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Monogram Program™/APIQR™

API
Monogram/APIQR
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api.org/ContactMonogram

February 3, 2021

TO: API Monogram/APIQR Participants
         API Auditors

FROM: API Monogram/APIQR Programs

RE: API Monogram/APIQR program audits: COVID-19 update

Due to the ongoing Covid-19 pandemic, API is continuing to evaluate its processes for audits conducted in the Monogram/APIQR Program. This notification describes changes that are effective immediately.

1. Off-site (remote) audits are now approved until June 30, 2021 for eligible facilities. Eligibility requirements include the following:
    a. The client must be operational and have the capability to execute the activities under the scope of their Monogram License and/or Certificate of Registration.
    b. The client must have personnel on-site to participate in interviews and to facilitate connectivity and access to documents and records.
    c. The client must agree to and facilitate the use of web-conferencing (e.g., Skype, Microsoft Teams, Zoom, Go-To Meeting, Facetime, WhatsApp, etc.) and other technologies to complete the audit off-site.
    d. The client must provide live streaming during the plant tour and the verification of product realization activities. (The facility must have a person on the floor facilitating the live streaming. Surveillance cameras do not meet this criterion.)
    e. The client must ensure that all employees, contractors, and consultants who could be present during the audit have consented to participation in the video conference.

2. We have received feedback that off-site audits might require more time due to the more difficult logistics associated with teleconferencing technology. As a result, the audit length for audits conducted remotely will be increased by up to a half (0.5) day per auditor assigned to conduct the audit. The increase will be granted at the request of the Lead Auditor.

If you have any questions, please contact us at www.api.org/ContactMonogram.

Your continued support of and participation in the Monogram/APIQR Program are greatly appreciated.

Sincerely,

Kevin Ferrick
Director, Monogram Program/APIQR
KF:kp