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Author(s): E. L. Buescher

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Abstract: As the barriers of free trade are removed and the hope of a World Market becomes a reality, the key to economic success will be higher-quality products and services. This is demonstrated by the growing acceptance of international quality standards, such as the ISO 9000 series standard, for which the main purpose is the assurance of consistency of product quality and reliability.

Underlying the increasing level of ISO 9000 registration activity is the fact that the ISO 9000 standards describe a technically sound quality system for use by manufacturing and service organizations. They find that meeting all requirements of the standard results in significant internal benefits and that the rewards are well worth the cost and effort.

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Edward L. Buescher

Abstract

As the barriers of free trade are removed and the hope of a World Market becomes a reality, the key to economic success will be higher-quality products and services. This emphasis on increased quality is demonstrated by the growing acceptance of international quality standards, such as the ISO 9000 series standard. ISO 9000 is a series of Quality Management System Standards that have been adopted by the European Community (EC) to assure consistency of product quality and reliability.

Underlying the increasing level of ISO 9000 registration activity is the fact that the ISO 9000 standards describe a technically sound quality system for use by manufacturing and service organizations. The standards are proving to be a valuable foundation for expanded quality practice to which other principles of quality management are applied. Many companies initially make use of the standards because of external demands - customer requirements, regulatory compliance or market competition. They soon find that meeting all requirements of the standard results in significant internal benefits and that the rewards are well worth the cost and effort necessary to become registered.

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I. Introduction - What is ISO 9000 ?

ISO is an acronym that represents the International Standards Organization. ISO is a private standards organization which was founded in 1946 to promote the development of international standards and related activities to facilitate the exchange of goods and services worldwide. The Geneva, Switzerland-based organization is composed of national committees from over 91 member countries, with the American National Standards Institute (ANSI) serving as the National Committee for the United States. The only area which the ISO standards fail to cover are the areas related to electric and electronic engineering, which are covered by the International Electrotechnical Commission (IEC).[1]

All standards developed by the ISO are voluntary; no legal requirements force countries to adopt them. However, countries and industries often adopt and attach legal requirements to ISO standards, thereby making the standards mandatory.

This paper will address what ISO 9000 is, how the standards evolved, case studies of companies who received ISO certification illustrating how they implemented the standards, the benefits of ISO 9000 certification, a comparison of ISO 9000 to other quality systems, and finally some shortcomings of the standards.

A. Background and Development of ISO 9000

In 1987, the International Organization for Standardization (ISO) published the ISO 9000 Series International Standards. The ISO 9000 series comprises generic standards that provide quality management guidance as well as quality assurance requirements and guidance. The standards apply to all types of companies; they can be adapted to fit both small and large corporations in all sectors of the economy, including those that are predominantly service sector suppliers.

While ISO publishes thousands of standards, the five documents in the ISO 9000 series (ISO 9000 - 9004) are beginning to have a growing impact on international trade. One driving force is the development of regional economic groups of nations, particularly the European Community via its "EC 1992" thrust.

The European Community has adopted the ISO 9000 series as part of its efforts to establish systems for product certification and quality systems registration. Registration involves the audit and approval of a quality management system against ISO 9001, ISO 9002, or ISO 9003 by an independent registrar.

The standard has also been adopted in the United States as the ANSI/ASQC Q90 series. Today, 55 countries have adopted the ISO 9000 series as a national standard, and thousands of companies worldwide have become registered to ISO 9001, ISO 9002, or ISO 9003. As of August 1992, there were more than 400

registered sites or facilities in the United States, representing nearly 300 companies.[2]

Perhaps the single most visible factor driving the acceptance of the ISO 9000 series is the effort to unify the twelve major European nations that comprise the European Community into a single internal market. These twelve full members are: Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain and the United Kingdom.

EC 92, as it is known, nominally became effective at midnight on December 31, 1992. The impact on trade within Europe and on trade with other countries has already been felt worldwide. In preparation for EC 92, the European Community has been developing a comprehensive framework for product certification, product standards and product testing.[3]

Quality systems registration to ISO 9001, ISO 9002, ISO 9003 plays an important role in this framework. The EC has adopted the ISO 9000 series verbatim; its version is the EN 29000 series. To understand fully the role of the ISO 9000 standards, it is important to briefly introduce EC 92.

B. The History of the European Community (EC)

The European Community (EC) originated with the 1957 Treaty of Rome, which was established to abolish tariffs and quotas among its six member states and to stimulate economic growth in Europe. At this time, the EC consisted of France, West Germany, Italy, Luxembourg, the Netherlands and Belgium.

Economic growth slowed during the 1970's and early 1980's, and Europe began to fear that the US, Japanese and Pacific Rim economies would dominate the world economy of the 21st century. The European nations, with their differing technical standards and requirements, were concerned that they would fall behind. In response, the EC, now consisting of twelve countries, called for a greater push toward a unified market and for the removal of trade barriers.

The 1987 Single European Act reinforced economic unification among the EC nations. Its goal is to establish an internal market by December 31, 1992, in which there is free movement of goods, persons, services and capital.[4]

At the same time, the EC developed a new approach to regulating products. It enlisted the aid of key European regional standards organizations to develop EC-wide, "harmonized" standards. The purpose of these standards was to eliminate the jumble of standards of the individual twelve member states. The EC has drafted nearly 300 regulations to implement the Single European Act.[5]

C. The Impact of ISO 9000 on the United States

The impact of the EC's unification and support of ISO 9000 is substantial for the US companies trading with Europe. The EC is gradually encouraging governmental standards agencies to establish new standards for every area of economic activity. This effort may create the most comprehensive product and quality standards in the world.

