APIQR PROGRAM

API Spec Q2 and ISO 9001:2015

AUDIT REPORT

Scope of the document:

This audit report includes the requirements of API Spec Q2, 2nd Edition and ISO 9001:2015. The designated API auditor is expected to fill out the entire report when conducting audits to the following organizations:

- Applicants for ISO 9001:2015 certification
- Applicants for API Spec Q2, 2nd Edition and ISO 9001:2015 certification
- Current API Spec Q2, 2nd Edition certified clients that are also ISO 9001:2015 certified.

Requirements specific to ISO 9001:2015 are highlighted with GRAY shading and they are not applicable when conducting audits to the following organizations:

- Applicants that do not include an ISO 9001:2015 application
- Current certified / licensed organizations that do not have an ISO 9001:2015 certificate

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:
*Required 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 Q2		ISO 9001:2015		Other (Note below)			
	Other criteria:							

Registration Scope
--Mark all changes to the scope on this section--

Registration	Cert #	Status	Expiration Date

Verification of Scope of Registration 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	
Exclusions taken are allowable, applicable and justified. Document any discrepancies. **Note:** Exclusion not allowed for organizations that include provision of service-related product in their scope of activities.		**Yes - Exclusions are Accurate/Appropriate**	
		No - Exclusions are not Accurate/Appropriate – *Mark all changes on the scope section above*	
Additional comments*: Provide an explanation for changes.*			
Changes to the QMS since previous audit (if applicable):			

Use of APIQR and ANAB Marks

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: 1) upon suspension or cancellation, or 2) In any manner that is determined misleading by API / APIQR.		
Applicant organization – APIQR and/or ANAB Marks **have not** been identified in promotional materials or other company documentation.		
Additional comments:		

Quality Management System Requirements

API Spec Q2, Section 4 / ISO 9001:2015, Sections 4.1, 4.2, 4.4, 5.2, 6.2		
In the space provided below, detail the objective evidence (documentation reviewed, records reviewed and personnel interviewed) to ensure conformance with QMS requirements. Detail any discrepancies / nonconformance identified.		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
Organization has established, documented, implemented and maintained a QMS for all services and service-related product provided for use in the petroleum and natural gas **industry.**		
Quality Manual/Other Documentation		
QM (or other documentation) addresses the following requirements: • Scope of the QMS • Each requirement of API Q2 • Allowable exclusions/basis for claiming them • Identification of legal/other requirements organization claims compliance		

QMS Processes		
Organization has determined: • Process inputs and outputs • Criteria and methods for effective operation and control of processes (see 4.1.4, Planning)		
Organization and Context (ISO 9001, 4.1)		
How has the organization determined: • internal and external issues relevant to purpose, strategic direction and how they affect QMS results		
Understanding Interested Parties (ISO 9001, 4.2)		
How has the organization determined: • interested parties that are relevant to QMS • The requirements of those interested parties that are relevant to the QMS.		
Quality Policy		
Quality Policy - defined, documented and approved by top management, and is communicated, understood, implemented and maintained at relevant functions. Available externally as appropriate. Includes a commitment to conform to requirements and continually improve the effectiveness of the QMS		
Compatible and supports the organization's strategic vision. Available to relevant interested parties, as appropriate (ISO 9001, 5.2.2)		
Quality Objectives		
• Documented • Approved by management • Established and communicated at relevant functions and levels • Established based on considerations of the output from Analysis of Data (see 6.3) • Measurable and consistent with the Quality Policy • KPIs identified for use in Data Analysis		
• Relevant to products, services, enhancement of customer satisfaction and the strategic vision of the organization • Be updated as appropriate (ISO 9001, 6.2.1)		

QMS Planning		
Management has ensured: • criteria and methods needed for the operation and control of all QMS processes are determined, managed and effective • the planning of the QMS is carried out in order to meet the Q2 requirements • the integrity of the QMS is maintained while changes are implemented • the planning to achieve quality objectives includes actions, resources, responsibilities, timeframe, and how results will be evaluated		
Planning to Achieve Quality Objectives (ISO 9001, 6.2.2)		
Describe how the organization has determined the activities, resources, responsibilities, completion dates and timeframes, and evaluation methods for achieving the quality objectives?		

