

ISO 9001:2015 – An introduction to the world's most popular standard

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Overview of topics

- What is ISO 9001?/Deconstructing the Scope Statement of ISO 9001
- Where do ISO standards come from?
- The impact of Annex SL
- ISO 9001:2015 “Cover to Cover”
- ISO 9001:2015 Key Ideas
- Concluding remarks/Questions

What is ISO 9001?

- ISO 9001 is officially titled “Quality management systems – requirements.”
- It's intent is provided in Section 1.0 “Scope” (this statement is unchanged in the past three editions of ISO 9001)
- *“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.”*

Deconstructing the scope statement

- Let's examine this scope piece by piece, as it is a vital part of understanding what ISO 9001 is all about.
 - *"This International Standard specifies requirements for a quality management system..."*
- The opening declaration establishes a key requirement for the entire standard and any person/party that wishes to use it. Namely, that ISO 9001 is not a product standard. It does not seek or intend to define how a product is manufactured.
- The organization that seeks certification to ISO 9001 is still expected to define for itself how the products are made and controlled.

Deconstructing the scope statement

- “...when an organization needs to demonstrate its ability to consistently provide products and services ...”
- The scope continues with another key statement – the inclusion of services.
- In the early years of ISO 9001, the thought was that it was primarily geared to organizations that manufactured tangible products. As time progressed, it was clear that the principles of ISO 9001 offered equal benefit to services based organizations.

Deconstructing the scope statement

- *“...that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction...”*
- Perhaps the central cornerstone of the ISO 9001 standard is its demand that organizations be attuned, receptive, and responsive to the needs of their customers.

Deconstructing the scope statement

- *“...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.”*
- These final statements acknowledge the ongoing nature of a quality management system (it's not something you implement and forget about!)
- Additionally, the inclusion of “improvement” as a direct callout is also foreshadowing the importance of improvement on the overall nature of ISO 9001.

Where do these standards come from?

- The International Organization for Standardization (ISO) is a collective made up of numerous international members;
- Each standard is assigned a Technical Committee (TC) for authorship;
- TC 176 is the Technical Committee assigned to ISO 9001;
- TC 176 includes members from each of the major industrialized nations;
- American National Standards Institute (ANSI)

How is ISO 9001:2015 organized?

- To understand the ordering of clauses and content within ISO 9001:2015, we must first explore a key document that was developed three years before ISO 9001:2015's publication – Annex SL.

What is Annex SL?

- Annex SL has also been referred to as the “High Level Outline” or “Annex XL.”
- Annex SL is part of a larger ISO publication called “ISO/IEC Directives Part 1 – Consolidated ISO Supplement – Procedures Specific to ISO.”
- ISO/IEC Directives Part 1 (and Annex SL therein) can be downloaded for free from the ISO website – www.iso.org

More details about Annex SL

- Annex SL was first published in 2012 and represented the output of a special committee of the ISO called the Joint Technical Coordination Group (JTCCG.)
- A 10 section “blueprint” for authoring all of the ISO family of standards.
- Annex SL promotes (among other things) utilization of common terms and core definitions.
- All standards published by ISO have completed their transition to Annex SL format.

Example of how Annex SL works

Annex SL Clause 9.2.1

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the XXX management system:

a) conforms to:

the organization's own requirements for its XXX management system;

the requirements of this International Standard/this part of ISO XXXX/this Technical Specification;

b) is effectively implemented and maintained.

ISO 9001:2015 Clause 9.2.1

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the **quality** management system:

a) conforms to:

1) the organization's own requirements for its **quality** management system;

2) the requirements of this International Standard;

b) is effectively implemented and maintained.

Annex SL includes 7 auditable sections – beginning with Section 4

- 4 Context of the organization
 - understanding the organization and its context
 - understanding the needs and expectations of interested parties
 - determining the scope of the quality management system
 - quality management system and its processes

Annex SL Sections 5 and 6

- 5 Leadership and Commitment
 - general
 - customer focus
 - policy
 - organizational roles, responsibility and authority
- 6 Planning
 - actions to address risks and opportunities
 - quality objectives and planning to achieve them
 - planning of changes

Annex SL Sections 7 and 8

○ 7 Support

- resources
- competence
- awareness
- communication
- documented information

○ 8 Operation

- operational planning and control
- requirements for products and services
- design and development of products and services
- control of externally provided processes, products, and services
- production and service provision
- release of products and services
- control of nonconforming outputs

