The 9000 Advisers

List of Quality System Standards

ISO 9000, ISO 9001 and ISO 9004

The ISO 9000 family of standards has been developed to assist organizations of all types and sizes to implement and operate effective quality management systems.

ISO 9000:2000 – Quality Management Systems – Fundamentals and Vocabulary
ISO 9000 describes fundamentals of quality management systems and specifies the terminology for quality management systems.

ISO 9001:2000 – Quality Management Systems – Requirements
ISO 9001 specifies requirements for a quality management system that can be used by any organization. This is the standard against which an organization can achieve registration, via a qualified third party audit.

The primary focus of the ISO 9001 standard is to address customer satisfaction through the use and continual improvement of quality planning and objectives. The standard requires that organizations utilize a process approach to achieve these goals.

The design and implementation of an organization's quality management system should be unique to that organization and should be influenced by customer needs, key quality objectives, the products and/or services provided, the specific processes/methods employed and the size and structure of the organization. It is not the purpose of ISO 9001 to imply uniformity in the structure of quality management systems or uniformity of documentation.

ISO 9004:2000 – Quality Management Systems – Guidelines for performance improvements
ISO 9004 provides guidelines to organizations for performance improvement. It is based on the same quality management principles as ISO 9001. This standard provides guidance on the application of quality management and describes what processes quality management systems should encompass. The goal of ISO 9004 is to assist an organization in establishing and improving its quality management system along with improving the processes of an organization in order to enhance performance.

ISO/TS 16949

ISO/TS 16949:2002 - Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations

This updated version of ISO/TS 16949 has been changed to integrate the ISO 9001:2000 requirements with automotive industry specific requirements.

ISO/TS 16949 is an ISO Technical Specification written in conjunction with the International Automotive Task Force (IATF), which consists of an international group of vehicle manufacturers, plus national trade associations. The specification aligns existing American (QS-9000), German (VDA6.1), French (EAQF) and Italian (AVSQ) automotive quality systems standards within the global automotive industry.

The 9000 Advisers

Many organizations are transitioning their current QS-9000 quality management systems to meet the requirements of ISO/TS 16949:2002. The reason for this transition is due to the scheduled obsolescence of QS-9000 in the year 2006.

ISO 14001

ISO 14001 - 2004 - Environmental Management Systems - Requirements with Guidance for Use

ISO 14001 is an environmental management system standard developed with the idea that implementing the standard should result in improved industry environmental performance. The standard utilizes a "plan, implement, check and review" approach to facilitate proactive environmental management.

ISO 14001 requires that an organization examine its processes and activities to identify significant environmental aspects the organization can control and over which it can be expected to have an influence. The standard can be used by any company, facility, or organization of any size, anywhere in the world. While ISO 14001 is likely to be used in manufacturing or processing industries, it also can be applied to virtually any service type organization.

AS9100

AS9100 - Quality Systems Aerospace - Model for Quality Assurance in Design, Development, Production, Installation and Servicing

Published by SAE - Society for Automotive Engineers, AS9100:2001 is based on ISO 9001:2000 and adds specific requirements that are critical for the aerospace industry.

AS9100 was developed using the ISO 9001, AS9000, and EN9000-1 standards and is a compilation of their requirements to produce a truly global standard that meets the requirements of aerospace companies worldwide. Since AS9100 is for use as a global aerospace community standard, AS9100 adds the additional requirements necessary to address both civil and military aviation along with other aerospace industry needs.

AS9003

AS9100 - Quality Systems Aerospace

AS9003 is based on the ISO 9000:1994 version which is tailor-made for small machine shops. This is the alternative for small organizations to become certified to the AS9100 standard. AS9003 contains the minimum requirements for supplier inspection and test quality system.

ISO/IEC 17025

ISO/IEC 17025- General Requirements for the competence of testing and calibration laboratories

Based upon ISO 9001, but designed for the special needs of testing laboratories, ISO/IEC 17025 addresses the proficiency of an organization to perform the testing and calibration activities.

ISO/IEC 17025 provides a framework for quality specifically for organizations that want to control their laboratory processes and are seeking to achieve third party accreditation. ISO/IEC 17025 covers all areas of laboratory management, including such items as sample preparation, analytical testing proficiency, record keeping, reports accommodation and environmental conditions, document control and corrective/preventive action.

ISO 19011

ISO 19011:2002 - Guidelines on Quality and/or Environmental Management Systems Auditing

ISO 19011:2002 replaces ISO 10011, ISO 14010, ISO 14011 and ISO 14012. By utilizing this new standard, organizations can save time, effort and money by reducing duplication of effort when conducting combined environmental and quality audits.

The standard offers a set of guidelines and principles that will enable anyone connected with an audit to perform effectively. The standard focuses primarily on the underlying processes of audit management so it can be adapted for use when auditing any management system.

OHSAS 18001

OHSAS 18001 - Occupational Health and Safety Management Systems-Specifications

OHSAS 18001 is an assessment specification for health and safety management systems and gives requirements for an occupational health and safety (OH&S) management system. The intent is to enable an organization to control its OH&S risks and improve its performance.

OHSAS 18001 was developed in response to widespread demand for a recognized standard against which a company could be certified and assessed and could meet their health and safety obligations in an efficient manner.

ISO 13485

ISO 13485:2003 - Medical devices - Quality management systems - Requirements for regulatory purposes

ISO 13485:2003 is a Quality Management System for medical devices, specifically for regulatory purposes. It is based on ISO 9001:2000 with some modifications. The standard includes a process model similar to that of ISO 9001:2000 but requires more documented procedures that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The ISO 13485:2003 standard is an update and compilation of the older ISO 13485:1996 & ISO 13488:1996 standards. This update was in response to the publication of ISO 9001:2000.

The ISO 13485:2003 standard does not reference the requirements of ISO 9001 but does provide medical device manufacturers with a standalone standard for quality management systems that need to demonstrate compliance to regulatory requirements.

ISO 15189

ISO 15189:2003 – Medical laboratories — Particular requirements for quality and competence

Published by the International Organization for Standardization, ISO 15189 is an ISO 9001:2000-based sector-specific standard intended to replace ISO/IEC 17025 for medical laboratories.

The full text of ISO 15189 contains many of the requirements of ISO 9001:2000 with supplemental guidance for implementation in laboratories based on ISO/IEC 17025:1999, general requirements for the competence of testing and calibration laboratories.

ISO 15189:2003 is an alternative to ISO 17025 for medical laboratories. It closely follows the structure of ISO/IEC 17025 (as shown in the correlation table of Annex A), but includes additional requirements specific to medical laboratories.