technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

L. Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraphs (34)(a) and (b) of the Instruction, from further environmental documentation because this rule involves editorial, procedural, and internal agency functions. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 46 CFR Part 31

Cargo vessels, Marine safety, Reporting and recordkeeping requirements.

■ For the reasons discussed in the preamble, the Coast Guard amends 46 CFR part 31 as follows:

PART 31—INSPECTION AND CERTIFICATION

■ 1. The authority citation for part 31 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2103, 3205, 3306, 3307, 3703; 46 U.S.C. Chapter 701; 49 U.S.C. 5103, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1. Section 31.10–21 also issued under the authority of Sect. 4109, Pub. L. 101–380, 104 Stat. 515.

■ 2. In § 31.10–16, revise paragraph (e) to read as follows:

§ 31.10–16 Inspection and certification of cargo gear-TB/ALL.

* * * * *

(e) The authorization for organizations to perform the required inspection is granted by the Chief, Office of Vessel Activities, Commandant (CG–543), and will continue until superseded, canceled, or modified. The following organizations are currently recognized by the Commandant (CG–543) as having the technical competence to handle the required inspection:

(1) National Cargo Bureau, Inc., with home offices at 17 Battery Place, Suite 1232, New York, NY 10004.

(2) The International Cargo Gear Bureau, Inc., with home office at 321 West 44th Street, New York, NY 10036.

Dated: June 19, 2008.

Stefan G. Venckus,

Chief, Office of Regulations and Administrative Law, United States Coast Guard.

[FR Doc. E8–14293 Filed 6–24–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket No. OST–2003–15245]

RIN 2105–AD55

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: The Department of Transportation is amending certain provisions of its drug and alcohol testing procedures to change instructions to collectors, laboratories, medical review officers, and employers regarding adulterated, substituted, diluted, and invalid urine specimen results. These changes are intended to create consistency with specimen validity requirements established by the U.S. Department of Health and Human Services and to clarify and integrate some measures taken in two of our own Interim Final Rules. This Final Rule makes specimen validity testing mandatory within the regulated transportation industries.

DATES: This rule is effective August 25, 2008.

FOR FURTHER INFORMATION CONTACT: Jim L. Swart, Acting Director (S–1), U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone number (202) 366–3784 (voice), (202) 366–3897 (fax), or *jim.swart@dot.gov* (e-mail).

SUPPLEMENTARY INFORMATION:

Background

The Omnibus Transportation Employee Testing Act of 1991, 49 U.S.C. 31300, *et seq.*, 49 U.S.C. 20100, *et seq.*, 49 U.S.C. 5330, *et seq.*, and 49 U.S.C. 45100, *et seq.* (the Omnibus Act), requires the U.S. Department of Transportation (DOT) to use the laboratories certified by, and testing procedures of, the U.S. Department of Health and Human Services (HHS) to ensure ''the complete reliability and accuracy of controlled substances tests.'' Since Congress specifically limited the scientific testing methodology upon which the DOT can rely in making its drug and alcohol testing regulations, we follow the HHS scientific and technical guidelines, including the amendments to their Mandatory Guidelines.

In its final rule of December 2000 [65 FR 79526], the U.S. Department of Transportation (DOT) made specimen validity testing (SVT) mandatory for the transportation industry contingent upon the HHS publishing its Mandatory Guidelines on SVT. DOT anticipated that HHS would, sometime in 2001, amend its Mandatory Guidelines to establish SVT requirements for HHS-certified laboratories. When it appeared that HHS would not establish final SVT requirements in 2001, we amended 49 CFR part 40 (part 40) to remove the mandatory requirement. We believed it advisable to wait until HHS completed its amendment before making SVT mandatory throughout the transportation industries for all DOT specimens.

On August 9, 2001, the DOT amended part 40 [66 FR 41952] to remove the mandatory requirement because HHS had not finalized its Mandatory Guidelines regarding SVT. SVT would remain authorized but not required.

The DOT issued a May 28, 2003 interim final rule (2003 IFR) [68 FR 31626] in response to scientific and medical information suggesting we modify testing criteria for some specimens that had been considered to be substituted and ultimately were treated as refusals to test. The 2003 IFR modified how the medical review officer (MRO) would deal with any substituted result with creatinine concentrations equal to or greater than 2, but less than or equal to 5 mg/dL [hereafter, ''2–5 mg/dL range'']. It did not change the HHS substitution criteria that we had used.