Annex SL Sections 9 and 10

- 9 Performance evaluation
 - monitoring, measurement, analysis and evaluation
 - internal audit
 - management review
- 10 Improvement
 - general
 - non-conformity and corrective action
 - continual improvement

ISO 9001:2015 – Cover to Cover

- Introduction Section
 - 0.1 – General: Provides an overview statement, intentions on whom the standard benefits, introduces the ideas of Risk Based Thinking, PDCA, and explains four key terms (three of these are getting official definitions for the first time):
 - Shall – mandatory requirement (numerous instances);
 - Should – recommendation (no uses within the auditable content);
 - May – permission (this term appears once in the auditable content); and
 - Can – possibility or capability – numerous instances.

ISO 9001:2015 – Cover to Cover

- Introduction Section

- 0.2 – Seven Quality Management Principles – reference to the ISO 9000 standard is given:
 - Customer Focus;
 - Leadership;
 - Engagement of People;
 - Process Approach;
 - Improvement;
 - Evidence-Based Decision Making; and
 - Relationship Management.
- 0.3 – Process Approach – reinforcement of the process approach and an improved graphic therein. Reinforcement of Plan-Do-Check-Act (PDCA) and an improved graphic therein.

ISO 9001:2015 – Cover to Cover

- Introduction Section
 - 0.3.3 – Risk Based Thinking – definition and explanation of importance
 - 0.4 – Relationship with other management system standards (ISO 9000 and ISO 9004)

ISO 9001:2015 – Cover to Cover

- Section 1 – Scope – General verbiage related to the applicability of ISO 9001;
- Section 2 – Normative Reference – Linkage to ISO 9000:2015 for all official terms and definitions;
- Section 3 – Terms and Definitions – currently without content, but could be used as a future placeholder for ISO 9001 specific definitions.

ISO 9001:2015 – Cover to Cover

- Sections 4-10 – As previously reviewed;
- Annex A – Informative – Several key points of information and counsel to be found here, including:
 - A.1 – Structure and terminology – reinforces the doctrine that an organization does not have to align their documentation to match ISO 9001:2015, nor does it have to use the specific terms found in the standard;
 - A.2 – Products and services – a fuller explanation of intent in changing all references of “product” to read “products and services”;
 - A.3 – Understanding the needs and expectations of interested parties – a more full explanation of intent in the identification of interested parties;
 - A.4 – Risk based thinking- an extensive section intended to assist in the more full understanding of this concept, emphasizing that a formal structure/process for Risk Management is not required;

ISO 9001:2015 – Cover to Cover

- Annex A continued
 - A.5 – Applicability – Further discussion on the logic for removing “exclusions” from the ISO 9001 standard and the new concept of “non-applicables”
 - A.6 – Documented Information – Further discussion on the new term that has replaced “Procedure”, “Record”, and “Document”;
 - A.7 – Organizational Knowledge – An explanation of requirements pertaining to competency and ongoing competency through various challenges an organization might face;
 - A.8 – Control of externally provided products and services – Provides an expansive explanation of this phrase and who it applies to.

ISO 9001:2015 – Cover to Cover

- Annex B – Further, extensive discussion on the relationship between ISO 9001 and other publications (ISO 9004, ISO 10001, etc.)
- Bibliography

Key ideas found in ISO 9001

- Over the next several slides, I'd like to give you an introduction to some of the more important fundamental ideas postulated by ISO 9001, including clausal linkages where possible.
 - Scope
 - Processes
 - Accountability
 - Effectiveness
 - Improvement

Key Idea 1 - Scope

- Early in the standard (Section 4.3) the Organization is directed to develop a “Scope Statement.”
- A Scope statement represents the extent and boundaries of your quality management system. Here are a few examples:
 - *Design, Fabrication and Assembly of Collapsible Tripods;*
 - *Distribution of Fasteners;*
 - *Plating, Heat Treating, Sorting of Metal Stampings.*

Key Idea 1 - Scope

- Ideally, the scope statement that you develop will eventually be the same as that shown on the ISO 9001:2015 certificate issued by PJR.
- Don't list an item on your scope that won't be available for audit.
 - An organization that has "Field Installation" in their scope statement needs to provide for a remote audit of the "Field Installation" activity if it is to be listed on the certificate.
 - An organization that has purchased new equipment that isn't up and running yet.

