RESULTS OF CONFORMANCE TESTING OF SCREENING DEVICES TO MEASURE ALCOHOL IN BODILY FLUIDS

A. L. FLORES

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INTERIM REPORT

PREPARED FOR

U.S. DEPARTMENT OF TRANSPORTATION
NATIONAL HIGHMAY TRAFFIC SAFETY ADMINISTRATION
OFFICE OF RESEARCH AND TRAFFIC RECORDS
WASHINGTON, D. C. 20590

Under National Highway Traffic Safety Administration Model Specifications for Screening Devices To Measure Alcohol in Bodily Fluids (59 FR 39382), Alcohol Screening Devices are devices which sample fluid from a human subject to indicate whether or not alcohol is present in the blood of that subject at or above a concentration of 0.02 BAC (grams alcohol per 100 ml). Any bodily fluid may be used for this determination, provided that a demonstrated scientific method for converting the measurement into BAC is available.

One device was submitted to the U.S. Department of Transportation Volpe National Transportation Systems Center for evaluation in August 2000 but is reported in this reporting period:

Device	Manufacturer
ABI(Alcohol Breath Indicator)	Han International Co., Ltd. Korea

The submitted screening device is a hand-held unit that uses a semi-conductor to detect breath alcohol. The device was found to meet all applicable requirements. Test results are tabulated below.

The Model Specifications are appended.

Han International Co. Ltd. August 2000
ABI (Alcohol Breath Indicator)

Test			Pass
1. Precision & Accuracy.			yes
20 trials at 0.008 BAC	# positive	0	
20 trials at 0.032 BAC	# negative	0	
2. Blank Reading:			yes
20 trials at 0.000 BAC	# positive	0	
	# negative	0	
3. Light Conditions			*NA
4. Cigarette Smoke.			yes
5 trials at 0.000 Bac	# positive	0	
5. Temperature.			
5.1 at 10degC			yes
20 trials at 0.008 BAC	# positive	0	
20 trials at 0.032 BAC	# negative	0	
5.2 at 40degC			yes
20 trials at 0.008 BAC	# positive	0	
20 trials at 0.032 BAC	# negative	0	
6. Vibration.			yes
20 trials at 0.008 BAC	# positive	0	
20 trials at 0.032 BAC	# negative	0	

BAC: grms alcohol /210 liters air @34degC

Requirements:

Not more than one negative at 0.032 BAC

Not more than one positive at 0.008 BAC

Not more than one negative greater than zero and no positives at 0.00 BAC

No positives in Test 4

*Not applicable. Device read-out does not require interpretation.

Appendix: Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids (59 FR 39382-39390).

DEPARTMENT OF TRANSPORTATION
National Highway Traffic Safety Administration
[NHTSA Docket No. 94-004; Notice 2]

Highway Safety Programs; Model Specifications for Screening Devices To Measure Alcohol in Bodily Fluids

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice.

SUMMARY: This notice establishes Model Specifications for the performance and testing of alcohol screening devices. These devices test for the presence of alcohol, and may use breath or other bodily fluids, such as saliva, to do so. NHTSA is establishing these specifications to support State laws that target youthful offenders (i.e., “zero tolerance” laws) and the Department of Transportation's regulations on Alcohol Misuse Prevention, and in recognition of industry efforts to develop new technologies (e.g., non-breath devices) that measure alcohol content from bodily fluids.

A Conforming Products List (CPL) will be published identifying the devices that meet NHTSA's Model Specifications. The CPL can serve as a guide for those interested in purchasing devices that screen for the presence of alcohol.

DATES: The Model Specifications established by this notice become effective August 2, 1994.

FOR FURTHER INFORMATION CONTACT:
Ms. Lori A. Miller, Office of Alcohol and State Programs, NTS-21, National Highway Traffic Safety Administration, 400 Seventh Street,SW., Washington, DC 20590. Telephone (202) 366-9835.

SUPPLEMENTARY INFORMATION: On December 15, 1992 (57 FR 59382), the U.S.Department of Transportation (DOT) published a notice of proposed rulemaking (NPRM) to implement the “Omnibus Transportation Employee Testing Act of 1991,” which requires alcohol testing programs in the aviation, motor carrier, rail, and mass transit industries. The Research and Special Programs Administration (RSPA) proposed similar regulations for the pipeline industry. In general, the NPRM proposed to prohibit covered employees from performing safety-sensitive functions when test results indicate alcohol concentration levels of 0.04 or greater. The NPRM proposed to apply slightly different

consequences to employees having alcohol concentration levels of 0.02 or greater but less than 0.04.

To determine alcohol concentration, the NPRM proposed to use breath as measured by those evidential breath testing devices (EBTs) listed on NHTSA's Conforming Products List (CPL) which are capable of providing a printed result, sequentially numbering the tests conducted, and distinguishing alcohol from acetone at the 0.02 BAC level. EBT's listed on NHTSA's CPL have been tested and determined to meet the agency's Model Specifications for EBTs, which were last amended on September 17,1993 (58 FR 48705).

In a final rule published on February 15, 1994 (59 FR 7340), DOT amended its regulations and added procedures for conducting alcohol testing in transportation workplaces (49 CFR Part 40). This final rule differed from the NPRM in a number of respects. The final rule required the use of breath testing devices listed on the CPL for EBTs. For screening devices, it permitted the use of EBTs on the CPL that do not print the result, but only if confirmation tests are conducted using EBTs listed on the CPL which are capable of providing a printed result. (These devices must also be capable of distinguishing alcohol from acetone at the 0.02 BAC level and sequentially numbering the tests conducted.)

NHTSA published a separate notice in the same issue of the Federal Register (59 FR 7372) proposing to adopt Model Specifications and a CPL that would permit additional alcohol testing devices to be used for screening purposes. In its notice, NHTSA proposed to establish Model Specifications for alcohol screening devices, which differ from the Model Specifications for Evidential Breath Testing devices in a number of important respects. It stated that the proposed Model Specifications are designed to test whether devices are suitable for screening, not evidential, purposes and that they are designed to test the performance of devices that may use bodily fluids other than breath (such as saliva) to determine the presence of alcohol.

