



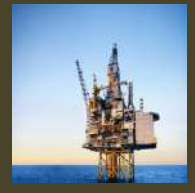
# Deming Certification & Rating Pvt. Ltd.

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## ISO 80369-20:2015 - Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods.

### What is ISO80369-20-2015 – Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods?

The **ISO 9000** family of quality management systems (QMS) is a set of standards that helps organizations ensure they meet customer and other stakeholder needs within statutory and regulatory requirements related to a product or service. ISO 9000 deals with the fundamentals of QMS, including the seven quality management principles that underlie the family of standards. ISO 9001 deals with the requirements that organizations wishing to meet the standard must fulfill.

Third-party certification bodies provide independent confirmation that organizations meet the requirements of ISO 9001. Over one million organizations worldwide are independently certified, making ISO 9001 one of the most widely used management tools in the world today. However, the ISO certification process has been criticized as being wasteful and not being useful for all organizations.

## Background

ISO 9000 was first published in 1987 by the International Organization for Standardization (ISO). It was based on the BS 5750 series of standards from BSI that were proposed to ISO in 1979. However, its history can be traced back some twenty years before that, to the publication of government procurement standards, such as the United States Department of Defense MIL-Q-9858 standard in 1959, and the United Kingdom's Def Stan 05-21 and 05-24. Large organizations that supplied government procurement agencies often had to comply with a variety of quality assurance requirements for each contract awarded, which led the defense industry to adopt mutual recognition of NATO AQAP, MIL-Q, and Def Stan standards. Eventually, industries adopted ISO 9000 instead of forcing contractors to adopt multiple—and often similar—requirements.

## Reasons for use

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The global adoption of ISO 9001 may be attributable to a number of factors. In the early days, the ISO 9001 (9002 and 9003) requirements were intended to be used by procuring organizations, such as contractors and design activities, as the basis of contractual arrangements with their suppliers. This helped reduce the need for subcontract supplier quality development by establishing basic requirements for a supplier to assure product quality. The ISO 9001 requirements could be tailored to meet specific contractual situations, depending on the complexity of the product, business type (design responsibility, manufacture only, distribution, servicing etc.) and risk to the procurer. If a chosen supplier was weak on the controls of their measurement equipment (calibration), and hence QC/inspection results, that specific requirement would be invoked in the contract. The adoption of a single quality assurance requirement also leads to cost savings throughout the supply chain by reducing the administrative burden of maintaining multiple sets of quality manuals and procedures.

A few years later, the UK Government took steps to improve national competitiveness following the publication of cmd 8621, and Third-Party Certification of Quality Management Systems was born, under the auspices of the National Accreditation Council of Certification Bodies (NACCB), which has become the United Kingdom Accreditation Service (UKAS).

In addition to many stakeholders' benefits, a number of studies have identified significant financial benefits for organizations certified to ISO 9001, with an ISO analysis of 42 studies showing that implementing the standard does enhance financial performance. Corbett *et al.* showed that certified organizations achieved a superior return on assets compared to otherwise similar organizations without certification.

Heras *et al.* found similarly superior performance and demonstrated that this was statistically significant and not a function of organization size. Naveha and Marcus claimed that implementing ISO 9001 led to superior operational performance in the U.S. automotive industry. Sharma identified similar improvements in operating performance and linked this to superior financial performance. Chow-Chua *et al.* showed better overall financial performance was achieved for companies in Denmark. Rajan and Tamimi (2003) showed that ISO 9001 certification resulted in superior stock market performance and suggested that shareholders were richly rewarded for the investment in an ISO 9001 system.

While the connection between superior financial performance and ISO 9001 may be seen from the examples cited, there remains no proof of direct causation, though longitudinal studies, such as those of Corbett *et al.* (2005), may suggest it. Other writers, such as Heras *et al.* (2002), have suggested that while there is some evidence of this, the improvement is partly driven by the fact that there is a tendency for better-performing companies to seek ISO 9001 certification.

The mechanism for improving results has also been the subject of much research. Lo *et al.* (2007) identified operational improvements (e.g., cycle time reduction, inventory reductions) as following from certification. Internal process improvements in organizations lead to externally observable improvements. The benefit of increased international trade and domestic market share, in addition to the internal benefits such as customer satisfaction, interdepartmental communications, work processes, and customer/supplier partnerships derived, far exceeds any and all initial investment.

