Quality Management System General

Audit Date:

Requirement: 4.1 and 4.2.2-QMS General

Verify Scope Verify the Exclusions is applicable and justified	Comments/Evidence/Findings:
How are the processes in the QMS necessary to meet customer requirements and improve the QMS identified in the Quality Manual? How are the sequence and interaction of these processes outlined in the Quality Manual?	Comments/Evidence/Findings:
How are procedures included or referenced in the quality manual?	Comments/Evidence/Findings:

Is there evidence that the system is being reviewed and improved? Site examples of documents that have been modified recently.

Document	Date Revised

Comments/Evidence/Findings:

How does the organization check to ensure that appropriate resources and information are available to ensure the effective operation of the company's processes? What does the organization monitor to know if things are working well? Is the data being analyzed? How? Is there objective evidence to prove this is happening?	Comments/Evidence/Findings:
What criteria and methods have been determined to ensure that the operation ad control of processes is effective?	Comments/Evidence/Findings:
What does the company do if processes are not working well? Is there objective evidence to prove this is happening? (Check CAPA's)	Comments/Evidence/Findings:
How does the organization handle outsourced product? How do they define the extent of control that is required of an outsourced supplier? Where is this defined? How do people know?	Comments/Evidence/Findings:

Requirement: 4.2.1-QMS Documentation Requirements

Are all required documents present? No need to audit the detail at this point, just ensure there is at least one documented procedure addressing the following:

Required Procedure	Current Revision
Documented Statements of Policy and Objectives	
Quality Manual	
Document Control Procedure	
Records Control Procedure	
Internal Audit Procedure	
Nonconforming Product Procedure	
Corrective Action Procedure	
Preventive Action Procedure	

Comments/Evidence/Findings:

QMS Records Requirements (4.2.1) Is there objective evidence that the following records are in use. There is no need to audit the detail right now, just look for the evidence of the records and that the record control parameters are defined.

Record	Current Rev.	Storage?	Electronic/ Paper	Filed By	Retained for?	Disposition Method
Records documenting education, training, skills and experience for all employees						
Management Review Records						
Evidence that the product realization process and the resulting product meet customer requirements.						
Contract Review including the actions arising after the initial review						
Design and Development (See section 7.3)						
Results of Supplier Evaluation, Approval and Monitoring and actions arising from the Supplier Management program (who's on probation, etc)						
If applicable, records of the unique identification of serialized product.						
Records documenting that processes where the resulting output cannot be verified by subsequent monitoring and measurement are being validated on an on-going basis.						
Records if customer property is lost are damaged.						
Calibration Records including records of what was done if equipment is found to be out of calibration						

Internal Audit Records						
Records indicating who released product for shipment or that service was performed adequately						
Records documenting customer approval if discrepant product is going to be shipped.						
Records of customer notification if discrepant product or service is shipped or rendered and discovered later						
Records of product or service non-conformities and the action taken.						
Records where product non-conformities are repaired or reworked and that they are corrected.						
Results of Corrective Actions						
Results of Preventive Actions						

Comments/Evidence/Findings:

Requirement: 4.2.3-Control of Documents

List the **types** (eg work instructions, routers, procedures, job aids) of documents that "have been determined by the organization to be necessary to ensure the effective planning, operation and control of its processes". Ensure the following parameters have been addressed in the **DOCUMENTED PROCEDURE**.

Check if the definition of each of the parameter exists in the **DOCUMENTED PROCEDURE.** If the organization does not use the document as a controlling document, record N/A in the box.

Document Type (eg work instructions, routers, BOM's, job aids, drawings, CNC programs)	Initial Approval?	Re-Approval?	Accessible?	Current Revision identified?	Changes identified?	Legible?	Obsolete clearly identified
1. Quality Manual							
2. Quality Procedures							
3. Work Instruction							
4. Customer Specs							
5. Drawings							

6. Setup Sheets							
7. Forms							
8. Electronic Forms							
9. Electronic Logs							
10. Computer Software Used for Verification							
11. Computer Software Used in the Product							
12.							
13.							
14.							
15.							

Comments/Evidence/Findings:

Review examples of at least one of EACH of the documents to ensure the procedure is being followed.

Document Reviewed	Initial Approval Evident?	Re-Approval Evident?	Accessible?	Current Revision identified?	Changes identified?	Legible?	Obsolete revisions handled correctly?
1. Quality Manual							
2. Quality Procedures							
3. Work Instruction							
4. Customer Specs (Considered Customer Owned Intellectual Property)							
5. Drawings							
6. Setup Sheets							

7. Forms							
8. Electronic Forms							
9. Electronic Logs							
10. Computer Software Used for Verification							
11. Computer Software Used in the Product							
12.							
13.							
14.							

15.							
16.							

Comments/Evidence/Findings:

Requirement: 4.2.3-Control of Documents-External Documents

Does the **DOCUMENTED PROCEDURE** define how External Documents are controlled? How does the organization know where external documents are stored? How do does the organization know this current revision has been approved for use? How are obsolete copies handled? How does the organization know when a document is revised that the changes have been reviewed and appropriately implemented? How does the organization know that the revisions are up to date?	Comments/Evidence/Findings:

Review examples of documents and check the following parameters to ensure the system for controlling external documents is working.

