Oxebridge Q002

Quality Management System Certification Audit Minimum Evidence Requirements

Ver. 1.2

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Revision History

Ver.	To be used for audits after:	Nature of Changes
1.1.1	15 March 2020	• Original release.
1.2	15 April 2020	• Change revision numbering scheme of this document to x.x format. • Changed references to “on-site audits” to read “practical audits.” • Added section 4.2 on audit levels and applicable clauses. • Section 4.1, added reference to Remote Auditing Methods.

1.0 Purpose

This document defines the minimum evidence requirements for each clause of Oxebridge Q001.

The intent of this document is to ensure that decisions for determining if nonconformities exist, and for ranking any such nonconformities, are based on objective evidence and solid rules. This reduces the introduction of subjectivity by auditors, and therefore reduces the likelihood of soft-grading or hard-grading audit results.

While the document is mandatory when used by accredited third parties conducting Q001 audits, the document may also be used by organizations for their internal audit activities.

2.0 References

Oxebridge Q001 – Quality Management System Requirements

Oxebridge Q003 – Quality Management System Certification Audit Requirements

Oxebridge Q004 – Quality Management System Certification Audit Scoring

Oxebridge Q005 – Quality Management System Certification Audit Terms and Definitions

Oxebridge Q006 – Quality Management System Certification Body Accreditation Requirements

Oxebridge Q007 - Quality Management System Certification Audit Minimum Audit Duration

Oxebridge Q008 – Quality Management System Certification Audit Report

Oxebridge Q017 - Quality Management System Certification Audit - Remote Auditing Methods

3.0 Terms and Definitions Specific to this Document

3.1 Sampling Terms

Tables 1 and 2 using the following terms to limit the evidence requirements to the real-world conditions of the organization and its QMS.

Term	Mandatory Interpretation
“Sample of Staff”	The auditors may determine an appropriate number of staff to interview. The sample size shall never be less than 2 (two) unless the organization has only one person in that role. [1]
“If available”	Evidence shall be verified only if the organization has artifacts from within the time frame defined and/or only the number of artifacts the organization has from within that time frame.
“If applicable”	Evidence shall be verified only if the organization requires the evidence per its own procedures or interpretations. If deemed not applicable, then no evidence verification is required.
“If created”	Evidence shall be verified only if the organization has created the evidence per its own interpretations. If not created, then no evidence verification is required.
“During the other audit activities”	Evidence may be gathered simultaneously with other auditing activities; i.e., separate auditing need not be performed to gather this evidence if it can be gathered during the audit of other activities. The number of artifacts gathered during the “other audit activities” would apply to this evidence as well.

3.2 Additional Terms Specific to This Document:

Artifact: a single instance of evidence, such as a record, file, example, interview, etc.

Deliverables: the output product for a service organization, such as a report, file, data delivery, training curriculum, etc.

For all other terms and definitions, refer to Q005.

4.0 Evidence Requirements

4.1 Overview

During certification audits, auditors are tasked with determining if an organization conforms to a given Q001 clause or not. Tables 1 and 2 provides minimum evidence requirements for manufacturing organizations and service providers respectively. These requirements apply whether the audit is utilizing Remote Auditing Methods (RAM) or traditional on-site auditing.

Oxebridge understands that the realities of the audit, the organization's interpretation of the standard, and many other factors may play into an auditor's decision on whether or not a clause is met, even when considering the minimum evidence. Where any significant deviation is expected, the auditor should communicate with the Certification Body for guidance on how to proceed.

As per Q002, the audit team will collectively determine if a finding constitutes a nonconformity, and then whether that nonconformity will be ranked as Major or Minor, per the definitions of Q005.

Tables 1 and 2 highlight Major Fallout Clauses with a red border.

4.2 Certification Levels

The Q001 scheme allows the client organization to select whether the intend on pursuing a Level 1 audit, or a Level 2 through 4 audit. For audits of Level 2 through 4, all the applicable requirements of Q001 apply, including all Major Fallout Clauses. Only clauses which are justifiably excluded may be ignored.

For Level 1 audits, only the clauses applicable for Level 1 shall be audited, minus any clauses which are justifiably excluded. This reduces the number of applicable Major Fallout Clauses applicable for Level 1 audits.

The applicable clauses for each Level is defined in Q004.

4.3 Evidence Sampling

The Minimum Evidence columns in Tables 1 and 2 indicate when a specific number of artifacts must be examined in order to prove conformity to each requirement. Where a Minimum Evidence column entry indicates "X" as a sample value, the CB shall utilize Table 3 to determine the Sample Code which will apply to the organization. The CB shall then determine the value of "X" for that requirement per the appropriate Sample Code column entry.

For example:

> A company has 256 employees, so would fall under Sample Code 3, per Table 3.
>
> An evidence requirement in Table 1 requires the CB to "verify X records within the past 12 months, if available."
>
> The S3 column indicates that for this size company "X" shall = 15 artifacts.
>
> Therefore, the CB shall verify 15 artifacts.

The number of actual artifacts may be less when limiting sampling terms are used, per the definitions in 3.1. For example:

> A company has 50 employees, so would fall under Sample Code 1.
>
> An evidence requirement in Table 1 requires the CB to "verify X records within the past 12 months, if available."
>
> The S1 column indicates that for this size company "X" shall = 5 artifacts.
>
> In this case, if the organization has 5 records, all five shall be verified; however, if the organization has only generated 3 records in 12 months, then all three shall be verified. No additional artifacts are necessary to verify because they do not exist.

If a Minimum Evidence column entry in Table 1 or 2 does not indicate the number of artifacts to obtain, then the auditor may decide on an appropriate number of artifacts to select.

If the Sample Code columns are blank for that requirement, then the sampling requirements defined in the Minimum Evidence column shall apply. If the Minimum Evidence column does not indicate the number of artifacts to obtain, then the auditor may decide on an appropriate number of artifacts to select.

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
1.0 Purpose	None – not audited					
2.0 References	None – not audited					
3.0 Terms and Definitions	None – not audited					
4.0 Quality Management System Scope						
4.1 Identifying Stakeholders	List of stakeholders					
4.2 Identifying Stakeholders' Concerns and Requirements	List of stakeholders' concerns and requirements					
4.3 Quality Management System Processes						
4.3.1 Internal Processes	• Verify the process definition for each QMS process • Interview one process owner for at least 75% of QMS processes • Verify process objective measurement data for all QMS processes • Verify process change evidence for any process changed within previous 12 months					
4.3.2 Outsourced Processes	• Verify at least **X%** of outsourced process providers are included in approved supplier records • Verify procedure	50%	50%	25%	25%	10%
4.3.3 Process Design	• For initial certification audit: verify all Process Designs • For recertification audits: verify **X** Process Designs for any new process created since last audit	100%	100%	50%	50%	25%
4.4 Quality Management System Scope	• Verify scope statement • Verify all exclusions are suitably justified					
5.0 Quality Management System Leadership						
5.1 Management Commitment						
5.1.1 Demonstration of Management Commitment	• Verify document defining management accountability • Verify management participation in planning activities (will be different for each organization, but may include meeting minutes) • Verify management signature on Quality Policy • Verify management review records include list of attendees, and includes top management					

