ISO 9001:2015

International Quality Management System Standard

An Executive Overview

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ISO 9001:2015

AN EXECUTIVE OVERVIEW

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FOREWORD

ISO 9000, the international quality system standards series, has been a major factor in the United States, the European Union and elsewhere in the world since its release in 1987. In the over 25 years since its first publication, the ISO 9001 standard has been through four revisions (1994, 2000, 2008, and 2015.) It was with the 2015 revision that some of the most substantial and important revisions in the history of the standard were released.

The new standard has achieved numerous ideals by this latest rewrite, including:

- Simplification of language;
- Consistency with other standards; and
- A flexible approach to the management of processes.

This guide was written to provide information about the ISO 9001:2015 standard, and its applications. Step by step, it outlines the general requirements of ISO 9001:2015, which can be applied to any type of industry or company.

Registration to ISO 9001:2015 offers a major competitive edge for organizations and is a virtual requirement in many marketplaces. Far-sighted firms are planning for registration by conducting a thorough investigation of the revised standard's interpretations.

Of course, every company, facility, and process is different. The ISO 9001:2015 standard continues to be flexible enough to accommodate these differences by offering the option of tailoring to omit inapplicable requirements such as design activity. To determine where requirements do not apply, interested organizations should hire the services of a reputable ISO 9000 consulting firm, with documented ISO 9000 implementation experience.

Firms planning a new registration to adopt ISO 9001:2015 and firms seeking to accommodate the 2015 revisions to an existing ISO 9001 quality management system should obtain the aid of an accredited consulting company in implementing the existing requirements of the standard as well as the new interpretations of the standard to their specific situations.

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Southfield, MI
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THE USERS OF THIS GUIDE

This guide will be useful to managers and other personnel in organizations that meet any of the following criteria:

- ISO 9001:2008 registered firms seeking conformity to the 2015 revisions
- Suppliers seeking to meet customer ISO 9001 registration mandates
- Companies seeking to remain abreast of worldwide quality management system standards development.
- Firms planning to improve their quality assurance and quality management programs
- Companies seeking a competitive advantage in the marketplace
- Firms desiring to make customer satisfaction a top priority
- Firms with facilities in the European Union (EU)
- Firms planning to establish facilities in the EU
- Firms planning to export to the EU

WHAT IS ISO 9000? _____

ISO 9000 is a series of quality management systems standards created by the International Organization for Standardization (ISO), a federation of national standards bodies based in Geneva, Switzerland. The American National Standards Institute (ANSI) is the member body representing the United States. All standards are assigned a Technical Committee (TC.) TC 176 is the committee that has responsibility for the ISO 9000 series of standards.

The ISO 9000 quality management standards are not specific to products or services, but apply to the processes that create them. The standards are generic in nature so that they can be used by manufacturing and service industries all over the world. First released in 1987 and revised in a limited manner in 1994, they underwent a major overhaul in 2000, and in 2008 interpretations were added to the ISO 9001:2000 standard.

The latest version of ISO 9001 represented the culmination of several key goals for the ISO. Chief among these was the design to have a common structure for all ISO standards. To achieve this, the ISO appointed a special Joint Technical Coordination Group (JTCG) in 2012 and tasked the JTCG with development of a "core text" for the ISO family of standard. The results of their efforts were given the name "Annex SL."

Annex SL – A Common Structure

Annex SL exists as part of a larger publication called *"ISO Directives Part 1, Consolidated ISO Supplement – Procedures specific to ISO."* This expansive document can be thought of a "playbook" for the ISO to follow in the development of standards. It is projected that all ISO standards will follow the Annex SL format by 2017. We will learn more about Annex SL and the standardized format over the next several pages of this Executive Overview.

The Origin of ISO 9000

ISO 9000 is the descendant of a number of earlier quality standards, including the British BS 5750 and DEF/STAN 05-8, the NATO AQAP-1 and the U.S. Department of Defense MIL-Q-9858A. The purpose for developing ISO 9000 was to simplify the international exchange of goods and services by creating a common set of quality standards.

BS 5750 had the greatest influence on this international standard when it was first released by ISO in 1987. Most industrialized nations quickly adopted harmonized versions of ISO 9000. These national versions, which are identical to the international standard, include the American ANSI/ISO/ASQ Q9000, sponsored by ANSI and the American Society for Quality (ASQ), and the European Union's EN 29000.

ISO 9001 is intended to provide requirements for an organization to establish, document and maintain a quality management system for ensuring the consistency of a process. It is not mysterious or esoteric, consisting instead of a group of common sense and generally well-known precepts laid out in an organized fashion.

When implemented correctly, ISO 9001:2015 can offer your company several advantages. It will guide you to build consistency into your products or services, and can help you to avoid costly warranty costs and rework.

Today, the international standards are sanctioned by the European Union (EU), making ISO 9001:2015 registration a virtual prerequisite for doing business in its member countries.

Previously, there were more than 20 ISO 9000 standards and documents, and this proliferation raised concerns among ISO 9000 users and consumers. In response, the TC committee agreed that the 2000 revision and all future revisions would consist of four primary standards, supported by several technical reports. In addition to the ISO 9001:2015 standard, these three additional primary standards are:

- **ISO 9000:2015**, *Quality Management Systems – Fundamentals and Vocabulary*. This document, which replaced the 2005 revision, provides all sanctioned interpretations for the numerous terms used throughout the various standards. ISO 9000:2015 also provides an examination of the Seven Quality Management Principles, including a statement of rationale. Finally, ISO 9000:2015 provides a number of helpful concept diagrams showing the intended interrelationships between ideas. ISO 9000:2015 is not a certifiable standard, but it can be of great benefit to a company newly starting out in pursuit of ISO 9001:2015 certification.

