Doc	Edition	Section	Question	Answer
Q1	9th	1	Background: API Spec Q1, Section 1 indicates that the requirements of API Spec Q1, apply to organizations that "… manufacture products or provide manufacturing-related processes…". An organization conducts repair and remanufacture of drilling and hoisting equipment in a shop environment. The scope of the QMS is defined as "Repair of Well Servicing, Drilling and Production Hoisting Equipment" and the repair and remanufacture activities offered are considered services. The activities performed include inspection and evaluation of the equipment returned from customers; identification of required repairs; and, the welding, fabrication, painting and other process required to complete the repairs. Question: Does API Spec Q1, and the requirements contained within API Spec Q1, apply to service-supply organizations that only offer shop repair services for drilling and hoisting equipment and do not manufacture original or new equipment?	Yes.

Q1	9th	3.1.6 / 5.6.1.1	In a recent API Q1 audit, my auditor interpreted API Spec Q1, Section 3.1.6 to mean that the distributor supplying plastic shrink wrap material is a critical supplier (thus needing a QMS compliant to ISO-9001). He based this on the fact that API-5CRA requires the shrink wrap to be 0.008" thick (see section 14.3.1). Although we specified the thickness on our PO and the vendor certified the thickness on his shipping papers, because he was not on our Approved Vendor List as a critical vendor and audited as having a quality system compliant to ISO, this was considered a finding in the audit. My question is, "Is this consistent with the committee's intention?" Because the shrink wrap is more of a commodity item, and was certified as compliant, and has never contributed to a non-conformance; I would have never classified this vendor as critical. Instead, based on a panel of experts in supply management our resources are best focused on the critical few suppliers that impact our quality such as raw material vendors, test houses, outsourcing heat treat, etc. and not the trivial many like a shrink wrap supplier.	No. API Spec Q1 does not specify that an auditor makes the determination of product criticality. API Spec Q1, Section 5.6.1.1.a states, in part, that the ***[Organization's] procedure*** shall address determination of the criticality of activities or products. Subsequently, the organization would be responsible for ensuring that that procedure is effectively implemented; and, the auditor would be responsible for auditing the level of conformity to the organization's implementation of its established procedure.
Q1	9th	3.1.21	Question: Is product maintenance, adjustment, repair, and/or on-site installation considered to be servicing only when installation is required by applicable product specifications?	No. The term "applicable product specification" applies only to installation....in the phrase on-site installation when installation is required by applicable product specification. Clause 5.7.1.2a specifies servicing to include review and implementation of the organization's, customer-specific, product servicing, and other servicing requirements. Therefore, servicing may be applicable as mandated by company procedure, contract or a third party, as well.
Q1	9th	4.4	Question: When API product or other external specification requirements, including addenda, errata and updates are used in the design or manufacture of product, the organization shall maintain a documented procedure for the integration of these requirements into the product realization process and any other affected processes. When we use external specification (ex: ASTM, ASME, etc.) as working method reference in our procedure, do we need to always updated (use latest one)?	No. API Q1, Section 4.4.3 states, "Documents of external origin shall be controlled to ensure that the relevant versions are used and maintained". NOTE: Use of a specific edition of an external or reference document can be based on contractual obligations or API/industry product specifications.

Q1	9th	4.4	Question: When our procedure use external document not update (2 year back before new one) and the latest revision has no negative impact changes to our procedure, does it violate clause 4.4.4?	No. NOTE: Participation in certification or licensing programs may require use of current or the most up-to-date reference documents. Check program rules for specific requirements for relevance of the specific document editions.
Q1	9th	4.4	Question: Has API set year limitation for updates external specification?	This is not a requirement that is addressed by API Spec Q1. Required updates to external specifications may be stipulated by customer requirements or by requirements identified in 3rd party certification or licensing programs.
Q1	9th	4.4.4	Background: API Q1 in Section 4.4.4 requires "When API product or other external specification requirements, including addenda, errata, and updates, are used in the design or manufacture of the product, the organization shall maintain a documented procedure for the integration of these requirements into the product realization process and any other affected processes' and Section 6.2.2.1 requires "The organization shall identify the audit criteria, scope, frequency, and methods to ensure that all processes of the quality management system claiming conformity to the requirements of this specification are audited at least every 12 months." Question: Is this to be interpreted that companies with Monograms must include the applicable Product Spec as part of their Internal Audits?	This question cannot be answered. Spec Q1 does not address monogram requirements**.** However, to the extent that the product realization process includes product specification requirements that may be applicable to the monogram program, these requirements must be included in the internal audit
Q1	9th	5.1.2b	Question: We have numerous proprietary license agreements/contracts as well as API monogram licenses. As these are mandated legal requirements for the product (s), is this acceptable evidence to fulfill the requirements of 5.1.2.b?	Yes. But per the definition of legal requirements (3.1.13, Obligation imposed on an organization, including those that are statutory or regulatory), the examples provided may only be part of a larger list of documents that are required to meet this clause.

