

# Detailed Outline of Headings – AS9100 Rev. D

## RATIONALE

## FOREWORD

## INTENDED APPLICATION

## INTRODUCTION

- 1.1 General
- 1.2 Quality Management Principles
- 1.3 Process Approach
  - 1.3.1 General
  - 1.3.2 Plan-Do-Check-Act Cycle
  - 1.3.3 Risk-Based Thinking
- 1.4 Relationship with Other Management System Standards

## QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS

- 1. **SCOPE**
- 2. **NORMATIVE REFERENCES**
- 3. **TERMS AND DEFINITIONS**
- 4. **CONTEXT OF THE ORGANIZATION**
  - 4.1 Understanding the Organization and Its Context
  - 4.2 Understanding the Needs and Expectations of Interested Parties
  - 4.3 Determining the Scope of the Quality Management System
  - 4.4 Quality Management System and Its Processes
- 5. **LEADERSHIP**
  - 5.1 Leadership and Commitment
    - 5.1.1 General
    - 5.1.2 Customer Focus
  - 5.2 Policy
    - 5.2.1 Establishing the Quality Policy
    - 5.2.2 Communicating the Quality Policy
  - 5.3 Organizational Roles, Responsibilities, and Authorities

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## **6. PLANNING**

- 6.1 Actions to Address Risks and Opportunities
- 6.2 Quality Objectives and Planning to Achieve Them
- 6.3 Planning of Changes

## **7. SUPPORT**

- 7.1 Resources
  - 7.1.1 General
  - 7.1.2 People
  - 7.1.3 Infrastructure
  - 7.1.4 Environment for the Operation of Processes
  - 7.1.5 Monitoring and Measuring Resources
    - 7.1.5.1 General
    - 7.1.5.2 Measurement Traceability
  - 7.1.6 Organizational Knowledge
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented Information
  - 7.5.1 General
  - 7.5.2 Creating and Updating
  - 7.5.3 Control of Documented Information

## **8. OPERATION**

- 8.1 Operational Planning and Control
  - 8.1.1 Operational Risk Management
  - 8.1.2 Configuration Management
  - 8.1.3 Product Safety
  - 8.1.4 Prevention of Counterfeit Parts
- 8.2 Requirements for Products and Services
  - 8.2.1 Customer Communication
  - 8.2.2 Determining the Requirements for Products and Services
  - 8.2.3 Review of the Requirements for Products and Services
  - 8.2.4 Changes to Requirements for Products and Services
- 8.3 Design and Development of Products and Services
  - 8.3.1 General
  - 8.3.2 Design and Development Planning
  - 8.3.3 Design and Development Inputs
  - 8.3.4 Design and Development Controls

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- 8.3.5 Design and Development Outputs
- 8.3.6 Design and Development Changes
- 8.4 Control of Externally Provided Processes, Products, and Services
  - 8.4.1 General
  - 8.4.2 Type and Extent of Control
  - 8.4.3 Information for External Providers
- 8.5 Production and Service Provision
  - 8.5.1 Control of Production and Service Provision
    - 8.5.1.1 Control of Equipment, Tools and Software Programs
    - 8.5.1.2 Validation and Control of Special Processes
    - 8.5.1.3 Production Process Verification
  - 8.5.2 Identification and Traceability
  - 8.5.3 Property Belonging to Customers or External Providers
  - 8.5.4 Preservation
  - 8.5.5 Post-Delivery Activities
  - 8.5.6 Control of Changes
- 8.6 Release of Products and Services
- 8.7 Control of Nonconforming Outputs
  
- 9. PERFORMANCE EVALUATION**
  - 9.1 Monitoring, Measurement, Analysis, and Evaluation
    - 9.1.1 General
    - 9.1.2 Customer Satisfaction
    - 9.1.3 Analysis and Evaluation
  - 9.2 Internal Audit
  - 9.3 Management Review
    - 9.3.1 General
    - 9.3.2 Management Review Inputs
    - 9.3.3 Management Review Outputs
  
- 10. IMPROVEMENT**
  - 10.1 General
  - 10.2 Nonconformity and Corrective Action
  - 10.3 Continual Improvement

