

Florida Department of Law Enforcement

Guy M. Tunnell, Commissioner

Jeb Bush, Governor Charlie Crist, Attorney General Tom Gallagher, Chief Financial Officer Charles H. Bronson, Commissioner of Agriculture

MEMORANDUM

TO: Department Inspectors and Agency Inspectors

Laura D. Barfield, Alcohol Testing Program Manager FROM:



DATE: April 17, 2006

SUBJECT: Dry Gas Standard Cylinders

The following information concerns Dry Gas Standard (DGS) cylinders used with the Intoxilyzer 8000 evidentiary breath test instrument in Florida. The approved source of DGS is Scott Specialty Gases, Inc. (Scott).

Cylinder Size: Scott manufactures two sizes of DGS disposable cylinders, 28L and 105L. The 105L cylinder is designed to fit the cylinder carrier attached to the Intoxilyzer 8000.

Label: Each DGS cylinder displays a label which notes the Lot Number, Ethanol Concentration, and Expiration Date.

- 1. The lot number consists of six (6) numbers and one (1) letter (Example: 504802I).
- 2. The Ethanol Concentration used in Florida instruments is 0.080 g/210L.
- 3. DGS cylinders must not be used beyond the expiration date.

Certificate of Analysis: Each DGS cylinder is accompanied by a copy of the Certificate of Analysis for that lot. You need only retain one copy of the Certificate of Analysis for each lot.

Handling and Disposal: DGS cylinder temperature should not exceed 120°F, which may cause the cylinder to rupture. DGS cylinders are considered hazardous materials for transport and disposal purposes.

If you have any questions concerning this information, please feel free to contact me at (850) 410-7810.

LDB

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Florida Department of Law Enforcement

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MEMORANDUM

TO:	Agency Inspectors
FROM:	Laura D. Barfield, Alcohol Testing Program Manager LDB
DATE:	March 14, 2006
SUBJECT:	Approved Source of Dry Gas Standard

The approved source of dry gas standard for the Intoxilyzer 8000 evidentiary breath test instrument in Florida is

Scott Specialty Gases, Inc. P.O. Box 310 Plumsteadville, PA 18949-0310 Phone 215-766-8861 Fax 215-766-0320

The official distributor of Scott Specialty Gases, Inc. dry gas standard is CMI, Inc. 316 East Ninth Street Owensboro, Kentucky 42303 Phone 866-835-0690 Fax 270-685-6678

You may contact Scott Specialty Gases, Inc. for more information about dry gas standard vendors in Florida.

The dry gas standard concentration to be used in accordance with Chapter 11D-8, FAC is 0.08 g/210L. When purchasing dry gas standard, you will receive a Certificate of Analysis for a dry gas standard lot with each **cylinder** from that lot. You need only retain one copy of the Certificate of Analysis for each lot.

If you have any questions concerning the dry gas standard, please feel free to contact me at (850) 410-7810.

LDB

cc:Department Inspectors

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Criminal Justice Professionalism Program Post Office Box 1489, Tallahassee, Florida 32302-1489 • (850) 410-8600 www.fdle.state.fl.us



Florida Department of Law Enforcement

Guy M. Tunnell, Commissioner

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MEMORANDUM

TO: Edward M. Spooner, Special Operations Administrator

FROM: Laura D. Barfield, Alcohol Testing Program Manager

DATE: March 21, 2006

SUBJECT: Scott Specialty Gases, Inc. Site Inspection

A site inspection of Scott Specialty Gases, Inc. was conducted on Wednesday, March 1, 2006 in Plumsteadville, Pennsylvania. I have attached the site inspection report for your review. Scott Specialty Gases, Inc. is the approved source for Dry Gas Standard used with the CMI, Intoxilyzer 8000 breath test instrumentation in the State of Florida.

If you have any questions, please feel free to contact me at 410-7810.

LDB

Attachment

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Florida Department of Law Enforcement Alcohol Testing Program Site Inspection Report – Dry Gas Standard Approved Source

Introduction

The Florida Department of Law Enforcement Alcohol Testing Program has approved Scott Specialty Gases, Inc., as the source of dry gas standard (DGS), which Scott calls Ethanol Breath Standard (EBS®), for use with the Intoxilyzer 8000 evidentiary breath test instrumentation as provided in Chapter 11D-8, Florida Administrative Code. FDLE's authority is derived from Section 316.1932, Florida Statutes. DGS is primarily used to verify an instrument's calibration.

On Wednesday March 1, 2006, FDLE members visited Scott's corporate headquarters and manufacturing facility in Plumsteadville, Pennsylvania. The visit included meetings with Scott's representatives, including Q & A sessions and a walking inspection of manufacturing, testing, and storage facilities. This report summarizes the site inspection and denotes information and documentation obtained or verified as a result.

Date

March 1, 2006

Location

Scott Specialty Gases, Inc. 6141 Easton Road, Building 1 Plumsteadville, PA 18949

Inspection Team

Laura D. Barfield, FDLE Alcohol Testing Program Manager Rafael E. Madrigal, FDLE Assistant General Counsel

Reference Materials

Products Specification Correspondence Sample Work Order Sample Label Sample Certificate of Analysis Product Reliability Report (Shelf-Life Study) Miscellaneous Brochures & Catalogs USDOT Conforming Products List of Calibrating Units

Corporate Information

Fred Merz – Chief Executive Officer Joe Munley - Group Vice President Dave Hughes - Plant Manager Steve Miller - Chief Technical Officer/Research and Development Vice President Ken Eichelmann - Product Manager Josh Luey - Production Supervisor Transportables, Eastern Region Lance Silverman - Former Vice-President, Research & Development

Scott Specialty Gases, Inc. is a pioneer in the industry and has been manufacturing DGS since the late 1980's, and assisted the National Institute of Standards and Technology (NIST) in establishing specifications and protocols for dry gas standard references. Scott prepares ethanol dry gas standard references using the NIST protocols, and then submits it to NIST for analysis. NIST analyzes them and certifies them as their ethanol dry gas standard references for use as analytical verification standards by ethanol gas manufacturers.

Pennsylvania Facility

Scott has six (6) regional manufacturing facilities, but the Pennsylvania regional facility is the only one that presently manufactures DGS. The facility houses both the company's headquarters and the manufacturing plant.