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	• Verify management analyzed Cost of Quality (may be done as part of Management Review) • Verify management's activities related to communicating the quality culture (will be different for each organization, but may include meeting minutes) • Interview top management on how it manages, leads and supports staff • Interview sample of staff to confirm they have management leadership and support					
5.1.2 Quality Culture	• Verify Quality Culture Plan • Interview sample of staff to ensure they are familiar with Quality Culture					
5.2 Quality Policy	• Verify Quality Policy • Interview sample of staff to ensure they are familiar with Quality Policy					
5.3 Responsibilities and Authorities	• Verify organization's documented definition of top management • Organization's documented definition of responsibilities and authorities (may be embedded in procedures) • Interview sample of staff to confirm they have the authority to carry out their responsibilities					
6.0 Quality Management System Planning						
6.1 Risk and Opportunity Management						
6.1.1 Approach to Risk and Opportunity Management	• Verify procedure • Verify how the organization determines which issues are risks, opportunities, or both.					
6.1.2 Risk Management	• Verify risk list has been developed and includes organization-identified risks • Verify risk mitigation plans for at least **X** of the highest-risk entries	2	3	5	8	10
6.1.3 Opportunity Management	• Verify opportunity list has been developed and includes organization-identified opportunities • Verify opportunity pursuit plans for at least **X** opportunities	1	1	2	2	5
6.2 Change Management	• Verify procedure • For initial certification audit: verify records related to at least **X** process changes, if available • For recertification audits: verify records related to at least **X** process changes since last audit, if available	1	1	2	2	5
7.0 Quality Management System Support						
7.1 Resources						
7.1.1 Resource Provision	• Interview sample of staff to confirm if adequate resources have been provided and if they have freedom to request resources.					

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
7.1.2 People	• Verify that positions critical to quality are filled or, if not, the organization is seeking to fill the positions.					
7.1.3 Infrastructure						
7.1.3.1 Provision of Infrastructure	• During the other audit activities, verify the condition of facilities is not causing product nonconformities or process failures • During the other audit activities, verify the condition of equipment is not causing product nonconformities or process failures • During the other audit activities, verify utilities, transportation resources and IT resources are not causing product nonconformities or process failures					
7.1.3.2 Validation of Equipment	• Verify how **X%** of equipment implemented within the last 12 months was validated prior to use (note: the organization will determine which equipment is subject to validation.)	100%	100%	50%	25%	10%
7.1.3.3 Preventive Maintenance	• Verify procedure • Verify at least **X** preventive maintenance records, if available	2	5	10	10	20
7.1.3.4 Tooling	• During the other audit activities, verify the use, identification and general condition of tooling used in at least **X** manufacturing processes or activities, if available	1	2	3	5	5
7.1.4 Work Environment	• During the other audit activities, verify all special work environments where additional controls are implemented (clean rooms, spray areas, ESD controlled areas, etc.), if applicable • For the special work areas audited, verify the last three months of related records related to work environment control, if created and if available • During the other audit activities, verify other work areas for general conformity • Verify related work environment control procedures, if created					
7.1.5 Inspection and Testing Resources						
7.1.5.1 Provision of Inspection and Testing Resources	• Verify inspection and test activities, if available ○ Of these, verify **X** devices or resources used are of the proper range, tolerance or suitability for the required inspection or tests	All	10	15	20	30

7.1.5.2 Calibrated Inspection and Testing Devices	• Verify procedure
	• Verify inspection and test activities which utilize calibrated devices, if available
	  ○ Of these, verify at least **X** inspection or test devices used, if available.
	  ○ Of these devices, verify the last available calibration record
	  ○ Of these devices, verify they are identified and traceable
		All	5	8	10	20

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these devices, verify they are handled and preserved properly • Reverse the audit direction, and capture information on a random set of at least **X** calibrated devices found in use. ○ Of these devices, verify the last available calibration record ○ Of these devices, verify they are identified and traceable ○ Of these devices, verify they are handled and preserved properly • If calibration is performed in-house, verify calibration procedures (or work instructions) match actual practice					
	• If calibration is performed by an outside laboratory, verify the records related to **X** outside labs, if available ○ Of these, verify the certificates provided by the lab include necessary information, including traceability to standards, as-found condition, environmental conditions. ○ Of these, verify all the labs are captured as approved suppliers per 8.4. ○ Verify that calibration is treated as an outsourced process per 4.4. • Verify at least one impact study related to an out-of-tolerance device found within the past 12 months, if available.	2	3	3	5	5
7.1.5.3 Non-Calibrated Inspection and Testing Resources	• Verify procedure • Verify inspection and test activities which utilize non-calibrated resources, if available ○ Of these, verify at least **X** non-calibrated resources used, if available. ○ Of these, verify each has been validated as fit for use per a procedure ○ Of these, verify the last 12 months' validation records, if available ○ Of these, verify they are being used per a procedure ○ Of these, verify they are handled and preserved properly ○ If any issues are found, repeat verification of an additional 30 devices, if available. • If validation is performed by an outside source, verify the records related to at least three outside sources, if available ○ Of these, verify all the outside sources are captured as approved suppliers per 8.4.	All	5	8	10	20
7.1.6 Knowledge	• Interview sample of staff to determine if the company retains knowledge so it cannot reasonably be lost in the event of staff changes.					
7.2 Competence & Training	• Select at least **X** positions in the company which are within the scope of the QMS, if available ○ Of these, verify there are records of minimum competence requirements ○ Of these, select at least **X** persons who currently hold the position	2	3	4	5	6

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, verify their training or human resource records prove they met the requirements or, if not, that waivers are on file • Verify any training matrix, training database, learning management system, etc., if created • Select at least **X** employees, if available ○ Of these, verify the on-the-job or other training records for the past 12 months, if available					
7.3 Awareness	• Select at least **X** employees, if available ○ Of these, verify most recent awareness training records	2	3	4	5	6
7.4 Communication						
7.4.1 Internal Communication	• Interview sample of staff to determine if internal communication occurs in all directions. • Interview sample of staff to determine if management does not retaliate against staff for reporting valid problems or nonconformities. • Interview top management to verify it communicates the status and health of the QMS to staff (this may include records, if created)					
7.4.2 External Communication	• Interview sample of staff to determine if communication with customers and suppliers is properly routed and responded to. • Verify complaint records for the past six months, if available.					
7.5 Documents and Records						
7.5.1 Development of Documents and Records	• Verify the current QMS document set (in general) • Verify the current QMS record set (in general)					
7.5.2 Control of Documents	• Verify procedure • Verify 100% of top-level procedures and at least **X** randomly selected other documents, if created ○ Of these, verify they are controlled per the procedure ○ Of these, verify the records of document review and approval • During the other audit activities, verify if any obsolete documents are still in use • During the other audit activities, verify if any documents are being used at their proper revision levels • During the other audit activities, verify that all documents that instruct are included in the QMS set and related controls • Verify at least **X** external documents in use, if available ○ Of these, verify they are being used at their proper revision level • Of all documents reviewed from above, verify these were available to staff when and where needed.	2	3	4	5	6

