

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:

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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.