



Annex SL: the core of your ISO journey

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Annex SL, simply put, is the starting point of your journey to compliance and accreditation with any major ISO standard, from 9001 and 27001 to 13485 and 17025.

Annex SL and its associated appendices provide a standardized and consistent management system structure around which all modern ISO standards are structured.

Crack Annex SL and its demands, and your organization can pivot to multiple discipline-specific ISO standard requirements with much more ease and control, and without confusion, duplication or operational variance.

This guide lays out the 10 ingredient clauses of Annex SL and what they mean for your business.

So whether your ISO focus is your medical device, laboratory, clinical practices, information security or laying the groundwork of a general quality management system, we hope this summary is a helpful stepping stone.



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The Annex SL framework

Annex SL comprises ten clauses, which form the broad framework for modern ISO management system standards.

The overarching 'high-level structure' of Annex SL can be supplemented with sub-clauses and discipline-specific language as required by individual standards.

Let's dive in.

Clause 1: Scope

The scope sets out the intended outcomes of your management system and the boundaries within which it operates. The outcomes are industry-specific and should be aligned with the context of your organization (see Clause 4!)

Clause 2: Normative references

Provides details of the reference standards and/or publications relevant to the particular standard.

Clause 3: Terms & definitions

Details the terms and definitions relevant to the standard, in addition to any formal related terms and definitions.



Clause 4: Context of the organization

As the flagstone of a management system, Clause 4 determines *why* your organization is doing what it's doing.

As part of the answer to this question, you need to identify any internal and external issues that can impact on your intended outcomes, as well as your interested parties and their requirements.

This closely aligns with Clause 1, the scope and boundaries of your management system, and with your business objectives.

Subclauses:

- 4.1 Understanding the organization and its context New requirement!
- 4.2 Understanding the needs and expectations of interested parties New requirement!
- 4.3 Determining the scope of the management system
- 4.4 The management system Enhanced Requirement (Process-based approach)!



Clause 5: Leadership

Annex SL places particular emphasis on *leadership*, not just *management* as set out in previous standards.

This means top management now has greater accountability and involvement in your organization's management system.

Leadership are now expected and required to:

- Integrate the requirements of the management system into your organization's core business processes
- Ensure the management system achieves its intended outcomes, and...
- Allocate the necessary resources to help it do so

Top management are also responsible for communicating the *importance* of the management system and to heighten employee awareness and involvement.

Subclauses:

5.1 Leadership and commitment New requirement!

5.2 Policy

5.3 Organizational roles, responsibilities and authorities Enhanced Requirement!

Clause 6: Planning

Clause 6 brings risk-based thinking to the forefront. Once your organization has highlighted its operational risks and opportunities in Clause 4, you need to stipulate *how* these will be addressed through planning.

The planning phase includes what, who, how and when these risks must be addressed. This proactive approach replaces previous ISO emphasis on preventative action, and reduces the need for corrective actions later on. Particular focus is also placed on the objectives of the management system.

These should be measurable, monitored, communicated, aligned to the policy of the management system, and updated when needed.

Subclauses:

6.1 Actions to address risks and opportunities Enhanced Requirement!

6.2 Management system objectives and planning to achieve them Enhanced Requirement!

6.3 Planning of changes

Clause 7: Support

After addressing the context, commitment and planning, your

organization will have to look at the support needed to meet your goals and objectives.

This includes resources, targeted internal and external communications, as well as 'documented information', that replaces previously used terms such as documents, documentation and records.

Subclauses:

7.1 Resources **Enhanced Requirement!**

7.2 Competence

7.3 Awareness

7.4 Communication **Enhanced Requirement!**

7.5 Documented information

Clause 8: Operation

The bulk of your management system requirements lies within this single clause. Clause 8 addresses both in-house and outsourced processes, while the overall process management includes both adequate criteria to control these processes and ways to manage planned and unintended change.

Subclauses:

8.1 Operational planning and control **Enhanced Requirement!**

8.2 Requirements for products and services

8.3 Design and development of products and services

8.4 Control of externally provided processes, products and services

8.5 Production and service provision

8.6 Release of products and services

8.7 Control of non-conforming output



Clause 9: Performance evaluation

Here your organization needs to determine what, how and when things are to be monitored, measured, analyzed and evaluated.

Internal auditing is a key component of this process to ensure your management system is successfully implemented and maintained, *and* conforms to the requirements of the organization and the specific ISO standard.

The final step, management review, focuses on whether your management system is suitable, adequate and effective.

Subclauses:

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal audit

9.3 Management review



Clause 10: Improvement

Modern ISO standards, driven by Annex SL, all emphasize embedding continuous quality improvement and optimization rather than the traditional, static 'certificate-on-the-wall' approach.

Clause 10 looks at ways to address non-conformity and corrective action, as well as strategies for improvement on a continual basis.

Subclauses:

10.1 Non-conformity and corrective action

10.2 Continual improvement

Take the next step on your quality journey

Want more information about the structure and requirements of the modern quality management system? Try our guide for preparing for certification to ISO 9001, the baseline quality management system standard.

Download free guide

What is ISO 9001 certification?

ISO is an independent, non-governmental, international organization with a membership of 114 national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant international Standards that support innovation and provide solutions to global challenges.

— ISO International Organization for Standardization

ISO 9001 is a certification you can acquire by following specific standards and guidelines for a quality management system with a strong customer-centric focus.

Becoming ISO 9001-certified ensures your customers receive top quality products and services consistently, and allows your organisation to begin its journey up the maturity curve to a world class QMS.

The journey to world class
Quality maturity curve



11 benefits of ISO 9001:2015 accreditation

01. Bringing quality and continuous improvement into the heart of your organisation
02. Aligned business
03. Leadership commitment
04. Opportunity and risk management
05. An integrated approach through Annex SL
06. Profitability
07. Governance
08. Adaptability
09. Customer focus
10. Consistent information
11. Resources

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