

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*