Individual External Document Reviewed	Current Revision Correct?	Distribution Defined?	Evidence of Approval?
a) Customer Specs			
b) ISO Standard			
c)			
d)			
e)			
f)			
g)			

Comments/Evidence/Findings:

Requirement: 4.2.4-Control of Records

Does the **DOCUMENTED PROCEDURE** define how records are controlled? If I am creating a new record do I know how to in general:

Parameter	Yes this is defined (please check the procedure)
What I need to do to make sure a record is identifiable to the person/event/or product?	
Where to define storage?	
Where to define how it is indexed?	
Where to define how long the record is retained?	
Where to define how it is disposed after the retention period is complete?	

Comments/Evidence/Findings:

Does the **DOCUMENTED PROCEDURE** define how records are protected? If there are electronic records how are they backed up?	Comments/Evidence/Findings:

General Comments

Quality Management Processes

Audit Date:

Requirement: 5.3-Quality Policy

Identify the Quality Policy	Comments/Evidence/Findings?
Comment on how the quality policy has been documented and approved to ensure • That it is appropriate to the organization (takes into account the relevant activities of the organization and is not too broad or vague) (5.3a)	Comments/Evidence/Findings?
• Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system. (5.3b)	Comments/Evidence/Findings?
• Provides a framework for setting and reviewing quality objectives (5.3c);	Comments/Evidence/Findings?
• Is communicated and understood within the organization	Comments/Evidence/Findings?
• Is reviewed for continuing suitability	Comments/Evidence/Findings?

Requirement: 5.4.2-QMS Planning

Ensure that the integrity of the QMS is maintained when changes are planned and implemented (5.4.2b)? (consider what actions are taken when standards or other regulatory requirements are revised or business conditions change)	Comments/Evidence/Findings?

Requirement: 5.5.1-Responsibility and Authority

How does management define the required positions within the organization?	Comments/Evidence/Findings?
How are changes to position requirements identified and implemented?	Comments/Evidence/Findings?

Requirement: 5.5.2-Management Representative

Identify the member of management that has been appointed by top management as the Management Representative: *Management Representative (Name/Title)*	Comments/Evidence/Findings?
How are the responsibilities of the management representative defined/documented to provide the freedom necessary to ensure that processes are established, implemented and maintained within the QMS (5.5.2a)?	Comments/Evidence/Findings?
Describe how and when the management representative reports to top management on the performance of the QMS (5.5.2b)?	Comments/Evidence/Findings?

Requirement: 5.5.3-Internal Communication

What methods are used to communicate the effectiveness of the QMS within the organization?	Comments/Evidence/Findings?
How does management ensure that roles, responsibilities, authorities are communicated within the organization (5.5.1)?	Comments/Evidence/Findings?
What methods are used to communicate QMS requirements throughout the organization, including awareness of the Quality Policy? Verify effectiveness (5.3d)?	Comments/Evidence/Findings?
How does the management representative promote the awareness of the customer requirements throughout the organization (5.5.2c)?	Comments/Evidence/Findings?

Requirement: 5.1 and 5.4.1-Quality Objectives

Is product Conformity and on-time delivery performance measured?	Comments/Evidence/Findings?

Objectives must be established at relevant functions within the organization by top management, measurable and consistent with the quality policy.

Objective	*How is objective measured?*	*Process Owner Defined?*	*Identify Component of the Quality Policy To Which Objective is Tied*	*Is the metric up to date?*
1. On-Time Delivery (Reqd.)				
2. Product Conformity (Reqd.)				
3.				

4.				
5.				
6.				
7.				

Additional comments/audit evidence regarding Objectives including strengths, weaknesses and details of any incomplete records from the above table:

Requirement: 7.1a-Product Objectives

The organization shall plan and develop the processes for product realization that determine the quality objectives and requirements for the product. (Note: These objectives may be verified concurrently with Product Measurements [section 8.2.4])

Objective	Measurement Method	
1.		
2.		
3.		
4.		
5.		
6.		
7.		

Additional comments/audit evidence regarding Product Objectives including strengths, weaknesses and details of any incomplete records from the above table:

Interview at least 10 employees in different rolls in the organization. Audit the effectiveness of the Quality Management Processes by interviewing them on their awareness of their roll in meeting requirements. Check for awareness in the following categories.

Employee	Quality Policy	Quality Objectives	Customer Perception	Quality Manual	Quality Management System
1.					
2.					
3.					
4.					

5.					
6.					
7.					
8.					
9.					
10.					

General Comments

Analysis Processes

Requirement: Analysis of Data (8.4)

What data have been determined, collected and analyzed to demonstrate the suitability and effectiveness of the QMS? [Such data analysis may be related to quality objectives and result in modifications to these objectives, number of nonconforming product, etc.]				
Identify types of data:				
Data Types	Analysis Method	Reported		
		How	Frequency	Identify Which Objective or Policy Aspect To Which Connected
On-Time Delivery				
Customer Satisfaction				
Supplier Information				
Product Conformity				
Internal Audit				

Identify changes to the effectiveness of the QMS or processes as a result of data analysis (8.5.1).	Comments/Evidence/Findings?

Requirement: 5.1 and 8.2.3-Monitoring and Measurement of Processes

What methods are applied for monitoring (and measuring) QMS processes? These methods shall demonstrate the ability of the processes to achieve planned results.	Comments/Evidence/Findings?
Look for examples including: Process Capability Analysis, Reaction Time, Cycle Time or Throughput, Product Conformity, Product Reliability, Yield, Effectiveness and Efficiency of People and Equipment, Waste Reduction, Cost Reduction	Comments/Evidence/Findings?
When Planned results are not achieved, what actions are taken to ensure conformity of the product?	Comments/Evidence/Findings?

