 standard, internal and customer communications was only alluded to, not made an explicit requirement. For example, clause 4.1.1 of the old standard, Quality Policy, requires the supplier to "ensure that this policy is understood, implemented, and maintained at all levels of the organization." Now two clauses of the new standard explicitly require the establishment of effective communications:

- Clause 5.5.3, Internal Communications, which requires top management to be sure "appropriate communication processes are established within the organization" and are used to communicate the effectiveness of the quality management system.
- Clause 7.2.3, Customer Communications, which requires the determination and implementation of effective means for communicating with the customer.

Worded to be more broadly applicable. The 1994 standard was written primarily from a manufacturing point of view although it did define "product" as including "service, hardware, processed materials, software, or a combination thereof" and capable of being either tangible or intangible (such as "knowledge or concepts"). The new standard expands even more on this definition through its notes under clause 3.4.2 (which defines "product") of ISO 9000:2000, *Fundamentals and Vocabulary*. But, more important, as Kanholm (2001) puts it:

> The whole vocabulary of ISO 9000:2000 sounds different. System elements are called processes; inspections and testing are called product verification and validation; production is called realization; and so forth. (p. 12)

Another significant change was replacing the term "supplier" with "organization" (for the entity to which the standard applied) and the term "subcontractor" with "supplier." This change brought the standard into line with "vocabulary currently used."

Besides changing specific words, the new standard has changed the wording

in certain requirements to make them more broadly applicable. Figure 8 is an example of this. It is obvious that the wording of the new standard is a broader statement of the requirement.

ISO 9001:1994 ("before")	ISO 9001:2000 ("after")
4.1.2.2 Resources. The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18*), for management, performance of work, and verification of activities including internal quality audits.	6.1 Provision of Resources. The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.

Figure 8. An example of more broadly applicable wording.
* Clause 4.18 is Training.

Finally, lest there be any doubt about the broad applicability of the new standard, clause 1.2, Application, states "All requirements in this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size, and product provided."

Continuous improvement a requirement. This change and the "process-oriented structure" and "customer satisfaction" (next) ones are probably the most significant and, indeed, are important enhancements to the standard in terms of moving from a "quality assurance/control" perspective to a "quality management" one. Whereas the 1994 standard spoke of merely "ensuring the continuing suitability and effectiveness" of the quality management system[8], the new standard, in a separate clause (8.5.1, Continual Improvement) states: "The organization shall continually improve the effectiveness of the quality management system [and it will do this] through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management

8) Clause 4.1.3, Management Review.

reviews." Besides this clause, continual improvement is mentioned in at least eight other places[9] in the new standard. Two of these are especially relevant for continuous improvement: 5.6, Management Review, specifying actions to improve the quality management system and product as outputs of the management review, and 8.4, Analysis of Data, to, among other things, see where "continual improvement of the effectiveness of the quality management system can be made."

Customer satisfaction now important. As with the "continuous improvement" requirement, the new standard has moved from merely being sure some specification is met to actively working to improve customer satisfaction. Clause 5.2, Customer Focus, under Management Responsibility makes a very clear statement: "Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction." Supporting this rather broad requirement are two other parts of the new standard: 7.2, Customer-related Processes, and 8.2.1 Customer Satisfaction. Clause 7.2 deals with the determination and review of requirements related to the product, and customer communications. Clause 8.2.1, requires the organization to determine how it will obtain and use "information relating to customer perception as to whether the organization has met customer requirements." In other words, clause 7.2 is concerned with getting the requirements right in the first place and 8.2.1 with following up to see if the customer really is satisfied (whether we got the requirements right or not!). It is important to note the 8.2.1 requirement uses the word "perception," implying that it is not whether you have met the requirement or not but *whether the customer believes you have*; a subtle (?) but important distinction.

Having now looked at some background, rationale for the change, what comprises the new standard family, and the major changes, we now turn to the stan-

9) Clauses 1.1b), 4.1, 5.1, 5.3, 5.6, 6.1, 8.1 and 8.4.

dard itself and will briefly consider each major part of it. The standard breaks down in to two main parts: clauses 0 through 3, dealing primarily with administrative aspects, and clauses 4 through 8, which set forth the main requirements.

6. Clauses 0–3 (Introduction, Scope, Normative Reference, and Terms and Definitions)

Clause 0 Introduction. The Introduction consists of four subclauses: *General*, *Process Approach*, *Relationship with ISO 9004*, and *Compatibility with Other Management Systems*.

0.1 General. Probably the most important point made here is that "adoption of a quality management system should be a strategic decision of an organization." That is, it is not something you do either because "everyone else is" or "you need to get your 'ISO ticket' punched" but because top management (i.e., the President/CEO) believes having a good quality management system is one of the best ways to ensure the organization's success.

0.2 Process Approach. This aspect of the new standard has already been discussed in section 5 above. Here the standard lists some of the benefits of using a process approach because of the importance it places on:

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement. (ANSI/ISO/ASQ Q9001-2000, p. ix)

This subclause also suggests that the "Plan-Do-Check-Act" (PDCA) methodology be applied to all processes for continual improvement. This methodology was first know as the Shewhart Cycle, named after one of the early pioneers in the quality control movement, Walter Shewhart. It was subsequently popularized by W. Edwards Deming, perhaps the most famous of all the quality improvement

gurus (Austenfeld, 2001). The PDCA cycle can be described as follows:

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

(ANSI/ISO/ASQ Q9001-2000, p. x)

0.3 Relationship with ISO 9004. One of the new features of ISO 9000 is something called "a consistent pair." This means that ISO 9001:2000 and ISO 9004:2000 are similarly structured to facilitate their use together. However, the standard emphasizes that only the requirements in ISO 9001 are mandatory for meeting the standard; the information in ISO 9004 is provided "as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement." This is not to say that continual improvement is not a requirement of ISO 9001, but rather that it is a starting point and ISO 9004 can provide further guidance.

0.4 Compatibility with Other Management Systems. ISO 9001:2000 has been aligned with the environmental standard, ISO 14001:1996. In fact, as already mentioned in section 4, the new auditing guidelines, ISO 19011, will apply to both standards.

This part also states that although the standard does not include requirements specific to other management systems, such as those for environmental or financial management, it is written in such a way that its requirements can easily be aligned with these other requirements. Also, an organization should be able to adapt its existing management system to ensure it complies with the ISO 9001 requirements. As a footnote here, I might add that the fundamental management

concepts and structure of ISO 9001 provide an excellent basis for developing or improving management systems which often simply "grow like Topsy"[10)]

Clause 1 Scope. This clause consists of two subclauses: *General* and *Application.*

1.1 General. The standard sets forth requirements for a quality management system that will let organizations (1) demonstrate their ability to provide product that meets customer/regulatory requirements and (2) enhance customer satisfaction through continual improvement.