On April 13, 2004, the HHS published a **Federal Register** notice revising its Mandatory Guidelines [69 FR 19644] with an effective date of November 1, 2004. Among the revisions contained in the HHS Mandatory Guidelines were requirements that laboratories modify substituted and diluted specimen testing procedures and reporting criteria. The HHS also revised

laboratory requirements for adulterated specimen testing and made SVT mandatory for Federal employee testing under the HHS Federal Workplace Drug Testing Program.

In an IFR (2004 IFR) [69 FR 64865] published on November 9, 2004, the DOT changed a number of items in part 40 to make them consistent with the HHS Mandatory Guidelines. We did this to avoid conflicting requirements that implementation of both rules would have had on laboratories and MROs.

While the HHS Mandatory Guidelines' approach to substituted test results allowed DOT to simplify its guidance to MROs on how to deal with those results, there were several important differences between the 2004 IFR and the HHS Guidelines. The most important among them was the fact that SVT, though authorized by part 40 and the 2004 IFR, was not yet required.

In the 2004 IFR, we indicated that we intended to fully address all aspects of the HHS changes to their Mandatory Guidelines in a notice of proposed rulemaking (NPRM). We also said that we would take into consideration any subsequent HHS materials (e.g., HHS MRO Manual) and would update our cost figures for SVT in the context of making SVT mandatory.

Subsequently, the DOT published—on October 31, 2005—an NPRM [70 FR 62276] responding to comments made to the 2003 IFR and to the 2004 IFR. The NPRM also proposed making SVT mandatory and included a number of other proposed technical changes, mostly clarifying the procedures related to testing and reporting of adulterated, substituted, and invalid specimens.

Summary of NPRM Comments

A total of 27 commenters responded to the 2005 NPRM, making 234 separate comments. Eight commenters were individuals with no known affiliations; seven were MROs representing themselves or their organizations; two were employers; one was a Third-Party Administrator (TPA); four represented associations; four represented labor unions; and one represented a drug testing laboratory.

Eleven commenters expressed general support for the DOT effort to establish clear requirements for SVT that were consistent with the HHS procedures. Of these eleven, one individual thought the SVT rules should be more rigorous; four others commended the DOT in its efforts; one TPA thought the effort admirable; two labor unions commended and supported the DOT's efforts; one association applauded the effort; and one laboratory supported DOT efforts to bring more consistency on SVT with the HHS.

Six commenters specifically supported making SVT mandatory and five specifically opposed this proposal. Several stated that authorizing SVT is sufficient to address adulteration and substitution issues. A number of commenters provided numerous technical suggestions, supported most of the proposed changes or additions, and were interested in establishing relevant procedures to address the various issues of adulterated, substituted, and invalid test results.

A number of commenters were concerned about the current state of science related to SVT testing as compared to that of drug testing. At least two commenters believed the DOT needed to require laboratories to utilize two separate methodologies for certain SVT. However, this would require laboratories to change testing protocols that the HHS does not mandate.

A number of commenters supported the DOT's proposal to rectify past problems related to substituted specimens and suggested a number of options and recommendations. We appreciate the input from the commenters and considered their comments in the Informational Notice Regarding Certain Substituted Specimens published in the **Federal Register** on September 11, 2007 [72 51887]. Because we addressed those issues in that notice, we will not deal with them in this final rule.

A number of commenters raised part 40 issues unrelated to the proposed SVT issues. We have not addressed these unrelated items in this preamble because they are outside the scope of the NPRM.

Finally, the NPRM proposed or asked a number of major policy questions relevant to SVT. We specifically address major policy issues in a separate section and address the others in section-by-section discussions.

Principal Policy Issues

Mandatory Specimen Validity Testing

The DOT proposed making SVT mandatory, as in the current HHS Federal employee testing program.

Most commenters concurred with DOT's proposal to make SVT mandatory. Some commenters acknowledged this was necessary because the increase in products designed to adulterate specimens has made tampering with specimens more prevalent. The commenters also supported mandatory SVT because it would bring better control over the SVT process.