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**

7.5.3 Control of Records	• Verify procedure
	• Verify at least **X** QMS record types
	  ○ Of these, verify they are being controlled per the procedure
	  ○ Of these, verify they are properly protected and preserved
	  ○ For hard records, verify physical storage and protection
	  ○ For electronic records, verify backups and server protections
	• Verify at least one supplier who is responsible for record control, if available and if applicable
	  ○ Verify the requirements for record control have been flowed down to the supplier via a contract, purchase order or similar instrument
		5	5	8	8	10

7.5.4 Internal Compliance with Documents and Records	• During the other audit activities, verify that staff are following procedures • During the other audit activities, verify that staff are completing records as required					
8.0 Operation						
8.1 Operational Process Planning and Control	• Verify Process Definitions include operational processes (manufacturing operations, etc.) • (Note: these activities can be combined into larger processes, or developed as standalone processes, based on the organization's choice.) • Verify statistical process control plans are based on statistically valid and/or published methods. • Verify procedure for statistical process control, if created.					
8.2 Capture and Review of Requirements						

8.2.1 Capture of Requirements	• Verify procedure
	• Verify at least **X** recent requests for work from customers, if available
	  ○ Of these, verify the organization captured the necessary requirements
	  ○ Of these, verify the records of the capture of requirements
		3	5	8	10	15

8.2.2 Review of Requirements	• Verify procedure
	• Verify at least **X** recent requests for work from customers, if available (may be some or all of the same from 8.2.1)
	  ○ Of these, ensure the records of review of requirements
	  ○ Of these, verify any quotes or proposals submitted to the customer in response to the request
	  ○ Of these, verify any "no bid" or cases where the organization declined the work as being out of its capability or capacity
		3	5	8	10	15

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, for any that were won and the customer ordered the products, verify the review of the proposal/quote vs the customer order and any subsequent resolution of differences					
8.2.3 Changes to Requirements	• Verify procedure • Verify at least **X** orders or jobs which were changed in the past 12 months, if available ○ Of these, verify records that the changes were reviewed ○ Of these, verify proper communication with the customer ○ Of these, verify any changes to in-process work were implemented properly	1	2	3	5	8
8.3 Design						
8.3.1 Design Approach	• Verify procedure					
8.3.2 Design Planning	• Verify design plan(s) (if separate from procedure in 8.3.1)					
8.3.3 Design Requirements	• Verify at least **X** design projects in the past 12 months, if available ○ Of these, verify all design requirements were captured ○ Of these, verify the records of the review of the design requirements	1	2	3	4	5
8.3.4 Designs	• Verify at least **X** design projects in the past 12 months, if available (may be the same as those assessed in 8.3.3) ○ Of these, verify the designs themselves ○ Of these, verify they meet all the requirements, as applicable ○ Of these, verify they are subject to revision control ○ Of these, verify they have records of initial review and approval	1	2	3	4	5
8.3.5 Design Reviews	• Verify at least **X** design projects in the past 12 months, if available (may be the same as those assessed in 8.3.3) ○ Of these, verify design reviews were conducted as required by the design plan and/or design approach procedure ○ Of these, verify any records of the design reviews	1	2	3	4	5
8.3.6 Design Verification	• Verify at least **X** design projects in the past 12 months, if available (may be the same as those assessed in 8.3.3) ○ Of these, verify records of design verification	1	2	3	4	5
8.3.7 Design Validation	• Verify at least **X** design projects in the past 12 months, if available (may be the same as those assessed in 8.3.3) ○ Of these, verify records of design validation ○ Of these, if testing was performed for design validation, verify the associated test procedures or work instructions	1	2	3	4	5
8.3.8 Design Changes	• Verify at least **X** design projects that underwent changes or revisions in the past 12 months, if available. ○ Of these, verify any records of design change review, approval and revision	1	2	3	4	5

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
8.4 Purchasing and Subcontracting						
8.4.1 Evaluation and Approval of Suppliers	• Verify procedure • Select at least **X** suppliers /subcontractors of raw materials, outsourced processes and/or critical support QMS services, if available ○ Of these, verify records that they suppliers were evaluated and approved per the procedure	3	5	8	15	20

8.4.2 Purchasing	• Verify procedure
	• Verify at least **X** recent purchases made by the organization of raw materials, outsourced processes and/or critical support QMS services in the past 12 months, if available
	  ○ Of these, verify the purchase request was submitted (purchase order, contract, etc.)
	  ○ Of these, verify they contain all necessary requirements
	  ○ Of these, verify they include any necessary flowdown requirements to the supplier
	  ○ Of these, ensure each supplier was evaluated and approved
	  ○ Of these, if any were purchases made for initial evaluation of the supplier, verify temporary supplier approval records
		3	5	8	10	15

8.4.3 Subcontracting	• Verify procedure
	• Verify at least **X** recent purchases made by the organization of subcontracted services in the past 12 months, if available
	  ○ Of these, verify the purchase request was submitted (purchase order, contract, etc.)
	  ○ Of these, verify they contain all necessary requirements
	  ○ Of these, verify they include any necessary flowdown requirements to the subcontractor
	  ○ Of these, ensure each subcontractor was evaluated and approved
		1	2	3	4	5

8.4.4 Verification of Received Items or Services	• Verify procedure
	• Verify at least **X** examples of deliveries made to the organization from suppliers or subcontractors in the past 12 months, if available
	  ○ Of these, verify records of verification of received items or services
	  ○ (Note: this may simultaneously be done as part of the audit of 8.6.2)
		3	5	8	10	15

8.4.5 Ongoing Evaluation of Suppliers	• Verify procedure • Verify overall records of supplier evaluation in the past 12 months • Verify examples of supplier poor performance in the past 12 months, if available					

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, verify records showing the problems were reported to the supplier ○ Of these, verify records showing the organization worked with the supplier to resolve the problems					
8.5 Production and Service Provision						
8.5.1 Control of Production and Service Provision						
8.5.1.1 Production and Service Controls	• During the other audit activities, interview sample of staff to determine if they are being provided adequate controls to ensure work is performed to meet requirements • Verify at least **X** current jobs in production ○ Of these, verify job documentation (e.g., travelers, routers, instructions, work orders, drawings, specifications, etc.) ○ Of these, verify the appropriate equipment and facilities have been provided ○ Of these, verify the appropriate records have been provided for use ○ Of these, verify staff have the proper training for the work required ○ Of these, verify any human error reduction methods have been called out and developed, if created • Verify at least two examples of where a production operation or method was changed, if available ○ Of these, verify the changes to related documents complied with 7.5.2. ○ Of these, verify any changes were only made by authorized personnel	3	5	8	10	15
8.5.1.2 Special Processes	• Verify special processes in use, if available ○ Of these, verify training records of staff performing the work ○ Of these verify related work instructions ○ Of these, verify special process validation records ○ Of these, verify equipment validation records ○ Of these, verify process equipment calibration records, if applicable ○ Of these, verify inspection and test records ○ Of these, verify use of applicable industry standards or specifications, if applicable ○ Of these, verify special process accreditation records, if applicable					
8.5.2 Product Identification and Traceability						
8.5.2.1 Product Identification	• Verify procedure					