1.2 Application. As already mentioned in section 5, this part states that the standard is "applicable to all organizations" regardless. Since some of the requirements may not apply to some organizations[11)], exclusions may be made but must be limited to clause 7, Product Realization, and not affect the provision of conforming product.

Clause 2 Normative Reference. This short clause says simply that ISO 9000, *Quality Management Systems—Fundamentals and Vocabulary*, is, by reference, part of ISO 9001.

Clause 3 Terms and Definitions. Another short clause that says the terms and definitions given in ISO 9000 apply when using ISO 9001. Also, "to reflect the vocabulary currently used" organization replaces the term "supplier" in the 1994 standard and supplier replaces the term "subcontractor." "This welcome change makes the new standard more universally applicable versus being merely a "contract compliance" type of document. As with the 1994 standard, this part also states that the term "product" can also mean "service."

---

10) This expression is from Harriet Beecher Stowe's book Uncle Tom's Cabin published in 1852. One of the characters was a little black girl who, when asked "Do you know who made you?," answered: "I spect I grow'd. Don't think nobody never made me."

11) For example, clause 7.3, Design and Development.

7. Clauses 4–8 (the System, Management, Resources, the Product, and Measurement)

Introduction. As the title of this section indicates the requirements of ISO 9001 are grouped into five main clauses:

- 4 Quality Management System
- 5 Management Responsibility
- 6 Resource Management
- 7 Product Realization
- 8 Measurement, Analysis and Improvement

Figure 9 (next page) shows how these five clauses breakdown further. Also Figure 9 shows how the new standard is much more process and system oriented by placing the Quality Management System clause above the others; i.e., the quality management system can be considered to be comprised of the other four clauses. We will now take a closer look at each of these five clauses.

Clause 4 Quality Management System. Two subclauses: *General Requirements* and *Documentation Requirements.*

4.1 General Requirements. The requirements set forth here represent an overview of the rest of the standard. In summary it states that organizations shall identify, control, resource, monitor, measure, analyze, and continually improve all the processes needed to "achieve planned results" (i.e., products that meet the customer's expectations). In line with the structure shown in Figure 9, the note to this subclause says that the quality management system should include "processes for management activities, provision of resources, product realization, and measurement."

4 Quality Management System
4.1 General Requirements
4.2 Documentation Rqmts
1 General
2 Quality Manual
3 Control of Documents
4 Control of Records

4.2 Documentation Requirements. As already mentioned in section 5 (Major

4 Quality Management System
4.1 General Requirements
4.2 Documentation Rqmts
1 General
2 Quality Manual
3 Control of Documents
4 Control of Records

5 Management Responsibility	6 Resource Management	7 Product Realization	8 Measurement Analysis & Improvement
5.1 Mgt Commitment	6.1 Prov of Resources	7.1 Planning of PR	8.1 General
5.2 Customer Focus	6.2 Human Resources	7.2 Cust-rel'd Proc's	8.2 Montr'g & Measurement
5.3 Quality Policy	1 General	1 Dtr of Rqs rt Prd	1 Cust Satisfaction
5.4 Planning	2 Cmp, Awr & Trng	2 Rev of Rqs rt Prd	2 Internal Audit
1 Quality Objs	6.3 Infrastructure	3 Customer Com	3 M&M of Processes
2 QMS Planning	6.4 Work Environment	7.3 Design & Dvlpment	4 M&M of Product
5.5 Resp, Auth & Com		1 D&D Planning	8.3 Cntrl of NC Product
1 Resp & Authority		2 D&D Inputs	8.4 Analysis of Data
2 Mgt Representative		3 D&D Outputs	8.5 Improvement
3 Internal Com		4 D&D Review	1 Continual Improvement
5.6 Mgt Review		5 D&D Verification	2 Corrective Action
1 General		6 D&D Validation	3 Preventive Action
2 Review Input		7 Cntrl of D&D Chs	
3 Review Output		7.4 Purchasing	
		1 Purchasing Proc	
		2 Purchasing Info	
		3 Ver of Pur Product	
		7.5 Prd & Svc Provision	
		1 Cntrl of P&P Prv	
		2 Val of Proc f P&SP	
		3 Indent & Tracblty	
		4 Customer Property	
		5 Presv of Product	
		7.6 Contrl of M&M Devs	

Figure 9. The ISO 9001 Quality Management System (for a complete breakdown without abbreviations, see Appendix C).

Changes), the new standard requires that, in addition to a quality manual, the following be documented: the quality policy, the quality objectives, the records, and certain procedures[12]. However, it also requires documents to ensure "the

12) The six listed in section 5.

effective planning, operation and control" of all the organization's processes. This means, with the exception of the six mandatory documented procedures, the organization must decide what other procedures should be documented.

This subclause also describes (1) what should be included in the quality manual, (2) the controls to be established to ensure adequate control of documentation, and (3) how records should be controlled. The standard requires that a documented procedure be created for each of these last two requirements: control of documentation and control of records; *the first two* of the six mandatory documented procedures.

Clause 5 Management Responsibility. As can be seen from the inset at the bottom left, this clause contains six subclauses: *Management Commitment*; *Customer Focus*; *Quality Policy*; *Planning*; *Responsibility, Authority and Communication*; and *Management Review*.

5.1 Management Commitment. Almost any prescription for improving an organization's performance cites "top management commitment" as the first and most important requirement; ISO 9001 is no different. This commitment will be shown by doing such things as communicating the importance of meeting customer requirements, establishing a quality policy and quality objectives, providing the resources needed, and holding management reviews.

5 Management Responsibility
- 5.1 Mgt Commitment
- 5.2 Customer Focus
- 5.3 Quality Policy
- 5.4 Planning
  - 1 Quality Objs
  - 2 QMS Planning
- 5.5 Resp, Auth & Com
  - 1 Resp & Authority
  - 2 Mgt Representative
  - 3 Internal Com
- 5.6 Mgt Review
  - 1 General
  - 2 Review Input
  - 3 Review Output

5.2 Customer Focus. This short subclause simply says top management shall be sure customer requirements are determined and met. This requirement is further elaborated on in subclauses 7.2.1, Determination of Requirements Related to the Product, and 8.2.1, Customer Satisfaction.

5.3 Quality Policy. The standard specifies criteria for the quality policy including that it include "a

commitment to comply with requirements and continually improve the effectiveness of the quality management system." It must also (1) provide a framework for quality objectives, (2) be effectively communicated, and (3) be reviewed for continuing suitability. Regarding the framework, Kanholm (2001) suggest citing specific areas such as a commitment to improve on-time deliveries. Then all objectives relating to this area would be grouped under it. The primary means for reviewing the policy's continuing suitability is the management review (subclause 5.6).