The facility requires security-access passes and is secured after hours by an automatic locking system, alarm system, and security cameras. All visitors are screened upon arrival and are accompanied by a Scott employee while in the facility.

Dry Gas Standard Product

Overview

Scott manufactures two sizes of DGS disposable cylinders, 28L and 105L. The size best suited for use in an Intoxilyzer 8000 is the 105L cylinder.

DGS is composed of high-quality pure liquid ethanol and liquid nitrogen. Both components are certified as pure by the supplier. Scott's DGS maintains its certified concentration for more than two years after the date of manufacture.

DGS cylinder temperature should not exceed 120°F, which may cause the cylinder to rupture. The CMI, Intoxilyzer 8000 compensates for barometric pressure when using DGS. DGS cylinders are labeled "Hazardous Materials" for transport and disposal purposes.

DGS Lots

A lot is the number of DGS cylinders filled at the same time, up to twenty-four (24) cylinders per lot. The lot number represents the date of manufacture, the manufacture run on a specific manifold on that date, and the filling manifold used. The manufacture date's first digit depicts the year, the next three digits depict the numbered day of the year, the last two digits depict the manufacture run, and the letter depicts the filling manifold used (Example: Lot #5048021 represents the second run of February 17, 2005, on manifold I).

A Certificate of Analysis is generated for each lot. Each DGS cylinder is labeled and a copy of the Certificate of Analysis is placed with each cylinder for distribution. At least two inspectors review the label and Certificate of Analysis on each DGS cylinder for accuracy and correctness.

DGS Labels

Each DGS cylinder displays a label which notes Lot #, Ethanol Concentration, and Expiration Date which is two years from the date of analysis. Each label is verified by a tracking and inspection process.

Manufacturing Process

Overview

All manufacturing processes and procedures are 9001/2000 Certified by the International Standards Organization (ISO), and are audited bi-annually by ISO.

Air monitors are located throughout the manufacturing plant to measure air quality for possible contaminants.

The DGS manufacturing process is ongoing and based on demand, and takes approximately five (5) days to complete. The plant is capable of producing a minimum of nine-hundred (900) 105L DGS cylinders. Although all DGS is manufactured at the Pennsylvania plant, other plants could be quickly re-tooled to meet additional demand.

Master Cylinders

The master cylinder is a 6800L, high pressure, reusable cylinder used to fill lots of disposable DGS cylinders.

The manufacturing process begins by preparing a master cylinder (Blend Master) which is heated and conditioned to ensure cleanliness and to prevent contamination prior to use. Master cylinders are then connected to a sealed-system manifold used only for DGS. A vacuum is applied to ensure that all master cylinders are empty and to verify the manifold seal. All master cylinders on the manifold are then simultaneously filled with DGS.

The DGS concentration is achieved as the liquid ethanol and liquid nitrogen are converted to gases and are blended (mixed) into the master cylinders. The blending of gases used in the manufacture of DGS is called FlexblendTM. This includes a "real time" analysis of the gas mixture being blended to ensure a proper concentration. All master cylinders filled at the same time will have the exact same concentration. Up to forty (40) master cylinders can be filled at one time. The filled cylinders are allowed to sit for one (1) day to ensure the stability of the gas mixture.

The contents of at least one blended master cylinder is analyzed using gas chromatography to ensure that the master cylinders contain the proper concentration and are not contaminated.

DGS Cylinders

DGS cylinders are heated and conditioned to ensure cleanliness and to prevent contamination prior to use. DGS cylinders are then connected to a sealed-system manifold used only for DGS A vacuum is applied to ensure that all cylinders are empty and to verify the manifold seal. All cylinders on the manifold are then simultaneously filled with DGS from a master cylinder connected to the manifold.

After a DGS lot is completed, the cylinders are allowed to sit for at least two (2) days to ensure the stability of the gas mixture. After that time each cylinder in the lot is analyzed using a flame ionization detector to ensure that each cylinder contains the proper concentration. At least one (1) cylinder from each lot is retained by Scott for stability and shelf-life testing.

Scott retains DGS records for seven (7) years for accounting purposes.

Quality Control

Scott uses NIST certified standard references to verify the concentration of master cylinders and each DGS cylinder. NIST certified standard references are analyzed before the analysis of blended master cylinders, and a NIST certified standard reference is analyzed before and after the analysis of each DGS cylinder. These processes verify that master cylinders and each DGS cylinder are traceable to NIST standards.

The analysis of each DGS cylinder results in issuance of one Certificate of Analysis for the entire lot certifying the concentration of all cylinders in that lot. A DGS cylinder from each lot is periodically analyzed to ensure that the concentration remains within the specified tolerances.

Distribution

Scott's official DGS distributors are the manufacturers of breath test instrumentation who receive and process orders. The official distributor for Florida users is CMI, Inc. Distributors receive DGS orders from customers and either Scott or the distributor will ship the product via FEDEX Ground or other comparable shipping method. Payment for DGS orders is made directly to the distributor.

Conclusion

Scott Specialty Gases, Inc. produces a quality dry gas standard for use with the CMI, Intoxilyzer 8000 breath test instrumentation. Scott has implemented more than adequate quality control processes to ensure an accurate and reliable product. Scott continues to satisfy all requirements under Chapter 11D-8, FAC, for the source of dry gas standard for the State of Florida.



