



Laboratory Services Division Corrective Action Preventative Action Plan

- 1) **Laboratory Program:** Evidential Breath Alcohol Testing (EBAT)
- 2) **Description of the Issue:**

The Intoxilyzer 9000 instrument (I-9000), SN 90-000381, located at the Weld County Southwest Services Building reported results for 33 individual subject evidential breath-alcohol tests performed (August 30, 2013 – January 21, 2014) which failed the Quality Control (QC) to verify calibration of the instrument. The reported Calibration Check (CAL Check) values in these 33 individual subject tests all fell below the established tolerance target value of 0.090 - 0.110 g/210L. The root cause of the problem was that the EBAT program staff failed to enter the target value of 0.090 - 0.110 g/210L into the I-9000 instrument during the initial certification process. The officers performing the tests also failed to identify the unacceptable CAL Check results during the evidential breath-alcohol test. The established tolerance values entered into the instrument by EBAT program staff during the certification process are designed to stop the test sequence on the I-9000 instrument when the CAL Check (QC) is outside of the target value during a subject test.

- 3) **Root Cause Analysis:**

Who discovered the discrepancy? CMI Inc., and the Evidential Breath Alcohol (EBAT) program staff

How was the discrepancy identified?

On May 9, 2014, during a routine conference call with the I-9000 manufacturer, CMI Inc., staff from the CDPHE EBAT program was informed by CMI Inc. that they had been contacted by a DUI defense attorney in Sterling, CO regarding a subject test conducted on March 8, 2014. This subject's test reported an out-of-range simulator temperature (the Guth 12V500 simulator is a peripheral instrument used to check the calibration of the I-9000 but is not considered a qualifying quality control measure like the CAL Checks). The subject test results were sent to CMI, Inc. on May 8, 2014 by the attorney and then provided to the EBAT program on May 9, 2014.

EBAT program staff conducted a comprehensive review of all Guth 12V500 simulator calibration checks performed on all I-9000 instruments statewide (approximately 48,000 calibration checks of which 12,000 were evidential subject tests) since being placed into service May 1, 2013. Review of the Guth 12V500 simulator calibration checks revealed that two evidential breath-alcohol tests had CAL Check results that fell below the acceptable established tolerance target value of 0.090 - 0.110 g/210L on one specific I-9000 (SN 90-00381), which prompted a more in depth review of not only the Guth 12V500 simulator calibration checks but all of the qualifying QC CAL Checks.

Further review of the QC CAL Checks data identified a total of 33 subject tests which failed the QC CAL Checks with data that fell outside of the established tolerance target value of 0.090 - 0.110 g/210L. All of these tests were performed between August 30, 2013 and January 21, 2014 and isolated only to the one specific I-9000 (SN 90-000381) located at the Weld County Southwest Services Building. The investigation confirmed all other I-9000 instruments were calibrated correctly, thus all results on other instruments were in the acceptable range.

When was the discrepancy discovered? May 9, 2014

How did the discrepancy affect the results?

CDPHE does not endorse the test results from the 33 total tests where the QC CAL Checks did not meet the acceptable established tolerance target value of 0.090 - 0.110 g/210L as specified in the current Board of Health rule (5CCR 1005-2).

4) **Assessment Review:**

History of previous problems (if "Yes" list and describe):

No

Date of last calibration:

I 9000 Serial Number: 90-000318 was last calibrated on April 4, 2014

5) **Analysis Results and Corrective Action(s) Taken:**

What was the immediate fix of the problem?

- The EBAT program immediately performed a review of all QC CAL Checks (approximately 48,000) performed on all I-9000 instruments in Colorado since May 1, 2013 when they were placed into service statewide.
- The EBAT program is currently working with CMI to implement a new version of software into I-9000 that will prevent the error from occurring again. The instrument will abort the entire test sequence if any parameters of the simulator or solution properties are out of tolerance.
- The instrument at the Weld County Southwest Services Building was recertified on April 4, 2014 (as scheduled for routine recertification) by the EBAT program staff and the target value was entered at that time. This has been reviewed and verified.
- Review of current EBAT procedures and policies
- Formal notification to the appropriate legal and law enforcement officials on June 5, 2014.

What preventative action will be imposed to ensure this does not happen again?

- A request was made to the manufacturer for additional simulator performance monitoring to be incorporated into the I-9000 that will prevent subject testing when simulator exceptions are encountered.
- CDPHE EBAT Program staff will conduct weekly Quality Assurance (QA) monitoring of QC CAL Checks to identify and correct problems.

What additional QA measures will be taken to monitor this issue?

- Ongoing QA monitoring of QC CAL Checks to evaluate the effectiveness of the actions taken.

Additional Recommended Corrective Actions:

- Notify the affected law enforcement agencies with the subject name, date of test, officer and case number of subjects' tests impacted.
- Publish the incident information on the EBAT program's website to ensure full disclosure and transparency is maintained.

Who will monitor this issue?

- The EBAT Program Manager, LSD Quality Assurance Manager, and LSD Division Director.

Comment:

- The calibration of the instrument is NOT in question and the instrument's ability to accurately measure alcohol concentration was not affected.
- To remain consistent with laboratory QC best practices, CDPHE does not endorse the test results from the 33 total tests where the calibration checks did not meet the acceptable tolerance of 0.090 g/210L and as specified in the current Board of Health rule (5CCR 1005-2).
- The QC CAL Checks are a quality control measure performed with each subject test. The QC CAL Check does NOT calibrate the instrument; instead, these checks are performed to verify the existing calibration on the instrument.

EBAT Law Enforcement Agencies and Number of Subjects Affected

24 – Colorado State Patrol

1 – Dacono Police Department

4 – Frederick Police Department

2 – Firestone Police Department

2 – Weld County Sheriff's Office

33 – Total affected test results (August 30, 2013 through January 21, 2014)