API MONOGRAM / APIQR PROGRAM

API Spec Q1 10th 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 10th 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 only 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 and Recertification audits of APIQR and Dual Facilities:

An audit of the full quality management system must be performed. All sections of this report must be completed.

For Surveillance Audits of Monogram-only Facilities:

Section headings with an asterisk (*) are the 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. Alternative Marking Agreement (AMA)
4. Product Realization (with the exception of *5.3 Risk Management and 5.10 Management of Change*)
5. Internal Audit (API Spec Q1 clause 6.2.2)
6. 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:		**Number of Employees (per myCerts):**		Verified Number of Employees:	
Duration:	*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 or if sum of employees does not equal verified number of employees):*

Audit Scope*

	API Spec Q1:10th ed.		ISO 9001:2015		
Audit Criteria:	API Spec(s):				
	Other criteria:				

License(s)/Certificate(s) Scope*

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

License	Cert #	Status	Expiration Date

Audit Report

Verification of Scope of Registration / Monogram License(s) and Exclusions			
Verify each of the following:	**Select One:**		**Finding #:**
Scope of Registration (as currently identified on Application/Certificate) 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 (as currently identified on Application/Certificate) 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 (as currently identified on Application/Certificate) 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*	
		N/A – No exclusions identified	
Significant changes to the QMS since previous audit (if applicable):			

Use of API Monogram, APIQR and ANAB Marks*

Control of the Application and Removal 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:** Identify the API Specification and observed evidence	**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:		

Alternative Marking Agreement (AMA)*

Refer to FM-011 *API Monogram Program Alternative Marking of Products License Agreement*
AMA Locations – Identify all AMA locations and mark any changes

Scenarios applicable (See FM-011, Table 1. Select all that apply)	☐Scenario 1 ☐Scenario 2 ☐Scenario 3	
Requirement:	**Objective Evidence/Comments:**	**Finding #**
Scenarios 1 & 2 only: • Subcontracted processes and API Monogram marking planned and documented as part of QMS • Maintains ownership of the product and sufficient inspection procedures • Processes and controls to verify conformance identified • Subcontractor (Marking Party) is an authorized API Marker • Mill test reports or certificates of compliance issued by either the Licensee or Marking Party include a statement identifying that processing, product conformance verification, and API Monogram application were performed at the facility by an authorized API Marker • Licensee remains responsible for all failures to meet the API specification, through delivery of the final product		
Scenario 3 only: • Subdivision of bulk items and API Monogram marking planned and documented as part of QMS • Maintains ownership of the product and sufficient inspection procedures • Processes and controls to verify conformance identified		

Audit Report

• Subcontractor (Marking Party) is an authorized API Marker • Licensee remains responsible for all failures to meet the API specification, through delivery of the final product		

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 Policy • Quality Objectives • QMS Planning and Exclusions • Internal and External Communication		
• When determining scope, organization considers external and internal issues - ISO 9001, 4.3 a) • When determining scope, organization considers requirements of interested parties – ISO 9001, 4.3 b) • Quality Objectives relevant to enhancement of customer satisfaction - ISO 9001, 6.2.1 d)		

API Spec Q1, Section 4.2 Management Responsibility		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
• Leadership and Commitment • Responsibility and Authority • Management Representative		
• Demonstrate leadership and commitment by promoting use of process approach and risk-based thinking – ISO 9001, 5.1.1 d)		

API Spec Q1, Section 4.3 Organization Capability		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
• Provision of resources • Organizational Knowledge • Personnel Competence • Training • Work Environment		

Audit Report

Personnel Sampled for Competency, Awareness and Training				
Name	**Job Title**	**Defined Competency Requirement(s)**	**Competency Records**	**Finding#:**

- *Defined Competency Requirement: Organization's required qualification/competency requirements for the specific position.*
- *Competency Records: Sampled employee records (e.g. education, experience, certificate, training, etc.)*

API Spec Q1, Section 4.4 Documentation Requirements		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
- QMS Documentation - Procedures - Control of Internal Documents - Control and Use of External Documents		

