OXEBRIDGE
QUALITY RESOURCES INTERNATIONAL LLC

Oxebridge Q001 – ISO 9001 Crosswalk v 1.2

The following table provides an assessment of how each Oxebridge Q001 clause complies with ISO 9001, and identifies any gaps which must be closed if certification to ISO 9001 is sought after using Oxebridge Q001.

To purchase a licensed copy of ISO 9001:2015, visit www.iso.ch.

Oxebridge Q001 v 1.2 Clause	ISO 9001:2015 Analog	Gap Actions / Comments
4.0 Quality Mgmt. System Scope	4.0 Context of the Organization	
4.1 Identifying Stakeholders	4.2 Understanding the needs and expectations of interested parties	Order reversed between 4.1 and 4.2; no other actions needed.
4.2 Identifying Stakeholders' Concerns and Requirements	4.1 Understanding the Organization and Its Context	Order reversed between 4.1 and 4.2; no other actions needed.
4.3 Quality Management System Processes	4.4 Quality management system and its processes	
4.3.1 Internal Processes	4.4 Quality management system and its processes 6.2 Quality objectives and planning to achieve them	Combines ISO 9001's concepts of "process measurements" and "quality objectives" into a single concept "process quality objectives." While this is, conceptually, a major change, it ensures automatic compliance with both of ISO 9001's requirements in one Q001 clause.
4.3.2 Outsourced Processes	4.4 Quality management system and its processes	No additional actions needed.
4.3.3 Process Design	No analog.	The design of processes has never been addressed in ISO 9001, yet process engineers understand this is possibly the most critical aspect of process management.
4.4 Quality Management System Scope	4.3 Determining the scope of the quality management system	No additional actions needed.
5.0 Quality Management System Leadership	5.0 Leadership	
5.1 Management Commitment	5.1 Leadership & Commitment	
5.1.1 Demonstration of Management Commitment	5.1 Leadership & Commitment	No additional actions needed.
5.1.2 Quality Culture	5.1.2 Customer focus	No additional actions needed.
5.2 Quality Policy	5.2 Policy	ISO 9001 requires additional language in the QP, including a statement of continual improvement and a statement to comply with applicable requirements. These statements are not required by Q001, so must be added to the QP in order to comply with ISO 9001.
5.3 Responsibilities and Authorities	5.3 Organizational Roles, Responsibilities and Authorities	ISO 9001 includes a longer list of requirements which are redundant with other clauses of ISO 9001, and so Q001 removes them; compliance should be very close, but it's recommended to carefully compare your system against the exact wording of ISO 9001 here, and make changes accordingly.
6.0 Quality Management System Planning	6.0 Planning	
6.1 Risk and Opportunity Management	6.1 Actions to address risks and opportunities	

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6.1.1 Approach to Risk and Opportunity Management	6.1 Actions to address risks and opportunities	No additional actions needed.
6.1.2 Risk Management	6.1 Actions to address risks and opportunities	No additional actions needed.
6.1.3 Opportunity Management	6.1 Actions to address risks and opportunities	No additional actions needed.
6.2 Change Management	6.3 Planning of changes 8.5.6 Control of changes	Combines two ISO 9001 clauses, but otherwise no additional actions needed.
7.0 Quality Mgmt. System Support	7.0 Support	
7.1 Resources	7.1 Resources	
7.1.1 Resource Provision	7.1.1 General	No additional actions needed.
7.1.2 People	7.1.2 People	No additional actions needed.
7.1.3 Infrastructure	7.1.3 Infrastructure	
7.1.3.1 Provision of Infrastructure	7.1.3 Infrastructure	No additional actions needed.
7.1.3.2 Validation of Equipment	No analog	Q001 adds this important requirement which has been missing from ISO 9001.
7.1.3.3 Preventive Maintenance	7.1.3 Infrastructure	Q001 expands on ISO 9001's generic requirement to "maintain infrastructure," which has never directly invoked preventive maintenance. This makes PM an explicit requirement, but scalable by the organization.
7.1.3.4 Tooling	No analog	Q001 adds this requirement to differentiate the controls for tooling from generic "equipment." Brings back some old MIL-Q-9858 language.
7.1.4 Work Environment	7.1.4 Environment for the operation of processes	No additional actions needed.
7.1.5 Inspection and Testing Resources	7.1.5 Monitoring and measuring resources	
7.1.5.1 Provision of Inspection and Testing Resources	7.1.5 Monitoring and measuring resources	No additional actions needed.
7.1.5.2 Calibrated Inspection and Testing Devices	7.1.5 Monitoring and measuring resources	No additional actions needed; clarifies and exceeds the requirements of ISO 9001 here.
7.1.5.3 Non-Calibrated Inspection and Testing Resources	No analog	This Q001 clause tries to separate manufacturer's calibrated tools from what services providers or software developers might use. Oxebridge admits this is still a bit complicated, and is working to simplify this further in future versions of Q001.
7.1.6 Knowledge	7.1.6 Organizational knowledge	No additional actions needed.

