Navigating Statutory & Regulatory Requirements Specified in API Spec Q1

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I Introduction

Over the years of auditing in regulated industries, I learned that organizations infrequently identify statutory and/or regulatory requirements applicable to their product unless specified by a customer.

Statutory and regulatory requirements may be local, regional, national, or international. They may be necessitated by the application of a product, process, or service; they may be identified directly through contractual requirements (e.g., related to customer contracts or purchase orders to the supply chain); or they may apply simply based upon a given location (e.g., domestic, international, onshore, offshore).

It is essential for organizations to perform due diligence and strive to determine which, if any, statutory and/or regulatory requirements may apply to their offerings and/or activities. As an example, being complacent or failing to understand whether these requirements may apply could result in:

a) From a business perspective:
   i) Penalties
   ii) Increased scrutiny and audits
   iii) Operational shutdown or suspension
b) From a human factors perspective:
   i) Neglecting safety procedures
   ii) Ignoring safety gear
   iii) Increasing the risk of accidents
   iv) Exposure to harmful substances

The focus of this document is related to statutory and regulatory requirements specified by API Spec Q1 to achieve product conformity. However, it is fair to say that achieving product conformity will involve a variety of process controls and other process activities, meaning:

- Besides the Q1 clauses that specify statutory and regulatory requirements, other Q1 clauses will interact with these clauses
- Health, safety, and environmental statutory and regulatory requirements will apply

Since Q1, 10th Edition has a relationship to ISO 9001:2015, its clauses specifying statutory and regulatory requirements were also analyzed and identified (see paragraph VI “Analysis of Statutory and Regulatory Requirements Between API Spec Q1, 10th Edition and ISO 9001:2015”).

The focus of this publication is for the oil and natural gas industry, as statutory and regulatory requirements relate to the following business sectors: manufacturing, repair, refurbishment, remanufacturing, and service companies as generally defined below:

- **Manufacturing** – creates new products
- **Repair** – fixes products that are broken but typically doesn't restore them to new condition
- **Refurbishment** – restores products to near-new condition, often with some components replaced
- **Remanufacturing** – is a more comprehensive process that brings products back to like-new or better condition, often including part upgrades
- **Service** – focuses on maintaining and supporting the ongoing operation of products without necessarily fixing or restoring them

The information provided here is meant as a general guide to promote careful consideration and does not cover all statutory and regulatory requirements relevant to these business sectors.

II Finding Statutory and Regulatory Requirements

While finding the applicable statutory and regulatory requirements may be challenging, sources of information that may be helpful in your journey may be:

- Located through customer-specified requirements
- Based upon location (e.g., domestic, international, onshore, offshore)
- Identified through online databases and listings of state and federal regulators
- Identified through industry trade associations

From the perspective of a trade organization, the API has more than 800 standards that are cited in various statutory and regulatory requirements worldwide. For instance, the API Global Industry Services brochure (GIS Fact Sheet) identifies the following:

a) *"3,800 Citations: in state regulations"*
b) *"650+ Citations: by U.S. federal government organizations: U.S. Coast Guard, U.S. EPA, FTC, BSE, OSHA and PHMSA"*
c) *"789 International References: by Brazil, Canada, India, Indonesia, Mexico, Saudi Arabia, United Arab Emirates and others"*

Furthermore, as quoted from API's website:

> *"The **API Standards: International Usage and Deployment** report demonstrates the role industry standards play in the development and spread of technologies and products used around the world to enhance environmental, health, safety, and sustainability. The report analyzes how 17 economies in energy producing regions use API's technical standards as the basis for government regulations and safety programs. The report is focused broadly on the use of API standards across all segments – not only in national laws and regulations but also in policy guidance, national standards, technical manuals, and industry practice."*

Many of the statutory and regulatory references provided are from US government sources, a few of which are shown below:

Table 1, Statutory and Regulatory Requirements Sources

Oil and Gas Industry, US Regulatory Agencies
Bureau of Safety and Environmental Enforcement (BSEE)
Code of Federal Regulations (CFRs)
Occupational Safety and Health Administration (OSHA)
Department of Transportation (DOT)
Environmental Protection Agency (EPA)
Consumer Product Safety Commission (CPSC)
European Regulations and Directives*

*__Note__: The following European Directives are commonly seen in organizations that manufacture valves:

a) Pressure Equipment Directive (PED) (2014/68/EU

b) ATEX (Atmospheric Explosibles) Directive 2014/34/EU

Keep in mind that even after identifying the applicable statutory and/or regulatory requirements for your situation, your work may not be finished. Additional health, safety, and/or environmental regulations could apply depending on the processes and activities associated with products.