- **ISO 9004:2009**, *Managing for the sustained success of an organization – A quality management approach*. This standard, which replaced ISO 9004-1:1994, *Quality Management and Quality System Elements – Part 1: Guidelines*, provides guidance beyond ISO 9001:2015 towards developing a comprehensive quality management system to improve an organization's overall performance.

  This document gives guidance on all aspects of a quality management system, based on the seven quality management principles found in ISO 9000:2015. ISO 9004 is useful in auditing the effectiveness of a company's quality management system, with the goal of achieving benefits for all stakeholder groups through sustained customer satisfaction. It is a reference standard in that a company cannot become registered to ISO 9004.

- **ISO 19011:2011**, *Guidelines for* A*uditing Management Systems*. Initially, ISO/TC 176 was to draft ISO 10011, *Guidelines for Auditing Quality Systems*, which would integrate and replace the three quality system auditing standards: ISO 10011-1:1990, *Guidelines for Auditing Quality Systems – Part 1: Auditing*, ISO 10011-2:1991, *Guidelines for Auditing Quality Systems – Part 2: Qualifications Criteria for Quality Systems Auditors*, and ISO 10011-3:1991, *Guidelines for Auditing Quality Systems – Part 3: Management of Audit Programs*. Instead, the Joint Working Group (JWG) on Quality and Environmental Auditing, consisting of experts from ISO/TC 176/SC 3, Auditing and ISO/TC 207, Environmental Management, SC 2, Environmental Auditing, agreed to draft a joint quality and environmental management systems auditing standard, ISO 19011. It applies to first, second and third party audits; auditor qualification criteria; and audit program management. ISO 19011 replaced ISO 10011-1, ISO 10011-2 and ISO 10011-3, along with the three environmental auditing standards: ISO 14010:1996, *Guidelines for Environmental Auditing – General Principles*, ISO 14011:1996, *Guidelines for Environmental Auditing – Audit Procedures – Auditing of Environmental Management Systems*, and ISO 14012:1996, *Guidelines for Environmental Auditing – Qualification Criteria for Environmental Auditors*.

REGISTERING TO ISO 9001:2015

ISO 9001:2015 registration is a tangible expression of a firm's commitment to quality that is internationally understood and accepted. ISO 9001 registered organizations almost universally realize major increases in customer acceptance, as well as reductions in costs. Many American firms, already subject to quality system standards imposed by major customers, find that the major effect of ISO 9001 registration is on their non-manufacturing functions, which tend to be overlooked by manufacturing-based quality systems.

ISO 9001 registration is carried out by certification bodies (commonly called registrars), which are accredited organizations that review the facility's quality manual and other documentation to ensure that they meet the standard, and audit the firm's processes to ensure that the quality management system described in the documentation is in place and is effective. Once registration is obtained, the registrar conducts regular surveillance audits of the facility to determine if its quality management system continues to meet the standard's requirements.

As it typically takes 6 to 18 months to complete the ISO 9001 registration process, organizations are advised not to put off registration for too long.

Key Steps to Completing a New Registration

Before an organization can be considered for registration, several preliminary steps should be taken.

The first step is to implement a quality management system that meets ISO 9001:2015 requirements.

To qualify for registration, it's not enough to just conform to the standard. Organizations must determine what their processes are, and what their intentions are for controlling their processes. Methodologies for the myriad requirements for records (called "Retained Documented Information in ISO 9001:2015) must also be determined. Many other questions of approach have to be answered as well, for requirements ranging from competency records to external provider evaluation. Organizations must ensure that the system they establish is robust, effective, transparent, and consistent.

After successfully completing the preliminary steps, a relationship must be established with a registrar. The registrar's job is to verify whether an organization's quality management system has been properly implemented and conforms to ISO 9001:2015 and any other applicable requirements.

Once the services of an accredited registrar have been obtained, a formal application must be filed. **When all of the documentation has been submitted, the registrar conducts a two stage audit. The first stage involves an audit of basic documentation including records of a full system internal audit followed by a formal management review. According to the ISO standard that controls registrar activities (ISO 17021), "Stage 1" audits may be done off-site. A telephone conference may occur in place of an on-site visit. The "Stage 1" auditor will identify items that require correction before the "Stage 2" audit can begin. Once the registrar determines that the Stage 1 basic documentation and data requirements are met, the "Stage 2" audit may proceed.**

The Stage 2 audit is a full system audit that takes place after the Stage 1 corrections are verified by the Stage 2 auditor. Performance data is checked for effectiveness relative to documented objectives. Product and service realization activities within the facility are checked for conformity to quality control plans as well as to effectiveness. Other management system activities are checked relative to documented processes and procedures. Please note, firms that are interested in registration to both ISO 9001:2015 and ISO 14001:2015 should discuss this objective with their registrar to determine whether the audits to the two standards may be conducted simultaneously.