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7.2 Competence & Training	7.2 Competence	No additional actions needed.
7.3 Awareness	7.3 Awareness	No additional actions needed.
7.4 Communication	7.4 Communication 8.2.1 Customer communication	
7.4.1 Internal Communication	7.4 Communication	No additional actions needed.
7.4.2 External Communication	8.2.1 Customer communication	No additional actions needed.
7.5 Documents and Records	7.5 Documented information	
7.5.1 Development of Documents and Records	7.5 Documented information	No additional actions needed.
7.5.2 Control of Documents	7.5 Documented information	No additional actions needed.
7.5.3 Control of Records	7.5 Documented information	No additional actions needed.
7.5.4 Internal Compliance with Documents and Records	No analog.	ISO 9001 has never required staff to actually ***follow*** the published QMS procedures; this Q001 clause corrects this oversight.
8.0 Operation	8.0 Operation	
8.1 Operational Process Planning and Control	8.1 Operational planning and control	ISO 9001 words these differently, and some of 8.1 is redundant with other ISO 9001 clauses. Q001 strips this down dramatically, removing redundant requirements entirely and moving the rest of the requirements elsewhere in the Q001 standard. It's recommended to carefully review your system against the exact ISO 9001 text to ensure full compliance.
8.2 Capture and Review of Requirements	8.2 Requirements for products and services	
8.2.1 Capture of Requirements	8.2.2 Determining the requirements related to products and services	No additional actions needed.
8.2.2 Review of Requirements	8.2.3 Review of requirements related to products and services	No additional actions needed.
8.2.3 Changes to Requirements	8.2.4 Changes to requirements for products and services	No additional actions needed.
8.3 Design	8.3 Design of products and services	
8.3.1 Design Approach	8.3.1 General	No additional actions needed; Q001 adds a lot here, allowing companies to adopt the design model (agile, waterfall, etc.) of their choosing.
8.3.2 Design Planning	8.3.2 Design planning	No additional actions needed.

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Oxebridge Q001 v 1.2 Clause	ISO 9001:2015 Analog	Gap Actions / Comments
8.3.3 Design Requirements	8.3.3 Design inputs	No additional actions needed.
8.3.4 Designs	8.3.5 Design outputs	No additional actions needed.
8.3.5 Design Reviews	8.3.4 Design controls	No additional actions needed.
8.3.6 Design Verification	8.3.4 Design controls	No additional actions needed.
8.3.7 Design Validation	8.3.4 Design controls	No additional actions needed.
8.3.8 Design Changes	8.3.6 Design changes	No additional actions needed.
8.4 Purchasing and Subcontracting	8.4 Control of externally provided processes, products and services	
8.4.1 Evaluation and Approval of Suppliers	8.4.1 General 8.4.2 Type and extent of control	No additional actions needed.
8.4.2 Purchasing	8.4.3 Information for external providers	No additional actions needed.
8.4.3 Subcontracting	No analog	Q001 recognizes that control of subcontractors is sometimes very different from control of suppliers, so the clause addresses these differences.
8.4.4 Verification of Received Items or Services	8.4.2 Type and extent of control	No additional actions needed.
8.4.5 Ongoing Evaluation of Suppliers	8.4.2 Type and extent of control	No additional actions needed.
8.5 Production and Service Provision	8.5 Production and service provision	
8.5.1 Control of Production and Service Provision	8.5.1 Control of production and service provision	
8.5.1.1 Production and Service Controls	8.5.1 Control of production and service provision	No additional actions needed.
8.5.1.2 Special Processes	8.5.1 Control of production and service provision	No additional actions needed; moves the requirements back to earlier editions of ISO 9001 which were clearer on this topic.
8.5.2 Product Identification and Traceability	8.5.2 Identification and traceability	
8.5.2.1 Product Identification	8.5.2 Identification and traceability	No additional actions needed.
8.5.2.2 Product Traceability	8.5.2 Identification and traceability	No additional actions needed.
8.5.2.3 Configuration Management	No analog	Q001 adds CM which has never been addressed in ISO 9001, but which affects many users of the standard. Provides for a scalable approach to CM, and may be excluded for those that don't utilize CM at all.