Communication Processes

API Spec Q2, Section 4.1.5 / ISO 9001:2015, Section 5.3, 7.4		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
Internal and External Communications		
Internal Process established for internal communications relating to the QMS and that effectiveness is communicated. Processes ensure that: • importance of meeting customer, legal, and other applicable requirements is communicated to relevant functions within the organization • results of analysis of data, including nonconforming services and SRP, (see 6.3) are communicated to relevant functions within the organization		
Ensuring the promotion of customer focus throughout the organization (ISO 9001, 5.3e)		
External Process determined, documented and implemented for external communications to ensure requirements are understood and risk is managed, including: • execution of inquiries, contracts, or order handling and amendments (see 5.1) • control of service and SRP information, including service-related nonconformities (see 5.10)		

• service quality plans and subsequent changes (see 5.7.2) • feedback and complaints (see 6.2.1) • communication of residual risk (see 5.3)		

Management Responsibility / Leadership

API Spec Q2, Section 4.2, 4.2.3 4.3.1 / ISO 9001:2015, Section 5		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
Resources and Support		
Top management / Organization • Ensures availability of resources needed to establish, implement, maintain, and improve the effectiveness of the QMS. • Ensures that the required resources, including people, infrastructure and work environment are in place to achieve product / servicing conformity.		
• Ensures integration of the QMS requirements into the business processes • Ensures QMS achieves its intended results • Engages, directs and supports persons to contribute to the effectiveness of the QMS • Supports other management roles to demonstrate their leadership as it applies to areas of responsibility (ISO 9001, Section 5.1.1)		
Responsibility and Authority		
Responsibilities, authorities, and accountabilities are defined, documented, assigned within and communicated throughout the organization.		
Management Representative		
Management Representative has been appointed and maintained by Top Management. Verify the following: • Competence, training & awareness for appointment; • Initiates actions to minimize occurrence of nonconformance; and • Applicable responsibility and authority granted and includes all requirements. • Supports improvement throughout the QMS		

Organizational Capability

API Spec Q2, Section 4.3 / ISO 9001:2015, Sections 7.1, 7.2, 7.3		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
Resources		
Organization: • Ensures that the required resources, including people, infrastructure and work environment are in place to achieve product / servicing conformity.		
• Considers capabilities of and constraints on existing internal resources (ISO 9001, 7.1.1)		
Personnel Competence		
• Organization determines the necessary competence for personnel needed to meet service and SRP requirements. • Organization maintains a documented procedure to address identification and documentation of required competencies and methods for achievement, methods for assessing and reassessing required competencies, evaluating effectiveness of training, and maintaining competencies. • Organization maintains records of personnel competence.		
Training and Awareness		
Verify that the organization: • provides for QMS training and job training; • includes customer-specified and/or customer-provided training; • identifies the frequency of training and that content complies with legal requirements; • ensure personnel are aware of the relevance and importance of their activities and how they contribute to the achievements of the quality objectives; • Maintains appropriate records.		
Facility identifies training needs and ensures that personnel receive adequate training to address competency needs.		
Effectiveness of actions are evaluated and maintained (i.e., competence evaluation) to ensure requirements are met.		
Organizational Knowledge (ISO 9001, 7.1.6)		
Verify that the organization: • Determined the knowledge necessary for operation of processes to achieve product /servicing conformity • Knowledge maintained and available		

• Process in place for evaluating changes in relation to current knowledge and determine actions to obtain/upd1ate necessary knowledge		

Personnel Sampled for Competency, Awareness and Training				
Name	**Title**	**Competency Defined / Record Evidenced**	**Training Record / Record Evidenced**	**Finding#:**

Work Environment

Organization has determined, provided, and maintained the work environment, including buildings, workspace and utilities; process equipment; supporting services and proper conditions needed to achieve conformity to applicable service or SRP requirements.		

