

Incident / Corrective Action Plan Form

Internal Audit Findings: Gloves

Incident/Corrective Action Number: 2023-08

Date of Discovery: May 10, 2023

Incident Date(s): May 10, 2023

Section: Seized Drugs

Reported By: Quality Assurance Manager

Classification: Corrective Action

Incident Type: Procedural

Description of Non-Conformity:

During direct observation of the 2023 Internal Audit, it was found that the analyst did not switch gloves between cases. The requirement to change gloves between cases was implemented in the Safety Manual which went into effect in June 2022. During the recent ANAB assessment in early August, it was brought to the attention of the Quality Manager that internal audit findings needed to be addressed as any other nonconformance, regardless of when the nonconformance occurred.

Root Cause Analysis:

The root cause was determined that the implementation of new policy, in addition to the analyst's extensive career, has caused a difficult transition in the habits surrounding PPE.

Level of Non-Conformity: I

Level of Non-Conformity Determination and its Impact on Casework:

Based on a review of the analyst's work product, documentation of the testing supports the conclusions drawn. However, not changing gloves between cases does bring up the issue of cross-contamination. This is a very real concern. Because this was a one-time observation, the nonconformance will be graded at the lowest level. Additional observations will require increased scrutiny.

Preventive Action(s): N/A

Proposed Corrective Action(s):

1. Speak with the analyst regarding the requirement of changing gloves between each case.
2. Have the analyst review the Safety Manual
3. Conduct random observations to determine if the requirement is being met by all Laboratory analyst.

Timeframe for Corrective Action(s): Immediate for first two proposals, three months for third proposal

<u>SOA Uld</u>	<u>Seized Drug</u>	<u>10/11/23</u>
Applicable Analyst / Discipline		Date
<u>Alvin Winters</u>		<u>22 Dec. 2023</u>
Lab Quality Manager		Date
<u>Jack Sanchez</u>		<u>11 Oct 2023</u>
Laboratory Director		Date