DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[NHTSA Docket No. 2007–27133]

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

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

ACTION: Notice of Proposed Amendments to Model Specifications for Screening Devices To Measure Alcohol in Bodily Fluids.

SUMMARY: This notice proposes revisions to Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids (Model Specifications) published in the **Federal Register** on August 2, 1994 (59 FR 39382). These devices test for the presence of alcohol using breath or bodily fluids such as saliva. The Model Specifications support State laws that target youthful offenders (i.e., ''zero tolerance'' laws) and the Department of Transportation's regulations on Alcohol Misuse Prevention, and encourage industry efforts to develop new technologies (e.g., non-breath devices) that measure alcohol content from bodily fluids.

This notice proposes to remove testing of Interpretive Screening Devices (ISDs) and use of the Breath Alcohol Sample Simulator (BASS) device from the Model Specifications. The ISDs do not provide an unambiguous test result, as test results for ISDs are subjective and require interpretation by a test administrator or technician. Because the agency has determined the BASS device is not necessary for inclusion in the Model Specifications, this notice proposes to remove all references to the BASS device.

Additionally, in order to ensure product integrity, this notice proposes guidelines for retesting devices when manufacturers contemplate changes, revisions, or upgrades to alcohol screening devices on the Conforming Products List (CPL).

The proposed revisions to these Model Specifications would not affect devices currently listed on the CPL.

DATES: Written comments may be submitted to this agency and must be received by January 14, 2008.

ADDRESSES: Comments should refer to the docket number and be submitted (preferably in two copies) to: Docket Management Facility, West Building, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. Alternatively, you may submit your comments electronically by logging onto the Docket Management System (DMS) Web site at *http://dms.dot.gov.* Click on ''Help'' to view instructions for filing your comments electronically. Regardless of how you submit your comments, you should identify the Docket number of this document. You may call the docket at (202) 647–5527. Docket hours are 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: *For technical issues:* Ms. De Carlo Ciccel, Behavioral Research Division, NTI–131, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; Telephone: (202) 366–1694. *For legal issues:* Ms. Allison Rusnak, Office of Chief Counsel, NCC–113, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; Telephone: (202) 366–1834.

SUPPLEMENTARY INFORMATION:

I. Background

As indicated in the Model Specifications published in 1994, the agency will modify and improve the Model Specifications as new data and test procedures become available and will alter the test procedures, as necessary, to meet unique design features of specific devices. Since publication of the Model Specifications, the agency has encountered difficulties ensuring the accuracy of testing ISDs and also has determined the use of the BASS is not necessary for inclusion in the Model Specifications. These events make it necessary to revise the Model Specifications.

A. Interpretive Screening Devices

The Model Specifications currently allow for evaluation of screening devices that require subjective interpretation of test results by a test administrator or technician. These ISDs differ from devices that provide objective test results, including the use of digital technology or the appearance of lights or marks based on the presence or absence of alcohol. For instance, use of pass/fail lights or enzymes that react with alcohol to produce an unambiguous mark provide objective test results.

The Model Specifications require that interpretive devices be evaluated subjectively under five lighting conditions (fluorescent, incandescent, mercury, sodium and daylight) by a panel of ten novice evaluators who are not color blind. Since publication of the Model Specifications, NHTSA evaluated eight separate ISDs. Of these eight ISD evaluations, none resulted in a successful outcome in the panel test described above. In one evaluation, the device passed the test under all lighting conditions except sodium. This device is no longer manufactured. Although many novice evaluators were able to judge the correct test outcome in the eight ISD evaluations, some could not, even though the manufacturers' instructions were conveyed to the evaluators and all evaluators passed tests to determine their color perception ability. This subjective interpretation of test results does not ensure accuracy and precision required to protect public safety. Due to repeated problems in evaluating ISDs, NHTSA is proposing to remove altogether testing of ISDs from the Model Specifications. Specifically, the agency proposes to update sections 3.2, 4.1 and 4.2, delete sections 4.3 and 4.4, and renumber sections accordingly. In addition, the agency proposes to delete from Appendix A all references to interpretive or color indicator tests.

