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API MONOGRAM / APIQR PROGRAM

API Spec Q1 9th Edition and ISO 9001:2015

AUDIT REPORT

Scope of the document:

This audit report shall be used when auditing organization claiming conformity to API Spec Q1 9th Edition as a Quality Management System. Also, it is applicable to those organizations that in addition to API Q1 are claiming conformity to ISO 9001:2015 and/or API product specifications included in the Monogram Program.

Requirements specific to ISO 9001:2015 are highlighted with GRAY shading and they are not applicable when conducting audits that do not include ISO 9001:2015 within the scope.

This report is not applicable to audits with a scope limited to ISO 9001:2015.

For audits including Monogram Licenses:

The designated API auditor shall fill out the relevant section of this document and all applicable FM-199 supplementary audit reports associated with the API product specifications under the scope of the audit.

For Surveillance Audits of Monogram-only Facilities:

Section headings with an asterisk (*****) are the only mandatory sections that must be filled out during surveillance audits of Monogram-only facilities. Applicable FM-199 audit reports shall be filled out entirely.

The mandatory sections are:

1. Audit Information, Audit Scope & License Scope
2. Use of API Monogram, APIQR and ANAB Marks
3. Product Realization (with the exception of *5.3 Risk Assessment and Management*, *5.5 Contingency Planning and 5.11 Management of Change*)
4. Internal Audit (API Spec Q1 clause 6.2.2)
5. Audit Summary, Audit Time Summary & Auditor Conclusion/Recommendation

Audit Report

Audit Information*

Facility ID:		Audit ID:	
Company Name/ Facility Name:		***Document any changes in the space below:***	
Facility Address:			
Primary Account Manager(s):			

Lead Auditor:					
Audit Team Members:					
Audit Start Date:		Audit End Date:			
Audit Type:		myCerts Number of Employees:		Verified Number of Employees:	
*Expected Audit Days:		*Assigned Audit Days:		*Actual Audit Days:	
Justification:	**Justification required if different from required audit days – Notify API of any changes and update Audit Plan*				

Shifts:	Start Time	End Time	No. of Employees	Audited? (Y/N)
Shift 1				
Shift 2				
Shift 3				
Explanation *(required for shifts not audited):*				

Audit Scope*

Audit Criteria *(verify applicable standards are available and current)*:	API Spec Q1:9th ed.		ISO 9001:2015		
	API Spec(s):				
	Other criteria:				

License Scope*

--Mark all changes to the scope on this section–

License	Cert #	Status	Expiration Date

Verification of Scope of Registration / Monogram License(s) and Exclusions			
Verify each of the following:	**Select One:**		**Finding #:**
Scope of Registration is accurate for the activities and processes performed by the facility.		**Yes – Scope is Accurate / Appropriate**	
		No – *Mark all changes on registration scope above*	
		N/A – No Certificates of Registration	
Monogram – product scope of Monogram License is accurate for the activities and processes performed by the facility and facility has the manufacturing capability for each product within the scope of the license(s).		**Yes**	
		No – *Mark all changes on license scope above*	
		N/A – No Monogram License(s)	
Exclusions taken are allowable, applicable and justified. Document any discrepancies. **Note:** Please see ***Advisory 6*** for allowable Monogram Program design exclusions.		**Yes – Exclusions, if any, are Accurate/Appropriate**	
		No - Exclusions are not Accurate/Appropriate – *Mark all changes on the scope section above*	
AMA (Alternative Marking Agreement) – if the facility has an AMA, identify the marking party and verify controls established.			
Additional comments*: Provide an explanation for changes.*			
Changes to the QMS since previous audit (if applicable):			

Use of API Monogram, APIQR and ANAB Marks*

Control of the Application of the API Monogram (API Spec Q1, Annex A.5)		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
Marking/monogramming procedure addresses all requirements of Annex A.5, including application and removal of the Monogram. Identify evidence of implementation, if applicable.		

