Title: EVALUATION OF THE INTOXILYZER 5000EN SOFTWARE REVISION #'S 1358.XX AND 7522.XX FOR APPROVAL AS AN EVIDENTIAL BREATH ALCOHOL TEST DEVICE

References:
2. Colorado Board of Health Rules and Regulations, Testing for Alcohol and Other Drugs, 5 CCR 1005-2
3. CMI Inc. manufacturer alignment and calibration procedures.
5. Intoxilyzer 5000EN, Model 1768, Evidential Breath Alcohol Test Device Certification Procedure

Method: Evaluation of the accuracy, precision and software functions of the Intoxilyzer 5000EN with software revisions 1358.XX and processor software revision 7522.XX installed.

Principle: Pursuant to Colorado Board of Health Rules and Regulations, Tests for Alcohol and Other Drugs, 5 CCR 1005-2, “Only instruments approved by the CDPH&E, shall be used for evidential direct breath alcohol testing. Approval or disapproval shall be based on laboratory evaluation by the CDPH&E of such instruments’ ability to meet the standards of performance set forth in these regulations and established laboratory instrument evaluation protocol. A proposed change to 5 CCR 1005-2 and the evidential breath alcohol test sequence requires a change in the software package for the Intoxilyzer 5000EN. The software change involves a re-evaluation of the accuracy, precision and software functions of the instrument. CDPH&E staff will evaluate the performance of the instrument with the new software, revision 1358.XX and processor software revision 7522.XX, to ensure compliance with the requirements of 5 CCR 1005-2 and this protocol.

Sample: No samples will be collected during this procedure.

Safety: Read MSDS for reagents used during this procedure for handling and safety precautions. Check glassware for chips and cracks. Observe laboratory safety procedures for operating electronic equipment.
Reagents:

1. 200 proof Ethanol
2. 121 Stock Ethanol Solution
3. Ethanol Solution, 0.000 g/210l BrAC, 0.020 g/210l BrAC, 0.040 g/210l BrAC, 0.080 g/210l BrAC, 0.100 g/210l BrAC, 0.129 g/210l BrAC, 0.160 g/210l BrAC, 0.200 g/210l BrAC and 0.387 g/210l BrAC
4. Acetone + Ethanol Solution
5. Acetaldehyde + Ethanol Solution
6. Toluene + Ethanol Solution
7. Dichloromethane + Ethanol Solution
8. Ethyl Acetate + Ethanol Solution
9. MTBE + Ethanol Solution
10. Diethyl Ether + Ethanol Solution
11. Methanol + Ethanol Solution
12. Isopropanol + Ethanol Solution
13. Tanqueray Sterling Vodka, 80 proof
14. Captain Morgan Spiced Rum, 70 proof
15. Skoal Bandits Straight Smokeless Tobacco
16. Alka Seltzer Anti-Acid Tablets
17. Alka Mints, Spearmint
18. Breath Spray – Sweet Breath
19. Scope Mouthwash
20. Listerine Pocketpaks Oral Care Strips
21. Anbesol, Maximum Strength Oral Pain Reliever
22. ChapStick Lip Balm – Cherry Flavored

Reagent Preparation:
See Preparation of 121 Stock Ethanol Solution Protocol
See instructions in the Procedure section of this Protocol

Equipment:
Intoxilyzer 5000EN
Software Package 1358.XX
Processor Software Package 7522.XX
Printer
Intoxilyzer Stand
Simulator, Guth 2100
Syringe, Graduated in uL
Syringe, Graduated in mL
Mouthpieces

Procedure:
1. Select the Intoxilyzer 5000EN that is to be used for the evaluation.
   a. Record the serial number on the Evaluation Form.
2. Remove the covers from the instrument.

3. Remove the old software from the instrument. Place the software package in a protective container and set aside.

4. Install the new software package in the instrument.
   a. Record the software package revision number(s) on the Evaluation Form.

5. Install covers on the instrument.

6. Turn the instrument “ON” and allow it to proceed through the automated warm up procedure.
   a. Ensure that the warm up period has been extended from 2 minutes to 10 minutes.
   b. Make sure that activating the RESET switch does not allow the 10 minute warm up period to be aborted.

7. Perform the automated calibration procedure.
   a. Ensure that the extra AIR BLANK after the calibration series has been added.
   b. Make sure that this AIR BLANK has been lengthened.

8. Certify the instrument per the Intoxilyzer 5000EN, Model 1768, Evidential Breath Alcohol Test Device Certification procedure.

