(2) Astronauts and pilots,
(3) The NASA workforce (including NASA employees working under NASA instruments), and
(4) High-value equipment and property.

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DEPARTMENT OF TRANSPORTATION
Office of the Secretary
49 CFR Part 40
[Docket OST–2002–13431]
RIN 2105–AD13
Procedures for Transportation Workplace Drug and Alcohol Testing Programs; Procedures for Non-Evidential Alcohol Screening Devices
AGENCY: Office of the Secretary, DOT.
ACTION: Final rule.
SUMMARY: The Department of Transportation (DOT) originally established procedures for use of non-evidential alcohol screening devices (ASDs) in April, 1995. At that time, we indicated that as additional ASDs were determined by the National Highway Traffic Safety Administration (NHTSA) to be capable of detecting the presence of alcohol at the 0.02 or greater level of alcohol concentration, they would be suitable for use within DOT regulated industry testing programs. Because NHTSA has approved a device, the operating mechanism of which differs from other ASDs, the Department had no Part 40 procedures for its use. This rule establishes procedures for the use of this device.
DATES: This rule is effective October 31, 2002.
FOR FURTHER INFORMATION CONTACT: Jim L. Swart, Drug and Alcohol Policy Advisor at 202–366–3784 (voice), 202–366–3897 (fax), or at: jim.swart@ost.dot.gov (e-mail).
SUPPLEMENTARY INFORMATION:
Background
When the Department originally published its alcohol testing rules on February 15, 1994 (54 FR 7302 et seq.), the Department established breath testing using evidential breath testing devices (EBTs) as the method to be used. However, in response to comments requesting additional flexibility in testing methods the Department said that NHTSA would develop model specifications, evaluate additional screening devices, and periodically publish a conforming products list of those additional screening devices that meet model specifications. The Department noted, too, that the Department would also have to undertake separate rulemaking proceedings to establish procedures for use by DOT-regulated industries of any devices after they are approved by NHTSA.
On April 20, 1995 (FR Vol. 60, No. 76), the Department published procedures for use of ASDs, both breath devices and saliva devices. At that time, the Department did not anticipate that additional devices would be developed that, while using breath or saliva as the means of obtaining a result, would necessitate new procedures for their use. As a result, the revised Part 40 (65 FR 79462) published December 19, 2000 stated, in part, that ASDs on the NHTSA conforming products list (CPL) could be used for Part 40 alcohol screening tests. Because NHTSA added an ASD to their CPL and the Department had no procedures for its use, we were forced to amend that rule. On August 9, 2001 (65 FR 41944) Part 40 was amended to read, “You may use an ASD that is on the NHTSA CPL for DOT alcohol tests only if there are instructions for its use in this part.”
This effectively prevented use of this ASD for DOT testing purposes even though it was on NHTSA’s CPL. The Department has taken steps to rectify this situation by developing procedures for this ASD’s use and by amending the regulation accordingly. We have also taken the step to fine-tune the regulation to include in regulation text the fact that breath alcohol technicians (BAT), knowledgeable of how to use an ASD (or ASDs), can conduct screening tests using them.
Instructions for use of the breath tube are somewhat parallel to those for the saliva device. Both devices prohibit use of the device after the expiration date has been reached. Both have procedures for conducting additional tests if proper procedures cannot be followed. Both have some similar fatal flaw criteria.
The breath tube requires the STT or BAT to remove a tube from the box and break the device’s ampule in the presence of the employee. The STT or BAT must then attach an inflation bag to the appropriate end of the tube. The employee is given the opportunity to hold the tube and provided instructions regarding how to blow (i.e., forcefully and steadily for approximately 12 seconds) through the tube. The rules also provide instructions for reading the results. In this case, the STT or BAT must compare the color of the crystals in the breath tube with the colored crystals on manufacturer-produced control tube. Comparisons must take place within specific time frames.
Fatal Flaws” require tests to be cancelled. Problems with the breath tube which cause fatal flaws are: The STT or BAT reads the device either sooner or after than the time allotted; and the device is used after its expiration date.
The breath tube works this way. When a person’s breath is blown though the tube it goes around and across the tube’s crystals. If the person’s breath contains no alcohol, the crystals remain their original color. However, if the person’s breath contains alcohol, the alcohol causes a chemical reaction leading to a change in crystal color. A color change matching the color of crystals in the control tube is indicative of a screening test result that must subsequently be confirmed using an EBT. Such a color change indicates that the screening test result is 0.02 or above.
Regulatory Analyses and Notices
This rule is not a significant rule for purposes of Executive Order 12866 and DOT. It does not increase costs on regulated parties. In fact it may facilitate the use of a device that may increase flexibility, and decrease costs, for employers who choose to use them. There are not sufficient Federalism implications to warrant the preparation of a Federalism Assessment. The Department certifies that this rule will not have a significant economic impact on a substantial number of small entities. To the extent that there is any such impact, it is expected to be a small favorable impact, since some small entities may be able to conduct screening tests at a lower cost.
The Department is issuing this as a final rule without opportunity for notice and public comment. The Department determined that doing so would be impracticable, unnecessary, and contrary to the public interest because this breath device already appears on NHTSA’s CPL and has, therefore, proven to be an accurate screening device for Part 40 alcohol screening tests.
List of Subjects in 49 CFR Part 40
Alcohol testing, Drug testing, laboratories, Reporting and recordkeeping requirements, Safety, Transportation.
PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