Requirement: 8.2.1-Customer Satisfaction

What methods have the organization implemented for obtaining and using information relating to customer perception (e.g., customer surveys) as to whether requirements have been met?	Comments/Evidence/Findings?
How has the organization effectively measured customer satisfaction and analyzed the results?	Comments/Evidence/Findings?
How does the organization here the “Voice of the Customer?” How is this communicated to the organization?	Comments/Evidence/Findings?

Requirement:7.2.3 and 8.5.2- Customer Complaints

How does the organization track and trend customer complaints?	Comments/Evidence/Findings?
Is the data analysis effective in driving improvements?	Comments/Evidence/Findings?
Is it clear that the immediate complaint has been handled?	Comments/Evidence/Findings?

General Comments

Continual Improvement Processes

Requirement: 8.2.1 and 8.5.1-Continual Improvement

What processes beyond corrective action has the organization put in place to gather ideas for improvement. How effective is the process in ensuring that changes are implemented. Examples could include suggestion programs, Corrective and Preventive Action, Lean Activities, Six Sigma Projects.	Comments/Evidence/Findings?
List examples of projects where data was analyzed and used to drive improvement projects.	Comments/Evidence/Findings?
(Section 8.2.1) Organizations shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assess the effectives ness of the results	Comments/Evidence/Findings?

Requirement: 8.2.2-Internal Audit

To what degree has a program for periodic QMS audits to be carried out been established and maintained, in order to determine whether the quality management system: • conforms to planned arrangements for quality management including the requirements of this International Standard (8.2.2a); and • has been effectively implemented and maintained, including records (8.2.2b).	Comments/Evidence/Findings?
Are records: Legible? Identifiable? Retrievable? Protected From Deterioration/Damage? THIS IS A REQUIRED ISO RECORD	Comments/Evidence/Findings?
When was the last audit cycle of the ENTIRE QMS completed?	Comments/Evidence/Findings?
Do any of the organization's customers require audits? How do these requirements make it to the Internal Audit Schedule?	Look for: Product Conformity
Identify Auditors who performed last internal audit and verify their educations, experience, skills or training records.	Comments/Evidence/Findings?

How is top management made aware of the results of this audit (i.e., audit reporting)?	Comments/Evidence/Findings?

Comment on the Effective Implementation of Audits Performed on the QMS based on the following:

Audit Planning (Scope, Frequency, Importance, Results of Previous Audits):	Responsibilities and Resources Allocated to Perform Audits (Auditors do not audit their own work):
Nonconformities Identified (Number, Type, Detail):	Follow-up to Nonconformities. Is the action taken verified as complete and effective? Are the results recorded?

Record the Audit Results Reviewed and Verify:

Process Audited	Date	Auditor	Auditor Training Record on File?	Notes Adequate?	Summary Adequate?	Corrective Action Written?	Verification Result Recorded?

Comments/Evidence/Findings?

Requirement: 8.5.2-Corrective Action

[Action taken on nonconforming activity, i.e., the nonconformity <u>has</u> <u>already</u> <u>occurred</u>] Who has ultimate responsibility for ensuring the nonconformity is reviewed/investigated and corrected?	Comments/Evidence/Findings?
What actions are taken by the organization to eliminate the cause of nonconformities?	Comments/Evidence/Findings?
Actions should include: - reviewing nonconformities - determining cause of nonconformities - evaluating action to prevent recurrence - determining/implementing action needed - recording of results - reviewing corrective action taken	Comments/Evidence/Findings?
How are corrective actions verified? How does the Organization ensure actions are not just complete but effective?	Comments/Evidence/Findings?
How are corrective actions initiated?	Comments/Evidence/Findings?
Identify what changes to procedures or other documents (not just product related) have resulted from corrective actions taken within the last 12-month period?	Comments/Evidence/Findings?

Requirement: 8.5.2-Preventive Action

[Action taken to minimize the likelihood of occurrence of a nonconforming activity, i.e., the nonconformity <u>has</u> <u>not</u> <u>yet</u> <u>occurred</u>] Who has been defined as the responsible authority(ies) for reviewing and investigating a potential nonconformity?	Comments/Evidence/Findings?
What actions are taken by the organization to minimize the likelihood of potential nonconformities? Actions should include: - determining potential nonconformities and their cause - evaluating action to prevent occurrence - determining/implementing action needed - recording of results - reviewing preventive action taken - How are preventive actions initiated?	Comments/Evidence/Findings?
How are preventive actions verified?	Comments/Evidence/Findings?

Identify what changes to procedures or other documents have resulted from preventive actions taken within the last 12-month period?	Comments/Evidence/Findings?

*Review Records - Complete the Following for C/P Actions Raised **Internally** during the Previous 12-Month Period*

CAPA#	Date:	(Potential) Nonconformity:	Action Taken:	Date Verified

Requirement: 5.6- Management Review - General

Identify date(s) of the management reviews that have occurred within the last 12-month period:	Comments/Evidence/Findings? .
Has the management review been documented with sufficient evidence to demonstrate that conformity with applicable requirements is maintained? If no, note deficiencies.	Comments/Evidence/Findings?
How are the processes reviewed for effectiveness during the management review? What does management measure to know?	Comments/Evidence/Findings?
Review the record to ensure that the record control is defined for all of the Management Review components. In particular, make sure the control for the schedule, the agenda, and the minutes are defined.	Comments/Evidence/Findings?
How effective are the Management Review meetings. How / to what extent has continual improvement been realized within the organization by effective use of the Management Review Meeting? (8.5.1)?	Comments/Evidence/Findings?

