



U.S. Department
of Transportation

**National Highway
Traffic Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

Mr. M. Rankine Forrester
CEO
Intoximeters, Inc.
2081 Craig Road
Saint Louis, MO 63146

MAY 18 2012


Dear Mr. Forrester:

The National Highway Traffic Safety Administration (NHTSA) has reviewed the Quality Assurance Plan (QAP) for the Intoximeters, Inc., **Alco Sensor V XL** evidential breath alcohol tester submitted in response to 49 CFR Part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Program" (65 FR 79462). We are pleased to inform you that the QAP dated April 2012 has been approved and meet the requirements of this regulation.

We will place the QAPs on file at NHTSA, together with a copy of this letter, for interested agencies. A copy will also be provided to the Department of Transportation Office of Drug and Alcohol Policy and to the Volpe Center for their records.

Please be advised that this office is to be notified immediately if any changes are made to this device or to this QAP. If you have any questions regarding the quality assurance program in relation to the 49 CFR Part 40, please do not hesitate to contact me at 202-366-1694 or decarlo.ciccel@dot.gov.

Sincerely,


J. De Carlo Ciccel
Program Analyst

cc: Ed Conde, Volpe
Jim Swart, OST

Quality Assurance Plan (QAP)
As Required by 49 CFR Part 40.233

Intoximeters, Inc. Alco-Sensor VXL

1. Approved Methods for Accuracy Checks and Calibrations (what type of standard is used?)

Intoximeters, Inc. (Intoximeters) recommends that accuracy checks and calibrations be performed using a dry gas standard which has a value between .020 and .150 g/210L* at sea level** and is approved for use by both NHTSA and Intoximeters. Alternatively, wet bath simulators which have been approved for use by NHTSA and Intoximeters can be utilized with properly certified and maintained ethanol solutions. These simulator solutions should have a stated breath alcohol concentration between .020 and .150 grams per 210 liters of breath.

Intoximeters further recommends that accuracy checks be performed with a standard which has a stated value at or near the level of interest for your alcohol testing program. *For Example: In workplace applications in the U.S., the level of interest may be .020 or .040 g/210L in order to meet the DOT procedural requirements. For law enforcement applications the level of interest may be .080 g/210L.*

In all cases, the compressed gas tanks, simulators and simulator solutions should be used and maintained only in accordance with the quality assurance plans provided by their respective manufacturers in order to insure that they produce consistent and reliable samples. Instruction for use of these standards with the instrument can be found in the documentation provided with the instrument.

* g/210L = grams of alcohol per 210 liters of breath

** Standard atmospheric pressure at sea level equals 760 millimeters of mercury (760mm Hg).

2. Intervals for Accuracy Checks (how often is the device checked for accuracy?)

Intoximeters Minimum Suggested Interval for Accuracy Checks

Intoximeters suggests that accuracy checks be performed at least monthly to validate accuracy and to establish a performance record. If an accuracy check has not occurred within the past 31 days, Intoximeters' best practices would suggest an accuracy check be run prior to running a subject test.

Additional Suggestions for Accuracy Checks

Intoximeters also recommends that an accuracy check be run on the instrument as soon after a positive confirmation test as is practical.

While monthly accuracy checks are adequate to demonstrate the precision and accuracy of the instrument, more frequent checks will provide additional credibility for your testing program.

3. Acceptable Tolerances on an External Accuracy Check (what is the allowed variance on a check?)

Acceptable Tolerance

The result of an accuracy check should not differ by more than .005 g/210L from the expected value of the standard.

When an accuracy check is run on an instrument and the displayed result differs by more than .005, as compared with the expected value of the standard gas sample, the user shall take the instrument out of service and have it recalibrated and checked for accuracy by a properly certified calibration technician before putting the instrument back into service. Reference 49 CFR Part 40.233(c).

Using Dry Gas Standards

Both weather conditions and operating at elevations other than sea level will change the absolute pressure from 760mm Hg and cause the expected value for the dry gas standard to change. It is important to account for changes in absolute pressure when performing accuracy checks and calibrations with dry gas standards. Although expected dry gas values vary with changes in atmospheric pressure, the analyzed result of a gas sample delivered must not differ by more than .005 g/210L from the *expected value* of the standard gas sample. There are 2 options for obtaining the correct expected value for your location.

- Approved dry gas standards obtained from Intoximeters include an elevation table on the label that allows you to determine the expected value of the dry gas standard if you know the elevation at which you will perform the accuracy check. **Example:** *in Santa Fe, New Mexico at 7,000 ft. elevation, given normal atmospheric conditions, using an approved dry gas standard labeled with a sea level value of .038 g/210L, the elevation table will show the expected dry gas value as .029. If an accuracy check is run when the expected value of the dry gas standard is .029, the tolerance requirement is met if the accuracy check result does not differ by more than .005 g/210L from the expected (.029) value.*
- Using an optional pressure correcting device (such as a True-Cal) with an approved dry gas standard provides the ability to precisely calculate the atmospheric pressure changes due to both elevation and weather conditions. The pressure correction device must contain a precision pressure sensor which monitors the atmospheric pressure and displays the expected value of the dry gas standard adjusted for the current atmospheric pressure at that moment. The pressure sensor devices in our TRUE-CAL product line, or the optional pressure sensor built in to the Alco-Sensor VXL, are programmed to correct a specified dry gas concentration. Make certain the device you are using is designed for the specific value of dry gas standard currently being used.

The Alco-Sensor VXL may ask the operator to enter/verify the value of the gas standard being used when performing an accuracy check or a calibration.

4. Inspection, Maintenance and Calibration Requirements (when is maintenance required?)

As previously stated, the instrument must be removed from service and calibrated by an authorized technician when the displayed result of an accuracy check differs by more than .005 from the expected value of the standard gas sample.

In addition, the instrument must be taken out of service for factory maintenance if:

- the calibration technician is unable to calibrate the instrument. In other words, after two attempts to calibrate the device, a successful accuracy check is not obtained;
- the instrument fails to maintain its calibration on three consecutive monthly accuracy checks;
- the instrument consistently takes more than two minutes to perform a breath analysis on a sample with a concentration less than .100 g/210L.

It is highly recommended that the instrument be inspected by a factory technician at least once every two years in service. Routine maintenance procedures are specified in the manuals of each instrument and must be followed in order to insure accurate test results.