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	• During the other audit activities, verify proper identification of raw materials, work in process (WIP), work awaiting inspection or testing, and finished product					
8.5.2.2 Product Traceability	• Verify procedure • During the other audit activities, verify proper serialization and/or batch traceability of work in process (WIP) and finished product • Verify serial number logs or database are accurate, if created • Verify batch logs are accurate, if created • Verify serialization complies with customer requirements, if applicable					
8.5.2.3 Configuration Management	• Verify procedure • During the other audit activities, verify proper identification of product throughout production vs the configuration information • During the other audit activities, verify design data (drawings, specifications, models, etc.) match the intended configuration					
8.5.3 Control of Third-Party Property	• Verify procedure • During the other audit activities, verify proper identification and control of third-party physical property, including tooling, equipment, raw materials, product, etc. • During the other audit activities, verify proper control over third-party intellectual property • Verify that any lost or damaged third-party property within the last 12 months was communicated and resolved with the third party.					
8.5.4 Preservation	• Verify procedure • During the other audit activities, verify proper preservation of raw materials, work in process (WIP), work awaiting inspection or testing, and finished product • During the other audit activities, verify proper controls are in place for handling • During the other audit activities, verify proper controls are in place for packaging (prior to final delivery) • During the other audit activities, verify proper controls are in place for contamination control / FOD • During the other audit activities, verify proper controls are in place for commingling control • During the other audit activities, verify proper controls are in place for internal storage • During the other audit activities, verify proper controls are in place for transportation (prior to final delivery) if applicable • During the other audit activities, verify proper controls are in place for protection (including shelf life control)					

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**

8.5.6 Delivery	• Verify procedure
	• Verify at least **X** shipments underway, if available
	  ○ Of these, verify procedure is being followed
	  ○ Of these, verify any customer packaging and/or shipping requirements are being followed
	• Verify at least **X** shipments from within the past six months (these can be previous shipments or same shipments as above)
	  ○ Of these, verify all appropriate shipping records are complete
	• Verify the organization is tracking shipping damage when it is responsible for shipping
		2	3	5	8	10

8.5.7 Post-Delivery Activities	• Interview management to determine what post-delivery activities are underway • For these activities, verify procedures have been developed • For these activities, verify records of post-delivery activities are maintained as required					
8.6 Inspection and Testing						
8.6.1 Inspection and Testing Requirements	• Verify inspection or test procedures • For all inspection or test records reviewed per 8.6.2 through 8.6.6 below, verify they contain all necessary information • Verify sampling plans are statistically valid or based on published or industry accepted standards • Verify customer or authority waivers for inspection in the past 12 months, if available • Verify some current jobs show that work does not proceed until the necessary inspections or tests are carried out • For any inspection or test failures noted, verify the controls for nonconforming product per 8.7 have been invoked					

8.6.2 Receiving Inspection	• Verify procedure, if created
	• Verify at least **X** examples of deliveries made to the organization from suppliers or subcontractors in the past 12 months, if available
	  ○ Of these, verify records of verification of received items or services
	  ○ (Note: this may be simultaneously done as part of the audit of 8.4.4)
		3	5	8	10	15

8.6.3 First Piece Inspection	• Verify procedure, if created • Verify at least **X** active jobs underway, if available ○ Of these, verify records of first piece inspection, if applicable	3	5	8	10	15
8.6.4 First Article Inspection	• Verify procedure, if created	1	2	3	4	5

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	• Verify at least **X** active jobs underway, if available ○ Of these, verify records of first article inspection, if applicable					
8.6.5 In-Process Inspection	• Verify procedure, if created • Verify at least **X** active jobs underway, if available ○ Of these, verify records of in-process inspection or testing	3	5	8	10	15
8.6.6 Final Inspection	• Verify procedure, if created • Verify at least **X** active jobs underway, if available ○ Of these, verify records of final inspection or testing	3	5	8	10	15
8.7 Control of Nonconforming Product or Service						
8.7.1 General Control of Nonconforming Product or Service	• Verify procedure					

8.7.2 Discovering and Recording Nonconforming Product or Service	• Verify at least **X** active jobs underway, if available
	  ○ Of these, verify records of nonconformities to ensure they include all requirements
	• Reverse the audit direction and verify any nonconforming product already segregated or identified
	  ○ Of these, verify records of nonconformities to ensure they include all requirements
	• In all cases observed above verify nonconforming product is properly:
	  ○ identified
	  ○ segregated
	  ○ reviewed
	  ○ corrected, if applicable
	  ○ studied for root cause, if applicable
	  ○ dispositioned
		3	5	8	10	15

8.7.3 Dispositioning Nonconforming Product or Service	• For any nonconforming product identified in 8.7.2 above, verify records show the proper disposition
	  ○ Of these, verify the nonconforming product has been processed per the disposition
	  ○ Of these, for any that were dispositioned as “repair” or “use-as-is” (or equivalents), verify records of the approvals by the customer or design authority
	  ○ Of these, verify records show that any nonconforming products subjected to rework or repair were then re-inspected					

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
9.0 Performance Evaluation						
9.1 Monitoring, Measurement, Analysis and Evaluation						
9.1.1 Overall QMS Evaluation	• Verify procedure					

9.1.2 Analysis and Evaluation	• Verify all of the following have been monitored and measured in some fashion within the last 12 months:
	  ○ Product / service quality
	  ○ Cost of quality
	  ○ Customer satisfaction
	  ○ Process performance (process quality objectives)
	  ○ Suppler / subcontractor performance
	• (Note: if all of these are already satisfied by the management review records, no additional evidence is required.)					