Documentation Requirements / Documented Information

API Spec Q2, Section 4.4 / ISO 9001:2015, Section 7.5

Procedures (required by API Spec Q2)

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 Q2 Clause	Requirement	Mark with "X" if available	Finding#	API Spec Q2 Clause	Requirement	Mark with "X" if available	Finding#
4.3.2.1	Competency and Training			5.7.6	Preservation of SRP		
4.4.2	Control of Documents			5.7.8	Preventive Maintenance, Inspection & Test Program (PMITP)		
4.5	Control of Records			5.8	Control of Testing, Measuring, Monitoring, & Detection Equipment (TMMDE)		
5.1.1	Review of Requirements			5.9	Service Performance Validation		
5.3	Risk Assessment & Management			5.10	Control of Nonconformities		
5.4.1	Design & Development			5.11	Management of Change		
5.5	Contingency Planning			6.2.1	Customer Satisfaction		
5.6	Purchasing			6.2.2	Internal Audit		
5.6.3	Verification of Purchased Services and Service-related Product			6.3	Analysis of Data		
5.7.1.1	Control of Service Execution			6.4.1	Improvement		
5.7.3	Identification & Traceability			6.4.2	Corrective Action		
5.7.4	SRP Status						
5.7.5	Customer Property						

Control of Documents

API Spec Q2, Section 4.4.2 / ISO 9001:2015, Section 7.5

Requirement:	Objective Evidence/Comments:	Finding #:
Documents required by the QMS are controlled to ensure that relevant versions are used and maintained. Appropriate formats Information is adequately protected.		
External documents are controlled to ensure that relevant versions are used and maintained.		
Obsolete documents are identified / removed to ensure against unintended use.		

Verify that a master list or equivalent has been established and is current.		

Control of Records / Documented Information		
API Spec Q2, Section 4.5 / ISO 9001:2015, Section 7.5		
Requirement:	**Objective Evidence/Comments:**	**Finding #:**
Controls include processes and responsibilities for identification, collection, alteration, storage, protection, retrieval, retention time and disposition..		
Documented information / records retained as evidence of conformity protected from unintended alterations (ISO 9001, 7.3.3.2)		
Records are established and controlled to provide evidence of conformity to requirements and the QMS, including records originating from outsourced activities.		
Records are maintained a minimum of 5 years or as required retention by customer, legal and other applicable requirements, whichever is longer.		

QMS Monitoring, Measurement, Analysis, and Improvement

API Spec Q2, Section 6.1 and 6.4.1 / ISO 9001:2015, Section 9.1.1 and 10.1		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
Monitoring, measurement, analysis, and improvement processes needed to ensure conformity to requirements are planned and implemented. Including what to monitor/measure, when to monitor/measure, when the monitor/measure results shall be evaluated. Determination of applicable monitoring / measuring methods and the extent of their use are included. Documented information retained as evidence of results of QMS performance and effectiveness evaluations.		
Records retained as evidence of results. (ISO. 9.1.1)		

Customer Satisfaction

API Spec Q2, Section 6.2.1 / ISO 9001, Sections 5.1.2c, 9.1.2		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
Procedure meets all requirements of the applicable standard and is controlled, implemented, and maintained, and addresses:		

• Frequency and methods for obtaining customer feedback • KPIs • Focus on enhancing customer satisfaction • Other info to determine customer satisfaction		
Records of the results of customer satisfaction are maintained.		

Analysis of Data

API Spec Q2, Section 6.3 / ISO 9001:2015, Section 9.1.3		
Requirements:	**Objective Evidence / Comments:**	
Analysis includes data generated from monitoring & measurement, internal & external audits, management reviews, and other relevant sources.		

Data Analysis shall provide information, including trends, 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				
Nonconformity to service design requirements				
Service execution and SRP performance				
Supplier performance				
KPIs, CSFs, and quality objectives				

Data is used to evaluate where continual improvement of the effectiveness of the QMS can be made.		
Analysis includes; • If planning has been effectively implemented • The effectiveness of actions to address risks and opportunities (ISO 9001, Section 9.1.3d and 9.1.3e)		

Internal Audits

API Spec Q2, Section 6.2.2 / ISO 9001:2015, Section 9.2		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
Internal audit - performed at least annually. *API interprets "Last Internal Audit" to mean the last complete audit of the ENTIRE QMS, whether performed at one time or over the period of 12 months.* Audit planning takes into account results of previous audits, criticality of the process being		

audited, and applicable changes affecting the QMS. Audit techniques include observation of the execution of inspection, assembly, testing, and maintenance processes Audit criteria, scope, frequency, and methods are identified to ensure that all processes are audited.		
Verify that the internal audit performed: • confirm whether the QMS conforms to the requirements of the applicable standard / specification; • has been effectively implemented and maintained, including records; • was performed by independent / objective, competent personnel; • applied suitable observation and evaluation methods to ensure the effectiveness of the area or process being audited • include outsourced activities that impact the quality of the service/SRP and that are performed at the facility; and • includes all elements required by the MS required to (prior to) claim conformance to requirements of the standard		
Nonconformance identified during the internal audit (e.g. response times, responsibilities, reporting, and records) are addressed.		

