Notice of Request for the Reinstatement of an Expired Information Collection

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to reinstate the following expired information collection:


DATES: Comments must be submitted before October 14, 1997.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the United States Department of Transportation, Central Dockets Office, PL-401, 400 Seventh Street, S.W., Washington, D.C. 20590. All comments received will be available for examination at the above address from 10:00 a.m. to 5:00 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard/envelope.

FOR FURTHER INFORMATION CONTACT: Ms. Sue Masselink, Office of Program Management, (202) 366-2053.

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

first issued on November 30, 1976 (41 FR 53389).

On December 14, 1984, NHTSA issued a notice to convert the mandatory standards for evidential breath testers and calibrating units for breath alcohol testers to Model Specifications for such devices (49 FR 48855 and 49 FR 48865, respectively) and to establish a Conforming Products List (CPL) of evidential breath testers and calibrating units meeting the Model Specifications. Amendments to the CPL have been published in the Federal Register since that time. Evidential breath testers are instruments that measure the alcohol content of deep lung breath samples with sufficient accuracy for evidential purposes. Calibrating units provide known concentrations of ethanol vapor for the calibration or calibration checks of instruments which measure breath alcohol.

NHTSA published a notice in the Federal Register (59 FR 67377) on December 29, 1994, amending the Model Specifications for calibrating units for breath alcohol testers and updating the CPL for calibrating units. The notice also proposed and sought comments about providing an alternate testing procedure for evaluating the accuracy and precision of dry-gas ethanol calibrating units.

Officials who use breath alcohol testers must verify their accuracy at appropriate intervals during use. The traditional means for ensuring accuracy has been by checking the breath tester calibration by use of a "wet bath" calibrator, a device which provides moist alcohol in air samples at accurately known concentrations. Dry gas calibrating units have become available as an alternate means for calibration checking.

A dry gas calibrator produces alcohol-in-inert gas samples (e.g., nitrogen or argon) at accurately known concentrations from a compressed gas cylinder. Dry gas calibrators, like wet bath calibrators, can be used to calibrate certain types of breath testers, but an evaluation of their precision and accuracy requires alternate procedures. Today’s notice amends the Model Specifications for Calibrating Units for Breath Alcohol Testers by incorporating an alternative testing procedure using National Institute for Standards and Technology Reference Gas Mixtures for the evaluation of dry gaseous ethanol calibrating devices and making other changes that were previously proposed to simplify the Model Specifications and to make them easier to read. Additional major changes were made to ensure accuracy and improve clarity of the document. Also, the term BrAC has replaced the term BAC throughout the model specifications to ensure consistency with usage recommended in the Uniform Vehicle Code.

Today’s notice also proposes an additional new alternate procedure for evaluating wet bath and dry gas calibrating units using infra-red spectroscopy. The agency believes that use of infra-red spectroscopy will offer several important advantages in the evaluation of both wet bath and dry gas calibrating units. Comments are sought regarding the agency’s proposal.

A. Comments Received

1. Overview

The agency received two comments in response to the notice of December 29, 1994: one from Scott Specialty Gas Co. (Scott Gas), a manufacturer of a dry gas calibrating unit, and one from U.S. Alcohol Testing (USAT), a manufacturer of an evidential breath test device and a wet bath calibrating unit that is currently listed on the NHTSA CPL. Scott Gas was generally supportive of the proposed revisions to the Model Specifications. USAT stated that it would favor the use of dry gaseous alcohol calibrating devices when it has been adequately demonstrated that dry-ethanol [calibration units] give results comparable to those obtained with conventional wet bath simulator calibration units.

Neither of the respondents specifically commented on the proposed revisions to simplify the Model Specifications. As stated in the notice, these proposed revisions did “not represent substantive alterations in the procedures followed or in the criteria used to determine whether devices meet these model specifications.” The proposed revisions have been adopted without change.

Both Scott Gas and USAT raised questions in their comments about those aspects of the Model Specifications relating to the proposed new alternate testing procedure for evaluating the accuracy and precision of dry gas calibrating units. The comments addressed a number of key issues, including the comparability of wet bath and dry gas calibrating units and certain specific conditions affecting dry gas calibrating units. The issues that were contained in the comments are summarized and discussed below.

2. Comparability Between Wet Bath and Dry Gas Calibrating Units

USAT commented that “[T]he use of a dry gas ETOH standard makes no physical sense until it can be demonstrated that the presence of water vapor in the breath samples analyzed has no effect on the analytical outcome on the ethanol concentration of the breath samples analyzed by the [evidential breath tester].”

While it is true that dry gas and human breath differ in moisture content, NHTSA has found no reason to exclude the use of dry gas calibrating units solely on this basis. If a calibrating unit (either wet bath or dry gas) meets the precision and accuracy criteria of the Model Specifications, the calibrating unit should be considered acceptable for general use.