III Less-Obvious Key Areas in API Specified Requirements Relevant to Statutory and Regulatory Compliance

There are two key areas outlined in API requirements that are essential to a strong statutory and regulatory program:

a) Spec Q1, Clause 4.4.4 Control and Use of External Documents

Statutory and regulatory requirements are regarded as external documents and must be implemented through clause 4.4.4, as shown in Table 2 below. In summary, this clause covers the following key controls:

i) Identification of external documents (e.g., statutory and regulatory requirements)

ii) Ensuring access to up-to-date information and integrating it into your Quality Management System (QMS)

iii) Implementing the requirements outlined in these documents

iv) Monitoring and applying any relevant changes to these documents into your QMS as they occur

Table 2, Control of Statutory and Regulatory Requirements

Q1, Clause **4.4.4 Control and Use of External Documents**
The organization shall maintain a documented procedure for the control of documents of external origin required for product realization and used by the organization, including API or other external specifications. The procedure shall address: a) identification and documentation of required documents; b) access and distribution of required documents, including relevant versions; c) integration of requirements into product realization and any other affected processes; d) process for identifying when changes to required documents have occurred, including addenda, errata, and updates; e) assessment of impact of changes; and f) integration of applicable changes. **Note:** Normative references that are identified within API product or other external specifications and are required during product realization can also be considered an external document.

b) Acknowledging the API as an Interested Party

Q1, clause, 4.1.4.1, Planning the Quality Management System, General, c) states "determine relevant interested parties and their requirements for the quality management system." The API is a key interested party and has specific legal requirements that apply to organizations holding an API Product Specification License under the API Monogram Program and/or a management system certification under the APIQR Program.

Organizations must understand and adhere to API's specific legal obligations, which include various statutory and regulatory requirements relevant to the industry (e.g., trade sanctions). These specific requirements can be found in the API Agreements available under API | API Monogram & APIQR Program Documents:

i) FM-002, API Monogram Licensing Program Requirements

ii) FM-004, APIQR Registration Program Requirements

IV Products Used Offshore in the US Outer Continental Shelf (OCS) Exploration and Production Activities

The OCS refers to the submerged land and seabed areas that extend beyond the 12-nautical-mile limit of territorial waters, generally extending from 12 nautical miles to 200 nautical miles offshore, or in some cases, even farther.

The OCS is considered part of the US Exclusive Economic Zone (EEZ), which extends up to 200 nautical miles from the US coastline.

Exploration and production activities fall under the auspices of the Bureau of Safety and Environmental Enforcement (BSEE). They are responsible for regulating and overseeing safety, environmental protection, and resource management in all US offshore areas on the OCS, including regions in the Gulf of Mexico, Alaska, the Pacific, and the Atlantic.

a) 30 CFR Part 250

Title 30:	Mineral Resources
Chapter II:	Bureau of Safety and Environmental Enforcement (BSEE), Department of the Interior
Subchapter B:	Offshore
Part 250:	Oil and Gas and Sulphur Operations in the Outer Continental Shelf

It is important for equipment manufacturers to understand the requirements specified by this regulation. While this document primarily applies to operators, requirements are contained therein that apply to product manufacturers, including performance criteria, operating and service conditions, maintenance, inspection, and testing.

Also, this CFR contains scores of references (more than 90) to API Product Specifications, Standards, Recommended Practices, and other documents. Compliance with codes and/or standards referenced in Federal Regulations is mandatory. Therefore, it is essential to maintain integrity within these specified requirements to avoid fines or penalties.

Note: BSEE's Safety Alert Program is a good source of information and may provide organizations with failure information related to the types of products they produce or the services they provide.

b) BSEE's Influence on the Content of Industry Standards

Regulators may create or change regulations depending upon a wide array of events, including but not limited to: catastrophic events, product failures, health and safety concerns, changes in political leadership, and technological advances.

Due to product failures, BSEE was responsible for changes to Q1, specifically the addition of the definition of "supply chain" and the modified requirements for the supply chain in Addendum 2 to the 9th Edition published in 2018 as a result of their Quality Control – Failure Incident Team "QC-FIT Report" findings. Shown below is a quotation from this report.

