Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
4.0 Quality Management System Scope		
4.1 Identifying Stakeholders		
Has the organization created and maintained a record of internal and external stakeholders who are affected by, or have an effect on, the organization's products, services and/or quality management system?	• List of stakeholders	• Same as Manufacturing
Do external stakeholders include customers and suppliers at a minimum?		
Do internal stakeholders include employees and top management at a minimum?		
4.2 Identifying Stakeholders' Concerns and Requirements		
Has the organization created and maintained a record of the concerns and requirements of the stakeholders identified in 4.1?	• List of stakeholders' concerns and requirements, for each stakeholder identified in 4.1.	• Same as Manufacturing
4.3 Quality Management System Processes		
4.3.1 Internal Processes		
Has the organization determined the processes within the scope of the quality management system?	• None.	• None
Has the organization prepared a documented process definition for each process which defines: a) the process owner(s)?	• Process definition for each QMS process.	• Same as Manufacturing
… b) a general description of the process flow and how it interacts with other processes?		
… c) process quality objectives as text statements defining the intended purpose of the process?		
… d) process metrics as the data to be collected and measured in order to determine if the process quality objective is being met?		
Do the process owner(s) then oversee the measurement of the process metrics?	• Interview responses • Process measurement records • Possibly management review records	• Same as Manufacturing
Based on this data, has top management established goals for these process quality objectives?		
When a process does not meet the goals, does top management take suitable action?		
Are changes to internal processes be performed in accordance with the change management requirements of 6.2?	• Interview responses • Process change evidence (possibly records)	• Same as Manufacturing
4.3.2 Outsourced Processes		
Are outsourced processes performed by approved suppliers per the requirements of 8.4?	• Approved supplier lists include outsourced process providers (per 8.4)	• Same as Manufacturing
Does the organization maintain a documented procedure that defines additional controls to be implemented to ensure each outsourced process meets requirements?	• Procedure.	• Same as Manufacturing
4.3.3 Process Design		
When the organization seeks to implement a new internal quality management system process, is the process designed in a controlled manner that includes: a) determining the intent of the process?	• Process Design Plan records	• Same as Manufacturing
… b) determining stakeholders?		
… c) determining responsibilities and authorities?		
… d) determining required resources?		
… e) determining associated risks and opportunities?		
… f) determining process quality objective(s)?		
… g) determining process metrics?		

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
… h) determining control points (reviews, inspections, tests, etc.)?		
… i) determining process control parameters?		
… j) determining the need for supporting documents and records?		
Has the organization recorded the process design plan which captures the above information?		
Does the process design plan include evidence of review and approval by appropriate management before implementation of the process?		
Once implemented, has the organization ensured the requirements of 4.3.1 are implemented for the new process?		
4.4 Quality Management System Scope		
Has the organization documented a scope statement that defines the locations, products, services, and processes to be included in the quality management system?	• Scope statement	• Same as Manufacturing
Does the scope statement indicate a justification as to why any clause of this standard is to be excluded?	• Scope statement	• Same as Manufacturing
Are clauses only excluded when the organization's activities do not include the activities covered by the clause?		
5.0 Quality Management System Leadership		
5.1 Management Commitment		
5.1.1 Demonstration of Management Commitment		
Does top management demonstrate its commitment to leading and improving the quality management system by: a) documenting how it takes accountability for the effectiveness of the quality management system?	• Document defining management accountability methods	• Same as Manufacturing
… b) providing evidence of participation in quality system planning activities?	• Interview responses • Meeting minutes • Planning documents records	• Same as Manufacturing
… c) signing the quality policy?	• Quality Policy	• Same as Manufacturing
… d) providing evidence of participation in management reviews (see 9.3)?	• Management review records	• Same as Manufacturing
… e) reviewing and analyzing cost of quality data (see 9.1.2)?	• Management review records	• Same as Manufacturing
… f) communicating the quality culture?	• Interview responses • Quality Culture Plan	• Same as Manufacturing
… g) providing evidence of how it manages, leads and supports subordinate staff?	• Interview responses and related evidence	• Same as Manufacturing
5.1.2 Quality Culture & Customer Focus		
Has top management adopted and implemented a culture of quality that focuses on satisfying the customer's requirements?	• Interview responses	• Same as Manufacturing
Is the definition of this culture and the plan for its implementation documented?	• Quality Culture Plan	• Same as Manufacturing
5.2 Quality Policy		
Has top management developed, documented and published a quality policy that: a) summarizes the organization's culture of quality?	• Quality Policy • Interview responses	• Same as Manufacturing
… b) is easily understood?		
… c) is relevant to the organization and its products or services?		
5.3 Responsibilities and Authorities		
Has the organization documented who is considered "top management" and thus responsible for the requirements of top management called out by this Standard?	• Organization's documented definition of top management	• Same as Manufacturing

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Does top management include the senior-most manager(s) responsible for the organization, giving consideration of the scope limitations defined per 4.4?		
Does top management ensure that responsibilities relative to the quality management system are defined and documented?	• Organization's documented definition of responsibilities and authorities (may be embedded in procedures)	• Same as Manufacturing
Does top management ensure that personnel have the necessary authority to carry out their responsibilities?	• Interview responses	• Same as Manufacturing
Do the defined responsibilities and authorities include: a) who is responsible for collecting process performance data and reporting it to top management?	• Organization's documented definition of responsibilities and authorities (may be embedded in procedures)	• Same as Manufacturing
… b) who is responsible for implementing procedures?		
… c) who will act as the point of contact for third parties when representing the quality management system?		
6.0 Quality Management System Planning		
6.1 Risk and Opportunity Management		
6.1.1 Approach to Risk and Opportunity Management		
Has the organization determined its approach to managing risks and opportunities, and define this in a documented procedure?	• Procedure	• Same as Manufacturing
Does the organization use the issues identified in 4.2 and determine which of these issues presents a risk, which of these issues presents an opportunity, or which of these issues presents both a risk and opportunity?	• Interview responses • Risk List • Opportunity List	• Same as Manufacturing
6.1.2 Risk Management		
Has the organization identified risks including: a) issues identified per 6.1.1 as being risks?	• Risk List	• Same as Manufacturing
… b) additional risks identified by management or staff at any time?		
… c) risks that arise from discussions, data analysis or any other reason during operation of the quality management system?		
Is a list of risks maintained as a record, and updated as appropriate?		
Has the organization developed a documented procedure defining how it manages risks?	• Procedure	• Same as Manufacturing
Does the procedure define a risk rating used to decide when a risk is acceptable vs. unacceptable?		
Has the organization developed risk mitigation plans for any risk rated as unacceptable?	• Risk mitigation plans	• Same as Manufacturing
Are risk mitigation plans recorded, implemented, and verified after completion?		
6.1.3 Opportunity Management		
Has the organization identified opportunities including: a) issues identified per 6.1.1 as being opportunities?	• Opportunity List	• Same as Manufacturing
… b) additional opportunities identified by management or staff at any time?		
… c) opportunities that arise from discussions, data analysis or any other reason during operation of the quality management system?		
Is a list of opportunities maintained as a record, and updated as appropriate?		
Has the organization developed a documented procedure defining how it manages opportunities?	• Procedure	• Same as Manufacturing
Does the procedure define how opportunities are to be identified, assessed, and rated?		
Does the procedure define an opportunity rating used to decide when an opportunity is worth pursuing vs. not worth pursuing?	• Opportunity pursuit plans	• Same as Manufacturing