Independent research has confirmed the comparability of dry gas and wet bath calibrating units and the accuracy of dry gas calibrating units. Kurt M. Dubowski and Natalie A. Essary studied the performance of dry gas calibrating units and concluded that “dry gas vapor-alcohol control [VAC] samples confirmed to established formal specifications and * * * compared favorably with simulator simulators for control tests of breath alcohol analyzers which are capable of adjusting VAC results for ambient atmospheric pressure.” Lance D. Silverman, et al. reported on the comparability of wet bath and dry gas calibrating units. These researchers determined that there was substantial equivalence between both types of calibrating units. Their data “based on collection of ethanol in an impinger and titration using a modified California Department of Health method * * * confirm[ed] the alcohol content of EBS compressed gases standards by an absolute, wet chemical method.”

3. Should the Model Specifications Be Expanded To Address Unique Conditions Affecting Dry Gas Calibrating Units?

USAT challenged the use of dry gas calibrating units based on the following factors: (a) condensation in the cylinder as a consequence of low temperatures during shipment; (b) the need to make corrections due to changes in atmospheric pressure; and (c) the performance of dry gas calibrators over a range of temperatures and concentrations.

NHTSA has considered these comments carefully and has concluded that dry gas calibrating units are suitable for evaluation according to the Model Specifications.
Specifications and believes that the Model Specifications are sufficient to ensure the accuracy and precision of dry gas calibrating units. However, in light of the concerns raised by USAT, the agency has amended the procedures for submitting a product for certification. When a manufacturer submits a product to the agency for testing, it now must submit also a set of the instructions that are provided to end users. The instructions must sufficiently describe the procedures to be followed to protect against condensation in dry gas cylinders that might occur as a result of freezing during shipment and to correct for atmospheric pressure.

(a) Condensation in Dry Gas Cylinders as the Result of Freezing

USAT commented that dry gas calibrating units were previously shown to have a “memory effect when transported or stored at temperatures somewhat below room temperature.” NHTSA acknowledges that dry gas calibrators could freeze during shipment and this could affect test results. As a result of freezing, alcohol could condense in the inside surface of the cylinder. If this were to happen, re-equilibration of the alcohol with the nitrogen after warming to room temperature could take a long time. It is possible that the gas in such cylinders might be used before re-equilibration occurred with the result that samples would be obtained at incorrect concentrations.

Manufacturers of dry gas calibrating units recommend that, after receiving the dry gas cylinders, users should warm the cylinders to room temperature, then lay them down on a flat surface and physically roll them back and forth for a period of ten minutes to ensure re-equilibration of the contents. To test whether this procedure would ensure that the dry gas calibrators remained accurate, several cylinders of Lion Laboratories AlcoCal dry gas calibrators were placed in the freezer compartment of a refrigerator overnight at a temperature of −15°C, then taken out of the freezer, warmed to room temperature and rolled on a table top for ten minutes. Data was collected confirming that tanks that were rolled after freezing gave accurate results.

As described in the section on procedures for product submission included at the end of this notice, when manufacturers submit their instruments for testing, they are required to submit copies of the instructions they provide to end users. NHTSA will examine these instructions to ensure that they provide sufficient information about this procedure. Products submitted without this information will not be tested.

(b) The Effect of Variable Atmospheric Pressure on Dry Gas Calibrators

USAT commented that dry gas calibrating units may exhibit a pressure-dependent concentration effect that wet bath calibrating units do not. The packaging of a dry gas calibrator compresses a large volume of an alcohol-in-inert gas mixture into a metal cylinder of only about one (1) liter. The concentration of the alcohol in the gas is given by the Ideal Gas Law: PV = nRT, where P is the pressure of the gas, V is the volume, n is the number of moles of gas, R is the gas constant, and T is the temperature of the gas. The concentration of the gas is obtained as a function of pressure and temperature: Concentration = n/V = P/RT.

When a calibration check is performed, some of the gas in the cylinder is released by operating the release valve. The volume of the released gas will expand and its pressure will drop until prevailing atmospheric pressure is reached. The gas is prepared so that the desired concentration is obtained at normal atmospheric pressure, 760 millimeters of mercury. However, atmospheric pressure varies slightly from day to day and can change suddenly at times. The most significant effect comes from high elevations, where prevailing atmospheric pressure is significantly lower than 760. Atmospheric pressure corrections are made using an equation derived from the Ideal Gas Law: C = C\_1 \times P/760, where C is concentration and P is the prevailing atmospheric pressure.

In order for any calibrating unit to operate properly under such atmospheric pressures, accurate pressure correction must be made. The agency has tested the dry gas calibrating units placed on the CPL in this publication using this pressure correction procedure and has determined that these devices meet the Model Specifications. The agency concludes that the pressure dependent concentration effect is consistent and well established and that pressure correction procedures suggested by manufacturers are effective and produce accurate results.

(c) The Performance of Dry Gas Calibrators Over Range of Temperatures and Concentrations

Throughout its written comments, USAT argues that dry gas standards should not be accepted because they have not been shown to be comparable to wet bath standards. USAT argues:

Further substantial equivalence of the dry-EtOH and wet simulators must be shown over the range of environmental temperatures and pressures likely to be encountered during normal field usage of any of the devices appearing on the CPL * * * [and] over the range of NHTSA tested concentrations * * * throughout the operating lifetime of the dry gas [calibrating units] * * * Results of comparative performance of dry-EtOH [calibrating units] versus wet simulator [calibrating units] need to be publicly presented in scientific forums and published in the technical literature to establish a level of confidence that dry gas [calibrating units] yield substantially equivalent results to those obtained for decades from conventional wet simulator [calibrating units].