> *Industry should evaluate API Specification Q1, Ninth Edition, June 2014 including the addendums, "Specification of Quality Management Systems Requirements for Manufacturing Organizations for the Petroleum and Gas Industry" for the following:*
>
> 1. *Consider including oversight and auditing of subcontracted second-tier, third-tier and lower-tiered vendors who perform a manufacturing process into API Specification Q1. This requirement would ensure that all components manufactured throughout the supply chain are "fit for service."*
> 2. *Ensure that the API monogram provides a sufficient auditing mechanism such that the OEMs are in full compliance with API Specification Q1 Ninth Edition.*
> 3. *Consider including fasteners for critical equipment in the API monogram program.*

Note: BSEE QC FIT Report

V The Importance of Integrating Health, Safety, and Environmental Statutory and Regulatory Requirements

Focusing on the business sectors discussed here, attention will be given to organizations involved in repair, refurbishment, remanufacturing, and service, as their activities often require the disassembly of equipment.

Organizations lacking situational awareness may inadvertently expose their workforce to hazardous conditions, particularly when it comes to trapped hydrogen sulfide (H_2S) gas and naturally occurring radioactive materials (NORM) that oil and gas industry equipment may encounter during its service life.

It is both surprising and concerning how many organizations are completely unaware that these risks could exist. While operating companies generally ensure that equipment is free from these hazards, this may not always be the case, especially for companies working in remote locations.

a) Hydrogen Sulfide (H_2S) Gas

H_2S may be present in equipment being received by an organization for repair, refurbishment or remanufacturing. Examples of equipment where H_2S could be present include but are not limited to: crude oil tanks, pipelines, wellheads, production manifolds, gas processing units, storage tanks, and valves.

Prior to handling such equipment and prior to it being received, the organization should ensure that their personnel have proper training and that they have in place emergency response plans and procedures to handle potential H_2S exposure effectively.

Some of the personal protective equipment that is essential to protect against the potential dangers of exposure includes, but is not limited to:

i) Respiratory Protection:

- Self-Contained Breathing Apparatus: Required for high concentrations of H_2S, as it provides an independent air supply.
- Air-Purifying Respirators with H_2S-specific cartridges: Suitable for lower concentrations of H_2S but not for high exposure levels.

ii) Gas Detection Monitors:

- Personal H_2S gas detectors should be worn to continuously monitor air quality and provide early warning if hazardous levels of H_2S are detected.

iii) Protective Clothing:

- Flame-resistant clothing: H_2S can be highly flammable, so wearing flame-resistant clothing helps prevent ignition in case of a gas leak.
- Chemical-resistant suits: In cases of potential exposure to liquid H_2S or its effects, chemical-resistant protective clothing is advised.

iv) Gloves:

- Chemical-resistant gloves: These should be worn to protect the hands from exposure to H_2S, especially when handling equipment or materials that may be contaminated.

v) Eye and Face Protection:

- Safety goggles or face shields: To protect the eyes and face from potential splashes or vapors of H_2S, particularly if working in confined spaces or near equipment being serviced.

vi) Hearing Protection:

- Earplugs or earmuffs: These should be used in noisy environments to protect against hearing damage, although it could mask alarm signals from gas detection equipment.

Organizations not familiar with these requirements should engage professional health, safety, and environmental support. The following OSHA websites provide additional resources related to this subject.

- Occupational Safety and Health Administration: Hydrogen Sulfide
- OSHA Hazard Information Bulletins: Chemical Exposures from Industrial Valve and Piping Systems

b) Naturally Occurring Radioactive Materials (NORM) and Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM)

NORM consists of radioactive material that comes out of the Earth's crust and mantle, and where human activity results in increased radiological exposure (World Nuclear Association). NORM includes materials such as uranium, thorium, and radium, which are naturally present in the Earth's crust.

TENORM refers to naturally occurring radioactive materials (NORM) that have been concentrated or otherwise altered by human activities – such as mining, oil and gas production, water treatment, or industrial processes – in ways that increase radioactivity levels.

While NORM itself is naturally present in the environment, TENORM occurs when human activities either concentrate these materials or expose them in forms that are more readily available for exposure (e.g., in waste products or residues).