NHTSA requested comments on these proposed Model Specifications.

Comments Received

The agency received twenty comments in response to the notice. Comments were received from manufacturers of screening devices and related equipment, persons representing sectors of the transportation industry subject to the DOT regulations (including rail, transit, motor carriers and pipelines) and substance abuse

program administrators, an interested individual and a health professional.

A) General Comments

The comments, in general, were supportive of the agency's proposed Model Specifications. Some of the comments praised the notice for proposing to increase flexibility, stimulate development and reduce barriers and cost for those charged with implementing DOT's new alcohol testing rules.

A number of commenters raised concerns about the schedule NHTSA would following publishing the final Model Specifications. DOT's final rule becomes effective for large employers (in general, with 50 or more safety-sensitive employees) on January 1, 1995. The commenters, therefore, urged the agency to issue the Model Specifications and approve conforming devices prior to that date. Two commenters recommended that if final rules and product evaluations are not completed within a specified period of time (one commenter suggested August 1 1994, another mid-1994), the effective date of DOT's final rule should be delayed.

In response to these comments, NHTSA has sought to publish the final Model Specifications as quickly as possible. As described further below, we intend to begin testing immediately, and hope to publish within 30 days from today's date a Conforming Products List (CPL) of screening devices that have been tested to date and conform to these Model Specifications. The CPL will be updated and published periodically, as further testing is completed.

A number of commenters raised issues that pertain to other notices that were published in the Federal Register on February 15, 1994, such as DOT's final rule (59 FR 7340) on Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR Part 40) or the final rules and common preamble (59 FR 7302) on the Limitation on Alcohol Use by Transportation Workers. Others raised issues that are also outside the scope of NHTSA's notice and request for comments. For example, one respondent commented that all alcohol testing should be performed by law enforcement representatives. Another respondent urged the Department to permit testing to be conducted only using evidential breath testing devices. Other commenters suggested that the use of non-breath alcohol tests (which use blood, saliva or urine samples) as a condition for employment is an invasion of privacy and a violation of individual rights.

NHTSA's Model Specifications contain the performance criteria and methods for the testing of alcohol screening devices. It does not address whether such devices are permitted to be used to perform screening tests, who is authorized to administer such tests or who is subject to them. These issues are addressed instead in DOT's final rules.

Other commenters raised questions or concerns regarding the Model Specifications for Evidential Breath Testing Devices, last revised on September 17, 1993 (58 F.R. 48705), or the Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs), published on April 7, 1992 (57 F.R. 11772).

Issues such as these are outside the scope of the notice published in February proposing Model Specifications for alcohol screening devices, and therefore have not been addressed in this notice adopting

B) Specific Comments on Model Specifications

No comments were received regarding some portions of the proposed Model Specifications. These portions have been adopted without change. For further discussion regarding these portions, interested persons should review the February notice. Portions of the proposed Model Specifications that generated comment, and the issues raised in the comments, are discussed below.

1. Purpose, Scope, Classification and Definitions

In its February 15, 1994 notice, NHTSA proposed to define an alcohol screening device as a device that is used to detect the presence of 0.020 or more BAC, and that indicates the test result by numerical read-out or by other means, such as by the use of lights or color changes. All comments addressing these aspects of the Model Specifications supported the definition. They have been adopted without change.

The notice proposed that the Model Specifications would provide that devices may measure any bodily fluid (including blood, breath or saliva), but that the output must be in blood alcohol concentration (BAC) units. It explains that NHTSA believes the relationship between BAC and the bodily fluid being measured is properly established so that a means for evaluating the device can be devised, and that NHTSA considers use of a one-to-one conversion factor between blood and saliva to be appropriate. NHTSA requested comments in the February 15 notice on the proposed use of a one-to-one conversion factor for saliva, and on what may constitute acceptable criteria for bodily fluids other than saliva, blood and breath.

All comments regarding the one-to-one conversion factor and the applicability of the proposed Model Specifications to blood, breath and saliva were supportive of NHTSA's proposal. These aspects of the Model Specifications have been adopted without change.

Comments were received from the manufacturer of an alcohol screening device that uses ocular vapor analysis. The type of analysis used by this device measures alcohol using vapors from the surface of the eye. The commenter requested that the model

specifications include the ocular vapor analysis technique as an acceptable and recognized method.

The Model Specifications, as proposed in the agency's February 15 notice and as finally adopted in today's Federal Register notice, define an alcohol screening device as a device that may measure “any bodily fluid” for the purpose of detecting the presence of 0.020 or more BAC. This definition is clearly broad enough to include use of the ocular vapor analysis technology.

NHTSA did not include in its proposal, however, testing procedures for all conceivable types of screening technologies. Rather, it proposed testing procedures for the types of screening technologies currently most commonly available. The notice explained that the agency would modify and improve the Model Specifications as new data and test procedures become available, and that it would alter the test procedures, if necessary, to meet unique design features of specific devices. If the test procedures need to be altered to test the ocular vapor analysis technology, NHTSA would make such alterations. Any needed alterations would be published in the Federal Register.

One commenter, a manufacturer of alcohol breath testing devices, raised concerns about devices that are not capable of detecting ethyl alcohol and isopropyl alcohol. The commenter stated that if devices cannot identify all three of these alcohols, they will produce false negative alcohol readings.

The definition of alcohol included in the proposed Model Specifications permits alcohol-screening devices to detect different types of alcohol (including ethyl alcohol, methyl alcohol and isopropyl alcohol), but does not require that devices must be capable of distinguishing between each type. To determine compliance with the Model Specifications, the agency proposed that it would conduct tests using ethanol.