5.4 Planning. Two items are covered here: quality objectives and quality management system planning. The quality objectives requirement has already been discussed in section 5 above; see that discussion.

The second item, quality management system planning, makes two very common sense statements: (1) top management will carry out planning to meet the requirements of the system[13] (as set forth in subclause 4.1) and the quality objectives and (2) top management will ensure the integrity of the system when it is changed. Although common sense enough, it is probably experience that has led the authors of the standard to include these requirements. After all, how often does planning get short shrift and changes are made without making adjustments to the existing system.

5.5 Responsibility, Authority and Communication. As can be seen in the inset on the previous page, this subclause covers three areas: responsibility and authority, management representative, and internal communication. Top management shall ensure responsibilities and authorities are defined and communicated. The 1994 standard also had such a clause but it tended to focus on certain personnel[14]; the new requirement make no such distinction.

---

13) Where "system" is used it will usually mean the same as "quality management system" and the context should make that clear.

14) See Figure 7 for a comparison.

The responsibilities of the management representative are (1) to be sure the processes needed are in place and maintained, (2) to report to top management on the quality management system's performance, and (3) to "promote awareness of customer requirements throughout the organization." This last requirement is new to the standard and is a further reflection of the standard's customer focus.

There is no equivalent to the internal communication requirement in the 1994 standard. Now top management shall ensure appropriate communication processes exist and are used to communicate the effectiveness of the quality management system. Although every organization has such processes (systems), Kanholm (2001) suggests the internal communication systems be explicitly identified along with who is responsible for their maintenance. Kanholm lists the following as typical elements of such systems: "documents, records, meetings, reviews, quality-related training, team briefings, bulletin boards, intranet sites, [and] suggestion boxes" (p. 26).

5.6 Management Review. In my opinion, this is one of the most important clauses of the new standard. It is only through periodic management reviews that top management can be sure it is continuing to satisfy the requirements of ISO 9001 and, therefore, those of its customers. This subclause consists of: general, review input, and review output. The general part simply says top management will hold reviews "at planned intervals, to ensure the continuing suitability, adequacy and effectiveness" of the quality management system including opportunities for improvement and whether any changes are needed. Inputs to the review are listed and include all information that aid in assessing and improving the system such as audit results and customer feedback. The output of the review "shall include any decisions and actions" concerning improvements to the system or product, and any resource needs.

Clause 6 Resource Management. Four subclauses: *Provision of Resources*, *Human Resources*, *Infrastructure*, and *Work Environment*. It is interesting to note

6 Resource Management
6.1 Prov of Resources
6.2 Human Resources
1 General
2 Cmp, Awr & Trng
6.3 Infrastructure
6.4 Work Environment

that at this point the requirements are now couched in "the organization shall" terms versus "top management shall." Perhaps this is because from now on the standard is dealing with requirements that apply to the organization more as a whole. However, from the wording under the Management Responsibility clause just described, it is reasonable to assume that "organization" is equivalent to "top management" wherever it appears.

6.1 Provision of Resources. The requirement here is to determine and provide the resources needed to implement, maintain, and continually improve the system and to enhance customer satisfaction. The statement of this requirement is more straightforward than that found in the 1994 standard. Also the inclusion of customer satisfaction is new. Cianfrani et al. (2001) provide a list of what would normally be included in an organization's resources: "personnel, time, buildings, equipment, utilities, materials, supplies, instruments, software, and transport facilities" (p. 63). Of course there are many other things that could be included depending on the type of organization. ISO 9001 breaks down resources according to human resources, infrastructure, and work environment.

6.2 Human Resources. The general part of this subclause simply requires that personnel be competent. The other part, competence, awareness, and training, sets forth five specific requirements: (1) determine necessary competencies, (2) provide necessary training or take other action to meet competency needs, (3) see if the actions taken were effective, (4) ensure everyone is aware of the importance of their job and how it contributes to the achievement of quality objectives, and (5) keep records of education, training, skills, and experience. Subclause 6.2 covers what element 4.18, Training, of the 1994 standard did but in a more comprehensive way. Also, of the five specific requirements, (3) and (4) are new. Requirement (4) seems an especially important addition in that it relates

to one of the eight principles of quality management cited in section 3 above, namely "involvement of people."

6.3 Infrastructure. This subclause and the following one (6.4, Work Environment) require provision of the infrastructure and work environment "needed to achieve conformity to product requirements." This wording makes these requirements more broadly applicable since, in the 1994 standard, they applied only to the "production, installation, and servicing processes which directly affect quality." Now, as Cianfrani et al. (2001) explain it, they "include the management processes; other resource processes (training, in particular); and the measurement, analysis, and improvement processes" (p. 71). Infrastructure includes buildings, workspace, utilities, equipment, and supporting services (e.g., transport and communications).

6.4 Work Environment. This one-sentence subclause says simply that the work environment necessary to achieve conformity to product requirements will be determined and managed. Cianfrani et al. (2001) provide some useful information about what this means in practical terms. For example, they say such an environment "can be considered a combination of human and physical factors." Human factors would include such things as work methods, safety rules, and ergonomics; physical factors would include such things as heat, noise, light, humidity, etc. (pp. 73–74).

Clause 7 Product Realization. As can be seen from Figure 9, this is the biggest section in the new standard and deals with the whole product/service production cycle from requirements determination to delivery and post-delivery activities. It is noteworthy that the expression "product realization" has been introduced into the new standard in lieu of the more restrictive term "production." As defined in the *Fundamentals and Vocabulary* standard, ISO 9000:2000, *product* is simply the "result of a process." Note 1 to this definition states:

There are four generic product categories, as follows:

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant). (p. 11)

This clause consists of these six subclauses: *Planning of Product Realization*, *Customer-related Processes*, *Design and Development*, *Purchasing*, *Production and Service Provision*, and *Control of Monitoring and Measuring Devices*.

7.1 Planning of Product Realization. By virtue of this requirement, the organization must determine (1) the quality objectives and requirements for the product; (2) the processes, documents, and resources specific to the product; (3) the required tests, inspections, and product acceptance criteria; and (4) the records needed to substantiate that process and product requirements have been met. According to Kanholm (2001) this specificity is a big improvement over the 1994 standard:

> Nothing in this clause is particularly new. This kind of quality planning was already required in ISO 9000:1994, although the requirements were more convoluted and difficult to enforce, allowing many companies to get certified with inferior or incomplete quality planning systems. These companies will now need to take quality planning more seriously, as findings will be much easier to identify against the stark and specific language of this clause. (pp. 36–37)

Note 1 of this subclause suggests the use of document called a "quality plan" as a good way to specify all the processes and resources that are to be applied to a specific product, project, or contract.

