#### **Office of Alcohol Testing**

Arkansas Department of Health Public Health Laboratory 201 S. Monroe Little Rock, Arkansas 72205

#### BREATH TESTING STANDARD OPERATING PROCEDURES

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## **OFFICE OF ALCOHOL TESTING**

## BREATH TESTING STANDARD OPERATING PROCEDURES

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## I. General Purpose Statement

The Public Health Laboratory serves the state of Arkansas by providing analytical services, training and education, and leadership in public health practice.

#### Office of Alcohol Testing Profile and History

The Office of Alcohol Testing (OAT), originally named the Division of Blood Alcohol, was established by Act 106 of 1969 as amended. Other pertinent legislation includes Act 246 of 1957 as amended (ACA 5-65-201 through 5-65-207) and Act 518 of 1995 as amended.

Program guidelines were based upon recommendations of the federal government to establish an independent regulatory agency not directly responsible to individuals or agencies of the law enforcement community to apply unbiased regulations with no opportunity for influence from individuals being regulated. To accomplish this, Arkansas, like most of the states, placed this agency in the State Department of Health.

These laws specifically provide that the Arkansas Board of Health is authorized in the following areas:

- adopt appropriate rules to carry out the intent and purpose of the law.
- methods of chemical analysis for blood, urine, or breath are to be approved by the State Board of Health, Arkansas Department of Health.
- individuals (law enforcement personnel) performing such tests are to be determined to be competent and permitted (certified) to do so by the Arkansas Department of Health.
- to limit by its rules the number of types of testing devices which may be approved.
- each evidentiary breath test device is to be certified by the department every three months.

#### <u>Mission</u>

The primary role of the Office of Alcohol Testing is to serve the interest of the public in terms of individual health and the health of the community by reducing drinking and driving incidents. This mission is accomplished by:

- Providing for legally and scientifically sound tests for determining the concentration of alcohol in the human body
- Assisting the law enforcement agencies working to eliminate the problem of the drinking driver
- Guarding the public against false or unfair charges

#### **Laboratory**

Laboratory analysis of blood samples for alcohol originated at ADH in 1970 along with the regulatory program and has become a service which law enforcement and the courts system have come to respect and depend upon. Approximately ninety percent of the samples analyzed are requested by law enforcement agencies. The remaining approximate ten percent of the samples are privately requested by the subject for potential use as defense evidence as allowed by the law. The Office of Alcohol Testing laboratory is the only laboratory in the state that routinely provides this service for forensic purposes for the entire state.

Other activities of the laboratory staff include:

- Performing on-site inspections of certified instruments at law enforcement agencies
- Proficiency testing for certified instruments which includes sample preparation and QC testing
- Analyzing quality control standards subject to approval
- Downloading of breath test data from certified instruments
- Computer monitoring of instrument performance
- Preparation and QC analysis of training samples

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- Reviewing current scientific literature
- Providing expert courtroom testimony relating to analysis of samples and results of inspections for both prosecution and defense
- Performing special research projects
- Evaluating new breath testing equipment
- Evaluating new alcohol testing procedures and protocols
- Breath testing equipment repair/ maintenance

#### **Training**

The Office of Alcohol Testing establishes training standards and training course content for law enforcement personnel for alcohol testing. Law enforcement officers are trained to operate certified breath testing instruments to assure accurate alcohol test results.

#### **Certification/ Administration**

Arkansas law requires that the Arkansas Department of Health provide for the certification of breath testing devices to assure accurate alcohol test results. Necessary components leading to a successful certification program include:

- Establishing requirements and protocol for sample collection and approval of methodology and equipment used for alcohol testing
- Designing technical standards in keeping with current scientific community standards for alcohol testing as well as legal mandates and nationwide trends
- Establishing a method of record keeping and defining records retention
- Ongoing revision of regulations

## II. Rules

The *Arkansas Rules for Alcohol Testing* outlines the requirements for the following functions of the Office of Alcohol Testing: certification, training, sample collection and handling, methods of analysis, and records and reporting.

Please refer to this document (which can be obtained by calling the Office of Alcohol Testing) to find that: The following rules for alcohol testing are duly adopted and promulgated by the Arkansas Department of Health as approved by the Arkansas State Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas, Act 106 of 1969 as amended and Act 346 of 1957 as amended, the same being Arkansas Code, Title 5, Chapter 65, and Act 518 of 1995 as amended.

## **III. SDS/ COA Location**

All SDS (Safety Data Sheet) and COA (Certificate of Analysis) paperwork are kept on file in the OAT Laboratory. SDS can also be found in LIMS (laboratory information management system).