For example, in the oil and gas industry, the extraction of oil and natural gas can result in the accumulation of radium or other radioactive elements in waste materials, such as sludge or scale buildup. Exposure to NORM / TENORM, typically occurs through inhalation, ingestion, or direct contact with contaminated materials.

i) Monitoring for NORM / TENORM

NORM / TENORM may be present in any equipment that comes into contact with wellbore fluids, including but not limited to drill pipes, drill bits, valves, manifolds, and drilling mud flow meters.

Organizations familiar with these conditions typically monitor for it using NORM monitors or meters, for example:

- Companies that rethread drill pipes often monitor incoming pipes requiring repair
- Steel mills that receive scrap metal for remelting monitor scrap shipments

Typically, if NORM / TENORM are detected, shipments are returned to the sender since processing contaminated materials or equipment is extremely expensive, not to mention the regulatory attention that it would attract.

Other organizations may be unaware that this condition exists and proceed with repairing equipment without recognizing the associated risk.

Note: Similarly, though not related to NORM / TENORM, I am aware of an oil and gas manufacturing company that had established a program to monitor all incoming metallic raw materials for radioactivity. The quality manager explained that they used a radiation survey meter and identified a radioactively contaminated load of bar stock that came from a steel mill in Eastern Europe.

ii) Examples of the US Code of Federal Regulations and Industry Publications:

- Environmental Protection Agency: TENORM: Oil and Gas Production Wastes TENORM: Oil and Gas Production Wastes | US EPA
- Occupational Safety and Health Administration: Ionizing Radiation, Ionizing Radiation - Hazard Recognition | OSHA.gov | Occupational Safety and Health Administration
- API Bull E2, Management of Naturally Occurring Radioactive Materials (NORM) in Oil and Gas Production
- International Association of Oil and Gas Producers (IOGP): Naturally Occurring Radioactive Materials - The Facts

iii) Examples of State NORM Regulations

- Louisiana Regulations, Title 33: Environmental Quality, Part XV. Radiation Protection, Chapter 14. Regulation and Licensing of Naturally Occurring Radioactive Materials (NORM)
- Georgia State "Regulation and Licensing of Naturally-Occurring Radioactive Materials (NORM)", October 1994
- Texas Regulations for Control of Radiation, Part 46 – Licensing of Naturally Occurring Radioactive Material (NORM)

VI Analysis of Statutory and Regulatory Requirements Between API Spec Q1, 10th Edition, and ISO 9001:2015

The following tables outline the citations related to statutory and regulatory requirements in both API Spec Q1 and ISO 9001:

- Table 3, Q1, 10th Edition Citations for "Legal" (page 13)
- Table 4, ISO 9001:2015 Citations for "Statutory & Regulatory" (page 14)

Note: In order to comply with statutory and regulatory requirements, other clauses of Q1 and/or ISO 9001 may have to be integrated into the equation.

The following subsections provide a summation of how statutory and regulatory requirements are addressed in Q1 and ISO 9001 and include the similarities and differences between the two standards.

a) How statutory and regulatory requirements are identified in API Spec Q1 and ISO 9001

Q1 identifies statutory and regulatory requirements as "legal requirements" via its definition in clause 3.1.11; whereas ISO 9001discusses the specific terminology, "statutory and regulatory." The definition of these terms may be found in ISO 9000.

Clause 3.6.6 **Statutory requirement** Obligatory requirement specified by a legislative body	Clause 3.6.7 **Regulatory requirement** Obligatory requirement specified by an authority mandated by a legislative body

b) Compliance to statutory and regulatory requirements

Q1 specifies "compliance" by its definition in clause 3.1.4. The ISO 9001 requirements discuss the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

#	Clause	Title	Citing
Q1	3.1.4	Compliance	Act of satisfying (verb) or the status of having satisfied (noun) legal requirements
9001	0.1	Introduction, General	The potential benefits to an organization of implementing a quality management system based on this International Standard are: a) the ability to consistently provide products and services that meet customer and applicable **statutory and regulatory** requirements

Other than the definition section, this is the only place where "compliance" is specified in Q1. The consequences for non-compliance can result in a range of penalties depending on the violation, including:

- Civil penalties (fines and orders to correct violations)
- Criminal penalties (fines or imprisonment, especially for willful or negligent violations)
- Suspension or revocation of licenses
- Lawsuits and legal liabilities

c) How statutory and regulatory requirements are initially addressed in each standard

ISO 9001 provides a more detailed explanation of statutory and regulatory requirements in its scope in clause 1, including the relationship with external and internal issues identified in clause 4.1 (i.e., the wording of Note 2) and interested parties as identified in clause 4.2.