API Monogram Marks sampled *(on products, letterhead, business cards or any other medium)*: ***Note:*** *The Monogram and License Number must be used together at all times. They cannot be used on test certificates, certificates of conformity, shipping documents, etc*.	**API Spec:**	**Verify each of the following:**	
			Applied by licensee only
			Includes mark and license number
			Applied to product at licensed facility location

Verify conformance of the following requirements. *Enter N/A if mark is not used.*	**Verified**	**Finding #:**
APIQR Marks are **only** on correspondence, advertising, and promotional materials that are related to the goods and services referenced in the scope of the Organization's registration.		
The APIQR / ANAB Mark **has not been** used on a product or product packaging, related documentation, or in such a way as to suggest that APIQR / ANAB have certified or approved any product, process or service of the registered organization.		
The APIQR and ANAB Marks are used **in conjunction with** the organization's name, location and registration certificate numbers.		
The ANAB Mark is used **in conjunction with** the APIQR Mark, and the size of the ANAB Mark does not exceed the size of the APIQR Mark.		
The APIQR and ANAB Marks **are** reproduced: 1. in black, its original colors or the predominant color of the letterhead or printing, 2. on a clearly contrasting background, and 3. In a size which makes the mark's features clearly distinguishable and without distortion of its dimensions.		
If applicable - Upon written notification, the organization **immediately ceased and desisted** in the use of the APIQR/ANAB Marks and/or API Monogram: 1) upon suspension or cancellation, or 2) In any manner that is determined misleading by API / APIQR.		
Applicant organization – APIQR, ANAB Marks and/or API Monogram **have not** been identified in promotional materials or other company documentation.		
Additional comments:		

Quality Management System Requirements

In the space provided below, detail the objective evidence (documentation reviewed, records reviewed and personnel interviewed) to ensure conformance to the identified QMS requirements. Detail any discrepancies / nonconformance identified.

API Spec Q1, Section 4.1 Quality Management System

Requirement:	Objective Evidence/Comments:	Finding #:
• QMS Scope • Quality Manual • QMS Processes • Quality Policy • Quality Objectives • QMS Planning • Internal and External Communication		
• Organization and Context - ISO 9001, 4.1 • Interested Parties - ISO 9001, 4.2 • Scope of the QMS - ISO 9001, 4.3 • Policy strategic direction - ISO 9001, 5.2.1 • Policy availability - ISO 9001, 5.2.2 • Quality Objectives relevance - ISO 9001, 6.2.1 • Quality Objectives planning – ISO 9001, 6.2.2		

API Spec Q1, Section 4.2 Management Responsibility

Requirement:	Objective Evidence/Comments:	Finding #:
• Availability of Resources • Commitment to the QMS • Responsibility and Authority • Management Representative		
• Leadership and Commitment – ISO 9001, 5.1.1		

API Spec Q1, Section 4.3 Organizational Capability

Requirement:	Objective Evidence/Comments:	Finding #:
• Provision of resources • Personnel Competence • Training and Awareness • Work Environment		
• Resources / General – ISO 9001, 7.1.1 • Organizational Knowledge – ISO 9001, 7.1.6		

Personnel Sampled for Competency, Awareness and Training

Name	Title	Competency Defined / Record Evidenced	Training Recorded	Finding#:

API Spec Q1, Section 4.4 Documentation Requirements		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
• QMS Documentation • Control of Documents • Use of External Documents in Product Realization. Ensure that all applicable official API specifications and normative standards are available for personnel to use. API specifications must not be unauthorized reproductions or altered versions.		

Procedures required by API Spec Q1

Verify that procedures required by the standard are established, documented, implemented, and maintained for continual suitability. (Please complete the Identification of QMS Procedures table and identify any nonconformities as applicable)

API Spec Q1 Clause	Requirement	Mark with "X" if available	Finding#		API Spec Q1 Clause	Requirement	Mark with "X" if available	Finding#
4.3.2.1	Competency and Training				5.7.4	Product Inspection/Test		
4.4.3	Control of Documents				5.7.5	Customer-supplied Property		
4.4.4	Use of External Documents				5.7.6	Preservation of Product		
4.5	Control of Records				5.7.7	Inspection & Testing		
5.1.1	Review of Requirements				5.7.8	Preventive Maintenance		
5.3	Risk Assessment & Management				5.8	Control of Testing, Measuring, & Monitoring Equipment		
5.4.1	Design & Development				5.9	Product Release		
5.5	Contingency Planning				5.10	Control of Nonconforming Product		
5.6	Purchasing				6.2.1	Customer Satisfaction		
5.6.3	Verification of Purchased Products or Activities				6.2.2	Internal Audit		
5.7.1.1	Control of Production				6.3	Analysis of Data		
5.7.1.2	Control of Servicing				6.4.2	Corrective Action		
5.7.1.5	Validation of Processes for Production and Servicing				6.4.3	Preventive Action		
5.7.3	Identification & Traceability				Annex A	Monogram Marking *(if applicable)*		