Scott Specialty Gases

6141 EASTON ROAD, P.O. BOX 310, PLUMSTEADVILLE, PA 18949-0310 215-766-8861 FAX 215-766-0320 www.scottgas.com

Ms Laura D. Barfield Florida Department of Law Enforcement Alcohol Testing Program Manager P.O. Box 1489 Tallahassee, FL 32302-1489 March 22, 2006

RECEIVED

Subject: Product Specifications / Capabilities of Scott Specialty Gases

FDLE Alcohol Testing Program

MAR 2 4 2006

Dear Ms Barfield,

We are pleased that you and Rafael Madrigal (Assistant General Counsel) were able to meet with us and tour our manufacturing facility on March 1st, 2006. In preparation of the State of Florida (your customer) switching over to the CMI Intoxilyzer[®] 8000 instruments and using our dry gas standards for calibration verification, I am pleased to review the Scott specific product specifications and to assure your customer of our capabilities by documenting our capabilities as follows:

- 105-liter steel cylinder.
- NIST (National Institute of Standards and Technology) traceable product.
- Gas concentration (nominal value) of 0.080 g/210L or the equivalent of 208.4 ppm balance nitrogen.
- Analytical accuracy of the nominal value is +/- 2%.
- Product shelf life is two (2) years.
- Certificate of Analysis one provided with each cylinder.
- Ouality Control each cylinder is individually analyzed and pressure checked prior to shipment.
- Bar code and expiration date conveniently located on the cylinder label in multiple locations so once the cylinder is installed on the 8000, it is still visible to the user.
- Manufacturing capacity to produce and ship over 300 cylinders per month, each month.
- Professional packaging of the cylinders in sturdy cardboard boxes with cardboard dividers.
- ISO-9001:2000 certified and maintained manufacturing facility (Plumsteadville, PA).
- NHTSA approved products as listed on their CPL (Conforming Products List).

In addition to our capabilities, attached are the following support documents:

- General statement of how Scott manufacturers its' product and QA processes. (Attachment I)
- General statement of how Scott product is traceable to NIST. (Attachment II)
- A blank sample Work Order, Label, and Certificate of Analysis. (Attachment III)
- A table of data that demonstrates the product stability of at least two years. (Attachment IV)

SCOTTY EBS[®] (Ethanol Breath Standards) Standards were the first ethanol standards available for dry method calibration for law enforcement and DOT testing applications. Scott will continue to set the standard in the manufacturing of dry gas standards by offering the highest quality products available and we are please that the State of Florida has partnered with CMI and Scott.

Best regards,

Ken Eichelmann Product Manager

Attachments

CC: CMI – Pam Hagan

Attachment I – Scott's EBS[®] Manufacturing and QA Processes Florida Department of Law Enforcement – Alcohol Testing Program

The manufacturing of the ethanol products in transportable cylinders used for alcohol testing and calibration verification begin with the making of the master mixture in a large cylinder, referred to as the master cylinder mixture. The raw material for the master cylinder is checked for quality. The master cylinder is prepared by pre-conditioning the cylinder. This is a proprietary process. Once the master cylinder is ready, a mixture of ethanol and nitrogen, as a balance gas, are blended into the large cylinder through a blending technique called FlexblendTM. This is a patented and proprietary process. The master cylinder is then analyzed against a known NIST traceable standard.

The transportable 105-liter cylinder is also pre-conditioned much in the same way as the master cylinder. Multiple 105-liter cylinders are then connected to a manifold, ready to be filled. The master cylinder is then connected to the manifold as well.

The 105-liter cylinders are then filled after a series of line purging operations. After a period of time, they are individually analyzed. The transportable 105-liter cylinders are analyzed and compared against the same NIST standard cylinder. All of the information regarding the master cylinder concentration, master cylinder number, and individual 105-liter cylinder concentration values are documented on the internal Scott work order. A label is applied to the cylinder which contains the concentration of the mixture, the lot number, expiration date, analytical accuracy, and work order number. In addition, a Certificate of Analysis is generated based on the analyzed concentration of the 105-liter cylinder.

The final step is a quality assurance check that the order paperwork and the physical product match up perfectly, including all the information for the cylinder label and Certificate. Once this is initialed by the QA manager, the Certificate is wrapped around the cylinder with a rubber band. The 105-liter cylinders are then placed in a box and shipped to the designated address on the work order.

Attachment II – Scott's EBS[®] Product Traceability to NIST Florida Department of Law Enforcement – Alcohol Testing Program

Scott Specialty Gases manufactures the ethanol in a nitrogen balance mixture as described in Attachment I. The NIST (National Institute of Standards and Technology) standard that is used as a reference standard is obtained and analyzed by NIST.

The naming of standards from NIST are classified as NIST traceable RGM (Reference Grade Material) and NTRM (NIST Traceable Reference Material) standards. The sequence of events is as follows:

- NIST manufacturers primary standards.
- Scott Gas manufactures a set of Flexblend[™] Standards. These are analyzed for homogeneity and stability.
- This data along with a few of the Scott Standards are sent to NIST.
- NIST analyzes and compares the Scott Standards with their own Primary Standards and then names Scott's Standards as RGMs. NIST then returns the cylinders along with the certification of the value to Scott.
- Scott then uses the NTRMs as the Standard SRMs (SRM Certified Scott Reference Material) against which all internal cylinders manufactured are analyzed.

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rom Ship-To Header: 561-747-8500 INCLUDE CUSTOMER'S PACKING SLIP WITH SHIPMENT

rom Bill-To Header: PACKAGES MUST BE MARKED WITH CORRECT CUSTOMER PO # ON SIDE OF BOX & ACCOMPANIED BY PACKING SLIP IN EACH BOX. COUNTRY OF ORIGIN - USA, CHECK CERTIFICATION SHEETS PRIOR TO SHIPPING, EACH CERT SHEET MUST BE CLEAN & A GOOD READABLE COPY.

rom Order Item: ATTACH "O" RING TO CYLINDER PRIOR TO SHIPPING CMI TO SUPPLY "O" RINGS FOR THIS PRODUCT ONLY DROP SHIPPING TO FLORIDA.

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ЕХР DATE EXP DATE EXP DATE EXP DATE EXP DATE EXP 1001335 M 4580	FEDERAL LAW FORBIDS TRANS- PORTATION IF REFILLED-PENALTY UP TO \$500,000 FINE AND 5 YEARS IMPRISONMENT (49 U.S.C. 5124).	CAUTION CAUTION High pressure gas. Can cause suffocation.	WARNING Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperature above 52°C (125°F) may cause contents to vent or cause bursting.	Never throw containcr into fire or incinerate. Store and use with adequate ventilation. Use with equipment rated for cylinder pressure. Use in accordance with appropriate Materials Safew Data Sheet	FIRST AID FIRST AID IF INHALED. remove to fresh air. If not breathing. give artificial respiration. If breathing is difficult, give oxygen.	FIRE ACTION Move container from fire area, if you can do so without risk. Cool container exposed to flames with water from the side until well after	the fire is out. FOR LABORATORY, LAW ENFORCEMENT AND	INDUSTRIAL/COMMERCIAL USE ONLY SGL105-CMI EXPIRATION DATE:
								lty Gases.
EXP DD/YYYX EXP DATE Standard Breath Standard Breath B S S S S S S S S S S S S S S S S S S S		EBS	Ethanol Breath Standard 0.080 BAC Ethanol +/- 2%	Balance Nitrogen	PROJECT # XXXXXX-XXXX	See Altitude Correction Chart for Conversion Certification: Traceable to N.J.S.T. RGM Ethanol Standards	CONTENTS: 105 Liters @ 1000 psig, 70°F (21°C	This SCOTTY®105 This SCOTTY product manufactured by Scott. SCOTTY® is a registered Trademark of Scott Specialty Gases
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Scott Specialty Gases, Inc.