During the on-site "Stage 2" audit, the registrar auditor interviews employees, reviews records, and performs a detailed inspection of the facility's quality management system documents. The purpose of the audit is to ensure that the facility's quality management system is functioning adequately and conforms to all ISO 9001:2015 requirements.

Afterward, the registrar reports its findings in an audit report. If any major or minor nonconformities are found, the organization (or auditee) must take corrective action to remedy the cause of the nonconformity. Nonconformities must be remedied within a set time frame, determined by the registrar. Once the registrar has closed out all outstanding nonconformities, a certificate of registration is issued.

To ensure that organizations are following ISO 9001:2015 requirements after registration is obtained, the registrar conducts on-site surveillance audits at least once each year.

Remember: In order to achieve registration to ISO 9001:2015, the organization must completely embrace the standard, which focuses on performance, consistency, and objective/audit evidence.

What to Look For in a Registrar

In selecting a registrar, it is extremely important for every organization to be aware of the relevant qualifications.

A registrar must:

- Be accredited by a national accreditation body, such as the ANAB (ANSI-ASQ National Accreditation Board) of the United States, the Raad voor Accreditatie (RvA) of the Netherlands, or the United Kingdom Accreditation Service (UKAS); to the requirements of ISO/IEC 17021 *Requirements for Bodies providing audit and certification of management systems.* Among other benefits, using an accredited registrar assures the following:

  – The registrar is required to provide a fair and documented process for any disputed findings, client complaints, or other similar situations;

  – The registrar can be reported, and by extension held accountable to the requirements of ISO 17021 by the accreditation bodies;

  – The registrar must ensure that their auditors are full competent for the audits they perform; and

  – All audits are subject to a wide ranging review process by numerous persons, assuring a fair and unbiased process.

- Maintain a listing of its ISO 9001 qualified auditors;

- Have personnel on its executive (registration) committee or governing board with industry experience and expertise in the appropriate Standard Industrial Classification (SIC), North American Industry Classification System (NAICS) or European Accreditation of Certification (EAC) codes;

What to Look For in an Auditor

Requirements have been established for the auditors working for accredited ISO 9001 registrars. Before an auditor can evaluate an organization's facility to verify whether its quality management system conforms to ISO 9001:2015 requirements, the auditor must satisfy the following conditions:

1) Auditors must have satisfactorily completed ISO 9001 training courses and demonstrated their knowledge of ISO 9001:2015. Certificates are awarded to those auditors who have successfully completed this training;

2) Auditors must comply with ISO 19011:2011, *Guidelines for auditing management systems*;

3) They must be recognized and qualified as ISO 9001 auditors under the registrar's criteria; and,

4) At least one member of an audit team must have relevant industry knowledge in the appropriate SIC, NAICS or EAC codes, as determined by the registrar's qualification process, for each client.

Before hiring the services of a registrar, it's a good idea to make sure the registrar and its auditors have met the above qualifications.

Auditors and other relevant registrar personnel are required to demonstrate knowledge and understanding of ISO 9001:2015 requirements; the seven quality management principles on which the revised standards are based, and the standard's many terms and definitions, both of which appear in ISO 9000:2015.

Registrars must take particular care in defining the scope of ISO 9001:2015 registration certificates and any cited "non-applicable clauses", as set forth in ISO 9001:2015, Section 4.3. When issuing a tailored registration certificate, a registrar must keep in mind that "such non-applicable clauses do not affect the organization's ability, or responsibility, to provide product that fulfills customer and applicable regulatory requirements."

THE BENEFITS OF ISO 9001:2015

ISO 9001 is an ideal quality management system for facilities that are serious about quality, with ISO 9001:2015 registration providing a competitive edge. ISO 9001:2015 registration gives the facility the benefit of an objectively evaluated and enforced quality management system.

Facilities that operate ISO 9001 quality management systems tend to exhibit a philosophy of prevention rather than detection; risk management of potential concerns, continuous review of critical process points; corrective actions and outcomes; consistent communication within the process, and among facility, suppliers and customers; thorough record keeping and efficient control of critical documents; total quality awareness by all employees; and a high level of executive management confidence and support.

These attributes lead to dependable process input, control of quality costs, increased productivity and reduced waste. A well-designed and implemented ISO 9001 quality management system creates a process that tends to be lean, sensitive to customer needs, highly reactive, efficient and positioned at the leading edge of its marketplace.

Any company that becomes registered to ISO 9001:2015 will be better positioned to do business overseas, especially in countries where the standard has become a virtual necessity for market entry. Registration also enables facilities to protect existing markets when their customers mandate it. It offers the potential of reducing time-consuming and expensive supplier audits, and is a powerful strategic benefit for facilities having current or planned business ties with the European Union (EU).

The EU Council of Ministers now mandates ISO 9001 registration for makers of such products as commercial scales, construction products, gas appliances, industrial safety equipment, medical devices and telecommunications terminal equipment.

More products may be added to this list under additional product directives. This is especially likely for products and services that are potentially hazardous involve personal safety or are otherwise affected by product liability or similar regulations.

Organizations that register to ISO 9001:2015 also enjoy a clear competitive edge over companies that are not registered. Registered organizations are authorized to display a special mark or logo, and firms throughout the U.S., the EU and elsewhere understand the significance behind that mark.

Bottom line: An organization that chooses to conform to ISO 9001 will be operating a top-notch quality management system that focuses on informed and competent management decision making, control of quality costs, increased productivity and reduced waste.

