

specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA section 3006(b), EPA grants a State's application for authorization as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a

copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This action nevertheless will be effective January 10, 2005, because it is an immediate final rule.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indians—lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: October 28, 2004.

Ira Leighton,

Acting Regional Administrator, EPA New England.

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST-2003-15245]

RIN 2105-AD47

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Interim final rule.

SUMMARY: The Department of Transportation is amending certain provisions of its drug and alcohol testing procedures to change instructions to laboratories and medical review officers with respect to adulterated, substituted, and diluted specimen results. This change is intended to avoid inconsistency with new requirements established by the U.S. Department of Health and Human Services that went into effect on November 1, 2004.

DATES: This rule is effective November 9, 2004. Comments to the interim final

rule should be submitted by December 9, 2004. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

(1) By mail to the Docket Management System (SVC-124), U.S. Department of Transportation, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001;

(2) By delivery to room PL-401 on the Plaza Level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366-9329;

(3) By fax to the Docket Management Facility at (202) 493-2251; or,

(4) By electronic means through the Web site for the Docket Management System at: <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this rulemaking. Comments to the docket will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The public may also review docketed comments electronically at: <http://dms.dot.gov>.

Anyone wishing to file a comment should refer to the OST docket number (OST-2003-15245).

FOR FURTHER INFORMATION CONTACT: Jim L. Swart, Deputy Director (S-1), Office of Drug and Alcohol Policy and Compliance, 400 Seventh Street, SW., Washington, DC 20590; telephone number (202) 366-3784 (voice), (202) 366-3897 (fax), or jim.swart@ost.dot.gov (e-mail).

SUPPLEMENTARY INFORMATION:

Purpose

Recently, the U.S. Department of Health and Human Services (HHS) revised their Mandatory Guidelines (69 FR 19644) with an effective date of November 1, 2004. Among the many revisions contained in the HHS Mandatory Guidelines are the requirements that laboratories modify substituted specimen and diluted specimen testing and reporting criteria. HHS revised laboratory requirements for adulterated specimen testing. HHS also requires each Federal agency to conduct specimen validity testing (SVT) to determine if urine specimens collected under HHS Federal Workplace Drug Testing Programs have been adulterated or substituted.

While the Department of Transportation (DOT) intends to fully address all aspects of the HHS changes to their Mandatory Guidelines in a notice of proposed rulemaking (NPRM) to be published in the near future, we believe that it is appropriate to make a few modifications to part 40 to avoid a number of inconsistent requirements that the application of both part 40 and HHS Mandatory Guidelines may have created for laboratories and medical review officers (MROs) since November 1, 2004. Consequently, in this document, we are taking the following steps:

1. We have removed from part 40 the requirement that MROs deal with substituted results in a two-tiered fashion (*i.e.*, medical review for some and recollection under direct observation for others). MROs will provide medical review and verification for all laboratory-reported substituted specimen results. This change is necessary because, under the HHS Mandatory Guidelines, there will be no specimens with creatinine levels greater than or equal to 2 mg/dL that will be considered substituted.

2. We have also removed all part 40 references to substituted specimens having creatinine levels greater than or equal to 2 mg/dL. These simply will no longer exist under HHS Mandatory Guidelines.

3. We have made laboratory testing criteria for specific gravity and creatinine concentration of substituted specimens and diluted specimens consistent with the HHS Mandatory Guidelines. A urine specimen will be considered dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030. Previously, urine specimens had been considered dilute when the creatinine concentration was above 5 mg/dL but less than 20 mg/dL and the specific gravity was greater than 1.001 but less than 1.003.

4. We have revised § 40.91 to make our authorized SVT consistent with the HHS Mandatory Guidelines. We have adopted HHS instructions that direct laboratories to perform validity tests for oxidizing adulterants and additional validity tests when certain conditions (*e.g.*, abnormal physical characteristics) are observed.

5. We have made laboratory results reporting requirements parallel to those in the HHS Mandatory Guidelines (with the exception of negative-dilute specimen results, explained in the section below).