CERTIFICATE OF ANALYSIS EBS[™] - Ethanol Breath Standard

Customer Name CMI 316 East Ninth Street Owensboro, KY 42303	Assay Laboratory Scott Specialty Gases 6141 Easton Road, Bldg. 1 Plumsteadville, Pa. 18949	Purchase Order: XXXXXX/XXXXXX Scott Project # XXXXXX Lot No.: XXXXXXX Expiration Date: Month Day, Year
REFERENCE STANDARD	CYLINDER #	CONCENTRATION ppm
N.I.S.T. Traceable Standards*	ALM-060154	103.6
	ALM-060204	118.1
	ALM-059962	222.2
	ALM-037472	251.0
CONTAINER TYPE:105		

LOT CERTIFIED VALUE CONCENTRATION

COMPONENTS Ethanol Nitrogen ppm (BrAC) 208.4 (0.080) Balance ACCURACY +/- 2%

*Certification: Traceable to N.I.S.T. RGM Ethanol Standards

Analyst:

Date: MM/DD/YYYY

Attachment IV – Scott's EBS[®] Product Reliability Florida Department of Law Enforcement – Alcohol Testing Program

The reliability of Scott's EBS[®] Ethanol Breath Standards in the 105-liter steel cylinder is based on extensive shelf life studies. The Scott product is private labeled for CMI and carries the same shelf life as the product would under the Scott Gas label. That shelf life is two (2) years from the initial analysis date and is documented on the cylinder label with an expiration date that is two years into the future, formatted mm/dd/yyyy.

The table below is a representative sample of the product stability produced by Scott Specialty Gases. These are cylinders from actual lots produced and sold over the last two to four years. They are all of the 0.080 g./210L = 208.4 PPM concentration* with an accuracy of +/- 2%, or a concentration range of 204.2 PPM to 212.6 PPM.

Lot # / Cylinder #	Initial Conc.	After 6 mo.	After 1 yr.	After 2 yrs.
2042011 / 15	209.66	209.28	210.85	210.19
210202I / 6	209.10	208.10	209.10	208.67
2135011 / 24	207.16	208.01	208.23	207.97
221201H / 19	207.40	207.94	207.48	207.79
2212011 / 8	208.16	209.39	208.99	209.21
221301H / 20	206.68	208.23	207.66	207.79
221302H / 15	206.78	207.64	207.48	207.45
221401H / 13	206.95	207.03	207.52	207.50
221402H / 1	207.76	208.52	208.19	207.98
221501H / 2	207.49	207.94	207.21	207.65
2255011 / 7	208.83	210.26	210.50	209.88
3227021 / 13	207.94	210.52	210.80	209.30
328401G / 2	209.97	208.80	208.24	206.40
3303021 / 21	211.57	210.70	210.43	208.16
4020011 / 13	209.09	209.21	208.94	206.97
4043011 / 16	209.26	208.17	208.30	205.29

(All concentration values in PPM (parts per million)

NOTE: * The correlation factor of 2605 for g/210L to PPM is based on documented research by Dr. Kurt Dubowski (while at the University of Oklahoma) and other researchers. The conversion formula is PPM / 2605 = g./210L (at 760mm, 34°C).



EBS[®]

Ethanol Breath Standards for CMI Analyzers

SCOTTY® EBS calibration gases are engineered to provide accurate calibration verification of CMI breath alcohol testing instruments. They are an integral design feature of CMI breath analyzers and used at the factory to ensure instrument performance prior to delivery. Prepared by Scott Specialty Gases, a world leader in specialty gas technology, EBS products are manufactured in an ISO-9001:2000-certified production facility, and cylinders are individually analyzed and pressure checked to ensure quality.

	ntrations in Nitrogen Balance ninal Values)
0.040 g/210L	104.2 ppm equivalent
0.045 g/210L	117.2 ppm equivalent
0.080 g/210L	208.4 ppm equivalent
0.085 g/210L	221.4 ppm equivalent
0.100 g/210L	260.5 ppm equivalent
0.105 g/210L	273.5 ppm equivalent







EBS Ethanol Breath Standards are available in two convenient cylinder sizes: 105-liter steel (above) and 28-liter aluminum (left).

SCOTTY EBS Features

- Guaranteed ±2% analytical accuracy (of nominal value) and 2-year shelf life provide accurate, dependable instrument calibration to help prevent faulty instrument readings
- Certificate of Analysis provided with each cylinder ensures product integrity and provides a detailed audit trail by unique cylinder number
- NHTSA APPROVED as listed on their Conforming Products List of Calibrating Units
- Direct traceability to National Institute of Standards & Technology (NIST) standards ensures reliable product accuracy
- Barcode and expiration date appearing on cylinder label are clearly visible when installed in the instrument

CENT INC. 316 East 9th Street, Owensboro, KY 42303 Toll Free: 1-866-835-0690 Fax: 270-685-6268 www.alcoholtest.com

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DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. 97-2789]

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:

49 U.S.C. Section 5310—Capital Assistance Program for Elderly Persons and Persons with Disabilities and 49 U.S.C. Section 5311-Nonurbanized Area Formula Program.

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 selfaddressed, 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.