9.2 Internal Audits						

9.2.1 Purpose of Internal Audits	• Verify at least **X%** of the internal audit reports from the last internal audit cycle
	  ○ Of these, verify the audit included assessment against the organization's procedures and the requirements of Q001.
	  ○ Of these, verify they determine whether each process was effective or not
		100	100	100	75	75

9.2.2 Conducting Internal Audits	• Verify procedure
	• Verify internal audit schedule or log
	• Verify at least **X%** of the internal audit reports from the last internal audit cycle
	  ○ Of these, ensure all requirements were met for each audit
	  ○ Of these, ensure all audits were conducted when scheduled
	  ○ Of these, ensure assigned auditors have training records related to internal auditor training
	  ○ Of these, if any audits were subcontracted, ensure internal auditing is treated as an outsourced process per 4.3.
		100	100	100	75	75

9.2.3 Internal Audit Evidence	• Verify at least **X%** of the most recent internal audit reports ○ Of these ensure the reports include objective evidence of both conformity and nonconformity	100	100	100	75	75
9.2.4 Reporting Internal Audit Nonconformities	• Verify at least **X%** of the most recent internal audit reports ○ Of these, where nonconformities were written, ensure each NC included the required elements	100	100	100	75	75

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, ensure any requiring corrective action were written up in the corrective action system per 10.2 ○ Of these, ensure any requiring preventive action were written up in the preventive action system per 10.3					
9.2.5 Internal Audit Reports	• Verify at least **X%** of the most recent internal audit reports ○ Of these, ensure the reports include all required information	100	100	100	75	75
9.3 Management Review						
9.3.1 Management Review Approach	• Verify procedure • Verify at least the last two management reviews have been conducted as scheduled					
9.3.2 Management Review Requirements	• Verify the last two management reviews ○ Of these, verify all required topics were discussed ○ Of these, verify process objectives and goals were reviewed and adjusted accordingly					
10.0 Improvement						
10.1 Pursuing Continual Improvement	• Verify opportunity list • Interview sample of top management to determine examples of how company is pursuing continual improvement					
10.2 Corrective Action						
10.2.1 Requesting Corrective Action	• Interview sample of staff to determine if they are empowered to submit requests for corrective action					
10.2.2 Processing Corrective Action Requests	• Verify procedure • Verify at least **X** recent corrective action records, if available	3	5	8	10	15
10.3 Preventive Action						
10.3.1 Requesting Preventive Action	• Interview sample of staff to determine if they are empowered to submit requests for preventive action					
10.3.2 Processing Preventive Action Requests	• Verify procedure • Verify at least **X** recent preventive action records, if available	1	2	3	4	5
10.4 Incident Investigation	• Verify if any incidents have been reported related to the company within the past 12 months; this must be done prior to the practical audit, per Q003 • Verify the company has identified incidents within the past 12 months, if applicable.					

Table 1 – Minimum Q001 Evidence Requirements – Manufacturing Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**

	• Verify corrective actions have been filed for each identified incident
	  ○ Of these, verify they are not overdue, and being actively worked
	  ○ Of these, if any are closed, verify the action was taken and verified as effective
	  ○ Of these, verify top management was involved in the corrective action and is monitoring its status					

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
1.0 Purpose	None – not audited					
2.0 References	None – not audited					
3.0 Terms and Definitions	None – not audited					
4.0 Quality Management System Scope						
4.1 Identifying Stakeholders	List of stakeholders					
4.2 Identifying Stakeholders' Concerns and Requirements	List of stakeholders' concerns and requirements					
4.3 Quality Management System Processes						
4.3.1 Internal Processes	• Verify the process definition for each QMS process • Interview one process owner for at least 75% of QMS processes • Verify process objective measurement data for all QMS processes • Verify process change evidence for any process changed within previous 12 months					
4.3.2 Outsourced Processes	• Verify at least **X%** of outsourced process providers are included in approved supplier records • Verify procedure	50%	50%	25%	25%	10%
4.3.3 Process Design	• For initial certification audit: verify all Process Designs • For recertification audits: verify **X** Process Designs for any new process created since last audit	100%	100%	50%	50%	25%
4.4 Quality Management System Scope	• Verify scope statement • Verify all exclusions are suitably justified					
5.0 Quality Management System Leadership						
5.1 Management Commitment						
5.1.1 Demonstration of Management Commitment	• Verify document defining management accountability • Verify management participation in planning activities (will be different for each organization, but may include meeting minutes) • Verify management signature on Quality Policy • Verify management review records include list of attendees, and includes top management					

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	• Verify management analyzed Cost of Quality (may be done as part of Management Review) • Verify management's activities related to communicating the quality culture (will be different for each organization, but may include meeting minutes) • Interview top management on how it manages, leads and supports staff • Interview sample of staff to confirm they have management leadership and support					
5.1.2 Quality Culture	• Verify Quality Culture Plan • Interview sample of staff to ensure they are familiar with Quality Culture					
5.2 Quality Policy	• Verify Quality Policy • Interview sample of staff to ensure they are familiar with Quality Policy					
5.3 Responsibilities and Authorities	• Verify organization's documented definition of top management • Organization's documented definition of responsibilities and authorities (may be embedded in procedures) • Interview sample of staff to confirm they have the authority to carry out their responsibilities					
6.0 Quality Management System Planning						
6.1 Risk and Opportunity Management						
6.1.1 Approach to Risk and Opportunity Management	• Verify procedure • Verify how the organization determines which issues are risks, opportunities, or both.					
6.1.2 Risk Management	• Verify risk list has been developed and includes organization-identified risks • Verify risk mitigation plans for at least **X** of the highest-risk entries	2	3	5	8	10
6.1.3 Opportunity Management	• Verify opportunity list has been developed and includes organization-identified opportunities • Verify opportunity pursuit plans for at least **X** opportunities	1	1	2	2	5
6.2 Change Management	• Verify procedure • For initial certification audit: verify records related to at least **X** process changes, if available • For recertification audits: verify records related to at least **X** process changes since last audit, if available	1	1	2	2	5
7.0 Quality Management System Support						
7.1 Resources						

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
7.1.1 Resource Provision	• Interview sample of staff to confirm if adequate resources have been provided and if they have freedom to request resources.					
7.1.2 People	• Verify that positions critical to quality are filled or, if not, the organization is seeking to fill the positions.					
7.1.3 Infrastructure						
7.1.3.1 Provision of Infrastructure	• During the other audit activities, verify the condition of facilities is not causing service nonconformities or process failures • During the other audit activities, verify the condition of equipment is not causing service nonconformities or process failures • During the other audit activities, verify utilities, transportation resources and IT resources are not causing service nonconformities or process failures					
7.1.3.2 Validation of Equipment	• Verify how **X%** of equipment related to service provision which was implemented within the last 12 months was validated prior to use (note: the organization will determine which equipment is subject to validation.)	100%	100%	50%	25%	10%
7.1.3.3 Preventive Maintenance	• Verify procedure • Verify at least **X** preventive maintenance records, if available	2	5	10	10	20
7.1.3.4 Tooling	• Verify the use of at least **X** devices used to assist the delivery or provision of the service for two projects in the last two months, if applicable and if available • (Note: For software developers this may be applied to development environments, test setups, operating systems.)	1	2	3	5	5
7.1.4 Work Environment	• During the other audit activities, verify all special work environments where additional controls are implemented (clean rooms, ESD controlled areas, secure locations etc.) • Verify general work areas for at least two service provision processes or activities • For the work areas audited, verify the last three months of related records related to work environment control, if created and if available • Verify related work environment control procedures, if created					
7.1.5 Inspection and Testing Resources						
7.1.5.1 Provision of Inspection and Testing Resources	• For service orgs, this will only be applicable if such devices are used to test the service • Verify inspection and test activities, if available ○ Of these, verify **X** devices or resources used are of the proper range, tolerance or suitability for the required inspection or tests	All	10	15	20	30