## **IV. Breath Instrument Solution Preparation**

The Office of Alcohol Testing is part of the Public Health Laboratory (PHL). Please refer to the PHL Clinical Quality Assurance Plan and Safety Plan for QA and Safety documents.

## Note: Solutions are to be prepared in the GC Lab only PPE Required: gloves, goggles, and a lab coat

Use only deionized water Label each with solution name Store solutions in cold room Solutions are prepared as needed and do not expire There is no temperature/ storage requirement. Analysis is performed according to the Blood Analysis SOP Preparation, analysis, and supervisor approval to be documented at: \\phlfs\PHL Share\OAT\Documents\New Solution Approval

#### EtOH/Acetone

- 1. Partially fill a 25L carboy with water, add 15ml of acetone and 38.3ml of 200 proof ethanol and dilute to the mark with water.
- 2. Drop in a large magnetic stir bar, secure cap, and mix solution for one hour.
- 3. Solution is to be verified by GC analysis (see the Blood Analysis SOP) and the EC/IR II.
- 4. Once the solution has been approved by the supervisor, the solution can then be transferred to 500ml plastic bottles.

#### .04X EtOH sample

- 1. Partially fill a 25L carboy with water, add 15.3mL of 200 proof ethanol, and dilute to the mark with water.
- 2. Drop in a large magnetic stir bar, secure cap, and mix solution for one hour.
- 3. Solution is to be verified by GC analysis and the EC/IR II.
- 4. Once the solution has been approved by the supervisor, the solution can then be transferred to 500ml plastic bottles.

#### .08X EtOH sample

- 5. Partially fill a 25L carboy with water, add 30.7mL of 200 proof ethanol, and dilute to the mark with water.
- 6. Drop in a large magnetic stir bar, secure cap, and mix solution for one hour.
- 7. Solution is to be verified by GC analysis and the EC/IR II.
- 8. Once the solution has been approved by the supervisor, the solution can then be transferred to 500ml plastic bottles.

#### .15X EtOH sample

- 1. Partially fill a 25L carboy with water, add 57.5mL of 200 proof ethanol, and dilute to the mark with water.
- 2. Drop in a large magnetic stir bar, secure cap, and mix solution for one hour.
- 3. Solution is to be verified by GC analysis and the EC/IR II.
- 4. Once the solution has been approved by the supervisor, the solution can then be transferred to 500ml plastic bottles.

### V. Proficiency Samples

#### a. Simulator Proficiency Samples for Installations

#### i. Scheduling

Proficiency samples are prepared as scheduled by OAT to be mailed to all currently certified installations as indicated on sample group records. Samples are to be mailed the first of the month.

Installations are in four groups (A, B, C, and D), with all groups receiving the same solution concentration. Sample numbers consist of the target concentration followed by the group letter (.15A, .08C etc.). **ii. Preparation** 

#### **EtOH Proficiency Sample:**

- 1. Partially fill a 25L carboy with water, add appropriate amount of 200 proof ethanol (as calculated below), and dilute to the mark with water.
- 2. Drop in a large magnetic stir bar, secure cap, and mix solution for one hour.
- 3. Keep carboy capped during mixing.
- 4. Solution is to be verified by GC analysis and the EC/IR II.
- 5. Once the solution has been approved by the supervisor, the solution can then be transferred to 500ml plastic bottles.

# Notes: Solutions are to be prepared in the GC Lab only PPE Required: gloves, goggles, and a lab coat.

These carboys have been calibrated and labeled for convenience in measurement. Ethanol should be kept in the flammable cabinet in the Food Lab when not in use.

#### iii. Calculations

For each batch, calculate the amount of ethyl alcohol to be added to prepare the appropriate concentration using the following formula:

 $K_A$  = the partition ration of ethanol between water and air at 34°C= 1.21 Density of absolute ethanol= .789 g/mL @ 25°C

<u>desired % x capacity of carboy in ml x  $K_A$  = ml ethyl alcohol to be added</u> 100 x density of absolute ethanol

Information concerning preparation for all solutions is to be filled in the appropriate areas of the Proficiency Prep Analysis workbook in excel on the computer at the time the work is completed.

Desired Concentration	
% w/v	mL of EtOH
.03	11.5
.04	15.3
.05	19.2
.08	30.7
.15	57.5
.16	61.3
.17	65.2
.18	69.0

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#### iv. Quality Control

All quality control testing is to be completed prior to packaging and mailing: refer to the Office of Alcohol Testing Quality Control Chart (found on page 10).