#	Clause	Title	Citing
ISO 9001	1	Scope	This International Standard specifies requirements for a quality management system when an organization: a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable **statutory and regulatory** requirements, and b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable **statutory and regulatory** requirements Note 2: Statutory and regulatory requirements can be expressed as **legal** requirements.
ISO 9001	4.1	Understanding the organization and its context	The organization shall monitor and review information about these external and internal issues. Note 2: Understanding the external context can be facilitated by considering issues arising from **legal**, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local
ISO 9001	4.2	Understanding the needs and expectations of **interested parties***	Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable **statutory and regulatory** requirements Note: See the American Petroleum Institute as an "Interested Party" herein
ISO 9001	8.2.3.1	Review of requirements related to products and services	The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include: d) **statutory and regulatory** requirements applicable to the products and services
Q1	4.4.1	Documentation Requirements, General	The quality management system documentation shall include: c) identification of **legal** and other applicable requirements to which the organization claims **compliance** that are needed to achieve product conformity
Q1	4.1.4.2	Exclusions	Excluded activities shall not affect the organization's ability, or responsibility, to provide product that satisfies customer and **legal requirements**

i) The documentation requirements outlined in clause 4.4.1 of Q1 mention statutory and regulatory requirements "needed to achieve product conformity." This could be misleading, as statutory and regulatory requirements may also apply to activities related to the product and its associated processes, including potential health, safety, and environmental considerations.

For example, the requirements specified in the following clauses do not specifically call out "legal" requirements, but statutory and regulatory requirements could definitely apply:

- 5.6.1 Control of Product Realization, General

  "The organization shall maintain a documented procedure that describes controls associated with product realization. The procedure shall address the following:
  j) implementation of product release (see 5.7), including applicable delivery and post-delivery activities."

- 5.6.8 Preservation of Product

  "The organization shall maintain a documented procedure describing the methods used to preserve the product and component parts throughout product realization and delivery. The procedure shall address the following:
  d) transportation"

  Activities related to transportation and delivery could involve compliance to the Federal Motor Carrier Safety Administration Regulations for Shipping by Vehicles requirements:

49 CFR Part 393	Loading and cargo securement, including the weight distribution
49 CFR Part 365-379	Operation of vehicles, including weight limits for interstate transportation
49 CFR Part 658	Federal vehicle weight limitations on interstate highways

- 5.3.2.1 Risk Assessment, Product Delivery

  "Risk assessment associated with product delivery shall include:
  a) facility/equipment availability including maintenance"

  Requirements for regulatorily required maintenance would apply. While traditionally handling and lifting equipment would typically fall under the auspices of an organization's health and safety department, this type of equipment can easily become applicable under the requirements of Q1, clause 5.3.

Equipment Type	**OSHA Regulation, 29 CFR 1910**
Overhead and Gantry Cranes	1910.179
Forklifts	1910.178
Slings	1910.184

ii) Specified legal, statutory and regulatory requirements identified in API Agreements (see paragraph III, 2) Acknowledging the American Petroleum Institute (API) as an Interested Party

iii) Product Used Offshore in the US Outer Continental Shelf Exploration and Production Activities (see paragraph IV, same title)

iv) The Importance of Integrating Health, Safety, and Environmental Statutory and Regulatory Requirements (see paragraph V**,** same title)

d) Communication

Both Q1 and ISO 9001 have a similar requirement but are worded differently.

Q1	4.1.5.1	Communication, Internal	The organization shall establish internal communication processes. The processes shall include communicating at relevant levels and functions within the organization: a) the importance of satisfying customer, **legal**, and other applicable requirements
ISO 9001	5.1.2	Leadership, Customer Focus	Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable **statutory and regulatory** requirements are determined, understood and consistently met

e) Determining the requirements related to products and services

Both Q1 and ISO 9001 have a similar requirement but are worded differently.

Q1	5.1.2	Contract Review, Determination of Requirements	The organization shall determine: b) **legal** and other applicable requirements
ISO 9001	8.2.2	Determining the requirements related to products and services	When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable **statutory and regulatory** requirements

f) Design Inputs

Both Q1 and ISO 9001 have a similar requirement but are worded differently.