9. **Software**
   In addition to the software checks performed in Section A of the Intoxilyzer 5000EN, Model 1768, Evidential Breath Alcohol Test Device Certification procedure perform the following software checks.
   a. **Operator Re-certification Option**
      i. Ensure this option has been added to Menu # 1.
      ii. Perform an Operator certification test using this option.
         A. Follow instructions on the instrument display to perform this test.
         B. The test sequence is the same as a standard
b. Calibration Guard for Standard Simulator Solution
   i. 30 Day Lockout
      A. The instrument will not allow a test to be performed beyond 30 days from the date the simulator solution was placed into service.
      B. The instrument gives a warning that 30 days on this solution is approaching every time the START TEST switch is activated.
      C. The warning begins on the 25th day and warns the operator that the instrument will lock out in X number of days.
      D. This warning identifies that it is for the simulator solution.
   ii. 100 Test Lockout
      A. The instrument will not allow more than 100 tests to be performed using this simulator solution.
      B. The instrument gives a warning that 100 tests is approaching every time the START TEST switch is activated.
      C. The warning begins with the 90th test and warns the operator that only X number of tests remain before the instrument will lock out.
      D. This warning identifies that it is for the simulator solution.
   iii. The Calibration Guard resets when a new Simulator Log Sheet is created.

c. First and Second Wet Bath Calibration Check Correlation
   i. Both calibration checks are within 10% of target value.
      A. Error message “NOT IN TOLERANCE”
ii. First and second calibration checks are with 10% of each other.
   A. Error message “CORRELATION ERROR” generated, printed and test aborted.

d. Test Sequence
   i. A C A B A I A (2 MINUTES) A B A C A
   ii. Air Blank, Wet Bath Calibration Check, Air Blank, Breath Test, Air Blank, Internal Standards Check, Air Blank, (2 Minute Wait Period), Air Blank, Breath Test, Air Blank, Wet Bath Calibration Check, Air Blank.
   iii. 2 minute countdown on display between tests.
   iv. 0.020 g alcohol/210IL correlation between the two subject breath tests.
      A. Error message “SUBJECT TEST CORRELATION ERROR” generated, printed and test aborted.
      B. Printout
         a. Subject test information,
         b. Results for all steps,
         c. Print X.XXX in subject test results area
   v. REFUSAL option available for both subject breath tests.

e. Instructor certification window opened from 360 days to 365 days.

f. Simulator Communication
   i. Time for simulator and instrument to communicate lengthened.
   ii. Instrument re-poll simulator within 10 seconds or as soon as possible.
   iii. Loss of connection error message “COMMUNICATION WITH SIMULATOR LOST, ATTEMPTING RE-CONNECTION”

g. Standard Simulator Log Sheet
   i. Letter “L” submenu added to Menu # 1.
10. **Accuracy, Precision and Linearity – Calibration Function**

a. 10 BrAC samples of each of the following levels of alcohol solution will be analyzed using the calibration function of the Intoxilyzer.
   
i. 0.000 g/210L BrAC
ii. 0.020 g/210L BrAC
iii. 0.040 g/210L BrAC
iv. 0.080 g/210L BrAC
v. 0.100 g/210L BrAC
vi. 0.129 g/210L BrAC
vii. 0.160 g/210L BrAC
viii. 0.200 g/210L BrAC
ix. 0.387 g/210L BrAC

b. All 10 BrAC samples must be within ±0.005 or ±5% of the target value, whichever is greater.

c. Precision of the 10 BrAC simulator samples must be within ±0.005 or ±5% whichever is greater.

11. **Accuracy, Precision and Linearity – Breath Function**

a. 10 BrAC samples of each of the following levels of alcohol solution will be analyzed using the breath test function of the Intoxilyzer.
   
i. 0.000 g/210L BrAC
ii. 0.020 g/210L BrAC
iii. 0.040 g/210L BrAC
iv. 0.080 g/210L BrAC
v. 0.100 g/210L BrAC
vi. 0.129 g/210L BrAC
vii. 0.160 g/210L BrAC
viii. 0.200 g/210L BrAC
ix. 0.387 g/210L BrAC

b. All 10 BrAC samples must be within ±0.005 or ±5% of the target value, whichever is greater.
12. **Detection of Mouth Alcohol**

a. 2 subjects will be tested every five minutes after rinsing their mouth with an alcoholic beverage.

b. Testing will continue until three valid tests are obtained.
   i. Prior to the subject rinsing their mouth with an alcoholic beverage a baseline test will be performed.
   ii. The subject will take .5 ounce of an alcoholic beverage into their mouth and swish it around. Hold the beverage in the mouth for 30 seconds and spit it out. DO NOT SWALLOW THE BEVERAGE.
   iii. Immediately provide a breath sample for analysis by the Intoxilyzer and record the time.
   iv. Continue providing breath samples every five minutes until three valid tests are obtained. DO NOT INGEST ANYTHING DURING THIS PERIOD.

c. **OTHER FOREIGN SUBSTANCES THAT MAY CAUSE MOUTH ALCOHOL ERROR MESSAGES.**
   i. Prior to introducing a foreign substance in the mouth the subject will provide a baseline breath sample for analysis by the Intoxilyzer.
   ii. Each of the following substances will be placed in the subject’s mouth for 1 minute or used as directed and then spit out.
      