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Oxebridge Q001 v 1.2 Clause	ISO 9001:2015 Analog	Gap Actions / Comments
8.5.3 Property Belonging to Third Parties	8.5.3 Property belonging to customers or external providers	No additional actions needed.
8.5.4 Preservation	8.5.4 Preservation	No additional actions needed.
8.5.5 Delivery	No analog	ISO 9001 has never addressed the shipping of product or final delivery of service; Q001 corrects this oversight.
8.5.6 Post-Delivery Activities	8.5.5 Post-delivery activities	ISO 9001 words this differently, verify compliance against exact ISO 9001 text.
8.6 Inspection and Testing	8.6 Release of products and services	No additional actions needed; returns to the usage of the terms “inspection” and “testing,” which ISO has avoided in recent editions.
8.6.1 Inspection and Testing Requirements	8.6 Release of products and services	No additional actions needed.
8.6.2 Receiving Inspection	8.4.2 Type and extent of control	No additional actions needed; calls out an explicit requirement for receiving inspection.
8.6.3 First Piece Inspection	8.6 Release of products and services	No additional actions needed; calls out an explicit requirement for first piece inspection.
8.6.4 First Article Inspection	No analog	No additional actions needed; calls out an explicit requirement for first article inspection.
8.6.5 In-Process Inspection	8.6 Release of products and services	No additional actions needed; calls out an explicit requirement for in-process inspection.
8.6.6 Final Inspection	8.6 Release of products and services	No additional actions needed; calls out an explicit requirement for final inspection.
8.7 Control of Nonconforming Product	8.7 Control of nonconforming outputs	
8.7.1 General Control of Nonconforming Product or Service	8.7 Control of nonconforming outputs	No additional actions needed.
8.7.2 Discovering and Recording Nonconforming Product & Service	8.7 Control of nonconforming outputs	No additional actions needed.
8.7.3 Dispositioning Nonconforming Product & Service	8.7 Control of nonconforming outputs	No additional actions needed.
9.0 Performance Evaluation	9.0 Performance evaluation	
9.1 Monitoring, Measurement, Analysis and Evaluation	9.1 Monitoring, measurement, analysis and evaluation	
9.1.1 Overall QMS Evaluation	9.1.1 General	The ISO 9001 clause includes some language that is redundant with other clauses; Q001 strips these, but compliance should be automatic regardless; no additional actions needed.
9.1.2 Analysis and Evaluation	9.1.2 Customer satisfaction 9.1.3 Analysis and evaluation	No additional actions needed.

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9.2 Internal Audits	9.2 Internal audit	
9.2.1 Purpose of Internal Audits	9.2 Internal audit	No additional actions needed.
9.2.2 Conducting Internal Audits	9.2 Internal audit	No additional actions needed; adds requirement to audit QMS at least annually, which is often enforced by Certification Bodies, even though the requirement does not exist in the ISO 9001 standard.
9.2.3 Internal Audit Evidence	No analog	ISO 9001 has never required objective evidence in internal audit reports; this clause corrects that oversight.
9.2.4 Reporting Internal Audit Nonconformities	No analog	Provides a method for writing audit nonconformities per ISO 31000.
9.2.5 Internal Audit Reports	9.2 Internal audit	No additional actions needed.
9.3 Management Review	9.3 Management review	
9.3.1 Management Review Approach	9.3.1 General	No additional actions needed; adds annual Management Review minimum frequency which is often enforced by Certification Bodies, even though the requirement does not exist in the ISO 9001 standard.
9.3.2 Management Review Requirements	9.3.2 Management review inputs 9.3.3 Management review outputs	No additional actions needed; far exceeds ISO 9001.
10.0 Improvement	10.0 Improvement	
10.1 Pursuing Continual Improvement	10.1 General 10.3 Continual Improvement	No additional actions needed.
10.2 Corrective Action	10.2 Nonconformity and corrective action	
10.2.1 Requesting Corrective Action	10.2 Nonconformity and corrective action	No additional actions needed.
10.2.2 Processing Corrective Action Requests	10.2 Nonconformity and corrective action	No additional actions needed.
10.3 Preventive Action	No analog	
10.2.1 Requesting Preventive Action	No analog	Q001 adds back in the older ISO 9001 requirements for preventive action which were deleted with the 2015 version.
10.2.2 Processing Preventive Action Requests	No analog	
10.4 Incident Investigation	No analog	Entirely new requirement that has never appeared in any ISO standard. Tries to address the problem of certified companies who retain certification after being responsible for deadly product releases, by forcing them to address such incidents.