Requirement: 5.6.2-Review Input

Identify Where/How Last Management Report Addresses Information On:	
- Results of Audits (5.6.2a)	
- Customer Feedback (5.6.2b)	
- Process Performance and Product Conformity (5.6.2c)	
- Reports & analysis of field nonconformities (if applicable)	
- Status of Corrective and Preventive Actions (5.6.2d)	
- Follow-up Actions from Previous Reviews (5.6.2e)	
- Changes that Could Affect the QMS (5.6.2f)	
- Changes to the company, quality standards (ISO 9001:2008), and the industry.	
- Recommendations for Improvement (5.6.2g)	

Requirement: 5.6.3-Review Output

Verify the Last Management Review Report Identifies Any Decisions on:	
- Improving the Effectiveness of the QMS (5.6.3a)	
- Product Improvements per Customer Requirements (5.6.3b)	
- Resource Needs (5.6.3c)	

General Comments

Product Design and Development Process

Audit Date:

The Auditor Shall Determine the Category (Design and Development Situation) That Applies to this Facility:
Product Design/Development Excluded from QMS & Confirmed as an Applicable Exclusion **CONTINUE TO THE NEXT SECTION (PLANNING OF PRODUCT REALIZATION) OF THE REPORT** Product Design/Development Required and Performed In-house **COMPLETE SECTION B AND SECTION C** Product Design/Development Required and Outsourced to an Organization **COMPLETE SECTION A, SECTION B AND SECTION C**

Requirement: 7.3-Design and Development-Section A

Facilities that outsource product design and development activities to another organization are responsible for ensuring that all design information is accurate, meets the requirements of the customer and/or product standard and the design process is controlled.	
Design/Development Performed Outside this facility (Yes/No)?, If Yes, Identify Name of Source:	Comments/Evidence/Findings?
Review the supplier approval record? Does it adequately cover design concerns?	Comments/Evidence/Findings?
Describe, in detail, the process used by the organization to ensure that the design process and design activities outsourced to the design organization will meet customer requirements	Comments/Evidence/Findings?
Describe the process used by the organization to ensure that the required design documents, received from the outsourced organization, are properly implemented into their quality management system as part of the relevant overlapping processes. In other words, how does the organization ensure that the outsourced design outputs are implemented correctly?	Comments/Evidence/Findings?

Requirement: 7.3-Design and Development-Section B-Plan and Inputs

Evidence of Planning and Revision *In cases where Design/Development is performed in house, this may be accomplished through direct observation of activities performed or through review of records.*	
Design and Development (7.3; 7.3.1) How does the organization plan and control the design and development of product to meet applicable requirements?	Comments/Evidence/Findings?
Design and Development Planning (7.3.1a; 7.3.1b; 7.3.1c) How has the organization defined the design and development stages, including review, verification and validation, as well as the required responsibilities? Such responsibilities shall include proper controls for designs developed outside the facility.	Comments/Evidence/Findings?

Design Inputs Include (7.3.2): functional and performance requirements applicable statutory and regulatory requirements information from previous designs (if applicable) other requirements (as applicable) How are the inputs recorded?	Comments/Evidence/Findings?
Design Changes (7.3.7): How are design changes controlled? Are the Changes: Identified? Do the records include evaluation of effect of parts and product already delivered Are Design Change Records Maintained?	Comments/Evidence/Findings?

Requirement: 7.3-Design and Development-Section B-Outputs

Design and Development Product Matrix Select a representative sampling (minimum of three) of design projects
Product Name
1.
2.
3.
4.
5.
6.
7.

Complete table for the products selected and identified above.
Identify Product Name and Yes(y) / No(n) / Not Applicable (n/a) for Each Column.

	Sample Selected (Referenced Above)							
Requirements	1	2	3	4	5	6	7	
Design Outputs Include (7.3.3): - Verification to meet input requirements								
- Appropriate information for purchasing, production and service provision.								
- Information for purchasing, production, service acceptance criteria.								
- **The material, process, manufacturing and assembly data needed to ensure conformity of the product.**								

Design Reviews Include (7.3.4): Evaluation of design results and identification of problems (if any) to - Evaluate the ability of the results of the design and development to meet requirements.								
- Identify problems and propose necessary actions\								
- **Authorize progression to the next phase**								
- Design Review Records Maintained? Legible? Identifiable? Retrievable? Protected From Deterioration/Damage								
Design Verification Includes (7.3.5): - Evaluation of design outputs against design inputs								
- Design Verification Records Maintained? Legible? Identifiable? Retrievable? Protected From Deterioration/Damage?								
Design Validation Includes (7.3.6): - Ensures product is capable of meeting requirements for specified application								
- Design Validation Records Maintained? Legible? Identifiable? Retrievable? Protected From Deterioration/Damage?								
Comments/Evidence								

Requirement: 7.1.3-Configuration management for Design and Development

Establish, implement, and maintain a configuration management process that includes, as appropriate: a. configuration management planning	Comments/Evidence/Findings?
b. configuration identification	Comments/Evidence/Findings?
c. change controls	Comments/Evidence/Findings?
d. configuration status accounting	Comments/Evidence/Findings?
e. configuration audits	Comments/Evidence/Findings?