In October 1991, the seven member states of the European Free Trade Association (EFTA) signed a draft European Economic Area (EEA) treaty with the European Community to join the single market beginning January 1, 1993. The members of EFTA are Austria, Finland, Iceland, Liechtenstein, Norway, Sweden, and Switzerland. Sweden and Austria have already applied for EC membership. In addition, Poland, Hungary, and the Czech and Slovak Federal Republic are interested in joining the European Economic Area (EEA). The result would be a unified market of 375 million people in a $5 trillion annual economy.[6]

The United States is the EC's largest foreign supplier. 1991 figures show the US exported about $103 billion in goods to the EC member countries. The US maintains the largest percentage of EC imports at more than 16.5 percent, and has been growing steadily. The US is interested in keeping and advancing its economic presence in the EC marketplace. US manufacturers can foresee millions of new customers for products and services. The challenge is to meet both product and quality system standards necessary for unrestricted trade within this market.[7]

II. Overview of the ISO 9000 Series Standards

The ISO 9000 series standard includes generic standards that provide quality management guidance and identify generic quality system elements necessary to achieve quality assurance. An individual company decides how these standards are to be implemented to meet its specific needs and the needs of its customers.

A company that has achieved ISO 9000 registration can prove that they have a documented quality system that is in use and that it is consistently followed. This does not mean that the ISO 9000 registered company produces products or services of higher quality than their unregistered competitors.

The ISO 9001, 9002, and 9003 standards merely require a company to document what it does and do what it documents. Jerry Mills, the Quality Assurance Manager for the ESCO Corporation, states,"ISO 9000 requires us to say what we do ... then do what we say". ESCO, a Portland, Oregon steel foundry, recently received a conditional registration to ISO 9002.

ISO 9000 is a series of five international standards (ISO 9000, 9001, 9002, 9003, and 9004), developed and published by the ISO Technical Committee (TC) 176 on quality systems. This series provides guidance on the selection of an appropriate quality management program for a supplier's operations. In the following section, a summary for each of the five standards will be presented.[8]

ISO 9000 - "Quality Management and Quality Assurance Standards - Guidelines for Selection and Use," explains fundamental quality concepts, defines key terms, and provides guidance on selecting, using and, if necessary, tailoring ISO 9001, 9002 and 9003 to specific operations.

ISO 9001 - "Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing," is the most comprehensive standard in the series. ISO 9001 covers all of the elements listed in ISO 9002 and 9003. In addition, it addresses design, development and servicing capabilities.

ISO 9002 - "Quality Systems - Model for Quality Assurance in Production and Installation," addresses the prevention, detection, and correction of problems during production and installation.

ISO 9003 - "Quality Systems - Model for Quality Standard," addresses requirements for the detection and control of problems during final inspection and testing.

ISO 9004 - "Quality Management and Quality System Elements - Guidelines," provides guidance for suppliers in developing and implementing a quality system and in determining the extent to which each quality system element is applicable. ISO 9004 examines each of the quality system elements in greater detail and can be used for internal and external auditing purposes.

Because ISO 9001 contains all of the elements listed in ISO 9002 and 9003, it is the heart of the standard and most of the elements will be discussed in greater detail. 20 elements make up the Quality System requirements in ISO 9001. They are listed below with a brief explanation.

A. The Quality System Requirements of ISO 9001:[1]

1. Quality Policy	Management shall define and document its policy and objectives for, and commitment to, quality. The supplier shall ensure that this policy is understood, implemented and maintained at all levels in the organization.
2. Quality System	The supplier shall establish and maintain a documented quality system as a means of ensuring that product conforms to specified requirements.
3. Contract Review	The supplier shall establish and maintain procedures for contract review and for the coordination of these activities.
4. Design Control	The supplier shall establish and maintain procedures to control and verify the design of the product in order to ensure that the specified requirements are met.
5. Document Control	The supplier shall establish and maintain procedures to control all documents and data that relate to the requirements of this International Standard. Changes to the documents shall be reviewed and approved.
6. Purchasing	The supplier shall ensure that purchased product conforms to specified requirements.
7. Purchaser Supplied Product	The supplier shall establish and maintain procedures for verification, storage and maintenance of purchaser supplied product provided for incorporation into the supplies.
8. Product Identification and Traceability	Where appropriate, the supplier shall establish and maintain procedures for identifying the product from applicable drawings, specifications or other documents, during all stages of production.
9. Process Control	The supplier shall identify and plan the production, and where applicable, installation processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions.
10. Inspection and Testing	The supplier shall ensure that incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements.
11. Inspection, Measuring and Test Equipment	The supplier shall control, calibrate and maintain inspection, measuring and test equipment to demonstrate the conformance of a product to the specified requirements.

12. Inspection and Test Status	The inspection and test status of product shall be identified by using markings, authorized stamps, tags, labels, routing cards, inspection records, test software, physical location or other suitable means, which indicate the conformance or nonconformance of a product with regard to inspection and tests performed.
13. Control of a Nonconforming Product	The supplier shall establish and maintain procedures to ensure that product that does not conform to specified requirements is prevented form inadvertent use or installation. Control shall provide for identification, documentation, evaluation, segregation, disposition of nonconforming product and for notification to the functions concerned. Nonconforming product may be reworked, accepted without repair by concession, regraded for alternative applications, or rejected and scrapped.
14. Corrective Action	The supplier shall establish, document and maintain procedures for implementing corrective action to prevent recurrence.
15. Handling, Storage, Packaging & Delivery	The supplier shall establish, document and maintain procedures for handling, storage, packaging and delivery of product.
16. Quality Records	The supplier shall establish and maintain procedures for identification, collection, indexing, filing, storage, maintenance and disposition of quality records.
17. Internal Quality Audits	The supplier shall carry out a comprehensive system of planned and documented internal quality audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.
18. Training	The supplier shall establish and maintain procedures for identifying the training needs and provide for the training of all personnel performing activities affecting quality. Appropriate records of training shall be maintained.
19. Servicing	Where servicing is specified in the contract, the supplier shall establish and maintain procedures for performing and verifying that servicing meets the specified requirements.
20.Statistical Techniques	Where appropriate, the supplier shall establish procedures for identifying adequate statistical techniques required for verifying the acceptability of process capability and product characteristics.