NHTSA does not disagree that the potential for false negative results may exist should be a technology be employed in a screening device that is specific to ethanol only and an individual has consumed methyl or isopropyl alcohol. However, the agency is aware of no screening devices using such a technology. Rather, the screening devices available today on the market generally employ technologies that are not specific to any single type of alcohol, and, therefore, are capable of detecting (but not distinguishing between) ethanol and the other alcohols.

As a result, and since ethanol is the alcohol most often consumed, we believe that the probability of obtaining false negative results by screeners that conform to these Model Specifications is extremely low. The proposed definition has been adopted without change.

2. Statistical Accuracy

In its February 15 notice, NHTSA proposed to test alcohol-screening devices at 0.008 and 0.032 BAC under normal laboratory conditions to determine their precision and accuracy at detecting the presence of 0.020 or more BAC (Test 1), and at 0.000 BAC to determine the performance of these devices when providing blank readings (Test 2).

The notice explained that the .008 and .032 BAC levels were selected based on criteria for precision and accuracy that are equivalent to those used for EBTs. The criteria require that devices perform at a level of accuracy within +/-0.005 of 0.020 BAC (thereby establishing target valves within 0.015 and 0.025 BAC), and a level of precision which yields a standard deviation not greater than 0.0042. To achieve a confidence rate of approximately 95% in the results of these 20 tests, we proposed to establish measurement points at 1.73 standard deviations (or 0.007 BAC) below and above the lower and upper values, respectively (i.e., 0.015-0.007=0.008 BAC and 0.025+0.007=0.032 BAC).

One commenter expressed the opinion that the proposed method of testing does not truly reflect the accuracy standard of +/-0.005 BAC with standard deviation not to exceed .0042 BAC. This commenter recommended that instruments should be tested instead at the .020 BAC level, that results should fall within the 0.15 and .025 BAC range, and that a deviation of not more than .0042 should be maintained. The commenter's response further stated that, to achieve a confidence rate of 95%, only 5% of the tests conducted should be outside the .015 to .025 BAC range.

The method proposed by this commenter would require that devices identify the precise BAC level detected by the instrument. The Model Specifications do not include such a requirement. Rather, they simply require that devices are capable of detecting the presence of alcohol at the 0.020 or greater BAC level. To accommodate the use of non-numerical as well as numerical alcohol screening devices, the Model Specifications use two test points that are 1.73 times the maximum allowed standard deviation on either side of 0.020 +/-0.005 BAC (0.008 and 0.032). The number of false positives and false negative
allowed were obtained based on the use of Student's distribution (a small sample approximation to the normal distribution).

One commenter illustrated a range of error that would be permitted under the proposed Model Specifications, and suggested that the Model Specifications be amended to permit a smaller range of error. Another commenter, addressing the same concern, proposed that the Model Specifications be amended to provide for the adjustment of the test at .032. This commenter recommends that we conduct 20 tests at .025 with no more than one false negative result and 20 tests at .015 with no more than two false

positives. NHTSA believes these proposals would require that screening devices perform at a higher level of precision than is required for EBTs. The procedures contained in the proposed Model Specifications have been adopted without change.

3. Test Methods

NHTSA proposed to use a Breath Alcohol Sample Simulator (BASS), non-alcohol human breath, and a calibrating unit to test breath devices. For non-breath devices, the agency proposed to use preparations of bodily fluids or scientifically acceptable substitutes. For example, the agency proposed to use aqueous alcohol test solutions equivalent to blood or saliva on a one-to-one basis to test saliva devices.

One commenter, a manufacturer of a saliva device, expressed its view that there are no fluids that are scientifically acceptable equivalents to bodily fluids. The commenter asserted that aqueous alcohol test solutions lack the viscosity, solid content and inhibitors that are present in bodily fluids such as saliva, and recommended that the agency instead collect saliva specimens from individuals known to be alcohol-free. According to the commenter, the non-alcohol saliva pool could then be spiked with various alcohol solutions for device evaluation.

NHTSA disagrees with this respondent's comment. The agency has data finding that aqueous alcohol test solutions are acceptable substitutes for saliva-alcohol testing purposes.[1] In addition, while we agree that aqueous solutions and saliva do have different characteristics, we have no reason to believe that these difference would interfere with the agency's ability to test the capability of saliva screening devices to detect alcohol content. The final Model Specifications continue to provide that aqueous alcohol test solutions will be used.

Two commenters recommended that NHTSA use alcohol reference material 1828, obtained from the National Institute of Standards and Technology (NIST), to prepare all standard solutions. One of these commenters also suggested that, following preparation, these solutions should themselves be analyzed against a referee method (enzymatic or gas chromatography), which has been calibrated using NIST standards.

NHTSA does not plan to use NIST 1828 material in its standard solutions. However, the agency presently uses the material for

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[1] Flores, A.L., Spicer, A. and Frank, J.F., ``Laboratory Testing of a Saliva-Alcohol Test Device by Enzymatics, Inc.,'' Washington, D.C., U.S. Department of Transportation, National Highway Traffic Safety Administration, Technical Report No. DOT-HS 807 893, December 1992.

the purpose for which it was intended, as a reference material for calibration purposes, and will continue to do so.

The agency proposed to conduct 40 trials under Test 1 (20 at .008 BAC and 20 at .032 BAC) and 20 trials under Test 2 (at .000 BAC). For reusable devices, these 60 trials would be conducted using a single unit. For disposable devices, these 60 trials would be conducted using 60 separate units.

NHTSA's notice explained that some alcohol screening devices indicate the presence of alcohol in a manner that is unambiguous and requires no interpretation, such as by the use of a light or numerical reading. For these devices, NHTSA proposed that Tests 1 and 2 (at .008, .032 and .000 BAC) would be performed by an investigator at the DOT Volpe National Transportation Systems Center (VNTSC). To conform to the Model Specifications, the notice stated that the device must perform with no positive results at .000 BAC, not more than one positive result at .008 BAC and not more than one non-positive result at .032 BAC. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, the device must perform with not more than one such result at .000 BAC.

