

Incident / Corrective Action Plan Form

Unmet AR 7.8.3.1.c).1 Standard, Element b) - Coverage Probability Report Requirement

Incident/Corrective Action Number: 2023-10

Date of Discovery: December 4, 2023

Incident Date(s): November 28, 2023 - December 4, 2023

Section: Toxicology

Reported By: ANAB Lead Assessor

Classification: Corrective Action

Incident Type: Unmet scope of accreditation standard

Description of Non-Conformity: All four cases reviewed by ANAB assessors were found to be lacking the coverage probability in the report per element b) of AR 7.8.3.1.1 standard. This standard is also noted in the Laboratory Operations Guide 21 regarding laboratory reports. This finding was cited as a nonconformance during the assessment for the re-addition of Toxicology to the Laboratory's scope of accreditation.

Accreditation Requirements for Forensic Testing and Calibration (2023)

7.8.3.1.c).1 The measurement uncertainty shall:

b) include the measured quantity value, y , along with the associated expanded uncertainty, U , and the coverage probability;

LOG-21-08 Laboratory Reports

3.4.1.3.3 For Alcohol reports, "Approved Laboratory procedures utilizing dual-column headspace GC-FID were followed to obtain the reported measurement. Unauthorized copies of this report shall not be distributed." Additionally, current Measurement Uncertainty values at the 99% confidence interval $U(k=3)$ shall be indicated. For example, "The measurement uncertainty at $U(k=3)$ has been determined to be 7.1% of the reported value. Thus, approximately 99% of all true values shall be within 7.1% of the reported measurement." Or similar wording.

Root Cause Analysis: Even with the recent addition of the two Toxicologists who had to examine all laboratory standard operating procedures, which include the laboratory operations guides, the main focus was the rebuilding of the Toxicology department to get blood alcohol testing back online. With the burden of rebuilding the Toxicology section, it was simply overlooked when editing the report during the drafting stages.

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Level of Non-Conformity: II

Level of Non-Conformity Determination and its Impact on Casework: The level of non-conformity was determined to be a level II based on the fact that it was found in the case reports reviewed by the ANAB assessors during their assessment. The impact on casework was insignificant as the cases were old proficiency exams and part of a competency - none of the cases were dispersed outside of the laboratory.

Preventive Action(s): N/A

Proposed Corrective Action(s):

1. Add the coverage probability to the report template.
2. Issue amended reports for the four reports that were generated.

Timeframe for Corrective Action(s): two weeks from date of last signature

Melina Henry
Applicable Analyst / Discipline

12/8/2023
Date

Kayla M. Bayle
Applicable Analyst / Discipline

12/8/2023
Date

Ali Wnt
Lab Quality Manager

8 Dec. 2023
Date

Derek Starn
Laboratory Director

07 Dec 23
Date