Management Review

API Spec Q2, Section 6.5 / ISO 9001:2015, Section 9.3		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
Identify date(s) of management reviews within the last 12-month period. (Verify that management reviews are conducted at least annually.)		
Management review has been documented with sufficient evidence to demonstrate conformity with applicable requirements.		
Review Input - Management review includes all inputs required by the applicable standard, including: • • Status and effectiveness of actions resulting from previous management reviews • Results of audits • Changes that could affect the QMS, including legal and other applicable requirements • Analysis of customer satisfaction, including customer feedback • Feedback from relevant interested parties • Process effectiveness • Results of risk assessment • Status of corrective actions • Analysis of supplier performance		

• Review and analysis of failures in service and/or SRPs • Recommendations for improvement		
• Performance of external providers • Adequacy of resources • Effectiveness of actions to address opportunities (ISO 9001, 9.3.2d and e)		
Review Output - Management review output includes a summary assessment of the effectiveness of the MS detailing any: • Required changes to the processes • Decisions and actions • Required resources • Improvement for service/SRP Top Management review and approval of Management Review. Documented and communicated to the organization. Records maintained.		

Improvement Processes – Corrective / Preventive Action

Corrective Action		
API Spec Q2, Section 6.4.2 / ISO 9001, Section 10.2		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
Corrective actions are taken (both internally and within the supply chain) to eliminate the cause of nonconformities. Actions include: • reviewing nonconformities • determining root cause/implementing corrections • dealing with consequences • evaluating the need for action, through cause identification, analysis and consideration of trends • improvements to customer satisfaction considered • implementing corrective action to avoid recurrence • identifying timeframe and responsible person(s) • verification of effectiveness • evaluating similar, potential nonconformities and implementing action to reduce the likelihood of occurrence, as appropriate • MOC (when applicable)		
Records of activities are maintained and identify activities performed to verify effectiveness of the corrective action taken.		
Describe, if appropriate, where and how updates to risk and opportunity information identified during planning has been performed (ISO 9001, 10.2.1e)		

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Realization of Service and Service-related Product

Audit Conditions	
The audit must determine the degree to which services are controlled, executed and delivered under the scope of the QMS. Determine the relevant activities / processes relating to the services delivered and the service-related product used that are being performed / executed and are available to sample during the audit.	
Note: Please identify any services that are being added to the scope of Registration, including services and/or service-related products that are "new" and have been added since the last audit. These services and/or service-related products must be considered when sampling objective evidence during the audit. For example, designs, process controls and capabilities, etc.	
Services and/or Service Related Products within the scope of the QMS:	**Available for review Yes or No**

Contract Review / Customer Related Processes

API Spec Q2, Section 5.1 / ISO 9001, Section 8.2	
List all Contracts reviewed / sampled *(minimum of 3 – include contract identification, customer name, date of contract and any other pertinent details below)***:** **NOTE:** Sampling must consider range of products with Licensing / QMS scope and sample must be increased based on number of products within scope, volume of work, etc.	**Services/Service-related Product:**

Determination of Service/SRP Requirements	**Detail evidence observed** *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**	**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
	Determination of requirements:		Customer requirements
			Legal / other applicable requirements
			Requirements not stated by customer
			Organizational requirements
		Also verify: Requirements confirmed and records maintained where no requirements are stated/documented by customer	
Review of Service/SRP Requirements	Review of requirements:		Reviewed prior to commitment
			Requirements defined
			Differing requirements resolved
			Capability confirmed
			Records maintained
			Records on any new requirements (ISO 9001, 8.2.3.2b)
Changes to Service/SRP Requirements	Changes to contract requirements:		Documents amended
			Changes communicated

Planning

API Spec Q2, Section 5.2 / ISO 9001, Sections 6 and 8.1			
Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
Planning	Planning of service and SRP realization:1		Assure QMS can achieve intended results. (ISO 9001, 6.1.1)
			Customer requirement, including critical success factors
			KPIs
			Legal / other applicable requirements
			Initial Risk Assessment
			Risks and **opportunities** determined and addressed (ISO 9001, 6.1)