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**

7.1.5.2 Calibrated Inspection and Testing Devices	• For service orgs, this will only be applicable if such devices are used to test the service
	• Verify procedure
	• Verify at least **X** inspection and test activities which utilize calibrated devices, if available
	  ○ Of these, verify at least three inspection or test devices used, if available.
	  ○ Of these devices, verify the last available calibration record
	  ○ Of these devices, verify they are identified and traceable
	  ○ Of these devices, verify they are handled and preserved properly
	  ○ If any issues are found, repeat verification of an additional 30 devices, if available.
	• Reverse the audit direction, and capture information on a random set of at least 10 calibrated devices found in use.
	  ○ Of these devices, verify the last available calibration record
	  ○ Of these devices, verify they are identified and traceable
	  ○ Of these devices, verify they are handled and preserved properly
	• If calibration is performed in-house, verify at least three calibration procedures (or work instructions) match actual practice
		All	5	8	10	20

	• If calibration is performed by an outside laboratory, verify the records related to at least **X** outside labs, if available
	  ○ Of these, verify the certificates provided by the lab include necessary information, including traceability to standards, as-found condition, environmental conditions.
	  ○ Of these, verify all the labs are captured as approved suppliers per 8.4.
	  ○ Verify that calibration is treated as an outsourced process per 4.4.
	• Verify at least one impact study related to an out-of-tolerance device found within the past 12 months, if available.
		2	3	3	5	5

7.1.5.3 Non-Calibrated Inspection and Testing Resources	• Verify procedure
	• Verify inspection and test activities which utilize non-calibrated resources, if available
	  ○ Of these, verify at least **X** non-calibrated resources used, if available.
	  ○ Of these, verify each has been validated as fit for use per a procedure
	  ○ Of these, verify the last 12 months' validation records, if available
	  ○ Of these, verify they are being used per a procedure
	  ○ Of these, verify they are handled and preserved properly
	  ○ If any issues are found, repeat verification of an additional 30 devices, if available.
		All	5	8	10	20

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	• If validation is performed by an outside source, verify the records related to at least three outside sources, if available ○ Of these, verify all the outside sources are captured as approved suppliers per 8.4.					
7.1.6 Knowledge	• Interview sample of staff to determine if the company retains knowledge so it cannot reasonably be lost in the event of staff changes.					

7.2 Competence & Training	• Select at least **X** positions in the company which are within the scope of the QMS, if available
	  ○ Of these, verify there are records of minimum competence requirements
	  ○ Of these, select at least **X** persons who currently hold the position
	  ○ Of these, verify their training or human resource records prove they met the requirements or, if not, that waivers are on file
	• Verify any training matrix, training database, learning management system, etc., if created
	• Select at least **X** employees, if available
	  ○ Of these, verify the on-the-job or other training records for the past 12 months, if available
		2	3	4	5	6

7.3 Awareness	• Select at least **X** employees, if available ○ Of these, verify most recent awareness training records	2	3	4	5	6
7.4 Communication						
7.4.1 Internal Communication	• Interview sample of staff to determine if internal communication occurs in all directions. • Interview sample of staff to determine if management does not retaliate against staff for reporting valid problems or nonconformities. • Interview top management to verify it communicates the status and health of the QMS to staff (this may include records, if created)					
7.4.2 External Communication	• Interview sample of staff to determine if communication with customers and suppliers is properly routed and responded to. • Verify complaint records for the past six months, if available.					
7.5 Documents and Records						
7.5.1 Development of Documents and Records	• Verify the current QMS document set (in general) • Verify the current QMS record set (in general)					
7.5.2 Control of Documents	• Verify procedure • Verify 100% of top-level procedures and at least ten randomly selected other documents ○ Of these, verify they are controlled per the procedure	2	3	4	5	6

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, verify the records of document review and approval • During the other audit activities, verify if any obsolete documents are still in use • During the other audit activities, verify if any documents are being used at their proper revision levels • During the other audit activities, verify that all documents that instruct are included in the QMS set and related controls • Verify at least **X** external documents in use, if available ○ Of these, verify they are being used at their proper revision level • Of all documents reviewed from above, verify these were available to staff when and where needed.					
7.5.3 Control of Records	• Verify procedure • Verify at least **X** QMS record types ○ Of these, verify they are being controlled per the procedure ○ Of these, verify they are properly protected and preserved ○ For hard records, verify physical storage and protection ○ For electronic records, verify backups and server protections • Verify at least one supplier who is responsible for record control, if available ○ Verify the requirements for record control have been flowed down to the supplier via a contract, purchase order or similar instrument	5	5	8	8	10
7.5.4 Internal Compliance with Documents and Records	• During the other audit activities, verify that staff are following procedures • During the other audit activities, verify that staff are completing records as required					
8.0 Operation						
8.1 Operational Process Planning and Control	• Verify Process Definitions include operational processes (service provision operations, etc.) • (Note: these activities can be combined into larger processes, or developed as standalone processes, based on the organization's choice.) • Verify statistical process control plans are based on statistically valid and/or published methods. • Verify procedure for statistical process control, if created.					
8.2 Capture and Review of Requirements						
8.2.1 Capture of Requirements	• Verify procedure • Verify at least **X** recent requests for work from customers, if available ○ Of these, verify the organization captured the necessary requirements	3	5	8	10	15

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, verify the records of the capture of requirements					
8.2.2 Review of Requirements	• Verify procedure • Verify at least **X** recent requests for work from customers, if available (may be some or all of the same from 8.2.1) ○ Of these, ensure the records of review of requirements ○ Of these, verify any quotes or proposals submitted to the customer in response to the request ○ Of these, verify any "no bid" or cases where the organization declined the work as being out of its capability or capacity ○ Of these, for any that were won, verify the review of the proposal/quote vs the customer order and any subsequent resolution of differences	3	5	8	10	15
8.2.3 Changes to Requirements	• Verify procedure • Verify at least **X** orders which were changed in the past 12 months, if available ○ Of these, verify records that the changes were reviewed ○ Of these, verify proper communication with the customer ○ Of these, verify any changes to in-process work were implemented properly	1	2	3	5	8
8.3 Design						
8.3.1 Design Approach	• Verify procedure • Note: For service orgs, this will apply to the design of the service; this is sometimes done as part of the development of the SOW, proposal or service plan.					
8.3.2 Design Planning	• Verify design plan(s) (if separate from procedure in 8.3.1)					
8.3.3 Design Requirements	• Verify at least **X** design projects in the past 12 months, if available ○ Of these, verify all design requirements were captured ○ Of these, verify the records of the review of the design requirements • Note: for service orgs, this may include service level agreements (SLAs) as well as contractual requirements. • Note for service orgs using an agile design model, scrums or sprints can be reviewed as opposed to entire design projects.	1	2	3	4	5
8.3.4 Designs	• Verify at least **X** design projects in the past 12 months, if available (may be the same as those assessed in 8.3.3) ○ Of these, verify the designs themselves ○ Of these, verify they meet all the requirements, as applicable ○ Of these, verify they are subject to revision control	1	2	3	4	5