Background

The DOT issued an interim final rule (IFR) on May 28, 2003 (68 FR 31624) in order to respond to scientific and medical information suggesting that we modify testing criteria for some specimens that were considered to be substituted and ultimately were treated as refusals to test. That 2003 IFR did not change the substitution criteria established by the HHS that we had used for our substitution criteria. However, the 2003 IFR required laboratories to report the numerical values of substituted specimens to MROs.

MROs were subsequently directed by the 2003 IFR to treat a substituted result as negative-dilute if the creatinine concentration was greater than or equal to 2 mg/dL. But, unlike part 40 procedures with other negative-dilute specimen results, MROs were instructed to direct employers to have the employee return to the collection site for a directly observed collection with no prior notice given to the employee. The result of the observed collection would be the result of record for the entire testing event. The HHS Mandatory Guidelines' approach to substituted test results allows DOT to simplify our guidance to MROs on how to deal with them.

The 2003 IFR solicited comments, and we received them from a dozen commenters. We will address these comments in the preamble to the forthcoming NPRM. In addition, some comments to the 2003 IFR mirrored comments that HHS received to the portion of the Mandatory Guidelines for which they requested comments. We will also take the HHS docket comments and their response to them into consideration in our upcoming NPRM.

While we have changed a number of items in part 40 to bring consistency between part 40 and the HHS Mandatory Guidelines (see previous section) regarding SVT, there are several important items on which the DOT and HHS rules will differ.

1. The DOT will maintain its current position that SVT is authorized but not required. In our 2000 regulation (65 FR 79462), we made SVT mandatory but retracted the requirement in technical amendments published in 2001 (66 FR 41944). We will not make SVT mandatory as a feature of this IFR, but may propose, in a forthcoming NPRM that we are considering, that such testing be made mandatory. Therefore, § 40.89 remains unchanged by this IFR. However, laboratories conducting SVT of DOT specimens must do so in accordance with the testing

requirements established in the HHS Mandatory Guidelines.

In proposing mandatory SVT in the NPRM, we would consider HHS' entire Mandatory Guidelines and any subsequent HHS handbook materials. We would also update our cost figures for SVT (that were originally calculated four years ago) in the context of such a proposal. Ultimately, this should enable DOT-regulated employers not currently conducting SVT the time needed to arrange with their laboratories and Consortia/Third Party Administrators to do so.

2. In this IFR, we will require MROs to treat laboratory reported negative-dilute results with creatinine levels greater than or equal to 2 mg/dL but equal to or less than 5 mg/dL as negative-dilutes that require immediate recollections under direct observation. Therefore, MRO procedures at § 40.155 reflect this requirement and employers will continue to follow their obligations for negative-dilute results at § 40.197(b) and (c).

3. To assist MROs with their negative-dilute results responsibilities, we will require laboratories to provide creatinine and specific gravity numerical values for all specimens they report to the MRO as being negative-dilute.

Regulatory Analyses and Notices

The statutory authority for this rule derives from the Omnibus Transportation Employee Testing Act of 1991 (49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*) and the Department of Transportation Act (49 U.S.C. 322).

This rule is not significant for purposes of Executive Order 12866 or the DOT's regulatory policies and procedures. It represents minor modifications to our procedures which are intended to further align our laboratory and MRO procedures with those requirements that are being directed by HHS. Their economic effects will be negligible. Consequently, the Department certifies, under the Regulatory Flexibility Act, this rule will not have a significant economic impact on a substantial number of small entities.

Under the criteria of section 553 of the Administrative Procedure Act (APA), an agency may, for good cause, determine that prior notice and public comment are impractical, unnecessary, or contrary to the public interest. The Department believes good cause exists for this interim change to be made without prior notice and public comment. It is imperative that some significant laboratory and MRO

requirements of the Department's regulation and that of HHS be harmonized.

List of Subjects in 49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

Issued this 4th Day of November, 2004, at Washington DC.

Norman Y. Mineta,
Secretary of Transportation.

■ For reasons discussed in the preamble, the Department of Transportation amends part 40 of Title 49 Code of Federal Regulations, subtitle A, as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

■ 1. The authority citation for 49 CFR Part 40 is revised to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*; 49 U.S.C. 322.

