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Monogram Program™ / APIQR™

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June 16, 2020

TO: Monogram Program Participants

FROM: Monogram/APIQR Program

RE: Performing Monogram Audits Remotely Due to COVID-19

Dear Monogram Program Participant,

The API Monogram/APIQR Program has successfully conducted remote audits for APIQR Registered clients (e.g. API Spec Q1, API Spec Q2) in response to the disruptions caused by COVID-19. Based on this success and in consultation with the Monogram Program Board, API will expand the pool of eligible audits to facilities that hold Monogram Licenses. Please note that Monogram/APIQR cannot offer the remote audit option in regions where COVID-19 is not considered a threat.

Audits eligible for the remote audit option must be performed prior to December 31, 2020. The audits covered are Surveillance, Renewal, Recertification, Re-audits and Change Audits. Additionally, facilities with an existing Monogram License(s) are eligible to apply for an APIQR Certificate of Registration(s) (e.g. API Spec Q1, API Spec Q2, ISO 9001). In this scenario, an audit to add a registration may be conducted through the remote audit option.

During the planning phases of your upcoming audit, the API auditor will discuss the remote audit option with your facility to ensure eligibility. If an on-site audit of your facility is not possible due to COVID-19 and the auditor determines that a remote audit can be effective, your facility's audit can be conducted remotely.

Organizations eligible to have their upcoming audit conducted remotely shall:
- Be operational while maintaining the capability to execute the activities within the scope of their Monogram License(s) and/or Certificate(s) of Registration,
- Have personnel subject to interviews on-site to facilitate connectivity and access to documents and records,
- Provide live streaming of product realization activities,
- Ensure that all employees, contractors, and consultants who could be present during the audit have consented to participation in the video conference, and
- Facilitate web-conferencing technology such as Skype, Microsoft Teams, Zoom Meetings, GoTo Meeting, etc.

As always, our client's confidentiality is paramount, and auditors will not require you to email documents and/or records since this information will be shared through web-conferencing

technology. However, the assigned auditor may require an electronic copy of the Quality Manual as part of the audit planning stage.

API fully acknowledges that this alternative may create challenges, but considering the global impact of COVID-19, it is necessary to protect the health and safety of your personnel and our contracted auditors as well as maintain your certification.

Please contact us at audits@api.org with any questions about this communication.

Best Regards,

Sharon Bowie
Manager, Monogram/APIQR
SB:hh