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## ANNEXES

ANNEX A	CLARIFICATION OF NEW STRUCTURE, TERMINOLOGY AND CONCEPTS
ANNEX B	OTHER INTERNATIONAL STANDARDS ON QUALITY MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS DEVELOPED BY ISO/TC 176 (INFORMATIVE)
ANNEX C	OTHER STANDARDS ON QUALITY MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS DEVELOPED BY THE INTERNATIONAL AEROSPACE QUALITY GROUP
ANNEX D	BIBLIOGRAPHY
ANNEX E	AVIATION, SPACE, AND DEFENSE BIBLIOGRAPHY

## FIGURES

FIGURE 1	SCHEMATIC REPRESENTATION OF THE ELEMENTS OF A SINGLE PROCESS
FIGURE 2	REPRESENTATION OF THE STRUCTURE OF THIS INTERNATIONAL STANDARD IN THE PDCA CYCLE

# ISO 9004:2009 Excerpt

## **8.3.3. Internal audit**

Internal audits are an effective tool for determining the levels of compliance of the organization's management system against given criteria, and provide valuable information for understanding, analysing and continually improving the organization's performance. Audits should be conducted by people who are not involved in the activity being examined, in order to give an independent view on what is being performed.

Internal audits should assess the implementation and effectiveness of the management system. They can include auditing against more than one management system standard, such as ISO 9001 (quality management) and ISO 14001 (environmental management), as well as addressing specific requirements relating to customers, products, processes or specific issues.

To be effective, internal audits should be conducted in a consistent manner, by competent personnel, in accordance with an audit plan.

Internal auditing is an effective tool for identifying problems, risks and nonconformities, as well as for monitoring progress in closing previously identified nonconformities (which should have been addressed through root cause analysis and the development and implementation of corrective and preventive action plans). Verification that the actions taken have been effective can be determined through an assessment of the improved ability of the organization to fulfil its objectives. Internal auditing can also be focused on the identification of good practices (that can be considered for use in other areas of the organization) as well as on improvement opportunities.

The outputs of internal audits provide a useful source of information for

- addressing problems and nonconformities,
- benchmarking,
- promoting good practices within the organization, and
- increasing understanding of the interactions between processes.

The results of internal audits are usually presented in the form of reports containing information on compliance against the given criteria, nonconformities, and improvement opportunities. Audit reports are also an essential input for management reviews. Top management should establish a process for the review of all internal audit reports, to identify trends that can require organization-wide corrective or preventive actions.

The organization should also take the results of other audits, such as second and third party audits, as feedback for corrective and preventive actions.

**NOTE** See ISO 19011 for further guidance on auditing.

# ISO 9004:2009 Excerpt

## **8.3.4. Self-assessment**

Self-assessment is a comprehensive and systematic review of the organization's activities and its performance in relation to its degree of maturity (see Annex A).

Self-assessment should be used to determine the strengths and weaknesses of the organization in terms of its performance as well as its best practices, both at an overall level and at the level of its individual processes. Self-assessment can assist the organization to prioritize, plan and implement improvements and/or innovations, where necessary.

The results of self-assessments support

- continual improvement of the organization's overall performance,
- progress towards achieving and maintaining sustained success for the organization,
- innovation in the organization's processes, products and structure, when appropriate,
- recognition of best practices, and
- the identification of further opportunities for improvement.

The results of self-assessments should be communicated to relevant people in the organization. They should be used to share understanding about the organization and its future direction. The results should be an input to management review.

NOTE 1 ISO 10014 provides a self-assessment tool directed specifically towards the financial and economic benefits of a quality management system for an organization.

NOTE 2 See Annex A for more information about self-assessment.

# AS9100 Definitions

A *Counterfeit Part* is an unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

*Product Safety* refers to the state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

*Special requirements* are those which have high risks to being achieved, such as performance requirements at the limit of industry capability or the organization's technical or process capability. They can be identified by the customer or the organization.

*Critical items* may result from the special requirements identified during the risk assessment mentioned previously. They are items (e.g., functions, parts, software, characteristics, processes) that have a significant effect on the product realization and use of the product, including safety, performance, form, fit, function, producibility, service life, etc. They require specific actions to ensure they are adequately managed.

A *key characteristic* is an attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation. A critical item may be further classified as a key characteristic if its variation needs to be controlled.

Refer to AS9100 Rev. D Section 3 *Terms and Definitions* for full text.