Requirements: 7.3.7-Revision Changes

How are revision changes controlled? How are the changes identified to employees?	Comments/Evidence/Findings?
Do the records include evaluation of effect of parts and product already delivered?	Comments/Evidence/Findings?
Are design change records Maintained? Legible? Identifiable? Retrievable? Protected From Deterioration/Damage	Comments/Evidence/Findings?

General Comments

Planning

Audit Date:

Requirement: 7.1-Planning of Product Realization

The organization shall plan and develop the processes needed for product realization.	
How are product realization processes planned and developed to meet product / service requirements? Describe how the facility determines: - quality objectives ad requirements for the product.	Comments/Evidence/Findings?
- the specific processes, documents and resources required to produce the product in accordance with customer and requirements (7.1b)	
- The process needed to ensure that product meets any applicable regulatory, statutory and product requirements (7.1b)	Comments/Evidence/Findings?
- The required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for acceptance (7.1c)	Comments/Evidence/Findings?
- The records required to provide evidence that the processes and products are meeting requirements (7.1d)	Comments/Evidence/Findings?
NOTE: In organizations where product realization processes are well established it will be necessary to review process changes or instances where product / services have been added or expanded. Describe how the facility has planned and developed the product realization processes where products / services have been added, product / service volumes have changed or expanded or where major process changes have been realized (if applicable)?	Comments/Evidence/Findings?

Requirement: 7.2.1 and 7.2.2- Determination and Review of Requirements Related to the Product or Service

The organization shall determine product requirements; ensure that differences are resolved and ensure capabilities exist. *Note: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogs or advertising material.*	Comments/Evidence/Findings?
How are changes to customer requirements handled before release to production and after? Is the process effective? How are relevant document changed and personnel notified?	Comments/Evidence/Findings?

How does the organization: - determine product requirements	Comments/Evidence/Findings?
- ensure that differences are resolve	Comments/Evidence/Findings?

- ensure that capabilities (including delivery) exist	Comments/Evidence/Findings?

Document / Contract Reviewed

Complete table for the contracts selected and identified above. Identify Yes / No / Not Applicable (n/a) for Each Column. All 'No' Identifiers shall require a finding to be raised.						
Requirement	Sample Selected (Referenced Above)					
	#1	#2	#3	#4	#5	#6
Have Product Requirements Been Adequately Defined? (7.2.2a)						
Have Contract/Order Differences Been Resolved? (7.2.2b)						
Evidence that Organization has Capability to Meet Requirements? Including Delivery Dates (7.2.2c)						
If Requirements Have Changed, Have Relevant Documents Been Amended or Documentation Evident?						
Has the record control been defined? Are records legible, identifiable, retrievable, and protected from deterioration/damage?						

Requirement 7.2.3-Customer Communication

How does the organization address effective communication to the customer dealing with: - Product information and marketing (7.2.3a)	Comments/Evidence/Findings?
- Enquiries, contracts, order handling (7.2.3b)	Comments/Evidence/Findings?

Requirement: 7.5.5- Preservation of Product

The organization shall preserve the conformity of the product and constituent parts during internal processing through delivery to the intended destination. **Describe** the controls and processes established and implemented to:	Comments/Evidence/Findings?

General Comments

Purchasing and Receiving

Requirement-4.2.1, 7.4.1 and 7.4.2-Supplier Selection and Performance Management Process

Comment on their supplier's ability to supply product in accordance with the organization's requirements. How does the facility control the purchasing processes?		Comments/Evidence/Findings?	
Criteria for selection, evaluation, and re-evaluation are established		Comments/Evidence/Findings?	
Records of evaluations and actions arising from the evaluations are maintained. THIS IS A REQUIRD ISO RECORD.		Comments/Evidence/Findings?	
Document/Purchase Order	Supplier	Date Last Evaluated	Supplier Required to Keep Records? Defined How?

Complete table for the suppliers selected and identified above.
Identify Product Name and Yes(y) / No(n) / Not Applicable (n/a) for Each Column.
All 'No' Identifiers shall require a finding to be raised and details provided therein. Use additional pages if required.

Requirement	Sample Selected (Referenced Above)					
	#1	#2	#3	#4	#5	#6
Have Criteria for Selection/Evaluation Been Defined? (7.4.1/7.4.1.2)						
Have Criteria for Re-evaluation of Suppliers Been Defined? (7.4.1/7.4.1.2)						
Have Evaluations been Performed and Results Maintained? (7.4.1)						
Supplier Records Maintained? Are They Legible? Identifiable? Retrievable? Protected?						

Complete table for the purchase orders selected and identified above.
Identify Product Name and Yes(y) / No(n) / Not Applicable (n/a) for Each Column.
.

Requirement	Sample Selected (Referenced Above)					
	#1	#2	#3	#4	#5	#6
Does Purchasing Information Describe Product (7.4.2)?:						
Adequacy of purchase requirements prior to issuance						
Purchase Order Records Maintained?						

Requirement: 7.4.3-Verification of Purchased Product

Identify the activities established and implemented to ensure that purchased product meets specified purchase requirements	Comments/Evidence/Findings?
A process of product recall is implemented when product released for use prior to completion of required incoming verification	Comments/Evidence/Findings?
Requirements for supplier delegations defined and a register of delegations maintained	Comments/Evidence/Findings?
Purchasing information defines information about the verification activities at the supplier's premises	Comments/Evidence/Findings?