NHTSA's notice explained that other devices indicate the presence of alcohol in a manner that requires interpretation and may involve some ambiguity, such as by the use of color changes. For these devices, NHTSA proposed that Tests 1 and 2 (at .008, .032 and .000 BAC) would be performed by ten individuals who have no knowledge of test BACs and qualify as test interpreters. VNTSC would select these individuals using manufacturer's restrictions, if any. These individuals would be asked to read the manufacturer's instructions for the interpretation of the device's read-out, and interpret the test results independently.

To conform to the Model Specifications, the notice proposed that the device must perform, with each interpreter, with no positive results at .000 BAC, not more than one positive result at .008 BAC and not more than one non-positive result at .032 BAC. If the device is capable to providing a reading of greater than 0.000 BAC and less than 0.020 BAC, the notice proposed that the device must perform, with each interpreter, with not more than one such result at .000 BAC. These aspects of the Model Specifications have been adopted without change.

An organization that represents substance abuse program administrators suggested that, if practical, the ten individuals select to interpret the devices should have no medical training since it is likely that the persons who will be administering the tests in the field will have no such training. The agency plans to select individuals with varying backgrounds and experience. While we do not believe there is justification for imposing a restriction on the selection of individuals who have medical

training, it is likely that few if any of the individuals selected will have such training.

A manufacturer of saliva screening devices suggested that the Model Specifications should provide for a familiarization period, to ensure that investigators and individuals who will be evaluating these devices are familiar with the manner in which the devices should operate.

The preamble to the proposed Model Specifications explained that individual evaluators will be asked to read the manufacturer's instructions before they perform their evaluations. These individuals will be provided sufficient time to become familiar with these instructions, and will also be given instructions for conducting the evaluations. Investigators will also provide themselves with sufficient time to read the manufacturer's instructions and become familiar with the devices they are testing, as well as the evaluation procedures. NHTSA stated in the February 15 notice that, through the independent interpretation by ten individuals, it believed the Model Specifications would ensure that the results of tested devices are visible and will remain so for a reasonable period of time and are likely to be interpreted in a consistent manner. The notice indicated that the tests would require approximately two hours to run. The agency requested comments on these aspects of the proposed Model and Specifications.

The comments were supportive of these aspects of the proposed Model Specifications, except that two commenters objected to the requirement that screening results remain visible for two hours. One of the commenters considered this to be an unreasonable requirement, particularly when (according to the commenter) the primary basis for the requirement is the convenience of the testing facility that will be evaluating the device. The other commenter was concerned that this two-hour period could invalidate the results, since some devices require that the user read and record the test result within a specific period of time (such as two minutes).

Upon further consideration based on these comments, NHTSA has decided to modify the requirement that results must remain visible for two hours. It is not feasible, however, for the agency to eliminate the requirement altogether. In part to facilitate the evaluation of these devices, and also to be consistent with the DOT Alcohol Testing Procedures (49 CFR Part 40), which provide that the waiting period between screening and confirmation tests must be at least 15 minutes but should be no longer than 20 minutes, NHTSA will modify its testing methods so that the interpretation of results will be accomplished within 20 minutes of dosing. Accordingly, the results of disposable interpretive devices will need to remain visible for a period of only 20 minutes.

The notice explained that, to NHTSA's knowledge, no reusable

devices currently use interpretive readings and the agency believes it is unlikely that manufacturers would begin to use such readings in reusable devices. Accordingly, NHTSA proposed that the Model Specifications would not include a methodology for testing reusable interpretive devices. We requested comments on this aspect of the proposed Model Specifications. The commenters that addressed this issue agreed with the agency's proposal.

For disposable devices that use interpretive readings, NHTSA proposed to combine Tests 1 and 2, and number the units and expose them to the three BAC levels using a methodology that would not reveal to the person interpreting the test the dosage received by any particular unit. NHTSA requested comments on this proposed methodology. No comments were received. The proposed methodology has been adopted without change.

The February notice proposed to test devices to determine whether acetone or, in the case of breath or saliva devices, cigarette smoke affects the functioning of the instruments. The notice also requested comments on whether devices should be tested for interference from other substances.

With regard to the test for acetone interference, one commenter agreed that there is a need for such a test. Another commenter strongly recommended that the test be deleted from the Model Specifications. The commenter argued that acetone is unlikely to interfere with the measurement of breath alcohol and, if persons have levels of acetone that are sufficiently high to cause interference, such persons should not be performing safety sensitive functions. In addition, the commenter stated that requiring devices to distinguish between alcohol and acetone would greatly increase instrument cost and restrict participation for certain instruments.

NHSTA has reconsidered its position on this issue, and decided that alcohol-screening devices should not be required to distinguish between alcohol and acetone, particularly since the instruments used for confirmation testing are capable of distinguishing between these substances. Based on existing data[2], we do not expect a high incidence of acetone interference and, in the unlikely event that a device indicates a positive result due to the presence of acetone; this will be detected in the

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[2] Flores, A.L. and Frank, J.F., “The Likelihood of Acetone Interference in Breath Alcohol Measurement,” Washington, DC, U.S. Department of Transportation, National Highway Traffic Safety Administration, Technical Report No. DOT HS 806 922, 1985. Frank, J.F. and Flores, A.L., “The Livelihood of Acetone Interference in Breath Alcohol Measurement,” Alcohol, Drugs, and Driving, 3 (2), 1-8, April-June 1987.

confirmation test. The Model Specifications have therefore been amended to eliminate the acetone test.

With regard to cigarette smoke and other interfering substances, we received only one comment, which stated that non-interference from smoking, eating and drinking should not be a conformance requirement since these activities can be avoided before a test is performed. If the evaluation of cigarette smoke is retained in the Model Specifications, this commenter recommended that it be performed for information purposes only.