7.2 Customer-related Processes. This subclause deals with (1) determination and review of requirements related to the product and (2) customer communication. Requirements related to the product fall into four categories: customer specified, necessary for intended use, regulatory, and any others determined by

7 Product Realization
7.1 Planning of PR
7.2 Cust-rel'd Proc's
1 Dtr of Rqs rt Prd
2 Rev of Rqs rt Prd
3 Customer Com
7.3 Design & Dvlpment
1 D&D Planning
2 D&D Inputs
3 D&D Outputs
4 D&D Review
5 D&D Verification
6 D&D Validation
7 Cntrl of D&D Chs
7.4 Purchasing
1 Purchasing Proc
2 Purchasing Info
3 Ver of Pur Product
7.5 Prd & Svc Provision
1 Cntrl of P&P Prv
2 Val of Proc f P&SP
3 Indent & Tracblty
4 Customer Property
5 Presv of Product
7.6 Contrl of M&M Devs

the organization. Cianfrani et al. (2001) recommend a written procedure that addresses each of these categories to be sure nothing is overlooked.

As far as reviewing the requirements, the standard states that this shall be done before a commitment is made to provide the product and ensure (1) the product requirements are defined, (2) any changes to the requirements are resolved, and (3) the organization has the ability to meet the defined requirements. Furthermore, records must be kept of review actions and, where there is no documented statement of the requirement, it must be confirmed with the customer.

Finally, the organization must ensure effective means for communicating with the customer exist for such things as product information, inquires, and feedback (including customer complaints).

7.3 Design and Development. As can be seen from the inset, this is the longest subclause and covers design and development planning, inputs, outputs, review, verification and validation, and control of design and development changes.

The planning shall include determining (1) the design and development stages, (2) the various review, verification, and validation[15] actions that need to take

15) The difference between verification and validation can be seen from the "official" definitions set forth in ISO 9000:2000:

- verification confirmation, through the provision of objective evidence, that *specified requirements have been met.*
- validation confirmation, through the provision of objective evidence, that *the requirements for a specific intended use or application have been fulfilled.*

place at each stage, and (3) the various responsibilities and authorities. Furthermore, an effective means of communication among all the groups involved must be arranged.

Inputs to the design and development process shall include functional, performance, and regulatory requirements; information from similar designs (if applicable); and any other requirement "essential for design and development." Outputs shall (1) meet the input requirements, (2) provide the information needed for purchasing, production, and service provision, (3) include or reference product acceptance criteria, and (4) state any characteristics essential for safe or proper use.

At appropriate stages in the design and development process, planned reviews shall take place (1) to see if the results of the process have the ability to meet requirements and (2) to identify and address any problems. Verification and validation (see footnote 15) shall be performed "in accordance with planned arrangements" made during the planning phase. Records shall be maintained of the results of all reviews, verifications, and validations performed.

Finally, any design and development changes shall be "reviewed, verified, and validated, as appropriate, and approved before implementation." Records shall be maintained of any changes and any change reviews.

7.4 Purchasing. This subclause requires that the organization ensure the "purchased product conforms to specified purchase requirements." It is to do this by (1) being sure these requirements are adequate prior to communication to the supplier and (2) implementing whatever checks are needed to ensure the purchased product, once received, meets the requirements. The extent of this effort will depend on the effect of the purchased product on the organization's product. This subclause also requires organizations to establish and (of course) use criteria for the "selection, evaluation, and re-evaluation" of suppliers.

7.5 Production and Service Provision. This subclause addresses five distinct

7 Product Realization
7.1 Planning of PR
7.2 Cust-rel'd Proc's
1 Dtr of Rqs rt Prd
2 Rev of Rqs rt Prd
3 Customer Com
7.3 Design & Dvlpment
1 D&D Planning
2 D&D Inputs
3 D&D Outputs
4 D&D Review
5 D&D Verification
6 D&D Validation
7 Cntrl of D&D Chs
7.4 Purchasing
1 Purchasing Proc
2 Purchasing Info
3 Ver of Pur Product
7.5 Prd & Svc Provision
1 Cntrl of P&P Prv
2 Val of Proc f P&SP
3 Indent & Tracblty
4 Customer Property
5 Presv of Product
7.6 Contrl of M&M Devs

areas: control of production and service provision, validation of processes, identification and traceability, customer property, and preservation of product. With regard to control, the production and service provision shall be planned and carried out under "controlled conditions." These conditions shall include such things as the availability of information describing the product's characteristics, work instructions, and the means for doing any required monitoring and measuring.

Validation of processes for production and service provision is concerned with processes that cannot be verified by monitoring and measurement; e.g., gluing, welding, plating, teaching, etc. For these processes, the standard requires, as applicable, the following: (1) criteria for approval of the process, (2) approval of equipment and personnel, (3) use of specific methods, (4) records, and (5) revalidation. In the 1994 standard these processes, requiring prequalification, were known as "special processes."

The requirement to identify and trace a product could arise for a number of reasons. Cianfrani et al. (2001) provide these examples of when it might be a requirement in a contract: "for certain medical devices, for defense/space vehicle assemblies, and for devices used in nuclear power plants" (p. 131). It may also be required to identify a service provider for certain kinds of service. Whatever the reason, when such is the case, this subclause addresses that requirement saying the product/service provider will be suitably identified throughout the realization process. In particular, there may be a need to identify a product's

status with respect to whatever monitoring and measurement it has undergone.

The "customer property" part of this subclause simply states that the organization shall be careful with any customer property and, should any problem arise in connection with that property (e.g, loss, damage, unsuitability for some intended purpose, etc.), it shall be reported to the customer and a record kept.

The final part of this subclause (preservation) requires the organization to preserve the conformity of the product "during internal processing and delivery to the intended destination." This part essentially states the same thing as element 4.15 of the 1994 standard (Handling, Storage, Packaging, Preservation, and Delivery) but in a much simper and briefer form.

7.6 Control of Monitoring and Measuring Devices. This subclause can be considered to have three main parts: (1) determining what needs to be monitored and measured and what is needed to do that in terms of equipment and processes, (2) ensuring that monitoring and measuring devices are properly maintained, and (3) if a device is found to be out of calibration and/or adjustment, any prior measurements by that device are rechecked. The proper maintenance of these devices includes keeping them calibrated and correctly adjusted and safeguarding them to prevent maladjustment or damage and deterioration. The requirement to recheck any prior measurements should a device be found out of calibration/adjustment implies that records need to be kept of which equipment has been used to make which product tests. The note to this subclause cites ISO 10012-1 and ISO 10012-2[16] for guidance.