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, verify they have records of initial review and approval					
8.3.5 Design Reviews	• Verify at least **X** design projects in the past 12 months, if available (may be the same as those assessed in 8.3.3) ○ Of these, verify design reviews were conducted as required by the design plan and/or design approach procedure ○ Of these, verify any records of the design reviews	1	2	3	4	5
8.3.6 Design Verification	• Verify at least **X** design projects in the past 12 months, if available (may be the same as those assessed in 8.3.3) ○ Of these, verify records of design verification	1	2	3	4	5
8.3.7 Design Validation	• Verify at least **X** design projects in the past 12 months, if available (may be the same as those assessed in 8.3.3) ○ Of these, verify records of design validation ○ Of these, if testing was performed for design validation, verify the associated test procedures or work instructions	1	2	3	4	5
8.3.8 Design Changes	• Verify at least **X** design projects that underwent changes or revisions in the past 12 months, if available. ○ Of these, verify any records of design change review, approval and revision	1	2	3	4	5
8.4 Purchasing and Subcontracting						
8.4.1 Evaluation and Approval of Suppliers	• Verify procedure • Select at least **X** suppliers /subcontractors of materials, outsourced processes and/or critical support QMS services, if available ○ Of these, verify records that they suppliers were evaluated and approved per the procedure	3	5	8	10	15
8.4.2 Purchasing	• Verify procedure • Verify at least **X** recent purchases made by the organization of support services, items used later in service deliverables, outsourced processes and/or critical support QMS services in the past 12 months, if available ○ Of these, verify the purchase request was submitted (purchase order, contract, etc.) ○ Of these, verify they contain all necessary requirements ○ Of these, verify they include any necessary flowdown requirements to the supplier ○ Of these, ensure each supplier was evaluated and approved ○ Of these, if any were purchases made for initial evaluation of the supplier, verify temporary supplier approval records	3	5	8	10	15
8.4.3 Subcontracting	• Verify procedure • Verify at least **X** recent purchases or contracts for subcontracted services in the past 12 months, if available	1	2	3	4	5

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, verify the purchase request was submitted (purchase order, contract, etc.) ○ Of these, verify they contain all necessary requirements ○ Of these, verify they include any necessary flowdown requirements to the subcontractor ○ Of these, ensure each subcontractor was evaluated and approved					
8.4.4 Verification of Received Items or Services	• Verify procedure • Verify at least **X** examples of deliveries of received items or support services in the past 12 months, if available ○ Of these, verify records of verification of received items or services ○ (Note: this may simultaneously be done as part of the audit of 8.6.2)	3	5	8	10	15
8.4.5 Ongoing Evaluation of Suppliers	• Verify procedure • Verify overall records of supplier evaluation in the past 12 months • Verify examples of supplier poor performance in the past 12 months, if available ○ Of these, verify records showing the problems were reported to the supplier ○ Of these, verify records showing the organization worked with the supplier to resolve the problems					
8.5 Production and Service Provision						
8.5.1 Control of Production and Service Provision						
8.5.1.1 Production and Service Controls	• During the other audit activities, interview sample of staff to determine if they are being provided adequate controls to ensure work is performed to meet requirements • Verify at least **X** current services currently underway ○ Of these, verify job documentation (e.g., service plans, instructions, work orders, specifications, etc.) ○ Of these, verify the appropriate equipment and facilities have been provided ○ Of these, verify the appropriate records have been provided for use ○ Of these, verify staff have the proper training for the work required ○ Of these, verify any human error reduction methods have been called out and developed, if created • Verify at least two examples of where service step or method was changed, if available ○ Of these, verify the changes to related documents complied with 7.5.2. ○ Of these, verify any changes were only made by authorized personnel	3	5	8	10	15
8.5.1.2 Special Processes	• Note: this is typically not applicable for service orgs • Verify special processes in use, if available					

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, verify training records of staff performing the work ○ Of these verify related work instructions ○ Of these, verify special process validation records ○ Of these, verify equipment validation records ○ Of these, verify process equipment calibration records, if applicable ○ Of these, verify inspection and test records ○ Of these, verify use of applicable industry standards or specifications, if applicable ○ Of these, verify special process accreditation records, if applicable					
8.5.2 Product Identification and Traceability						
8.5.2.1 Product Identification	• Verify procedure • During the other audit activities, verify proper identification of materials used in service delivery, service deliverables (including deliverable reports or certificates) • Note: If the service provided is the delivery of expertise, then this would include the identification of persons assigned to the project or contract for the delivery of this expertise					
8.5.2.2 Product Traceability	• Verify procedure • During the other audit activities, verify proper serialization and/or traceability of deliverables, if applicable • Verify such activities comply with customer requirements, if applicable					
8.5.2.3 Configuration Management	• Verify procedure • Note: the level of complexity of configuration management will be depended on the organization • Verify configuration baselines, if applicable • Verify configured item lists(s), if applicable • Verify the proper configuration status of at least 10 configured items, if applicable and if available • Verify configuration change control is done per the procedure, if applicable • During the other audit activities, verify proper implementation of configuration management of configured items					
8.5.3 Control of Third-Party Property	• Verify procedure • During the other audit activities, verify proper identification and control of third-party physical property, including tooling, equipment, materials, etc. • During the other audit activities, verify proper control over third-party intellectual property					

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	• Verify that any lost or damaged third-party property within the last 12 months was communicated and resolved with the third party.					
8.5.4 Preservation	• Verify procedure • During the other audit activities, verify proper preservation of materials and deliverables • During the other audit activities, verify proper controls are in place for handling, if applicable • During the other audit activities, verify proper controls are in place for packaging of deliverables, if applicable • During the other audit activities, verify proper controls are in place for contamination control, if applicable. • During the other audit activities, verify proper controls are in place for commingling control, if applicable • During the other audit activities, verify proper controls are in place for internal storage, if applicable • During the other audit activities, verify proper controls are in place for transportation (prior to final delivery) if applicable • During the other audit activities, verify proper controls are in place for protection of deliverables, if applicable • Note: all of the above may include such controls during service delivery, or related to preservation of deliverables.					