III. ISO 9000 CASE STUDIES

Listed below are the outlines and key points that several companies found useful in attaining their ISO 9000 registration.

A. Du Pont - Suzan Jackson, services engineer and ISO 9000 consultant and coordinator for Du Pont's Quality Management and Technology Center, states that there are nine milestones on the way to registration. She calls them a "Roadmap for ISO 9000 Registration". This roadmap uses a stairstep approach which is listed below:[10]

1. Management Decision and Commitment
   - Management must define and document the quality policy.
   - Management must make sure that the quality policy is understood, implemented, and maintained at all levels.
   - Management must define the responsibility, authority, and interrelationship of all personnel who manage, perform, and verify work affecting quality.
   - Management must identify verification requirements within the quality system and provide adequate resources to meet those requirements, including

assigning trained personnel.

- Management must appoint a management representative who has the responsibility and authority to make sure that the standards are implemented.

- Management must participate in periodic management reviews of the quality system to ensure that it is still suitable and effective.

In order for management to fulfill its responsibilities which are listed above, it would be beneficial to perform the following:

- Get a good working knowledge of the ISO 9000 standards by taking the training right along with their people.

- Meet regularly with the task team or the area coordinators during the implementation process to review its progress and to provide assistance where needed.

- Support ISO 9000 in communications with the staff and site personnel.

- Communicate upward to their own management on the status of ISO 9000 implementation and any resource needs they have.

- Become involved in ISO 9000 by assisting in internal

auditing.

2. Establish a management representative, steering group, and area coordinators.

   - Establish a management representative.

   - Establish a steering group.

   - Establish area coordinators.

3. Internal audits begin. There are two kinds of audits which are listed below:

   - The Adequacy Audit. This involves comparing existing documentation to the requirements of ISO 9000 to find areas which need improvement.

   - The Compliance Audit. This involves touring the plant and talking to the people to insure that the quality systems are being followed.

4. First Draft of the Quality Manual. Jackson notes ,"A quality manual is not an absolute requirement of ISO 9000." The standards only state that you need to document your quality system. However, some kind of quality manual is a good way to show an overview of your quality system. Also, many

third-party auditors may expect or require a quality manual. Some common mistakes made in writing a quality manual are:

- Many organizations have one person write a quality manual. It is unlikely that one person alone would have adequate knowledge of all the processes performed throughout the entire organization.

- Another common pitfall in writing a quality manual is trying to write a finished manual too early. At an early stage, it is likely that the organization has not met all of the provisions of the particular ISO 9000 standard being implemented. This would make the document a work of fiction. Often upgrades in practices and procedures are required. It is important to provide training to all personnel so they will be able to work effectively under the new guidelines.

5. Procedures in Place and Documented. Once the new procedures are in place and documented effectively, a third-party registrar should be contacted. A registrar should be chosen early in the process because many of them have long waiting lists.

6. Registrar Makes the Initial Visit. You need to have an initial visit with your registrar's representatives to outline the size of your business, to tell them what your business is all about, and to give them an idea of the size of the assessment they will be making. You will need to plan assessments so that they fit into your schedule. Also, you should become

familiar with the registrar's procedures because not all registrars work the same way. You should also take the following steps at this time:

- Revise and approve your quality manual. It should not be authorized until it reflects the way the entire system is actually operating.

- Perform adequacy and compliance audits. This may be the second or third time for these internal audits, depending on how long the implementation has taken you. These audits will still uncover areas needing corrective action.

- Conduct a Management Review. In the management review, a cross-functional management group reviews the state of the quality system and examines whatever quality indicators are appropriate for their business, including such factors as internal audit results, product quality data, customer complaints, and customer satisfaction, to find out whether the quality system is working effectively.

- Submit your quality manual to the registrar.

7. The Pre-Assessment. This step is optional and is a type of dress rehearsal. The pre-assessment could be performed by your chosen registrar, or by a third-party consulting group. If you choose to have your registrar do your pre-assessment, be aware that accredited registrars cannot offer any consulting advise; that would be a conflict of interest which would

compromise their neutrality.

8. The Final Assessment. Before the final assessment actually takes place, reach an agreement with your registrar concerning the schedule and length of the assessment. A typical assessment for a site of 200 to 300 employees would take two auditors three of four days. The auditors do the same thing that you did during your internal audits. They tour the worksite and look at the quality systems being used. They are verifying that the system in place is the same one that the quality manual outlines and that it meets the ISO 9000 requirements. It is common to have a few deficiencies even if a pre-assessment has been performed.

After the quality systems have been inspected, a closing meeting occurs at the site that is seeking registration. It is in this meeting that you will be told if you have passed.

9. Registration. Some registrars make a distinction between major and minor discrepancies, or nonconformances. A major discrepancy would be that the registrar has discovered that part of the quality system required by ISO 9000 is missing, or part of a system is not working. Or that the people in the shop aren't following the documented work procedures. A major discrepancy would cause you to fail the audit.

However, an auditor might discover several minor nonconformances and you could still receive registration. A list of these discrepancies will be

provided by the auditor. All of the minor discrepancies would need to be corrected in a given amount time before the certificate is awarded. Most auditors will not return to inspect the problem areas, instead they will require you to mail them proof that you have resolved the problems. If the registrar is satisfied with your improvement efforts, a certificate will be mailed to you.[11]

Maintaining ISO 9000

After spending one year or more to become registered, it is often tempting to relax after attaining an ISO 9000 Certificate. However, you must now maintain your quality system and strive to further improve your quality. The system is maintained through some of the requirements of the standard, which include internal quality audits, corrective action procedures, and management reviews.

