To Our Valued Monogram/APIQR Clients,

The following information provides the minimum requirements for responding to audit nonconformities. By sharing this information, we intend to improve customer service by decreasing the amount of time required to resolve your audit findings and reducing the cycle time to licensing and/or registration.

Please provide complete audit responses that address each audit nonconformance identified by the auditor. Your audit will not be reviewed by API until complete responses are received.

1. Your organization's response to each audit nonconformance must have four (4) components: **Correction, Root Cause Analysis, Corrective Action, and Evidence**.

1.1. **Correction**:
    1.1.1. Describe the actions taken to correct the nonconformance.
        (API only accepts completed actions; therefore, your response must be in the past tense.)
    1.1.2. Determine if there are any other occurrences of the nonconformance that exist elsewhere in your QMS, and describe the actions taken to correct them.
    1.1.3. Determine if your organization may have manufactured and/or delivered nonconforming product. If so:
- Describe the actions taken to correct any nonconforming product(s).
- Determine if the Monogram was applied to these product(s). If so, provide an explanation and evidence of Monogram removal.
- Provide evidence of customer notification and customer acknowledgement.

    1.1.4. Provide the date(s) of correction completion/implementation.

1.2. **Root Cause Analysis**:
    1.2.1. Explain the root cause.
- The root cause explains "why" the nonconformity occurred.
- A simple re-wording of the nonconformance statement will not be accepted.
- The root cause is not directed at an individual, but rather explains which gaps in the QMS led to the nonconformance.

    1.2.2. Note that the immediate cause may not be the root cause. If the question "why" can continue to be asked about your response, then the analysis *may* not have determined the root cause of the nonconformance.
    1.2.3. Phrases such as "Oversight", "Human Error", and "Lack of Awareness" will require further root cause analysis and explanation.

1.3. **Corrective Action**:
    1.3.1. Explain all actions taken and controls implemented to address the root cause.
        (API only accepts completed actions; therefore, your response should be in the past tense.)
    1.3.2. Explain how the corrective action has minimized the likelihood of recurrence.
    1.3.3. Explain how your organization evaluated the effectiveness of the corrective action.
    1.3.4. Provide the date(s) of corrective action completion/implementation.

1.4. **Evidence**:
    1.4.1.   For findings classified as Major, evidence of correction and corrective action implementation and completion must be uploaded for review.
    1.4.2.   For findings that involve nonconforming product (see 1.1.3):
- Evidence of removal of the Monogram from product must be uploaded for review.
- Evidence of customer notification and acknowledgement must be uploaded for review.

    1.4.3.   For any finding where supporting evidence has been requested by the reviewing associate, the requested evidence must be uploaded for review.
    1.4.4.   All evidence must include English language annotation or translation.
    1.4.5.   Only upload evidence within each finding that is related to the identified nonconformance.
    1.4.6.   Upload all evidence for each finding prior to selecting "Submit for Review". Failure to do so may cause the audit to be sent to API without all evidences having been uploaded.

➤ **Additional notes for providing audit responses:**
- API only considers "completed" actions acceptable. *__Future__* system revisions, training sessions, reviews, *etc.,* though indicating intent, do not substantiate a completed action.
- You must use myCerts.api.org to submit your organization's audit responses to API. All login information has been emailed to the facility contact(s) listed in myCerts.
- Responses must be provided in the text boxes available in myCerts. API does not accept attachments in lieu of typed answers.
- Ensure detailed descriptions are provided in the response to substantiate the actions taken. The API Associate responsible for the review may request additional evidence of implementation during the review process.
- If training is part of the correction(s) or corrective action(s), your organization must include a detailed description of the training and an evaluation of the training to show it was effective.
- When API has finished reviewing your audit responses, your organization will be notified through the myCerts website of any unresolved findings that must be addressed to complete the audit review process. This may require additional actions, explanations and/or evidence.
- If you have any questions about how to use myCerts, please email myCertsSupport@api.org

We hope you find this information helpful and will use it when responding to audit nonconformities. We thank you for your continued interest in the Monogram/APIQR program.