Specifications for Screening Devices that measure alcohol in bodily fluids (59 FR 39382).

EFFECTIVE DATE: August 15, 1995. FOR FURTHER INFORMATION CONTACT: Dr. James F. Frank, Office of Alcohol and State Programs, NTS-21, National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC 20590; Telephone: (202) 366-9581. SUPPLEMENTARY INFORMATION: On August 2, 1994, Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids were published in the Federal Register (59 FR 39382). In these model specifications, NHTSA recognized industry efforts to develop new technologies. These specifications establish performance criteria and methods for testing alcohol screening devices using either breath or other bodily fluids to measure alcohol content. NHTSA established these specifications to support State laws that target youthful offenders (i.e., "zero tolerance" laws) and the Department of Transportation's initiative to prevent alcohol misuse. NHTSA published its first CPL for screening devices on December 2, 1994 (59 FR 61923; with a correction in 59 FR 65128). Five devices were on that first list.

Since the publication of that list, two additional disposable, single-use salivaalcohol screening devices have been evaluated at the Volpe National Transportation System Center in Cambridge, MA and found to conform to the model specifications for screening devices: Chematics' "Alco-Screen 02<sup>TM</sup>" and Roche Diagnostic Systems' "On-Site Alcohol".

It should be noted, however, that while the ALCO-SCREEN 02<sup>™</sup> salivaalcohol screening device manufactured by Chematics, Inc. passed the requirements of the model specifications when tested at 40°C  $(104^{\circ}F)$ , the manufacturer has indicated that the device cannot exceed storage temperatures of 27°C (80°F). (Instructions to this effect are stated on all packaging accompanying the device.) Accordingly, the device should not be stored at temperatures above 27°C (80°F) and, if the device is stored at or below 27°C (80°F) and used at higher temperatures, the test should be completed immediately. When these devices were stored at or below 27°C (80°F) and tested at 40°C (104°F) immediately (i.e., within a minute), the devices met the model specifications and the results persisted for 10-15

minutes. When these devices were stored at or below  $27^{\circ}$ C ( $80^{\circ}$ F) and were equilibrated at  $40^{\circ}$ C ( $104^{\circ}$ F) for an hour prior to sample application, the devices failed to meet the model specifications. Storage at temperatures above  $27^{\circ}$ C ( $80^{\circ}$ F), for even brief periods of time, may result in false negative readings.

It should be noted also that while the ON-SITE ALCOHOL saliva-alcohol screening device manufactured by Roche Diagnostics Systems passed all of the requirements of the model specifications, readings should be taken only after the time specified by the manufacturer. For valid readings, the user should follow the manufacturer's instructions. Readings should be taken one (1) minute after a sample is introduced at or above 30°C (86°F); readings should be taken after two (2) minutes at 18-29°C (64°F-84°F); and readings should be taken after five (5) minutes when the sample is introduced at temperatures at or below 17°C (63°F). If the reading is taken before five minutes have elapsed under the cold conditions, the user is likely to obtain a reading that underestimates the actual saliva-alcohol level.

The Conforming Products List is therefore amended as follows:

## CONFORMING PRODUCTS LIST OF ALCOHOL SCREENING DEVICES

Manufacturer	Devices(s)
(1) Alco Check International* Hudsonville, MI	•Alco Check 3000 D.O.T. •Alco Screen 3000.
(2) Chematics, Inc., North Webster, IN	•ALCO–SCREEN 02 <sup>TM</sup> . <sup>1</sup>
(3) Guth Laboratories, Inc.*, Harrisburg, PA	<ul><li>Alco Tector Mark X.</li><li>Mark X Alcohol Checker.</li></ul>
(4) Repco Marketing, Inc., Raleigh, NC	•Alco Tec III.
(5) Roche Diagnostic Systems, Branchburg, NJ	•On-Site Alcohol. <sup>2</sup>
(6) Sound Off, Inc.,* Hudsonville, MI	•Digitox D.O.T. •Alco Screen 1000.
(7) STC Diagnostics, Inc., Bethlehem, PA	•Q.E.D. A150 Saliva Alcohol Test.

\* The devices listed by this manufacturer are the same device sold under tow different names.

<sup>1</sup> It should be noted, however, that while the ALCO–SCREEN 02<sup>TM</sup> saliva-alcohol screening device manufactured by Chematics, Inc. passed the requirements of the model specifications when tested at 40° C (104° F), the manufacturer has indicated that the device cannot exceed storage temperatures of 27° C (80° F). (Instructions to this effect are stated on all packaging accompanying the device.) Accordingly, the device should not be stored at temperatures above 27° C (80° F) and, if the device is stored at or below 27° C (80° F) and used at higher temperatures, the test should be completed immediately. When these devices were stored at or below 27° C (80° F) and used at higher temperatures, the test should be completed immediately. When these devices were stored at or below 27° C (80° F) and tested at 40° C (104° F) immediately (i.e., within a minute), the devices met the model specifications and the results persisted for 10–15 minutes. When these devices were stored at or below 27° C (80° F) and were equilibrated at 40° C (104° F) for an hour prior to sample application, the devices failed to meet the model specifications. Storage at temperatures above 27° C (80° F), for even brief periods of time, may result in false negative readings.

the test should be completed immediately. When these devices were stored at or below 27° C (80° F) and tested at 40° C (104° F) immediately (i.e., within a minute), the devices met the model specifications and the results persisted for 10–15 minutes. When these devices were stored at or below 27° C (80° F) and were equilibrated at 40° C (104° F) for an hour prior to sample application, the devices failed to meet the model specifications. Storage at temperatures above 27° C (80° F), for even brief periods of time, may result in false negative readings. <sup>2</sup> While this device passed all of the requirements of the model specifications, readings should be taken only after the time specified by the manufacturer. For valid readings, the user should follow the manufacturer's instructions. Readings should be taken one (1) minute after a sample is introduced at or above 30° C (86° F); readings should be taken after two (2) minutes at 18° C–29° C (64.4° F–84.2° F); and readings should be taken after five (5) minutes when testing at temperatures at or below 17° C (62.6° F). If the reading is taken before five (5) minutes has elapsed under the cold conditions, the user is likely to obtain a reading that underestimates the actual saliva-alcohol level.

Note that devices 1, 3, 4 and 6 are breath alcohol testers that use semiconductor type sensors. Devices 2, 5, and 7 are saliva alcohol testers that use enzymatic techniques to measure the alcohol concentration in a saliva sample. Issued on: August 10, 1995.

## James Hudlund,

Acting Associate Administrator for Traffic Safety Programs. [FR Doc. 95–20179 Filed 8–14–95; 8:45 am] BILLING CODE 4910–59–M

## Denial of Motor Vehicle Defect Petition from Victor A. Fleming

This notice sets forth the reasons for the denial of a petition submitted to the NHTSA under 49 U.S.C. 30162(a)(2) (formerly section 124 of the National Traffic and Motor Vehicle Safety Act of 1966, as amended).