NHTSA expects the likelihood of cigarette smoke interference will be much greater than acetone interference, and has decided to retain the cigarette smoke test. As provided in the Model Specifications, the test will be performed in accordance with the manufacturer's instructions. Any waiting period specified in the manufacturer's instructions will be strictly observed. The test will be performed within one minute after the person smokes the cigarette where no waiting period is specified in the manufacturer's instructions. NHTSA did not propose to conduct a test for interference from eating and drinking, and we have not added any such test in the final Model Specifications.

The commenter also suggested that, if the Model Specifications continue to include a cigarette smoke test, that the method used for conducting this test on saliva screening devices should be similar to that used for breath screening devices. NHTSA concurs that this comment, and has revised the Model Specifications to clarify its application to both saliva and breath devices.

The agency also proposes to conduct high (40 deg.C) and low (10 deg.C) ambient temperature and vibration tests for alcohol screening devices to determine their ability to function under a range of environmental conditions. NHTSA proposes that these tests would be performed by an investigator at VNTSC. Five trials would be conducted at .000 BAC under Test 3.2. Forty trials (including 20 at .008 and 20 at .032 BAC) would be conducted under each of these other tests.

One commenter, a manufacturer of a passive alcohol sensor, noted that the proposed temperature range for testing is more severe than that for EBT testers. This commenter is correct. The temperature range is more severe because it is anticipated that screening tests may be performed outside in widely varying temperature conditions. Tests performed with EBTs are generally performed indoors where temperatures are controlled. The proposed temperature range has been adopted without change.

Another commenter, a manufacturer of a saliva test device, suggested that the specimens for saliva testing should be held at body temperature (37 deg.C) while performing the two ambient temperature evaluations “to stimulate real-life situations.” NHTSA disagrees with this comment. When saliva tests are being conducted in the field, the temperature of the saliva will change

soon after the sample is taken from the person's mouth. NHTSA therefore believes the procedures contained in its proposed Model Specifications more accurately simulate the conditions under which actual testing will be conducted. This portion of the Model Specifications has been adopted without change.

The manufacturer of an alcohol breath-testing device commented that disposable devices, which cannot be checked for calibration on a periodic basis, should be evaluated throughout their useful life. This manufacturer also recommended that devices which require that results be checked through a visual inspection should be tested under a variety of light conditions, such as fluorescent, mercury vapor, sodium vapor and daylight.

NHTSA disagrees that the Model Specifications should provide for the evaluation of disposal devices throughout their useful life. As explained in the February 15 notice, manufacturers of alcohol screening devices must meet the requirements contained in FDA's Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820), and they must include labels on their devices that meet the requirements contained in FDA's Labeling regulations for devices used for medical purposes (21 CFR 809.10), even if the devices are not to be used for medical purposes.

The Labeling Instructions for Alcohol Screening Devices included as an Appendix to the February notice instructed, among other things, that the label “Provide the reagent's shelf life and opened expiration dating, if applicable.” In addition, manufacturers must determine shelf life and expiration dating in accordance with FDA's regulations on Good Manufacturing Practices.

NHTSA has asked users of alcohol screening devices to provide both acceptance and field performance data to the agency's Office of Alcohol and State Programs (OASP) when such data are available. As we explained in the February notice, if information gathered indicates that a device on the CPL is not performing in accordance with the Model Specifications, that a manufacturer is not complying with FDA's Good Manufacturing Practices, or that a device's label does not comply with FDA's Labeling regulations, an investigation would be conducted and appropriate measures would be taken. For these reasons, the Model Specifications have not been amended to provide for the evaluation of disposable devices throughout their useful life.

NHTSA accepts the recommendation that certain devices should be tested under a variety of light conditions. The Model Specifications have been amended to provide that interpretive devices which require that results be checked through a visual inspection should be tested under incandescent, mercury vapor, sodium vapor and daylight as well as fluorescent conditions.

To conform with the Model Specifications, the notice proposed that the device must perform with no positive results at each

test performed at .000 BAC, not more than one positive result at each test performed at .008 BAC and not more than one non-positive result at each test performed at .032 BAC. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, the notice proposed that the device must perform with not more than one such result at .000 BAC. No comments were received regarding this aspect of the proposal. It has been adopted without change, except that the final Model Specifications clarify that there can be no more than one “can't Tell” result for disposable interpretive devices.

4. FDA Involvement

When alcohol screening devices are used for medical purposes, the manufacturers of the devices are required to obtain marketing clearance from the Food and Drug Administration (FDA), in accordance with FDA regulations that address issues such as quality assurance in manufacturing, shelf-life and labeling. Currently, FDA does not assert jurisdiction (provide marketing clearance) for alcohol screening devices used for law enforcement purposes and workplace testing.

However, because of the nature of alcohol screening devices and the conditions under which they are to be used, NHTSA stated in its February 15 notice that it is important for manufacturers of these devices to conform with certain requirements, imposed by FDA on devices used for medical purposes, prior to the inclusion of the devices on NHTSA's CPL.

Accordingly, NHTSA proposed to require that each device submitted for testing under the Model Specifications be accompanied by a self-certification from the manufacturer, certifying that it meets the requirements contained in FDA's Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820), and that the device's label meets the requirements contained in FDA's Labeling regulations for devices used for medical purposes (21 CFR Part 809.10), even if the devices are not to be used for medical purposes.

NHTSA received a number of comments regarding this aspect of its proposal. One commenter favored direct FDA regulation of all workplace alcohol testing products and, if necessary, FDA enforcement. This commenter encouraged DOT and NHTSA to continue their discussions with FDA. Another commenter agreed that the guidelines written in FDA's Good Manufacturing Practices regulation could be useful as a basis for labeling and manufacturing requirements, but this and other commenters recommended that FDA not get involved. According to one commenter, “FDA is already overloaded, and long delays could result from their involvement in this project.” Another commenter recommended that, “if an instrument is not to be used in the medical field . . . FDA [should] not assert jurisdiction.”

By requiring a self-certification, NHTSA was not proposing to require that manufacturers obtain FDA marketing clearance, but simply that the manufacturers self-certify that they meet the above-referenced requirements. NHTSA stands by this aspect of its proposal.