Select a representative (minimum of 3) purchased products.

Document/Purchase Order	Supplier
1.	
2.	
3.	
4.	
5.	
6.	

Complete table for the purchased product selected and identified above.
Identify Product Name and Yes(y) / No(n) / Not Applicable (n/a) for Each Column. .

	Sample Selected (Referenced Above)					
Requirement	#1	#2	#3	#4	#5	#6
Have Criteria for Receiving Inspection Been Defined? (7.4.3)						
Have Criteria for Receiving Inspection Been Met? (7.4.3)						
Verification / Receiving Records Maintained						

Additional comments/audit evidence regarding Purchasing activities and explain all 'No' responses from above:

Requirement: 7.5.3- Identification and Traceability-Receiving

What processes have been implemented to ensure product identification throughout Receiving Process?	Comments/Evidence/Findings?
Where traceability is a requirement, how is it controlled and recorded? .	Comments/Evidence/Findings?
How does production know it is okay to use the material?	Comments/Evidence/Findings?

Requirement: 7.5.4-Customer Property-Receiving

The organization shall exercise care with customer property while it is in the organization's control. (Note: Customer Property can include intellectual property). **Describe** the processes established to ensure that customer property is: - Identified? - Verified? - Protected/Safeguarded?	Comments/Evidence/Findings?

Requirement: 7.5.5-Preservation of Product -Receiving

The organization shall preserve the conformity of the product and constituent parts during internal processing through delivery to the intended destination. **Describe** the controls and processes established and implemented to: **Consider:** • Cleaning • Special handling for sensitive products (ESD) • Marking and labeling including safety warnings • Shelf life control and stock rotation • Special handling for hazardous materials	Comments/Evidence/Findings? . .

For each type of product or material, review at least three examples. Ensure the product is identified, it's inspection status is known, and if traceability is required, the process is being followed: (Pick 3 Examples)

Applies	Item	Record Specific Items Reviewed	Identified?	Inspection Status Known?	Traceability Exists (if required)?

Additional comment regarding the effectiveness of how product is identified.

Requirement: 4.1, 7.4.1, and 7.4.2-Outsourced Processes

General Requirements (4.1) Where an organization chooses to outsource any process that affects product conformity, the organization shall ensure control over such processes.	Comments/Evidence/Findings?

Identify all outsourced processes:

Process (e.g., Design, NDE, Welding; Internal Audits; Inspection & Testing; Man. Rep.):	Type of Control(s) [i.e., Method of Evaluation]	Effective (Y/N) If "No" detail below.	Method of Revalidation (Re-qualification)
1.			
2.			
3.			
4.			
5.			
6.			

Comments/Evidence:

General Comments

Product and Service Realization Processes

Requirement: 7.5.1-Control of Production and Service Provision

The organization shall plan and carry out production and service provision under controlled conditions	Comments/Evidence/Findings?

Select a representative sampling (minimum of 3) of the production/service activities /documents.
Observe activities performed, if possible.

Production/Service Activity and/or Documents	QMS Reference (Product Specification)
1.	
2.	
3.	
4.	
5.	
6.	

Complete table for the activities selected and identified above.
Identify Product Name and Yes(y) / No(n) / Not Applicable (n/a) for Each Column.
'No' Identifiers may require a finding to be raised and details provided therein. Use additional pages if required.

Requirement	Sample Selected (Referenced Above)					
	#1	#2	#3	#4	#5	#6
Information that describes the characteristics of the product available? (7.5.1a)						
Work Instructions available, as required? (7.5.1b)						
Suitable equipment in use? (7.5.1c)						
Suitable tooling and fixtures are in use? Are they controlled?						
Suitable software programs are in use? Are they controlled?						
Suitable samples/models are in use? Are they controlled?						
Availability and use of monitoring/measuring devices? (7.5.1d)						
Monitoring and Measuring Activities Implemented? (7.5.1e)						

Release, Delivery and Post-delivery Activities Implemented (7.5.1f) Note: Post-delivery Activities are those related to in-facility duties such as completion of documentation, customer communications, records maintenance, etc. Post-delivery activities also include, but are not exclusively related to, after-sales servicing, warranty work, etc.						

Requirement: 7.5.2-Validation of Processes for Production and Service Provision

The organization shall validate processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.	Comments/Evidence/Findings?

Select a representative sampling (minimum of 3) of the production/service processes requiring validation

Production/Service Processes and/or Documents	QMS Reference (Product Specification)
1..	
2.	
3.	
4.	
5.	
6.	

Complete table for activities selected and identified above. Identify Yes(y)/No(n)/Not Applicable (na) for Each Column. 'No' Identifiers may require a finding to be raised and details provided therein. Use additional pages if required.