			Resources/work environment
			Service/SRP design
			Contingency planning
			required verification, validation, monitoring, measurement, inspection, and test activities, including suitable TMMDE is utilized, specific to the service and SRP and the criteria for acceptance,
			management of interfaces with other party's SRP
			MOC & Changes carried out in a planned manner.
			Records maintained

Risk Assessment & Management

API Spec Q2, Section 5.3 / ISO 9001:2015, Sections 4.4.1, 5.1.2 and 6.1		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
A process has been established to control risks throughout the execution of service, including: • Risks identified; • Addresses work environment • Identifies risk management tools and techniques • Mitigation/prevention control measures selected, communicated and implemented to reduce/avoid exposure to loss; • Notify customer of remaining risks.		
Tools, techniques and their application for risk identification, assessment and mitigation are utilized by the organization.		
Records of risk assessment & actions taken maintained.		

Identify process interaction / examples of Risk Assessment & Management implementation and tools / techniques used:		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**
		Risks Identified
		Risks Assessed
		Actions taken - Mitigation / Preventive Controls Selected, Communicated, and implemented
		Actions integrated into QMS and effectiveness evaluated
		Remaining Risk Communicated-External Communication (4.1.5.2)

		Records Maintained
Identify process interaction / examples of implementation and tools / techniques used to determine and address <u>opportunities</u> (in addition to risks) (ISO 9001, 4.4.1, 5.1.2 and 6.1):		Opportunities determined
		Actions taken (including those needed to enhance desirable effects & achieve improvement)
		Actions integrated into QMS and effectiveness evaluated

Design & Development

Select all that apply:	
	Performed in-house
	Performed at a different location within the same organization
	Outsourced

List service designs sampled / verified: *Select a representative sampling (minimum of three) of the services provided within the scope* Verify that the applicant has a design in place for **<u>ALL</u>** of the services that are part of the scope of registration.	**Services**

Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
Design & Development	Design & Development Planning (5.4.1):		Procedure as per 5.4.1
			Interfaces determined and controlled
			Completion, review and verification of each stage
			Responsibilities and authorities
			Organization considered: • Nature, complexity and duration • Need for customer and user involvement • Requirements for subsequent provision of products • Customer and relevant interested party expectations on controls (ISO 9001, 8.3.2 a & g-i)
	Design & Development Inputs (5.4.2):		Inputs as per API Spec Q2, 5.4.2
			• Potential consequences of failure • Inputs adequate for purpose, complete & unambiguous

			• Conflicting inputs resolved (ISO 9001, 8.3.3)
			Records Maintained
		Also verify: - Customer requirements (5.1) - Legal requirements - SRP functional and technical requirements - Environmental and operating conditions - Results from risk assessment (5.3) - Requirements from external sources - Historical performance	
	Design & Development Outputs (5.4.3):		Outputs as per API Spec Q2, 5.4.3
			Records Maintained
		Also verify: - Acceptance criteria identified / referenced - Critical service-related products identified / referenced - Adequate for subsequent processes & provision of products and/or services - Specify characteristics essential for intended purpose and safe provision	
	Design & Development Verification (5.4.4):		Review as per API Spec Q2, 5.4.4 in accordance with plans (5.4.1)
			Records of results maintained
	Design & Development Final Review & Approval (5.4.5):		Final Review and approval as per API Spec Q2, 5.4.5
			Independent (person other than developer)
			Records Maintained
	Design & Development Changes (5.4.6):		Changes reviewed and verified in accordance with the same controls as the original design and development (Q2, 5.11)
			Records Maintained
			Records contain information on who authorized changes and action taken to prevent adverse impacts. (ISO 8.3.6c,d)
Design & Development Controls – Outsourced (5.4.1)	Supplier's Competency and Control of Outsourced Activities (5.4.1):		Supplier compliance with requirements of API Spec Q2, 5.4
			Records Maintained
		Also verify: - Resources, responsibilities, authorities and their interfaces - Suppliers control, when design activities are outsourced	

Contingency Planning

API Spec Q2, Section 5.5 / ISO 9001:2015, Section 8.2.1e)		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
Verify that contingency planning is based on assessed risks (API Spec Q2, 5.3 and includes incident and disruption prevention and mitigation measures.) Verify integration into services and supporting processes between the organization, its suppliers and customers.		
Output of contingency planning is documented and updated as required. Internal and external communication controls in place, including those relevant to the customer.		