For technical assistance or a copy of the Device Good Manufacturing Practices Manual for Medical Devices, manufacturers should contact FDA's Division of Small Manufacturers by calling toll free at 1-800-638-2041.

NHTSA's February notice included, as an Appendix, a proposed set of Labeling Instructions for Alcohol Screening Devices that had been prepared in consultation with FDA to assist manufacturers of alcohol screening devices in developing a label that conforms to 21 CFR Part 809.10. The labeling instructions addressed issues such as restrictions that may apply to operators of the device and conditions under which the device should or should not be operated.

One respondent commented on certain aspects of the labeling instructions. The commenter supported the inclusion of details on calibration, calibration frequency, and the manufacturer's name, address, and telephone and fax numbers, but disagreed that an “800” number is necessary. In addition, the commenter stated that frequency is subject to use, and some users will prefer to return a unit to the manufacturer rather than engage in its calibration.

For the convenience of users, many of who will be conducting alcohol screening tests in the field, the Labeling Instructions for Alcohol Screening Devices, which are included as an Appendix to today's notice, continue to provide that manufacturers list an 800 number the user may contact for further information or technical assistance. With regard to the calibration of devices, the Labeling Instructions continue to provide that disposable devices are pre-calibrated, and need no additional calibration. They also continue to provide that reusable devices require calibration, and instruct that the labels on such devices provide information regarding how calibrations are to be conducted, instructions for calibration and recalibration and the criteria for acceptability of calibration.

These Model Specifications are not regulations. Organizations and agencies may adopt these Model Specifications and rely on NHTSA's test results or may conduct their own tests according to their own procedures and specifications. It should be noted, however, that transportation employers covered by 49 CFR Part 40, Procedures for Transportation Workplace Drug and Alcohol Testing Programs, are required to use only alcohol testing devices that meet the criteria established by that regulation.

NHTSA intends to begin testing of alcohol screening devices immediately, and hopes to publish a CPL of devices that have been tested to date and conform to these Model Specifications within 30 days from today's date. The CPL will be updated and published

periodically, as further testing is completed. Once the first CPL is published, DOT will develop and issue procedural rules for using approved alcohol-screening devices in transportation workplaces, including provisions for how and where such devices can be used and the steps that must be taken to collect bodily fluids. Employers are reminded that these screening devices are not authorized for use under 49 CFR Part 40 until that regulation is amended.

Procedures

The procedures proposed in the February 15 notice have been adopted without change. Testing of products submitted by manufacturers to these Model Specifications will be conducted by the DOT Volpe National Transportation Systems Center (VNTSC), DTS-75, Kendall Square, Cambridge, MA 02142. Tests will be conducted semiannually, or as necessary. Manufacturers are required to apply to NHTSA for a test date by writing to the Office of Alcohol and State Programs (OASP), NTS-21, 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, manufacturers will be required to deliver their devices to VNTSC. If the devices are disposable, the manufacturer must deliver 300 such devices; if the devices are disposable, interpretive and require that results be checked through a visual inspection (and therefore must be tested under various light conditions), the manufacturer must deliver 600 such devices; if the devices are reusable, the manufacturer must submit only a single device. If a manufacturer of a reusable device wishes to submit a duplicate, backup instrument, it may do so. The manufacturer shall be responsible for ensuring that the devices operate properly and are packaged correctly. The manufacturer must also deliver the operator's manual (or instructions) and the maintenance manual (if any) normally supplied with the purchase of the device, as well as specifications and drawings, which fully describe these devices. Proprietary information will be respected. (See 49 CFR Part 512, regarding the procedure by which NHTSA will consider claims of confidentiality.)

In addition, the manufacturer must submit a self-certification, certifying that the manufacturer meets the requirements in FDA's Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820), and that the device's label meets the requirements in FDA's Labeling regulations for devices used for medical purposes (21 CFR Part 809.10), even if the devices are not to be used for medical purposes. See the Appendix to this notice.

The manufacturer has the right to check its devices between the time of their arrival at VNTSC and the start of the tests, but will have no access to the devices during the tests. Any malfunction of a device, which results in failure to complete any of the tests satisfactorily, will result in a determination that the device does not conform to the Model Specifications. If a device is found not to conform, it may be resubmitted for the next testing series after appropriate corrections have been made.

NHTSA plans to begin testing of alcohol screening devices immediately to determine whether they comply with the performance criteria included in the Model Specifications.

A Conforming Products List (CPL) will be updated and published periodically. It will include a list of alcohol screening devices that were submitted with the proper certifications and found to meet or exceed the Model Specifications.

One commenter requested that manufacturers should be permitted to commercialize their products as soon as they receive notification from NHTSA that their product has been found to meet or exceed the Model Specifications, rather than wait until the CPL listing their device is published. NTSHA intends to notify manufacturers that their devices meet the Model Specifications, and manufacturers may receive such notices and an evaluation report prior to the publication of a CPL listing their instrument. A decision about the point at which it would be appropriate for manufacturers to commercialize their instruments, however, is outside the scope of this notice.

NHTSA intends to modify and improve these Model Specifications as new data and test procedures become available and to alter the test procedures, if necessary, to meet unique design features of a specific device. For each such modification, NHTSA would provide notification in the Federal Register and would retest devices when necessary.

OASP is the point of contact for information about acceptance testing and field performance of devices. NHTSA requests that users of these devices provide both acceptance and field performance data to OASP when such data are available. Information from users will help NHTSA monitor whether alcohol-screening devices are performing according to the NHTSA Model Specifications.

If information gathered indicates that a device on the CPL is not performing in accordance with the Model Specifications, NHTSA will direct VNTSC to conduct a special investigation. An investigation may include visits to users and additional tests of the device obtained from the open market. If the investigation indicates that the devices actually sold on the market are not meeting the Model Specifications, the manufacturer will be notified that the device may be removed from the list. In this

event, the manufacturer will 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 device should remain on the list. If the device is removed from the list, the manufacturer will be permitted to resubmit an improved device to VNTSC for testing when it believes the problems causing its failure have been resolved. Upon submission, the manufacturer must submit a statement describing what has been done to overcome the problems, which led to failure of the device.