The Seven Quality Management Principles

ISO 9000:2005, Section 2.3 set forth seven quality management principles, which have been identified for leading an organization toward improved performance. Beyond simply listing the Principles, ISO 9000 also provides rationale, benefits, and information on possible approaches to each Principle. These Principles are the basis of ISO 9001:2015. They are:

a. Customer Focus. Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

b. Leadership. Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

c. Engagement of People. Competent, empowered, and engaged people at all levels are the essence of an organization and drive the organization's ability to create and deliver value.

d. Process Approach. Desired results are achieved more efficiently when activities and related resources are managed as processes within a coherent system.

e. Improvement. Improvement of the organization's overall performance should be an ongoing focus of the organization.

f. Evidence Based Decision Making. Decisions based on the analysis of data and information is more likely to deliver desired results.

g. Relationship Management. An organization and its external interested parties are interdependent and share a role in each other's success.

ISO 9001:2015 Process-Based Structure and Clauses

The revised continues to be consistent with the plan-do-check improvement cycle, and continues to use the process management structure widely used in business today. It introduces several new clauses intended to drive Risk Based Thinking.

The reader is reminded that the Annex SL format provided in this structure is the same used by ISO 14001:2015 and all other ISO issued standards.

Non-Auditable clauses of ISO 9001:2015 are:

1. **Scope** – which provides a general statement about to whom ISO 9001:2015 is intended to apply.

2. **Normative Reference** – which provides an explanation of the linkage between ISO 9001:2015 and ISO 9000:2015.

3. **Terms and Definitions** – which establishes the use of ISO 9000:2015 for all official definitions.

Auditable clauses of ISO 9001:2015 are:

4. **Context of the Organization** (4 clauses), which mandate an organization to determine the scope of its system, ascertain interested parties, and in general determine the breadth of their quality management system, which defines and manages processes in order to produce a consistent product or service and allow for continual improvement.

5. **Leadership** (3 clauses), under which management defines policy, organizational roles, and assures focus on the customer. It is emphasized that Leadership means a shared responsibility for the management of the quality system.

6. **Planning** (3 clauses), under which the primary requirements related to risk management, as well as objectives (planning, reporting, etc.) are found. A set of requirements pertaining to management of changes is also found here.

7. **Support** (5 clauses), which provide requirements pertaining to all of the various resources an organization needs to effectively operate their quality system, including people (competency) measurement devices (calibration/verification), and documented information (maintained and retained.)

8. **Operation** (7 clauses), which provides requirements pertaining to the crucial and central activities of a quality management system. All of the "day-to-day" activities are found here, including interaction with customers, design of products/services, and interface with external providers, and control of production/service provision.

9. **Performance Evaluation** (3 clauses), which provide requirements pertaining to three of the most crucial methods used by Organizations to self-regulate their quality management system and ensure its effectiveness. These are Management Review, Internal Audit, and Customer Satisfaction.

10. **Improvement** (3 clauses), which provides requirements pertaining to the actions that should be taken as a result of evaluations and other output monitoring actions discussed in earlier parts of the standard. Ideas covered here include Corrective Action and Continual Improvement.

Taken together these seven auditable sections can be thought of as a three part approach to the functioning of a quality management system, as follows:

Foundation/Basic Building Blocks (Sections 4-7)

The first four sections of auditable content taken together represent the basic pieces that an organization needs to establish to enable a successful quality management system. Without these pieces, the later requirements will likely not be successful.

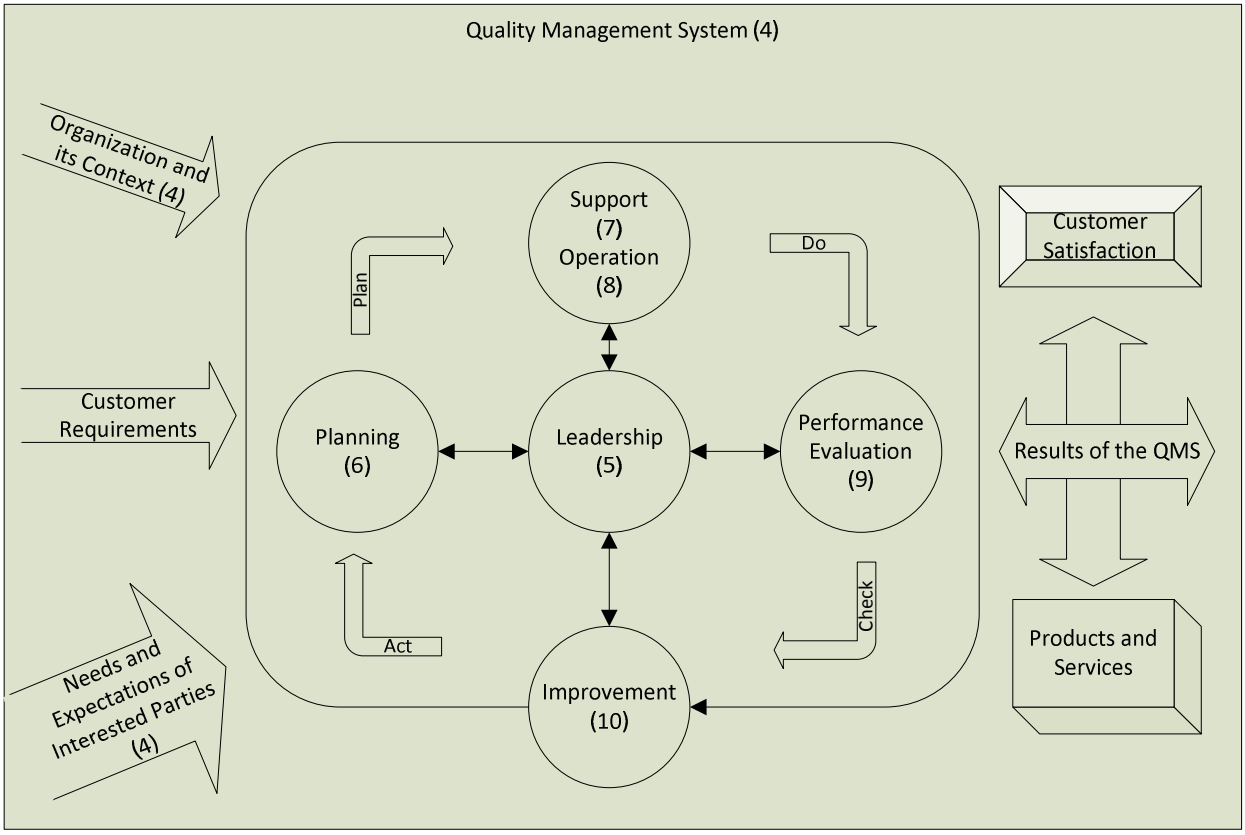
Day to Day Activities (Section 8)