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Does the organization develop an opportunity pursuit plan for any opportunity rated as worth pursuing?		
Are opportunity pursuit plans recorded, implemented, and verified after completion?		
6.2 Change Management		
Are changes to the quality management system carried out in accordance with a documented procedure?	• Procedure • Change records	• Same as Manufacturing
Does the change management procedure ensure that: a) changes are formally requested?		
… b) changes undergo review and approval by appropriate management?		
… c) change plans are recorded and implemented?		
… d) change plans include intended dates of implementation, if appropriate?		
… e) once implemented, the change is evaluated to ensure it was effective and did not cause unexpected problems?		
… f) documents or records are created or updated, if necessary?		
7.0 Quality Management System Support		
7.1 Resources		
7.1.1 Resource Provision		
Does top management promote a culture that allows staff to request resources related to the quality management system?	• Interview responses	• Same as Manufacturing
Does top management give proper consideration to such requests?		
7.1.2 People		
Has the organization provided employees, contractors, staff, temporary help, etc., necessary for the effective implementation of the quality management system processes, and/or to ensure quality of products and services?	• Interview responses • Current staffing needs vs staff	• Same as Manufacturing
7.1.3 Infrastructure		
7.1.3.1 Provision of Infrastructure		
Has the organization provided and maintained the infrastructure necessary for the quality management system processes, and/or to ensure quality of products and services?	• Observation of facilities, utilities, equipment, transportation resources, IT resources	• Same as Manufacturing
Does infrastructure include, at a minimum: a) facilities?		
… b) utilities?		
… c) equipment?		
… d) transportation resources?		
… e) information technology (IT) resources?		
7.1.3.2 Validation of Equipment		
Is equipment directly impacting on product quality checked prior to regular use to ensure it functions properly and does not introduce nonconformities?	• Validation activities, records (if created)	• Same as Manufacturing
7.1.3.3 Preventive Maintenance		
For facilities and equipment with a significant effect on product quality, has a preventive maintenance program been developed to reduce unplanned defects or downtime?	• List of equipment or facilities subject to PM • Interview responses • Observation of equipment and facilities	• Same as Manufacturing
Is the preventive maintenance program defined in a documented procedure?	• Procedure	• Same as Manufacturing
Are records of preventive maintenance maintained?	• PM records	• Same as Manufacturing
7.1.3.4 Tooling		

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Are tooling, jigs, fixtures and other support devices identified to distinguish them from product, if such confusion is likely?	• Observation of tooling, jigs, fixtures or other support devices	• For service orgs, this may include any devices used to assist the delivery or provision of the service • For software developers this may be applied to development environments, test setups, operating systems.
Are such items identified as to their intended product or service, unless they are intended for general use?		
Are such items maintained to the extent required to ensure their ongoing suitability?		
7.1.4 Work Environment		
Has the organization provided and maintained the work environment necessary for the quality management system processes, and/or ensure quality of products and services?	• Observation of work environment in general, and assess for possible risks to quality • Observation of environment control methods • Related procedures (if used)	• Same as Manufacturing
Do the controls for the work environment include physical, electronic and atmospheric conditions that would cause negative impact on quality if not properly managed (i.e., temperature, heat, humidity, lighting, air quality, etc.)?		• Service orgs must also consider these factors, as they apply to the delivery of the service.
7.1.5 Inspection and Testing Resources		
7.1.5.1 Provision of Inspection and Testing Resources		
Are resources needed for the inspection or testing of products or services provided?	• Observation of inspection tools in use	• Same as manufacturing if such tools are used in the delivery of service.
Has the organization ensured that these resources are suitable for the specific type of inspection and testing to be performed (e.g., of sufficient accuracy, suitable tolerances)?		
7.1.5.2 Calibrated Inspection and Testing Devices		
Are inspection and testing devices used to accept or reject products or services calibrated in accordance with a documented procedure?	• Procedure • Observation of calibrated devices • Observation of calibration methods • Interview responses • Observation of handling and preservation of devices	• Same as manufacturing if such tools are used in the delivery of service. • For software development, this may include CPU clocking or other controls used in the testing environment.
Does the calibration procedure include: a) a definition of the calibration frequency for each resource?		
… b) the calibration method for each device;		
… c) who will perform the calibration for each device (e.g., the organization or an approved supplier);		
… d) how devices will be uniquely identified to trace back to the calibration records;		
… e) how devices will be identified with their current calibration status, so that users know when they are overdue;		
… f) how such devices are to be maintained to ensure ongoing proper functioning and capability; and		
… g) how such devices are to be protected from mishandling, damage or deterioration that would invalidate the calibration.		
Are records of calibration maintained?	• Calibration records	
When the organization performs calibration, are the methods used defined in one or more documented procedures?	• Calibration work instructions or procedures	
When the organization chooses to outsource calibration, is this defined and managed as an outsourced process?	• Outsourced process procedure(s) – see 4.4.2	
Is calibration performed against traceable standards, so that there remains an unbroken chain of metrological traceability through to recognized standards?	• Calibration certificates and/or records	
If no such traceability is possible, has the organization documented its validation of the calibration method employed?	• Observation of validation methods	
Does the organization record an impact study when a resource is reported as being defective, nonconforming or otherwise out of tolerance?	• Impact studies	