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	Personnel Competence			5.6.7	Externally Owned Property		
4.3.2.2	Training			5.6.8	Preservation of Product		
4.4.3	Control of Internal Documents			5.6.9	Inspection, Testing, and Verification		
4.4.4	Control and Use of External Documents			5.6.10	Preventive Maintenance		
4.5	Control of Records			5.7	Product Release		
5.1	Contract Review			5.8	TMMDE		
5.3	Risk Management			5.9	Control of Nonconforming Product		
5.4	Design			5.10	Management of Change (MOC)		
5.5.1	Purchasing Control			6.2.1	Customer Satisfaction		
5.5.3	Verification of Purchased Products, Components or Activities			6.2.2	Internal Audit		
5.6	Control of Product Realization			6.3	Analysis of Data		
5.6.4	Validation of Processes			6.4.2	Corrective Action		
5.6.5	Identification & Traceability			Annex A.5	Control of the Application and Removal of the API Monogram *(if applicable)*		
5.6.6	Inspection/Test Status						

Audit Report

API Spec Q1, Section 4.5 Control of Records		
Requirement	**Objective Evidence/Comments:**	**Finding #:**
• Records established and controlled • Procedure • Records retention		

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 but not available for review (records review)

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 number, customer name, date of contract and any other pertinent details below)*:	**API Spec / Product:**

Audit Report

Requirement:	Objective Evidence/Comments:	Finding #:
• Determination of Requirements • Review of Requirements • Changes to 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 Management		
Requirement:	Objective Evidence/Comments:	Finding #:
• Risk Assessment Procedure • Impact on Delivery • Impact on Quality of Product • Changes Impacting Product Quality • Contingency Planning • Records		
• Actions to address opportunities – ISO 9001, 6.1.1 • Planning how to evaluate effectiveness of action to address opportunities – ISO 9001, 6.1.2(b)(2) • Actions are proportionate to potential impact – ISO 9001, 6.1.2		

API Spec Q1, Section 5.4 Design*			
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 Monogram license in "Applicant" status requires verification of all product designs within the application scope.*
- *Any newly added product requires verification of design, if design is required.*

Audit Report

Design Package Requirements *(Annex A, A.6 – Monogram Only)*	Verify that the licensee/applicant has all required design packages available for each product under the scope of each Monogram License (Yes/No. If no, provide details/identify NC):	
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
• Planning • Inputs • Outputs • Review • Verification and Final Review • Validation and Approval • Changes		
• D&D Planning considers nature, duration and complexity of design activities – ISO 9001, 8.3.2 a) • D&D planning considers the level of control expected by customers and other interested parties – ISO 9001, 8.3.2 i)		

API Spec Q1, Section 5.5 Purchasing *		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**

• Purchasing Control
  o Procedure
  o Initial Supplier Evaluation—Critical Purchases
  o Initial Supplier Evaluation – Critical Purchases – Customer Specified, Proprietary, and/or Legal Limited
  o Initial Supplier Evaluation—Noncritical Purchases
  o Supplier Reevaluation
  o Records
  o Outsourcing
• Purchasing Information
• Verification of Purchased Products, Components or Activities
  o Procedure
  o Critical Purchases
  o Noncritical Purchases
  o Records		

• Organization communicates requirements for external provider's interaction with organization – ISO 9001, 8.4.3d • Organization communicates requirements for		

Audit Report

control and monitoring of external provider's performance – ISO 9001, 8.4.3e		

Suppliers Sampled – Critical Purchases:	Product / Component / Activity Performed: *(identify if limitation per 5.5.1.3 has been claimed)*

Suppliers Sampled – Noncritical Purchases:	Product / Component / Activity Performed:

List all outsourced activities and processes (if applicable):

API Spec Q1, Section 5.6 Control of Product Realization*
Description of Production/Service _Capabilities_   • *Describe the organization's capability, including available machinery and test equipment, required for manufacturing of products within the scope of certification.*   • *Identify products, monogrammable and nonmonogrammable, the organization is capable of providing.*
Description of Production _Processes_ *(describe what manufacturing/service processes 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: machining > fit-up > welding > heat treatment > ultrasonic testing > assembly > hydrotest, etc.*
Production and Servicing Processes reviewed / sampled:

Audit Report

Process/Area:	Personnel interviewed: (Name and position)	Product/Service:	Work Instruction	Product/service/ part identified?	Inspection status identified?	Process control documents:

Control of Production Requirements:	Objective Evidence / Comments:	Finding #:
• Procedure		
• Quality Plan		
• Process Control Documents		
• Prevention of human error – ISO 9001, 8.5.1g • Post-delivery activities – ISO 9001, 8.5.5		

API Spec Q1, Section 5.6.4 Validation of Processes*								
Records reviewed for processes requiring validation (Y/N/NA) *(select all that apply)*:								
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					

Requirements:	Objective Evidence / Comments:	Finding #:
• Procedure • Equipment • Personnel • Specific Methods • Acceptance Criteria • Records • Revalidation • Evidence of meeting requirements when outsourced		

API Spec Q1, Section 5.6 Control of Product Realization *

Audit Report

Requirements:	Objective Evidence / Comments:	Finding #:
• Identification and Traceability		
• Product Inspection / Test Status		
• Externally Owned Property		
• Preservation of Product		
Inspection, Testing, and Verification • In-process Inspection, Testing, and Verification • Final Inspection, Testing, and Verification		
• Records		
• Preventive Maintenance		

API Spec Q1, Section 5.7 Product Release *		
Requirements:	Objective Evidence / Comments:	Finding #:
• Procedure • Release upon satisfactory completion of planned arrangements • Release of conforming products or authorized under concession • Identification of individual releasing product • Records maintained		

API Spec Q1, Section 5.8 Testing, Measuring, Monitoring, and Detection Equipment (TMMDE)*		
Requirements:	Objective Evidence / Comments:	Finding #:
• Procedure • Equipment • TMMDE Equipment from Other Sources • Records		

Equipment observed / sampled (minimum of 3)**:**

Note: Ensure that all inspection and testing requirements of the applicable product specification are addressed

Equipment Unique ID	Description	Frequency	Due Date

API Spec Q1, Section 5.9 Control of Nonconforming Product *		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Procedure • Nonconforming Product During Product Realization • Nonconforming Product After Delivery • Addressing Nonconforming Product • Release of Nonconforming Product Under Concession • Customer Notification of Nonconforming Product • Records		

Management of Change

API Spec Q1, Section 5.10 Management of Change		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Procedure • MOC Application • MOC Notification • Records		

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. • 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: o Performance of Internal Audit		

o Audit Review and Closure		

API Spec Q1, Section 6.3 Analysis of Data		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
The Analysis should include data generated from the following activities, for example: - Data generated from monitoring and measurement, - internal audits. - audits of the organization by external parties, - management reviews. - other relevant sources.		
• Evaluate if planning has been implemented effectively – ISO 9001, 9.1.3 d) • Evaluate effectiveness of actions to address risks and opportunities – ISO 9001, 9.1.3 e)		

API Spec Q1, Section 6.4 Improvement		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Organization shall continually improve the effectiveness of the QMS • Corrective Action		

API Spec Q1, Section 6.5 Management Review		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
• Management reviews are conducted at least every 12 months. • Input Requirements • Output Requirements		

Audit Report

Audit Summary*

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

Number of Findings:	Major Nonconformities *(Systemic)*:		Minor Nonconformities *(Isolated)*:		Concerns:	
Comments:						

Strengths:

Opportunities for Improvement (OFIs):

Summary of the closure and verification of corrective actions for previous findings, if any:

Overall assessment of the capability of the facility to manufacture product(s) (Monogram), the effectiveness of the management system, and the facility's ability to perform activities/provide products within the scope of registration:

Were audit objectives achieved (Y/N)? (See Audit Plan document for description of objectives. If audit objectives were not achieved, provide detailed explanation and notify API immediately)		Comments:
Were there significant deviations from the audit plan (Y/N)? (If any deviations from audit plan, identify reasons and upload an as-performed revision of the audit plan to myCerts)		Comments:

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 Licensing & Registration 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 Target Date:** *(Preliminary date subject to change)*

Audit Report

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	Date:	Time:
Closing Meeting	Date:	Time:

Participants (Name & Position) - 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.