#### v. Analysis

Solutions are to be analyzed using the method outlined in the Blood Analysis SOP.

When analyzing proficiency samples, calibration, and verification standards to be analyzed are:

- .04 CER Standard (in triplicate)
- .10 CER Standard (in triplicate)
- MIX
- .121CS
- Proficiency samples (in triplicate)

MIX is a mixture sample of acetone, iso-propanol, and methanol. There should be no ethanol result for this sample.

Acceptable results must fall within the following limits of the target values:

- a) Averages of .121CS: <u>+</u>.010
- b) Average of proficiency solutions: +.005
- c) Average of CER Standards: <u>+</u>.005

#### vi. Bottling and Storing

When mixing is complete and quality control has been successfully completed, transfer the solution to clean, dry 500 mL plastic bottles. Extra bottles are labeled with the appropriate solution name and are stored in the cold room.

#### vii. Mailing

As each installation is certified, it is assigned to one of four sample groups and listed in the appropriate sample group record (found at \\phlfs\PHL\_share\OAT\Documents\ Proficiency Reports). Prior to mailing samples, check the group list against the Action Log for those instruments that are suspended. A "suspension" indicates no sample is to be sent. From this list, prepare a Proficiency Testing Report form for each installation. Enter the mailing date in the space provided in the memorandum section near the top of the form. In the space marked "Sample Number", enter the appropriate sample code.

Double check names with the proficiency sample group list. Make sure to send multiple forms to installations with multiple instruments. Pack the report form(s) for a particular installation with the sample in the corresponding container.

#### b. Proficiency Samples from External Vendors

OAT participates in breath alcohol proficiency testing through Collaborative Testing Services (CTS) and Airgas.

When the samples are received by lab personnel, the QA office must be notified so that the sample can be entered into the QA proficiency tracking system.

The procedure for the preparation and analysis of the breath alcohol proficiency sample will be provided by the company.

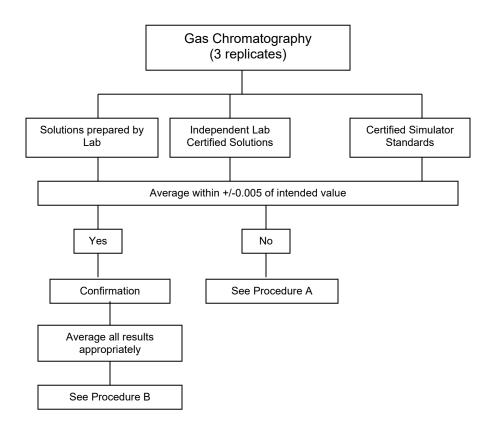
When the analysis has been completed, the results will be submitted to the supervisor, QA office, and lab director for approval. Once approved the results can be submitted.

CTS provides a participant mean/ grand mean result. If the reported results are within +/- .010 of OAT's reported results, the proficiency test will be considered as Satisfactory. If they are outside that then it is considered Unsatisfactory.

Airgas will give a Pass/Fail.

When the results are returned from the company, the supervisor will notify the lab and QA office as to whether the results of the proficiency samples are satisfactory or unsatisfactory. Copies of the vendor report will be passed to the QA office for documentation review and signature. The proficiency tracking system will then be updated. In the event of an Unsatisfactory the supervisor will start a corrective action.

## VI. Quality Control Chart



## **Procedure:** If the average of any of the solutions prepared by the lab do not test within the assigned limits on all tests, prepare the appropriate solution(s) again.

If standard(s) do not test within the assigned limits repeat the entire analysis procedure.

If the analysis procedure is repeated and if, for any reason, the standard(s) do not test within the assigned limits, notify the supervisor immediately so that appropriate corrective action can be taken.

The supervisor must approve any deviations from this procedure.

**NOTE:** When approving water proficiency samples, an Evidentiary Breath Test Instrument (EBT) is used as an additional check. Three proficiency type tests are to be run for each solution. The average result of the three tests must be within +/-.010 of its intended value, or the solution must be prepared again.

#### a. Receiving Results

- Proficiency Testing Reports are to be dated upon receipt.
- Place the Proficiency Test Reports in the in-box located next to the OAT fax machine upon receipt.
- Refer to the Proficiency Sample Processing and Actions Chart (found on page 14).