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Does this study analyze the impact of the problem, whether or not any product or services were negatively affected, and what actions are to be taken, up to and including a recall?		
7.1.5.3 Non-Calibrated Inspection and Testing Resources		
When calibrated devices are not suitable for use in inspection or testing of a product or service, are non-calibrated resources for inspection and testing developed and provided?	• Same as service provider	• Verify the types of tools or methods used. This may be inspection checklists, audit lists, procedures, test software, etc.
Has the organization ensured that these resources are suitable for the specific type of inspection and testing to be performed (e.g., of sufficient accuracy, suitable usability, etc.)?		• Ensure these appear valid for use.
Are non-calibrated inspection or testing resources validated in accordance with a documented procedure?		• Procedure. • Verify validation method can ensure resource is effective • Verify frequency and re-validation methods are defined • Verify definition of who will perform validation • Verify such resources are identified, where they can be (form names, procedure names, software file names, etc.) • Verify resources are updated and maintained as needed
Does this procedure define: a) the method of validating the resource so that it provides confident results?		
… b) the frequency and methods of any re-validation of the resource, if necessary?		
… c) indication of who will perform the validation (e.g., the organization or an approved supplier)?		
… d) how such resources will be identified so that users clearly understand which resources to use?		
… e) how such resources are maintained and updated to ensure ongoing usefulness?		
Are records of validation of such resources maintained?		• Verify records of resource validation.
When the organization chooses to outsource validation of its non-calibrated inspection or testing resources, is this defined and managed as an outsourced process?		• Verify outsourced process procedure(s) include third-party verification providers – see 4.4.2
7.1.6 Knowledge		
Has the organization determined the knowledge necessary for the quality management system processes, and/or ensure the quality of products and services?	• Interview responses	• Same as Manufacturing
Has the organization implemented methods to reduce the loss of such knowledge when changes to staff occur?		
7.2 Competence & Training		
Has the organization recorded the necessary competence of staff in terms of minimum education, training, and experience?	• Job descriptions / position descriptions • Position requirements matrix • Procedures (may define this information in some cases)	• Same as Manufacturing
Has the organization then provided training or other actions to ensure persons achieve that competence, when needed?	• Training records	• Same as Manufacturing
Where management elects to waive a specific competence requirement for a person, is the justification to do so recorded?	• Training waiver records	• Same as Manufacturing
Does the organization provide additional training as required (e.g., on-the-job training, skills advancement, process improvement training, etc.)?	• Training records	• Same as Manufacturing
Does training include applicable quality management system documentation for the position?		
Does the organization maintain a documented procedure defining its training program?		
Are records of training maintained?		
7.3 Awareness		

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Does training also include initial orientation and periodic re-training on: a) the quality policy (per 5.2)?	• Training records • Interview responses	• Same as Manufacturing
… b) the organizational quality culture (per 5.1.2)?		
… c) each person's relevant process quality objectives (per 4.3)?		
… d) each person's contribution to the quality management system?		
… e) how to report quality management system problems and nonconformities?		
Are there records of the awareness training?		
7.4 Communication		
7.4.1 Internal Communication		
Has the organization ensured that methods are implemented to allow internal communication in all directions (i.e. management to staff, staff to management, staff to staff, between processes, etc.)?	• Interview responses	• Same as Manufacturing
Does top management ensure that no retaliation is taken against staff who report valid problems or nonconformities related to the organization's quality management system, products or services?		
Does top management periodically communicate the status and health of the quality management to staff, and invite suggestions or opportunities for improvement?	• Interview responses	• Same as Manufacturing
7.4.2 External Communication		
Has the organization ensured that incoming communication from customers and suppliers is properly routed, responded to, and any issues addressed as needed?	• Interview responses	• Same as Manufacturing
Does this communication ensure that customer complaints are captured and processed per the requirements of 10.2?	• Complaint records	• Same as Manufacturing
7.5 Documents and Records		
7.5.1 Development of Documents and Records		
Has the organization developed documents and records to support and the quality management system processes?	• QMS document set • QMS record set	• Same as Manufacturing
Does this include documented procedures and records required by this Standard, as well as any required by the organization itself?		
7.5.2 Control of Documents		
Has the organization developed a documented procedure which defines how documents are: a) drafted?	• Procedure • Observation of documents for review, approval, publication, revision • Observation of documents in use by staff	• Same as Manufacturing
… b) reviewed?		
… c) approved?		
… d) published?		
… e) revised?		
Are all quality system documents which instruct subject to this procedure?		
Are records of document approval and release maintained?	• Records of document review	• Same as Manufacturing
Are quality system documents subject to revision control?	• Evidence of document revision	• Same as Manufacturing
Where feasible, do revised documents have a means of identifying the changes made to the document?	• Documents change histories or equivalent	• Same as Manufacturing
Are obsolete documents identified as obsolete, to ensure they are not accidentally confused with current documents?	• Observation of documents in use	• Same as Manufacturing
Are documents of external origin managed to ensure the proper revision is obtained and used, per requirements?	• Observation of external documents in use	• Same as Manufacturing
Are all documents readily available where they are needed by staff?	• Observation of staff's access to documents	• Same as Manufacturing
7.5.3 Control of Records		
Has the organization developed a documented procedure which defines how records are: a) created?		• Same as Manufacturing