USAT commented that “Dry gas EtOH [calibrating units] must be required to show equivalent performance over the entire range of environmental conditions used to test wet bath simulator [calibrating units].” The agency tests both wet bath and dry gas calibrating units according to the Model Specifications. The agency believes that the Model Specifications require testing over an appropriate range of temperatures and concentrations. Dry gas calibrating units are required to show equivalent performance over the entire range of environmental conditions used to test wet bath calibrating units.
4. Are Dry Gas Calibrating Units Sufficiently Accurate?

USAT states that it would favor use of dry gas calibrating units when "it has been adequately demonstrated that dry ETOH [calibrating units] give results comparable to those obtained with conventional 'wet bath simulator calibration units.'"

The same Model Specifications used to test the accuracy and precision of wet bath calibrating units are used to ensure the quality and performance of dry gas calibrating units. All units are tested over the same range of temperatures and concentrations. All dry gas calibrating units placed on the CPL in this publication conform to the Model Specifications. Any unit that fails to meet the requirements of the Model Specifications would not be included on the agency’s list of conforming products.

5. Miscellaneous Issues

(a) Quality Assurance Plan

Scott Gas recommended that the agency require Quality Assurance Plans (QAPs) for calibrating units. QAPs are used to provide information on the correct use, proper maintenance procedures and other specific requirements of a calibration device. Scott Gas recommended that the QAP address issues such as NIST traceability, mechanisms for product coding and traceability, list of proper delivery equipment, specifications on the containers being submitted for approval, shipping and storage information, written laboratory certification and manufacturing procedures, DOT specification documentation on containers, a specified uncertainty at the 95% confidence level and shelf life results.

NHTSA strongly endorses the need for quality control in manufacturing, but believes that this is addressed appropriately by the manufacturers of these instruments. When calibrating units are used by law enforcement officials, quality control measures are also taken under the programs of each state. In transportation workplace testing, quality control is ultimately handled by the existing requirement for QAPs for evidential breath testers and alcohol screening devices (Screeners) which address calibration accuracy. The evidential breath tester QAPs call for calibration checks using an approved calibrating unit. If an evidential breath tester or a Screener gives an incorrect reading when a calibration check or a calibration is conducted, it suggests that there is an error in the system consisting of the evidential breath tester (or Screener), the breath alcohol technician, or the calibrating unit. NHTSA believes that the safeguards already in place in the QAPs for evidential breath testers and Screeners make it unnecessary to require an additional QAP specific to the calibrating unit.

(b) Stability of Dry Gas Calibrators Over Their Operating Life

USAT commented that "Further substantial equivalence of the dry-EtOH and wet simulators must be shown over the range of NHTSA tested concentrations throughout the operating lifetime of the dry gas calibrating units." Scott Gas also commented that "presentation of gas manufacturer stability documentation to NHTSA, before inclusion on the CPL, plus NHTSA evaluation of aged product should be done in order to assess the "real life" performance of the product."

The agency’s experience indicates that dry gas calibrating units are normally stable even after years of storage. In addition, NHTSA has verified that National Institute of Standards and Technology Reference Gas Mixtures used to evaluate dry gas cylinders remained stable to within ±0.001 BrAC for a one year period. The agency has concluded that manufacturers will not be required to provide stability documentation. NHTSA shall certify that the CPL does, in fact, reflect calibrating units which meet the performance criteria set forth in the Model Specifications. NHTSA reserves the right to test any unit on the CPL throughout its useful life to ensure that the unit is performing in accordance with the Model Specifications. In addition, in the section on procedures for a product submission, included at the end of this notice, NHTSA requests that users of calibrating units provide both acceptance and field performance data to NHTSA’s Office of Traffic Injury Control Programs. NHTSA will conduct a special investigation if information gathered from the field indicates that a device on the CPL is not performing in accordance with the Model Specifications.

After the recent expansion of the use of dry gas calibrators, one manufacturer found that the concentration of some dry gas calibrators had changed from the stated concentrations after weeks or months of storage. A recall of all cylinders in use was ordered. The problem was investigated and, after extensive testing it was traced to defects in certain cylinders and was corrected.
Agency testing indicates that dry gas calibrating units can be used with infra-red and fuel cell breath testers.\(^1\) The agency tested four fuel cell testers, one fuel cell/infra-red combination tester with readout from the fuel cell sensor, and one infra-red tester to obtain wet and dry comparison data. The instruments tested were:

LifeLoc, Inc. BPA 3000 and BPA 3000X (FC) 
CMI, Inc. Intoxilyzer 400 (FC)
Intoximeters, Inc. Alcosensor IV (FC) 
National Draeger, Inc. Breathalyzer 7410-II (FC) 
Intoximeters, Inc. EC-IR (FC/IR) 
CMI, Inc. Intoxilyzer 5000 (IR)