If information gathered indicates that the manufacturer of a device on the CPL does not comply with the requirements in FDA's Good Manufacturing Practices regulations for devices used for medical purposes or that the device's label does not comply with the requirements in FDA's Labeling regulations for devices used for medical purposes, NHTSA will investigate the matter in consultation with FDA and will notify the manufacturer that the device may be removed from the list. The manufacturer will have 30 days from the date of notification to reply. Based on any data provided by the manufacturer and investigative findings, NHTSA will decide whether the device should remain on the list. If the device is removed from the list, the manufacturer will be permitted to resubmit a self-certification, certifying that the manufacturer complies with these FDA requirements when it believes the problems causing its non-compliance have been resolved. Upon resubmission, the manufacturer must submit a statement describing what has been done to overcome the problems, which led to non-compliance.

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 and it has been determined that it has no federalism implication that warrants the preparation of a federalism assessment.

In accordance with the foregoing, the Model Specifications for performance testing of alcohol screening devices are set forth below.

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

Michael B. Brownlee,
Associate Administrator for Traffic Safety Programs.

Model Specifications for Alcohol Screening Devices

1. Purpose and Scope

These specifications establish performance criteria and methods for testing of alcohol screening devices. Alcohol screening devices use bodily fluids to detect the presence of 0.020 or more BAC with sufficient accuracy for screening purposes.

These specifications are intended primarily for use in the conformance testing of alcohol screening devices.

2. Classification

2.1 Disposable Alcohol Screening Devices
Alcohol screening devices designed for a single use.
2.2 Reusable Alcohol Screening Devices
Alcohol screening devices designed to be reused.

3. Definitions.

3.1 Alcohol
The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols including methyl or isopropyl alcohol.

3.2 Alcohol Screening Device
A device that is used to detect the presence of 0.020 or more BAC. The device may measure any bodily fluid for this purpose, but shall provide output in BAC units. Test results may be indicated by numerical read-out or by other means, such as by the use of lights or color changes.

3.3 Blood alcohol concentration (BAC)
Grams alcohol per 100 milliliters of blood or grams alcohol per 210 liters of breath in accordance with the Uniform Vehicle Code, Section 11-903(a)(5)[3] (BrAC is often used to indicate that the measurement is a breath measurement); or grams alcohol per 100 milliliters of saliva.

3.4 Calibrating Unit
A device that produces an alcohol-in-air test sample of known concentration that meets the NHTSA Model Specifications for Calibrating Units (49 FR 48865).

3.5 Breath Alcohol Sample Simulator (BASS)
A device that provides an alcohol-in-air test sample with known and adjustable alcohol concentration profile, flow rate,

[3] Available from the National Committee on Traffic Laws and Ordinances, 405 Church Street, Evanston IL 60201.

and air composition at 34 deg. centigrade. (See NBS Special Publication 480-41,
July 1981[4] for a description of a BASS unit suitable for use in the required testing.)

3.6 Bodily Fluid

Any bodily fluid capable of being used to estimate alcohol concentration, provided the relationship between such bodily fluid and BAC has been established according to scientifically acceptable standards. Such fluids include but are not limited to blood, exhaled deep lung breath and saliva.

3.7 Scientifically Acceptable Substitutes

Fluids that have been scientifically accepted as equivalent to bodily fluids for testing purposes, such as aqueous alcohol test solutions on a one-to-one basis for blood or saliva.

4. Test Methods and Requirements

Testing will be performed according to the instructions which normally accompany the submitted device and under the conditions specified in the tests below.

4.1 Test 1. Precision and Accuracy

Perform 40 trials under normal laboratory conditions using fluorescent light, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use the BASS device for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

For disposable alcohol screening devices that indicate the presence of alcohol in a manner that requires interpretation, combine Tests 1 and 2, in accordance with 4.3 below.

For alcohol screening devices that indicate the presence of alcohol in a manner that does not require interpretation, perform the test using a VNTSC investigator. To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.2 Test 2. Blank Reading

Perform 20 trials under normal laboratory conditions using

[4] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

fluorescent light at 0.000 BAC. Use non-alcoholic human breath for breath devices and preparations of non-alcoholic bodily fluids or scientifically acceptable substitutes for non-breath devices.

For disposable alcohol screening devices that indicate the presence of alcohol in a manner that requires interpretation, combine Tests 1 and 2, in accordance with 4.3 below.

For alcohol screening devices that indicate the presence of alcohol in a manner that does not require interpretation, perform the test using a VNTSC investigator. To conform, no positive results. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, not more than one such result.

4.3 Methodology for Combining Tests 1 and 2 for Disposable Interpretive Devices

Perform the test under normal laboratory conditions using fluorescent light using ten individuals who qualify as test interpreters (according to the manufacturer's restrictions, if any) and who have no knowledge of test BACs. Ask each individual to read the manufacturer's instructions for interpretation of the device's read-out.

Label sixty devices from 1 to 60 and randomly separate them into three groups of twenty. Record the numbers in each group. Use two of the groups of devices for Test 1 and the remaining group for Test 2. Dose each group at the BAC levels specified in Tests 1 and 2. Order the sixty devices into a single set from 1 to 60 and ask each individual to independently interpret the results of these trials.

Ask each individual to record each result as being one of the following: “at .00 BAC”; “above .00 and below. 02 BAC”; “at or above .02 BAC”; or “can't tell”. Dosing of devices and interpretation of results will be accomplished within a twenty-minute period.

To conform, to each interpreter, no positive results at .000 BAC, not more than one positive result at .008 BAC, not more than one non-positive result at .032 BAC and not more than one “can't tell” result. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, with each interpreter, not more than one such result at .000 BAC.

