

# Detailed Outline of Headings – ISO 9001:2015

- 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
  
- 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
    - 7.1.6 Organizational knowledge
  - 7.2 Competence
  - 7.3 Awareness
  - 7.4 Communication

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- 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
- 8.2 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
  - 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
  - 8.5.2 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

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## **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

# 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.

The ISO 9004 Standard also contains an excellent Self-Assessment tool for reviewing the organization's activities and its performance in relation to its degree of maturity.