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
… b) filed?	• Procedure • Observation of physical records storage and protection • Backups of electronic records • Observation of record retention and disposition methods	
… c) preserved, including backup and protection of electronic records?		
… d) retained, including minimum retention times?		
… e) disposed of?		
Has the organization flowed down requirements for quality system record retention to any suppliers who hold such records for the organization?	• Purchase Order terms and conditions • Subcontractor/supplier contracts	• Same as Manufacturing
7.5.4 Internal Compliance with Documents and Records		
Has the organization ensured that its employees and staff comply with the requirements of its quality management system procedures and complete necessary quality system records as directed?	• Observation of staff's adherence to procedures	• Same as Manufacturing
Do the organization's employees and staff work to the latest revision of quality management system procedures unless otherwise directed by specific work requirements?	• Observation of documents in use by staff	• Same as Manufacturing
8.0 Operation		
8.1 Operational Process Planning and Control		
Before work commences, does the organization ensure that operational processes are included in the defined quality management system processes (see 4.3), and that the process objectives, metrics and controls are adequate and implemented?	• Process Definitions	• Same as Manufacturing
If statistical process control is to be implemented, are the methods defined in a documented procedure?	• Procedure	• Same as Manufacturing, if implemented (often is not applicable for service orgs)
Are statistical process control techniques statistically valid and/or based on published and industry-accepted methods?	• Observation of SPC methods	
8.2 Capture and Review of Requirements		
8.2.1 Capture of Requirements		
Does the organization ensure all applicable requirements are captured before a decision to accept work is finalized?	• Interview responses • Observation of incoming work vs. org capabilities and capacity	• Same as manufacturing but some service orgs may also have to capture service level agreements (SLAs), formal statements of work (SOWs), or more detailed contractual requirements. • Business development pipeline
Is the capture of requirements performed in accordance with a documented procedure?	• Procedure	
Does the capture of customer requirements include: a) requirements provided by the customer directly?	• Records of requirements	
… b) requirements not provided by the customer, but known to the organization as being applicable?		
… c) related statutory and regulatory requirements related to the product or service?		
… d) information from any applicable prior work?		
Are all such requirements recorded prior to review?		
8.2.2 Review of Requirements		
Does the organization ensure all applicable requirements are reviewed before a decision to accept work is finalized?	• Procedure • Records of requirements review	• Same as Manufacturing, but proposal development for some service orgs may be a much more robust, complicated activity, involving many stakeholders. Assessment should ensure the org adequately reviewed all requirements (cost, technical,
Is the review of requirements performed in accordance with a documented procedure?		
Does the review of customer requirements ensure: a) the organization has the capability and capacity to perform the work?		
… b) the organization can meet required quality levels or expectations?		

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
… c) the organization can satisfy any applicable statutory and regulatory requirements related to the product or service?		quality, etc.) before agreeing to the work. • Business development pipeline
If the organization cannot meet all requirements, does it then either negotiate with the customer to resolve any issues, or decline the work altogether?	• Interview responses	• Same as Manufacturing
Is a record of the review of requirements maintained, along with the final decision to accept or decline the work?	• Records of requirements review	• Same as Manufacturing
If the organization provides a preliminary proposal or quotation for the work, does it review any subsequent orders received from the customer against the original proposal or quotation?	• Quotes / proposals vs. resulting customer order or contract.	• Same as Manufacturing
If any differences are noted, has the organization resolved these with the customer before beginning work?		
8.2.3 Changes to Requirements		
Does the organization have a documented procedure that defines how it address changes to requirements once work has begun?	• Procedure • Observation of communication between org and customer re: changes • Change records • Observation of changes	• Same as Manufacturing, but review how changes to services are addressed and implemented. • Verify how services already underway are suspended or changed to reflect the changes
Does this procedure address changes prompted by the customer as well as changes prompted by the organization itself?		
Does this procedure also address how any work currently underway will be processed to address the change, if applicable?		
Are records of changes to requirements maintained?		
8.3 Design		
8.3.1 Design Approach		
Has the organization defined its approach to design activities in a documented procedure?	• Procedure	• The Q001 standard allows a service org to exclude this clause, as it's still somewhat product-biased. However, the rules here can be applied to the design of service. If so, then a procedure would be required here.
Does this procedure include a description of how the organization meets all the other requirements of clause 8.3?		
Does this procedure address the design of products at a minimum, but address the design of services as deemed appropriate by the organization?		
8.3.2 Design Planning		
Has the organization developed and documented one or more design plans?	• Design plan(s)	• Service orgs typically have individual design plans for each project; these would apply here. • Agile or hybrid design models based on scrums and sprints can be used, but the design plan would likely have to define how the org "tailored" its approach to meet the requirements. The requirements could be applied at the sprint level, or the project level, for example.
Does the design plan define: a) the design approach, if not already defined from the documentation in 8.3.1?		
… b) the responsibilities and authorities for the design activities;		
… c) how design requirements will be captured (8.3.3);		
… d) how designs will be produced (8.3.4);		
… e) the required design reviews (8.3.5);		
… f) the required verification (8.3.6) and validation (8.3.7) activities;		
… g) methods for requesting and controlling design changes (8.3.8);		
… h) the internal and external resources needed for the design activities;		
… i) any intended customer or third-party interactions for the design activities;		
… j) the requirements for subsequent manufacturing of the designed product or provision of the designed services;		
… k) the expected completion dates for the design-related activities or milestones; and		
… l) the specific records required.		
8.3.3 Design Requirements		
Has the organization determined the requirements for the intended product or service being designed?	• Design requirements	• Same as Manufacturing

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Has the organization considered: a) functional and performance requirements?		• Service providers often have a highly developed Statement of Work (SOW) to define many requirements, and/or may refer to the proposal that was submitted for the project. • Software designers may have stories, use cases, etc., alongside technical and operational requirements.
… b) information derived from prior designs?		
… c) information derived from similar designs?		
… d) applicable statutory and regulatory requirements?		
… e) standards, specifications or codes relevant to the design?		
Are the requirements clear and complete, and any conflicting design requirements resolved?		
Are the design requirements recorded?		
8.3.4 Designs		
Does the output of the design activity take the form of formal, documented and approved designs?	• Designs (in whatever form).	• Organizations that provide only services, and no product at all, may address this by writing procedures that define how the service will be delivered. This becomes the "design," although later may become a work instruction.
Do the designs include, as appropriate: a) adequate definition of the product or service with the intent of ensuring it can be manufactured or delivered at a later date?		• Statement of work (SOW) • Service plan(s) • Contract(s) • Proposal(s) • Service orgs may include SLA's here.
… b) applicable acceptance criteria, including acceptable tolerances, to allow for subsequent inspection and testing during production or service provision?		
… c) raw materials to be used, including any certification requirements for such materials?		• Service orgs could interpret this as including supporting services that will be incorporated into the final service.
… d) specific suppliers to be used for raw materials or outsourced processes?		• Service orgs could interpret this as relating to teaming partners or subcontractors.
… e) applicable tools, jigs, fixtures, production equipment and/or inspection equipment to be used?		• Service orgs could interpret this as development environments, supporting tools for service, service inspection methods, etc.
Are designs subject to revision control, and have records of initial review and approval?	• Records of review and revision control of designs.	• Same as Manufacturing
8.3.5 Design Reviews		
In addition to the initial review of designs discussed in 8.3.4, does the organization arrange other design reviews as appropriate for the chosen design approach (8.3.1) and design plan(s) (8.3.2)?	• Observation of any additional design reviews conducted, • Associated records.	• Service orgs typically conduct preliminary design reviews, critical design reviews, and other such activities. • There should be records of these activities.
When such additional reviews are performed, are records maintained of the results of the review and any actions to be taken, including design improvements or revisions?		
8.3.6 Design Verification		
Is design verification performed to ensure the design satisfactorily addresses all design requirements as appropriate for the chosen design approach (8.3.1) and design plan(s) (8.3.2)?	• Observation of design verification methods • Associated records.	• Some service orgs may engage in Independent Verification & Validation (IV&V) which would satisfy 8.3.6 and 8.3.7, even if not done in the same order. • Verification may also simply be a roundtable review of the design
Are records of design verification maintained?		