API Spec Q1, Section 4.5 Control of Records		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
• Controls include processes and responsibilities for identification, collection, storage, protection, retention, retrieval and disposition. • Records are established and controlled to provide evidence of conformity to requirements and the QMS, including records originating from outsourced activities. • Records are maintained based on the required retention times as specified in the applicable standard, product spec, and / or the customer / QMS requirements.		
• Documented information – ISO 9001, 7.5.3.2		

QMS Monitoring, Measurement, Analysis, and Improvement

In the space provided below, detail the objective evidence (documentation reviewed, records reviewed and personnel interviewed) to ensure conformance to the identified QMS requirements. Detail any discrepancies / nonconformance identified.

API Spec Q1, Section 6.1 General		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Monitoring, measurement, analysis, and improvement processes needed to ensure conformity to requirements are planned and implemented. • Including determination of the applicable methods, techniques of analysis of data and extent of use.		

API Spec Q1, Section 6.2 Monitoring, Measuring and Improving		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**

• Customer Satisfaction
• *Internal Audits:
  ○ Requirements
  ○ Performance
  ○ Review and Closure
• Process Evaluation		

API Spec Q1, Section 6.3 Analysis of Data		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
Analysis includes data generated from monitoring & measurement, internal audits, management reviews, and other relevant sources.		
Analysis and Evaluation – ISO 9001, 9.1.3d,e		

Data Analysis shall provide information relating to each of the following: *(identify any other evidence of analysis of data, if applicable)*				
Data Types	**Analysis Method**	**Reported**		
		How	**Frequency**	**Objective / KPI**
Customer Satisfaction				
Product Conformity				
Nonconformities/ product failures after delivery/use				
Process trends and characteristics				
Supplier Performance				
Quality Objectives				

API Spec Q1, Section 6.4 Improvement		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Organization shall continually improve the effectiveness of the QMS • Corrective Action • Preventive Action		
• Risks and opportunities update – ISO 9001, 10.2.1e • Actions to address risks and opportunities – ISO 9001, 6.1		

API Spec Q1, Section 6.5 Management Review		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Verify that management reviews are conducted at least every 12 months. • Input Requirements • Output Requirements		
• Management review inputs – ISO 9001, 9.3.2d,e		

Product Realization*

Audit Conditions	
Audit sampling priority should be established according to the conditions outlined below.	
Category	**Category Definition**
1	Monogram product currently being manufactured and available for review
2	Monogrammable (product meeting all requirements but not marked) product currently being manufactured and available for review
3	Non-monogrammable product currently being manufactured and available for review

4	Monogram product manufactured since the last API audit but not available for review (**records review**)
5	Monogrammable product manufactured since the last API audit but not available for review (**records review**)
6	Non-monogrammable product manufactured since the last API audit

Complete the table below based on the above classifications:		
Category	**Product/Service Identification**	**Specification (as applicable)**

In the space provided below, detail the objective evidence (documentation reviewed, records reviewed and personnel interviewed) to ensure conformance to the identified QMS requirements. Detail any discrepancies / nonconformance identified.

API Spec Q1, Section 5.1 Contract Review *

List Contracts reviewed / sampled *(Include contract identification, customer name, date of contract and any other pertinent details below)*:	**API Spec / Product:**

Requirement:	**Objective Evidence/Comments:**	**Finding #:**
• Determination of Requirements • Review of Requirements		

API Spec Q1, Section 5.2 Planning *

Requirement:	**Objective Evidence/Comments:**	**Finding #:**
• Planning of Product Realization • Output of Planning		

API Spec Q1, Section 5.3 Risk Assessment and Management

Requirement:	Objective Evidence/Comments:	Finding #:
• Risk Assessment Procedure • Impact on Delivery • Impact on Quality of Product		
• Actions to address risks and opportunities – ISO 9001, 4.4.1, 5.1.2 and 6.1		