Requirements	Sample Selected (Referenced Above)					
	#1	#2	#3	#4	#5	#6
Are methods used by the organization to define criteria for review and approval of processes established and maintained? (7.5.2a)						
Has required equipment been approved?(6.3, 7.5.1c, 7.5.2b)						
Have qualification requirements been established and implemented for personnel? (6.2.2a, 7.5.2b)						
Are specific methods/procedures/work instructions developed and maintained? (7.5.1b, 7.5.2c)						
Comment on how Process Records are maintained to ensure that they are (4.2.4, 7.5.2d): a. Legible? b. Identifiable? c. Retrievable? d. Protected From Deterioration/Damage?						
Is a process implemented for revalidation of production and service provision and equipment (as necessary for example for a special process or preventative maintenance)? (4.2.3b, 4.2.4, 7.5.2e)						

Requirement: 7.5.3-Identification and Traceability

What processes have been implemented to ensure product identification throughout product realization?	Comments/Evidence/Findings?
Where traceability is a requirement, how is it controlled and recorded?	Comments/Evidence/Findings?
How is product status, with respect to monitoring and measuring, determined throughout product realization? (7.5.3)	Comments/Evidence/Findings?
How are acceptance media (stamps, electronic signatures, passwords) controlled?	Comments/Evidence/Findings?

For each type of product or material, review at least three examples. Ensure the product is identified, it's inspection status is known, and if traceability is required, the process is being followed:

Applies	Item	Inspection Status Known?	Traceability Exists (if required)?
Raw Material			
Components			
Work In Progress			
Warehouse Storage			

Additional comment regarding the effectiveness of how product is identified.

Requirement: 7.5.4-Customer Property

The organization shall exercise care with customer property while it is in the organization's control. (Note: Customer Property can include intellectual property). **Describe** the processes established to ensure that customer property is: Identified?	Comments/Evidence/Findings?
Verified?	Comments/Evidence/Findings?
Protected/Safeguarded?	Comments/Evidence/Findings?

Requirement: 7.5.5- Preservation of Product

The organization shall preserve the conformity of the product and constituent parts during internal processing through delivery to the intended destination. **Describe** the controls and processes established and implemented to: **Consider:** • Cleaning • Special handling for sensitive products (ESD) • Marking and labeling including safety warnings • Shelf life control and stock rotation • Special handling for hazardous materials	Comments/Evidence/Findings?
Package product?	Comments/Evidence/Findings?
Store product?	Comments/Evidence/Findings?
Protect product?	Comments/Evidence/Findings?

General Comments

Product Monitoring/Measuring Processes

Requirement: 7.6-Control of Monitoring and Measuring Devices

How has the organization determined what monitoring and measuring devices are needed to provide evidence of conformity?	Comments/Evidence/Findings?
Verify that the organization has established processes for monitoring and measuring to be carried out in a manner consistent with monitoring and measuring requirements.	Comments/Evidence/Findings?
What processes have been implemented and maintained to assess the validity of previous measuring results when the monitoring and measuring is found to not conform to requirements? What processes have been implemented to ensure appropriate action is taken on affected equipment or product?	Comments/Evidence/Findings?
Comment on how Monitoring/Measurement Equipment Records are maintained to ensure that they are: a. Legible? b. Identifiable? c. Retrievable? d. Protected From Deterioration/Damage? THIS IS A REQUIRED ISO RECORD	Comments/Evidence/Findings?

Complete the Following Using Monitoring/Measuring Equipment Reviewed During the Audit:
Note: Ensure selection of Master Gauges as appropriate

Equipment Type	Serial No.	Cal. Date	Accuracy	Cal. Frequency	Calibration Status	Answer Yes/No		
						NIST*	Stored	Safeguard
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								

**If No National/International Reference Standard Is Available, Ensure That The Basis For Traceability For Calibration Has Been Established*	
Is Software used to in monitoring and measurement? How does the organization confirm that software satisfies the intended application? Is this done prior to initial use? How is this reconfirmed or configuration management used to maintain suitability for use?	Comments/Evidence/Findings?

If applicable, review at least examples of software that is used for monitoring and measurement.

Software Reviewed	Confirmed Prior to Use	Reconfirmed or Configuration Controlled?

Additional comments/audit evidence regarding Monitoring/Measuring Equipment Controls within the QMS (Raise a finding for all nonconformity issues identified in the table above):

Requirement-8.2.3 Monitoring and Measuring of Processes

How does the organization monitor and measure its processes to ensure they are effective?	Comments/Evidence/Findings?
Find examples of corrective actions for processes.	Comments/Evidence/Findings?

Requirement-8.2.4-Monitoring and Measuring of Product

What processes are implemented and maintained to ensure that the organization monitors and measures the characteristics of the product to verify product requirements have been met?	Comments/Evidence/Findings?
Does the organization use statistical techniques to monitor and measure product? If not, why not?	Comments/Evidence/Findings?
Has monitoring and measuring requirements been identified at appropriate intervals to ensure conformity with requirements? If no, identify deficiencies.	Comments/Evidence/Findings?
Review records to ensure that product release/delivery has not proceeded until planned arrangements have been completed (unless approved by relevant authority or the customer).	Comments/Evidence/Findings?
Are the records maintained to ensure evidence of conformity:	Comments/Evidence/Findings?
Verify that records identify the person(s) authorizing release of product.	Comments/Evidence/Findings?

Complete the Following Using Observations, In-Process, or Final Inspection Records of Applicable Product (per API Specification or ISO Scope):

Product	Record Date	Evidence of Conformity	Release Date
1.			
2.			
3.			
4.			
5.			