Identify process interaction / examples of Contingency Planning implementation:	**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
		Actions required, roles/responsibilities identified
		Actions to mitigate effects of disruptive incidents
		Internal/external communication controls (4.1.5)
		Records maintained

Purchasing / Externally Provided Products, Processes and Services

API Spec Q2, Section 5.6 / ISO 9001:2015, Section 8.4			
Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed):*		**Check each requirement upon verification** *(explanation must be given for any blank boxes):*	
Purchasing Controls	Control of Purchasing:		Criticality of activities/products determined
			Selection/evaluation based on ability to supply services/products per requirements
			Type and extent of control defined on criticality
			Criteria, scope, frequency and methods of reassessment defined
			List of approved suppliers and scope of approval
			Controls include products/services being provided to customer directly by external provider.
		Also verify: Changes in critical suppliers handled through MOC (5.11.2 c)	

Critical Suppliers – Evaluation and Reevaluation

Suppliers of Critical Services / SRP Sampled:	**Service / Activity Performed / SRP Supplied:**	**Check each requirement upon verification** *(explanation must be given for any blank boxes)*:	
			Initial assessment at supplier prior to initiation of agreement
			Verification of QMS conformance
			Verification of controls applied internall to and to supply chain to meet requirements
			Reevaluation per 5.6.1.4
			Records Maintained
		Also verify: Corrective action and effectiveness of implementation in accordance with 6.4.2	
Suppliers of Other Services / SRP Sampled:	**Service / Activity Performed / SRP Supplied:**	**Check each requirement upon verification** *(explanation must be given for any blank boxes)*:	
			Verification of QMS performance
			Assessment of supplier to meet organization's purchasing requirements
			Assessment upon delivery
			Reevaluation per 5.6.1.3
			Records Maintained
		Also verify: Corrective action and effectiveness of implementation in accordance with 6.4.2	

Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* :		**Check each requirement upon verification** *(explanation must be given for any blank boxes)*:	
Purchasing Information (5.6.2)	Purchasing Information *(include contracts/POs sampled - minimum of 3)* :		Acceptance criteria documented
			Requirements for: • Supplier interactions • Control and monitoring of supplier performance (ISO 9001, 8.4.3d&e)
			Records Maintained
		Also verify: Documented requirements per 5.6.2(a)(b)(c)(d)(e), where applicable	
Verification of Purchased Services and Service-related Product (5.6.3)	Verification of conformance to requirements *(include records reviewed as evidence of conformance)*:		Verification activities records maintained
		Also verify: Controls for verification at supplier's premises, where applicable	

Outsourced Service and SRP (5.6.3)	**Evidence of conformance to requirements for outsourced service and service-related product:**		Verification activities records maintained

Execution of Service

API Spec Q2, Section 5.7.1 / ISO 9001:2015, Section 8.5.1 & 8.5.5
Description of Service <u>Capabilities</u> *[What capabilities does the facility have, including machinery and equipment available. Also provide additional detail about all services facility is capable of providing.]:*
Description of Service <u>Processes</u> *(describe the service processes that are **<u>actually being delivered at the customer / field</u>** sites and the SRP related processes that take place in the facility and their interactions):* ***Processes must be described in detail and this includes field service processes and shop activities relating to maintenance of SRP.***
Service / SRP Processes reviewed/sampled: **NOTE:** You **<u>MUST INCLUDE</u>** at least 3 samples of field service processes that were/are performed at the well sites, customer locations, etc. AND 3 samples of processes related to shop control over SRP maintenance, validation, etc. This CANNOT be limited to processes / process controls related to SRP in the shop environment related to PMITPs and other SRP activities.