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
		with stakeholders before trial runs.
8.3.7 Design Validation		
Is design validation performed to ensure a product or service resulting from the design meets the design requirements, as appropriate for the chosen design approach (8.3.1) and design plan(s) (8.3.2)?	• Design validation methods and records. • First Article Inspection records	• Service validation may be done through trial runs with records maintained of results. • This may also include simulation runs of software, or testing on test servers prior to going live on public servers.
Where tests are used for design validation, are these done in accordance with documented test methods?	• Validation testing procedures or work instructions	
Are records of design validation maintained?	• Design validation records	
8.3.8 Design Changes		
Are changes to designs reviewed and approved prior to implementation?	• Observation of design change methods • Engineering Change Orders (ECO) method, or similar methods. • Records of design reviews • Design revisions	• Same as Manufacturing
Do revised designs have their revision levels advanced to distinguish them from prior designs?		
Are records of design changes and approvals maintained?		
Do design revision records include a suitable description of the nature of the change?		
8.4 Purchasing and Subcontracting		
8.4.1 Evaluation and Approval of Suppliers & Subcontractors		
Does the organization evaluate and approve suppliers of materials, products and support services in accordance with a documented procedure?	• Approved supplier list / records • Enterprise Resource Planning (ERP) entries for products showing approved suppliers	• Same as Manufacturing • Some service orgs may also have Teaming Agreements with third-party suppliers or subs.
Does this include any subcontractors, including those used to support quality management system activities?		
Are records maintained of suppliers, the approval status and their scope of approval?		
In all cases, has the organization retained final responsibility for products or services provided by suppliers or subcontractors?		
8.4.2 Purchasing		
Does the organization conduct purchasing of items and services in accordance with a documented procedure?	• Procedure	• Same as Manufacturing
Does the organization only purchase items and services from suppliers who have been evaluated and approved?	• Purchases vs approved supplier records	• Same as Manufacturing
Where the organization purchases test items or services for evaluation purposes, is the temporary supplier approval condition recorded?	• Temporary supplier approval records	• Same as Manufacturing
Is the temporary supplier approval updated when the evaluations are complete?		
Does the organization provide the supplier with a purchase request for the items or services to be purchased?	• Purchase Orders • Contracts	• Same as Manufacturing
Do such purchase requests include, at a minimum: a) description of the items or services to be purchased?		
… b) any required delivery dates requested by the organization?		
… c) any applicable organizational requirements related to the item or service?		
… d) any applicable statutory or regulatory requirements related to the item or service?		
Are records of purchases, including the purchase requests, retained?		
8.4.3 Subcontracting		
Where the organization subcontracts activities or services, is this done in accordance with a documented procedure?	• Procedure	• Same as Manufacturing

Requirement	Acceptable Evidence	
	Manufacturing	**Service Provider**
Does the organization use contracts or other documents to define the required services to be provided by subcontractors and outsourced process providers?	• Subcontract agreements, contracts • Purchase Orders	• Service orgs are likely to have considerably more details subcontracts • This may apply to subcontractors when the org is the "prime" on a contractor, or it may only apply to subcontractors used for support services, but whom are not recognized as a "sub" by the customer.
Do such contracts or documents clearly define any applicable requirements, limitations, and scope of work?		
8.4.4 Verification of Received Items or Services		
Are purchased items or services verified as conforming to requirements before used by the organization?	• Observation of verification activities • Observation of receiving inspections	• Same as Manufacturing • For service orgs this will apply to products purchased which are then delivered as part of the service • This may also apply to any subcontractor services delivered to the customer on behalf of the service org.
Are verification of received items and services performed in accordance with a documented procedure?	• Procedure	
Are records of the verification of received items or services maintained?	• Receiving inspection records • Service acceptance records • Other records of verification of received items	
8.4.5 Ongoing Evaluation of Suppliers		
Does the organization perform ongoing evaluation of suppliers and subcontractors to monitor their performance in accordance with a documented procedure?	• Procedure	• Same as Manufacturing • Teaming partner reviews • Subcontractor SLA performance data
Is the level of evaluation and control over each supplier determined based on the criticality of the supplier and/or the products or services provided?		
Does the organization advise the supplier when performance is found to be unacceptable, and work to resolve the issue with the supplier or disqualify them from future purchasing consideration?	• Supplier Corrective Action Requests (SCARs) or equivalent • Notices of defects to suppliers	• Same as Manufacturing
Are records of supplier evaluation and actions taken maintained?	• Records of supplier / subcontractor evaluation	• Same as Manufacturing
8.5 Production and Service Provision		
8.5.1 Control of Production and Service Provision		
8.5.1.1 Production and Service Controls		
Has the organization provided production and service personnel with the appropriate controls to ensure work is performed which meets requirements?	• Observation of activities	• Observation of service activities
Do such controls include, as appropriate: a) documentation and/or records which define the work to be performed, product or service requirements, and inspection and test criteria?	• Travelers / routers • Work Orders • Job documentation • Work instructions • Drawings • Specifications	• Service deliverables • Service reports • Work instructions • Specifications • SOW • Proposal • Contract with customer
… b) equipment required for the work, including inspection and testing devices?	• Observation of equipment and devices	• Same as Manufacturing
… c) suitable equipment and facilities?	• Observation of facilities	• Same as Manufacturing
… d) description of the records to be completed during work?	• Records	• Same as Manufacturing