Taken together, the requirements provided in Section 8 are almost a process flow in and of themselves. Beginning with Operational Planning in 8.1 and Customer Requirements Determination in 8.2 the organization is supposed to figure out what is needed, later taking steps such as designing the product (8.3), purchasing materials (8.4) and ensuring that production/service is carried out consistently (8.5.1.) Auditors typically spend at least 60% of available audit time in Section 8. The processes it attempts to control are inevitably the most important in any organization.

Analysis and Improvement (Sections 9 and 10)

The standard concludes with a pair of Sections that attempt to collect all of the best methods that a company should use to ensure that its processes are effective, its customers are satisfied, and that continual improvement is being achieved. Many auditors review these sections early in an audit to develop audit trails.

All quality management system requirements for achieving conformity of product and/or service may be placed within this process model. Leadership can be thought of as impacting all of the various activities of the quality management system. The Plan-Do-Check-Act cycle follows the various processes of the organization. Careful planning based on input from customers and other interested parties leads to effective operations, which in turn are evaluated with improvement actions taken where needed or desired. The ultimate goal of these interacting activities is a consistent effective product/service that satisfies all customers.


Quality Management System (4)
Organization and its Context (4)
Customer Requirements
Needs and Expectations of Interested Parties (4)
Plan
Do
Act
Check
Support (7)
Operation (8)
Planning (6)
Leadership (5)
Performance Evaluation (9)
Improvement (10)
Customer Satisfaction
Results of the QMS
Products and Services

ISO 9001:2015 QUALITY MANAGEMENT SYSTEM REQUIREMENTS _____

All ISO 9001:2015 clauses are briefly described below.

4 – Context of the Organization

4.1 Understanding the organization and its context requires the organization to determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. It also requires the organization to monitor and review information about these external and internal issues. Issues are understood to include positive and negative factors or conditions for consideration. Understanding of external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. Understanding of internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties requires an organization to determine the interested parties and requirements therein that are relevant to the quality management system. The organization is also required to monitor and review information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system requires the organization to determine the boundaries and applicability of the quality management system to establish its scope. When doing so, the organization should consider the external and internal issues referred to in 4.1, the requirements of relevant interested parties referred to in 4.2, and what their products and services are. Organizations are required to apply all the requirements of ISO 9001:2015 if they are applicable within the determined scope of the quality management system. The scope of the organization's quality management system has to be available and maintained as documented information. The scope must stipulate the types of products and services covered, and provide justification for any requirement of ISO 9001:2015 that the organization has determined as not applicable to the scope of its quality management system. Conformity to ISO 9001:2015 may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.4 Quality management system and its processes establish two different sets of requirements:

4.4.1 Requires the organization to establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015. It requires the organization to determine the processes needed for the quality management system and their application throughout the organization. It requires the organization to determine the inputs required and the outputs expected from these processes, determine the sequence and interaction of these processes, to determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes, to determine the resources needed for these processes and ensure their availability, to assign the responsibilities and authorities for these processes, to address the risks and opportunities as determined in accordance with the requirements of 6.1, to evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results, and to improve the processes and the quality management system.

4.4.2 Requires the organization to maintain documented information to support the operation of its processes, and to retain documented information to have confidence that the processes are being carried out as planned.