Title: 49 U.S.C. Section 5310—Capital Assistance Program for Elderly Persons and Persons with Disabilities and 49 U.S.C. Section 5311 Nonurbanized Area Formula Program. (*OMB Number: 2132–0500.*)

Background

The Capital Assistance Program for Elderly Persons and Persons with Disabilities provides financial assistance for the specialized transportation service needs of elderly persons and persons with disabilities. The program is administered by the States and may be used in all areas, urbanized, small urban, and rural. The Nonurbanized Area Formula Program provides financial assistance for the provision of public transportation services in nonurbanized areas and this program is also administered by the States. 49 U.S.C. Sections 5310 and 5311 authorize FTA to review applications for federal financial assistance to determine eligibility and compliance with statutory and administrative requirements. Information collected during the application stage includes the project budget, which identifies funds requested for project implementation; a program of projects, which identifies subrecipients to be funded, the amount of funding that each will receive, and a description of the projects to be funded; the project implementation plan; the State management plan; a list of annual certifications and assurances; and public hearings notice, certification and transcript. The applications must contain sufficient information to enable FTA to make the findings required by law to enforce the program requirements. Information collected during the project management stage includes an annual financial status report, an annual program status report, and pre-award and post-delivery audits. The annual financial report and program status report provide a basis for monitoring approved projects to ensure timely and appropriate expenditure of federal funds by grant recipients.

Respondents: State and local government, business or other for-profit institutions, non-profit institutions, and small business organizations.

Estimated Annual Burden on Respondents: 102.44 hours for each of the respondents.

Estimated Total Annual Burden: 11,370 hours.

Frequency: Annual.

Issued: August 7, 1997.

Gordon J. Linton,

Administrator.

[FR Doc. 97–21333 Filed 8–12–97; 8:45 am] BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. 94-068; Notice 2]

Highway Safety Programs; Model Specifications for Calibrating Units for Breath Alcohol Testers; Conforming Products List of Calibrating Units

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT. **ACTION:** Notice; request for comments.

SUMMARY: This 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 (NIST) Reference Gas Mixtures (RGMs) 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. This notice also proposes and seeks comment on a new alternate procedure for evaluating the accuracy of both wet bath and dry gas breath alcohol calibrating units using infra-red spectroscopy. Published with this notice is an amended Conforming Products List (CPL) of calibrating units that meet the Model Specifications. This amended list includes five new listings, one wet bath unit and four dry gas units.

DATES: The amendments to the Model Specifications and the issuance of the Conforming Products List of calibrating units meeting the Model Specifications become effective on August 13, 1997. Comments on the alternate testing procedure using infra-red spectroscopy proposed as an amendment to the Model Specifications published herein must be received by October 14, 1997.

ADDRESSES: Comments regarding the alternate testing procedure should refer to the docket number and the number of this notice and be submitted (preferably in ten copies) to the NHTSA Docket Section, Rm. 5109, 400 Seventh St., S.W. Washington, D.C. 20590 (Docket hours are from 9:30 a.m. to 4 p.m.).

FOR FURTHER INFORMATION CONTACT: Dr. James F. Frank, Impaired Driving Division, Office of Traffic Injury Control Programs (OTICP), NTS-11, 400 Seventh St., SW, Washington, DC 20590. Telephone (202) 366–5593.

SUPPLEMENTAL INFORMATION: On August 18, 1975 (40 FR 36167), NHTSA published a standard for Calibrating Units for Breath Alcohol Testers. A Qualified Products List of calibrating units for breath alcohol testers, of devices which met the standard, was

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 alcoholin-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 minor 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 ethanol calibrating devices when "it has been adequately demonstrated that dry-EtOH [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 conformed to established formal specifications and * * * compared favorably with simulator effluents 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."²

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

¹ Dubowski, K. and N.A. Essary "Vapor-Alcohol Control Tests with Compressed Ethanol-Gas Mixtures: Scientific Basis and Actual Performance." Journal of Analytical Toxicology (1996)20, 484. ² Silverman, L.D., Wong, K. and Miller, S. "Confirmation of Ethanol Compressed-Gas Standard Concentrations by a NIST-traceable, absolute chemical method and comparison to wet breath alcohol simulators." Accepted for Publication in the Journal of Analytical Toxicology, 1997.

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, reequilibration 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 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.³

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 pressuredependent 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 Law⁴: 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: $C = C_{760}$ X 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.

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. While manufacturers already provide information on pressure corrections in their instructions to end users, these Model Specifications have been amended to require that the instructions include information about how atmospheric pressure corrections should be made. NHTSA will examine manufacturers' instructions to ensure that they provide sufficient information about these pressure correction procedures. Products submitted without this information will not be tested. NHTSA believes that these procedures will be effective when used by properly qualified breath alcohol technicians.

(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.

³Flores, Arthur, "Dry Gas Calibration Units Report" U.S. Department of Transportation Volpe National Transportation Systems Center, Cambridge MA, September 1996.

⁴ Farrington Daniels & Robert Alberty, "Physical Chemistry" 3rd Ed., John Wiley & Sons, New York. 1966.

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. (c) National Institute of Standards and Technology Reference Gas Mixtures

In the Notice published on December 24, 1994, NHTSA proposed to revise the Model Specifications to permit use of National Institute of Standards and Technology Reference Gas Mixtures (NISTRGMs) as reference samples to evaluate the accuracy of dry gas

calibrating units by gas chromatography. Use of these dry gas standards allows reliable evaluation of dry gas calibrators by the gas chromatograph technique. USAT commented that:

It is rumored that NISTRGMs are manufactured by Scott Specialty Gases/Scott Medical Products Inc. If true, the NHTSAproposed substitution of NISTRGMs to replace wet bath simulator standards for the testing of any Scott Gas gaseous standards amounts to one manufacturer certifying itself and claiming the blessing of both NIST and NHTSA.

The NISTRGMs obtained by the Volpe center were manufactured by Scott Specialty Gases, but were obtained from and analyzed independently by the Department of Commerce National Institute for Standards and Technology (NIST). NIST attested in writing to the accuracy of each individual cylinder of gas which was obtained by the Volpe Center.

(d) The Comparability of Dry Gas Calibrating Units When Used With a Variety of Evidential Breath Testing Devices

USAT commented that "dry gas standards are likely to give different results when used on [evidential breath testers] based on different technologies." According to USAT, there have been reports that dry gas calibrating units do not yield the same results for certain breath testers as wet bath calibrating units. USAT asserts that a small "offset" in test result reportedly occurs when dry gas calibrators are used for these breath testers compared with wet calibrators at the same concentration. The offset for fuel cell breath testers is reported to be -0.002BrAC when dry calibrators are used to check calibration of fuel cell evidential breath testers.

