

# ISO 9001:2000 – TRANSITION GUIDE

## Introduction

This ISO 9001:2000 Transition Guide covers the meaning of a quality management system, major revisions in the ISO 9001:2000 standard, and the major challenges facing organizations seeking to comply with the new requirements. It is provided free of charge for information purposes only, and is not to be construed as providing consulting services.

## Quality Management Systems

Under ISO 9001:2000, a quality management system encourages organizations to analyze customer requirements and to meet them. It defines the processes for realization of the product or service that is acceptable to the customer. The system also exists to keep these processes under control and provides a framework for continual improvement. Finally, the system provides confidence to the organization and its customers that the organization is able to provide products or services that fulfill requirements.

Stated another way, an ISO 9001:2000 quality management system encompasses all of the activities that the organization performs to satisfy the quality-related expectations of its customers.

## Major Revisions to the ISO 9000 Standard

ISO 9001:2000 represents a major change from the 1994 standard. Quality professionals can debate the question of what constitutes a major change, but for the purposes of this transition guide, let's consider the following:

### 1. Three standards have been replaced by one

There are three system standards within the 1994 ISO quality management family. They are:

1. **ISO 9001** “Quality Systems – Model for Quality Assurance in Design, Development, Production, Installation and Servicing”,
2. **ISO 9002** “Quality Systems – Model for Quality Assurance in Production, Installation, and Servicing”, and
3. **ISO 9003** “Quality Systems – Model for Quality Assurance in Final Inspection and Test”.

These three standards are being replaced by one standard: **ISO 9001**, “Quality Management Systems – Requirements”. ISO 9002 was used by organizations that did not perform design or development. ISO 9003 was used by organizations that only provided final inspection and testing services. Companies that would have previously used ISO 9002 or ISO 9003 standards will now use the new ISO 9001 standard and exclude the areas that do not apply to their business.

The 1994 revision documents will be withdrawn December 15, 2003. Until then, both the 1994 revisions and the 2000 revisions are valid for registration, although no registrars are issuing new registrations to the 1994 versions. Also note the term "Quality Assurance" no longer appears in the title of the standard. Quality management is considered a more advanced and far-reaching concept than quality assurance.

## **2. Twenty elements have been replaced with five clauses**

The 1994 version of ISO 9001 required conformance with 20 elements (sometimes referred to as clauses). This caused problems in some organizations, not only because of the number of clauses, but also because of the order in which they were listed and the lack of connection or flow between them. While applicable in most organization, the way the clauses were presented really did not represent the way organizations did business. While most organizations prepared their quality manuals and, hence, their quality systems in a manner that followed strict, point-by-point conformance to the elements, many chose to develop their systems according to their business structure. In other words, their systems were designed and implemented the way they “worked”, not according to the order presented in the standard. The 20 elements were embodied in these business systems, of course, but their order of presentation was secondary to outlining the way the organization did business.

Some auditors actually preferred the element-by-element method believing that it was easier to determine conformance. They could look at the quality manual along side the standard and simply check off the elements as they appeared in the manual.

ISO 9001:2000 replaces the 20 clauses of the 1994 standard with five:

Clause 4: Quality Management System

Clause 5: Management Responsibility

Clause 6: Resource Management

Clause 7: Product Realization

Clause 8: Measurement, Analysis, and Improvement

Clauses 1, 2 and 3 are Scope, Normative reference, and Terms and definitions, respectively, and are not part the standard that describes requirements for implementation.

## **3. Customer Satisfaction**

Customer satisfaction is the *principal objective* of the ISO 9001:2000 quality management system. Organizations must determine customer needs and expectations, ensure awareness of those customer requirements throughout organization, and consider these requirements in establishing objectives for improvement. To ensure this focus on the customer, there is also a significant new emphasis (and associated requirements) for customer communication.

## **4. Emphasis is placed on the “Process”**

If you look at the 1994 standard’s 20 clauses and compare them to the five main elements of the new standard, it will become readily apparent that the emphasis now is on the “process” or, more

specifically:

- Understanding and meeting (customer) requirements
- Considering processes in terms of value added (from the customer's perspective)
- Evaluate processes in terms of performance and effectiveness, and
- Using objective measurements of process as the basis for continual improvement.

## **5. Management Involvement and Responsibility**

Management involvement was required in the 1994 standard, but in the 2000 version the requirements have been broadened and significantly strengthened. Top management need not participate in the daily operation of the quality management system, but these individuals are required to establish the quality policy and the quality objectives, conduct management reviews, ensure availability of resources, and communicate the importance of meeting customer requirements and any applicable regulatory mandates. It is certainly debatable, but many quality professionals consider management involvement to be the most important consideration for success of a quality management system.

