DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST–2003–15245]

RIN 2105–AD26

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Interim final rule.

SUMMARY: The Department of Transportation (DOT) is amending a provision of its drug and alcohol testing procedures to change the instructions to medical review officers (MROs) with respect to reporting specimens as dilute or substituted. The change is based on the Department's experience since the adoption of its current rule and new scientific information on the subject.

DATES: This rule is effective May 28, 2003. Comments on the interim final rule should be submitted by August 26, 2003. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Anyone wishing to file a comment should refer to the OST docket number (OST–2003–15245). You may submit your comments and related material by only one of the following methods: You may mail your comments to the Docket Management System, U.S. Department of Transportation, room PL–401, 400 7th Street, SW., Washington, DC 20590–0001; or you may submit your comments electronically through the Web site for the Docket Management System at *http://dms.dot.gov.* For instructions on how to submit comments electronically, visit the Docket Management System Web site and click on the ''Help'' menu.

The Docket Management Facility maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at room PL–401 on the plaza level of the Nassif Building at the same address during regular business hours. You may also obtain access to this docket on the Internet at *http://dms.dot.gov.*

Anyone is able to search the electronic form of all comments received into the docket for this rulemaking by the name of the person submitting the comment (or signing it, in the case of a comment submitted on behalf of a business, association, or other organization). You may review DOT's complete Privacy Act statement in the **Federal Register** published April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, Washington, DC, 20590, 202–366–9310 (voice), 202–366–9313 (fax), or *bob.ashby@ost.dot.gov* (e-mail) or Ken Edgell, Acting Director, Office of Drug and Alcohol Policy and Compliance (ODAPC), 400 7th Street, SW., Room 10403, Washington, DC 20590, 202–366–3784 (voice), 202–366–3897 (fax), or *kenneth.edgell@ost.dot.gov* (e-mail).

SUPPLEMENTARY INFORMATION: In its current drug and alcohol testing procedures (49 CFR part 40), the Department sets forth criteria for determining when a specimen should be considered substituted (see § 40.93(b)). This provision states that:

> As a laboratory, you must consider the primary specimen to be substituted if the creatinine concentration is less than or equal to 5 mg/dL and the specific gravity is less than or equal to 1.001 or greater than or equal to 1.020.

These criteria, which are taken directly from Department of Health and Human Services (HHS) program documents, are important because, if an employee's specimen meets them, the employee will be regarded as having refused the drug test, typically with consequences equivalent to those for a positive test.

Substitution testing and criteria were controversial subjects during the rulemaking that created the current part 40. In the preamble to the final rule, the Department extensively discussed these issues (see 65 FR 79478–79481; December 19, 2000). The Department concluded, based on studies by HHS and the Department of Transportation, that the creatinine criterion of less than or equal to 5 mg/dL was appropriate. We concluded that it was very unlikely that employees could produce urine meeting that standard through physiological means.

Nevertheless, the current rule provides procedures through which a medical review officer (MRO) verifies tests that a laboratory reports as substituted, including a means through which an employee can demonstrate that there is a legitimate medical explanation for the laboratory result (§ 40.145). If the MRO, after evaluating the employee and receiving the recommendation of a referral physician and the results of a demonstration that the individual can produce a low-creatinine specimen by natural means, ultimately finds that there is a legitimate medical explanation, the MRO will cancel the test result.

More recently, however, information has evolved suggesting that the Department's treatment of substitution matters should be reconsidered. The Department has become aware of a small number of cases in which individuals appear to have had legitimate medical explanations for producing specimens with a creatinine level of less than or equal to 5 mg/dL. These explanations have involved showings by a few individuals that they can produce low-creatinine specimens in demonstrations for a referral physician. Also, there is an increasing consensus among scientific and medical experts in relevant fields that the 5 mg/dL standard may not be appropriate. That is, there is probably a very small, but not insignificant, number of individuals who may, under normal circumstances, produce urine with creatinine concentrations below that level.

