| ISO 9001:2015 | ISO 9001:2008 | Summary |
|---|---|---|
| **4. Context of the organization** | **4. Quality Management System** | |
| 4.1 Understanding the organization and it context | New requirement<br><br>*"This process determines factors which influence the organizations purpose, objectives and sustainability."* | This requires organizations to determine issues/factors relevant to their business which affect their purpose, strategic direction and their ability to achieve goals and objectives. |
| 4.2 Understanding the needs and expectations of interested parties | New requirement<br><br>*"The relevant interested parties are those that provide significant risk to organizational sustainability if their needs and expectations are not met."* | This requires organizations to determine relevant "interested parties" and their needs and expectations. This goes beyond customer to include those who impact the organization's ability to achieve its goals and objectives. |
| 4.3 Determining the scope of the QMS | 1.2 Application | No significant change |
| 4.4 QMS and its processes | 4.1 General requirements | **Enhanced requirement**:<br>Process inputs, outputs, performance indicators, and risk and opportunities, are now explicit requirements |
| **5. Leadership** | **5. Management Responsibility** | |
| 5.1 Leadership and commitment | | **Enhanced requirement**: Top management's responsibility has shifted from "ensuring" to "accountability" for effectiveness of the QMS.<br>Responsibility also includes promoting use of the process approach and risk-based thinking |
| 5.2 Quality Policy | 5.3 Quality Policy | No significant change |
| 5.3 Organizational roles, responsibility and authorities | 5.5 Responsibility, authority and communication | No significant change |

| ISO 9001:2015 | ISO 9001:2008 | Summary |
|---|---|---|
| **6. Planning** | **5.4 Planning** | |
| 6.1 Actions to address risks and opportunities | New requirement | Risk and opportunities (R&O) that could affect the organization and its ability to achieve expected results (goals and objectives) need to be identified, taking into consideration issues/factors relevant to the business and requirements of interested parties. Planned actions to address R&Os are required; actions are proportional to potential impact. |
| 6.2 Quality objectives and planning to achieve them | 5.4 Planning | **Enhanced requirement**: Higher expectation regarding plans to achieve objectives. |
| 6.3 Planning of changes | 5.4.2 Quality management system  planning | No significant change |
| **7. Support** | **6. Resource Management** | |
| 7 .1 Resources<br>7.1.1. General<br>7.1.2 People<br>7.1.3 Infrastructure<br>7.1.4 Environment for operation of processes<br>7.1.5 Monitoring and measuring resources<br><br>7.1.6 Organizational knowledge | 6.1 Provision of resources<br>6.2 Human resources<br>6.3 Infrastructure<br>6.4 Work environment<br>7.6 Control of monitoring and measuring equipment<br>New requirement | No significant changes<br><br>Organizational knowledge is new. Organizations need to determine the knowledge necessary for the operation of its processes and to achieve product/service conformity.   This is specific to an organization, often gained from experience. |
| 7.2 Competence | 6.2 Human resources | No significant change |
| 7.3 Awareness | 6.2.2 Competence, training and awareness | No significant change |
| 7.4 Communication | 5.5.3 Internal communications | No significant change |
| 7.5 Documented information | 4.2 Documentation requirements | No significant change |

| ISO 9001:2015 | ISO 9001:2008 | Summary |
|---|---|---|
| **8. Operation** | **7. Product Realization** | |
| 8.1 Operational planning and control | 7.1 Planning of product realization | No significant change |
| 8.2 Requirements for products and services | 7.2 Customer related processes | No significant change |
| 8.3 Design and development of products and services<br><br>8.3.1 General | 7.3 Design and development<br><br>New requirement | The organization is required to establish, implement, and maintain a design and development process, if Design is applicable. |
| 8.4  Control of externally provided products and services | 7.4 Purchasing | No significant change |
| 8.5 Production and service provision | 7.5 Production and service provision | No significant change |
| 8.6 Release of products and services | 8.2.4 Monitoring and measurement of product | No significant change |
| 8.7 Control of non-conforming outputs | 8.3 Control of nonconforming product | No significant change |
| **9. Performance evaluation** | **8. Measurement, Analysis and Improvement** | |
| 9.1 Monitoring, measurement, analysis and evaluation | 8.1 General<br>8.2.1 Customer<br>8.4 Analysis of data | No significant change |
| 9.2 Internal audit | 8.2.2 Internal audit | No significant change |
| 9.3 Management Review | 5.6 Management Review<br>Added requirements | New requirements to review additional inputs:<br>• Changes in external and internal issues<br>• Effectiveness of actions taken to address risks and opportunities |
| **10. Improvement** | | |
| 10.1 General | 8.5.1 Continual improvement | No significant change |
| 10.2 Nonconformity and corrective action | 8.5.2 Corrective action | No significant change |
| 10.3 Continual improvement | 8.5.1 Continual improvement | No significant change |