Measurements were made alternately using a sample from a wet bath calibrator, then a sample from a dry gas calibrator. Five measurements of each type of sample were made on each of the testers. The wet calibrator solutions were prepared to produce the same concentrations as the corresponding dry gas. Wet samples were produced using Repco Marketing simulators (wet bath calibrating units). Dry samples were obtained from dry gas calibrating units from Scott Specialty Gases, Inc. (0.04 BrAC) and Gateway Airgas, Inc. (0.04 and 0.088 BrAC). The concentration of the Scott gas was verified by Intoximeters, Inc. and the concentration of the gas from Gateway Airgas was verified by infra-red spectroscopy at the Volpe center. The factory calibrations of the breath testers were not adjusted. The reliability of the “true value” of the wet or dry standards can be taken as known values to within about ±0.001 BrAC. Thus, the true value of a wet sample or a dry sample at 0.040 BrAC can be expected to be correct to within about ±0.001 BrAC.

The differences between wet bath and dry gas calibrating units were negligible when the comparisons were made using infra-red breath testers. These differences were around 0.002 BrAC and are not noticeable unless comparisons are made carefully, because this value is near the accuracy limit of the calibrating units.

The differences observed when comparisons were made using fuel cell type breath testers, the next most widely used type of breath tester, were more noticeable, especially at high alcohol levels. The offset for fuel cell breath testers averaged somewhat less than 4% of the nominal BrAC when dry gas calibrators were used to check calibration of fuel cell evidential breath testers. The offsets found for the breath testers ranged from – 0.0014 BrAC to 0.0026 BrAC when compared at the 0.04 BrAC level, and from – 0.0020 to 0.0052 when compared at the 0.088 level. The standard deviations for the wet and dry data were in the fourth decimal place except in one instance when a value of 0.002 was obtained, which was still acceptable. These results indicate that the offsets are small and reproducible enough that reliable corrections can be applied to ensure accurate test results.

The offsets observed cannot be assumed to arise only from the inherent differences in measurement of moist samples compared to the measurement of dry samples since there are also uncertainties of ±0.001 in the true concentration of wet bath or dry gas calibration unit vapors.

Offsets must be indicated by manufacturers in their instructions to end users. Manufacturers are required to include their instructions in a submission of a calibrating unit for testing. The agency will examine the instructions to ensure that they provide sufficient information on offsets necessary for fuel cell breath testers. Products submitted without this information will not be tested.

Gas Chromatograph breath testers depend on extensive surface interaction with the sample being analyzed, and the greatest differences between dry and wet standards are seen with this type of breath tester. In its laboratory, NHTSA has found that the effects are not stable. They vary with type and condition of resolving column used. Accordingly, NHTSA believes that dry gas calibrating units should not be used with gas chromatograph breath testers because the results are too variable. The agency will include a footnote on the CPL concerning the use of dry gas standards with gas chromatograph evidential breath testers, indicating that the agency does not recommend the use of dry gas calibrating units with gas chromatograph evidential breath testers.

B. Procedures for a Product Submission

Testing of calibrating units submitted by manufacturers to these Model Specifications will continue to be conducted by the DOT Volpe National Transportation Systems Center (VNTSC). Tests will continue to be conducted semi-annually or as necessary. Manufacturers wishing to submit calibrating units for testing must apply to NHTSA for a test date (Office of Traffic Injury Control Programs, NTS-11, NHTSA, 400 Seventh Street, S.W., Washington, D.C. 20590).

Normally, at least 30 days will be required from the date of notification until the test can be scheduled. One week prior to the scheduled initiation of the test program, the manufacturer will deliver at least one unit of the device to be tested to: VNTSC, DTS-75, 55 Broadway, Kendall Square, Cambridge MA 02142. The manufacturer shall be responsible for ensuring that the unit is operating properly. If the manufacturer wishes to submit a duplicate, backup unit, it may do so.

When a manufacturer delivers a device to be tested, it shall also deliver to VNTSC specifications and drawings that fully describe the unit and the Operator’s Manual and Maintenance Manual normally supplied with purchase of the equipment. Proprietary information will be respected. (See 49 CFR Part 512, regarding the procedures by which NHTSA will consider claims of confidentiality.)

The manufacturer shall also deliver the instructions that will accompany the device when it is sold. The instructions shall include information about the procedures to be followed to protect against possible condensation that might occur as a result of freezing during shipment and to correct for atmospheric pressure. The instructions shall also include information about any offsets that may apply to the use of a particular type of breath tester. NHTSA will examine these instructions to ensure that they provide sufficient information about these matters. Products submitted without this information will not be tested.

The manufacturer will have the right to retest the calibrating unit between arrival in Cambridge and the start of the test, and to ensure that the calibrating unit is in proper working condition but will have no access to it during the tests. Any malfunction of the calibrating unit which results in failure to complete any of the tests satisfactorily will result in a finding that it does not conform to the Model Specifications. If a unit fails to conform, it may be resubmitted for testing after appropriate corrective action has been taken. On the basis of these results, NHTSA will publish a Conforming Products List (CPL) identifying the calibrating units that conform to the Model Specifications.

