



# PERRY JOHNSON REGISTRARS, INC.



## ISO 9001 Overview

### **What is ISO 9001?**

Under the official title “Quality Management Systems – Requirements,” ISO 9001's official scope statement has remained unchanged over its last three editions and is as follows:

*“This International Standard specifies requirements for a quality management system when an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.”*

Since the scope statement is a vital part of understanding what ISO 9001 is all about, it should be fully understood. The opening declaration establishes a key requirement for the entire standard as a whole and any person or party wishing to use it. Namely: ISO 9001 is *not* a product standard. It does not seek or intend to define how a product is manufactured. Rather, the organization seeking ISO 9001 certification is expected to define for itself how products are made and controlled.

The further inclusion of services within the scope statement is also crucial. In the early years of ISO 9001, the predominant thought was that the standard was mainly geared toward organizations manufacturing tangible products. Over time, however, it became clear that the principles of ISO 9001 offered benefits to service-based organizations as well as manufacturers.

Perhaps the central pillar of the ISO 9001 standard is its demand that organizations are attuned, receptive, and responsive to their customers' needs. The final words of the scope subsequently acknowledge the ongoing, ever-changing nature of a quality management system; it is not something that can be implemented and then ignored to run as-is in perpetuity. The additional inclusion of the word “improvement” is a direct callout that foreshadows the importance of improvement in the overall execution of ISO 9001.



## ***Where do ISO standards come from?***

ISO is the common name for the International Organization for Standardization, a collective made up of many international members. Founded in its current form in 1947, the ISO not only publishes certification standards for a variety of industries and operations, but also produces technical reports, specifications, corrigenda, and guides on various topics. Each ISO standard is assigned its own Technical Committee (TC) for authorship. ISO 9001 is overseen by TC 176, which includes representation from each of the major industrialized nations.

## ***What is Annex SL and what does it mean?***

Annex SL is a key document which was developed three years prior to the publication of ISO 9001:2015 by a special ISO committee called the Joint Technical Coordination Group (JTCG). It has been referred to as the “High Level Outline” or “Annex SL” as a part of a larger ISO publication called “ISO/IEC Directives Part 1 – Consolidated ISO Supplement – Procedures Specific to ISO.”

A 10-section “blueprint” for authoring all of the ISO-family standards, Annex SL promotes (among other things) utilization of common terms and core definitions. Prior to the introduction of Annex SL, different terms were used between standards to refer to similar or identical concepts, which led to no small amount of confusion, especially for organizations seeking certification to more than one standard. Most of the ISO standards have at the time of this document's publication completed their transition to Annex SL format.

There are seven auditable sections to Annex SL: Section 4 (context of the organization), Section 5 (leadership and commitment), Section 6 (planning), Section 7 (support), Section 8 (operation), Section 9 (performance evaluation), and Section 10 (improvement). A full copy of Annex SL may be downloaded free of charge from the ISO website – [www.iso.org](http://www.iso.org).

## ***ISO 9001:2015 Key Ideas***

Some of more important fundamental ideas presented in ISO 9001 include scope, processes, accountability, effectiveness, and improvement.

Early in the standard (4.3), the organization is directed to develop a “scope statement.” A scope statement represents the extent and boundaries of the quality management system. Ideally, the scope statement developed will be the same as that shown on the ISO 9001:2015 certificate issued by your certification body. It is important to note that an item unavailable for auditing (such as newly-purchased equipment that is not yet running) should not be added to the scope; anything included in the scope *must* be available for audit.

Another early core idea in ISO 9001 is the determination of processes and how they interface with each other (section 4.4).





This portion of the standard states that a quality management system is made up of processes. The concept of “process” is a key one in the realm of ISO standards, and PJR encourages organizations to make their processes as personal and unique to their business model as possible. By personalizing processes, it can help ensure the the quality management system is adding value to the organization and that it is understood by all. A point of caution regarding processes: they should not be, if at all possible, named after sections of the ISO 9001 standard.

Accountability is most directly addressed in Section 5.1.1; the standard demands that Top Management make itself accountable for the efficacy of the quality management system. This key idea is also demanded in clause 8.6 (product release records must “name names”), clause 10.2 (problems must be responded to with appropriate systemic action), and several others.

There are several requirements in ISO 9001:2015 that require the organization to measure the effectiveness of something. The idea is that the organization should know at any given time how well – or how poorly – things are going in their operation. The idea of effectiveness begins and is most succinctly established in clause 4.4.1c where it is stated that the organization must:

*“determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of processes.”*

Other clauses where the idea of effectiveness measures comes up include: 6.2.1, 7.2, 8.4, 8.6, 9.1.2, 9.1.3, 9.2, 9.3, and 10.1.

The final pillar of the standard, improvement, is explored primarily in section 10.1 of ISO 9001:2015. This clause indicates that the organization must identify and choose opportunities for improvement, implementing any necessary actions to meet customer requirements and enhance satisfaction. “Improvement” represents an evolution of an older concept called “continual improvement.” In its current form, improvement is acknowledged as being possible in a number of key ways, including reactive changes and breakthroughs. Improvement is further referenced throughout ISO 9001:2015 in the following sections: 4.4, 5.1.1, 5.2.1D, 5.3C, 6.1.1D, 7.1.1, 7.3, and 9.3.2F.

## **Conclusion**

As daunting as ISO certification may seem to those unfamiliar, ISO 9001:2015 is possibly the best starting point for an organization looking to “get their feet wet” with certification. Over 900,000 companies are registered to ISO 9001 worldwide, easily making it the most widely-utilized standard. It is important to keep in mind the big picture of what the standard is promoting: consistent, satisfactory products and services that meet requirements through a system of improvement and assurance.

For more information on ISO 9001:2015, including free webinars, online training, and other complimentary resources, visit our website at [www.pjr.com](http://www.pjr.com).

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