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
… e) any specific training for the work?	• Training records	• Same as Manufacturing
… f) tooling, devices or special methods to reduce human error?	• Observation of tooling or special methods (e.g., poka-yoke)	• Same as Manufacturing, if utilized
Are changes or revisions to work-specific instructions or documentation only made by authorized personnel, and subject to formal document change rules per 7.5.2?	• Travelers / routers • Work Orders • Job documentation • Work instructions • Drawings • Specifications	• Same as Manufacturing • SOW changes • Contract modifications • Procedure changes
8.5.1.2 Special Processes		
Where any special process work or activity cannot be verified by the organization through normal inspection or testing, has the organization implemented additional controls, including as applicable: a) additional training of personnel responsible?	• Training records	• Same as Manufacturing, if applicable
… b) additional documented work instructions?	• Work instructions	
… c) additional records of special process validation?	• Special process validation records	
… d) validation of the equipment used?	• Equipment validation records	
… e) calibration of process equipment?	• Process equipment calibration records	
… f) additional inspection or testing methods?	• Inspection and test records	
… g) use of applicable industry standards or specifications?	• Job documentation or instructions	
… h) special process accreditation?	• Accreditation records	
8.5.2 Product Identification and Traceability		
8.5.2.1 Product Identification		
Does the organization identify product at all times to ensure it is not misplaced, commingled, or misidentified?	• Observation of product throughout facility	• For service orgs, this applies to deliverables such as products included with the service, deliverable reports, delivered software, etc.
Does this include the status of inspection and testing, as appropriate?		
Is product identified so that it cannot be mistaken for raw materials, tooling or equipment?		
Are product identification methods defined in a documented procedure?	• Procedure	• Same as Manufacturing
8.5.2.2 Product Traceability		
If individual product serialization, traceability and/or batch identification is required, does the organization implement appropriate methods to ensure this?	• Observation of product throughout facility • Serial logs / databases • Serialization records • Batch logs	• For service orgs, this applies to deliverables such as products included with the service, deliverable reports, delivered software, etc. – and only when these need to be individually identified.
Where serial or batch numbers are used, does the organization ensure these are not duplicated?		
Where necessary, do any records related to the product reference the individual product serial numbers or batch number for which the records refer?		
Are product traceability methods defined in a documented procedure?	• Procedure	• Same as Manufacturing
8.5.2.3 Configuration Management		

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Where the organization produces or works with assemblies or complex parts that require configuration management controls, are these controls implemented so that sub-components and sub-assemblies are traceable to the final assembly, and all applicable paperwork is representative of the configuration?	• Configuration baselines • Configuration database • Drawings / models • Bills of Materials (BOMs) • Observation of product throughout facility • Configuration audit records • Configured Item list • Travelers / routers	• Same as Manufacturing • Service providers may treat many additional items as Configured Items, including deliverables, resources, internal documents, and more. • For software developers this will likely include controls for the configuration of the software products
Are configuration management methods defined in a documented procedure?	• Procedure	• Same as Manufacturing • Service orgs may have multiple procedures to support this
8.5.3 Control of Third-Party Property		
Does the organization ensure proper handling, identification, protection, and preservation of property belonging to third parties, including customers or suppliers, when the organization has control over the property?	• Observation of third-party product throughout facility • Observation of third-party intellectual property use	• Same as Manufacturing • Will include any usage of third-party property when services are performed on the customer's site
Does this include both physical property and intellectual property, including third-party data?		
When third party property is lost, damaged, or compromised, does the organization report this to the property's owner and retain records of the issue?	• Communications with customers	• Same as Manufacturing
Is the control of third-party property performed in accordance with a documented procedure?	• Procedure	• Same as Manufacturing
8.5.4 Preservation		
Does the organization preserve product at all times to the extent necessary to ensure quality?	• Observation of product throughout facility • Observation of perishable items' expiration dates • Observation of preservation activities • FOD controls / program • Travelers / routers • Work instructions	• For service orgs, this applies to deliverables such as products included with the service, deliverable reports, delivered software, etc. • For electronic deliverables, this would require backups, firewalls, antimalware protections, etc.
Do preservation activities include handling, packaging, contamination control, commingling control, shelf life control of perishable items, internal storage, transmission or transportation, and protection?		
Are preservation activities defined in a documented procedure?	• Procedure	• Same as Manufacturing
8.5.5 Delivery		
Does the organization deliver completed products or services in accordance with applicable requirements?	• Observation of packaging and shipping activities	• Service delivery records • Customer acceptance reviews • Contract close-out records • Post-mortem meetings or reviews
Do these requirements include, as applicable: a) customer's preferred or required delivery method?	• Shipping instructions • Travelers / routers	
… b) required packaging?	• Observation of packaging	
… c) required documentation and/or records to accompany the product or service?	• Shipping documents	
Where the organization performs delivery, does the organization preserve the quality of product throughout transit until delivery?	• Shipping records • Observation of finished product loading • Nonconformity reports related to shipping damage	
Where appropriate, does the organization define delivery activities in a documented procedure?	• Procedure	

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Are records of product service and delivery maintained?	• Shipping records	
8.5.6 Post-Delivery Activities		
Has the organization defined what post-delivery activities it is responsible for and perform them in accordance with all applicable requirements?	• Observation of post-delivery activities	• Service delivery records • Customer acceptance reviews • Contract close-out records • Post-mortem meetings or reviews
Where appropriate, has the organization defined post-delivery activities in one or more documented procedures?	• Service procedures • Field work procedures • Other post-delivery procedures	
Are records of post-delivery activities maintained when required?	• Site service records • Field work records • Repair records • Other post-delivery records	
8.6 Inspection and Testing		
8.6.1 Inspection and Testing Requirements		
Does the organization perform inspection and/or testing on products and services to ensure all requirements have been met before final delivery or service conclusion?	• Observation of inspection and testing methods • Travelers / routers	• Contractual requirements • Observation of inspection and testing methods • SOW • Inspection records (for each type of inspection) • Test records (for each test) • Test procedures
Are inspections and tests performed in accordance with one or more documented procedures?	• Inspection or test procedures	
For all applicable inspection and test types listed in 8.6.2 through 8.6.6, are records maintained and include at a minimum: a) the results of the inspections or tests?	• Inspection records (for each type of inspection) • Test records (for each test) • Detailed Inspection Plans (DIPs)	
… b) the person or persons conducting the inspections or tests?		
Where sampling plans are used for inspection or testing, are these documented, statistically valid and/or based on published and industry-accepted standards?	• Sampling plans	• Same as Manufacturing
Does the organization ensure that product that is not inspected or tested is not delivered unless under waiver by the customer or other relevant authority?	• Customer or authority waivers	• Same as Manufacturing
Are such waivers recorded?		
Does work not proceed until the required inspections and tests are completed, and the results show that the requirements have been met?	• Inspection or test records • Travelers / routers	• Contractual requirements • Observation of inspection and testing methods • SOW • Inspection records (for each type of inspection) • Test records (for each test) • Test procedures
Where requirements have not been met, are the controls for nonconforming product defined in 8.7 invoked?	• Nonconformance records	• Same as Manufacturing
8.6.2 Receiving Inspection		
Where deemed appropriate to meet the requirements of 8.4.4, is inspection or testing of received items or services performed?	• Receiving inspection records • Observation of receiving inspection activities	• Same as Manufacturing, but applicable to items purchased in support of service or project
8.6.3 First Piece Inspection		
Where deemed appropriate, is a representative product or batch from the beginning of an operation inspected or tested to ensure the operation is reliable for ongoing production?	• First piece inspection records • Observation of first piece inspection activities	• Service orgs may interpret this as referring to simulations, dry runs, test runs, etc. • Some may use Design Reviews to satisfy this.
Is first piece inspection repeated when significant changes to the production operation are made?		