Restoring units will be conducted when necessary. NHTSA intends to modify and improve these Model Specifications as new data and improved test procedures become available. (The test procedures may be altered in specific instances, if necessary, to meet the unique design features of a calibrating unit). If these Model Specifications are modified, notification will be made in the Federal Register. If NHTSA determines that retesting to the modified
specifications is necessary, a manufacturer whose equipment is listed on the CPL will be notified to resubmit the equipment for testing to the modified specification only.

NHTSA will certify that the CPL does, in fact, reflect calibrating units which meet the performance criteria set forth in the Model Specifications. NHTSA reserves the right to test any unit on the CPL throughout its useful life to ensure that the unit is performing in accordance with the Model Specifications.

If at any time a manufacturer plans to change the design of a calibrating unit currently on the CPL, the manufacturer shall submit the proposed changes to the Office of Traffic Injury Control Programs for review. Based on this review, NHTSA will decide whether the change will require restesting of the unit. Normally, such restesting will be accomplished the next time testing is performed. Guidance to manufacturers on considerations governing this decision are available from NHTSA’s OTICP, upon request.

OTICP will be the point of contact for information about acceptance testing and field performance of equipment already on the list. When it is available, NHTSA requests that users of calibrating units provide both acceptance and field performance data to OTICP. Information from users will be used to: (1) help NHTSA determine whether units continue to perform according to the NHTSA Model Specifications and (2) ensure that field use does not indicate excessive breakdown or maintenance problems.

If information gathered indicates that a device on the CPL is not performing in accordance with the Model Specifications or demonstrates problems involving the device, NHTSA will direct VNTSC to conduct a special investigation. This investigation may include visits to users and additional tests of the unit obtained from the open market. If the investigation indicates that the units actually sold on the market are not meeting the Model Specifications, then the manufacturer will be notified that the unit may be removed from the list. In this event the manufacturer shall have 30 days from the date of notification to reply.

Based on the VNTSC investigation and any data provided by the manufacturer, NHTSA will decide whether the unit should remain on the list. Upon resubmission, the manufacturer must submit a statement describing what has been done to overcome the problems that led to the dropping of the unit in question from the list.

C. Infra-red Spectroscopy

In this notice, NHTSA is proposing an alternate procedure which uses infra-red spectroscopy for the evaluation of dry gas units (see Appendix A). It is proposed as an amendment to the Model Specifications for Calibrating Units published in this notice. In infra-red spectroscopy, the wet bath or dry gas sample to be analyzed is passed into a chamber through which infra-red radiation is transmitted. The wavelength of the transmitted radiation is chosen so that some of it is absorbed by alcohol. According to the Beer-Lambert Law of absorption of radiation, the amount of energy absorbed by the sample in the chamber is proportional to the concentration of the alcohol in the sample. By measuring the amount of radiation transmitted when the sample chamber is empty and the amount transmitted when the sample is present, the concentration of the alcohol in the sample can be determined.

In this notice, NHTSA is proposing an alternate procedure which uses infra-red spectroscopy for the evaluation of dry gas units (see Appendix A). It is proposed as an amendment to the Model Specifications for Calibrating Units published in this notice. In infra-red spectroscopy, the wet bath or dry gas sample to be analyzed is passed into a chamber through which infra-red radiation is transmitted. The wavelength of the transmitted radiation is chosen so that some of it is absorbed by alcohol. According to the Beer-Lambert Law of absorption of radiation, the amount of energy absorbed by the sample in the chamber is proportional to the concentration of the alcohol in the sample. By measuring the amount of radiation transmitted when the sample chamber is empty and the amount transmitted when the sample is present, the concentration of the alcohol in the sample can be determined.

The agency believes that use of infra-red spectroscopy will offer several important advantages. First, the technique can be used to evaluate both wet bath calibrating units and dry gas calibrating units because surface interactions do not effect the analysis. Second, standards used in the evaluations can be prepared at the Volpe Center, eliminating the necessity of obtaining standards from an outside source.

D. Comments

Interested persons are invited to comment on the proposed alternate procedure described in this notice. It is requested, but not required that 10 copies be submitted. Comments must not exceed 15 pages in length (49 CFR 553.221). Necessary attachments may be appended to those submissions without regard to the 15 page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

All comments received before the close of business on the comment closing date indicated above will be considered, and will be available for examination in the docket at the above address, both before and after that date. To the extent possible, comments filed after the closing date will also be considered. However, the amendments to the Model Specifications may be published at any time after that date, and any comments received after the closing date and too late for consideration with regard to the action will be treated as suggestions for future revisions to the Specifications. NHTSA will continue to file relevant material in the docket after the closing date as it becomes available. It is recommended that interested persons continue to examine the docket for new material.

Those persons who desire to be notified upon receipt of their comments in the docket should enclose a self-addressed stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

E. Conforming Products List

The Conforming Products List (CPL), which appears as Appendix B to this notice, lists the calibrating units that have been retested to date at the lower BACs (i.e., at 0.020, 0.040, 0.080, and 0.160) and found to conform to the Model Specifications reprinted herein. The CPL also lists devices that have not been tested at these lower BAC levels, but which were listed on a previous CPL for calibrating units (59 FR 26030) on the basis that they were tested and found to conform to the earlier model specifications when tested at BAC levels 0.050, 0.100 and 0.150. These devices have been identified with an asterisk.