B. Dow Corning - Les Schnoll, ISO Program and Quality Auditing Manager at Dow Corning Corporation, is reminded of a remark once made by quality expert W. Edwards Deming. With tongue in cheek, Dr. Deming suggested that companies do not have to improve their quality because, after all, survival is not compulsory.[11]

Schnoll feels that it will become a requirement for companies to become ISO 9000 registered if they want to survive in future market. His main reason to support this claim is that the European Community demands ISO 9000 compliance.

However, it isn't just Europe that is insisting on ISO 9000 registration, over half of the 90 member bodies belonging to the International Organization for Standardization (ISO) have accepted or ratified these standards.[13]

One of the newcomers to the ISO 9000 scene is Japan. Japan is rewriting its national standards to reflect the ISO 9000 standards. There is now a growing concern that there may be more trade barriers into Japan than there will be into Western Europe. Because of these important issues, Dow Corning's objective is to register all of their sites worldwide. They already have over one third of their U.S. sites registered to at least one of the ISO 9000 standards.[14]

Schnoll's branch of Dow Corning deals with the manufacture of medical devices and pharmaceutical which are already monitored by the Food and Drug Administration (FDA). It is interesting to note that by 1997, the FDA will have modified its guidelines to incorporate the ISO 9001 standard. In doing so, Schnoll is hopeful that Dow Corning will be able to satisfy both an ISO 9000 audit and an FDA audit at the same time.[15]

Schnoll mentioned that in order to meet all of the regulations that apply with the new standards almost every employee in the corporation went through training, Quality Improvement Teams and a Corporate Quality Committee was formed of the top 14 executives in the corporation. Again this emphasizes the importance of having management's commitment in implementing ISO 9000 standards. This started an era of Strategic Quality Management.[16]

With this new era, the philosophy of continuous quality improvement was adopted. This philosophy was formed on a three pillar foundation which included the following:[ii]

1. Quality Attitude - Containing such factors as:
   - Management commitment
   - The corporate quality policy
   - The corporate quality objectives

2. Quality System - A system based on ISO 9000 which includes the organization, the controls, and the documentation.

3. Quality Tools - Includes statistical quality control, training, and teamwork.

Dow Corning also tried to avoid six "lacks" that could deter maintaining a quality system. These are:[ii]

- Lack of appropriate organization
- Lack of training
- Lack of discipline
- Lack of resources
- Lack of time
- Lack of top management support

Focusing on these areas for continuous quality improvement helped Dow Corning receive their ISO 9000 certification. Les Schnoll also noted ten major benefits from receiving its ISO 9000 registration.
The ten benefits are listed below:[19]

1. Customers have been more receptive to forming customer /supplier partnership relationships with the company.

2. A "prevention" attitude has been implemented throughout the organization.

3. There is evidence of a documented quality system to show customers.

4. Adequate training gives employees better knowledge of jobs and quality systems.

5. There is a greater focus on the needs of the customers.

6. Ability to compete in the world marketplace has been enhanced.

7. There has been a reduction in the number of costly and time-consuming customer audits.

8. The company is able to provide objective evidence of compliance with a set of nonbiased criteria as assessed by an independent third party.

9. Customers have been able to reduce their number of incoming inspections.

10. Finally, the company has gained enhanced marketability through use of a recognized logo/mark. When registration is attained, you can use the registrar's logo and certificate number on virtually everything except products. This can have a powerful impact in marketing.

IV. Comparison of ISO 9000 to Other Quality Standards

Quality systems are an American invention, dating back to the end of the Second World War, when military production required manufacturing in great quantities. Standards of the ISO 9000 series (known as the Q 90 series in the United States) are the most up-to-date versions of documents that contain requirements for quality systems. These requirements address quality systems, rather than products.

While traditional quality systems remain focused on inspection of the final product, modern quality systems shift the greater part of the attention to the manufacturing processes were the quality, or lack of quality, is actually

built into a product. ISO 9000 is based on the principle that prevention of defects during manufacturing is much more effective and efficient than repairing or rejecting a deficient product after it has been produced.

The ISO 9000 standards are one of several quality system standards that are used by industry. This section of the paper compares the ISO 9000 standards to other well-known quality standards, such as:

- The Malcolm Baldridge National Quality Award
- The Deming Prize
- Auto Industry Quality Standards
- The US Department of Defense's MIL-Q-9858A and MIL-I-45208A Standards

Requirement of the five systems:

ISO 9000 - The ISO 9000 series requirements are clearly defined, but how the requirements are to be met is left largely to the organization. Clear documentation of all work processes affecting quality is required, but that documentation can be written as work instructions, basic training for employees, attached as a rider on a particular manufactured item of service, or even displayed as process flow chart in a work area.

The ISO 9000 series concentrates almost entirely on results criteria, although process criteria may meet some ISO 9000 series requirements, depending upon the lead assessor. Registration to the ISO 9000 series

probably requires the least change in organizational involvement. A traditional, mass-inspection oriented organization could be easily registered.[11]

A. MBNQA - A major goal of the Malcolm Baldridge National Quality Award (MBNQA)
is to increase the competitiveness of the US worldwide. MBNQA guidelines are clearly differentiated and the methods for meeting the guidelines are fairly well-defined. MBNQA guidelines are documentation-dependent. An organization committed to basing its quality initiative upon the MBNQA guidelines must expect a high level of documentation in many areas. MBNQA guidelines are somewhat more results-oriented than ISO 9000 standards, but the organization is required to follow both results and process criteria. MBNQA requires specific organizational involvement and change.[12]
Notes: Appendix A has a table which compares ISO 9000 to MBNQA principles.

