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# API Q1 OR ISO 9001

An effective quality management system helps organizations consistently meet customer requirements. **API Specification Q1, 10th Edition** is a QMS standard for organizations that provide products specifically for the petroleum and natural gas industry. API Spec Q1 has historically been developed with product manufacturers in mind, although with the 10th edition, other types of organizations may also implement the standard. Organizations may also consider **ISO 9001:2015**, an international QMS standard aimed at optimizing operational processes and enhancing customer satisfaction in any industry.

## WHICH STANDARD BEST SUITS YOUR ORGANIZATION'S NEEDS?

**Below, we explore API Q1's key performance benefits and nuances.**

1. **PRIORITIZE OIL AND GAS:** API Spec Q1 meets many of the ISO 9001 requirements, plus additional elements deemed necessary by the oil and gas industry. ISO 9001 is a one-size-fits-all that may not accommodate evolving technology, public expectations, and the unique risks faced by the oil and gas industry.

2. **ENHANCE COMPLIANCE AND SAFETY:** Both API Q1 and ISO 9001 allow for the exclusion of non-applicable requirements; however, API Q1 restricts exclusions to specific areas like design, validation of processes and externally owned property. This targeted approach ensures that essential components of the QMS are not overlooked, fortifying safety and compliance standards beyond the more flexible allowances permitted under ISO 9001.

3. **MAINTAIN CLEAR COMMUNICATION:** API Q1 outlines a comprehensive management of change (MOC) process that prioritizes risk mitigation and transparency, keeping all stakeholders, including customers, fully informed about changes, risks and implementation details. In contrast, ISO 9001 requires organizations to plan for changes and "consider" certain aspects of the change — detailed communications and documentation are not mandated.

4. **PROMOTE ACCURACY:** API Q1 establishes stringent calibration requirements for all equipment used in monitoring product conformity and process parameters, including extensive requirements for the information that must be documented. This is critical for maintaining high safety and quality standards. ISO 9001 allows companies more leniency in determining which equipment requires calibration.

5. **DRIVE EFFECTIVE OVERSIGHT:** API Q1 mandates that a management representative with authority to oversee QMS compliance be assigned, reinforcing accountability and maximizing quality management. The standard also mandates internal audits every 12 months, including direct observation of critical activities. In contrast, ISO 9001 offers more generalized guidance audits without frequency or observational requirements.

6. **ACHIEVE CONSISTENT QUALITY:** API Q1 maintains strict standards for documenting critical processes using procedures, including procedures for competence, purchasing, and design. Additionally, API Q1 includes a minimum records retention timeline of 10 years.

7. **VALIDATE PROCESSES:** API Q1 mandates validation for crucial processes where outputs cannot be verified by subsequent monitoring, such as welding and non-destructive evaluation (NDE). More specifically, API Q1 requires that the validation procedure address equipment, personnel qualifications, methods, acceptance criteria, records and revalidation. Additionally, API Q1 mandates a minimum for which processes must be validated. No such criterion is defined in ISO 9001.

8. **REDUCE RISKS:** API Q1 mandates a rigorous, proactive process for identifying and mitigating the unique, high-risk environment associated with oil and gas, particularly risks associated with product delivery and quality. The basic requirements in ISO 9001 are not specific to any type of risk.

9. **IDENTIFY RELIABLE SUPPLIERS:** API Q1 tailors its approach to supplier management to address the specific needs and risks of the industry rather than adopting ISO 9001's more generalized guidelines. API Q1 establishes a tiered evaluation system for critical suppliers, with detailed and rigorous requirements for high-risk suppliers, in some cases requiring an on-site assessment as part of the evaluation process. Additionally, API Q1 has extensive requirements for the process of verifying purchased products, components, or activities, which minimizes supply chain disruptions.

10. **MINIMIZE DOWNTIME:** API Q1 emphasizes preventive maintenance for all equipment, reducing operational disruptions. This proactive approach extends beyond ISO 9001's general requirement to maintain.

