

FM-198 Q1_ISO 9001 Revision: 8.0

Effective Date: 07/11/22

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 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 Assessment and Management, 5.5 Contingency Planning and 5.11 Management of Change)
- 5. Internal Audit (API Spec Q1 clause 6.2.2)
- 6. Audit Summary, Audit Time Summary & Auditor Conclusion/Recommendation



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Audit Information*									
Facility ID:				Audi	t ID:				
Company Name/				Docu	ıment	any chang	es in the spac	e below:	
Facility Name:									
Facility Address:									
Primary Account Manager(s):									
Lead Auditor:									
Audit Team Members:				Ī		ľ			
Audit Start Date:						nd Date:			
Audit Type:			Number of E (per myCert		<mark>yees</mark>		Verified Nun Employees:	nber of	
Duration:	*Assigned Audit Days		V			*Actu	<u>ıal</u> Audit Days	S:	
Justification:	*Justification required if diff	ferent f	from required a	nudit da	/s – No	tify API of ar	ny changes and ι	ıpdate Audit Pla	an
Shifts:	Start Time		End T	ime		No. of	Employees	Audite	ed? (Y/N)
Shift 1									
Shift 2									
Shift 3									
Explanation (required for	shifts not audited or if sui	m of e	mployees do	es not	equal	verified nur	mber of employ	ees):	
		A	Audit Sco	pe*					
	API Spec Q1:9 th ed.		ISO 9001:2	015					
Audit Criteria:	API Spec(s):								
	Other criteria:								
	Licens	se(s)	/Certifica	ite(s)	Sco	pe*			
			es to the sc			_			
<u>License</u>	Cert #	-				<u>Status</u>		Expiratio	n Date



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Verify each of the following:		ect One:	Finding #:
		Yes - Scope is Accurate / Appropriate	
Ecope of Registration is accurate for the activities and rocesses performed by the facility.		No – Mark all changes on registration scope above	
processes periorings by the launity.		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		Yes	
		No – Mark all changes on license scope above	
for each product within the scope of the license(s).		N/A - No Monogram License(s)	
Exclusions taken are allowable, applicable and justified. Document any discrepancies.		Yes – Exclusions, if any, are Accurate/Appropriate	
Note: Please see <i>Advisory 6</i> for allowable Monogram Program design exclusions.		No - Exclusions are not Accurate/Appropriate – Mark all changes on the scope section above	

Use of API Monogram, APIQR and ANAB Marks*

Control of the Application of	of the API Monogram (API	Spec Q1, A	nnex A	.5)		
Requirements: Objective Evidence / Comments:						
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, letter other medium):	nead, business cards or any	API Spec:	Verif	y each of the	following:	
Note: Identify the API Specification and observed eviden	ce			T		
				Applied by I	icensee only	
				Includes ma		
				Applied to p		
Verify conformance of the following requiremen	ts. Enter N/A if mark is not	t used.		Verified	Finding #:	
APIQR Marks are only on correspondence, advertising, a goods and services referenced in the scope of the Organ	•	are related to	the			
The APIQR / ANAB Mark <u>has not been</u> used on a produ in such a way as to suggest that APIQR / ANAB have cer of the registered organization.						
The APIQR and ANAB Marks are used in conjunction was registration certificate numbers.	<u>vith</u> the organization's name, loo	cation and				



Additional comments:

Audit Report

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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.

Alternative Marking Agreement (AMA)*

Refer to FM-011 <i>API Monogram Program Afternative Markir</i>	ig of Products Lic	ense Agreement	
AMA Locations - Identify all AMA locations and mark any change	es .		
	_		
Scenarios applicable (See FM-011, Table 1. Select all that apply)	□Scenario 1	□Scenario 2	☐Scenario 3
Requirement:	Objective Evide	ence/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 onl <u>y</u> :			
 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			
Subcontractor (Marking Party) is an authorized API Marker.			