4.4 Test 3. Light Conditions (only interpretive devices, which require that results be checked through a visual inspection)

Perform Tests 1 and 2, in accordance with 4.3, under each of the following light conditions: incandescent light; mercury vapor light; sodium vapor light; and daylight.

Under each light condition, the device must meet the criteria

established in 4.3: To conform, with each interpreter, no positive results at .000 BAC, not more than one positive result at .008 BAC, not more than one non-positive result at .032 BAC and not more than one “can't tell” result. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, with each interpreter, not more than one such result at .000 BAC.

4.5 Test 4. Cigarette smoke interference (only breath and saliva test devices)

Perform five trials at 0.000 BAC. Select an alcohol-free person who smokes cigarettes for this test. Ask the person selected to smoke approximately one half of a cigarette. Within one minute after smoking, or after a waiting period specified in the manufacturer's instructions, administer the alcohol screening device test according to the manufacturer's instructions. Then ask the person to smoke another inhalation and repeat the test to produce a total of five trials. To conform, no positive results.

4.6 Temperature

Test at low and high ambient temperature.

4.6.1 Test 5.1 Low Ambient Temperature

Perform 40 trials at 10 deg.C, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.6.2 Test 5.2 High Ambient Temperature

Perform trials of 40 devices at 40 deg.C, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.7. Test 6. Vibration

Perform 40 trials, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for

breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

Mount the screening device on a shake table and vibrate the table in simple harmonic motion through each of its three major axes, as specified below. Sweep through each frequency range in 2.5 minutes, then reverse the sweep to the starting frequency in 2.5 minutes. The 40 disposable testers may be placed in a suitable box mounted on the shake table. Test after vibration.

Amplitude (inches, peak to peak)	Frequency (hertz)
0.30	10 to 30
0.15	30 to 60

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

Appendix

Labeling Instructions for Alcohol Screening Devices Intended Use

Provide the intended use including the specimen matrix (e.g. saliva, breath), the assay type (quantitative, semi-quantitative) the purpose of performing the assay and the individual designated to perform the assay.

e.g. this product is intended for the (quantitative, semi-quantitative) determination of alcohol in--define matrix for e.g., saliva, breath, sweat) to perform screening alcohol assays. This product is recommended for use by individuals who have been trained in the administration of screening devices.

Description of Testing System

Provide the principles of the procedure for performing the

alcohol screening assay. e.g. this product uses alcohol dehydrogenase, infrared technology, etc. to perform the test.

Chemical Reaction Sequence

Describe the chemical reaction sequence, if applicable.
Reagents: List the concentration, strength, and composition of the reactive ingredients.
List the non-reactive ingredients.

Reagent Preparation and Storage

Provide instructions for preparing the reagents, if applicable.
Provide instructions for storing the reagents, if applicable.
Provide any signs of deterioration of the reagents, if applicable.
Provide the reagent's shelf life and opened expiration dating, if applicable.

e.g. Unopened tests are stable until the date printed on the product container when stored at 22-28 deg.C. Opened test must be used at once.

Provide a caution not to use the reagents beyond the expiration dating.

Precautions:

1. List any reagents that may be hazardous such as caustic compounds, sodium azide or other hazardous reagents and instructions for disposal, if applicable.
2. If visually read, warn the user the result should not be interpreted by readers who are color-blind or visually impaired.
3. Provide warning to user to treat all samples as potentially infective. Include instructions for handling and disposal of the sample.

Specimen Collection

Provide instructions for collecting and handling the sample.
Provide criteria for specimen rejection, if applicable.

Calibration

Disposable tests are pre-calibrated. No additional calibration is required. Reusable(Instrumented) tests require calibration.
Provide information regarding how calibrations are to be conducted, if applicable, including the number and concentration

of calibrators, and the frequency of calibration. Provide instructions for calibration and recalibration. Provide the criteria for acceptability of calibration.

Test Procedure (Disposable)

Provide adequate step-by-step instructions for performing the test. If the test is disposable (non-instrumented) and involves a color reaction, include the time frame for which the test must be read and recorded. e.g. read within 15 minutes.

Test Procedure (Reusable/Instrumented)

Provide adequate step-by-step instruction for performing the test.
Provide the installation procedures and, if applicable, any special requirements.
Provide the space and ventilation requirements.
Provide the description of the required frequency of equipment maintenance and function checks.
Provide the instructions for any remedial action to be taken when the equipment performs outside of operating range.
Provide any operational precautions and limitations.
Provide instructions for the protection of equipment and instrumentation from fluctuations or interruptions in electrical current that could adversely affect test results and reports, if applicable.

Quality Control (QC)

Disposable Tests

If applicable, the function and stability of the test can be determined by examination of the procedural “built in” controls contained in the product. If these controls are not working, the test is invalid and must be repeated.

Disposable/Instrumented Devices

If external quality control materials are used, provide number, type, matrix and concentration of the QC materials.
Provide directions for performing quality control procedures.
Provide an adequate description of the remedial action to be taken when the QC results fail to meet the criteria for acceptability.
Provide directions for interpretation of the results of quality control samples.

Results

Describe how the user obtains the test results, from a colored bar, instrument read-out, printout, etc.
Describe the results in terms of blood alcohol concentration.
Describe what concentration indicates a positive result and what concentration indicates a negative result.

Limitations

List the substances or factors that may interfere with the test and cause false results including technical or procedural errors.

Dynamic Range

Provide the operating range of the product.

Precision and Accuracy

Precision and Accuracy specifications are included in the National Highway Traffic Safety Administration's (NHTSA's) Model Specifications for Alcohol Screening devices. Only devices that meet these model specifications will be included on NHTSA's Conforming Products List for alcohol screening devices.

Specificity

List the substances that have been evaluated with your product that do or do not interfere at the concentration indicated.

References

Provide pertinent bibliography

Technical Assistance

List an 800 number the user may contact for further information or technical assistance.