## Certification

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The International Organization for Standardization (ISO) does not certify organizations themselves. Numerous certification bodies exist, which audit organizations and upon success, issue ISO 9001 compliance certificates. Although commonly referred to as "ISO 9000" certification, the actual standard to which an organization's quality management system can be certified is ISO 9001:2015 (ISO 9001:2008 expired around September 2018). Many countries have formed accreditation bodies to authorize ("accredit") the certification bodies. Both the accreditation bodies and the certification

bodies charge fees for their services. The various accreditation bodies have mutual agreements with each other to ensure that certificates issued by one of the accredited certification bodies (CB) are accepted worldwide. Certification bodies themselves operate under another quality standard, ISO/IEC 17021, while accreditation bodies operate under ISO/IEC 17011.

### List of International Organization for Standardization standards

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This is a list of published International Organization for Standardization (ISO) standards and other deliverables. For a complete and up-to-date list of all the ISO standards, see the ISO catalogue.

The standards are protected by copyright and most of them must be purchased. However, about 300 of the standards produced by ISO and IEC's Joint Technical Committee 1 (JTC 1) have been made freely and publicly available.



#### ISO Brand

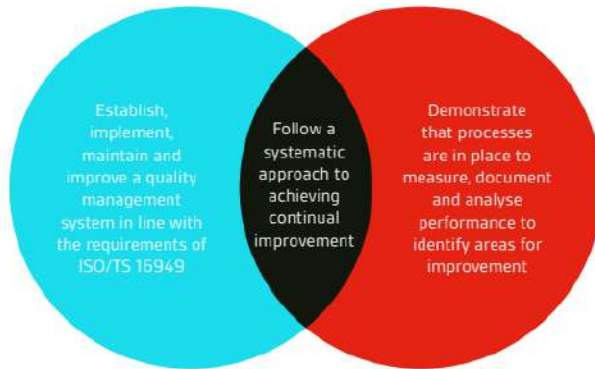
This is a dynamic list and may never be able to satisfy particular standards for completeness. You can help by adding missing items with reliable sources.

Which of the ISO standard provide guidelines for management system?

ISO 27001: Information Security Management System

ISO 27001 is the standard for an Information Security Management System (ISMS). The basic objective of the standard is to provide a model for establishing and maintaining an effective IT information management system based on the process approach.

**The principal requirements of the standard are illustrated below:**



The next few pages of the guide takes you through the Plan-Do-Check-Act (PDCA) methodology, common in all ISO management systems and how DCS can help and support you on your ISO/TS 16949 journey.

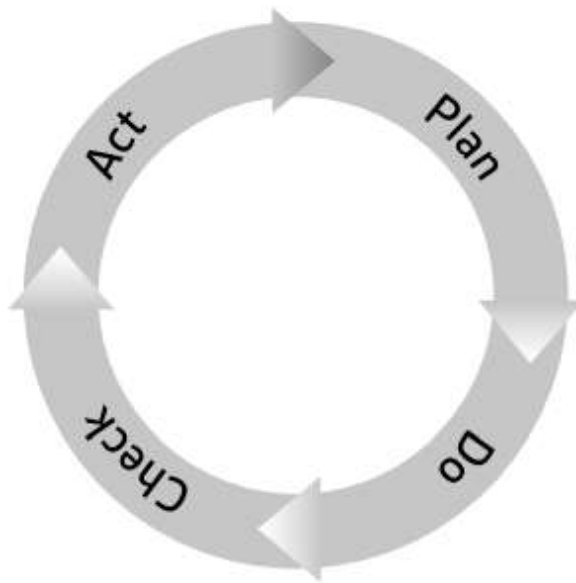
### Understanding the principles of continual improvement

#### Act

Correct and improve your plans to meet and exceed your planned results

#### Check

Measure and monitor your actual results against your planned objectives



#### Plan

Establish objectives and draft your plans (analyse your organization's current systems, establish overall objectives, set interim targets for review and develop plans to achieve them)

#### Do

Implement your plans within a structured management framework