B. Deming-Based TQM - Deming-based TQM is much less defined than ISO 9000 or MBNQA. It has no firm requirements other than to meet and/or exceed customer needs through an understanding of the organization and the effects of current management practices, and by use of applied statistics. It expects the senior managers of an organization to consider management style through a scientific examination of Deming's 14 points, and then to prove or disprove those points as they apply to the organization.[13]

Deming expects senior managers to establish a controlled, customer-focused, continuously improving organization. Documentation illustrating processes is necessary. It is the organization's responsibility to document processes to communicate effectively to those who need to know. Deming-based TQM involves the most organizational involvement and change of the previous systems.[14]

Appendix B has a table which compares ISO 9000 to Deming principles.

C. **Auto Industry Quality Standards** - The European Community (EC) motor vehicle legislation dates back to 1970 and has addressed such areas as: noise and exhaust systems, emissions, lamps and indicators, road-worthiness, passenger restraints, field-of-vision, wipers, defrosters, heaters, fuel tanks, impact protection, and tire tread depth. Most of the legislation and its amendments are dated prior to the existence of the ISO 9000 standards.[15]

However, the EC is currently seeking to require auto manufacturers to meet the ISO 9002 equivalent. If approved, it would be mandatory for all new EC produced or imported vehicles in 1996 to have been manufactured in accordance with ISO 9002 guidelines. In preparation for this future legislation, many US suppliers are already seeking registration to ISO 9000 guidelines.[16]

The move to require ISO 9000 registration is not being widely accepted among the Big Three auto makers (General Motors, Ford and Chrysler). The Big Three, along with their suppliers, the American Society for Quality Control and the Automotive Industry Action Group (AIAG) have teamed up to harmonize their

systems for supplier total quality assessment, including the possible integration of ISO 9000 standards.

The Big Three began their effort to develop a total quality system for their suppliers in the mid-1980's. The OEMs sought to accelerate the rate of supplier's quality improvement. Because each OEM had different requirements, each developed a company-specific system for their suppliers. Chrysler's "Supplier Quality Assurance" was announced in 1986. Ford's "Q1 was announced in 1981 and its extension "Total Quality Excellence" in 1987. General Motors' "Targets for Excellence" was announced in 1986. These three supplier quality programs were introduced before the ISO 9000 series were formed, have a broader scope, are specific and prescriptive, and are integrated into the business practices of the OEMs to meet their individual requirements.[7]

While the three systems are similar in nature, they are different in requirements, standards, assessment procedures, rating systems, operating processes, nomenclature and reporting format and methods. Only standardization of these differences will allow the suppliers to more rapidly seek quality improvement and reduce transaction costs. In July 1988, ASQC's Automotive Division Executive Council authorized a Supplier Quality Requirements Task Force. The Task Force quickly received the OEM's involvement and support.[8]

In October 1990, the Task Force released the "Measurements Systems Analysis (MSA) Reference Manual" to over 13,400 suppliers. This manual is now undergoing gradual implementation, as each OEM revises and re-issues its quality assessment procedures. Another achievement of the Task Force was that a common "Initial Sample Inspection Report" has been developed. This report warrants conformance of a supplier's initial product sample to OEM requirements, based on statistical and operating process data satisfying all three supplier assessment systems, and it ensures identical supplier and OEM MSA process.[29]

The ASQC/AIAG Task Force, working with OEMs and suppliers to harmonize OEM quality systems, has achieved some success in standardizing supplier's quality assessment systems. Although, there has been little effort to date to pursue ISO 9000 registration, the standardization of the assessment systems is certainly a step in the right direction.

D. US Department of Defense's MIL-Q-9858A and MIL-I-45208A Standards

The US Department of Defense (DoD) has been developing more interest in ISO 9000 Quality System Standards since it is considering replacing its old specifications (MIL-Q-9858A and MIL-I-45208A). However, some problems need to be resolved before the DoD can begin incorporating ISO 9000 standards into its contracts. ISO 9000 and ISO 9001 standards are called Q90 and Q91 respectively because they are technically identical.[30]

There are two conditions that must be met before standards can be used in DoD contracts. First, the standards must be adopted for use by the DoD. This condition has been met, because the US equivalent of ISO 9000, 9001, 9002, 9003 and 9004 standards, called Q90, Q91, Q92, Q93 and Q94 standards have been listed in the DoD "Index of Specifications and Standards".[32]

Second, DoD buying offices must be directed by the Federal Acquisition Regulation (FAR) and the DoD Federal Acquisition Regulation Supplement (DFARS) to use the adopted standards; this has not been done. Therefore, the ISO 9000 series will not be in general use in DoD contracts until DFARS is revised.[33]

The major reason that the DoD has not adopted the ISO 9000 series standards is that there are still a number of major administrative, implementation and technical differences between the two sets of documents which have not been reconciled to DoD's satisfaction. Q91 and Q92 are equivalent to MIL-Q-9858A, but Q93 does not compare to MIL-I-45208A. Q93 (ISO 9003) is used where conformance to requirements is to be ensured "solely at final inspection and test". MIL-I-45208A is used where technical requirements of a contract require "both in-process and final end-item inspection..." The provisions of MIL-I-45208A greatly exceed those of Q93. The problem is that there is no ISO quality document even close to it.[33]

After all of the existing contracts which use the old military specifications expire, most of the ISO 9000 specifications will probably be adopted. Therefore, it is only a matter of time until ISO becomes approved.

V. Shortcomings of ISO 9000

As mentioned above, the ISO 9000 guidelines are not static and inflexible. Therefore, it is beneficial to analyze the shortcomings of the existing standards to make the necessary improvements in future revisions of the standards.

The ISO 9000 series of standards was intended for application across all industries and for all companies. Due to this diverse character and scope, ISO 9000 cannot satisfy the needs of all companies. ISO 9000 Quality Management System forms an essential foundation for the development of an affective Total Quality Management System. Some of the elements needed for a total quality management system that are not required by ISO guidelines include the cost of quality, customer satisfaction, continuous improvement, product safety and liability.