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
		• Otherwise, same as Manufacturing
8.6.4 First Article Inspection		
Where deemed appropriate or required by the customer, is a first article inspection performed utilizing a designated sample part or batch?	• FAI records • Observation of FAI activities • Customer FAI requirements	• Service orgs may interpret this as referring to simulations, dry runs, test runs, etc. • Otherwise, same as Manufacturing
Does first article inspection include activities necessary to ensure all applicable production steps, materials, certifications, suppliers, equipment and methods result in a product that meets all requirements, including physical characteristics?		
8.6.5 In-Process Inspection		
Where deemed appropriate, are inspections and/or tests of products being produced, or services being delivered, performed to ensure quality?	• In-process inspection records • Observation of in-process inspection activities • Travelers / routers	• Service inspection and test records • Performance logs • Observation of service activities
8.6.6 Final Inspection		
Are final inspections and/or tests performed to ensure products or services meet requirements before delivery or completion?	• Final inspection records • Observation of final inspection activities • Travelers / routers	• Service inspection and test records • Performance logs • Final delivery acceptance records • Observation of service activities
8.7 Control of Nonconforming Product or Service		
8.7.1 General Control of Nonconforming Product or Service		
Does the organization ensure that nonconforming product is not used or delivered?	• Observation of production and inspection/testing activities	• Observation of service activities
Has the organization maintained a documented procedure on the controls for nonconforming product or service, which covers how the organization complies with 8.7.2 and 8.7.3?	• Procedure	• Same as Manufacturing
8.7.2 Discovering and Recording Nonconforming Product or Service		
Does the organization segregate nonconforming product, or cease nonconforming services, and subject them to review?	• Observation of nonconforming product • Nonconformity reports • Nonconformity logs • Other nonconformity records	• Same as Manufacturing
Does the review of nonconforming product or service include: a) identification of the nonconforming product or service?		
… b) review of the nature of the nonconformity?		
… c) initial correction of the nonconformity?		
… d) determination of the cause(s) of the nonconformity?		
… e) disposition (see 8.7.3)?		
Are records of the nonconforming product or service maintained?		
8.7.3 Dispositioning Nonconforming Product or Service		
Do possible dispositions of nonconforming product or service include, as appropriate: a) scrap / discard product?	• Nonconformity reports • Other nonconformity records • Customer / authority waivers • Return to vendor records	• Same as Manufacturing
… b) cancel service?		
… c) rework to bring the nonconforming product into conformity without altering the design?		
… d) repair, to bring the nonconforming product into conformity by altering the design?		
… e) providing alternate or improved service to address the nonconforming service?		
… f) return to supplier?		
… g) use-as-is?		
… h) regrade?		
… i) other dispositions determined by the organization?		

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Are records of the nonconformity dispositions maintained?		
Are dispositions of repair or use-as-is approved by the customer and/or design authority holder, with records of such approvals maintained?		
Are products subjected to rework or repair then re-inspected, with records of the reinspection maintained?	• Reinspection / retest records	• Same as Manufacturing
9.0 Performance Evaluation		
9.1 Monitoring, Measurement, Analysis and Evaluation		
9.1.1 Overall QMS Evaluation		
Does the organization evaluate the performance and effectiveness of the quality management system in accordance with a documented procedure?	• Procedure	• Same as Manufacturing
9.1.2 Analysis and Evaluation	•	
Does the organization analyze and evaluate quality system data related to the following, at a minimum: a) product / service quality?	• Interview responses • Management Review records • Supplier evaluation records • Process objective data • Customer satisfaction data • Cost of quality data • Other QMS analysis records	• Same as Manufacturing
… b) cost of quality?		
… c) customer satisfaction?		
… d) process performance against the defined process quality objectives?		
… e) the performance of suppliers and subcontractors?		
9.2 Internal Audits		
9.2.1 Purpose of Internal Audits		
Does the organization conduct internal quality system audits to ensure the quality management system: a) conforms to the organization's requirements and procedures?	• Internal audit records	• Same as Manufacturing
… b) conforms to the requirements of this Standard?		
… c) is effectively implemented and maintained?		
9.2.2 Conducting Internal Audits		
Are internal audits performed in accordance with a documented procedure which covers how the organization meets all the requirements of clause 9.2?	• Procedure • Internal audit schedule / log • Internal audit reports / records • Corrective action requests (related to audit findings) • Preventive action requests (related to audit findings	• Same as Manufacturing
Does the internal audit activity include planning of: a) the frequency of audits?		
… b) the scope of audits?		
… c) the internal audit method(s) to be used?		
… d) records to be completed?		
… e) the internal auditors assigned to each audit?		
Has the organization scheduled audits according to the results of prior audits, process performance issues, or other concerns?		
Does the frequency of internal audits ensure that all quality management system processes and/or clauses of this Standard are audited at least annually?		
Does the organization maintain the schedule of internal audits as a formal record?		
Are internal auditors selected to ensure objectivity and the impartiality of the audits?		
Is training of internal auditors performed in accordance with requirements established by the organization per 7.2?	• Internal auditor training records	• Same as Manufacturing
Where internal audits are subcontracted to third parties, is this controlled as an outsourced process per 4.3?	• Outsourced process records	• Same as Manufacturing
9.2.3 Internal Audit Evidence		
Do auditors gather and capture objective evidence to support audit findings?	• Internal audit reports / records	• Same as Manufacturing