Description of service / SRP processes:	Personnel interviewed/position/title:	Process control documents (verify revision):

Control of Service Execution (5.7.1.1)	**Detail evidence observed** *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**	**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
	Controls established and implemented for execution of service:		Procedure as per 5.7.1.1
			Risk assessment & management (5.3)
			Design requirements (5.4); contract requirements(5.1)
			Required equipment (5.8)
			Training and competence (4.3.2)
			Actions to prevent human error (ISO 9001, 8.5.1g)
		Also verify: - Implementation of Quality Plan, if required - Work instructions, when applicable - Monitoring & measuring activities - Product release activities	
Post-delivery activities (ISO 9001, 8.5.5)	Controls established for any required post-delivery activities:	Considerations: - Statutory / regulatory requirements - Potential undesired consequences - Nature, use and intended lifetime - Customer requirements and feedback	
Documentation (5.7.1.2)	Documentation of controls (routers, travelers, checklists, etc.):		Includes requirements for verifying conformance with quality plans, procedures, customer requirements
			Reference instructions
			Acceptance criteria
		Also verify: Inspection holds and witness points	

Product Quality Plan(s)

API Spec Q2, Section 5.7.2 / ISO 9001:2015, Section 8.5.1			
Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
Service Quality Plans (5.7.2)	Quality Plans sampled - <u>sample and identify</u> service quality plans for services that fall within the QMS scope. Consider all services within the scope, services executed, contracts executed, jobs performed, etc.		Verify SQP identifies (5.7.2.2): - Compliance with customer/legal requirements - Responsible functions, including external parties (customers) - Subcontractors and controls - Procedure/document references - Acceptance inspections - Service equip/monitoring devices - Risk identification and controls - Critical services and SRP - Required deliverables and records
			Revisions documented / approved (5.7.2.3)

			Communicated (5.7.2.3)

Identification and Traceability

API Spec Q2, Section 5.7.3 / ISO 9001:2015, Section 8.5.2			
Verify that SRP controls are communicated and implemented for use of the SRP in the field to deliver/perform the services at well sites, customer sites, etc.			
Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
Identification/ Traceability	Identification / traceability reviewed / sampled:		Records maintained Also verify : - Service-related product identified - Critical SRP identified and **traceable to PMITP records and original manufacturer** (4.5, 5.7.8) - Maintenance/replacement of identification/marks
Status of Service-related Product			
API Spec Q2, Section 5.7.4 / ISO 9001:2015, Section 8.5.2			
Product Inspection / Test Status	Status of Service-related product reviewed/sampled:		Records maintained indicating conformity / nonconformity of product
Customer / External Provider Property *(if applicable)*			
API Spec Q2, Section 5.7.5 / ISO 9001:2015, Section 8.5.3			
Customer-supplied property	Controls in place for property owned by the customer:		Records maintained Also verify: - Requirements for reporting to customer - Includes intellectual property and customer-specified data
External provider property (ISO 9001, 8.5.3)	Controls in place for property owned by external providers:		Documented information retained

Preservation of Service-related Product			
API Spec Q2, Section 5.7.6 / ISO 9001:2015, Section 8.5.4			
Note: **Verify that SRP controls are communicated and implemented for use of the SRP** in the field to deliver/perform the services at well sites, customer sites, etc.			
Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
Preservation of Service-related Product			Identification / traceability marks
			Transportation, handling, packaging, storage and protection
			Records maintained
		Also verify: Applies to constituent parts of service-related product	
Validation of Service-related Product			
API Spec Q2, Section 5.7.7 / ISO 9001:2015, Section 8.5.1f			
Verify that SRP controls are communicated and implemented for use of the SRP in the field to deliver/perform the services at well sites, customer sites, etc.			
Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
Validation of Service-related Product			Completed prior to execution of the service
			Appropriate to criticality
			Records of results of validation maintained
Inspection and Testing			
API Spec Q2, Section 5.7.8 / ISO 9001:2015, Sections 7.1.3, 8.5.1a and 8.6			
Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* **:** **Note:** Verify the implementation of PMITPs for SRP related to the services delivered and that are part of the QMS scope. Identify the specific SRP and PMITP information below.		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
Preventive, Maintenance, Inspection and Test Program (PMITP) (5.7.8)			Procedure as per 5.7.8
			Corrective/preventive/predictive maintenance actions
			Activity reports for direct verification for reuse
			List of critical spare parts
			Frequency/condition requiring maintenance, inspection, and/or testing
			Controls for equipment integrity and DAC maintained

		Also verify: - Usage history considered in PMITP - Acceptance criteria for PM in place and effectively communicated - MOC process for original performance requirements that cannot be met

Control of Testing, Monitoring and Measuring Equipment

API Spec Q2, Section 5.8 / ISO 9001:2015, Section 7.1.5		
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 for the execution of the service/provision of service-related product. Also verify: Control of out-of –tolerance equipment and assessment of previous measurements.		