Another potential problem that should be considered prior to seeking registration is that all organizations that offer ISO 9000 certification are not necessarily registered or accepted by the accreditation bodies. The European bodies have created a well-defined certification process controlled by compliance audits. This traceable process has been developed to ensure the control, consistency and assurance of high certification standards. However, this is not the situation worldwide. Therefore, it is wise to choose your certification company carefully to ensure that they are a recognized certification body with accreditation through one of the existing

accreditation bodies.

Another problem is that the registration process is involved and lengthy, taking up to 18 to 24 months.

The cost of obtaining ISO registration can be high. A company That was registered by the British Standards Institute (BSI) claimed that it spent $8500 for the cost of registration, and an additional $13,500 on consultant charges. In addition, there are annual assessment return visits which typically cost $1500 per year.[34]

The US Automotive producers are reluctant to pursue ISO registration. The Big Three's resistance to adopt ISO 9000 registration had much to do with the strong automotive market in the 1980's. It was difficult to convince them that they could benefit by cooperation with others. There were also other reasons for resistance to change. They are listed below:[35]

- Belief that differences in a quality system provide a company with a competitive advantage.
- Security issues connected to third-party assessments were not acceptable, especially in light of Japan's "time to market" advantage.
- Misidentification of ISO 9000 series as a European standard instead of a global standard.
- Unfamiliarity with descriptive rather than prescriptive approach to quality system requirements.

- Concern about the abilities of suppliers and in-house quality managers to comprehend and apply specific requirements appropriate to individual quality systems based solely on ISO documents.
- ISO 9000's lack of emphasis on planned continuous improvement, TQM, or other statistical methods.

The military has an interesting problem in pursuing ISO registration. The use of quality audits by a third-party could threaten or weaken national security. Therefore, ISO would probably not be used for the acceptance of products from a prime supplier. However, some unsecured contracts from subcontractors could use the ISO quality system.

VI. Conclusion

Despite the high costs and the unsettled issues, the global drive toward quality system registration to the ISO 9000 standards has begun. Many around the world are using registration to the ISO 9000 series standards as a means to differentiate quality companies from the rest in the field.

Companies deciding not to pursue ISO 9000 registration may find themselves falling far behind the competition. John Hinds, the new president of International Organization for Standardization (ISO) and president of AT&T, says that US companies must understand and adopt international standards if they are to compete effectively in the world. According to quality expert Philip Crosby, "It's becoming very clear now that quality is not so much an asset per se as a price of getting into the game. If you don't have it, you can't play. And if you can't produce it, they won't be interested in you."[26]

Bibliography

Peach, Robert W., The ISO 9000 Handbook (Virginia: CEEM Information Services, 1992).

Bureau of Business Practice, ISO 9000: Handbook of Quality Standards and Compliance (New Jersey: Prentice Hall, 1992).

International Organization for Standardization, ISO 9000: International Standards for Quality Management (2nd ed.).(Geneva, Switzerland: ISO 1992).

Hutchens, Spencer, "Facing the ISO-9000 Challenge," Compliance Engineering, Summer, 1992, pp. 21-26.

Sawin, Steve, "Managing Your Suppliers with ISO 9000," Compliance Engineering, Fall, 1992, pp. 24-26.

Maass, Richard A., Brown, John O., & Bossert, James L., Supplier Certification - A Continuous Improvement Strategy. (Milwaukee:American Society for Quality Control, 1987).

Law, Trevor, "Understanding ISO 9000: User Benefits and Drawbacks." Modern Casting December 1992: pp. 30-32.

Farren, J. Micheal, "The New Europe and Global Competitiveness," Business America February 24, 1992: pp. 2.

Notes

1.Hutchens, Spencer, "Facing the ISO-9000 Challenge," Compliance Engineering, Summer, 1992: 21-26.

2.Peach, Robert W., The ISO 9000 Handbook (Virginia: CEEM Information Services, 1992) 2.

3.Peach 2.

4.Peach 5.

5.Farren, J. Micheal, "The New Europe and Global Competitiveness," Business America, February 24, 1992: 2.

6.Burgess, John, "Competing in a Diverse Market," The Washington Post, December 6, 1991: A1.

7.Farren 6.

8.International Organization for Standardization, ISO 9000: International Standards for Quality Management (2nd ed.) (Geneva, Switzerland: ISO, 1992) 59.

9.International Organization for Standardization 59.

10.Bureau of Business Practice, ISO 9000: Handbook of Quality Standards and Compliance (New Jersey: Prentice Hall, 1992) 123-132.

11.Bureau of Business Practice 133.

12.Bureau of Business Practice 175.

13.Bureau of Business Practice 175.

14.Bureau of Business Practice 176.

15.Bureau of Business Practice 177.

16.Bureau of Business Practice 178.

17.Bureau of Business Practice 180.

18.Bureau of Business Practice 180.

19.Bureau of Business Practice 182.

20.Peach 134.

21.Peach 135.

22.Peach 135.

23.Sawin, Steve, "Managing Your Suppliers with ISO 9000," Compliance Engineering Fall, 1992: 24.

24.Sawin 25.

25.Peach 151.

26.Peach 151.

27.Peach 154.

28.Peach 155.

29.Peach 157.

30.Peach 159.

31.Peach 161.

32.Peach 162.

33.Peach 163.

34.Law, Trevor, "Understanding ISO 9000: User Benefits and Drawbacks." Modern Casting December 1992: 31.

35.Peach 153.

36.Maass, Richard A., Brown, John O., & Bossert, James L., Supplier Certification - A Continuous Improvement Strategy (Milwaukee: American Society for Quality Control, 1987) 9.

APPENDIX A.