#### b. Processing Results

- All results are to be entered into the sample group forms found in \\phlfs\PHL\_share\OAT\Documents\ Proficiency Reports.
- The forms and tickets are to be checked daily for accuracy of results.
- As each form is marked, accurate results are to be logged; a checkmark is to be placed after "Continue" and the initials of the chemist processing the forms is to be placed after "By" in the box labeled "For Health Department Use Only" at the bottom of the form.
- On the last month of each quarter, new certificates are issued from the Proficiency Test Reports. New certificate dates are to be written in the "For Health Department Use Only" box. A checkmark is also to be placed after "Continue" and initials are placed after "By". Quarterly certificate dates are the first day of the first month in the quarter through the first day of the first month in the following quarter.
  - Example: the certificate for the first quarter of the year would be:
    - 01-01-20XX to 04-01-20XX
- Once entered, pass to the supervisor for review. Once reviewed the supervisor will pass the paperwork to the administrative staff. As additional forms and tickets are received and processed, they are to be reviewed and passed to the administrative staff.
- If the form is returned with missing information, check the evidence ticket, make entries to the form and initial and date.
- Make sure the test is completed as a "Proficiency Test". If the test result is entered incorrectly on the form, but the evidence ticket shows a valid test, correct the result and initial and date the correction.
- If the results are outside the standard of accuracy, or if there are any other problems noted with the test, then a resample is necessary.
- If results are too high, then the instrument will need to be removed from service until another sample can be issued.

#### c. Processing Resamples

• All resamples/ results are to be entered into the sample group forms found in \\phIfs\PHL\_Share\OAT\Documents\Proficiency Reports\Proficiency Prep Analysis.

If a resample is required, and the installation does not have the original sample to re-run, then the following steps are to be taken:

- Record the results of the first sample on the sample group form and cross-reference to the line where a resample is assigned, filling in the installation name and instrument serial number.
- On the original Proficiency Testing Report form: write the reason for resampling in the comments section, fill in the resample number assigned, the due date, initial in the "By" space, and mail a resample. Make sure not to check the "Continue" section.
- It should be attached to the back of the resample form when it is returned.
- A Resample Form is to be completed with the current date, installation name, instrument serial number, due date, and sample number.
- A resample should be sent from the same group as the original sample. If all those samples have been used, then a sample from another group will be sent.
- The resample should be shipped within one working day of receipt.

• Resample results are due seven days from the date the resample is shipped.

#### d. Processing Actions

- The administrative staff will issue revised certificates when an instrument's certification status changes.
- When processing actions, be sure to indicate the correct dates to appear on the new certificate.

# NOTE: Be careful not to issue a certificate beginning on the 1<sup>st</sup> day of the calendar quarter if an instrument or installation was not certified at that time.

- Actions (initial certifications, recertifications, suspensions, and revocations) are processed in accordance with the applicable steps on the Routing Slip.
- All actions are logged in the Action Log, the Instrument Summary Sheet, the Visit Logs, and in the sample group forms.

#### e. Suspensions

- The 15<sup>th</sup> of the month is the deadline for receipt of sample results- unless approved by the supervisor.
- If results are not received by late afternoon on the 15<sup>th</sup> (or first workday following), you may remove those instruments from service through the polling computer located in the OAT electronics lab.
- If those installations do not call by the end of the month to be put back in service to run their proficiency sample, you may proceed to suspend those instruments as of the date the instrument was removed from service.
- If unable to remove from service, call these installations and inform them of suspension. Document this call on the proficiency report.
- Complete the appropriate steps as indicated on the Routing Slip.
- Pass the completed paperwork to the administrative staff for further processing.
- If an instrument was in the laboratory for service and is ready to return to the installation, but results cannot be received by the 15<sup>th</sup>, suspension may be delayed. Remove the instrument from service; prepare a proficiency sample and a Proficiency Testing Report form to be sent with the instrument. Have the installation call to have the instrument returned to service when they are ready to run the sample.
- The instrument should be removed from service and lab personnel should instruct the installation to call for return to service when they are ready to analyze the sample.
- If accurate results are reported, there will be no lapse in certification.
- If no results were obtained before service or if the instrument is not picked up in time to obtain
  results by the last workday of the month, remove the instrument from service, and suspend the
  instrument.
- In no case should action be delayed beyond the last workday of the month.
- Laboratory personnel should not release instruments after the 15<sup>th</sup> without a proficiency sample or recertification sample; unless acceptable proficiency sample results were received before the Instrument arrived for maintenance.
- If the installation has the current quarter's proficiency sample unopened back at their office, then that sample may be used.
- If the instrument was suspended, then accurate recertification results should be confirmed with the lab before the installation uses the instrument.

#### f. Revocations

- Certification of instruments that have been suspended for six months or longer may be revoked.
- Fill in the appropriate portions of the Revocation Letter and then follow the steps on the Routing Slip to complete the revocation.

