

Incident / Corrective Action Plan Form

Unmet ISO/IEC 17025:2017 7.8.2.1 Standard – Item Description in Report

Incident/Corrective Action Number: 2023-09

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: Two out of the four cases reviewed by ANAB assessors were found to be lacking the description of the items of evidence in the report per element g) of ISO/IEC 17025:2017 7.8.2.1 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.

ISO/IEC 17025:2017

7.8.2.1 Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

g) a description, unambiguous identification, and, when necessary, the condition of the item;

LOG-21-08 Laboratory Reports

1.3 The report communicates, at a minimum, a description of items received and tested, the results of testing, and conclusions that may contain opinions and interpretations.

3.2 Elements of a Laboratory Report:

3.2.11 Description of the items analyzed

Root Cause Analysis: The reports issued were two previous Collaborative Testing Services proficiency tests that were used for competency testing of the new toxicologists. As they were previous cases, the description was not changed for the items of evidence.

Level of Non-Conformity: II

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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 half of the cases 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 laboratory reports were dispersed outside of the laboratory.

Preventive Action(s): N/A

Proposed Corrective Action(s):

1. Anyone who performs analysis, technical review, and administrative review must re-familiarize themselves with LOG-21-08 Laboratory Reports, which meets the ISO/IEC 17025 7.8.2.1 g) standard.
2. Issue amended reports for the two reports that were generated lacking evidence descriptions.

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

Melina Denny
Applicable Analyst / Discipline

12/8/2023
Date

Rayla M. Bayle
Applicable Analyst / Discipline

12/8/2023
Date

Chin Wuth
Lab Quality Manager

8 Dec. 2023
Date

Derek Sizer
Laboratory Director

07 Dec 2023
Date