Equipment sampled *(minimum of 6)***:**

MUST include at least 3 samples (records minimally) of testing, monitoring, measuring and detection equipment that is used to deliver the services in the field (as applicable). This should not be limited to equipment used in the shop environment as part of the PMITP for SRP.

Equipment:	**Description:**	**Cal Date:**	**Due Date:**		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**
					Uniquely identified
					Calibration status identified
					Protected/safeguarded
					Traceable to Nat'l/int'l standard
					Included on registry
					Acceptance criteria defined and appropriate
					Equipment suitable
					Records maintained
					Also verify: - Computer software confirmation - Externally provided equipment

Service Performance Validation & Product/Service release

API Spec Q2, Section 5.9 / ISO 9001:2015, Section 8.3.4d,e; 8.6			
Specifically relates to in-process and post job activities to validate that the services performed and delivered at the well sites, customer sites, etc. meet requirements. **Verify process through records review/interview with responsible field personnel/management.**			
Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
Service Performance Validation (Q2, 5.9)			Procedure as per 5.9
			Carried out at appropriate stages
			Evidence of conformance (KPIs, critical success factors)
			Records maintained
Release of Product or Service (ISO 9001, 8.3.4d,e,f; 8.6)			Actions taken on any problems identified in verification/validation
			Release upon satisfactory completion of planned arrangements
			Evidence of conformity with acceptance criteria
			Identification of individual releasing product
			Records maintained
		Also verify: - Approval of release by authority/customer when planned arrangements are not met	

Control of Nonconformities

API Spec Q2, Section 5.10 / ISO 9001:2015, Section 8.7			
Detail evidence observed *(including records and documents reviewed, personnel interviewed, and processes observed)* **:**		**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
Control of Nonconformities			Procedure
			Method of addressing non-conforming product per API Spec Q2, 5.10.2
			Concession approved by relevant authority and/or customer
			Verification & documentation
			Customer notification
			Records maintained
		Also verify: - Proper identification to prevent unintended use - Addressing the nonconformity - Identification, documentation, analysis and actions taken for nonconforming product identified after delivery - Risk assessment includes supplier performance. Ensure risks are identified and controlled. - Authority deciding action identified.	

Management of Change

API Spec Q2, Section 5.11 / ISO 9001:2015, Section 6.3 and 8.5.6		
Requirements:	**Objective Evidence / Comments:**	**Finding #:**
MOC process has been established to ensure that integrity of the MS when changes are planned and implemented. Facility identifies potential risks associated with changes prior to making the change. Changes are approved as required prior to making changes		
Consideration given to purpose, potential consequences, resource requirements, changes in responsibilities and authorities related to the change(s) (ISO 9001, 6.3)		
Describe how the facility ensures that the MOC process is used for changes that may affect the QMS negatively, including changes: • to the organizational structure; • in key or essential personnel; • in critical suppliers; • to approved designs • to original equipment for service-related product		

• to MS processes, changes resulting from CA / PA • caused by temporary deviations from procedures/requirements (situational) • to the work enviroment		
Describe the organization's process for notification of changes. When is notification required? To who is notification required?		
Top management has assigned specific responsibities and authorities for managing QMS changes (ISO 9001, 5.3 e)		
Records (documented information) describe the results of review changes, the person authorizing and any necessary actions arising from the change review. (ISO 8.5.6)		

Identify process interaction / examples of Management of Change implementation:	**Check each requirement upon verification** *(explanation must be given for any blank boxes)***:**	
		Risks identified prior to change
		Purpose, consequences, resources, responsibilities/authorities considered (ISO 9001, 6.3)
		Approved prior to change
		Notification of change
		Relevant documents amended
		Records maintained

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 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 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 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 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 registration. API makes the final determination of certification status and shall be the sole judge of whether 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 AARs and final audit report. (Digital Signatures are acceptable)	
Organization Representative (optional):	Date:

Enter the next audit date for Dual/Registration Audits below *(Does not apply to Monogram only audits)*:

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

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

Opening / Closing Meeting Attendance Sheet

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.		