Q1	9th	5.7.1.5	Question: Purchased materials – When materials such as forgings and wrought materials are purchased from steel manufacturers (who perform the heat treatment and in some cases NDT), is it a requirement of API Spec Q1, 9th Edition, Section 5.7.1.5 for the licensee to also validate the steel manufacturer's process controls for processes requiring validation?	No. Based on the information provided, this is a purchase issue and therefore all that is required is verification of that the product meets the contract requirements on receipt (5.6.3). Outsourcing (5.6.1.6) and validation (5.7.1.5) do not apply since the product requirements do not expect that the organization perform the forging activity itself, but simply to use forged product. Therefore, by extension, validation of those processes such as forging does not apply. Note however, that validation of a supplier's processes is likely to be required in two cases: a) When this is included in the process of the initial qualification of a critical supplier per 5.6.1.2 and for reevaluation (optionally) per 5.6.1.4; or b) When the activity does become one of outsourcing (Section 5.6.1.6), i.e. the supplier is performing the activity on behalf of the organization when such an activity is required by the product spec or other obligation (contract).
Q1	9th	5.7.1.5	Background: A pipe mill was audited recently and the mill was making API 2B pipes and API 5L pipes and monogramming those pipes. During verification of validation of processes, as per 5.7.1.5 of API Q1, Ninth edition, Nondestructive testing (NDT) processes were taken for sampling. Documented procedure for validating the current NDT procedures was requested. The Organization demonstrated by showing the current NDT procedures. Current NDT procedures did not comply with requirements for validating the NDT procedures. The current NDT procedures comply with Annexure E and Annexure K of API 5L 45th edition. But there is no evidence to demonstrate these current procedures comply with 5.7.1.5 requirements for validating those procedures. Question: Is it the intention of Q1 satisfied by demonstrating the current NDT procedures as an evidence for 5.7.1.5?	Yes, but only when the applicable [product] specification does not explicitly identify the NDT process as one that requires validation. NOTE Based on the limited information provided in the background, validation of NDT procedures (for conformance to API Q1, 5.7.1.5) may not be applicable to API 5L since this document does identify processes requiring validation (see API 5L, Section 8.2) and NDT is not listed therein. However, the validation of NDT processes and evidence of conformance to API Q1 DOES apply for API 2B manufactured product since this document does not specifically identify the processes requiring validation. Therefore, the list of processes needing validation identified in API Q1 does apply, including NDT. The requirements of one specification (5L) cannot be applied to another specification (2B), unless the latter specifies the requirements normatively (2B does not reference 5L for performance of NDT).

Q1	9th	5.7.6	Question: In clause 5.7.6, does the definition of product include finished product only (which is in our case is pipe); or include equipment used to produce finished product (pipe), such as spare parts to be used for maintenance of equipment?	Yes (only to the first part of the question). In this case, product preservation (per API Q1, 5.7.6) would impact only the item being made and applicable constituent parts under the specification. It does not include the equipment used in making the equipment. Such equipment would be covered under API Q1, 5.7.8 and 5.8, as applicable.
Q1	9th	5.7.7.3	Background: While performing an Audit on a facility that is transitioning to the 9th edition, they use a machinist to do in-process inspection of their own work which is acceptable under Clause 5.7.7.2 (*In-process Inspection and Testing*). These finished components can be sold to a customer on a PO and there was no definition of "finished product" in API Q1 9th edition. Queston: If "finished product" is whatever is listed on the Purchase order, can a company meet Clause 5.7.7.3 Final Inspection and Testing requirement "Personnel other than those who performed or directly supervised the production of the product shall perform final acceptance inspection at planned stages of the product realization process" simply by just having an Inspector review the dimensional inspection report of the Machinist (who inspected his own work) and then sign off the product as cleared to stock?	No. Final acceptance inspection (Spec Q1, Section 3.1.2, Demonstration through monitoring or measurement that the product conforms to specified requirements) must be performed by someone other than the person who performed a given activity. A review of in-process inspection reports may provide verification of the work that was performed. However, it does not meet the intent of performing the actual final acceptance inspection by someone not directly involved in the manufacture of the product.