Performance requirements contained in NHTSA's Model Specifications for evidential breath testers require that these instruments be accurate to ± 0.005 or 5% of test BrAC, whichever is greater, with a standard deviation not greater than 0.004. The performance requirements for calibrating units require the devices to be accurate to within 0.002 BrAC of the test BrAC with relative standard deviation of 2%. Any offset associated with a particular calibrator is not considered. Agency testing indicates that dry gas calibrating units can be used with infrared and fuel cell breath testers.⁵ 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 dry comparison data. The instruments tested were:

Life Loc, Inc. PBA 3000 and PBA 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 first 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 0.0052when 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 certain 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 check 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.

Retesting of 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 provided in the **Federal Register**. If NHTSA determines that retesting to the modified

⁵Flores, Arthur, "Dry Gas Calibrating Units Report", U.S. Department of Transportation, Volpe National Transportation Systems Center, Cambridge, MA. September, 1996.

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 retesting of the unit. Normally, such retesting 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 infrared 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,6 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 infrared 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 commentors 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 selfaddressed 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 (58 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 EBSTM' Gaseous 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 NISTRGM. 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.

⁶ Farrington Daniels & Robert Alberty, "Physical Chemistry" 3d Ed. John Wiley & Sons, New York, 1966.

43422

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 or calibration checks 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).⁷ BrAC is often used to indicate that the measurement is a breath measurement, i.e. gram alcohol per 210 liters of breath.

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:

RSD=(SD/Mean)×100 percent

2.4 Standard Deviation (SD). A common indication of precision in the measurement of the concentration of a succession of N vapor samples. SD={Sum $(X_i-X_m)^2/(N-1)$ }^{1/2} where X_i=a single measurement result; X_m=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.

 $SE=X_m$ -test 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, $a=Y_m-bX_m$, and slope, $b=(SumX_iY_i-NX_mY_m)/(SumX_i^2-nX_m^2)$.

3.0 Tests and Requirements

If the BrAC of the CU is fixed, perform the tests at the fixed BrAC; otherwise,

prepare the CU for testing at 0.08 BrAC except as otherwise required in Test 1 below. Each of the tests require 10 measurements to three decimal places using the test procedure specified in 3.1. The CU will be operated according to the manufacturer's instructions. Unless otherwise specified, the tests will be performed in the absence of drafts and at prevailing normal laboratory temperature, humidity, and barometric pressure. Performance requirements are: -0.002 BrAC \leq SE \leq + 0.002 BrAC; RSD $\leq 2\%$

Test 1. Precision and Accuracy. Test at each specified BrAC.

Test 1.1: 0.020 BrAC

Test 1.2: 0.040 BrAC

Test 1.3: 0.080 BrAC

Test 1.4: 0.160 BrAC

Test 2. Ambient Temperature. Use a temperature chamber controllable to $\pm 2^{\circ}$ C. Soak the CU at the specified temperature for 1 hour, being careful to prevent drafts on the device, then test at that temperature.

Test 2.1: 10 °C

Test 2.2: 30 °C.

Test 3. Input Power. If the CU is powered by nominal voltages of 120 volts AC or 12 volts DC, condition the device for one half hour at the appropriate input voltage specified below, then test at that voltage. Monitor the input power with a voltmeter accurate to $\pm 2\%$ full scale in the range used and re-adjust the voltage, if necessary. If the voltage is AC, conduct tests 3.1 and 3.2. If the voltage is DC, conduct tests 3.3 and 3.4.

Test 3.1: 108 Volts/AC

Test 3.2: 123 Volts/AC

Test 3.3: 11 Volts/DC

Test 3.4: 15 Volts/DC

Test 4. Electrical Safety Inspection. Examine the CU for protection of the operator from electrical shock. Examine for proper use of input power fuses, and verify that there are no exposed male connectors at high potential. Determine that overheating does not occur during operation and that undue fire hazards do not exist.

3.1 Test Procedure (Original, Wetbath)

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, Ka/ w = 0.000393 8 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 ³/₄ 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, warm 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

⁷ Available from National Committee on Uniform Traffic Laws and Ordinances, 405 Church Street, Evanston, IL 60201.

⁸ RN Harger, BB Raney, EG Bridwell, MF Kitchel, J. Biol. Chem. 183, 197–213 (1950). Additional data from Harger in a private communication (see 49 FR 48869).

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.

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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.



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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-ininert 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. General. The method uses the Beer-Lambert Law of absorption of radiant energy by fluids $I = I_o X e^{-abc}$

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 thernostated 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 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, $K_{a/w} = 0.000393^2$ 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. This 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. Pressure regulating valve with teflon delivery hose for controlling flow and delivery of flushing gas.

Step B1. Prepare the spectrometer for measurement of vapor samples. Prepare the CU for use according to manufacturer's instructions.

Step B2. Fill a reference sample bottle to ³/₄ full with water and two reference sample bottles to ³/₄ full with the above reference solutions. Insert stopper assemblies ensuring that the end of the bubble line reaches to at least 4 inches below the surface of the solution, then place the bottles in the water bath with water level up to the stopper. Allow 1 hour for temperature equilibrium to be achieved.

Step B3. Connect the bubble line of the sample bottle containing water only to the flushing gas valve and the vapor line to the spectrophotometer inlet and flush the sample chamber with water vapor and obtain the detector voltage reading. Then flush the detector chamber with flushing gas only and obtain the detector reading. Repeat 2 times to obtain 3 sets of readings. If the CU being evaluated is a wet bath device, skip this step and proceed to Step 4. Step B4. In the manner of Step 3, obtain 5 sets of detector readings using one of the reference alcohol solution bottles.

Step B5. In the manner of Step 3, obtain 10 sets of detector readings from the CU being evaluated. If the CU is a wet bath device, use the flushing gas fill the sample chamber, operating the device according to manufacturer's instructions. If the CU device is a dry gas device, fill the sample chamber according to manufacturer's instructions.

Step B6. Repeat Step 5 using the other reference alcohol solution bottle.

Step B7. Repeat Step 3.