5 – Leadership

5.1 Leadership and commitment

5.1.1 General requires top management to demonstrate leadership and commitment with respect to the quality management system by taking accountability for the effectiveness of the quality management system, ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization, ensuring the integration of the quality management system requirements into the organization's business processes, promoting the use of the process approach and risk-based thinking, ensuring that the resources needed for the quality management system are available, communicating the importance of effective quality management and of conforming to the quality management system requirements, ensuring that the quality management system achieves its intended results, engaging, directing and supporting persons to contribute to the effectiveness of the quality management system, promoting improvement, and supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus requires top management to demonstrate leadership and commitment with respect to customer focus by ensuring that customer and applicable statutory and regulatory requirements are determined, understood and consistently met, the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed, and that the focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Establishing the quality policy requires top management to establish, implement and maintain a quality policy that is appropriate to the purpose and context of the organization and supports its strategic direction, provides a framework for setting quality objectives, includes a commitment to satisfy applicable requirements, and includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the quality policy requires the quality policy to be available and be maintained as documented information, be communicated, understood and applied within the organization, and be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities requires top management to ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. It further requires top management to assign the responsibility and authority for ensuring that the quality management system conforms to the requirements of ISO 9001:2015, ensuring that the processes are delivering their intended outputs, reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management, ensuring the promotion of customer focus throughout the organization, and ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6 – Planning

6.1 Actions to address risks and opportunities

6.1.1 Requires the organization to consider the issues referred to in 4.1 and the requirements referred to in 4.2 and then to determine the risks and opportunities that need to be addressed to give assurance that the quality management system can achieve its intended result(s), to enhance desirable effects, to prevent, or reduce, undesired effects, and to achieve improvement.

6.1.2 Requires the organization to plan actions to address these risks and opportunities, to determine how to integrate and implement the actions into its quality management system processes and to evaluate the effectiveness of these actions. Actions taken to address risks and opportunities must be proportionate to the potential impact on the conformity of products and services.

6.2 Quality objectives and planning to achieve them

6.2.1 Requires the organization to establish quality objectives at relevant functions, levels and processes needed for the quality management system. It further requires that quality objectives be consistent with the quality policy, be measurable, take into account applicable requirements, be relevant to conformity of products and services and to enhancement of customer satisfaction, be monitored, be communicated, and be updated as appropriate. Lastly, it requires the organization to maintain documented information on the quality objectives.

6.2.2 Requires the organization (with regards to Quality Objectives) to determine what will be done, what resources will be required, who will be responsible, when it will be completed, and how the results will be evaluated.

6.3 Planning of changes requires (when an organization determines that there is a need for changes to the quality management system,) that those changes be carried out in a planned manner (per 4.4.) Furthermore, it requires the origination to consider the purpose of the changes and their potential consequences, the integrity of the quality management system, the availability of resources, and the allocation or reallocation of responsibilities and authorities.

7 – Support

7.1 Resources

7.1.1 General requires the organization to determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. It further requires the organization to consider the capabilities of, and constraints on, existing internal resources, and what needs to be obtained from external providers.

7.1.2 People requires the organization to determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure requires the organization to determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure is understood to include buildings and associated utilities, equipment, including hardware and software, transportation resources, and information and communication technology.

7.1.4 Environment for the operation of processes requires the organization to determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. Environment is understood to include a combination of human and physical factors, such as social (e.g. non-discriminatory, calm, non-confrontational), psychological (e.g. stress-reducing, burnout prevention, emotionally protective), and physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise). These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and measuring resources

7.1.5.1 General requires the organization to determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. It further requires the organization to ensure that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken, and are maintained to ensure their continuing fitness for their purpose. Finally, it requires the organization to retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability requires that when measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification to be retained as documented information. It also requires that measuring equipment be identified in order to determine their status, and safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. Finally, it requires the organization to determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and to take appropriate action as necessary.

7.1.6 Organizational knowledge requires the organization to determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. It also requires that knowledge be maintained and made available to the extent necessary. When addressing changing needs and trends, the organization must consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence requires the organization to determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system, to ensure that these persons are competent on the basis of appropriate education, training, or experience, to take actions (where applicable) to acquire the necessary competence, to evaluate the effectiveness of the actions taken; and to retain appropriate documented information as evidence of competence.

7.3 Awareness requires the organization to ensure that persons doing work under the organization's control are aware of the quality policy, relevant quality objectives, their contribution to the effectiveness of the quality management system, including the benefits of improved performance, and the implications of not conforming with the quality management system requirements.

7.4 Communication requires the organization to determine the internal and external communications relevant to the quality management system, including on what it will communicate, when to communicate, with whom to communicate, how to communicate, and who communicates.

7.5 Documented information

7.5.1 General requires the organization's quality management system to include documented information required by ISO 9001:2015, documented information, as well as documented information determined by the organization as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and updating requires that when creating and updating documented information, the organization ensures appropriate identification and description (e.g. a title, date, author, or reference number), format (e.g. language, software version, graphics) media (e.g. paper, electronic) and review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Requires documented information required by the quality management system and by ISO 9001:2015 to be controlled to ensure it is available and suitable for use, where and when it is needed. It further requires that documented information be adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 Requires the organization (as it pertains to control of documented information) to address the following activities, as applicable. Distribution, access, retrieval and use, storage and preservation, including preservation of legibility, control of changes (e.g. version control), and retention and disposition. It further required that documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system be identified as appropriate, and be controlled. Finally it requires documented information retained as evidence of conformity is protected from unintended alterations.