API Spec Q1, Section 5.4 Design and Development *			
Select all that apply:			
	Performed in-house		Performed at a different location within the same organization
	Outsourced		Excluded *(For Monogram licenses, confirm with Advisory 6)*
List design packages sampled / verified: *Select a representative sampling of the applicable products (API Specifications and/or Scope of Registration)* • *Any license in "application" status requires verification of <u>all</u> product designs within that specification.* • *Any product additions to existing licenses must have evidence of existing designs.*			
Design Package Requirements *(Annex A, A.6 – Monogram Only)*	Verify that the licensee / applicant has a design package for each product under the scope of each Monogram License		

Requirement:	Objective Evidence/Comments:	Finding #:
• Planning • Inputs • Outputs • Review • Verification and Final Review • Validation and Approval • Changes		
• D&D Planning – ISO 9001, 8.3.2 • Consequences of failure – ISO 9001, 8.3.3e		

API Spec Q1, Section 5.5 Contingency Planning		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Contingency planning based on assessed risk • Contingency planning output		

API Spec Q1, Section 5.6 Purchasing *		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**

• Purchasing Control
  ○ Procedure
  ○ Initial Supplier Evaluation – Critical Purchases
  ○ Initial Supplier Evaluation – Noncritical Purchases
  ○ Supplier Reevaluation
  ○ Supplier Evaluation – Records
  ○ Outsourcing
• Purchasing Information
• Verification of purchased products and activities		

• External providers – ISO 9001, 8.4.3d & e		

Critical Suppliers Sampled:	**Product / Component / Activity Performed:**
Non-Critical Suppliers Sampled:	**Product / Component / Activity Performed:**

List all outsourced activities and processes (if applicable):	

API Spec Q1, Section 5.7 Production and Servicing Provision *
Description of Production / Servicing <u>Capabilities</u> *[What capabilities does the facility have, including machinery and equipment available. Also provide additional detail about all monogrammable and non-monogrammable products facility is capable of manufacturing]*

Description of Production and/or Servicing Processes *(describe what manufacturing/servicing processes actually take place at the facility and interactions):*

Processes must be described in specific detail to provide information regarding the capabilities of the facility being audited. *For example, production processes must be identified clearly as machining, assembly, welding, heat treatment, etc.; testing processes must be identified clearly as hydro-testing, nondestructive examination, etc.*

Production and Servicing Processes reviewed / sampled:

Process (Area):	Personnel interviewed and position/title:	PO / WO number:	Description of product/ service/part:	Product/service/ part identified?	Inspection status identified?	Process control documents (verify revision):

Records reviewed for processes requiring validation *(select all that apply; enter additional records reviewed)***:**

	NDE		Welding		Heat Treatment		Coating and Plating		Other
	Personnel Qualification		WPS / PQR		Personnel Qualification		Personnel Qualification		
	Equipment Qualification		WPQ		Procedure/WIs		Procedure/WIs		
	Work Environment		Welder Continuity Log		Furnace Surveys		Equipment		
	Procedure Qualification		Personnel Qualification				Work Environment		
			Equipment Qualification						

Control of Production and Servicing Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Production		
• Servicing		
• Process Control Documents		
• Product Realization Capability Documentation		
• Validation of processes		
• Prevention of human error – ISO 9001, 8.5.1g • Post-delivery activities – ISO 9001, 8.5.5		

Requirements:	Objective Evidence / Comments:	Finding #:
• Product Quality Plans		
• Identification and Traceability		
• Product Inspection / Test Status		
• Customer – supplied Property		
• Preservation of Product ○ Storage and Assessment		
• Inspection and Testing ○ In-process Inspection and Testing ○ Final Inspection and Testing		
• Preventive Maintenance		
• External provider property – ISO 9001, 8.5.3		

API Spec Q1, Section 5.8 Control of Testing, Measuring and Monitoring Equipment *		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
Organization has determined the testing, monitoring, and measurement requirements and the associated equipment and resources, including people, needed to ensure conformance. Equipment and resources suitable for specific testing, monitoring and measuring activities.		
Controls established and implemented to ensure that equipment is identified, calibrated, maintained, and used in a manner consistent with requirements.		

