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25 March 2016

TO: APIQR Registered Organizations
APIQR Applicants

RE: APIQR ISO 9001:2015/ISO 14001:2015 TRANSITION PROCESS UPDATE

As of 11 March 2016, APIQR has been transitioned by ANAB (ANSI-ASQ National Accreditation Board), our accreditation body for ISO 9001 and ISO 14001 registrations. This means that APIQR can now audit and grant certificates to the 2015 edition of the two standards.

As you may recall from our previous letter of 5 November 2015, the transition plan has two important dates that your organization must consider:

1. All audits scheduled on or after September 1, 2016 shall be conducted to the requirements of ISO 9001:2015.
2. All applications for ISO 9001/ISO 14001 registrations shall be for the 2015 editions starting May 1, 2016.

Since the last communication, APIQR has received numerous questions regarding the transition process and requirements. These questions are listed with answers in the attached Frequently Asked Questions (FAQs) file. Please continue to forward your questions that are not on the list to certification@api.org so they can be answered and added to the list.

One of the questions that is most often asked pertains to how API is supporting organizations to meet the requirements of the new standards. To identify support activities needed by registered or applicant organizations, for example, training, API is requesting your participation in a quick survey that can be accessed using the link: <https://www.surveymonkey.com/r/API-ISO-Survey>. If the link does not work, please cut and paste the URL address in your browser. Any feedback that you can provide in the survey will be greatly appreciated. Your input will help us tailor our support to our client needs.

Please contact certification@api.org if you have questions or need further information.

Very Respectfully,

CHRISTOPHER J. KINNAN
Program Manager, Monogram/APIQR

FAQs regarding transition to ISO 9001:2015 and ISO 14001:2015

(Information provided herein will be updated as necessary. Questions will be added and answered as API receives them.)

Updated as of 25 March 2016

1. ISO 9001:2015/ISO 14001:2015 were published on September 15, 2015 and organizations are given 3 years to transition, i.e, until September 15, 2018. Why is API starting to audit registered organizations in September 1, 2016?

API is starting to audit against the requirements of ISO 9001:2015/ISO 14001:2015 to ensure that ALL APIQR-registered organizations are transitioned before the deadline of September 15, 2018. The process of transitioning organizations takes time – from the audit, to the review of your audit or responses to nonconformities, to the time that it takes API to make the certification decision. This process, at a minimum, will take 6 months. Additionally, there will be instances where a re-audit may be required. The re-audit follows the same process and may take the same amount of time.

2. Will API provide training on ISO 9001:2015 and ISO 14001:2015?

API is considering developing training on ISO 9001:2015 as a way of supporting your organization to transition. The API subcommittee that is responsible for API Spec Q1 (API SC18) is currently developing a gap analysis that will help facilities prepare for their transition. Additionally, API is surveying its clients to determine interest in some form of API-U training. Please provide API with feedback on what type of training would best meet your organization's need by participating in a quick survey. You can access the survey using this link.

<https://www.surveymonkey.com/r/API-ISO-Survey>

The survey is intended to enable API identify actions to support your organization in meeting the requirements of ISO 9001:2015. Your inputs or feedbacks are highly appreciated.

API will not be providing training on ISO 14001:2015. Your organization may take this training from any 3rd party training provider.

3. *Our surveillance audit is scheduled on June 2016. Will the audit be to the requirements of ISO 9001:2015?*

API will start to audit to the requirements of ISO 9001:2015 on September 1, 2016. Therefore, if your facility's audit is scheduled on June 2016, it will be to the requirements of ISO 9001:2008. However, it is highly recommended that your organization start reviewing the new standard and incorporate the requirements into your management system so you will be ready when API performs the next required audit of your facility after September 1, 2016.

4. *If we decide to transition to the 2015 version, when will API audit us? Is the audit duration longer?*

API requires that all facilities be transitioned to the 2015 versions of the standards by September 15, 2018. In order to facilitate this transition API will start auditing to the requirements of ISO 9001:2015 or ISO 14001:2015 on September 1, 2016. API has established the details of its transition strategy which includes additional audit time, based on the size and complexity of the facility, to cover the new requirements.

5. *Our audit is not due until December 2016. If our organization is not ready to be audited to the requirements of ISO 9001:2015/ISO 14001:2015 by this date, will API audit us against the new requirements?*

Yes, API will audit your organization to the requirements of ISO 9001:2015 and/or ISO 14001:2015.

6. *What if we fail the audit because we have not implemented the new requirements, will we lose our ISO 9001:2008 certification? (In short, will our ISO 9001:2008 registration be suspended?)*

API will review the audit results in determining the status of your existing ISO 9001:2008 certification. If the audit results indicate that your management system is conforming to ISO 9001:2008 but not to the requirements of ISO 9001:2015, your organization will still be certified to ISO 9001:2008. However, you will not be transitioned to ISO 9001:2015 until API has verified that you meet all the requirements in your next audit. API may be

required to perform an additional audit in the event that your next scheduled audit cannot be completed prior to the September 15, 2018 transition deadline.