This information was discussed at a conference sponsored by the Federal Aviation Administration in Tampa, Florida, on February 4–6, 2003. The conference brought together toxicologists, nephrologists and other physicians, MROs, technical experts in various fields, and DOT and HHS officials. Attendees at the conference generally agreed that it would be appropriate to lower the creatinine criterion. The purpose of doing so would be to largely eliminate the possibility that individuals who could naturally produce urine creatinine concentrations below that current standard would be identified as having substituted a specimen. As directed by the Senate Appropriations subcommittee with jurisdiction over the FAA, which expressed concern about the possibility of some employees inadvertently failing to meet current validity standards, the Department will shortly submit to that subcommittee a final report incorporating the material discussed at the conference. When the Department submits this report, we will also post it in the docket for this rulemaking.

The Department is continuing to work with HHS, laboratories, and other interested persons on issues related to substitution. This process may take considerable time. Meanwhile, the Department believes that it is sensible to take an interim step to minimize the possibility of individuals who can naturally produce urine with creatinine concentrations of less than or equal to 5 mg/dL being identified as having substituted their specimens.

Consequently, in this interim final rule, we are taking the following steps.

1. We are directing laboratories to report to MROs, on Copy 1 of the Custody and Control Form (CCF) (also in the optional laboratory report), the creatinine and specific gravity quantifications for all DOT specimens that meet the regulatory substitution criteria. In these situations, laboratories will be required to include a notation on Copy 1 saying, for example, ''Creatinine, 4.5 mg/dL; Specific Gravity, 1.001.'' Note, however, that we are not changing existing substitution criteria (see § 40.93).

2. In making this report, laboratories would report quantitative values for creatinine only when the creatinine concentration in a specimen was above a laboratory's minimum detection limit. Anything below this limit would be reported as ''creatinine not detected.'' If MROs inquire what a particular laboratory's limit of detection is for a particular specimen, the laboratory should provide this information. It is our understanding that all HHS-certified laboratories have a limit of detection for creatinine of 1 mg/dL or less

3. When an MRO gets a report from the laboratory that the creatinine level in a specimen is less than 2 mg/dL or is ''creatinine not detected,'' the MRO will report the specimen to the employer as ''substituted.'' When the MRO gets a report from the laboratory that the creatinine level in a specimen is greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, the MRO will report the specimen to the employer as ''dilute,'' just as if the creatinine concentration were greater than or equal to 5 but less than 20 mg/dL (and also negative or positive, as provided in § 40.155).

4. When the MRO gets a report from the laboratory that the creatinine level in a specimen is 2 mg/dL or above but less than or equal to 5 mg/dL, the MRO—in addition to reporting the specimen to the employer as dilute—must take an additional step. This step is to direct the employer to require the employee to undergo an immediate recollection under direct observation. The employer must then ensure that this recollection takes place.

The rationale for changing the reporting procedure for specimens in the 2–5 mg/dL creatinine concentration range is to provide the maximum margin of safety to ensure that people who may naturally produce low creatinine levels—most cases that have been brought to the Department's attention have been in the 4.1–4.9 mg/dL range—will not be reported to employers as having substituted their specimens. The Department is aware that this procedural change may for a time slightly increase the risk of individuals attempting to substitute their specimens to evade detection of drug use. We believe that this risk is outweighed by the benefit of avoiding unfairly identifying persons as having substituted specimens. Because specimens in the specified range may create greater concern than less dilute specimens that a substitution may have been attempted, we believe that heightened scrutiny of these specimens is warranted. We believe that the requirement for recollection under direct observation is justified as a safeguard against tampering with specimens.

[Here, and in other places in the rule, where we express a quantitative value as a whole number (*e.g.*, 2 or 5), we mean exactly that number (*e.g.*, 2.0 or 5.0).]

This series of steps will not cause laboratories to change existing criteria or procedures, limiting burdens on them to the ministerial step of adding a brief notation of existing data on an existing form. Based on laboratories' experience, laboratories are likely to have to follow these procedures in only about 2000 out of the several million DOT specimens tested each year.