Step B8. Calculations. For each measurement pair, I_0 is the detector voltage obtained for the flushing gas alone in the sample chamber and I is the voltage obtained for the flushing gas with reference sample or test sample in the sample chamber corrected for water vapor absorption, i.e.; the detector voltage obtained for headspace reference samples at 0.000 BrAC. Use the average of 6 voltage readings obtained for the water samples for the correction for water vapor absorption $(I=I_{sample} - I_{water})$. In the case of wet bath device samples, there is no correction for water vapor absorption. If the detector is biased, I will be the difference between the bias voltage and the above voltage.

Calulate the absorbance of each of the 10 reference samples. Divide each absorbance by the corresponding BrAC of the sample. Obtain the mean (which is the factor ab), SD, and RSD for the 10 ratios. If the RSD is more than 2%, trouble shoot the procedure and repeat.

Calculate the absorbance for each of the 10 CU test samples. Divide each by the ab factor to obtain the BrAC for each of the 10 CU samples. Obtain the mean, SD, RSD, and SE.

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



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Appendix B—Conforming Products List of Calibrating Units for Breath Alcohol Testers [Manufacturer and Calibrating Unit].¹

- 1. CMI, Inc., Owensboro, KY:
- Toxitest II
 Federal Signal Corporation, CMI, Inc., Minturn, CO:
- Toxitest Model ABS120*
 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 Simulator²
 - 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 Bernadino, CA:

- Simulator*
- 9. National Draeger, Inc., Durango, CO.Mark II–A
- 10. PLD of Florida, Inc., Rockledge, FL:BA 500
- 11. Protection Devices, Inc., U.S. Alcohol Testing, Inc., Rancho Cucamonga, CA:
 - 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).
- 14. Smith & Wesson Electronic Co., Springfield, MA:
- Mark II–A Simulator*
- 15. Systems Innovation, Inc., Hallsteaed, 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.

[FR Doc. 97–21331 Filed 8–12–97; 8:45 am] BILLING CODE 4910–59–P

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.,

¹ 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.

² 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.



Ms Laura D. Barfield Florida Department of Law Enforcement Alcohol Testing Program Manager P.O. Box 1489 Tallahassee, FL 32302-1489

March 22, 2006

RECEIVED

Subject: Product Specifications / Capabilities of Scott Specialty Gases

MAR 2 4 2006 FDLE Alcohol Testing Program

Dear Ms Barfield,

We are pleased that you and Rafael Madrigal (Assistant General Counsel) were able to meet with us and tour our manufacturing facility on March 1st, 2006. In preparation of the State of Florida (your customer) switching over to the CMI Intoxilyzer[®] 8000 instruments and using our dry gas standards for calibration verification, I am pleased to review the Scott specific product specifications and to assure your customer of our capabilities by documenting our capabilities as follows:

- 105-liter steel cylinder.
- NIST (National Institute of Standards and Technology) traceable product.
- Gas concentration (nominal value) of 0.080 g/210L or the equivalent of 208.4 ppm balance nitrogen.
- Analytical accuracy of the nominal value is +/- 2%.
- Product shelf life is two (2) years.
- Certificate of Analysis one provided with each cylinder.
- Quality Control each cylinder is individually analyzed and pressure checked prior to shipment.
- Bar code and expiration date conveniently located on the cylinder label in multiple locations so once the cylinder is installed on the 8000, it is still visible to the user.
- Manufacturing capacity to produce and ship over 300 cylinders per month, each month.
- Professional packaging of the cylinders in sturdy cardboard boxes with cardboard dividers.
- ISO-9001:2000 certified and maintained manufacturing facility (Plumsteadville, PA).
- NHTSA approved products as listed on their CPL (Conforming Products List).

In addition to our capabilities, attached are the following support documents:

- General statement of how Scott manufacturers its' product and QA processes. (Attachment I)
- General statement of how Scott product is traceable to NIST. (Attachment II)
- A blank sample Work Order, Label, and Certificate of Analysis. (Attachment III)
- A table of data that demonstrates the product stability of at least two years. (Attachment IV)

SCOTTY EBS[®] (Ethanol Breath Standards) Standards were the first ethanol standards available for dry method calibration for law enforcement and DOT testing applications. Scott will continue to set the standard in the manufacturing of dry gas standards by offering the highest quality products available and we are please that the State of Florida has partnered with CMI and Scott.

Best regards.

Ken Eichelmann Product Manager

Attachments

CC: CMI – Pam Hagan

FREMONT, CA * SAN BERNARDINO, CA * DENVER, CO * CHICAGO, IL * BOSTON, MA * TROY, MI * BREDA, THE NETHERLANDS * SALT LAKE CITY, UT * SOUTH PLAINFIELD, NJ * SARINIA, ONTARIO * PLUMSTEADVILLE, PA * HOUSTON, TX * SHEFFORD, UNITED KINGDOM



Scott Specialty Gases

6141 EASTON ROAD, P.O. BOX 310, PLUMSTEADVILLE, PA 18949-0310

215-766-8861 FAX 215-766-0320

www.scottgas.com

RECEIVED

JUL 01 2005

FDLE Alcohol Testing Program

June 28, 2005

Laura Barfield Program Manager Alcohol Testing Program Florida Department of Law Enforcement 1819 Miccosukee Commons Tallahassee, FL 32308

Dear Laura,

Thank you for talking the time to meet with me last Friday in Miami. I gained a better understanding of what we need to provide you to satisfy your state rules.

I have enclosed literature on Scott Specialty Gases, including our current catalog, to give you a broader understanding of who we are and what we do.

If your schedule permits, I am available any day during the weeks of July 11th and July 18th for you to come in for a plant tour.

I look forward to working with you.

Best regards

Ken Eichelmann Product Manger



Scott Specialty Gases

6141 EASTON ROAD, P.O. BOX 310, PLUMSTEADVILLE, PA 18949-0910 215-766-6861 FAX 215-766-0320 www.scottgas.com

April 15, 2005

Ms Laura D. Barfield Florida Department of Law Enforcement Alcohol Testing Program Manager P.O. Box 1489 Tallahassee, FL 32302

Subject: Product Specifications / Capabilities of Scott Specialty Gases

Dear Ms Barfield.