Clause 8 Measurement, Analysis and Improvement. This clause consists of

16) Full titles:
- ISO 10012-1:1992 *Quality Assurance Requirements for Measuring Equipment—Part 1: Metrological Confirmation System for Measuring Equipment*
- ISO 10012-2:1997 *Quality Assurance Requirements for Measuring Equipment—Part 2: Guidelines for Control of Measurement Processes*

these subclauses: *General*, *Monitoring and Measuring*, *Control of Nonconforming Product*, *Analysis of Data*, and *Improvement*.

8.1 General. This subclause is another example of how the new standard has been broadened in it application. Figure 10 shows just how much more encompassing the new standard is compared with the 1994 standard. Not only has "inspection and testing" been broadened to include analysis and improvement, the object of these activities now includes the quality management system and continual improvement. Statistical techniques are to be included for consideration when determining applicable methods for these activities.

ISO 9001:1994 ("before")	ISO 9001:2000 ("after")
4.10.1 General (under Inspection and Testing; partially). The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met.	8.1 General (under Measurement, Analysis and Improvement; partially). The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system.

Figure 10. Comparing subelement 4.10.1 with subclause 8.1 to show that ISO 9001:2000 is much more encompassing.

8.2 Monitoring and Measurement. Four important requirements are included in this subclause: customer satisfaction, internal audits, and the monitoring and measurement of processes and product. The "customer satisfaction" requirement, although very short, is one of the important changes to the standard as discussed in section 5 above. The organization is to determine the methods for obtaining and using information about the customer's perceptions regarding whether his or her requirements have been met. I believe the important points here are:

- As mentioned in section 5, the standard makes it clear the organization

must try to understand how the *customer* sees its performance, not how it *thinks* it is doing.

- Not only is the information to be gathered but *used*, and this use must be determined. (The implication is that this determination will occur *before* the information is gathered since an important, but often not followed, principle when in gathering information is to first decide what you are going to do with it; otherwise it often becomes merely an "information gathering" exercise.)

The next part deals with internal audits. The requirement is for audits to be conducted at planned intervals to check if the system conforms to requirements and "is effectively implemented and maintained." Furthermore, these audits are to take "into consideration the status and importance of the processes and areas to be audited..." so you are spending most of your precious audit time on the most important areas. This requirement is almost the same as in the 1994 standard. However, these are some important points that are now quite explicit: (1) the audits will be at planned intervals, (2) they will take into consideration the results of previous audits, and (3) the independence of the auditor is clearer ("auditors will not audit their own work"). Cianfrani et al. (2001) provide a good discussion about the difference between internal audits, management reviews (internal audit results are input for these reviews), and self-assessments (a more general look at the overall effectiveness and efficiency of the organization). Self-assessments are not a requirement but ISO 9004:2000, clause 8.2.1.5, Self-assessment, says top management should consider doing these and provides guidance. The note to this part cites ISO 10011-1, ISO 10011-2, and ISO 10011-3 for guidance

8 Measurement
Analysis & Improvement
8.1 General
8.2 Montr'g & Msurment
1 Cust Satisfaction
2 Internal Audit
3 M&M of Processes
4 M&M of Product
8.3 Cntrl of NC Product
8.4 Analysis of Data
8.5 Improvement
1 Continual Imprvment
2 Corrective Action
3 Preventive Action

on conducting audits[17]. All responsibilities and requirements related to internal audits shall be set forth in a documented procedure; *the third* of the mandatory six.

The next part of this subclause (8.2) requires that the quality management system *processes* be monitored and measured to demonstrate their ability to meet planned results. According to Kanholm (2001) this means "setting specific, measurable objectives and checking whether these objectives are being achieved within specified timeframes" (p. 52). Kanholm also states that this requirement can be satisfied by meeting other parts of the standard; e.g., for setting objectives: 5.4.1 (Quality Objectives) and 5.6 (Management Review); for monitoring and measurement: 8.2.2 (Internal Audit), 8.2.1 (Customer Satisfaction), 8.4 (Analysis of Data), 8.3 (Control of Nonconforming Product), and 7.4 (Purchasing); and for addressing deficiencies: 8.5.2 (Corrective Action), 8.5.3 (Preventive Action), and 8.5.1 (Continuous Improvement). Cianfrani et al. (2001) make the point that since all processes cannot be monitored/measured, the organization must home in on the key ones and, among these, those least stable.[18]

The last part of this subclause requires that the *product* be monitored/measured "at appropriate stages of the product realization process..." As with the last part,

---

17) Full titles:

- ISO 10011-1:1990, *Guidelines for Auditing Quality Systems—Part 1: Auditing*
- ISO 10011-2:1990, *Guidelines for Auditing Quality Systems—Part 2: Qualification Criteria for Quality Systems Auditors*
- ISO 10011-3:1990, *Guidelines for Auditing Quality Systems—Part 3: Management of Audit Programmes*

As mentioned in section 4, these three guidance documents, along with three similar ones associated with ISO 14001 (the environmental standard), are to be replaced soon (2002?) by ISO 19011, *Guidelines on Quality and/or Environmental Management Systems Auditing.*

18) This, of course, is only common sense (sometimes an uncommon commodity) and, as just mentioned, is also the way internal audit programs are to be run.

dealing with monitoring/measurement of the system's processes, this one is sort of a catch-all. Compliance with other parts of the standard, should satisfied this part; for example, 7.3.3–7.3.5 dealing with design and development review, verification, and validation; 7.4.3 dealing with verification of purchased product; and 7.5.1 dealing with control of production and service provision. However, this part also requires that, unless appropriately authorized, "product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed." Furthermore, the person authorizing release shall be indicated in the records.

8.3 Control of Nonconforming Product. This requirement is essentially the same as element 4.13 of the same name in the 1994 standard and is meant to ensure any nonconforming product is caught before release and, once detected, how the organization is to deal with it. One new requirement, as noted by Kanholm (2001), is for the organization to take appropriate action if nonconforming product is detected *after* deliver/use. "The controls and related responsibilities and authorities" are to be defined in a documented procedure; *the fourth* of the mandatory six.

8.4 Analysis of Data. This is essentially a new requirement but, as so many really are, a common sense one. The purpose of the analysis is to "demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement... ...can be made." The standard specifically requires the analysis to provide information about customer satisfaction, product conformity, characteristics and trends of processes and products, and suppliers. As mentioned when discussing the customer satisfaction requirement under 8.2 (Monitoring and Measurement), it is important to decide on what use will be made of the information (Cianfrani, et al., 2001).