This CPL also includes five new listings: four dry-gas calibrating units and one wet-bath calibrating unit. The dry gas units include: Model EBS™ Gasous Ethanol Breath Standard submitted by Scott Specialty Gases, Inc. of Plumsteadville, PA; the Ethanol Breath Alcohol Standard submitted by Gateway Airgas (previously known as A.G. Specialty Gas Company, or Acetylene Gas Company) of St. Louis, MO; the AlcoCal Breath Alcohol Standard submitted by Lion Laboratories, plc of Cardiff, Wales, UK; and Compressed ethanol-in-nitrogen submitted by Liquid Technology Corporation of Orlando, FL. All of the dry-gas calibrating units were tested using the alternate procedure that uses the NISTRM. The new wet-bath unit is Model 3402C submitted by Repco Marketing, Inc., of Raleigh, NC.

In consideration of the foregoing, NHTSA amends the Model Specifications for Calibrating Units, as last published in the Federal Register on December 29, 1994 (59 FR 67377), as set forth below. NHTSA proposes to further amend these Model Specifications, as set forth in Appendix A.
Model Specifications for Calibrating Units for Breath Alcohol Testers

1.0 Purpose and Scope

These specifications establish performance criteria and methods for testing of calibrating units which provide known concentrations of ethanol vapor for the calibration of breath alcohol testers. The results of this testing are intended for use in the conformance testing for the maintenance of a Conforming Products List for calibrating units.

2.0 Definitions

2.1 Conformance testing. Testing to check the conformance of a product with these model specifications in advance of and independent of any specific procurement action.

2.2 Concentration units. Blood alcohol concentration: grams alcohol per 100 milliliters blood or grams alcohol per 210 liters of breath in accordance with the Uniform Vehicle Code, Section 11-903(a)(5).

2.3 Relative Standard Deviation (RSD). The ratio of the standard deviation (SD) of a series of measurements to the mean of the series expressed as a percentage:

\[ \text{RSD} = \left( \frac{\text{SD}}{\text{Mean}} \right) \times 100 \%
\]

2.4 Standard Deviation (SD). A common indication of precision in the measurement of the concentration of a succession of N vapor samples.

\[ \text{SD} = \sqrt{\frac{\sum (X_i - \bar{X})^2}{N-1}} \]

where \( X_i \) is a single measurement result; \( \bar{X} \) = the average of the measurements; \( N \) = the number of measurements made in the test.

2.5 Systematic Error (SE). An indication of the accuracy of the measurement of the concentration of a succession of vapor samples.

\[ \text{SE} = \text{X}_{\text{m}} - \text{test} \text{ BrAC} \]

2.6 Least Squares Fit Calibration Curve. A line fitted to a number of measurement pairs, one the independent value (X) and the other the dependent value (Y), over a measurement range.

The fitted line is of the form: \( Y = a + bX \), where intercept, \( a = \bar{Y} - b\bar{X} \), and slope, \( b = \frac{\sum (X_i - \bar{X})(Y_i - \bar{Y})}{\sum (X_i - \bar{X})^2} \).

3.0 Tests and Requirements

3.1 Test Procedure (Original, Wet-bath)

Equipment and Supplies: Gas Chromatograph capable of complete resolution of ethanol in test samples, with heated gas sampling valve. Water bath thermostated at 34°C ± 0.1°C. Glass Reference Sample Bottles (300 ml capacity or greater) with Stopper and Inlet and Outlet Air Hoses (see Figure 1). Hoses should be about 1/8” OD Teflon tubing. Reference Ethanol Solutions prepared using class A glassware and American Chemical Society reagent grade ethanol or USP grade ethanol. The purity of the ethanol used shall be compared with the National Institute of Standards and Technology (NIST) Standard Reference Material for ethanol. Use the value of Harger, et al., for the partition ratio for concentration of ethanol in head space to concentration in solution at 34°C, \( K_a = 0.00393 \) to prepare two solutions which, when thermostated at 34°C, produce head space ethanol vapor concentrations that bracket the test BrAC by no more than ±20%. Small Air Pump for bubbling air through reference solutions (see Figure 1).

Step 1. Prepare the Gas Chromatograph for measurement of vapor samples. Adjust instrument temperatures, gas flows, detector, and recording device for optimum response for ethanol. Prepare the CU for use according to manufacturer’s instructions.

Step 2. Fill two reference solution bottles to 7/8 full with above reference solutions. Insert stopper assemblies with bubble line and alcohol vapor line in place and put bottles in the water bath with water level up to the stopper. Connect air pump to bubble line. Connect alcohol vapor line to gas chromatograph sampling valve inlet fitting. Allow 1 hour for temperature equilibrium to be achieved.