The Department wishes to provide guidance to program participants concerning some questions we anticipate may arise in the implementation of these amendments to part 40 and related provisions. First, there may be some substituted specimens in process on the date this amendment becomes effective. If a laboratory has tested a specimen, found that it meets the substitution criteria of § 40.93, but has not yet reported the substituted result to the MRO on the effective date of this amendment, the laboratory should report it as substituted with the quantitative creatinine and specific gravity values, as this amendment provides.

If an MRO has received a substituted result before the effective date of the amendment and has not yet reported the result to the employer on the effective date of the amendment, the MRO should request the quantitations from the laboratory before reporting the result to the employer. The MRO would then report the result to the employer as substituted or dilute, as this amendment provides.

If the employer received a substituted result from the MRO before the effective date of this amendment, the employer would continue to treat the result as substituted, as provided in part 40 prior to these amendments. The employer in this case is not required to go back to the MRO or laboratory and obtain the quantitations for creatinine and specific gravity.

There could be situations in which a laboratory finds enough drug or metabolite in a specimen to report it as positive and at the same time determines that the specimen is substituted or, more likely, adulterated. Suppose, in such a situation, testing of the split does not confirm the substitution or adulteration finding. Program participants would still treat the test as a positive test for the drug.

Also, in order to reconfirm a substitution finding, it is not necessary for the laboratory testing the split to come to precisely the same quantitative result as the primary laboratory. Suppose the primary laboratory's quantitation for creatinine is 1.2 mg/dL. The second laboratory's quantitation is 1.8 mg/dL. Both results are less than 2 mg/dL. In this situation, we regard the initial result as having been reconfirmed. On the other hand, suppose the quantitation of creatinine by the first laboratory for the primary specimen is 1.9 mg/dL, and the quantitation of creatinine by the second laboratory for the split specimen is 2.3 mg/dL. In this case, the MRO would report the result of the split specimen as ''dilute'' (see numbered paragraph 3 above) with instructions to the employer to conduct an immediate recollection under direct observation.

We emphasize that, in the case where creatinine is reported as ''creatinine not detected'' (see amended § 40.97(e)(2)), the proper action for the MRO is to report the specimen to the employer as substituted. While the procedures of § 40.145 apply to such a case, § 40.151(i) tells MROs not to accept as a legitimate medical explanation for a substituted specimen an assertion that an employee can produce urine with no detectable creatinine.

Regulatory Analyses and Notices

This rule is not a significant rule under Executive Order 12866 or the Department of Transportation's Regulatory Policies and Procedures. Costs to laboratories and MROs will be minimal, since the rule merely makes a minor change in the way existing results are reported in a very small percentage of cases. There will be no significant burdens or economic effects on any of the participants in the drug testing process. Consequently, the Department certifies, under the Regulatory Flexibility Act, that 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, the Department has determined that prior notice and public comment on this rule are impractical, unnecessary, or contrary to the public interest. This is because, given the information now available to the Department, we have concluded that it is necessary to make an interim change immediately to avoid the possibility that individuals will be incorrectly reported as having substituted a specimen. For the same reason, the Department finds good cause to make this rule effective immediately.

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 16th day of May, 2003, at Washington, DC.

Norman Y. Mineta,

Secretary of Transportation.

■ For the reasons set forth in the preamble, the Department of Transportation amends 49 CFR Part 40 as follows:

PART 40—[AMENDED]

■ 1. The authority citation for Part 40 continues to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 *et seq.*

■ 2. Amend § 40.67 by revising paragraph (a) to read as follows:

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

(a) As an employer, you must direct an immediate collection under direct observation with no advance notice to the employee, if:

(1) The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to you that there was not an adequate medical explanation for the result;

(2) The MRO reported to you that the original positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be performed; or

(3) The laboratory reported to the MRO that the specimen was substituted with a creatinine concentration greater than or equal to 2 mg/dL and less than or equal to 5 mg/dL and the MRO reported the specimen to you as negative and dilute (see §§ 40.145(a)(1) and 40.197).