7. *Is there additional audit cost involved for us to transition to the ISO 9001:2015 and/or ISO 14001:2015?*

Based on the gap analysis performed by API, there new requirements in ISO 9001:2015 that are not in API Spec Q1, 9th edition. To cover these requirements during the audit, API may add time to your normal audit duration. There are no additional costs related to the transition beyond the costs for the audit time.

8. *If we have until 2018 to fully implement and conform to the requirements, why will API be auditing my facility to the ISO 9001 and ISO 14001:2015 requirements beginning on September 1, 2016?*

Note that ISO 9001:2015 and ISO 14001:2015 became effective on September 15, 2015. While organizations are given 3 years to transition, it does not mean that API should only audit to the requirements after the 3-year transition period. As indicated in item #1 above, API is starting to audit on the requirements of ISO 9001:2015/ISO 14001:2015 to ensure that ALL APIQR-registered organizations are transitioned before the deadline of September 15, 2018.

Moreover, API will review the audit results in determining the status of your existing ISO 9001:2008 or ISO 14001:2004 certification. If the audit results indicate that your management system is conforming to ISO 9001:2008 or ISO 14001:2004 but not to the requirements of ISO 9001:2015 or ISO 14001:2015, your organization will still be certified to ISO 9001:2008 or ISO 14001:2004. However, you will not be transitioned to ISO 9001:2015 or ISO 14001:2015 until API has verified that you meet all the requirements in your next audit. API may perform a special audit in case the next scheduled audit is too late for your organization to be transitioned.

9. *Will API provide us information on the comparison of requirements of API Spec Q1, 9th edition and ISO 9001:2015?*

Yes, the API subcommittee that is responsible for API Spec Q1 (API SC18) is currently developing a gap analysis that will help facilities prepare for their transition. However, API cannot commit at this time on when the work will be completed.

It is highly recommended that your organization perform a gap analysis or a comparison of the requirements. This exercise will assist your organization in identifying changes to be made to your management system to conform to the new standards while strengthening your understanding of the requirements.

10. *Does API Spec Q1, 9th edition satisfy the requirements of ISO 9001:2015?*

The 9th edition of API Spec Q1 meets **most** of the requirements of ISO 9001:2015. However, there are subtle differences in the language and how the requirements are written. With respect to the 9th edition of API Spec Q1, ISO 9001:2015 requirements can be classified in three distinct groups as follows:

- Requirement is equivalent to API Spec Q1, 9th ed. in intent and language
- Requirement is equivalent to API Spec Q1, 9th ed. in intent but language is different
- Requirement has no equivalent in API Spec Q1, 9th edition

11. *Does API plan to publish a 10th edition of API Spec Q1 to satisfy all requirements of ISO 9001:2015?*

The API subcommittee on quality has initiated work to revise the current edition of API Spec Q1 to consider the requirements of ISO 9001:2015. However, there is no definite timeframe when this work will be completed.

12. *We are aware that API is starting the process of revising API Spec Q1 to include the ISO 9001:2015 requirements. Many licensees like our organization would prefer to implement one quality update that meets both the next edition (10th) of API Spec Q1 and ISO 9001:2015. Can we wait for API Spec Q1 to be published before we update our quality management system?*

As noted in item #11 above, there is no definite timeframe when the work to revise API Spec Q1 will be completed. The deadline to transition all ISO 9001:2008 registrations to ISO 9001:2015 has been set (September 15, 2018) by ISO. API's timeline takes into consideration all activities that must be performed to transition your organization's current ISO 9001 registration to the new standard.

API agrees that it is more practical and efficient for your organization to implement changes your quality management system to meet both ISO 9001:2015 and the expected

10th edition of API Spec Q1 at the same time. However, the uncertainty in the date when the latter will be published poses a high risk that your ISO 9001 registration will not be transitioned to the 2015 edition should your organization decide to pursue this option. Note that all ISO 9001:2008 registrations will no longer be valid after September 15, 2018.

- 13. Our company is looking at withdrawing our ISO 9001 registration and wait for the publication of API Spec Q1, 10th edition to make changes to our quality management system. We will re-apply for ISO 9001:2015 registration after API Spec Q1, 10th edition is published. How will this decision impact our current API Spec Q1 registration?***

It will not affect your current API Spec Q1 registration. However, should you decide to apply for ISO 9001:2015 registration later, your organization will be required to undergo a registration audit consisting of a stage 1 and stage 2 audit before you will be granted certification to ISO 9001. This audit is required regardless of where your API Spec Q1 registration is in the three-year certification cycle and can be performed in conjunction with your annual surveillance or recertification audit for API Spec Q1.