Q1	9th	5.7.7.3	Background: In most of our facilities, the Testing & Assembly departments are combined and the assembler performs the actual testing of the product. Test results are documented by the tester to demonstrate compliance with the quality plan and/or documented procedures. A qualified individual other than the one who assembled and tested the product or directly supervised the assembly and testing of the product performs the final acceptance inspection based on monitoring and review of the testing documentation. Question: The second paragraph of API Specification Q1, 9th Edition clause 5.7.7.3 establishes requirements for personnel who perform final acceptance inspection. Is it the intent of this paragraph to also establish requirements for personnel who perform testing of product?	No.
Q1	9th	5.7.7.3	Question: One of our facilities is considering deploying a true cell manufacturing concept where there will be a cell leader responsible for all product realization processes for the manufacturing cell. In this concept, the inspectors who perform final acceptance inspection of the parts manufactured in the cell report to the cell leader but are independent of the machinists manufacturing the parts. The cell leader is clearly held accountable for all product realization processes for the cell as if it was a separate manufacturing entity. Is it a requirement of Clause 5.7.7.3 for personnel performing final acceptance inspection to report independently from production supervision?	No. API Q1 only requires that the final inspection be performed by someone independent of the manufacturing of the product that is to be inspected but does not address how that person fits into the organization's reporting structure or organizational hierarchy.
Q1	9th	5.11.2d	Question: Do I need an MOC, if I am rewriting parts of a procedure, introducing new verb-age, in house? No customer involvement. Basically for instance if I want to change from cleaning a unit with hoses in the yard to remove the hoses before cleaning, this requires an MOC?	Yes. Per the organization's procedure for control of the MOC process, when the proposed change may produce a negative impact on the product (API Q1, 5.11.2). and No. When the proposed change has little negative impact on the product.

Q1	9th	6.2.2	Internal Audits – We have been asked in recent audits for evidence that our internal audits have covered the API Product Specs for which we have a license. Section 6.2.2 details the requirements for the internal audits of the Quality Management System, but does not discuss the auditing of the API Product Specification requirements as a requirement. Section 6.2.3 does address process evaluations and product compliance, but has a note that indicates the performance of an internal audit and management review satisfies the requirement. When QMS audits are conducted for the Product Realization Processes, the products requirements are reviewed and the degree of compliance is used as the basis for determining compliance level during the audits. Question: Based on the language of 6.2.2, is it a requirement of API Specification Q1, 9th Edition for the user organization to conduct documented audits against the product specification requirements?	No. A separate internal audit specifically against the product specification is not required by any clause in 6.2.2. However, the organization is expected to provide objective evidence that the product requirements have been audited internally. This may include evidence of product requirements being included and maintained in applicable internal procedures that were a part of the internal audit (see NOTE in 6.2.2.2).
Q1	9th	6.2.2	Question: Is it required to use a documented checklist in the performance of the Internal Audit?	No.
Q1	9th	6.2.2.1	Background: Section 6.2.2.1 – Internal Audits. An outsourced activity performed at our facility is monitored during performance of the activity by an employee. The documentation required and presented has all associated information to validate the activity performed. This documentation is reviewed as a part of the internal audit. (Example: annual calibration of immovable equipment.) 6.2.2.1 General, states: “Outsourced activities that impact the quality of the product and that are performed at the organization’s facility shall be included as part of the internal audit of the organization.” Question: Does this statement mean that all outsourced activities that impact product quality must be scheduled to coincide with the facilities internal audit in order to comply with 6.2.2.1?	No. All elements of the management systems do not need to be audited at the same time or in one consolidated audit. All outsourced activities housed and performed on-site must be included in the internal audit process, but internal audits may be performed at any time within a defined 12-month period and in any manner deemed acceptable by the organization to meet the audit requirements specified by 6.2.2.

Q1	9th	6.2.2.1 / 6.5.1	Background: Clause 6.2.2.1 - The organization shall identify the audit criteria, scope, frequency, and methods to ensure that all processes of the quality management system claiming conformity to the requirements of this specification are audited at least every 12 months. Clause 6.5.1 The organization's quality management system shall be reviewed at least every 12 months by the organization's management … To meet requirements of Clause 6.2.2.1 and 6.5.1 the organization conducts 1 internal audit at each facility in a particular month and 1 Management Review in March every year, respectively. For example, a company conducts Management Review on March 11 in 2015, and in 2016 plans to conduct the Management Review on March 18. Question: Does an audit or management review conducted the same month each year meet the requirements of clause 6.2.2.1 and clause 6.5.1 of API Specification Q1 Ninth Edition?	Yes.
Q1	9th	6.2.2.2	Background: API Q1 in Section 6.2.2.2 requires "Audits shall be performed by competent personnel (see 4.3.2.2) independent of those who performed or directly supervised the activity being audited to ensure objectivity and impartiality of the audit process" and Section 4.3.2.2 requires "Personnel shall be competent based on the appropriate education, training, skills, and experience needed to meet product and customer requirements." Question: Does this mean that Internal Auditors records need to state Auditor API Q1 competency?	No. The specific requirements for competency are established by the user of the document.