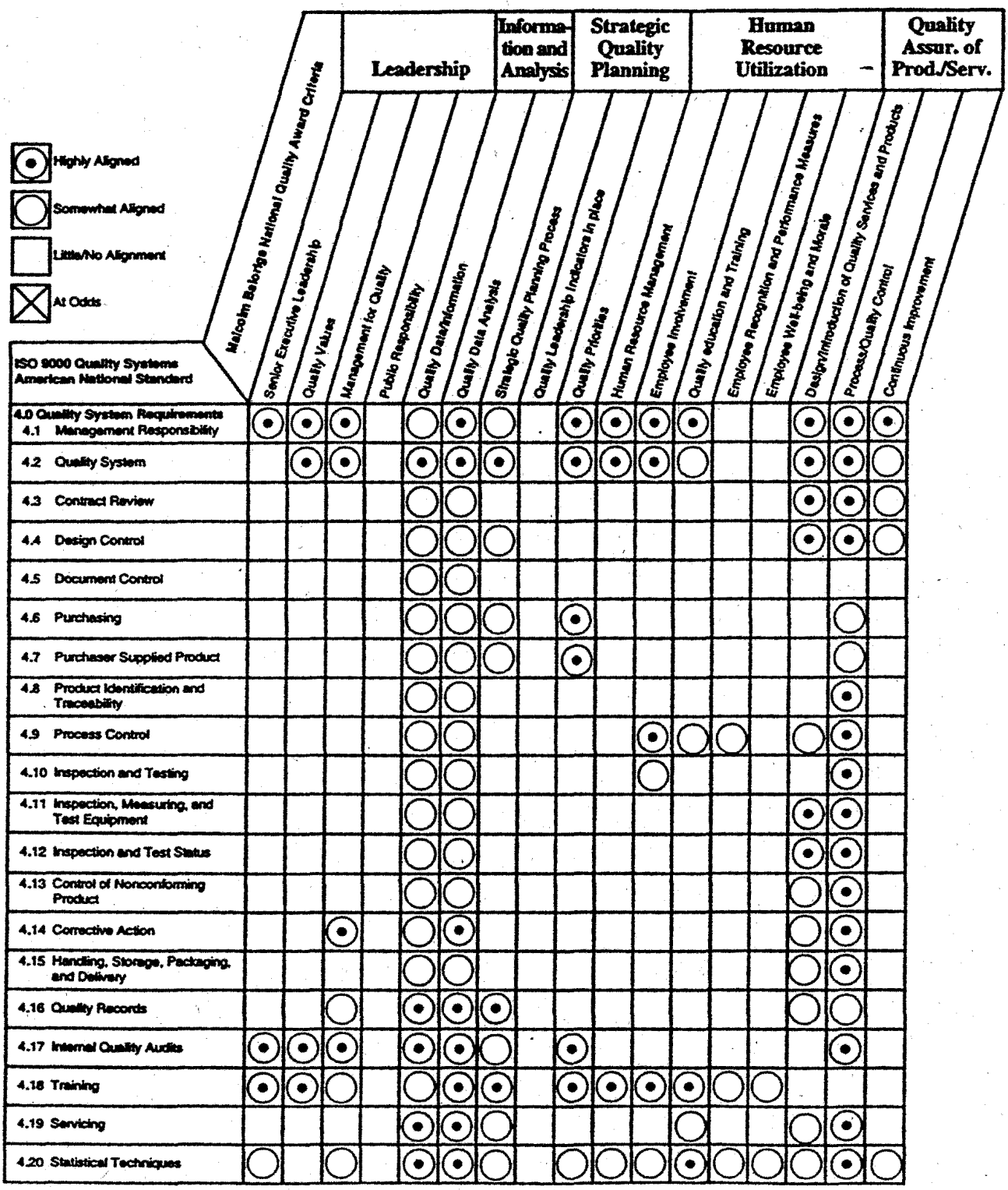

Table 6-1: Extent to which ISO 9000 requirements align with MBNQA guidelines.