SCOTTY EBS[®] (Ethanol Breath Standards) Standards were the first ethanol standards available for dry method calibration for law enforcement and DOT testing applications. Early on, Scott Specialty Gases partnered with CMI to supply all of your Ethanol Breath Standard gas cylinder needs and have continued to do so for over the last ten plus years.

We are pleased to learn that the State of Florida (your customer) is switching over to the CMI Intoxilyzer[®] 8000 instruments and will be using our dry gas standards for calibration verification. To review the Scott Gas specific product specifications and to assure your customer of our capabilities, we are pleased to document these as follows:

- 105-liter steel cylinder.
- Gas concentration (nominal value) of 0.080 g/210L or the equivalent of 208.4 ppm balance nitrogen.
- Analytical accuracy of the nominal value is +/- 2%.
- Product shelf life is two (2) years.
- Certificate of Analysis one provided with each cylinder.
- Quality Control each cylinder is individually analyzed and pressure checked prior to shipment.
- Cylinder analysis is done using a Horiba GC/FID analyzer.
- Bar code and expiration date conveniently located on the cylinder label in multiple locations so once • the cylinder is installed on the 8000, it is still visible to the user.
- Manufacturing capacity to ship over 350 cylinders per month, each month.
- Professional packaging of the cylinders in sturdy cardboard boxes with cardboard dividers.
- ISO-9001:2000 certified and maintained manufacturing facility (Plumsteadville, PA).
- Stability data is maintained on retained cylinders as part of our standard manufacturing ٠ procedures. Although confidential, this information is available to review if requested.
- NIST (National Institute of Standards and Technology) traceable. ٠
- NHTSA approved products as listed on their CPL (Conforming Products List).

In addition to our capabilities, product accuracy and attention to quality control, Scott Specialty Gases, is the sole-source producer for NIST of Standard Reference Materials (SRMs) candidates. These mixtures are analyzed and certified by NIST as SRMs and then resold to all of our competitors as reference materials against which they measure their gas mixtures.

We will continue to set the standard in the manufacturing of dry gas standards by offering the highest quality products available and we are please that the State of Florida has selected to partner with CMI, our largest distributor of the SCOTTY EBS products for the breath testing market.

Best regards,

Her Eichelmann / HX

Ken Eichelmann Product Manager RECEIVED APR 1 9 2005

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Ethanol Breath Standard Approved for use with *Intoxityzer 8000*

Informational Sheet

Product:	Ethanol Breath Standard 105-Liter Cylinder
Concentration:	.080 BAC Ethanol ±2% Balance Nitrogen
Distributor:	CMI, Inc. 316 East Ninth Street Owensboro, KY 42303 Phone: 866-835-0690 Fax: 270-685-6678 Web: <u>www.alcoholtest.com</u>
Part Number:	340129FL
Price:	\$93.80 per cylinder
Freight:	Shipment via UPS Ground. Freight charges waived. Delivery 5 – 7 business days after order is placed at CMI.
Shelf Life:	24 months
Usage:	Approximately 300 calibration checks per cylinders
Recommendation:	Keep at minimum one additional gas cylinder on hand per instrument being utilized for testing.

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316 E. 9th St. Owensboro, KY 42303 1-866-835-0690 Fax: 270-685-6678 www.alcoholtest.com

April 15, 2005

Florida Department of Law Enforcement Alcohol Testing Program PO Box 1489 Tallahassee, FL 32302-1489 Attn: Ms. Laura Barfield

Dear Ms. Barfield,

CMI, Inc. is pleased to provide a quotation for the dry gas cylinder used to verify the calibration of the Intoxilyzer 8000. Details of our quotation may be found below.

Product:	Ethanol Breath Standard 105-Liter Steel Cylinder
Manufacturer:	Scott Specialty Gases
Concentration:	.080 BAC Ethanol +/- 2% Balance Nitrogen or 208.4 ppm
Shelf Life:	24 months
Price:	\$93.80 per cylinder
Freight:	Waived

Ms. Barfield, if you require further information, please do not hesitate to contact me at your earliest convenience.

Sincerely,

2. Nagan Panela 4 Pamela J. Hagan

Technical Sales Manager





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Pamela J. Hagán Technical Sales Manager





Confined Space Monitoring with SCOTTY® Transportable Gases

LEGISLATION / REGULATIONS

Confined space generally describes areas that are:

- Large enough for a person to bodily enter and perform work assignments.
- Limited or restricted entry/exit.
- Not designed for continuous employee occupancy.

OSHA defines a permit-required confined space as a confined space that has one or more of the following characteristics:

- 1. Contains or has the potential to contain a hazardous atmosphere.
- 2. Contains material with the potential for engulfment.
- 3. Has an integral configuration such that an entrant could be trapped or asphyxiated by inwardly converging walls, or a floor that slopes downward and tapers into a smaller cross section.
- 4. Contains any other recognized serious safety or health hazard.

APPLICATION

Manholes, sewers, boilers, silos, vessels, vats, pipelines, tunnels, storage tanks, ship compartments and underground vaults are all classified as confined spaces.

Portable and fixed gas detectors are used to monitor confined space areas for toxic and flammable gases as well as oxygen deficiency.

These detectors require routine calibration to ensure accuracy. Fixed detectors are typically calibrated quarterly. Portable detectors should be tested prior to each usage.

SCOTTY SOLUTION

Scott Specialty Gases offers all of the calibration gases necessary to perform critical instrument calibration for confined space monitoring. A large selection of concentrations are available in a variety of transportable cylinder sizes.

Typical gases used are: H₂S, CO, CO₂, CH₄ or C₃H₈, and O2. These gases and others are available in single and multi-component mixtures.

SCOTTY Transportable products offer:

- · High quality, accuracy & stability
- No cylinder demurrage or rental expense
- Reduced shipping costs
- One-way shipping charges only
- "Go anywhere" portability
- Easy on-site storage

Scott Specialty Gases is ready to work with you! Call your local sales representative or 1-800-21-SCOTT.



Scott Specialty Gases

Order online at www.scottgas.com

- Enough product for the application with no waste
- SCOTTY Express fast delivery
- · Convenient online ordering at scottgas.com



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Chicago Area 630-860-1824 Denver Area 303-442-4700 Detroit Area 248-589-2950

Houston Area 281-474-5800 Los Angeles Area 909-887-2571 New York Area 908-754-7700

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