8.5.6 Delivery	• Verify procedure
	• Verify at least **X** examples of the delivery of a service or deliverable underway, if available
	  ○ Of these, verify procedure is being followed
	  ○ Of these, verify any required deliverables' packaging and/or delivery requirements are being followed
	• Verify at least **X** submissions of deliverables to the customer from within the past six months (these can be previous shipments or same shipments as above), if available
	  ○ Of these, verify all appropriate delivery records are complete
	• Verify the organization is tracking shipping damage when it is responsible for shipping, if applicable
		2	3	5	8	10

8.5.7 Post-Delivery Activities	• Interview management to determine what post-delivery activities are underway • For these activities, verify procedures have been developed • For these activities, verify records of post-delivery activities are maintained as required					
8.6 Inspection and Testing						
8.6.1 Inspection and Testing Requirements	• Verify inspection or test procedures • Verify the service inspection requirements related to at least three service projects, if available and if applicable • For all inspection or test records reviewed per 8.6.x below, verify they contain all necessary information • Verify sampling plans are statistically valid or based on published or industry accepted standards, if applicable					

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	• Verify customer or authority waivers for inspections or tests in the past 12 months, if available • Verify at least three current projects show that work does not proceed until the necessary inspections or tests are carried out • For any inspection or test failures noted, verify the controls for nonconforming service per 8.7 have been invoked					

8.6.2 Receiving Inspection	• Verify procedure, if created
	• Verify at least **X** examples of items or services received in the past 12 months, if available
	  ○ Of these, verify records of verification of received items or services
	  ○ (Note: this may be simultaneously done as part of the audit of 8.4.4)
		3	5	8	10	15

8.6.3 First Piece Inspection	• Verify procedure, if created and if applicable • Verify at least **X** active service projects underway, if available ○ Of these, verify records of first piece inspection, if applicable • Note: Service orgs may interpret this as referring to simulations, dry runs, test runs, etc. Some may use Design Reviews to satisfy this.	3	5	8	10	15
8.6.4 First Article Inspection	• Verify procedure, if created and if applicable • Verify at least **X** active service projects underway, if available ○ Of these, verify records of first article inspection, if applicable • Note: Service orgs may interpret this as referring to simulations, dry runs, test runs, etc.	1	2	3	4	5
8.6.5 In-Process Inspection	• Verify procedure, if created and if applicable • Verify at least **X** active service projects underway, if available ○ Of these, verify records of in-process inspection or testing	3	5	8	10	15

8.6.6 Final Inspection	• Verify procedure, if created
	• Verify at least **X** active service projects underway, if available
	  ○ Of these, verify records of final inspection or testing of deliverables
	  ○ Note: for some service orgs, this may be final acceptance testing, customer acceptance, or final service inspections.
		3	5	8	10	15

8.7 Control of Nonconforming Product or Service						

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
8.7.1 General Control of Nonconforming Product or Service	• Verify procedure					

8.7.2 Discovering and Recording Nonconforming Product or Service	• Verify at least **X** active service projects underway, if available
	  ○ Of these, verify records of nonconformities to ensure they include all requirements
	• In all cases observed above verify nonconforming service has been properly:
	  ○ identified
	  ○ ceased, if applicable
	  ○ reviewed
	  ○ corrected, if applicable
	  ○ studied for root cause, if applicable
	  ○ dispositioned
		3	5	8	10	15

8.7.3 Dispositioning Nonconforming Product or Service	• For any nonconforming services identified in 8.7.2 above, verify records show the proper disposition
	  ○ Of these, verify the nonconforming service has been processed per the disposition
	  ○ Of these, for any that were dispositioned as “repair” or “use-as-is” (or equivalents), verify records of the approvals by the customer or service design authority
	  ○ Of these, verify records show that any nonconforming services subjected to rework or repair (or equivalents) were then re-inspected					

9.0 Performance Evaluation						
9.1 Monitoring, Measurement, Analysis and Evaluation						
9.1.1 Overall QMS Evaluation	• Verify procedure					

9.1.2 Analysis and Evaluation	• Verify all of the following have been monitored and measured in some fashion within the last 12 months:
	  ○ Service quality
	  ○ Cost of quality
	  ○ Customer satisfaction
	  ○ Process performance (process quality objectives)
	  ○ Suppler / subcontractor performance					

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	• (Note: if all of these are already satisfied by the management review records, no additional evidence is required.)					
9.2 Internal Audits						
9.2.1 Purpose of Internal Audits	• Verify at least **X%** of the most recent internal audit reports ○ Of these, verify the audit included assessment against the organization's procedures and the requirements of Q001. ○ Of these, verify they determine whether each process was effective or not	100	100	100	75	75
9.2.2 Conducting Internal Audits	• Verify procedure • Verify internal audit schedule or log • Verify at least **X%** of the most recent internal audit reports ○ Of these, ensure all requirements were met for each audit ○ Of these, ensure all audits were conducted when scheduled ○ Of these, ensure assigned auditors have training records related to internal auditor training ○ Of these, if any audits were subcontracted, ensure internal auditing is treated as an outsourced process per 4.3.	100	100	100	75	75
9.2.3 Internal Audit Evidence	• Verify at least **X%** of the most recent internal audit reports ○ Of these ensure the reports include objective evidence of both conformity and nonconformity	100	100	100	75	75
9.2.4 Reporting Internal Audit Nonconformities	• Verify at least **X%** of the most recent internal audit reports ○ Of these, where nonconformities were written, ensure each NC included the required elements ○ Of these, ensure any requiring corrective action were written up in the corrective action system per 10.2 ○ Of these, ensure any requiring preventive action were written up in the preventive action system per 10.3	100	100	100	75	75
9.2.5 Internal Audit Reports	• Verify at least **X%** of the most recent internal audit reports ○ Of these, ensure the reports include all required information	100	100	100	75	75
9.3 Management Review						
9.3.1 Management Review Approach	• Verify procedure • Verify at least the last two management reviews have been conducted as scheduled					
9.3.2 Management Review Requirements	• Verify the last two management reviews ○ Of these, verify all required topics were discussed					

Table 2 – Minimum Q001 Evidence Requirements – Service Organizations		ARTIFACT SAMPLE CODES				
Q001 Clause	**Minimum Evidence**	**S1**	**S2**	**S3**	**S4**	**S5**
	○ Of these, verify process objectives and goals were reviewed and adjusted accordingly					
10.0 Improvement						
10.1 Pursuing Continual Improvement	• Verify opportunity list • Interview sample of top management to determine examples of how company is pursuing continual improvement					
10.2 Corrective Action						
10.2.1 Requesting Corrective Action	• Interview sample of staff to determine if they are empowered to submit requests for corrective action					
10.2.2 Processing Corrective Action Requests	• Verify procedure • Verify at least **X** recent corrective action records, if available	3	5	8	10	15
10.3 Preventive Action						
10.3.1 Requesting Preventive Action	• Interview sample of staff to determine if they are empowered to submit requests for preventive action					
10.3.2 Processing Preventive Action Requests	• Verify procedure • Verify at least **X** recent preventive action records, if available	1	2	3	4	5
10.4 Incident Investigation	• Verify if any incidents have been reported related to the company within the past 12 months; this must be done prior to the practical audit, per Q003 • Verify the company has identified incidents within the past 12 months, if applicable. • Verify corrective actions have been filed for each identified incident ○ Of these, verify they are not overdue, and being actively worked ○ Of these, if any are closed, verify the action was taken and verified as effective ○ Of these, verify top management was involved in the corrective action and is monitoring its status					

Table 3 – Artifact Sampling Table

ORGANIZATION'S TOTAL EMPLOYEES		SAMPLE CODE
Min	Max	
1	75	**S1**
76	200	**S2**
201	500	**S3**
501	2000	**S4**
2001	5000	**S5**