Quality Management System Standards

ISO 9000 standards are good business practices that will improve communications, efficiency, and profits while reducing errors, scrap, and rework.

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Two studies have revealed that overall awareness of the ISO 9000 International Quality Management System Standards among U.S. businesses is still below 50 percent [1] [2]. This article is intended to increase general awareness for helping owners, shareholders, executives, and project managers address inevitable decisions regarding the standards. In particular, project managers are faced with the daily responsibility for ensuring provisions exist for implementing requirements described in the standards applicable to project-specific products and/or services.

Currently, it is true that ISO quality standards apply to fairly well defined business sectors and applications. However, over time these standards will prove their inherent quality improvement benefits for any application. Also, as more owners, executives, and project managers recognize that baseline requirements in the standards are merely good business practices that will improve communications, efficiency, and profits while reducing errors, scrap, and rework, the standards will automatically become prerequisites for managing projects and operating companies. Project managers will benefit by more accurately measuring project quality performance.

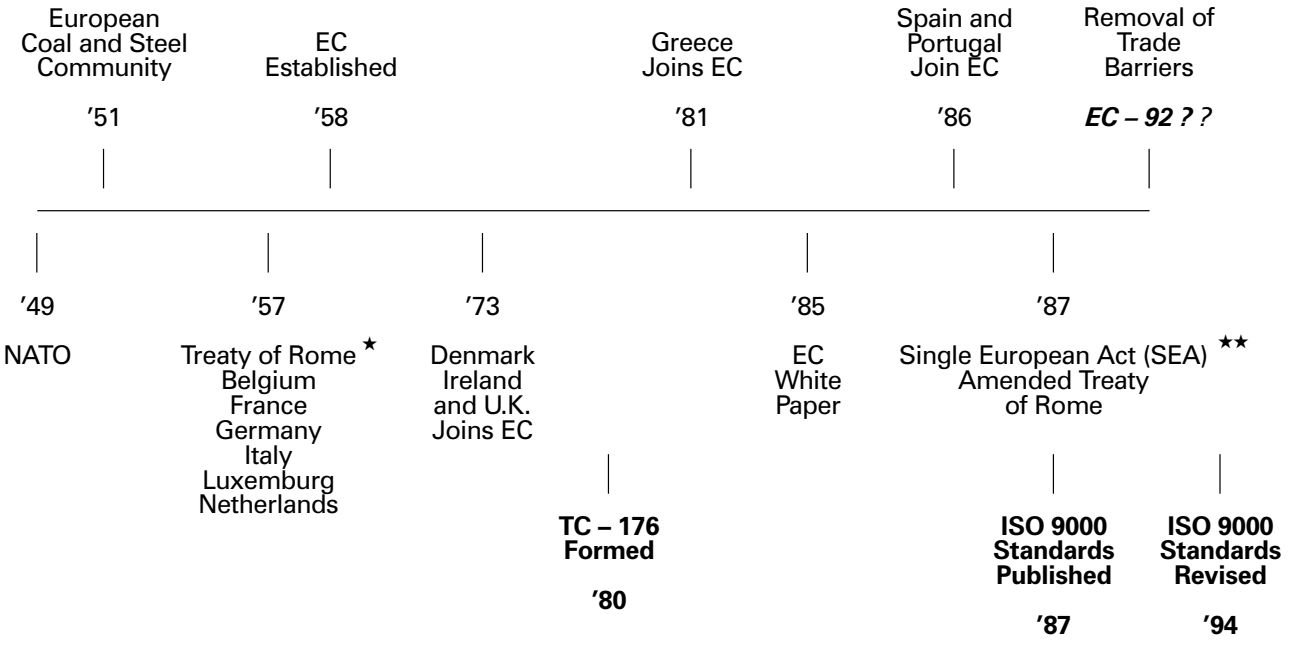
International Quality Movement

The concept of quality management has rapidly evolved and matured during the past decade. Quality, as it applies to the operations of a business, has moved forward from the classical "Inspection Function" (error detection) to the more modern "Quality Management Systems" approach (error prevention). This evolution is attributable to numerous factors, some that are obvious and inherent in our business culture, such as accelerated schedules and delivery requirements, increased labor costs, increased customer expectations, and international competition. Another factor that is significant in this evolution is the "Human Factor." Basically, people have pride in their work and in general do not like to have it "inspected," especially with the potential fear of being wrong.

The most significant factor with the entire quality management issue is: Who is responsible for product or service quality throughout the processes of performing the work internal and external to each organization? It is this very factor that is the root cause for some continued confusion over ownership of quality with many companies in U.S. business sectors. The most fundamental step in starting any quality management effort is to formally address this issue so there is no doubt about the various quality-related roles within the company. The primary tool of the Quality Professional for assisting the company with quality efforts is the quality management plan (discussed later).

