

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.