Key Idea 1 - Scope

- Be careful about being too “wordy” in your scope statement. Consider the following scenario. An organization has the following as their scope statement:

“Laser Cutting, Waterjet Cutting, Progressive Die Cutting, Plating, Heat Treating, and Distribution of Flanges, Springs, Shims, Bolts, and Barrels.”

- In the above example – PJR has to audit:
 - *Laser Cutting,*
 - *Waterjet Cutting,*
 - *Progressive Die Cutting,*
 - *Plating,*
 - *Heat Treating, and*
 - *Distribution*

(continues on next slide)

Key Idea 1 - Scope

“Laser Cutting, Waterjet Cutting, Progressive Die Cutting, Plating, Heat Treating, and Distribution of Flanges, Springs, Shims, Bolts, and Barrels.”

- We also have to ensure the following product groups are sampled:
 - *Flanges,*
 - *Springs,*
 - *Shims,*
 - *Bolts, and*
 - *Barrels.*

Key Idea 2 - Processes

- Another core idea that is first mentioned early (Section 4.4) is the directive that organizations determine what their processes are and how they interface with each other.
- Section 4.4 states that a quality management system is made up of processes.
- The concept of “Process” is a key one in the world of ISO standards. PJR has an entire webinar called “The Interaction of Processes and its importance to a successful audit” that covers this topic in great depth.

Key Idea 2 – Processes

- The concept of Processes cascades throughout the ISO 9001 standard, including (but not limited to) the following clauses:
 - “Use of the process approach” is first mentioned in clause 5.1.1d;
 - Aligning quality objectives to processes is discussed in clause 6.2.1;
 - Ensuring competent staff for available for all processes is discussed in clauses 7.1.2 and 7.1.6
 - Ensuring effective infrastructure for all processes is discussed in clause 7.1.3
 - Control over “external” processes is discussed in clause 8.4
 - Review of process performance is specified in clause 9.3.2c3

Key Idea 2 - Processes

- PJR encourages you to make your processes as personal and unique to your business as possible.
 - This will go a long way to ensuring that your quality management system is adding value to your organization and that you understand it.
- Resist the urge to name your processes after the sections of the ISO 9001 standard!

Key Idea 3 – Accountability

- ISO 9001:2015 demands inclusion of all persons that fall within the scope of the quality management system.
- This inclusion is most directly addressed in Section 5.1.1, where the standard demands that Top Management make itself accountable for the effectiveness of the quality management system.

Key Idea 3 - Accountability

- Other key places where accountability is demanded:
 - Product release records must “name names” (clause 8.6);
 - Problems (including complaints) must be responded to with appropriate systemic action (clause 10.2);
 - Organizations must define roles, responsibilities, and authorities (clause 5.3);
 - All personnel must be cognizant of the quality policy (clause 5.2.2B), and how they contribute to the effectiveness of the quality management system (clause 7.3.)

Key Idea 4 – Effectiveness

- ISO 9001:2015 has numerous requirements 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.

Key Idea 4 - Effectiveness

- This basic idea of effectiveness measures begins and is most succinctly established in clause 4.4.1c where it states 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”*

Key Idea 4 - Effectiveness

- Other key areas where the idea of effectiveness measures is discussed:
 - Tracking of quality objectives (6.2.1);
 - Evaluation of competency actions (7.2);
 - Evaluation of external provider performance (8.4);
 - Product/service inspection (8.6);
 - Customer satisfaction (9.1.2);
 - Overall trending of the quality management system (9.1.3);
 - Assessment of the system via internal audit (9.2);
 - Review of key system aspects via management review (9.3); and
 - Efforts targeting improvement (10.1)

Key Idea 5 – Improvement

- The final cornerstone concept we will explore today is Improvement.
- As currently referenced, Improvement represents an evolution of an older concept called “Continual Improvement.”
- The current concept of Improvement acknowledges that improvement is possible in a number of key ways (continual improvement, reactive changes, breakthroughs, etc.)