* * * * *

■ 3. Amend § 40.97 by revising paragraph (a) (7) and paragraph (e) to read as follows:

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

* * * * *

(a) * * *

(7) Substituted, with quantitative values for creatinine and specific gravity, and remarks; or

* * * * *

(e)(1) You must provide quantitative values for confirmed positive drug and adulterated 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 also provide to the MRO quantitative values for creatinine and specific gravity for all substituted test results when the result is above your detection limit. If the result is not above your detection limit, you must report ''creatinine not detected'' to the MRO. You must make these reports for in all cases of substituted tests, without a request from the MRO.

* * * * *

■ 4. Amend § 40.131(a) by adding, in the first sentence, after the word ''substituted'' and before the comma, the words ''with a creatinine concentration of less than 2 mg/dL.''

■ 5. Amend § 40.145 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 test for a drug or drug metabolite, unless the creatinine concentration for a substituted specimen was reported by the laboratory to be equal to or more than 2 mg/dL.

(1) If the laboratory has reported the creatinine concentration for a substituted specimen as equal to or more than 2 mg/dL, you must report the specimen to the DER as being dilute, as provided in § 40.155 of this part. Notwithstanding any other provision of this part, you must also instruct the DER that a second collection under direct observation must take place immediately.

(2) If the laboratory has reported the creatinine concentration for a substituted specimen as less than 2 mg/dL or ''creatinine not detected,'' you must follow the procedures set forth in paragraphs (b) through (h) of this section.

* * * * *

(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 criteria for creatinine of less than 2 mg/dL and for specific gravity of less than or equal to 1.001 or greater than or equal to 1.020.

* * * * *

■ 6. Amend § 40.155 (a) by adding, after the words ''reports that a specimen is dilute,'' the words ''or reports that a specimen is substituted with a creatinine quantitation of greater than or equal to 2 mg/dL.''

■ 7. Amend § 40.187(a) by adding a new paragraph (a)(3), to read as follows:

§ 40.187 What does the MRO do with split specimen laboratory results?

(a) * * *

(3) In the case of a reconfirmed substituted result, in which the creatinine concentration for the primary specimen was less than 2 mg/dL and the creatinine concentration of the split specimen is between 2 and 5 mg/DL, inclusive, report the result to the employer as ''dilute'' and instruct the employer to conduct an immediate recollection under direct observation.

* * * * *

■ 8. Revise § 40.191 (a)(6) to read as follows:

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

(a) * * *

(6) Fail or decline to take an additional drug test the employer or collector has directed you to take (see, for instance, § 40.197(b));

* * * * *

■ 9. Revise § 40.197 to read as follows:

§ 40.197 What happens when an employer receives a report of a dilute specimen?

(a) As the employer, if the MRO informs you that a positive drug test was dilute, you simply treat the test as a verified positive test. You must not direct the employee to take another test based on the fact that the specimen was dilute.

(b) As an employer, if the MRO informs you that a negative test was dilute, take the following action:

(1) If the MRO directs you to conduct a recollection under direct observation (*i.e.*, because the creatinine concentration of the specimen was equal to or greater than 2mg/dL, but less than or equal to 5 mg/dL (*see*

§ 40.145(a)(1)), you must do so immediately.

(2) Otherwise (*i.e.*, if the creatinine concentration of the dilute specimen is greater than 5 mg/dL), you may, but are not required to, direct the employee to take another test immediately.

(i) Such recollections must not be collected under direct observation, unless there is another basis for use of direct observation (see § 40.67 (b) and (c)).

(ii) You must treat all employees the same for this purpose. For example, you must not retest some employees and not others. You may, however, establish different policies for different types of tests (*e.g.*, conduct retests in pre-employment situations, but not in random test situations). You must inform your employees in advance of your decisions on these matters.