Equipment observed / sampled *(minimum of 3)*:
Note: Ensure that all inspection and testing requirements of the applicable product specification are addressed

Equipment:	Description:	Cal Date:	Due Date:

API Spec Q1, Section 5.9 Product Release *		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**

• Procedure • Release upon satisfactory completion of planned arrangements • Identification of individual releasing product • Records maintained		

API Spec Q1, Section 5.10 Control of Nonconforming Product *		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Procedure • Method of addressing nonconforming product • Release of nonconforming product under concession • Customer notification • Records		

Management of Change

API Spec Q1, Section 5.11 Management of Change		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**

• MOC Process Implementation
  ○ Changes in the Organizational Structure
  ○ Changes in Key or Essential Personnel
  ○ Changes in Critical Supplies
  ○ Changes to MS Procedures
• MOC Notification		

• Planning of changes – ISO 9001, 6.3 • Responsibilities and Authorities –ISO 9001, 5.3e		

Audit Summary*

The API audit is based on a sampling process of the available information

Number of Findings:	Major *(Systemic)*:		Minor *(Isolated)*:		Concerns:	
Comments:						
Strengths:						
Opportunities for Improvement (OFIs):						

Provide a summary of the closure and verification of corrective actions for previous findings, if any:
Provide an overall assessment of the capability of the facility to manufacture product(s) (Monogram):
Provide an overall assessment of the effectiveness of the management system and the facility's ability to perform activities / provide products within the scope of registration:

Audit Time Summary*

	Date	Start Time	End Time	Facility Rep Initials
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				

If audit duration is longer than 7 days, please add additional daily start/stop time.
Time spent auditing offsite or at other locations, such as subcontractors, must be identified and noted in the audit report.

Auditor Conclusion / Recommendation*

NOTE: API makes the final determination of certification status and shall be the sole judge of whether licensing/registration will be granted/maintained

	Registration and / or Licensing may be granted / continued / reinstated based on satisfactory implementation of a Management System and / or demonstrated capability to meet applicable specification requirements with no nonconformities identified.*
	Registration and / or Licensing may be granted / continued / reinstated subject to the review of the nonconformance(s) identified and acceptance of appropriate corrective action(s) by the API Licensing and Registration Committee. *
	Registration and / or Licensing may be subject to the review of the audit results and nonconformance(s) identified, acceptance of appropriate corrective action(s) and additional actions as defined by the API Registration & Licensing Committee. This decision may include a re-audit to verify the required corrective actions, withdrawal, suspension and or cancelation. *
**** Note:** Audits may result in suspension or cancellation of the organization's license(s) and/or registration(s) or withdrawal of application for licensing/registration. API makes the final determination of certification status and shall be the sole judge of whether licensing/registration will be granted/maintained. You will be notified by API if your license/registration is adversely affected by the results of this audit.*	

If any part of this audit was performed remotely, please specify (to be completed by Lead Auditor):

- Which processes were audited remotely:
- Whether the remote auditing techniques were effective in achieving the audit objectives:
- Areas that require special attention during the next on-site audit, if applicable. Please provide a detailed explanation.

Final Auditor / Audit Team Remarks:

Organization's Representative Comments:

By signing below, I (we) attest that the information above is accurate and has been collected by the audit team during the performance of the audit that was assigned to me (us) by API and that audit recommendations and conclusions were communicated to the organization. (Digital Signatures are acceptable)

Audit Team Leader:	Date:
Audit Team Member:	Date:
Audit Team Member:	Date:

By signing this document, it is not an admission of the acceptance of any nonconformities/concerns identified by the audit team. The signature only confirms that the audit was performed and the audit recommendations and audit conclusions were communicated by the auditor. API reserves the right to have final determination of the level of nonconformity identified in the audit report. (Digital Signatures are acceptable)

Organization Representative (optional):	Date:

Enter the next audit date below :

- Initial 1st Surveillance audit after stage 2 initial audit – 9 months after the last day of the initial stage 2 audit
- 1st surveillance audits – 30 months before expiration date
- 2nd surveillance audits – 18 months before expiration date
- Recertification/Renewal audits – 6 months before expiration date

Next Audit Type:	**Next Audit Date:** *(Preliminary date subject to change)*

Opening / Closing Meeting Attendance Sheet

When performing the opening and closing meeting, please refer to the Opening and Closing meeting guidelines			
Facility ID:		**Audit ID:**	

Audit Team Leader:	
Audit Team Members:	
Audit Observer(s):	
Opening Meeting (Day & Time):	
Closing Meeting (Day & Time):	

Participants (Name & Title) - Initial/check the meetings attended	Opening	Closing

The information contained in this report is confidential and subject to the confidentiality agreement between the Audit Team/Auditor(s) and API. Details of the assessment results are found in the succeeding pages of this report.