

# 2015 ISO 9001 Plain English Structure

This page is a summary only. It does not present our entire product. If you would like to see the rest of this material, please [place an order](#). Our products use language that is clear, precise, and easy to understand.

## 4. Context

- 4.1 Understand your organization and its unique context.
- 4.2 Clarify the needs and expectations of interested parties.
- 4.3 Define the scope of your quality management system.
- 4.4 Develop a QMS and establish documented information.
  - 4.4.1 Establish a QMS that complies with this standard.
  - 4.4.2 Maintain QMS documents and retain QMS records.

## 5. Leadership

- 5.1 Provide leadership by focusing on quality and customers.
  - 5.1.1 Provide leadership by encouraging a focus on quality.
  - 5.1.2 Provide leadership by encouraging a focus on customers.
- 5.2 Provide leadership by establishing a suitable quality policy.
  - 5.2.1 Provide leadership by formulating your quality policy.
  - 5.2.2 Provide leadership by communicating your quality policy.
- 5.3 Provide leadership by defining roles and responsibilities.

## 6. Planning

- 6.1 Define actions to manage risks and address opportunities.
  - 6.1.1 Consider risks and opportunities when you plan your QMS.
  - 6.1.2 Plan how you're going to manage risks and opportunities.
- 6.2 Set quality objectives and develop plans to achieve them.
  - 6.2.1 Establish quality objectives for all relevant areas.
  - 6.2.2 Develop plans to achieve objectives and evaluate results.
- 6.3 Plan changes to your quality management system.

## 7. Support

- 7.1 Support your QMS by providing the necessary resources.
  - 7.1.1 Provide internal and external resources for your QMS.
  - 7.1.2 Provide suitable people for your QMS and your processes.
  - 7.1.3 Provide the infrastructure that your processes must have.
  - 7.1.4 Provide the appropriate environment for your processes.
  - 7.1.5 Provide monitoring, measuring, and traceability resources.
  - 7.1.6 Provide knowledge to facilitate process operations.
- 7.2 Support your QMS by ensuring that people are competent.
- 7.3 Support your QMS by explaining how people can help.
- 7.4 Support your QMS by managing your communications.
- 7.5 Support your QMS by controlling documented information.
  - 7.5.1 Include the documented information that your QMS needs.
  - 7.5.2 Manage the creation and revision of documented information.
  - 7.5.3 Control the management and use of documented information.
    - 7.5.3.1 Control your organization's documents and records.
    - 7.5.3.2 Control how documents and records are controlled.

## 8. Operations

- 8.1 Develop, implement, and control your operational processes.
- 8.2 Determine and document product and service requirements.
  - 8.2.1 Communicate with customers and manage customer property.
  - 8.2.2 Clarify product and service requirements and capabilities.
  - 8.2.3 Review product and service requirements and record results.
  - 8.2.4 Amend documents if product or service requirements change.
- 8.3 Establish a process to design and develop products and services.
  - 8.3.1 Create an appropriate design and development process.
  - 8.3.2 Plan product and service design and development activities.
  - 8.3.3 Determine product and service design and development inputs.
  - 8.3.4 Specify how design and development process is controlled.
  - 8.3.5 Clarify how design and development outputs are produced.
  - 8.3.6 Review and control all design and development changes.
- 8.4 Monitor and control external processes, products, and services.
  - 8.4.1 Confirm that products and services meet requirements.
  - 8.4.2 Establish controls for external products and services.
  - 8.4.3 Discuss your requirements with external providers.
- 8.5 Manage and control production and service provision activities.
  - 8.5.1 Establish controls for production and service provision.
  - 8.5.2 Identify your outputs and control their unique identity.
  - 8.5.3 Protect property owned by customers and external providers.
  - 8.5.4 Preserve outputs during production and service provision.
  - 8.5.5 Clarify and comply with all post-delivery requirements.
  - 8.5.6 Control changes for production and service provision.
- 8.6 Implement arrangements to control product and service release.
- 8.7 Control nonconforming outputs and document actions taken.
  - 8.7.1 Control nonconforming outputs to prevent unintended use.
  - 8.7.2 Document nonconforming outputs and the actions taken.

## 9. Evaluation

- 9.1 Monitor, measure, analyze, and evaluate QMS.
  - 9.1.1 Plan how to monitor, measure, analyze, and evaluate.
  - 9.1.2 Find out how well customer expectations are being met.
  - 9.1.3 Evaluate effectiveness, conformity, and satisfaction.
- 9.2 Use internal audits to examine conformance and performance.
  - 9.2.1 Audit your quality management system at planned intervals.
  - 9.2.2 Develop an internal audit program for your organization.
- 9.3 Carry out management reviews and document your results.
  - 9.3.1 Review suitability, adequacy, effectiveness, and direction.
  - 9.3.2 Plan and perform management reviews at planned intervals.
  - 9.3.3 Generate management review outputs and document results.

## 10. Improvement

- 10.1 Determine improvement opportunities and make improvements.
- 10.2 Control nonconformities and take appropriate corrective action.
  - 10.2.1 Correct nonconformities, causes, and consequences.
  - 10.2.2 Document nonconformities and the actions that are taken.
- 10.3 Enhance the suitability, adequacy, and effectiveness of your QMS.

This page is a summary only. It does not present our entire product. If you would like to see the rest of this material, please [place an order](#). Our products use language that is clear, precise, and easy to understand.

**Praxiom Research Group Limited**  
First Edmonton Place 14 Floor 10665 Jasper Ave  
Edmonton, Alberta, Canada, T5J 3S9 780-461-4514  
info@praxiom.com info@praxiom.org praxiom@gmail.com  
We ship worldwide. Our products are used in over 100 countries.

©2022 Praxiom Research Group Limited. All Rights Reserved.