Key Idea 5 - Improvement

- Improvement is explored primarily in section 10.1 of ISO 9001:2015. This clause indicates that that organization must:
 - *“The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.”*

Key Idea 5 – Improvement

- Like the other key ideas we've discussed today, Improvement is revisited as a concept again and again throughout the ISO 9001:2015 standard.
 - Section 4.4 – states that the organization must “continually improve” its quality management system.
 - Section 5.1.1 – states that management must “promote improvement”;
 - Section 5.2.1D – states that the Quality Policy must address continual improvement;

(list continued on the next slide)

Key Idea 5 – Improvement

- Section 5.3C – states that assigned responsibilities must include reporting on opportunities for improvement;
- Section 6.1.1D – states that risk action efforts should target improvement;
- Section 7.1.1 – states that resources should enable the organization to achieve continual improvement;
- Section 7.3 – states that persons who work for the organizations should be aware that their efforts impact improvement; and
- Section 9.3.2F – statement that opportunities for improvement should be among the items discussed in management review meetings.

What about the new version of ISO 9001?

- You may have heard some chatter about a new version of ISO 9001 coming out. While it is true that the committee has begun working in a preliminary fashion, we know very little about what's coming and have no firm dates in terms of publication or transition timeline.
- The only firm new/revised requirement pertains to Climate Change – let's explore this concept just a bit further.

The “Climate Change” amendment

- In late February 2024 – the ISO took the unusual step of publishing an amendment to ISO 9001 without reissuing the standard in whole.
- This amendment was published on the ISO website and is actually free to acquire.
- This amendment specified two clausal updates. Let’s review what those statements specifically said in the broader context of the standard itself.

Section 4.1 – updated with “Climate Change” language

- *The organization shall 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.*
- *The organization shall monitor and review information about these external and internal issues.*
- *The organization shall determine whether climate change is a relevant issue.*

Section 4.2 – updated with “Climate Change” language

- *Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:*
 - *a) the interested parties that are relevant to the quality management system;*
 - *b) the requirements of these interested parties that are relevant to the quality management system.*
- *The organization shall monitor and review information about these interested parties and their relevant requirements.*
- *Note: Relevant interested parties can have requirements related to climate change.*

What do these “Climate Change” updates mean for my company?

- The IAF (the official governing body over audit activities) issued the following guidance for assessment of these two new clauses:
- *Certified organizations should ensure that they have considered Climate Change aspects and risks within the development, maintenance, and effectiveness of their own management system(s). Climate Change, along with other issues, should be determined as relevant or not and if so, considered within an evaluation of risk, within the scope of the management systems standards.*
- *With the new additions on Climate Change, Certification Bodies are expected to ensure that Climate Change has been considered and if determined to be a relevant issue for its management system, included in any objectives and mitigation activities by the organization, as required. If it was considered not to be a relevant issue by the organization for its management system, the CB is expected to ensure the effectiveness of the organization's process to make this determination and implementing related actions, when applicable.*

What does all that mean in plain English?

- Essentially our expectation is going to be that you have considered Climate Change as a potential relevant issue to your quality management system and have acted accordingly.
- It is absolutely possible for an organization to conclude that climate change has no bearing on them or their interested parties – we just need to be able to see evidence of how that decision was reached.

Conclusion

- ISO 9001:2015 remains the world's most utilized standard (just over 900,000 registered companies.)
- Organizations seeking certification to ISO 9001:2015 would do well to bear in mind the “big picture” of what ISO 9001:2015 seeks to promote.

Ready for a deeper dive?

- PJR also has a “clause by clause” primer course for anyone who is new to ISO 9001:2015 and needs to have a better understanding in preparation for audit or other purposes.
 - The title for this course is *“ISO 9001:2015: A Clause By Clause Analysis”*
- The course can be found on our website and is free!

Please tune in for one of our other webinars

- *“ISO 9001:2015 – Anticipating Auditor Expectations in Key Areas”*
 - This webinar explores what some of the more common “issues” are in ISO 9001:2015 audits and what is typically expected for these areas.
- *“Your Ongoing Relationship with PJR”*
 - This brand-new webinar explores the various resources that PJR has at its disposal for those times when things change in your organization. It will also include an in-depth review of the unpleasant (but necessary) dispute process.
- *“The Interaction of Processes and its importance to a successful audit.”*
 - This webinar explores the crucial topic of processes and how to correctly understand them.
- We offer a variety of webinars on other topics including Stage 1 Audits, AS9100, ISO 13485:2016, IATF 16949, and ISO 14001:2015.

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