## **6. Continual Improvement**

Continual improvement was a part of the 1994 standard, being most evident in the internal auditing, corrective action, and preventive action clauses. Now, however, continual improvement must be a "planned process" and must be demonstrated. Continual improvement is further facilitated in the new standard by the requirement to establish, communicate, monitor, and measure quality objectives. For clarification, ask your registrar what they will be looking for.

## **7. Data Collection and Analysis**

Organizations are now required to analyze data to obtain information about customer satisfaction, the organization's conformance to customer requirements, characteristics and trends of processes and products, and supplier performance.

## **8. Less Prescriptive and More Flexible Documentation**

Documented procedures are now required in only six areas:

- Control of documents (4.2.3)
- Control of quality records (4.2.4)
- Internal audits (8.2.2)
- Control of nonconforming product (8.3)
- Corrective action (8.5.2)
- Preventive action (8.5.3)

Organizations must be careful here, however. It could be a serious error to assume that the only documentation requirements are a quality manual and these six procedures. While these six are required, the organization must determine the family of documents needed to ensure effective planning, operating, and control of processes.

Ultimately, the need for procedures, or, additionally, work instructions, must be based on the organization's size, the type of activities that the organization performs, the complexity of these processes and their interactions with other processes, and the competency of personnel. Small organizations may be able to develop quality systems where the required six procedures are included in the quality manual and few others are needed for effective operation of the business. This is probably not workable for larger, more complex organizations.

## **9. New Definitions**

In addition to the major changes, consider these new definitions:

1. The 1994 standard defined product as, "The result of activities or processes." In the 2000 standard, product is the "result of a system of activities that use resources to transform inputs to outputs (i.e., result of a "process")".
2. In the 1994 standard, quality was defined as the "totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs". In the 2000 standard, quality is the, "ability of a set of inherent characteristics of a product, system, or process to fulfill requirements of customers and other interested parties".
3. Note also that the 1994 terms supplier, sub-supplier, and customer have been replaced with organization, supplier, customer, respectively in the 2000 standard.

## **10. Permissible Exclusions**

Exclusions were handled somewhat differently under the 1994 version of the standard than they are in the 2000 standard. For example, if your organization did not design products or services, it sought registration under ISO 9002. Or, if the organization did not service products (Clause 4.19 of the 1994 standard), it simply stated this in the quality manual.

Likewise for other clauses of the 1994 standard that may not have applied. In the 2000 version of the standard, exclusions are only allowed for Section 7 (Product Realization) requirements, and only if it can be demonstrated those requirements do not apply. Some typical exclusions might relate to:

- Design and/or development;
- Customer property, (that is, the organization never handles customer property);
- Identification and traceability of product; or
- Control of monitoring and measuring devices.

Whatever the exclusion, it must be fully explained and justified in the quality manual. The many organizations that actually did design, but chose to register to 9002, will not be allowed to exclude design under the 2000 revision.

## **Greatest Challenges to Implementation**

Finally, what are the greatest challenges that organizations will face as they attempt to develop and implement an ISO 9001:2000 quality management system? Consider these:

1. Getting top management involvement - The 1994 version of ISO 9000 required management involvement in several areas, most notably with respect to management review. In 2000, top management must be involved during the development, as well as the implementation and maintenance of the quality management system. This is clearly reflected by the numerous requirements in element 5 that start with "Top management shall ensure that...." The management responsibility element also includes ensuring that customer requirements are determined and met in (5.2).

2. Incorporating a process approach - Understanding and documenting its processes is one of the most significant undertakings that will confront organizations seeking ISO 9001:2000 registration. Manufacturers may find this relatively painless, since the manufacturing process, by its nature, is rather straightforward. The challenge will likely confront those in the service sector that perform a variety of diverse activities for their clients. Keep in mind that the process approach applies to every activity that affects quality. Process owners should be able to talk in terms of process inputs, process outputs, process control, and what is done when the process is not under control.

3. Customer satisfaction - Clause 8.2.1 states "...the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements." The standard does not specify how to collect the information. However, the information is to be communicated throughout the organization (5.5.2c), is to be part of the input to management review (5.6.2b) and is to be analyzed (8.4a).

4. Establishing measurable objectives - Clause 5.4.1 of the standard states, "Top management shall ensure that quality objectives...are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy [emphasis added]." Objectives must be quantifiable, as opposed to the "feel good" language appearing in many goal, mission, or policy statements. Then, once quantified, these objectives must be regularly tracked and the data used as input to management review. Achieving quality objectives is one of the primary means of demonstrating improvement.

5. Continual improvement - there is an explicit requirement (8.5.1) to improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

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