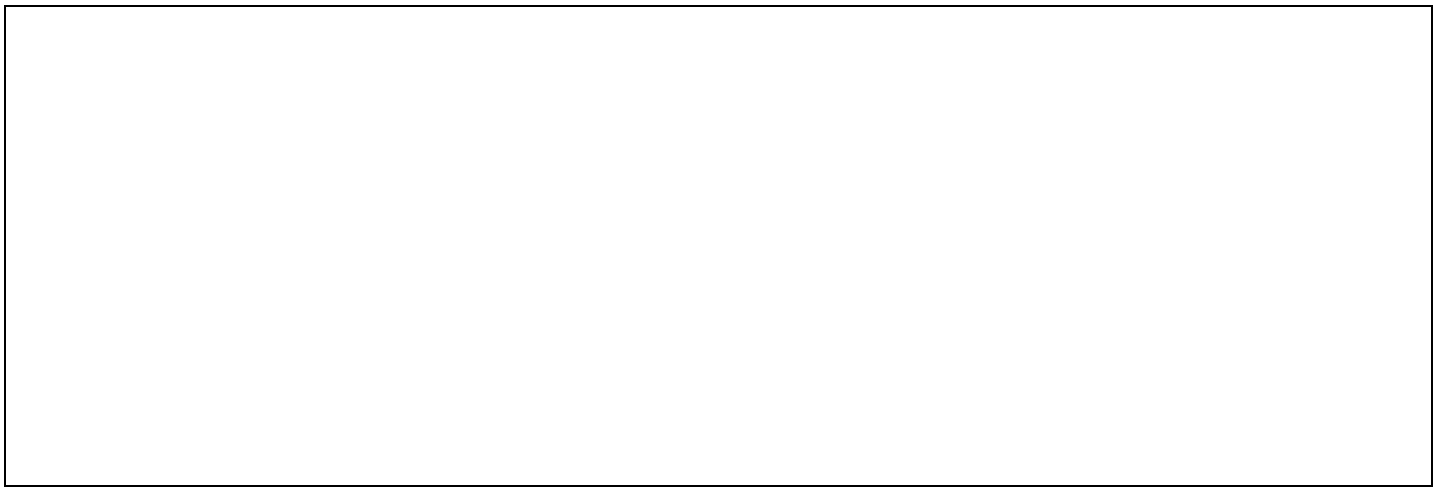
Requirement: 8.3-Control of Nonconforming Product

Identify the processes implemented to prevent unintended use or delivery of product that does not conform to specified requirements.	Comments/Evidence/Findings?
Identify the personnel responsible for control of nonconforming product:	Comments/Evidence/Findings?
Are Nonconforming Product records: a. Legible? b. Identifiable? c. Retrievable? d. Protected From Deterioration/Damage? THIS IS A REQUIRED ISO RECORD.	Comments/Evidence/Findings?
What processes are used to ensure that corrected nonconforming product is re-verified to demonstrate conformity?	Comments/Evidence/Findings?
How are concessions documented?	Comments/Evidence/Findings?
What is the process for evaluation, release and acceptance of nonconforming products (under concession) that do not satisfy manufacturing and/or design acceptance criteria?	Comments/Evidence/Findings?
What is the process for notifying customers in the event that product which does not conform has been delivered? Verify process and that customer notification records exist (if applicable)	Comments/Evidence/Findings?

Complete the Following Using Nonconforming Product Report Records:

Nonconforming Product	Disposition Action	Action to Eliminate Nonconformity	Re-verified	Report Date
1.				
2.				
3.				
4.				
5.				
6.				
7.				

General Comments



Human Resources Related Processes

Requirement: 6.2.1-Competence

Select Representative Sampling of Personnel Performing Work Affecting Quality		
Position	*Competency Measurement (6.2.2a)*	*Competency Verification (6.2.1)*
1.		
2.		
4.		
5.		
6.		
Additional comments/audit evidence regarding competency determinations and verification including details of any incomplete records from the above table (Raise a finding for any deficiencies to meet competency requirements, above):		

Requirement: 6.2.2 and 4.2.1 and 6.2.2-Awareness and Training

How does the organization ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes.	Comments/Evidence/Findings:
How does the organization determine the necessary competence for personnel performing work affecting product quality? (6.2.2a) **[Refer to outsourcing section, as required, for verification of outsourced personnel competence]**	Comments/Evidence/Findings?
How does the facility identify training needs and ensure that personnel receive adequate training to address competency needs. What other methods has the facility used to address competency needs (outsourcing, process changes, etc)? (6.2.2b)	Comments/Evidence/Findings?
How does the organization address the training requirements for personnel to meet position competency requirements? (6.2.1 / 6.2.2)	Comments/Evidence/Findings?

How is the effectiveness of the training actions determined and maintained (i.e., competence evaluation)? (6.2.2c)	Comments/Evidence/Findings?

Complete the Following Using Personnel Interviewed throughout the Audit (Yes/No Response Acceptable):

Person / Position	Qualifications (Y/N)		How/When Made Aware of Activities with Respect to QMS, Objectives and Policy?
	Defined?	Evidence?	
1.			
2.			
3.			
4.			

Additional comments/audit evidence regarding Training Activities within the QMS (Raise a finding for all "No" indications above or other training issues):

Requirement: Infrastructure (6.3)

How does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements as related to: Buildings, workspace utilities?	Comments/Evidence/Findings?
Process equipment (hardware & software)?	Comments/Evidence/Findings?
Support services (e.g., transportation)?	Comments/Evidence/Findings?
How is risk assessed?	Comments/Evidence/Findings?

Requirement: Work Environment (6.4)

How does the organization ensure (manage) the work environment needed to achieve conformity to the product requirements?	Comments/Evidence/Findings?
How is risk assessed?	Comments/Evidence/Findings?