8 – Operation

8.1 Operational planning and control requires the organization to plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6. This is to be accomplished by determining the requirements for the products and services, establishing criteria for the processes and the acceptance of products and services, determining the resources needed to achieve conformity to the product and service requirements, implementing control of the processes in accordance with the criteria, determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements. Furthermore it requires that the output of this planning be suitable for the organization's operations. The organization must control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. Finally, it requires that the organization ensures control of the outsourced processes (per 8.4).

8.2 Requirements for products and services

8.2.1 Customer communication requires that communication with customers includes providing information relating to products and services, handling enquiries, contracts or orders, including changes, obtaining customer feedback relating to products and services, including customer complaints, handling or controlling customer property, and establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements for products and services requires that when determining the requirements for the products and services to be offered to customers, the organization must ensure that the requirements for the products and services are defined, including any applicable statutory and regulatory requirements, as well as those considered necessary by the organization. Furthermore, the organization must determine that it can meet the claims for the products and services it offers.

8.2.3 Review of the requirements for products and services

8.2.3.1 Requires the organization to ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization must conduct a review before committing to supply products and services to a customer. This review must include requirements specified by the customer, including the requirements for delivery and post-delivery activities, requirements not stated by the customer, but necessary for the specified or intended use, when known, requirements specified by the organization, statutory and regulatory requirements applicable to the products and services and contract or order requirements differing from those previously expressed. Furthermore it mandates that the customer's requirements must be confirmed by the organization before acceptance when the customer does not provide a documented statement of their requirements.

8.2.3.2 Requires the organization to retain (as applicable) documented information on the results of the review, and on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services require the organization to ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services

8.3.1 General requires the organization to establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning requires the organization (when they determine the stages and controls for design and development) to consider the nature, duration and complexity of the design and development activities, the required process stages, including applicable design and development reviews, the required design and development verification and validation activities, the responsibilities and authorities involved in the design and development process, the internal and external resource needs for the design and development of products and services, the need to control interfaces between persons involved in the design and development process, the need for involvement of customers and users in the design and development process, the requirements for subsequent provision of products and services, the level of control expected for the design and development process by customers and other relevant interested parties, and the documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and development inputs requires the organization to determine the requirements essential for the specific types of products and services to be designed and developed. It further requires the organization to consider functional and performance requirements, statutory and regulatory requirements, standards or codes of practice that the organization has committed to implement, and potential consequences of failure due to the nature of the products and services. It further requires that inputs be adequate for design and development purposes, as well as complete and unambiguous. Finally, it requires that conflicting design and development inputs be resolved and that the organization retain documented information on design and development inputs.

8.3.4 Design and development controls requires the organization to apply controls to the design and development process to ensure that the results to be achieved are defined, that reviews are conducted to evaluate the ability of the results of design and development to meet requirements, that verification activities are conducted to ensure that the design and development outputs meet the input requirements, that validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use, that any necessary actions are taken on problems determined during the reviews, or verification and validation activities, and that documented information of these activities is retained.

8.3.5 Design and development outputs requires the organization to ensure that design and development outputs meet the input requirements, are adequate for the subsequent processes for the provision of products and services, include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria, and specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. Furthermore, it requires the organization to retain documented information on design and development outputs.

8.3.6 Design and development changes requires the organization to identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. It further requires the organization to retain documented information on design and development changes, the results of reviews, the authorization of the changes, and the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services

8.4.1 General requires the organization to ensure that externally provided processes, products and services conform to requirements. It further requires the organization to determine the controls to be applied to externally provided processes, products and services when products and services from external providers are intended for incorporation into the organization's own products and services, when products and services are provided directly to the customer(s) by external providers on behalf of the organization, or when a process, or part of a process, is provided by an external provider as a result of a decision by the organization. This requirement further stipulates that the organization must determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Lastly the organization is required to retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control requires the organization to ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. Furthermore, it requires the organization to ensure that externally provided processes remain within the control of its quality management system, to define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output, to take into consideration the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements, as well as the effectiveness of the controls applied by the external provider. This requirement also stipulates that the organization must determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for external providers requires the organization to ensure the adequacy of requirements prior to their communication to the external provider. It further requires the organization to communicate to external providers its requirements for the processes, products and services to be provided, including specific products and services, methods, processes, equipment; and requirements pertaining the release of products and services. This requirements further requires that the organization communicate additional information to external providers including required competence, including any required qualification of persons, the external providers' interactions with the organization, control and monitoring of the external providers' performance to be applied by the organization, and verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.5 Production and service provision

8.5.1 Control of production and service provision requires the organization to implement production and service under controlled conditions. Controlled conditions are understood to include (as applicable) the availability of documented information that defines the characteristics of the products to be produced, the services to be provided, or the activities to be performed, as well as the results to be achieved. Controlled conditions is also taken to include the availability and use of suitable monitoring and measuring resources, the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, the use of suitable infrastructure and environment for the operation of processes, the appointment of competent persons, including any required qualification, the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement, the implementation of actions to prevent human error, and the implementation of release, delivery and post-delivery activities.

8.5.2 Identification and traceability requires the organization to use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. It further requires the organization to identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. Lastly, it requires the organization to control the unique identification of the outputs when traceability is a requirement, and to retain the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external providers requires the organization to exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. It further requires the organization to identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. Lastly, it requires that when the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization must report this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation requires the organization to preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8.5.5 Post-delivery activities require the organization to meet requirements for post-delivery activities associated with the products and services. It further requires the organization (when determining the extent of post-delivery activities that are required) to consider any applicable statutory and regulatory requirements, the potential undesired consequences associated with its products and services, the nature, use and intended lifetime of its products and services, any applicable customer requirements, and any relevant customer feedback.