- Pass the finished paperwork to the supervisor for review. The paperwork will then be passed to the administrative staff.
- A revocation may be delayed due to special circumstances at the discretion of the supervisor.

#### g. Recertifications

- If a suspended instrument has not missed a regularly scheduled inspection visit, and there have been no other changes that would have affected eligibility for certification, it can be recertified by analysis of a proficiency sample.
- Complete a Recertification Sample Form and send with the recertification sample.
- Make an entry also in the appropriate portion of the sample group forms that a sample has been sent.
- Recertification is effective as of the date that the office was notified of accurate results.
- Once the paperwork is received, proceed with the steps noted on the routing slip to recertify the instrument as of the date notified. The paperwork will then be reviewed by the supervisor and passed to the administrative staff.
- When results are received after the date the test was performed, without documentation that laboratory personnel verified results, confirm there were no legal tests run during the interim. If subject samples were run during that time, check with the supervisor concerning the date of recertification.
- If the instrument is recertified during the third month of the calendar quarter, be sure to initiate two certificates: one for the remainder of the present quarter, and one for the following quarter.
- Log the recertification according to the procedure in the Processing Actions section of this document.

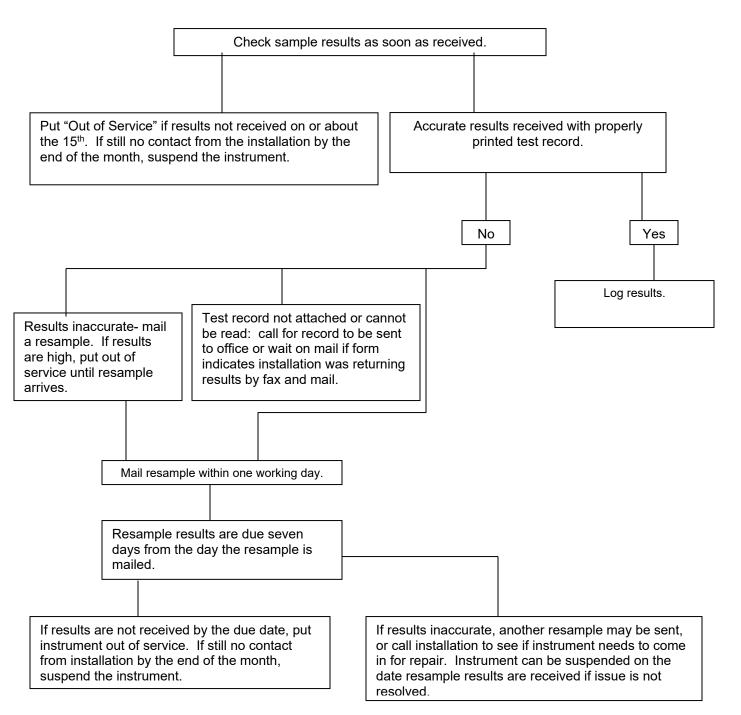
#### h. Initial Certifications

- See the Inspection Trip Section of this SOP.
- Initial certifications are processed from inspections only.

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## VIII. Proficiency Sample Processing and Actions Chart



Note: The supervisor must approve any extensions granted to installations and any deviations from this procedure.

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## IX. Court Testimony

#### a. Subpoenas

Subpoenas are received through the mail, email, fax, or delivery to the laboratory.

#### b. Court Prep

Prior to the court date, pull the file copy of the analysis report. Make copies of the log pages and calibration checks. Review the records and make notes of any noteworthy information.

Take the sample (when available) and place in a sealed plastic bag to take to court. The sample should remain in the custody of the chemist. If the court needs to keep the sample, then have them sign the sample transfer section of the report, indicating that the court took legal responsibility for that sample.

#### c. Testimony

Chemists may give testimony in the following areas:

- ADH procedures for receiving, handling, storing, and analyzing samples.
- exact procedure followed by the chemist.
- "Arkansas Regulations for Alcohol Testing" and how they apply to the procedures performed; and
- explanation of analysis results and units employed.

Chemists may also be responsible for testifying about inspections of breath test instruments they performed at installations. The chemist should obtain specific information concerning the request including:

- date(s),
- installation,
- instrument,
- any specific questions they may have.

If there are questions outside the chemist's normal job scope, then advise the court to subpoen athe director or assistant director.

At the completion of court, the chemist is to return the sample and paperwork to ADH. If the court requires keeping the paperwork leave them a copy.

## X. Inspection Trips

These are the main types of inspection visits:

- Initial Certification
- New Location
- Inspection / Recertification Visit
- Maintenance Visit.