B. Breath Alcohol Sample Simulator

The Model Specifications currently provide for the use of the Breath Alcohol Sample Simulator (BASS) device for providing alcohol-in-air test samples. The use of the BASS device is not necessary for inclusion in the Model Specifications because the BASS device is intended for use in testing the sampling efficiency of evidential breath testers. There is no sampling efficiency test in the Model Specifications for alcohol screening devices. The alcohol-in-air test sample for breath alcohol screening devices is supplied by a calibrating unit. Therefore, the agency proposes to remove section 3.5 and all references to the BASS device from these Model Specifications, and renumber sections accordingly. The agency would also revise section 3.4 to include the updated citation for NHTSA's Model Specifications for Calibrating Units.

C. Guidelines for Re-Testing Modified Screening Devices

The Model Specifications provide procedures to conduct special investigations and re-test a device if information gathered indicates that a device listed on the CPL is not performing in accordance with the Model Specifications. The agency proposes the addition of Appendix B to provide guidance regarding notification and re-testing when manufacturers contemplate revisions to devices listed on the CPL. The proposed Appendix follows the language used in the Model

Specifications for evidential breath testing devices (58 FR 48705).

Upon notification by a manufacturer of a contemplated change to a device listed on the CPL, NHTSA proposes that it would determine whether re-testing is required. Such determination would look at several factors, including the nature and reason for the change, the scope of the change, the effects of the change on the performance of the device, and how the change will be documented for the benefit of the user.

NHTSA would list device revisions and whether re-testing was required in the next update to the CPL. Appendix B also would state that NHTSA may re-test any device listed on the CPL at any time to determine continued compliance and performance with the Model Specifications. A device found not to perform in accordance with the Model Specifications would be subject to the special investigation procedures discussed below.

II. Procedures

This notice proposes no changes to the procedures for the Model Specifications other than those discussed above. This section describes the current procedures. The DOT Volpe National Transportation Systems Center (VNTSC), RTV–4F, Kendall Square, Cambridge, MA 02142 tests products manufacturers submit to determine whether the products meet the model specifications. Tests are conducted semiannually, or as necessary. Manufacturers are required to apply to NHTSA for a test date by writing to the Office of Behavioral Safety Research, NTI–130, NHTSA, 1200 New Jersey Avenue, SE., Washington, DC 20590. At least 30 days are typically required from the date of notification until the test can be scheduled.

One week prior to the scheduled initiation of the test program, manufacturers must deliver their devices to VNTSC. If the devices are disposable, the manufacturer must deliver at least 300 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 so do. The manufacturer is 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) that would be supplied or is supplied with the purchase of the device, as well as specifications and drawings fully describing the device and its use. 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 according to the U.S. Food and Drug Administration (FDA) 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 809.10), even if the devices are not to be used for medical purposes. See Appendix A to this notice.

The manufacturer has the right to check its device(s) between the time of its arrival at VNTSC and the start of the tests, but will have no access to the device(s) during the tests. Any malfunction of a device resulting 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 to the Model Specifications, it may be resubmitted for the next testing cycle after appropriate corrections have been made. The agency reserves the discretion to determine the appropriateness of any retest.

The agency intends to update and republish the CPL in the **Federal Register** annually. Republications of the CPL add conforming alcohol screening devices tested since the last CPL republication.

NHTSA will continue to provide notification in the **Federal Register** when the agency amends the Model Specifications as new data and test procedures become available and will retest devices when necessary.

The NHTSA Office of Behavioral Safety Research is the point of contact for information about acceptance testing and field performance of devices. NHTSA requests that users of alcohol screening devices provide both acceptance and field performance data to the Office of Behavioral Safety Research 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 as obtained from the open market. If the investigation indicates that a device actually sold on the market does not meet the Model Specifications, the manufacturer will be notified that the device may be removed from the CPL. 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 CPL. If the device is removed from the CPL, 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 resubmission, the manufacturer must submit a statement describing what has been done to overcome the problems that 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 CPL. 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 CPL. If the device is removed from the CPL, the manufacturer will be permitted to resubmit a self-certification, certifying that the manufacturer or its device 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 that led to non-compliance.

