

Quality Variance Incident Tracking# 17-174

Incident Date: 08/30/2017	Case Numbers:	
Type: Corrective Action Request	Labs: BTP	
QV Submitted: 11/15/2017	Functional Area:	
Submitter: Maier, Bruce	Substantive: Yes	
Phase: Complete	Immediate Action Taken: Investigation Needed	

Incident and Circumstances:

On August 30, 2017, a BAC Technician was presented an evidentiary complete breath document from Draeger instrument ARHC-0009 in preparation for a trial. The document showed the instrument allowed the start of the breath test before the completion of the required 15 minute observation period. BTP management and all primary technicians were notified of the issue as well as the manufacture, Draeger Safety Diagnostics Inc.

Draeger Safety Diagnostics Inc. began troubleshooting the issue and could not replicate the observation time issue.

On November 11, 2017, the original technician reported two other Draeger instruments that produced complete breath test documents that showed breath tests allowed before the end of the 15 minute observation periods. The technician reported the arresting trooper (operating officer) told him on one of the instances he entered the observation time that matched the current time displayed on the instrument, expecting the countdown timer to be displayed. The instrument allowed data entry to continue as if the 15 minute observation time had elapsed. The Trooper stopped the test and re-entered the observation start time, now different than the time displayed on the instrument and the countdown timer appeared with the correct time remaining.

What Policy, Procedures or Requirement is in question:

RCW 46.61.506

Noted in Report? NA

Immediate Actions Taken:

On Aug 30, 2017, BTP management, all primary BAC technicians, and the manufacture, Dreger Safety Diagnostics Inc. were notified. Archived breath test files from the breath test in questioned were sent to Dreger to assist them in their evaluation of the problem.

Dreger Safety Diagnostics Inc. began troubleshooting the issue and could not replicate the observation time issue and had no answer to explain the observation time issue.

On Nov 8, 2017, Dreger Safety Diagnostics Inc. notified of the finding by the technician. They were able to duplicate the described sequence from the arresting trooper operator. Dreger will make a software fix to correct the observation timer problem. The fix will likely be in a new software update for several other functionality changes requested by WSP.

On Nov 15, 2017, BTP searched the breath test data base and compiled a list of 66 complete breath tests that were allowed prior to completion of the required 15 minute observation period. Notification letters will be sent to all prosecutorial jurisdictions with observation time affected breath tests.

On Nov 15, 2017, all BAC technicians notified to immediately post signs at each Dreger instrument location reminding operators to ensure the completion of the 15 minute observation period prior to the first breath test and a warning of the possibility of the instrument to accept all data and a breath test prior to completion of the 15 minutes.

Preventative Action:

All BAC technicians will be notified to instruct operators during refresher and transition training of the discovered flaw with the observation timer and to be aware of it until Draeger completes the software fix and all instruments are updated with it.

Details:

- A Technical procedure error
- B Failed to follow procedure
- C Sample incorrectly prepared
- D Method not clearly defined or misinterpreted
- E Reporting error: complete and accurate information not provided in report
- F Misinterpretation of data or incorrect conclusion
- G Documentation errors
- H Equipment or software malfunctions
- I Missed or failed calibration/quality check
- J Administrative Procedural error
- K Evidence Handling/Security errors
- L Evidence compromised: contamination or loss
- M Typographical or grammatical errors

Root Causes:

Root Cause: BAC operators not paying attention to the required 15 minute observation period

Description:

The Draeger 9510 breath test instruments can allow the start of a breath test before completion of the required 15 minute observation period.

Corrective Actions:

Addresses: BAC operators not paying attention to the required 15 minute observation period

Corrective Action: **Due:** 06/30/2018 **Status:** Complete

Draeger Inc. is currently working on a software fix to not allow the instruments to accept a breath test before completion of the 15 minute observation period and start the countdown clock displayed to the operators if an observation time is entered that is not in the future or more than 15 minutes prior to the entry.

Preventative Action:

All BTP Technicians have posted signs at all Draeger instrument field locations to remind operators to ensure comp

People:

Assignments:

CAP Supervisor	Maier, Bruce
Lab Manager BTP	Sharpe, Robert
Corrective Action Plan	Maier, Bruce
Root Cause Analysis	Maier, Bruce

Approvals:

SAS Review Neilson, Erik R	11/17/2017
CAP Review Neilson, Erik R	11/30/2017
CAP Result Review Neilson, Erik R	02/07/2018

Approval Comment Log:

2/7/2018 7:10:35 AM enei225
CAP Review Approved by: Neilson, Erik R

11/30/2017 10:39:46 AM enei225
CAP Review Approved by: Neilson, Erik R

11/17/2017 6:36:02 AM enei225
QV/Nonconformance Entry Review Approved by: Neilson, Erik R

11/16/2017 5:40:00 PM AR_ESCALATOR
Returned to Awaiting Approval

11/16/2017 9:56:51 AM enei225
QV/Nonconformance Entry Reviewed by: Neilson, Erik R

The ultimate solution requires a software modification from Draeger, which, when completed will close this issue. In the meantime, the technicians have been alerted and are alerting the field operators.

Attachments (see Attachments tab for documents):

- Initial Letter
- Initial Letter
- Initial Letter
- Follow-up Letter
- Adams County notification letter & enclosure
- Bellingham notification letter & enclosure
- Benton County notification letter & enclosure
- Burlington notification letter & enclosure
- East Wenatchee notification letter & enclosure
- Edmonds notification letter & enclosure
- Ellensburg notification letter & enclosure
- Ephrata Dist. Court notification letter & enclosure
- Everett notification letter & enclosure
- Ferry County notification letter & enclosure
- Kennewick notification letter & enclosure
- Longview notification letter & enclosure
- Lynnwood notification letter & enclosure
- Marysville notification letter & enclosure
- Mount Vernon notification letter & enclosure
- Mountlake Terrace notification letter & enclosure
- Pasco notification letter & enclosure
- San Juan County notification letter & enclosure
- Skagit County - Brown notification letter & enclosure
- Skagit County - Ryan notification letter & enclosure
- Snohomish County notification letter & enclosure
- Spokane notification letter & enclosure
- Stevens County notification letter & enclosure
- Toppenish notification letter & enclosure
- Whatcom County notification letter
- Whitman County notification letter & enclosure
- Yakima notification letter & enclosure
- Yakima County notification letter & enclosure
- Corrective Action Report

ASCLD:

11/16/2017	Initial Letter	
11/17/2017	Response from ASCLD	No
11/17/2017	Initial Letter	
11/01/2017	Follow-up Letter	
02/07/2018	Corrective Action Report	