8.5 Improvement. This subclause covers continual improvement, corrective action, and preventive action. As mentioned in section 5, the requirement to con-

tinually improve the system is probably one of the most important changes to the standard. This part lists seven things that are to be used for this: the quality policy, quality objectives, audit results, analysis of data, corrective action, preventive action, and management reviews. Of these, the most important is management reviews since it is here that all the other things are considered, leading to improvement decisions and actions.

The last two requirements of the standard are for corrective action and preventive action. Corrective action is action taken to prevent the recurrence of a nonconformity and preventive action is action taken to prevent the occurrence of a nonconformity in the first place. In both cases a documented procedure is required (*the fifth and sixth* of the mandatory six) that spells out everything required to deal with the nonconformity or potential nonconformity such as determining the cause and taking remedial action. One new (and important) requirement is that now a record shall be made of actions taken.

8. Why the New Standard Will Result in Better Organizations

By this time it should be obvious that the new standard, if conscientiously followed, will result in a better organization. The 1994 standard was written mostly in terms of meeting the minimum requirements for quality management; the new standard's whole tenor is one of going beyond the minimum required and seeking to continually improve one's processes and product. Indeed, the standard incorporates much of the wisdom of one of the foremost thinker about what constitutes a sound organization in terms of good management. This is W. Edwards Deming who, at the age of 93, passed away in December 1993. Deming was active in the quality movement almost up to his last days on earth. His famous Fourteen Points (see Appendix B) will continue to provide the basis for transforming organizations from the all too typical "command and control" type to the "everyone empowered and working together" type. A careful study of Deming's

approach to quality management (see Austenfeld, 2001) will show that its principles are, for the most part, embodied in the new ISO 9001 standard.

Accordingly the new standard can now be used as an excellent model for an organization's basic management system. If an organization does all the things prescribed in the new standard it will be operating on sound management principles. Of course this basic system will need to be supplemented with other systems such as those dealing with strategy, finance, the environment, etc. However, there is probably no reason an organization could not use ISO 9001:2000 as the foundation of its management system — it is logical, comprehensive, and easy to understand.

9. Conclusions

This paper has attempted to describe the new ISO 9000 standard which, by now, is a little more than a year old. It has done this by covering some background, discussing some reasons why the change was considered necessary, describing the new ISO 9000 family, discussing the major changes, and, finally, briefly going over each major clause and subclause of ISO 9001:2000, the requirements part of the new standard.

Section 8 provided a short discussion about why the new standard will result better organizations. The short answer is that, if conscientiously followed, it will transform the organization into one that is no longer concerned with meeting the minimum requirements but obsessed with continually improving it processes and products. By doing this it will not just satisfy its customers but surprise and delight them with its excellence. Therefore, I think we can now answer the question posed by the title to this paper: does the new ISO 9000 standard represent an *evolution* or *revolution*? ISO 9000:2000 truly represents a quantum step forward in quality management. Not only does it set forth requirements that will lead to an excellent quality management system, it says to everyone, managers

and workers alike, we will do more than meet minimum requirements–we will continually excel! Given that, ISO 9000:2000 is a *revolution*!

References

ANSI/ISO/ASQ Q9000-2000, 2000, *Quality Management Systems — Fundamentals and Vocabulary*. Milwaukee, WI: Quality Press.

ANSI/ISO/ASQ Q9001-2000, 2000, *Quality Management Systems — Requirements*. Milwaukee, WI: Quality Press.

ANSI/ISO/ASQC Q9001–1994, 1994, *Quality Systems — Model for Quality Assurance in Design, Development, Production, Installation, and Servicing*. Milwaukee, WI: Quality Press.

Austenfeld, R. B., Jr. (2001, September). W. Edwards Deming: The Story of a Truly Remarkable Person. *Papers of the Research Society of Commerce and Economics – Hiroshima Shudo University*, pp. 49–102.

Cianfrani, C. A., Tsiakals, J. J., & West, J. E. (2001). *ISO 9000:2000 Explained* (2nd ed.). Milwaukee, WI: Quality Press.

Companies Turn to Grades, and Employees Go to Court (2001, March 19). *The New York Times on the Web* (http://www.nytimes.com).

Deming, W. E. (1986). *Out of the Crisis*. Cambridge, MA: MIT, Center for Advanced Engineering Study.

ISO home page (2001) (http://www.iso.ch).

Kanholm, J. (2001). *ISO 9000:2000 New Requirements: 28 New Requirements, Checklist and Compliance Guide* (3rd ed.). Pasadena, CA: AQA Co.

Ketola, J. & Roberts, K. (2001). *ISO 9000:2000 in a Nutshell* (2nd ed.). Chico, CA: Paton Press.

Scholtes, P. R. (1988). *The Team Handbook*. Madison, WI: Joiner Associates.

Stephens, K. S. (1994, Fall). ISO 9000 and Total Quality. *Quality Management Journal*, pp. 57–71.

Toyota Motor Corporation (1997). *Outline of Toyota as of Mar. 1997* (Toyota brochure).

Wilson, L. A. (1996, January). Eight-Step Process to Successful ISO 9000 Implementation: A Quality Management System Approach. *Quality Progress*, pp. 37–40.

Young, B. G. (1999). After ISO 9000 — Now What? (Preconference tutorial at the 11th Annual Quality Management Conference, Charlotte, NC, January 20, 1999).

APPENDIX A - page 1 of 2

THE ISO 9000 FAMILY OF STANDARDS

(ISO home page, 2001, under *ISO 9000*)

Standards and Guidelines	Purpose
ISO 9000:2000 *Quality Management Systems — Fundamentals and Vocabulary*	Establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family which you need to avoid misunderstandings in their use.
ISO 9001:2000 *Quality Management Systems — Requirements*	This is the requirement standard you use to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction. It is now the only standard in the ISO 9000 family against which third-party certification can be carried out.
ISO 9004:2000 *Quality Management Systems—Guidelines for Performance Improvements*	This guideline standard provides guidance for continual improvement of your quality management system to benefit all parties through sustained customer satisfaction.
ISO 19011 *Guidelines on Quality and/or Environmental Management Systems Auditing (currently under development)*	Provides you with guidelines for verifying the system's ability to achieve defined quality objectives. You can use this standard internally or for auditing your suppliers.
ISO 10005:1995 *Quality Management — Guidelines for Quality Plans*	Provides guidelines to assist in the preparation, review, acceptance and revision of quality plans.
ISO 10006:1997 *Quality Management — Guidelines to Quality in Project Management*	Guidelines to help you ensure the quality of both the project processes and the project products.
ISO 10007:1995 *Quality Management — Guidelines for Configuration Management*	Gives you guidelines to ensure that a complex product continues to function when components are changed individually