These proposed amendments have been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that there are no federalism implications that warrant the preparation of a federalism assessment.

In accordance with the foregoing, the proposed amendments of the Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids, are set forth below.

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 (see below) 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 must be indicated unambiguously by numerical read-out or by other means, such as by the use of lights or by the appearance of a distinctive mark but not by color change.

3.3 Blood Alcohol Concentration (BAC)

Grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath in accordance with the Uniform Vehicle Code, Section 11–903(a)(5)[1] (BrAC is often used to indicate that the measurement is a breath measurement); or grams of alcohol per 100 milliliters of saliva.

3.4 Calibrating Unit

A device that produces an alcohol-in-air test sample of known concentration and that meets the NHTSA Model Specifications for Calibrating Units (72 FR 34742).

3.5 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.

3.6 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 that 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 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. Perform tests 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 at 0.000 BAC. Use non-alcoholic human breath for breath devices and non-alcoholic bodily fluids or scientifically acceptable substitutes for non-breath devices. Perform tests 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 Test 3. 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.

4.4 Temperature

Test at low and high ambient temperature.

4.4.1 Test 4.1. Low Ambient Temperature

Perform 40 trials at 10 degrees Centigrade (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.

4.4.2 Test 4.2. High Ambient Temperature

Perform trials of 40 devices at 40 degrees 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.

4.5 Test 5. 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. Disposable testers may be placed in a suitable box mounted on the shake table. Test after vibration.

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

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 A—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.

[1] Available from the National Committee on Uniform Traffic Laws and Ordinances, 107 S. West Street, #10, Alexandria, VA 22314. Web site address: *http://www.ncutlo.org.*

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 reagents' 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° 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. 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 and determining the results.

Test Procedure (Re-Usable/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 the 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 an 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

Only devices that meet the precision and accuracy of 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.

Appendix B—Guidelines for Re-testing of Modified Screening Devices

Manufacturers contemplating revisions to an alcohol screening device listed on the Conforming Products List (CPL) are advised that the revision may affect the status of the device on the CPL. The manufacturer should inform NHTSA of the contemplated change so that a judgment can be made whether or not re-testing the revised alcohol screening device is necessary. The following lists the type of information NHTSA uses in determining the necessity to re-test an alcohol screening device, and is provided as guidance to manufacturers:

- Manufacturer and Model Name.
- Nature and reason for change.
- Scope of change (e.g., Will existing devices be retrofitted? Will the change apply to some users but not others?)
- Will the change affect performance of the device with regards to the Model Specifications? (Precision and accuracy, blank reading, temperature operations, or vibrations.)
- How will the change(s) be documented for the benefit of the user? (e.g., Will the change(s) be documented in service bulletins and/or service manuals? If not, why not?)

If necessary for clarity, drawings of the listed and changed device may also be helpful in the NHTSA's deliberations.

If, upon review of information provided by a manufacturer, it is determined that re-testing is not warranted, a statement to that effect will be included in the next scheduled CPL update.

Additionally, NHTSA reserves the right to re-test any device on the open market to determine continued compliance and performance in accordance with these Model Specifications. Devices found not to comply with or perform in accordance with the Model Specifications are subject to the investigation provisions stated above in Section II, Procedures.

(Authority: 23 U.S.C. 403; 49 CFR 1.50; 49 CFR Part 501).

Issued on: December 14, 2007.

Marilena Amoni,

Associate Administrator for the Office of Research and Program Development.

[FR Doc. E7–24282 Filed 12–13–07; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–33 (Sub–No. 246X)]

Union Pacific Railroad Company—Abandonment Exemption—in Walker County, TX

Union Pacific Railroad Company (UP) has filed a notice of exemption under 49 CFR Part 1152 Subpart F—*Exempt Abandonments* to abandon a 1.67-mile line of railroad known as the Huntsville Industrial Lead, extending from milepost 5.0 to milepost 6.67 near Huntsville, in Walker County, TX.[1] The

[1] By pleading filed December 3, 2007, UP corrected the line description to read milepost 5.0

Continued