This section will outline what paperwork, tools, solutions, and parts are needed for each inspection.

# <u>NOTE:</u> For each inspection a copy of the installation's logbook must be brought back showing which tests were logged during the inspection.

#### a. Initial Certification

The following may be needed for an initial certification visit:

Installation Application

- Logbook
- Installation Visit Report
- Release form for Complimentary Transportation
- Service/ Repair Worksheet
- Instrument Service Record
- Instrument Information Summary
- Instrument seals
- True-Cal
- Location Drawing

In addition, the following may be needed to complete the visit:

- Solutions: low, high, .08, ethanol/ acetone mixture
- Calibration equipment: dry-gas cylinder
- Make sure instrument polls/ interacts at the new location
- If the new instrument is replacing an existing certified instrument, make sure to revoke the one being taken out of service.

#### **b. New Location**

Check with the supervisor about a new location inspection to make sure which tests need to be performed. In general:

- If the new location is in a new building, then the appropriate checks (same as an annual inspection visit) will need to be performed.
- If the instrument is moved back to its old location, or is moved within the same building, then a visit is not required. A diagnostic check and supervisor test will need to be done in the new location. The new location is then updated on the location drawing.

#### c. Inspection or Recertification Visit

The following may be needed for an inspection or recertification visit:

- Installation Visit Report
- Release form for Complimentary Transportation
- Service/ Repair Worksheet
- Instrument Service Record
- Instrument Information Summary
- Copy of instrument location drawing
- Extra Logbooks
- Instrument seals
- Instrument reports to be used in checking the logbook
- True-Cal

In addition, the following may also be needed to complete the visit:

- Make sure that the instrument is polling/ interacting from ADH
- Dry gas cylinder- check tank pressure prior to trip
- Solutions: low, high, .08, ethanol/ acetone mixture
- Calibration equipment: dry-gas cylinder

NOTE: Inspection visits will occur at a minimum every two years.

#### d. Maintenance Visit

These are the forms that may be needed for a maintenance visit:

- Installation Visit Report
- Installation Visit Report Supplement A
- Release form for Complimentary Transportation

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- Service/ Repair Worksheet
- Copy of instrument location drawing
- Extra Logbooks
- Instrument seals
- True-Cal

In addition, the following may also be needed to complete the visit:

- Make sure that the instrument is polling/ interacting from ADH
- Solutions: high, .08, ethanol/ acetone mixture
- Calibration equipment: dry-gas cylinder

#### e. Post Visit

#### **Travel Reimbursement (TR1)**

Once a trip is completed a TR1 form must be completed online for reimbursement of expenses for overnight trips.

#### **Trip Reports**

Completion and processing of trip reports should be within two working days after trip.

#### Actions Resulting from Trip

Actions resulting from a trip are to be processed according to procedure within two working days. Use a Routing Slip to be sure all necessary steps are completed. Inform the supervisor of all actions. Instructions for actions are found in the Proficiency Sample Processing and Actions section of this SOP.

## XI. Breath Instrument Service/ Repair

#### a. Notification of Problem

When an instrument requires service, attempt to identify all problems as thoroughly as possible. If it is determined that the instrument will need to be delivered to OAT for service, then a Service Record form shall be started.

- Record the date, installation name, and serial number of the instrument.
- Check and/or describe the reason for the service.
- If any attempts were made to resolve the problem via phone, data lines, or maintenance visit, record what was done, and any outcomes in the "Summary of Work Performed" section.
- A Service/Repair Worksheet shall be clipped to the Service Record. (Be sure to include the serial number, Installation name and number, and the description of the problem on this form as well.)
- These forms should be placed in the appropriate bin in the electrical laboratory where they will be easily found when the instrument is received.

#### **b. Instrument Receiving**

If an instrument arrives without the office having been previously notified, the previous section should be completed first.

- Retrieve the service forms for the instrument, and place checkmarks next to all accessories that were received with the instrument.
- Date, sign, and have the person providing the instrument sign the form acknowledging the transfer of the instrument and accessories.
- Record the date and serial number in the service log to determine the "Job #."

- Record the job number on the service record and service/repair worksheet.
- Retrieve the service folder for the instrument and place it with the instrument and partially completed forms.