APPENDIX A – page 2 of 2

THE ISO 9000 FAMILY OF STANDARDS

Standards and Guidelines	Purpose
ISO/DIS 10012 *Quality Assurance Requirements for Measuring Equipment — Part 1: Metrological Confirmation System for Measuring Equipment*	Gives you guidelines on the main features of a calibration system to ensure that measurements are made with the intended accuracy.
ISO 10012-2:1997 *Quality Assurance for Measuring Equipment—Part 2: Guidelines for Control of Measurement of Processes*	Provides supplementary guidance on the application of statistical process control when this is appropriate for achieving the objectives of Part 1.
ISO 10013:1995 *Guidelines for Developing Quality Manuals*	Provides guidelines for the development, and maintenance of quality manuals, tailored to your specific needs
ISO/TR 10014:1998 *Guidelines for Managing the Economics of Quality*	Provides guidance on how to achieve economic benefits from the application of quality management.
ISO 10015:1999 *Quality Management — Guidelines for Training*	Provides guidance on the development, implementation, maintenance and improvement of strategies and systems for training that affects the quality of products.
ISO/TS 16949:1999 *Quality Systems — Automotive Suppliers—Particular Requirements for the Application of ISO 9001:1994*	Sector specific guidance to the application of ISO 9001 in the automotive industry.

APPENDIX B - page 1 of 7

DEMING'S FOURTEEN POINTS

(Deming, 1986, pp. 23–24 and Austenfeld, 2001, Appendix A)

Point 1: *Create constancy of purpose towards improvement of product and service, with the aim to become competitive and to stay in business, and to provide jobs.* Here Deming is stressing the need for management to make a real commitment to quality so that everyone else in the company has confidence *that there will be a future.* Specifically, management must innovate, put resources in research and education, and "constantly improve the design of product and service." Management must be concerned with business far beyond the next quarter's dividends!

Point 2: *Adopt the new philosophy. We are in a new economic age. Western management must awaken to the challenge, must learn their responsibilities, and take on leadership for change.* According to Deming, for the transformation (of Western management) to occur: "We can no longer tolerate commonly accepted levels of mistakes, defects, material not suited for the job, people on the job that do not know what the job is and are afraid to ask..." (p. 26). Citing the precision with which the Japanese train system operates — as opposed to what we often find in America, for example — Deming relates this set of instructions for getting to a company in Japan: "0903 h Board the train. Pay no attention to trains at 0858, 0901. 0957 h Off."

Point 3: *Cease reliance on mass inspection to achieve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.* The main idea here is that it is better to randomly sample the process's output for purposes of maintaining statistical quality control rather than having 100% inspection. Deming mentions a printing company that had prided itself on proofreading everything eleven times yet still needed help due to con-

APPENDIX B - page 2 of 7

DEMING'S FOURTEEN POINTS

stant customer complaints. The problem: each of the eleven inspectors relied on the other ten! In other words: you can't inspect quality into a product or service. Instead, you should work to constantly improve the process — improved quality will automatically result.

Point 4: *End the practice of awarding business on the basis of price tag. Instead, minimize total cost. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust.*[19] Deming quotes from an actual government advertisement for professional help: "For delivery and evaluation of a course on management for quality control for supervisors.... An order will be issued *on the basis of price*." Worse yet, such a practice will drive those who would have delivered good products and services out of business. Common sense tells us that you can't make quality products out of poor quality material. The other idea contained in this point is that it is a good idea to establish long-term relationships with your suppliers. This way you can work together to improve the quality of the supplies and, accordingly, that of the product in which they are used. As the product's quality improves and it becomes more successful, the additional profit can be shared with the supplier thus encouraging further improvements!

Point 5: *Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease costs*. Some of the things Deming mentions here are continual improvement through a better understand customer requirements, development of better relationships with suppliers, doing a better job of hiring, training, and supporting workers, and considering/experimenting with all ways that a process might be made better (maybe

19) Deming discusses this point extensively in *Out of the Crisis* (17 pages).

APPENDIX B - page 3 of 7

DEMING'S FOURTEEN POINTS

just by changing the temperature or humidity). Toyota takes this point seriously; for example, in 1995 Toyota Motors received 764,402 suggestions and *99% were adopted* (Toyota Motor Corporation, 1997).

Point 6: *Institute training on the job*. Deming cites an example, perhaps all too common, of a worker simply being told to "go to work" without having the job explained to him and, to make matters worse, a foreman who "knows nothing." Managers need to be trained in all aspects of the company operation and given an appreciation of variation. Unfortunately, most American managers have not had experience at the "factory floor" level. Deming also brings up the importance of recognizing that people learn in different ways.

Point 7: *Institute leadership. The aim of supervision should be to help people and machines and gadgets to do a better job. Supervision of management is in need of overhaul, as well as supervision of production workers*. Deming here is saying the job of management is not "supervision" but "leadership." This means knowing enough about the worker's job to be able to give him or her the help needed. It also means not managing by the numbers as in "zero defects" or just meeting or not meeting some specification. The goal of leadership should be to empower (with the training and equipment needed) and encourage the worker to continual improve the process, not meet some relatively arbitrary specification or make some quota number.

Point 8: *Drive out fear, so that everyone may work effectively for the company*. Workers and supervisors will often do what management wants out of fear, even if it has long-term adverse consequences. One example Deming cites is a foreman who knew the production line needed to be shut down for repairs but took a chance in an attempt to meet management's quota for castings. When his worst

APPENDIX B - page 4 of 7

DEMING'S FOURTEEN POINTS

fears were realized, not only wasn't the quota met, but the line was down for four days for repairs! Fear will lead to such things as an inspector passing poor quality products and fudging figures. A secure environment must be created where the worker knows it is OK to report a problem and a spirit of working together to solve problems prevails over blaming.

Point 9: *Break down barriers between departments. People in research, design, sales, and production must work as a team, to foresee problems of production and in use that may be encountered with the product or service.* Another common problem in companies is the left hand not knowing what the right hand is doing, Deming gives the example of a perennial design problem that the servicemen continued to correct because there was no system for feedback to manufacturing to eliminate the problem in the first place! Departments need to think in terms of who their internal customers are and develop a good working relationship with them.

Point 10: *Eliminate slogans, exhortations, and targets for the work force asking for zero defects and new levels of productivity. Such exhortations only create adversarial relationships, since the bulk of the causes of low quality and low productivity belong to the system and thus lie beyond the power of the work force.*

What good are slogans when nothing is changed to help the worker do a better job. Deming's famous Red Bead experiment dramatically demonstrates the futility of exhorting workers to do better when the system remains the same. As the experiment shows, the (stable) system will never allow the workers to do better until management changes it.