(c) The following provisions apply to all tests you direct an employee to take under paragraph (b) of this section:

(1) You must ensure that the employee is given the minimum possible advance notice that he or she must go to the collection site;

(2) You must treat the result of the test you directed the employee to take under paragraph (b) of this section—and not a prior test—as the test result of record, on which you rely for purposes of this part;

(3) If the result of the test you directed the employee to take under paragraph (b) of this section is also negative and dilute, you are not permitted to make the employee take an additional test because the result was dilute. Provided, however, that if the MRO directs you to conduct a recollection under direct observation under paragraph (b)(1) of this section, you must immediately do so.

(4) If the employee declines to take a test you directed him or her to take under paragraph (b) of this section, the employee has refused the test for purposes of this part and DOT agency regulations.

[FR Doc. 03–13242 Filed 5–27–03; 8:45 am]

BILLING CODE 4910–62–U

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 171

[Docket No. RSPA–02–12064 (HM–232)]

RIN 2137–AD67

Hazardous Materials Security Plans; Information Collection Approval

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Final rule.

SUMMARY: This final rule announces Office of Management and Budget (OMB) approval of information collection request (ICR) OMB No. 2137–0612, ''Hazardous Materials Security Plans''. This information collection has been approved by OMB until April 30, 2006. This final rule also makes appropriate revisions to regulations concerning the Paperwork Reduction Act to incorporate this new information collection approval under OMB Control No. 2137–0612.

DATES: The effective date of this final rule is June 20, 2003. This ICR expires on April 30, 2006.

FOR FURTHER INFORMATION CONTACT: Deborah Boothe or T. Glenn Foster, Office of Hazardous Materials Standards (DHM–10), Research and Special Programs Administration, Room 8422, 400 Seventh Street, SW., Washington, DC 20590–0001, Telephone (202) 366–8553.

ADDRESSES: Requests for a copy of an information collection should be directed to Deborah Boothe or T. Glenn Foster, Office of Hazardous Materials Standards (DHM–10), Research and Special Programs Administration, Room 8422, 400 Seventh Street, SW., Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. Background

On March 25, 2003, the Research and Special Programs Administration (RSPA, we) published a final rule to enhance the security of hazardous materials transported in commerce (68 FR 14510). In this final rule, shippers and carriers of certain highly hazardous materials must develop and implement security plans. In addition, all shippers and carriers of hazardous materials must assure that their employee training includes a security component. The effective date of this final rule is March 25, 2003.

On April 30, 2003, OMB approved information collection for the development of and maintenance of security plans, OMB No. 2137–0612, ''Hazardous Materials Security Plans'', until April 30, 2006. Because OMB approved the information collection after publication of the March 25, 2003 final rule, we are announcing the OMB approval and incorporating this new information collection approval into § 171.6, ''Control numbers under the Paperwork Reduction Act.'', under OMB Control No 2137–0612.

OMB regulations (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (*see* 5 CFR 1320.8(s)) and specify that no person is required to respond to an information collection unless it displays a valid OMB control number. In accordance with the Paperwork Reduction Act of 1995, RSPA has received OMB approval of the following ICR and § 171.6(b)(2) is revised by incorporating the following information collection:

OMB Control Number: 2137–0612.

Title: Hazardous Materials Security Plans.

This information collection approval expires on April 30, 2006. This information collection request was approved by OMB on April 30, 2003.

II. Summary of Regulatory Changes

Section 171.6

We are revising the table in paragraph (b)(2) to incorporate a new information collection, OMB No. 2137–0612, ''Hazardous Materials Security Plans,'' and the affected sections, which include a new part 172, subpart I—Security Plans and §§ 172.800, 172.802, and 172.804.

III. Rulemaking Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule is not considered a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was not reviewed by the Office of Management and Budget. This rule is not significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034). Because of the minimal economic impact of this rule, preparation of a regulatory impact analysis or a regulatory evaluation is not warranted.