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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, Se	ction 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 resourcesPersonnel CompetenceTraining and AwarenessWork Environment							
 Resources / General – ISO 9001, 7.1.1 Organizational Knowledge – ISO 9001, 7.1.6 							



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Personnel Sampled for Competency, Awareness and Training									
Name	Job Title	ob Title Defined Competency Competency Records Requirement(s)							

- 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 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#
4.3.2.1	Competency and Training		
4.4.3	Control of Documents		
4.4.4	Use of External Documents		
4.5	Control of Records		
5.1.1	Review of Requirements		
5.3	Risk Assessment & Management		
5.4.1	Design & Development		
5.5	Contingency Planning		
5.6	Purchasing		
5.6.3	Verification of Purchased Products or Activities		
5.7.1.1	Control of Production		

API Spec Q1 Clause	Requirement	Mark with "X" if available	Finding#
5.7.4	Product Inspection/Test		
5.7.5	Customer-supplied Property		
5.7.6	Preservation of Product		
5.7.7	Inspection & Testing		
5.7.8	Preventive Maintenance		
5.8	Control of Testing, Measuring, & Monitoring Equipment		
5.9	Product Release		
5.10	Control of Nonconforming Product		
6.2.1	Customer Satisfaction		
6.2.2	Internal Audit		
6.3	Analysis of Data		



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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			

Product Realization*

Audit Condition	s				
Audit sampling	priority should be established according to the conditions outlin	ed below.			
Category	Category Definition				
1	Monogram product currently being manufactured and available for	review			
2	Monogrammable (product meeting all requirements but not marked manufactured and available for review	d) product currently being			
3	Non-monogrammable product currently being manufactured and a	vailable for review			
4	Monogram product manufactured since the last API audit but not a	vailable for review (records review)			
5	Monogrammable product manufactured since the last API audit bureview)	t not available for review (records			
6	Non-monogrammable product manufactured since the last API auditorial (records review)	lit but not available for review			
	Complete the table below based on the above classification	cations:			
Category	Product/Service Identification	Specification (as applicable)			



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In the space provided below, detail the objective evidensure conformance to the identified QMS requireme			ved) to
	ec Q1, Section 5.1 Contract Review *		
List Contracts reviewed / sampled (Include co contract and any other pertinent details below):	ontract number, customer name, date of	API Spec / Product:	
Requirement:	Objective Evidence/Comments:		Finding #
 Determination of Requirements Review of Requirements 			
API	Cons. Od. Continue 5 2 Planning *		
	Spec Q1, Section 5.2 Planning *		
	Objective Evidence/Comments:		Finding #
Requirement: Planning of Product Realization Output of Planning			Finding #
Planning of Product Realization Output of Planning	Objective Evidence/Comments:		Finding #
Requirement: Planning of Product Realization Output of Planning API Spec Q1, Se	Objective Evidence/Comments:	nt	
Planning of Product Realization Output of Planning	Objective Evidence/Comments:	nt	Finding #
Requirement: Planning of Product Realization Output of Planning API Spec Q1, Se Requirement: Risk Assessment Procedure Impact on Delivery	Objective Evidence/Comments:	nt	

Outsourced

Select all that apply:

Performed in-house

Performed at a different location within the same organization

Excluded (For Monogram licenses, confirm with Advisory 6)



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Any Monogram license	mpling of the applicable produc	ts (API Specifications and/or Scope of Registration) verification of <u>all</u> product designs within the application scope. gn, if design is required.	
Design Package Requirements (Annex A, A.6 – Monogram Only)		ant has all required design packages available for each product unde ense (Yes/No. If no, provide details/identify NC):	r the
Requirement:		Objective Evidence/Comments:	Finding #:
 Planning Inputs Outputs Review Verification and Final Validation and Approx Changes Controls over outsour 	val		
D&D Planning – ISOConsequences of fail	9001, 8.3.2 ure – ISO 9001, 8.3.3e		

API Spec Q1, Section 5.5 Contingency Planning			
Requirements:	Objective Evidence / Comments:	Finding #:	
Contingency planning based on assessed riskContingency 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 Reevaluation Supplier Evaluation – Records Outsourcing Purchasing Information Verification of purchased products and			



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activities				
activities				
• External providers – ISO 9001, 8.4.3d & e				
Suppliers Sampled – Critical Purchases:	Product / Component / Activity Performed:			
Suppliers Sampled – Noncritical Purchases:	Product / 0	Compor	ent / Activity Performed:	
List all outsourced activities and prod	esses (if ap	plicable	2):	
			.	
		5.7 Produ	ction and Servicing Provision *	
 Description of Production/Service <u>Ca</u> Describe the organization's capabili 		available	e machinery and test equipment, required for manufac	cturina
of products within the scope of certification	fication.			Juliu ig
Identify products, monogrammable a	and nonmon	ogramm	able, the organization is capable of providing.	
Description of Production and/or Serv	rice Process	ses (des	cribe what manufacturing/service processes take plac	ce 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 / s	sampled		