Q1	5.4.3	Design Inputs	Inputs shall include functional and technical requirements, and the following, as applicable: f) **legal** requirements g) consequences of potential product failure, when required by **legal** requirements, industry standards, customers, or deemed necessary by the organization
ISO 9001	8.3.3	Design and development inputs	The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: c) **statutory and regulatory** requirements

g) Purchasing Control

Q1 discusses legal requirements as they apply to “customer-specified suppliers and suppliers limited by proprietary, and/or legal requirements when clause 5.5.1.3 applies.”

Q1 **does not** address the ISO 9001 requirement: “The potential impact of the externally provided processes, products, and services on the organization’s ability to consistently meet customer and applicable statutory and regulatory requirements.”

Neither Q1 nor ISO 9001disusses the need to specify purchasing requirements if statutory and/or regulatory requirements apply to supply-chain product, processes, or activities.

Q1	5.5.1.1	Purchasing Control, Procedure	g) identification of customer specified suppliers and suppliers limited by proprietary, and/or **legal** requirements when 5.5.1.3 applies
Q1	5.5.1.6	Purchasing Control, Records	Records of identification of approved suppliers, customer specified suppliers, and suppliers limited by proprietary, and/or **legal** requirements shall be maintained (see 4.5)
ISO 9001	8.4.2	Control of externally provided processes, products and	The organization shall: c) take into consideration:

		services, Type and extent of control	1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable **statutory and regulatory** requirements

h) Planning

Q1 discusses planning for the control of the "product realization process" addressed in clause 5.6.

However, ISO 9001 **does not** address statutory and regulatory requirements applicable to clause 8.1 Operational Planning and Control.

Q1	5.2	Planning	The organization shall identify and plan the processes and documents needed for product realization. In planning, the organization shall address the following: c) **legal** and other applicable requirements

i) Post-Delivery Activities

ISO 9001 addresses statutory and regulatory requirements related to post-delivery activities; however, Q1 does not.

ISO 9001	8.5.5	Post-delivery activities	In determining the extent of post-delivery activities that are required, the organization shall consider: a) **statutory and regulatory** requirements

j) Management Review

Q1 addresses statutory and regulatory requirements in the management review process; however, ISO 9001 **does not**.

Q1	6.5.2	Management Review, Input Requirements	The input to management review shall include, as a minimum: c) changes that could affect the quality management system, including: 1) changes to **legal** and other applicable requirements (such as industry standards)

k) Management review

Q1 addresses records as they relate to statutory and regulatory requirements; however, ISO 9001 **does not**.

Q1	4.5	Control of Records	Records shall be retained for a minimum of 10 years or as required by customer, **legal**, and other applicable requirements, whichever is longer

Table 3, Q1, 10th Edition Citations for "Legal"

#	Clause	Title	Citing
1.	3.1.4	Compliance	Act of satisfying (verb) or the status of having satisfied (noun) legal requirements
2.	3.1.11	legal requirement	Statutory or regulatory requirements
3.	4.1.4.2	Exclusions	Excluded activities shall not affect the organization's ability, or responsibility, to provide product that satisfies customer and **legal requirements**
4.	4.1.5.1	Communication, Internal	The organization shall establish internal communication processes. The processes shall include communicating at relevant levels and functions within the organization: a) the importance of satisfying customer, **legal**, and other applicable requirements
5.	4.4.1	Documentation Requirements, General	The quality management system documentation shall include:: c) identification of **legal** and other applicable requirements to which the organization claims **compliance** that are needed to achieve product conformity
6.	4.5	Control of Records	Records shall be retained for a minimum of ten years or as required by customer, **legal**, and other applicable requirements, whichever is longer
7.	5.1.2	Contract Review, Determination of Requirements	The organization shall determine: b) **legal** and other applicable requirements
8.	5.2	Planning	The organization shall identify and plan the processes and documents needed for product realization. In planning, the organization shall address the following: c) **legal** and other applicable requirements
9.	5.4.3	Design Inputs	Inputs shall include functional and technical requirements, and the following, as applicable: f) **legal** requirements g) consequences of potential product failure, when required by **legal** requirements, industry standards, customers, or deemed necessary by the organization
10.	5.5.1.1	Purchasing Control, Procedure	g) identification of customer specified suppliers and suppliers limited by proprietary, and/or **legal** requirements when 5.5.1.3 applies
11.	5.5.1.6	Purchasing Control, Records	Records of identification of approved suppliers, customer-specified suppliers, and suppliers limited by proprietary, and/or **legal** requirements shall be maintained (see 4.5)
12.	6.5.2	Management Review, Input Requirements	The input to management review shall include, as a minimum: c) changes that could affect the quality management system, including: 1) changes to **legal** and other applicable requirements (such as industry standards)