#### c. Service

- Perform a sufficient number and type of tests to recreate all problems. (If conditions cannot be met to recreate the problem, then service may be performed at the discretion of the supervisor.)
- Resolve the problem through proper troubleshooting techniques.
- Perform all functional checks as outlined on the Service forms.
- If the instrument has been suspended or if the repairs are not complete until after the 15<sup>th</sup> of the month, "Remove from Service" through the polling computer. [The installation will have to call the lab to notify personnel that they are ready to run the appropriate sample. The instrument can then be put back in service.]
- If instrument was opened for repair, apply a signed and dated seal to the rear of the assembled instrument once the cover is put back in place. Make sure to place seal over the cover seam.
- Complete all applicable sections of the Service Record and Service/Repair Worksheet and place them in the service folder with the tickets for each test run during the service.
- Inform installation of service completion and plan for its return.
- Record and initial the date of service completion on the appropriate line in the service log.

#### d. Instrument Return

- Retrieve the Service forms for the instrument, and place checkmarks next to all accessories being returned with the instrument.
- Date, sign, and have the person receiving the instrument sign the form acknowledging the transfer of the instrument and accessories.
- Review the completed Certification Status section of the Service Record and make any applicable arrangements needed to recertify or continue certification for the instrument.
- Record the date and means of return in the service log. If the instrument was repaired in the field or if a new instrument was Initially Certified, these things should also be noted in the service log.

## XII. Dry-gas Cylinder Approval

Dry-gas cylinders for use in the Intoximeter EC/IR II will be placed into the OAT laboratory instrument for analysis. Enter the appropriate value, lot #, and expiration date and run a supervisor test. Compare the result of the supervisor test to the target value of the cylinder. Place the results sheet and COA with the instrument paperwork. If the results are +/- 0.005 of the target, contact the supervisor.

**NOTE:** OAT participates in a dry-gas cylinder refill program with Intoximeter. When enough tanks have been collected, they can be shipped back to Intoximeter. The tanks will be cleaned and refilled. Upon return to OAT the approval process is the same as above.

• A certified shipper in hazardous materials needs to be contacted to ship the tanks back to Intoximeter. Contact Safety and/or Specimen Receiving for a certified shipper

## XIII. BAIIDs (Breath Alcohol Ignition Interlock Devices)

This section will outline what paperwork, materials, solutions, and instruments are needed for inspection; procedure of inspection; and other duties to keep files current.

Every year, an inspection of installation and monitoring is performed by a representative from the Office of Alcohol Testing.

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Prior to each inspection, appointments are made with each Supplier representing the different approved devices. If possible, set up the inspection on a day the Supplier will have both an installation and a monitoring.

#### **Inspection Supplies:**

- Inspection Report Form
- BAIIDs Regulations

#### **BAIIDs Inspection:**

- Check certificate of analysis on wet bath solutions or gases used in calibration.
- If installer uses wet bath simulator, check for cleanliness and correct temperature with digital thermometer.
- While device is being installed:
  - o the inspector is to observe installation making sure device is installed correctly
  - that no damage is done to subject's vehicle
  - o that the device is installed as to not interfere with operation of vehicle
  - o that the installer makes sure the subject does not watch the installation of the device
- After installation of the device, the installer should instruct the driver on its use and make sure driver is able to blow properly and start vehicle
- Monitoring of a vehicle's device- this consists of downloading information from device and calibration of device at least every 60 days. Data is sent to home office or manufacturer and any violation reports are sent to driver control.
- Inspector fills out inspection report and has installer sign the document. If any problems were noted on report the inspector can discuss them with the installer so the action can be corrected.

The inspector should check files on a yearly basis to make sure a current certificate of liability insurance is on file.

OAT takes any complaints made by suppliers or subjects using the device. Actions are taken to try to resolve problems that arise. Complaints and actions are filed under each manufacturer.

OAT is also responsible for the approval of new devices. Once the device is approved, a new supplier list is sent to driver control.

## **XIV. Corrective Actions**

Corrective actions will be written for any of the following errors:

- Improper storage of samples
- Failure to comply with SOP requirements
- Proficiency test failure
- Reporting of incorrect results

Corrective actions are initiated and tracked at the following site through the LIMS system.

## XV. Analyst Training

All new hire and/or transferred analyst are placed on a six (6) month probationary period mandated by the Department of Health. During this probationary period, which may be extended if required, the training analyst will be instructed in various requirements and duties for their position. At NO time will the probationary analyst perform analysis on legal samples until they have completed the certification procedure and been approved by the section director.

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The training will include the following:

- Complete Review of Standard Operating Procedures
- Breath Instrument Service/Repair.
- Proficiency Samples Preparation and Processing of Results.
- Court Testimony.
- Inspection Trips

These training criteria will be done concurrently and require significant observations and interactions with the other analysts.

The section director will complete the Analyst Training Certification Checklist to be kept on file as part of the Analyst Certification Procedure.