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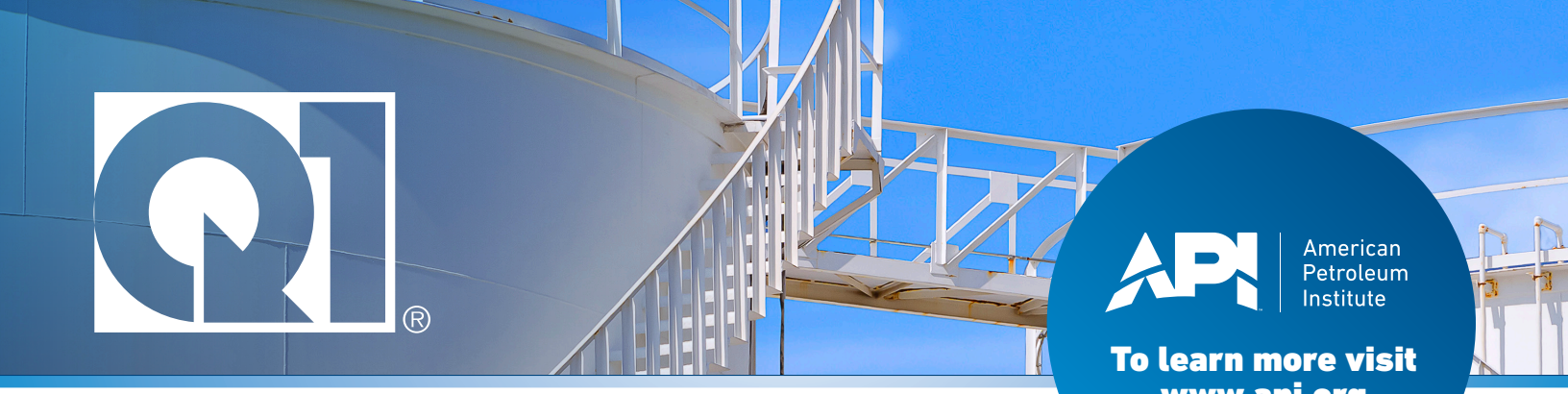

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The table below provides more specific examples of API Q1 requirements that are included in the specification to address the needs and concerns of the oil and gas industry. This is not an all-encompassing list, and organizations are encouraged to perform a thorough review of API Q1 to better understand the effort needed to implement a conforming QMS.

| PROCESS | API Q1 REQUIREMENTS |
|---|---|
| **EXCLUSIONS** | • Only specific clauses can be excluded from the QMS when justifiable, including design, validation of processes & externally owned property. |
| **MANAGEMENT OF CHANGE (MOC)** | • MOC process must be implemented to address changes, resources, risks, review and approval, notification, and verification.<br>• MOC specifies who needs to be notified, including circumstances where customers must be notified.<br>• Risk assessment must be performed when the change could impact product quality.<br>• MOC is required for changes in organizational structure, key personnel, supply chain, scope, procedure, or capability.<br>• The entire process must be documented. |
| **CONTROL OF MEASURING EQUIPMENT** | • Requirements must be applied to all measuring equipment used to provide evidence of product conformity or used to monitor process parameters.<br>• Q1 includes additional requirements for documenting unique identification, calibration status, calibration method and acceptance criteria, “as-found” and “as-left”.<br>• Q1 also includes additional requirements for third party, proprietary, employee-owned, and customer-owned equipment. |
| **MANAGEMENT REPS** | • Q1 maintains a requirement to appoint a Management Representative responsible for the QMS. |
| **PROCEDURES** | • Q1 includes more than 25 requirements for a documented procedure to describe the processes.<br>• Examples of procedures that must be addressed include competence, training, risk management, design, purchasing, inspection and testing, & nonconforming product. |

| PROCESS | API Q1 REQUIREMENTS |
|---|---|
| **RISK MANAGEMENT** | • Risk analysis must include, at a minimum, risks associated with product delivery and product quality.<br>• Requirements for contingency plans are also required.<br>• Risks and contingency plans must be documented. |
| **DESIGN** | • Q1 includes requirements related to customer notification when design changes are performed. |
| **PURCHASING AND CONTROL OF SUPPLY CHAIN** | • Purchases must be classified as critical or non-critical; critical purchases can further be classified as high-risk.<br>• Initial supplier evaluation for critical purchases includes evaluation of QMS, control of supply chain and one of the following: on-site assessment, remote assessment, or inspection of received product.<br>• Remote assessments must include real-time audio/visual observation.<br>• For high-risk suppliers, a combination of assessments may be required.<br>• Evaluation interval must be determined based on risk and supplier quality performance.<br>• Re-evaluation criteria is the same as initial evaluation criteria. |
| **VERIFICATION OF PURCHASED PRODUCT OR ACTIVITY** | • For critical products, verification must include required documentation and applicable versions of Standards or other documents.<br>• Procedure must address inspection/testing methods, frequency, and responsible party.<br>• Determinations must be based on risk and supplier quality performance. |
| **PROCESS CONTROL DOCS** | • Organization must maintain process control documents (e.g. routers, travelers) throughout the product realization process. |
| **VALIDATION OF PROCESSES** | • Processes identified in a product specification must be validated.<br>• If none identified in the product specifications, the following processes must be validated: welding, heat treatment, non-destructive examination (NDE) and coating.<br>• Procedure must address equipment, personnel qualifications, methods, acceptance criteria, records, and revalidation. |
| **PREVENTIVE MAINTENANCE** | • Organization must establish a procedure and process to perform preventive maintenance on equipment used for product realization. |
| **INTERNAL AUDIT** | • Internal audit must be performed at least every 12 months.<br>• Internal auditors must physically observe critical activities during the internal audit. |
| **RECORDS** | • Records must be retained for at least 10 years. |

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