Inquiries:
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Audit Response Instructions

To Monogram/APIQR Clients,
The following information provides the minimum requirements for responding to audit nonconformances. By sharing this information, our intention is to reduce the amount of time required to resolve audit nonconformance(s) and shorten licensing and/or registration cycle times.

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

1. An 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 and provide the date(s) of completion/implementation.
(API only accepts completed actions; therefore, your response must be in the past tense.)

1.1.2. Determine if the facility manufactured and/or delivered nonconforming product as a result of the nonconformance. If yes:

- Describe the actions taken on nonconforming product(s) (both in stock and shipped).
- Determine if the facility applied the Monogram to these product(s). If yes, provide evidence that the Monogram has been removed. If removal of the Monogram is not possible, please explain why this is the case.
- If the facility determines that it shipped nonconforming product(s), provide evidence that customers have been notified of the situation.

(Note: Facilities should take proactive steps to determine whether there are any other occurrences of the nonconformance that exist elsewhere in their QMS. Please include this information in the response.)

1.2 **Root Cause Analysis**:

1.2.1 Provide results from the root cause analysis performed.

- Explain "why" the nonconformance occurred.
- Ensure that the response is not simply a re-wording of the nonconformance statement.
- Verify that the root cause is not directed at an individual, but rather provides an explanation of the gaps in the QMS that led to the nonconformance.
- For multi-site registrations, explain how all sites were considered in the investigation.

(Note: The immediate cause may not be the root cause. If the question "why" can continue to be asked about a response, then the analysis may not have determined the root cause of the nonconformance.)

1.2.2 Avoid using phrases such as "Oversight", "Human Error", and "Lack of Awareness" as these will require further clarification/explanation.

1.3 **Corrective Action**:

1.3.1 Explain action(s) taken to address the root cause and provide the dates of completion/implementation for the corrective actions.
(API only accepts completed actions; therefore, your response should be in the past tense.)

1.3.2 Explain how each corrective action minimizes the likelihood of recurrence.

1.3.3 For multi-site registrations, identify whether the actions have been implemented at all locations. If not, provide appropriate justification.

1.4 **Evidence:**

1.4.1 For nonconformances classified as Major, upload for review evidence of correction and corrective action completion/implementation.

1.4.2 For nonconformances that involve nonconforming product (see 1.1.2), provide the following uploads for review:

- Evidence of removal of the Monogram from product.
- Evidence of customer notification.

1.4.3 For any nonconformance where supporting evidence has been requested by the reviewing staff, upload the requested evidence for review.

1.4.4 Ensure that all evidence includes English language annotation or translation.

1.4.5 Only upload evidence within each nonconformance that is related to the identified nonconformance.

1.4.6 Upload all evidence for each nonconformance prior to selecting "Submit for Review". Failure to do so will delay the review of the audit.

➢ **Addressing repeat nonconformance(s):**

- Please explain why (root cause) the nonconformance recurred and describe the actions taken to ensure that, in the future, corrective actions will be effective in preventing recurrence.

➢ **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.
- Audit responses to API must be submitted through myCerts.api.org. Responses must be provided in the text boxes available in myCerts. API does not accept attachments in lieu of typed answers.
- Detailed descriptions must be provided in the responses to substantiate the actions taken. The API staff responsible for the review may request additional evidence of implementation during the review process.
- When API has finished reviewing the audit responses, the facility will be notified through the myCerts website of any unresolved nonconformances that must be addressed to complete the audit review process. This may require additional actions, explanations and/or evidence.

The Monogram/APIQR Team hopes this information proves to be helpful, and we thank you for your organization's continued interest in the Monogram/APIQR Program.