      A. Skoal Bandits Straight Smokeless Tobacco  
      B. Alka Seltzer Anti-Acid Tablets  
      C. Alka Mints, Spearmint  
      D. Breath Spray – Sweet Breath  
      E. Scope Mouthwash  
      F. Listerine Pocketpaks Oral Care Strips  
      G. Anbesol, Maximum Strength Oral Pain Reliever  
      H. ChapStick Lip Balm – Cherry Flavored  
      I. Big Red Cinnamon Gum  
      J. Halls Cough Drops, Ice Blue  
      K. Jolly Rancher Fire  
      L. Tic Tacs Fresh Mints
iii. Immediately provide a breath sample for analysis by the Intoxilyzer and record the time.

iv. Continue providing breath samples every five minutes until three valid tests are obtained. DO NOT INGEST ANYTHING DURING THIS PERIOD.

13. Detection of Interfering Substances - Breath Function

a. 3ul of each of the following interfering substances and 2ul of ethanol will be injected into a dry simulator at room temperature and blown into the Intoxilyzer for analysis.
   i. Acetone
   ii. Acetaldehyde
   iii. Toluene
   iv. Dichloromethane
   v. Ethyl Acetate
   vi. MTBE
   vii. Diethyl Ether
   viii. Methanol
   ix. Isopropanol

b. Immediately blow the simulator contents into the Intoxilyzer for analysis and record the time.

c. Continue providing samples for analysis every five minutes until three consecutive 0.000 g/210L BrAC results are obtained.

14. Detection of Interfering Substances - Ambient Conditions

a. Each of the following interfering substances will be held next to the Intoxilyzer external breath tube during an AIR BLANK function.
   i. Acetone
   ii. Acetaldehyde
   iii. Toluene
   iv. Dichloromethane
   v. Ethyl Acetate
   vi. MTBE
   vii. Diethyl Ether
   viii. Methanol
   ix. Isopropanol
Interpretation: Successful completion of this evaluation will prove that the changes made to the software of this instrument did not affect the accuracy, precision and linearity of the instrument. It will also show that all of the software changes that were requested were made and operate properly.

Waste Management:

1. It is the laboratory's responsibility to comply with all federal, state, and local regulations governing waste management, particularly the hazardous waste identification rules and land disposal restrictions, and to protect the air, water and land by minimizing and controlling all releases from fume hoods and bench operation. Compliance with all sewage discharge permits and regulations is also required.

2. For further information on waste management consult the “Waste Management Manual for Laboratory Personnel”, available from the American Chemical Society's Department of Government Regulations and Science Policy, 1155 16th Street N.W., Washington D.C.

3. The appropriate disposal procedure for each laboratory chemical solution used in this analysis is summarized in Table 1.

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<tr>
<th>Solution</th>
<th>Disposal Method</th>
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<tr>
<td>Ethanol Solutions</td>
<td>Place in brown nalgene bottles and use in class kits</td>
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<tr>
<td>Interferent + Ethanol Solutions</td>
<td>Dilute with water. Dispose to sanitary sewer.</td>
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<tr>
<td>Excess Samples</td>
<td>Dilute with water. Dispose to sanitary sewer.</td>
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### Revisions:

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#### Approvals

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Supplemental Evaluation on software for Ambient Conditions

Software Version 1358. _____

1. (1.al) Detection – Ambient Conditions .008 first Air Blank

   Baseline Test: _________

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<th>Intoxilyzer Result</th>
<th>Error Message</th>
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2. (1.alII) Detection – Ambient Conditions .015 first Air Blank

   Baseline Test: _________

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3. (1.a.III) Detection – Ambient Conditions .020 first Air Blank

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4. (l.a.IV) Detection – Ambient Conditions .040 first Air Blank

Baseline Test: 

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5. (l.a.V) Detection – Ambient Conditions .008 follow on Air Blank

Baseline Test: 

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6. (1.a.VI) Detection – Ambient Conditions .015 follow on Air Blank

Baseline Test: _________

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7. (1.a.VII) Detection – Ambient Conditions .020 follow on Air Blank

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8. (1.a.VIII) Detection – Ambient Conditions .040 follow on Air Blank

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