Table 4, ISO 9001:2015 Citations for "Statutory and Regulatory"

#	Clause	Title	Citing
1.	0.1	Introduction, General	The potential benefits to an organization of implementing a quality management system based on this International Standard are: a) the ability to consistently provide products and services that meet customer and applicable **statutory and regulatory** requirements
2.	1	Scope	This International Standard specifies requirements for a quality management system when an organization: a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable **statutory and regulatory** requirements, and b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable **statutory and regulatory** requirements. Note 2: Statutory and regulatory requirements can be expressed as **legal** requirements.
3.	4.1	Understanding the organization and its context	The organization shall monitor and review information about these external and internal issues. Note 2: Understanding the external context can be facilitated by considering issues arising from **legal**, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.
4.	4.2	Understanding the needs and expectations of interested parties	Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable **statutory and regulatory** requirements
5.	5.1.2	Customer Focus	Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable **statutory and regulatory** requirements are determined, understood and consistently met
6.	8.2.2	Determining the requirements related to products and services	When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable **statutory and regulatory** requirements
7.	8.2.3.1	Review of requirements related to products and services	The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include: d) **statutory and regulatory** requirements applicable to the products and services
8.	8.3.3	Design and development inputs	The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: c) **statutory and regulatory** requirements
9.	8.4.2	Control of externally provided processes, products and services, Type and extent of control	The organization shall: c) take into consideration: 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable **statutory and regulatory** requirements
10.	8.5.5	Post-delivery activities	In determining the extent of post-delivery activities that are required, the organization shall consider: a) **statutory and regulatory** requirements

VII Conclusion

The task of navigating statutory and regulatory requirements could be challenging. Q1 and ISO 9001 have slightly different approaches.

a) Q1's approach:

   i) Frames statutory and regulatory requirements under the term "legal" and emphasizes that an organization claiming **compliance** must ensure product conformity.

   ii) Since API is an interested party, users of Q1 must consider "legal" requirements specified by API Agreements (e.g., trade sanctions), which could be viewed as part of product conformity, especially if they involve the delivery of a product to a banned international location.

b) ISO 9001's approach:

   i) ISO 9001 identifies statutory and regulatory requirements in a broader sense, allowing organizations to assess their applicability within the context of their operations.

While not explicitly required, it would be beneficial for both Q1 and ISO 9001 to address the potential need for integrating health, safety, and environmental statutory and regulatory requirements as they relate to products, process controls, and activities.

There are differences between Q1 and ISO 9001, but they are not mutually exclusive. Compliance with statutory and regulatory requirements are strengthened when the requirements of both are integrated into the same Quality Management System.

Bud Weightman is Exemplar Global's longest-serving lead auditor, with more than 40 years of international experience. He is the founder and president of Qualified Specialists International (QSI), established in 1989. Throughout his career, Bud has consulted, trained, audited, and presented in more than 30 countries. He has extensive expertise in regulated industries, including oil and gas, US nuclear power, and military demilitarization facilities, as well as a broad range of business sectors such as manufacturing, fabrication, distribution, steel mills, oilwell cement production, laboratories, construction, equipment repair and refurbishment, oilfield services, drilling operations, equipment failure investigations, rig nonproductive time, supply chain management, and project execution.

Footnotes

American Petroleum Institute, 200 Massachusetts Avenue, NW, Suite 1100, Washington, DC 20001-5571, USA

- API Spec Q1, 9th Edition, Addendum 2, Errata 3, Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry
- API Spec Q1, 10th Edition, Addendum 1, Errata 1, 2 & 3, Quality Management System Requirements for Organizations Providing Products for the Petroleum and Natural Gas Industry

ISO, 1 ch. de la Voie-Creuse, P.O. Box 56 ; Postal Code. CH-1211, Geneva 20, Switzerland

- ISO 9000:201, 4th Edition, Quality management systems – Fundamentals and vocabulary
- ISO 9001:2015, 5th Edition, Amendment 1 (2024-02, Quality management systems – Requirements

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