Step 3. Turn on air pump which has been pre-set to pump air through the reference solution bottle-gas chromatograph sampling assembly at a rate just sufficient to thoroughly flush the system in 10 seconds. After flushing is complete, allow the sample to relax to atmospheric pressure, then inject the reference sample onto the gas chromatograph column. In this way, obtain 5 chromatograms of one of the reference solution head space ethanol vapors.

Step 4. Thoroughly flush the sample loop with vapors from the CU device, while avoiding over-pressurizing of the sampling system. To prevent condensation of alcohol, warn the transfer line if necessary. Allow the sample to relax to atmospheric pressure, then inject the sample onto the column. In this way, obtain 10 ethanol chromatograms using the CU device.

Step 5. Repeat step 3 using the second reference solution.

Step 6. Calculations. Peak height to BrAC conversion factor. For each ethanol peak obtained in step 2 and step

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\[ R_S = \frac{w_{\text{peak}}}{{\text{BrAC}}_{\text{peak}}} \]

where \( w_{\text{peak}} = 0.000393 \) and \( w = 0.0000393 \) to prepare two solutions which, when thermostated at 34°C, produce head space ethanol vapor concentrations that bracket the test BrAC by no more than ±20%. Small Air Pump for bubbling air through reference solutions (see Figure 1).

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5, calculate a conversion factor for ethanol concentration by dividing the equivalent BrAC of the vapor sample by the peak height obtained for that sample. From the ten samples, obtain the mean and the RSD of the conversion factors. If the RSD obtained fails to meet the criteria for RSD in 3.0, perform necessary troubleshooting and repeat the procedure from Step 1. Use the mean of the conversion factors to calculate the BrAC for each of the 10 ethanol peaks obtained in step 4. Calculate the mean, the RSD, and the systematic error of the experimental BrACs.

Figure 1. Wet Bath Reference Sample Set-up. Sample lines 1/8” Teflon. The bubble line should extend at least 4 inches below surface of the solution. The length of the alcohol vapor line from the headspace to the gas chromatograph should be minimized.

3.2 Test Procedures (for dry gas Calibrating Units): Alternate Test Method Using National Institute of Standards and Technology Reference Gas Mixtures (NISTRGMs) in Place of Wet Bath Reference Samples

The following alternate method for the evaluation of dry gaseous ethanol calibration devices is presented.

Additional required material: For the alternate method for evaluation of dry gaseous ethanol calibration devices, the following will be required: Four cylinders of National Institute of Standards and Technology ethanol-inert gas Technical Reference Gas Mixtures (NISTRGMs) which span the BrAC range 0.01 to 0.16.

Alternate Procedure for evaluation of dry gaseous ethanol calibration devices. This procedure substitutes the use of NISTRGMs in place of the wet bath reference samples when evaluating dry gas CUs.

**Step A1.** Connect one of the NISTRGM cylinders to the inlet of the gas chromatograph sampling valve and pass reference gas through the sampling system at a rate just sufficient to thoroughly flush the system in about 10 seconds. Allow the sample to relax to atmospheric pressure, then inject the sample onto the column. In this way, obtain 5 chromatograms of the reference gas.

**Step A2.** Repeat Step A1 for each of the four NISTRGM reference gas mixtures.

**Step A3.** Calculate the RSD of the concentration divided by peak height data obtained in Step A1 and Step A2. If the calculated RSD meets the criteria of 3.0, calculate the slope and intercept of the least squares fit calibration line for conversion of peak height to BrAC. Using the average peak height of each NISTRGM and the slope and intercept data, calculate the concentration of each NISTRGM. If the resulting concentrations are within the stated accuracy of the NISTRGM, proceed to Step A4.

**Step A4.** Connect the calibrating device to the inlet of the gas chromatograph sampling system and allow the calibrating device gas to flow at a rate just sufficient to thoroughly flush the sampling system in about 10 seconds. Allow the sample to relax to atmospheric pressure, then inject the sample onto the column. In this way, obtain 10 chromatograms of the calibrating device gas.

**Step A5.** Calculations. Using the peak height data obtained in Step A4 and intercept and slope data obtained in Step A3, calculate the BrAC for each of the 10 peak heights. Calculate the mean, RSD, and systematic error of the calculated BrACs.

**Authority:** 23 U.S.C. 402; delations of authority at 49 CFR 1.50 and 501.

Issued: August 7, 1997.

James Hedlund,
Associate Administrator for Traffic Safety Programs.

**Appendix A—Proposed Alternate Procedure Using Infra-Red Spectroscopy**

This appendix presents an alternate procedure using infra-red spectroscopy that is suitable for evaluating vapor samples from either wet-bath CUs, or from dry-gas CUs.
3.3 Proposed Test Procedures (for dry gas or wet bath calibrating units).

3.3.1 General. The method uses the Beer-Lambert Law of absorption of radiant energy by fluids. A glassware and American Chemical Society reagent grade ethanol or USP grade ethanol. The purity of the ethanol used shall be compared with the National Institute of Standards and Technology (NIST) Standard Reference Material for ethanol. Use the value of Harger, et al., for the partition ratio for concentration of ethanol in head space to concentration in solution at 34°C, \( K_{0/20} = 0.000393 \) to prepare two aqueous alcohol solutions which bracket the test BrAC by no more than ±20%. A cylinder of inert flushing gas, which is optically clear in the absorption region used for measurement. The gas will be used to flush the sample chamber of the spectrophotometer and to deliver reference headspace vapors and wet bath sample vapors into the sample chamber.