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
Is the evidence captured in a manner that is verifiable by third parties at a later date?		
Do the findings of internal audits include: a) evidence of conformity?		
… b) evidence of actual nonconformities (see 9.2.4)?		
… c) evidence of potential nonconformities (see 9.2.4)?		
… d) opportunities for improvement made by the internal auditors?		
9.2.4 Reporting Internal Audit Nonconformities		
Where either actual or potential nonconformities are reported, are these reported in a manner that includes the following three details: a) a clear description of the requirement (e.g., clause reference, procedure citation, etc.)?	• Internal audit reports / records • Corrective action requests (related to audit findings) • Preventive action requests (related to audit findings)	• Same as Manufacturing
… b) a clear description of the objective evidence reviewed or observed?		
… c) a clear description of why the objective evidence shows the requirement was not met?		
Do actual nonconformities require corrective action per 10.2?		
Do potential nonconformities require preventive action per 10.3?		
9.2.5 Internal Audit Reports		
Are records of internal audit reports maintained?	• Internal audit reports / records	• Same as Manufacturing
Do these records contain at a minimum: a) the audit plan details per 9.2.2?		
… b) evidence reviewed per 9.2.3?		
… c) descriptions of nonconformities per 9.2.4?		
9.3 Management Review		
9.3.1 Management Review Approach		
Does top management review the quality management system's performance in accordance with a documented procedure?	• Procedure	• Same as Manufacturing
Does the management review procedure define: a) the methods for management review?		
… b) the minimum frequency for management review?		
… c) the minimum personnel required to attend the management review?		
… d) the topics to be reviewed at management review (see 9.3.2)?		
Is the management review conducted at a minimum annually?		
9.3.2 Management Review Requirements		
At a minimum, does the management review include a review of the following aspects: a) necessary changes and updates to stakeholders (per 4.1)?	• Management review records • Corrective action requests (related to management reviews) • Preventive action requests (related to management reviews) • Process quality objective goals	• Same as Manufacturing
… b) necessary changes and updates to stakeholders' issues (per 4.2)?		
… c) risks and related mitigation plans (per 6.1.2)?		
… d) opportunities and related pursuit plans (per 6.1.3)?		
… e) process performance metrics (per 4.3)?		
… f) customer satisfaction (per 9.1.2)?		
… g) cost of quality (per 9.1.2)?		
… h) performance of suppliers and subcontractors (per 8.4.1)?		
… i) training effectiveness and related needs (per 7.2)?		
… j) the adequacy of resources (per7.1)?		
… k) trends related to corrective and preventive actions (per 10.2 and 10.3)?		
… l) internal and external audit results (per 9.2)?		
… m) status of incident investigations (per 10.4)?		
… n) the status of actions from previous management reviews?		

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
… o) changes to the organization or the quality management system?		
… p) opportunities for improvement for the quality management system?		
Does the organization maintain records which capture evidence of the review of the aspects listed above, and any decisions made as a result?		
10.0 Improvement		
10.1 Pursuing Continual Improvement		
Does the organization pursue continual improvement of its products, services, and quality management system processes by: a) following up and updating the opportunities pursued as defined in 6.1.3?	• Opportunities list • Interview responses • Other records of opportunities and improvements	• Same as Manufacturing
… b) implementing additional opportunities based on the analysis of data in 9.1.2 and management review results of 9.3?		
10.2 Corrective Action		
10.2.1 Requesting Corrective Action		
Does the organization empower employees and staff to request corrective action on existing nonconformities related to: a) poor quality management system process performance and/or failure of a process to meet a goal?	• Interview responses • Corrective action records	• Same as Manufacturing
… b) trends in product or service nonconformity?		
… c) internal or external audit findings of nonconformity?		
… d) customer complaints?		
… e) reductions in levels of customer satisfaction?		
… f) any other reason determined appropriate by management?		
10.2.2 Processing Corrective Action Requests		
Is the method for processing corrective actions defined in a documented procedure?	• Procedure	• Same as Manufacturing
Is each corrective action request: a) recorded?	• Corrective action records	• Same as Manufacturing
… b) assigned to a subject matter expert or team for resolution?		
… c) have documented containment taken to correct the immediate nonconformity, if applicable to the issue?		
… d) have a root cause analysis conducted and documented by the subject matter expert or the team?		
… e) have a corrective action plan documented and implemented which seeks to resolve the root cause(s) and prevent the nonconformity from recurring?		
… f) reviewed for effectiveness upon completion of the corrective action plan?		
… g) re-issued or some other action taken when the corrective action plan is found deficient?		
… h) closed when the corrective action plan is found sufficient?		
… i) escalated to higher management when the corrective action request is not responded to properly?		
Do records of corrective actions include the corrective action request itself, along with evidence of the completion of (a) through (h) above, and a log of corrective actions which allows for trend analysis?		
10.3 Preventive Action		
10.3.1 Requesting Preventive Action		
Does the organization empower employees and staff to request preventive action on potential nonconformities related to the	• Interview responses • Preventive action records	• Same as Manufacturing

Requirement	Acceptable Evidence	
	Manufacturing	Service Provider
organization's products, services or quality management system processes?		
10.3.2 Processing Preventive Action Requests		
Is the method for processing preventive actions defined in a documented procedure?	• Procedure	• Same as Manufacturing
Is each preventive action request: a) recorded?	• Preventive action records	• Same as Manufacturing
… b) assigned to a subject matter expert or team for resolution?		
… c) have a root cause analysis conducted and documented by the subject matter expert or the team, if deemed appropriate based on the nature of the request?		
… d) have a preventive action plan documented and implemented which seeks to prevent the nonconformity from occurring?		
… e) reviewed for effectiveness upon completion of the preventive action plan?		
… f) re-issued or some other action taken when the preventive action plan is found deficient?		
… g) closed when the preventive action plan is found sufficient?		
Do records of preventive actions include the preventive action request itself, along with evidence of the completion of (a) through (g) above, and a log of preventive actions which allows for trend analysis?		
10.4 Incident Investigation		
Does the organization investigate any incident involving defective or nonconforming products or services delivered to customers or released to the market, whether reported by the customer, media reports, or other third parties?	• Incident reports • Corrective action records	• Same as Manufacturing
At a minimum is the investigation performed according to the corrective action requirements of 10.2?		
Does top management oversee the investigation and records maintained?		