8.5.6 Control of changes requires the organization to review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. It further requires the organization to retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services requires the organization to implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. It further requires the release of products and services to the customer not to proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. Lastly it requires the organization to retain evidence of conformity with the acceptance criteria, and ensure traceability to the person(s) authorizing the release.

8.7 Control of nonconforming outputs

8.7.1 Requires the organization to ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. It further requires the organization to take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services. Additionally, this requirement mandates that the organization deal with nonconforming outputs in one or more of the following ways. These include correction, segregation, containment, return or suspension of provision of products and services, informing the customer, and obtaining authorization for acceptance under concession. Lastly, it requires that conformity to the requirements must be verified when nonconforming outputs are corrected.

8.7.2 Requires the organization to retain documented information that describes the nonconformity, describes the actions taken, describes any concessions obtained, and identifies the authority deciding the action in respect of the nonconformity.

9 – Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General requires the organization to determine what needs to be monitored and measured, the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results, when the monitoring and measuring to be performed, and when the results from monitoring and measurement to be analyzed and evaluated. Furthermore, it requires the organization to evaluate the performance and the effectiveness of the quality management system. Lastly, it requires the organization to retain appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction requires the organization to monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. Further the organization is required to determine the methods for obtaining, monitoring and reviewing this information.

9.1.3 Analysis and evaluation requires the organization to analyze and evaluate appropriate data and information arising from monitoring and measurement. Furthermore, it requires that the results of analysis be used to evaluate conformity of products and services, the degree of customer satisfaction, the performance and effectiveness of the quality management system, if planning has been implemented effectively, the effectiveness of actions taken to address risks and opportunities, the performance of external providers, and the need for improvements to the quality management system.

9.2 Internal audit

9.2.1 Requires the organization to conduct internal audits at planned intervals to provide information on whether the quality management system conforms to the organization's own requirements for its quality management system, as well as the requirements of ISO 9001:2015, and to ensure that the quality management system is effectively implemented and maintained.

9.2.2 Requires the organization to plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which must take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. The organization is further required to define the audit criteria and scope for each audit, to select auditors and conduct audits to ensure objectivity and the impartiality of the audit process, to ensure that the results of the audits are reported to relevant management, to take appropriate correction and corrective actions without undue delay, and to retain documented information as evidence of the implementation of the audit program and the audit results.

9.3 Management review

9.3.1 General requires top management to review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

9.3.2 Management review inputs stipulates that the management review be planned and carried out taking into consideration the status of actions from previous management reviews, any changes in external and internal issues that are relevant to the quality management system, any information on the performance and effectiveness of the quality management system, including trends in customer satisfaction/feedback from relevant interested parties, the extent to which quality objectives have been met, process performance and conformity of products and services, nonconformities and corrective actions, monitoring and measurement results, audit results, and the performance of external providers. It further requires that inputs include a discussion of the adequacy of resources, the effectiveness of actions taken to address risks and opportunities (per 6.1), and any opportunities for improvement.

9.3.3 Management review outputs requires the outputs of the management review to include decisions and actions related to opportunities for improvement, any need for changes to the quality management system, and resource needs. It further requires the organization to retain documented information as evidence of the results of management reviews.

10 – Improvement

10.1 General requires the organization to determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. It further requires that improvement action must include improving products and services to meet requirements as well as to address future needs and expectations, as well as correcting, preventing or reducing undesired effects and improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and corrective action

10.2.1 Requires that when a nonconformity occurs, including those arising from complaints, the organization must react to the nonconformity and, as applicable take action to control and correct it and deal with the consequences. Furthermore, it requires the organization to evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by reviewing and analyzing the nonconformity, by determining the causes of the nonconformity, by determining if similar nonconformities exist, or could potentially occur, by implementing any action needed, by reviewing the effectiveness of any corrective action taken, updating risks and opportunities determined during planning, if necessary, and by making changes to the quality management system, if necessary. Furthermore it requires that corrective actions be appropriate to the effects of the nonconformities encountered.

10.2.2 Requires the organization to retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken, as well as the results of any corrective action.

10.3 Continual improvement requires the organization to continually improve the suitability, adequacy and effectiveness of the quality management system.

CONCLUSION

Since its initial release in 1987, the ISO 9001 quality management systems standard has had an enormous impact on thousands of organizations around the world.

In the short run, implementing an ISO 9001:2015 quality management system has a major and positive impact on quality, productivity and cost reduction. And ISO 9001:2015 registration can give American businesses unmatched credibility and competitive advantages in the European Union.

In the long run, ISO 9001:2015 implementation and registration will preserve and create domestic and international markets for American businesses in virtually every field. Even now, many major American businesses and government agencies are requiring ISO 9001:2015 registration as a supplier quality assurance qualification.

The 2015 standard furthers a tradition of flexibility, and through its alignment with Annex SL ensures that the organization can easily and seamlessly incorporate as many additional standards (ISO 14001, ISO 50001, etc.) as it sees fit.

THE STANDARD SHOULD BE OBTAINED FROM WWW.ISO.ORG OR WWW.ANSI.ORG.