■ 2. Section 40.67 is amended by revising paragraph (a)(3) to read as follows:

§ 40.67 When and how is a directly observed collection conducted?

(a) * * *
(3) The laboratory reported to the MRO that the specimen was negative-dilute with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, and the MRO reported the specimen to you as negative-dilute and that a second collection must take place under direct observation (see § 40.197(b)(1)).

■ 3. Section 40.91 is amended by revising paragraphs (a), (b), (c), (d), and (e) and by removing paragraph (f) as follows:

§ 40.91 What validity tests must laboratories conduct on primary specimens?

(a) You must determine the creatinine concentration on each primary specimen. You must also determine its specific gravity if you find the creatinine concentration to be less than 20 mg/dL.
(b) You must determine the pH of each primary specimen.
(c) You must perform one or more validity tests for oxidizing adulterants on each primary specimen.

(d) You must perform additional validity tests on the primary specimen when the following conditions are observed:

- (1) Abnormal physical characteristics;
- (2) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (*e.g.*, non-recovery of internal standards, unusual response); or
- (3) Possible unidentified interfering substance or adulterant.

(e) If you determine that the specimen is invalid and HHS guidelines direct you to contact the MRO, you must contact the MRO and together decide if testing the primary specimen by another HHS certified laboratory would be useful in being able to report a positive or adulterated test result.

■ 4. Section 40.93 is revised to read as follows:

§ 40.93 What criteria do laboratories use to establish that a specimen is dilute or substituted?

(a) As a laboratory, you must consider the primary specimen to be dilute when:

- (1) The creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL, and
- (2) The specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(b) As a laboratory, you must consider the primary specimen to be substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests and on both the initial and confirmatory specific gravity tests on two separate aliquots.

■ 5. Section 40.97 is amended by revising (a)(2), (6) and (7) and (e)(1) and (2), and adding paragraph (e)(3), to read as follows:

§ 40.97 What do laboratories report and how do they report it?

- (a) * * *
(2) Negative-dilute, with numerical values for creatinine and specific gravity;
* * * * *
- (6) Adulterated, with numerical values (when applicable), with remark(s);
- (7) Substituted, with numerical values for creatinine and specific gravity;
* * * * *

(e)(1) You must provide quantitative values for confirmed positive drug test results to the MRO when the MRO requests you to do so in writing. The MRO's request may be either a general request covering all such results you

send to the MRO or a specific case-by-case request.

(2) You must provide the numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO.

(3) You must also provide to the MRO numerical values for creatinine and specific gravity for the negative-dilute test result, without a request from the MRO.

* * * * *

§ 40.131 [Amended]

■ 6. Section 40.131(a) is amended by removing, after the word "substituted" and before the comma, the words "with creatinine concentration of less than 2 mg/dL".

■ 7. Section 40.145 is amended by revising paragraphs (a) and (e)(2) to read as follows:

§ 40.145 On what basis does the MRO verify test results involving adulteration or substitution?

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive for a drug or drug metabolite.

* * * * *

(e) * * *
(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine through physiological means, meeting the creatinine concentration criterion of less than 2 mg/dL and the specific gravity criteria of less than or equal to 1.0010 or greater than or equal to 1.0200 (see § 40.93(b)).

* * * * *

■ 8. Section 40.155 is amended by revising paragraphs (a) and (c) to read as follows:

§ 40.155 What does the MRO do when a negative or positive test result is also dilute?

(a) When the laboratory reports that a specimen is dilute, you must, as the MRO, report to the DER that the specimen, in addition to being negative or positive, is dilute.

* * * * *

(c) When you report a dilute specimen to the DER, you must explain to the DER the employer's obligations and choices under § 40.197, to include the requirement for an immediate recollection under direct observation if the creatinine concentration of a negative-dilute specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/dL.

§ 40.197 [Amended]

■ 9. Section 40.197 (b)(1) is amended by replacing the words “(see

§ 40.145(a)(1))” with the words “(see § 40.155(c))”.

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