#### a. Breath Instrument Service and Repair

The training analyst will be given a copy of the most current repair manual available for the breath testing devices. The section director will select another analyst to do hands-on training with the training analyst. The training analyst, when possible, should be assigned repairs on instruments owned by the Agency and used solely for training purposes by the Training Staff. This will allow for any incident where the repairs are not time critical and would have no legal ramifications. After the training analyst has shown ability to handle routine repairs or maintenance, they will be allowed to work without oversight. All repairs must be checked by the overseeing analysts prior to the instrument being returned to service. The overseeing analyst will notify the section director of the training progress at which time the section director may approve the new analyst to begin repairing legal instruments.

As funding permits, the training analyst will be additionally trained by the instrument manufacturer, either here at the Agency or at their training center. In most cases this will occur after the Agency's six (6) month probationary period has ended.

#### b. Proficiency Samples Preparation and Processing of Results

The training analyst will assist the designated lead analyst with all aspects of the preparation, analysis and processing of the proficiency samples and results, following the guidelines found in the appropriate sections of the SOP.

#### c. Court Testimony

Court testimony may be required in numerous cases in which the analysis results may be introduced as evidence. OAT is considered a "neutral" party. The main concern is that all subjects receive a fair and accurate test result from the breath testing instrument and/or the analysis of bodily fluids.

Whenever possible during the probationary period, the new analyst should accompany other analysts and/or the section director on their court dates and observe their testimony. Questioning the existing analysts about their court experiences is also a good method of becoming aware of what to expect in court.

The basics of court testimony is simple. For breath testing instruments and bodily fluid analysis, you may only give testimony on the following areas:

- Your specific actions about the sample analysis or the breath testing instrument.
- The Agency's Standard Operating Procedures.
- The Regulations involved.
- Explanation of your results.
- Your background. (i.e., education, employment history, specific training, curriculum vitae, etc.)

One of the pitfalls of court testimony is excessive verbal response. It is best to keep all responses short and to the point. The analyst is not there to win a conviction or an acquittal, but to testify on their actions and general information concerning alcohol testing.

Whenever possible, the section director and/or another analyst will accompany the new analyst on their first few court appearances. They are there for support should the new analyst be uncomfortable or asked questions they feel are not within their ability to answer. The observers will not testify unless directed to by the court.

#### d. Inspection Trips

Whenever possible during the probationary period, the training analyst should accompany and observe other analyst on routine and special Inspection visits. The training analyst will assist in the completion of all records used by the Agency about the certification of the instrument, facility, personnel, etc.

The section director may accompany the training analyst on special inspection visits for the purpose of evaluating the analyst progress. The section director will determine when the new analyst may conduct inspections and/or visits without accompaniment.

## XVI. Health and Safety Warnings

- Standard laboratory protective clothing, gloves, and eye covering is required.
- Eating, drinking, applying make-up, and handling contact lens are prohibited in the laboratory.
- OAT Lab will follow the AR-PHL Safety Manual. Copies are in the OAT Office Area and in iPassport.
- Analyst must attend general lab safety training annually.

## XVII. Forms

This section outlines the forms referenced in the earlier sections of this SOP. Please refer to the appropriate section to make sure the correct form is used.

Form Name:		<u>Form #:</u>
a.	Action Log	PHL-13-12
b.	Analyst Training Certification Checklist	PHL-13-01
C.	Intox Service Record	PHL-13-13
d.	Intox Service/ Repair Worksheet	PHL-13-14
e.	GC Solution Preparation and Analysis	PHL-13-05
f.	Application for Certification of Intoximeter EC/IR II/ II.t	PHL-13-15
g.	Intox Installation Inspection Report	PHL-13-16
h.	Itinerary	PHL-13-18
i.	Proficiency Test Memo	PHL-13-19
j.	Proficiency Test Resample Memo	PHL-13-20
k.	Proficiency Recertification Sample Memo	PHL-13-21
I.	Application for Certification to Perform Breath Tests	PHL-13-22
m.		PHL-13-23
n.	Proficiency Samples and Standards- Preparation and Analysis	PHL-13-24
0.	Quality Control Log for Standard Analyzes	PHL-13-09
р.	Release from Financial Responsibility for Complimentary Transportation	PHL-13-25
q.	Revocation Letter	PHL-13-26
r.	Routing Slip	PHL-13-27
S.	Sample Groups	PHL-13-28
t.	BAIIDS Inspection Report	PHL-13-29
u.	Replacement Card Request	PHL-13-32
۷.	Temporary Loan Receipt	PHL-13-37