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Process/Area:	Personnel interviewed: (Name and position)	Product/Service:	Work Instruction	Product/service/ part identified?	Inspection status identified?	Process	s control ents:
Control of Proc Requirements:	duction and Serv	icing	Objective Eviden	ce / Comments:			Finding #:
Production							
Servicing							
Process Co.	ntrol Documents						
Product Rea	alization Capability	Documentation					
	f human error – IS activities – ISO 9						

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			
equirements:		Objective Evidence /	Comments:	Finding #:
Procedure Equipment Personnel Specific Methods Acceptance Criteria Records Revalidation				



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API Spec Q1, Section 5.7 Production and Servicing Provision *			
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			

AP	I Spec Q1, Section 5.8 Contro	of Testing, Measuring and Monitoring E	quipment *
Requirements:		Objective Evidence / Comments:	Finding #:
•	letermine the testing,		
-	asurement requirements and		
•	pment needed to provide nity to those requirements.		
evidence of comon	inty to those requirements.		
	ources suitable for specific		
	and measuring activities.		
Controls established that equipment is id	d and implemented to ensure		
	ed in a manner consistent		
with requirements.			
Equipment observ	ed / sampled (minimum of 3):		
	- '	of the applicable product specification are addre	ssed
Equipment Unique ID	Description	Frequency	Due Date
			l



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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 #:	
 Potential risks identified MOC Process Implementation Changes in the Organizational Structure Changes in Key or Essential Personnel Changes in Suppliers of critical product/service Changes to MS Procedures MOC Notification 			
 Planning of changes – ISO 9001, 6.3 Responsibilities and Authorities –ISO 9001, 5.3e 			

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. 			



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API Spec Q1, Section 6.2 Monitoring, Measuring and Improving

Requirements:

Objective Evidence / Comments:

Finding #:

Customer Satisfaction

*Internal Audits:

Requirements
Performance & Frequency
Review and Closure

Process Evaluation

API Spec Q1, Section 6.3 Analysis of Data							
Requirements:			Objective E	vidence / Comments	s:		Finding #:
Analysis includes data gene & measurement, internal au reviews, and other relevant	udits, management	ing					
Analysis and Evaluation – I	SO 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				is of data, if a	oplicable)		
Data Types	Method of Data Collection		lethod of Analysis	Objective/KPI	Result		ons (if ded)
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 			

API Spec Q1, Section 6.5 Management Review			
Requirements:	Objective Evidence / Comments:	Finding #:	



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 Management reviews are conducted at least every 12 months. Input Requirements Output Requirements 	
Management review inputs – ISO 9001, 9.3.2d,e	

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 Improve	ement (OFIs):				
Summary of the closure	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, an	d the facility's ability to perfor	m activities/provide products	within the scope of registration:		
Were audit objectives ac		Comments:			
	description of objectives. If audit objeatiled explanation and notify API imm				
•	eviations from the audit plan (*			
(If any deviations from audit plate performed revision of the audit	an, identify reasons and upload an a plan to myCerts)	S-			

Audit Time Summary*

	Date	Start Time	End Time	Facility Rep Initials
Day 1				
Day 2				



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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 appoint attention during the part on site audit if applicable. Blacco provide a detailed.
 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:



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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)

communicated to the organization. (Digital Signatures are ac	ceptable)		
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 Ist 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 Target Date: (Preliminary date subject to change)			



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Opening / Closing Meeting Attendance Sheet

When performing the opening and closing meeting, please refer to the Opening and Closing meeting guidelines			
Facility ID:	ne opening and crosning meeting, please relet to the C	Audit ID:	irig guideiiries
Audit Team Leader:		714411131	
Audit Team Members:			
Audit Observer(s):	Deter	Time	
Opening Meeting Closing Meeting	Date:	Time:	
Olosing Meeting	Date:	Time:	
Participants (Name & P	rosition) - Initial/check the meetings attended	Opening	Closing
		F. J. W. W.	
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.			