Peach, Robert W., P. 136

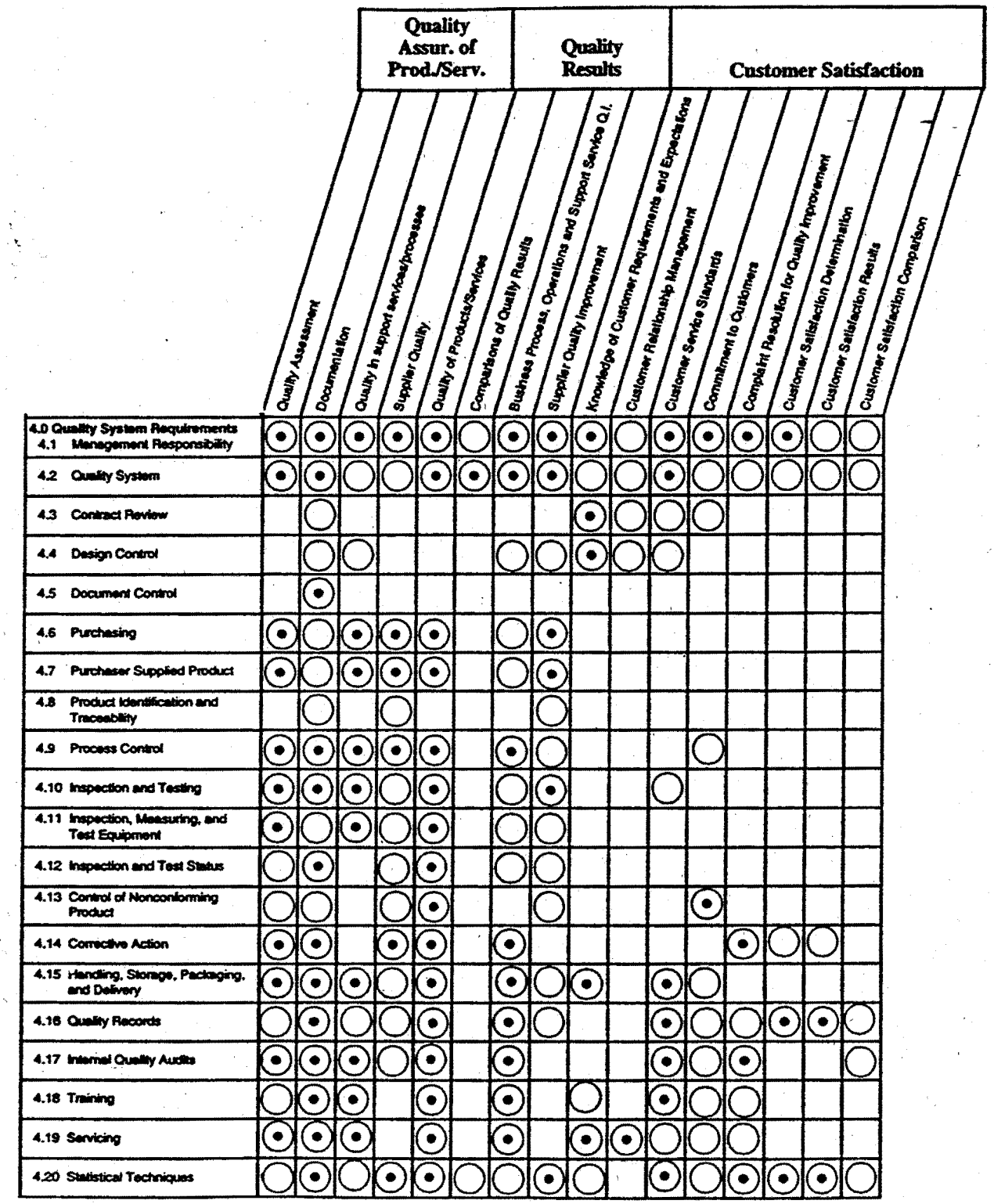

Table 6-1: Extent to which ISO 9000 requirements align with MBNQA guidelines (continued).

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APPENDIX B.

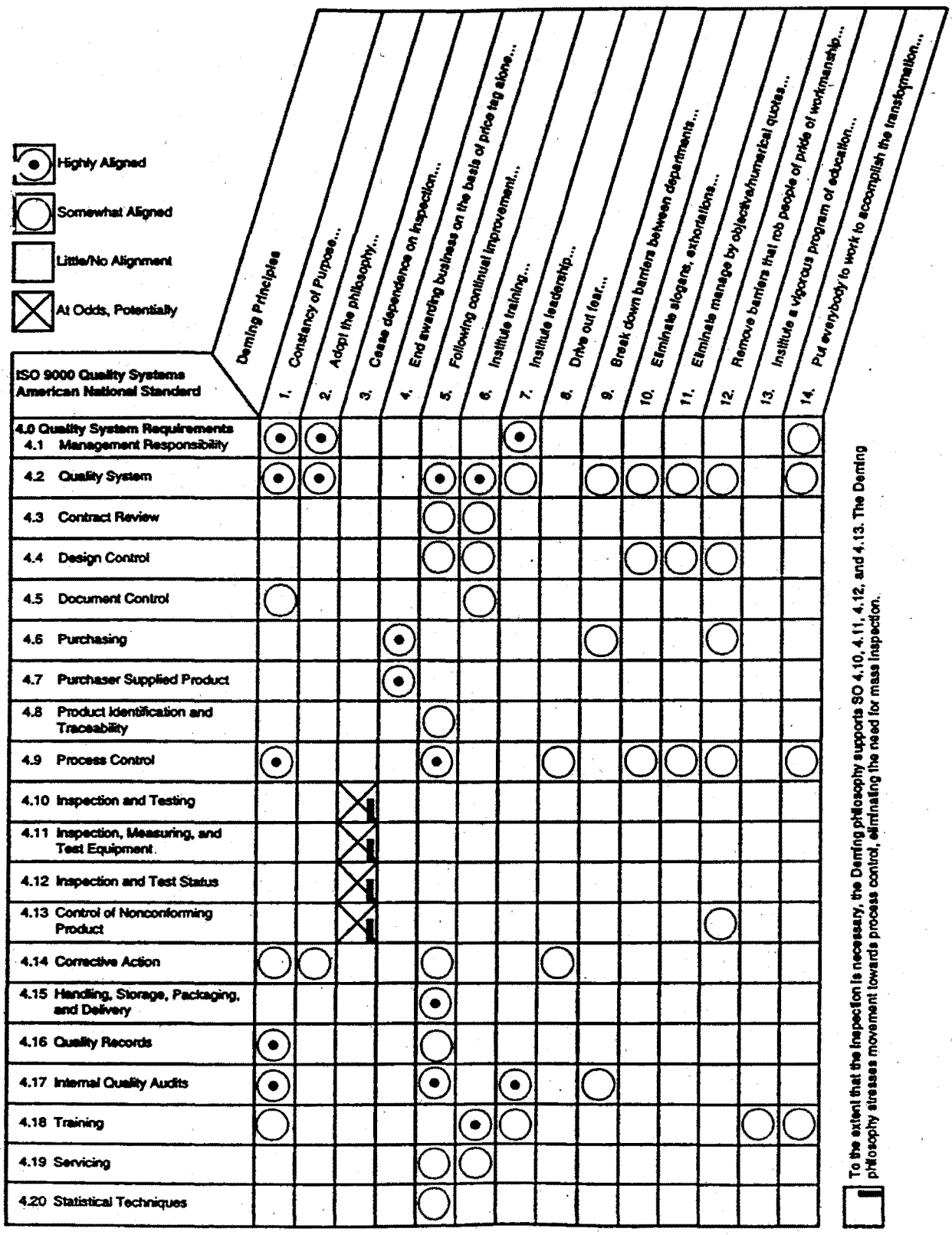

Table 6-2: Extent to which ISO 9000 requirements align with Deming principles.

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