Point 11a: *Eliminate work standards (quotas) on the factory floor. Substitute leadership.* Point 11b: *Eliminate management by objectives. Eliminate manage-*

APPENDIX B - page 5 of 7

DEMING'S FOURTEEN POINTS

ment by the numbers, numerical goals. Substitute leadership. As Deming so eloquently points out, work standards (quotas) are great demoralizers. Take the case of the woman required to handle 25 reservation/information calls an hour for some airline. Due to circumstances beyond her control, calls often took longer than the average of 1/25 of an hour (2.4 minutes) the standard called for. The results was a dilemma: either give courteous and helpful service or rush the call often angering the customer. Instead, as already mentioned, the process must be studied and and systematically improved.

As for management by the numbers, the main problem is saying "we will increase productive (or anything) by, say, 10% next year" *without a plan or method for doing so.* It's as if somehow that increase will occur without any change in the way the company has been doing business — impossible, with a lot of frustration being the only result.

Point 12a: *Remove barriers that rob the hourly workers of their right to pride of workmanship. The responsibility of supervisors must be changed from mere numbers to quality.* Point 12b: *Remove barriers that rob people in management and in engineering of their right to pride of workmanship. This means,* inter alia, *abolishment of the annual review or merit rating and of management by objectives.* Some of the barriers to pride of workmanship cited by Deming (1986) in *Out of the Crisis* are: foremen who are afraid to make decisions or don't know their job well enough to give leadership, equipment not working right, inadequate training, and being required to use poor quality materials. Deming cites many real life examples.

Point 12b, about eliminating the annual review or merit rating, is perhaps the only point that is controversial. However, Deming's basis for this point is similar

APPENDIX B - page 6 of 7

DEMING'S FOURTEEN POINTS

to that for Point 3, Cease reliance on mass inspection. As Deming puts it:

> Basically what is wrong is that the performance appraisal or merit rating focuses on the end product, at the end of the stream, not on leadership to help people. *This is the way to avoid the problem of people.*[20] A manager becomes, in effect, manager of defects [emphasis added]. (p. 102)

Besides this, such rating systems tend to foster competition among workers rather than teamwork. They also tend to foster an attitude of "not rocking the boat" and focusing more on how to get a good rating (e.g., tell the boss what he/she wants to hear) rather than using the knowledge possessed to help the company.

Instead, Deming says the performance of all workers doing a similar job should be tracked and plotted on a control chart. Should anyone's performance fall outside reasonable limits, an investigation should be conducted to determine the cause (inadequate training, bad equipment, etc.). In fact, it is usually the system, not the individual worker, that is at fault when something goes wrong or there is poor performance. In fact, according to Scholtes (1988), about 85% of the problems an organization encounters is due to the system. Given that you have been careful to select good people, given them appropriate training and the chance to gain experience, and provided motivation, they will almost invariable do a good job *if the system lets them.*[21]

Point 13: *Institute a vigorous program of education and self-improvement.* As opposed to Point 6, *Institute training on the job*, this one is talking about just

20) Probably most of us know from our experience in the workplace or even at home how difficult it is for us to deal directly with people, especially about what might be perceived as a deficiency on the part of someone. Simply put, we fear confrontation.

21) That the rating system is "alive and well" is testified to by a recent New York Times article (Companies Turn to, 2001)

APPENDIX B - page 7 of 7

DEMING'S FOURTEEN POINTS

making your people better through education and other means such as giving them additional responsibilities. To quote Deming from *Out of the Crisis*: "People require in their careers, more than money, ever-broadening opportunities to add something to society, materially and otherwise" (p. 86).

Point 14: *Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job*. This simply means moving beyond words to action. Management must study, understand, and agree on what the other 13 points mean and then disseminate this information to all the others in the company and develop concrete plans for accomplishing the points.

APPENDIX C – page 1 of 4

BREAKDOWN OF ISO 9001:2000

Introduction

0.1 General

0.2 Process Approach

0.3 Relationship with ISO 9004

0.4 Compatibility with Other Management Systems

Quality Management Systems—Requirements

1 Scope

1.1 General

1.2 Application

2 Normative Reference

3 Terms and Definitions

4 Quality Management System

4.1 General Requirements

4.2 Documentation Requirements

4.2.1 General

4.2.2 Quality Manual

4.2.3 Control of Documents

4.2.4 Control of Records

5 Management Responsibility

5.1 Management Commitment

5.2 Customer Focus

5.3 Quality Policy

5.4 Planning

5.4.1 Quality Objectives

APPENDIX C – page 2 of 4
BREAKDOWN OF ISO 9001:2000

5.4.2 Quality Management System Planning

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

5.5.2 Management Representative

5.5.3 Internal Communication

5.6 Management Review

5.6.1 General

5.6.2 Review Input

5.6.3 Review Output

6 Resource Management

6.1 Provision of Resources

6.2 Human Resources

6.2.1 General

6.2.2 Competence, Awareness and Training

6.3 Infrastructure

6.4 Work Environment

7 Product Realization

7.1 Planning of Product Realization

7.2 Customer-related Processes

7.2.1 Determination of Requirements Related to the Product

7.2.2 Review of Requirements Related to the Product

7.2.3 Customer Communication

7.3 Design and Development

7.3.1 Design and Development Planning

APPENDIX C – page 3 of 4
BREAKDOWN OF ISO 9001:2000

7.3.2 Design and Development Inputs

7.3.3 Design and Development Outputs

7.3.4 Design and Development Review

7.3.5 Design and Development Verification

7.3.6 Design and Development Validation

7.3.7 Control of Design and Development Changes

7.4 Purchasing

7.4.1 Purchasing Process

7.4.2 Purchasing Information

7.4.3 Verification of Purchased Product

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

7.5.2 Validation of Processes for Production and Service Provision

7.5.3 Identification and Traceability

7.5.4 Customer Property

7.5.5 Preservation of Product

7.6 Control of Monitoring and Measuring Devices

8 Measurement, Analysis and Improvement

8.1 General

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

8.2.2 Internal Audit

8.2.3 Monitoring and Measurement of Processes

8.2.4 Monitoring and Measurement of Product

APPENDIX C – page 4 of 4
BREAKDOWN OF ISO 9001:2000

8.3 Control of Nonconforming Product

8.4 Analysis of Data

8.5 Improvement

8.5.1 Continual Improvement

8.5.2 Corrective Action

8.5.3 Preventive Action