§ 40.245 What is the procedure for an alcohol screening test using a saliva ASD or a breath tube ASD?

(a) As the STT or BAT, you must take the following steps when using the saliva ASD:

(1) Check the expiration date on the device or on the package containing the device and show it to the employee. You may not use the device after its expiration date.

(2) Open an individually wrapped or sealed package containing the device in the presence of the employee.

(3) Offer the employee the opportunity to use the device. If the employee uses it, you must instruct the employee to insert it into his or her mouth and use it in a manner described by the device’s manufacturer.

(4) If the employee chooses not to use the device, or in all cases in which a new test is necessary because the device did not activate (see paragraph (a)(7) of this section), you must insert the device into the employee’s mouth and gather saliva in the manner described by the device’s manufacturer. You must wear single-use examination or similar gloves while doing so and change them following each test.

(5) When the device is removed from the employee’s mouth, you must follow the manufacturer’s instructions regarding necessary next steps in ensuring that the device has activated.

(b) If you were unable to successfully follow the procedures of paragraphs (a)(3) through (a)(5) of this section (e.g., the device breaks apart, the employee did not fill the inflation bag), you must discard the device and conduct a new test using a new one.

(ii) The new device you use must be one that has been under your control or that of the employee before the test.

(iii) You must note on the “Remarks” line of the ATF the reason for the new test. (Note: You may continue using the same ATF with which you began the test.)

(iv) You must offer the employee the choice of using the device or having you use it unless the employee, in the opinion of the STT or BAT, was responsible (e.g., the employee dropped the device) for the new test needing to be conducted.

(v) If you are unable to successfully follow the procedures of paragraphs (a)(3) through (a)(5) of this section, the device does not activate, you must discard the device and conduct a new test, in the same manner as provided in paragraph (a)(6) of this section. In this case, you must place the device into the employee’s mouth to collect saliva for the new test.

(c) You must read the result displayed on the device no sooner than the device’s manufacturer instructs. In all cases the result displayed must be read within 15 minutes of the test. You must then show the device and its reading to the employee and enter the result on the ATF.

(d) You must never re-use devices, swabs, gloves or other materials used in saliva testing.

(e) You must note the fact that you used a saliva ASD in Step 3 of the ATF.

(f) As the STT or BAT, you must take the following steps when using the breath tube ASD:

(1) Check the expiration date on the device or on the package containing the device and show it to the employee. You must not use the device after its expiration date.

(2) Remove a device from the package and break the tube’s ampule in the presence of the employee.

(3) Secure an inflation bag onto the appropriate end of the device, as directed by the manufacturer on the device’s instructions.

(4) Offer the employee the opportunity to use the device. If the employee chooses to use (e.g. hold) the device, instruct the employee to blow forcefully and steadily into the blowing end of device until the inflation bag fills with air (approximately 12 seconds).

(5) If the employee chooses not to hold the device, you must hold it and provide the use instructions in paragraph (b)(4) of this section.
§ 40.267 What problems always cause an alcohol test to be cancelled?

As an employer, a BAT, or an STT, you must cancel an alcohol test if any of the following problems occur. These are “fatal flaws.” You must inform the DER that the test was cancelled and must be treated as if the test never occurred. These problems are:

(a) In the case of a screening test conducted on a saliva ASD or a breath tube ASD:

(1) The STT or BAT reads the result either sooner than or later than the time allotted by the manufacturer and this Part (see § 40.245(a)(8) for the saliva ASD and § 40.245(b)(8) for the breath tube ASD).

(2) The saliva ASD does not activate (see § 40.245(a)(7); or

(3) The device is used for a test after the expiration date printed on the device or on its package (see § 40.245(a)(1) for the saliva ASD and § 40.245(b)(1) for the breath tube ASD).

(b) In the case of a test conducted on a breath tube ASD:

(1) The STT or BAT fails to comply with § 40.245(b)(1) for the breath tube ASD.

(2) The breath tube ASD does not activate (see § 40.245(a)(7); or

(3) The breath tube ASD is used for a test after the expiration date printed on the breath tube ASD.

You must cancel an alcohol test if any of the following problems occur:

(CFR 49 366–371)