

ISO 9001:2015 Certification Overview

What is ISO 9001 certification?

ISO 9001 is an international standard developed by the International Organization for Standardization (ISO) that specifies requirements for a quality management system (QMS). Organizations use ISO 9001 to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements. It is the most popular ISO standard and the only standard to which every organization can certify.

Experts in ISO review and revise ISO 9001 every 6-8 years. Major revisions occurred in 1994, 2000, 2008, and 2015. The latest revision, ISO 9001:2015, was published in September 2015.

Structure of ISO 9001:2015

ISO 9001:2015 follows a high-level framework common to all management systems:

Clause 0: Introduction

Clause 1: Scope

Clause 2: Normative references

Clause 3: Terms and definitions

Clause 4: Context of the organization

Clause 5: Leadership

Clause 6: Planning

Clause 7: Support

Clause 8: Operation

Clause 9: Performance evaluation

Clause 10: Improvement

Key Principles of ISO 9001:2015

1. Customer focus and customer satisfaction
2. Leadership
3. Involvement of people
4. Process approach
5. A systematic approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

Documents Required for Implementation of ISO 9001:2015

Mandatory Documents:

- Scope of the QMS (clause 4.3)
- Quality policy (clause 5.2)
- Quality objectives (clause 6.2)
- Supplier evaluation criteria (clause 8.4.1)

Mandatory Records:

- Equipment calibration and maintenance (clause 7.1.5.1)
- Training and qualification records (clause 7.2)
- Product/service requirement reviews (clause 8.2.3.2)
- Design and development records (clauses 8.3.2-8.3.6)
- Product characteristics and customer property (clauses 8.5.1, 8.5.3)
- Production change control and conformity records (clauses 8.5.6, 8.6)
- Nonconformance records (clause 8.7.2)
- Internal audit and management review results (clauses 9.2, 9.3)
- Corrective action results (clause 10.1)

Non-Mandatory Documents:

- Context and interested parties procedure (clauses 4.1, 4.2)
- Risk and opportunity procedure (clause 6.1)
- Competence and training procedure (clauses 7.1.2-7.3)
- Equipment maintenance procedure (clause 7.1.5)
- Document control procedure (clause 7.5)
- Sales, design, production, warehousing procedures (clauses 8.2-8.5.4)

How to Implement ISO 9001:2015

1. Get top management commitment
2. Compare existing system with ISO 9001
3. Form an implementation team
4. Make an implementation plan
5. Assign roles and set timelines
6. Conduct awareness training
7. Develop and document the QMS
8. Implement the QMS
9. Conduct internal audit
10. Conduct management review
11. Do a pre-assessment audit
12. Apply for certification
13. Continuously review and improve

Benefits of ISO 9001:2015

- Improved organizational performance and productivity
- Waste reduction

- Increased efficiency
- Enhanced customer satisfaction
- Revenue growth
- Global recognition
- Stronger supplier relationships
- Ongoing improvement