The three primary quality management issues that most companies are currently addressing for their own specific reasons are Total Quality Management (TQM), Malcolm Baldrige National Quality Award, and ISO 9000 Quality System Standards. Each of these has its own set of objectives, conditions and criteria. A simple review and comparison of the following TQM principles, Baldrige values/concepts, and ISO system elements reveals common quality-related data as it applies to overall company performance.

Figure 1. Timeline Toward ISO 9000 Standards [6]



★ Treaty of Rome: Goal to create integrated community-wide market free of restrictions on movement of goods, services, people, and capital.

★★ SEA: Goal of completing the Single Internal Market by 1992 and restructuring decison-making procedures.

TQM/Baldrige/ISO

Total Quality Management. During the early and mid '80s many events took place that helped shape what is now generally accepted as TQM principles. Some of the events included The Department of Defense Master Plan on TQM, the Commerce Department's concerns with foreign competition, numerous new books on workplace changes including Japan's work processes, and the influences of U.S. quality gurus W. Edwards Deming, Joseph M. Juran, Phil Crosby, and Armand V. Feigenbaum. The principles of TQM include determine customers' requirements; perform to customers' requirement; implement defect prevention systems; performance measurement by cost of quality; zero defects as company performance standard; everyone accountable for meeting requirements (total employee involvement).

Malcolm Baldrige National Quality Award. This award was created by Public Law 100-107 and signed into law on August 20, 1987 [4]. The Award Program, responsive to the purposes of Public Law 100-107, led to the creation of a new public-private partnership. Principal support for the program comes from The Foundation for the Malcolm Baldrige National Quality Award, established in 1988. The award is named for Malcolm Baldrige, who served as Secretary of Commerce from 1981 until his tragic death in 1987. The award criteria framework addresses seven core values and concepts: leadership; information and analysis; strategic quality planning; human resource development and management; management of process quality; quality and operational results; customer focus and satisfaction.

ISO 9000 Quality Systems Standards. The five generic quality management standards were developed by the International Organization for Standardization (Technical Committee TC-176) based in Geneva, Switzerland [3]. The committee was commissioned in 1980 and the standards were published in 1987. The standards (includes three for contractual definition) provide a basis for implementing and improving quality management and quality assurance within any product or service company. Ultimately the standards provide the basis for a company to achieve quality system registration. Achieving registration does not guarantee defect-free products and services; however, it does demonstrate that a company has a system in place for affecting and improving quality—a distinct competitive advantage. System development/registration takes 9 to 24 months, depending on the company scope of operations. The 1994 revised standards include guidelines and contractual models:

Guidelines

ISO 9000-01 Guidelines on Selection and Use
ISO 9004-01 Guidelines on Management/System Elements

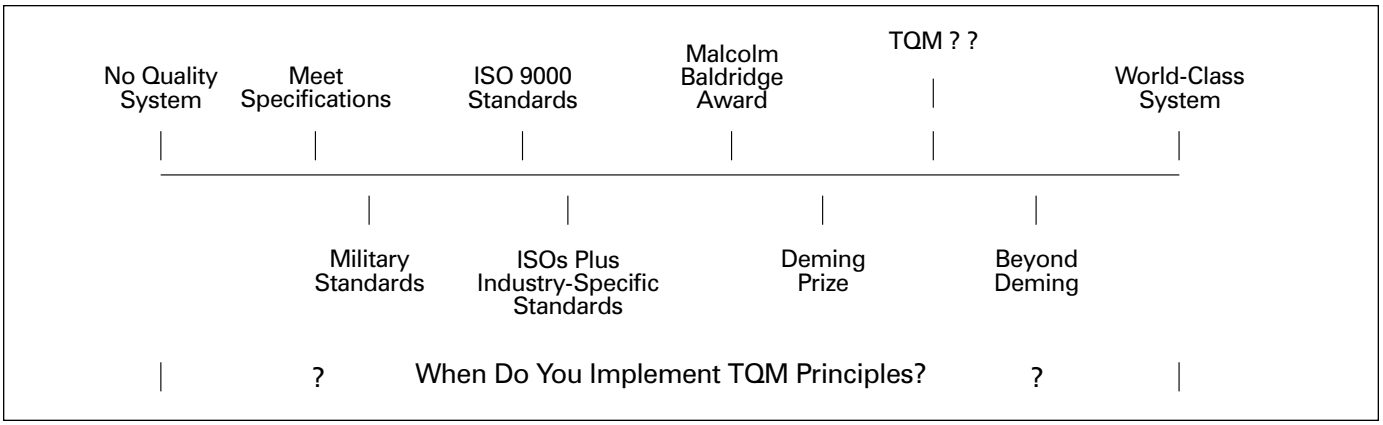
Contractual Models

ISO 9001 20 Quality Management Elements (full scope)
ISO 9002 19 Quality Management Elements
ISO 9003 16 Quality Management Elements