Where:
- \( I_o \) is the energy entering the sample chamber of a spectrophotometer containing the sample to be analyzed.
- \( I \) is the energy transmitted from the sample chamber.
- \( a \) is the absorptivity of the sample.
- \( b \) is the radiation path length of the sample chamber.
- \( c \) is the concentration of the sample in the sample chamber.

A convenient form of the Beer-Lambert law is

\[
\ln(I_o/I) = abc
\]

where the term \( \ln(I_o/I) \), the logarithm of the ratio of incident to transmitted energy, is called the absorbance of the sample. In the procedure described below, the terms a and b are treated as a single quantity, ab, and the term c is BrAC.

3.3.2 Test Procedure.

Equipment and Supplies. Infra-red Spectrophotometer with sample chamber that can be heated to above 40°C. A non-dispersive instrument with appropriate band pass filters and configured to measure breath alcohol samples, such as an infra-red evidential breath tester listed on the NHTSA Comforting Products List for evidential breath testers may be used. The detector voltage of the instrument must be accessible for measurement. The sampling hoses of the device may be altered for more convenient processing of test samples. Water bath thermostated at 34°C ±0.1°C. Glass Reference Sample Bottles (300 ml capacity or greater) and Stoppers with Bubble and Alcohol Vapor lines (see Figure 2). Reference Ethanol Solutions prepared using Class A.
Infra-red (IR) and fuel cell breath testers may be calibrated with either wet-bath or dry-gas CUs. However, it is inadvisable to use dry gas CUs when calibrating gas chromatograph EBTs.

Several variations of the Model 34C Simulator have also been submitted to NHTSA for evaluation and meet these Model Specifications. They are: Model 34C Cal DOJ; Model 34±C±FM; and 34C±NPAS.

1. CMI, Inc., Owensboro, KY:
   - Toxitest II
2. Federal Signal Corporation, CMI, Inc., Minturn, CO:
   - Toxitest Model ABS120*
3. Gateway Airgas, Inc. (Formerly known as AG Specialty Gas, and Acetylene Gas Company), St. Louis, MO.
   - Ethanol Breath Alcohol Standard (a dry gas standard).
4. Guth Laboratories, Inc., Harrisburg, PA:
   - Model 34C Simulator 2
   - Model 3412
   - Model 10-4
   - Model 1214
5. Intoximeters, Inc., St. Louis, MO:
   - Alco Breath Alcohol Standard* (a dry gas standard)
6. Lion Laboratories, plc, Cardiff, Wales, UK (a subsidiary of CMI, Inc.)
   - AlcoCal Gas Standard (a dry gas standard).
7. Liquid Technology Corporation, Orlando, FL
   - Alcohol-in-Nitrogen Calibrating Unit (a dry-gas standard).
8. Luckey Laboratories, Inc., San Bernardino, CA:
   - Simulator*
   - Mark II-A
10. PLD of Florida, Inc., Rockledge, FL:
    - BA 500
    - LS34 Model 6100*
12. Repco Marketing, Inc., Raliegh, NC:
    - AS-1
    - Model 3402C
13. Scott Specialty Gases, Inc., Plumsteadville, PA
    - Model EBS™ Gaseous Ethanol Breath Standard (a dry-gas standard).
    - Mark II-A Simulator*
15. Systems Innovation, Inc., Hallstead, PA
    - True-Test MD 901*
16. U.S. Alcohol Testing, Rancho Cucamonga, CA:
    - Alco-Simulator 2000*
    - Alco—Simulator 61000* Instruments marked with an asterisk (*) meet the Model Specifications in 49 FR 48864 (December 14, 1984), i.e. instruments tested at 0.050, 0.100, and 0.150. Instruments not marked with an asterisk meet the model specifications detailed in this notice, and were tested at 0.020, 0.040, 0.080, and 0.160 BrAC.

**Figure 2. Equipment set-up. Bubble and sample lines 1/8″ teflon, minimized length. Depth of bubble line into reference solution at least 4″. The alcohol vapor line from the headspace to the IR spectrophotometer should be minimized.**

**DEPARTMENT OF TRANSPORTATION**

National Highway Traffic Safety Administration

[Docket No. 97–051; Notice 1]

Notice of Receipt of Petition for Decision That Nonconforming 1987–1997 Kawasaki ZX400 Motorcycles Are Eligible for Importation

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Notice of receipt of petition for decision that nonconforming 1987–1997 Kawasaki ZX400 motorcycles are eligible for importation.

**SUMMARY:** This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1987–1997 Kawasaki ZX400 motorcycles that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

**DATES:** The closing date for comments on the petition is September 12, 1997.

**ADDRESSES:** Comments should refer to the docket number and notice number, and be submitted to: Docket Section, Room 5109, National Highway Traffic Safety Administration, 400 Seventh St.,