For example, ISO 9001, Quality Management System Elements (20 full scope), includes:

4.1 Management Responsibility
4.2 Quality System
4.3 Contract Review

Figure 2. Timeline Toward Quality System Excellence



4.4 Design Control
4.5 Document and Data Control
4.6 Purchasing
4.7 Control of Customer-Supplied Product
4.8 Product Identification/Traceability
4.9 Process Control
4.10 Inspection and Testing
4.11 Inspection, Measuring, and Test Equipment
4.12 Inspection and Test Status
4.13 Control of nonconforming Product
4.14 Corrective and Preventive Action
4.15 Handling, Storage, Packaging, Presentation and Delivery
4.16 Control of Quality Records
4.17 Internal Quality Audits
4.18 Training
4.10 Servicing
4.20 Statistical Techniques

EC-92 Timeline Toward ISO 9000 Standards

December 31, 1992 (EC-92), was the date when many economic barriers between the 12 European Community (EC) nations were to be dismantled after decades of reform in Europe. The results were to create a "single internal market" and new opportunities for companies within a market population of 338 million. The impetus for harmonization of standards is detailed in the EC "new approach directives" that target issues such as product safety, worker safety, health, environmental performance, and product liability.

Hundreds of new product standards are being developed in Europe as a result of the directives. This effort will require numerous products to be identified with applicable CE Product Marks prior to entry into the European market (CE—Communaute Europeene—is a six-character label, the 3rd through 5th characters specify under which accrediting body certification was provided) [9]. ISO 9000 quality system implementation and registration in many cases will be the method used to verify, through documentary evidence, that products conform to specified requirements.

The standards have been adopted by numerous countries around the globe and overwhelmingly adopted and implemented in the EC. U.S. representatives from the Department of Commerce and Office of European Community Affairs are concerned that American companies have not positioned themselves soon enough for achieving registration (approximately 10 percent of the U.S. export market goes to Europe). However, some U.S. companies that may not require registration have recognized this trend and are positioning themselves for achieving "system compliance" in order to remain competitive with companies that do achieve registration.

Timeline Towards Quality System Excellence

What is interesting about the international quality movement in the United States is that the "system framework" delineated in the ISO 9000 standards provides the groundwork for building on TQM principles and Baldrige values/concepts. Yet the ISOs have followed TQM/Baldrige from a timing standpoint (see historical key dates, below). Also, ISO has not received the visibility in the U.S. that TQM/Baldrige have, primarily because the perception is that ISO 9000 is only a requirement to perform work in Europe. Some companies have spent thousands of dollars trying to achieve Baldrige status and then usually figure out that they do not even have the basic quality management system that ISO addresses. Finally, the ironic part is that ISO will help provide the system framework for describing the quality data required for TQM and Baldrige, even though ISO may not be a company requirement (see timeline towards quality system excellence) [5].

It is important, for perspective, to have the following key dates in mind in the development of quality concepts:

Late 1800s	Craftsman/operator quality control
1900–15	Foreman quality control
1916–35	Inspection quality control
1936–55	Statistical quality control
1955–83	Quality assurance systems
1980	ISO 9000 Technical Committee TC-176 (formed)
1983	Total Quality Management principles/practices
1987	Malcolm Baldrige National Quality Award
1987	ISO 9000 Quality Management System Standards
1990	Empowerment/ self-directed work teams

Expectations

Based on the various principles, concepts, and criteria previously presented, it is no wonder that many U.S. company owners, executives, and project managers are frustrated with setting direction and making commitments on one or more of the primary quality management issues. Adding to the frustration are the timing of these issues, the subjective cost and return on investment factors, the potential impact on work in-progress, and the fact that companies in the various business sectors are at different phases of involvement or commitment. Some companies will recognize the long-term benefits and implement systems on their own, whereas others will be required to do so based on customer requirements.

Quality Management Project Plan

As cited previously in this article, each of the primary quality management issues has specific concepts, principles, and criteria that could be uniquely applied to each company's work practices, processes, and culture. For a company to commit to moving forward with just one issue, time and resources are required to effectively plan the project in order to successfully achieve implementation. Historically, each issue takes a different amount of time for achieving meaningful results through full implementation. Typical variables include client requirements, company size, product/service sectors, cultural issues/considerations, work in-progress, regulatory issues, employee attitudes.

The initial focal point for any quality management effort within a company should be the development of a formal quality management plan. In order to prepare and execute an effective plan, top management must identify and fully support individuals that will assist in developing and implementing the plan. The plan should be as comprehensive as needed to address the full scope of quality management efforts, including milestones, as determined by management. Modern Project Management (MPM) methods should be used for controlling, measuring, and achieving the milestones—hence management should adopt the approach *"To Plan and Execute a Quality Management Project Plan That Evolves Into a Dynamic Quality System."*

The content of the plan will include information and items that will help guide the organization into the future for ultimately developing, implementing and maintaining a quality management system that truly complements and enhances overall operations. The plan is typically a dynamic document that changes if and when essential elements in the direction of quality management efforts change within the company. In effect, the quality management project plan must become an integral part of the overall company strategic business plan.

Typical quality management project plan contents include project summary; team members/responsibilities; current quality system vs. ISO; scope of registration; resources (financial/human); project schedule/milestones; progress reporting.

Cost Factors

Initially, many individuals perceive ISO 9000 as new requirements that represent major changes in the way they run their business (perceived as inherent additional costs). For most companies that perform well, implementing an ISO 9000 quality system is merely an exercise in fully documenting company policies, procedures, and work instructions throughout the various levels of the organization (or upgrading an existing system) and then routinely working in compliance with these documents. *"Companies that perform well typically have 90 percent of the core information required for implementing an effective ISO 9000 quality system."*

A number of cost factors are associated with ultimately implementing and maintaining an effective ISO 9000 Quality System. The most apparent question from a business perspective relative to cost is: When will the company reach a break-even point and begin to realize a return on investment? Considering the current economic conditions for some companies, this factor is not to be taken lightly. The cumulative cost (and the cumulative profit) for implementing and maintaining an effective quality system will vary for each company. There are a number of common cost factors that should be considered on any ISO 9000 effort: common cost factors; project planning/management; human resources and training; materials and equipment; registrar fees; product certification (if required); impact on work in-progress; supplier/subcontractor involvement; system maintenance.

It is suggested that management view and manage the costs associated with an ISO 9000 effort as two types: project and operations. Project (startup) costs include scope/field of application; development; implementation; registration (or compliance). Operations (maintenance) costs include registration maintenance; procedure/instruction revisions; inspections/audits/training; tests/special data requirements.

Current project management software programs used by many companies provide an excellent method for monitoring the costs and reporting progress associated with the project phase. For small companies a simple cost code method can be used for monitoring project costs. Also, software programs on the market today provide an excellent baseline for starting the operations-related "cost of quality" measurement process.

Cost of Quality

Many books and articles have been published on the "cost of quality," especially during the past 15 years. In the 1979 book by Philip B. Crosby, *Quality is Free*, cost of quality was addressed and defined in three categories: prevention, appraisal, and failure costs [7]. In his 1984 book, *Quality Without Tears,* Crosby defined Cost of Quality in two areas: "price of nonconformance"—all the expenses involved in doing things wrong, and "price of conformance"—what is necessary to spend to make things come out right [8]. In the latter, he is quoted as saying "The cost of quality has not been used as a management tool because it hasn't been presented to management in terms it can understand."

Measuring the cost of quality is not yet a mandatory requirement in the ISO standards; however, it is a recommendation found in the ISO 9004-1 Guidelines, paragraphs 4.3 and 6.0. The

standard takes the position that "the calculation and evaluation of costs associated with all quality elements and objectives should always be an important consideration, with the objective of minimizing quality losses." ISO 9004 definitions on cost of quality are in effect the same as those in Crosby's book *Quality is Free*.

Benefits

There is a general consensus from numerous companies that have achieved registration (or just system compliance) and within the ISO 9000 community at large that the benefits far exceed the initial costs of implementing an ISO system. The most recognized benefits include increased profits; assurance of contract compliance; increased market share; reductions in-errors/scrap/rework; improved communications/ productivity; teamwork/ employee involvement; identification of training needs; recognition and quality system registration.

Results

With any one of the efforts, as a minimum, a company will be on a continued learning curve and discover inherent self-improvements as long as everyone supports and feeds the effort. The lines of communication typically open and the work flow processes improve. There is also a potential "fear factor" associated with these quality management issues that include feelings of "What is buried in the wood pile?" and "Do I really know what my daily responsibilities are?" Due to the wide array of human, administrative, and technical factors involved in any quality management effort, some companies will achieve success while others experience failure.

Meeting TQM, Baldrige, and ISO results (separately or collectively) are predicated on typical factors such as:

- Top management commitment and involvement – these efforts typically represent some change
- Employee commitment and involvement
- Definition and delegation of authority and responsibilities with open communications
- Formal quality management plan – development, approval, revision and effective execution (vision, mission, goals, objectives, phases, activities, direction shared with all employees)
- Resources – financial, human (internal/external), training, equipment, materials
- High level of accuracy/availability of company data for meeting scheduled milestones
- Patience – set reasonable goals (company culture/people issues are heavily involved).

A Word About Commitment

Full commitment from every single company member is the only real factor that will guarantee the initial and ongoing success of any quality management system effort. Good luck on your ISO 9000 quality management system efforts!

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