A number of commenters expressed concern that the science of SVT has yet to evolve to the same level of accuracy, reliability, and defensibility as the science of drug testing. Some of these commenters recommended that SVT should remain elective.

Several commenters believed that the DOT should require all laboratories to employ two separate SVT methodologies for adulterants because this would ensure more confirmed adulteration results. The commenters reasoned that laboratories would be more likely to report invalid results if they only used one SVT methodology.

Other comments on mandatory SVT included concerns about costs and the extent of adulterant testing. Some commenters believed the DOT's cost estimates for SVT were low. They requested clarification on the anticipated costs of initiating mandatory testing. Commenters also expressed concerns that laboratories were not testing for all adulterants.

DOT Response

The DOT continues to believe that mandatory testing for specimen validity is an appropriate response to the use of adulterants and attempts to subvert the collection and testing process. The HHS Mandatory Guidelines established SVT requirements with which laboratories must comply in order to become and remain HHS-certified. The HHS has stated that its SVT standards are designed to produce the most accurate, reliable, and correctly interpreted test results.

Currently, when DOT specimens are tested for validity, the HHS procedural standards apply. There is no reason to presume that these standards are scientifically insufficient. Therefore, we will require that urine specimens tested under the DOT-industry programs will be subject to the HHS procedural standards for SVT.

We will continue to utilize HHS instructions to laboratories for establishing cutoffs and directing laboratory analysis regarding creatinine levels. Within part 40, we added procedures to allow an employee to provide evidence to the MRO that he or she can produce a urine specimen below the 2.0 mg/dL cutoff. We created this procedural safeguard in the 2000 regulation because a small number of employees assert they may be capable of providing urine specimens with creatinine levels below 2.0 mg/dL, and that such low creatinine levels are not the result of tampering with their specimens. By adding an evidentiary process for results below the 2.0 mg/dL cutoff, we believe that we have created

sufficient safeguards to protect employees from being wrongfully accused of tampering with their specimens.

The DOT shares the commenters' concerns about laboratories choosing to use one adulterant testing methodology because using one methodology instead of two may result in obtaining invalid results rather than confirmed adulterated results. However, HHS mandates all scientific and procedural requirements for drug testing at HHS-certified laboratories. HHS provides guidance to the laboratories on use of a secondary confirmatory methodology when a laboratory performs confirmatory adulteration testing. HHS authorizes, but does not require, laboratories to perform confirmatory adulteration testing. The Omnibus Act requires the DOT to incorporate the HHS scientific and technical guidelines, and we do not have the authority to impose additional scientific and technical requirements upon the laboratories.

While current laboratory testing data show a slight rise in invalid results and a slight decline in adulterated results over previous years, we do not have data based solely upon implementation of full SVT because the DOT has not required full implementation. As a consequence, the DOT will initiate permanent 6-month reviews of laboratory data on DOT-regulated specimens to obtain more specific information about this issue now that SVT will be mandatory for all DOT-regulated specimens. We will look at the reasons drug test results are classified as invalid versus adulterated to determine if use of one methodology instead of two is likely to cause more invalid results and fewer confirmed adulterated results. Part 40 requires laboratories to submit to DOT specific information regarding their SVT following full implementation. The regulatory text requiring this information is at § 40.111; and the required data are listed at Appendix C. We will use this information in our continuing discussions with HHS and others regarding SVT. We also want the information so that we can know the full scope of laboratory data on DOT-regulated tests.

The DOT cost estimates for full SVT and for laboratory data collections are in the regulatory analyses and notices section of this preamble.

Requirement for Laboratories To Contact MROs Before Reporting Invalid Results

The DOT asked if we should continue to require laboratories to contact MROs before reporting invalid results.

Several commenters, mostly MROs, responded to this question and generally indicated that laboratories are not routinely contacting them about invalid results as required by HHS and DOT. Some commenters were concerned that the rule text does not specify whether the MRO or the laboratory has the final decision on the disposition of the specimen. Also, the commenters expressed concern about whether the employer would be required to pay for sending the specimen to another laboratory. One commenter pointed out that DOT is requiring the MRO to discuss the result with ''the certifying scientist'' while HHS requires the MRO to discuss the result with the ''laboratory.'' Some laboratory personnel other than a certifying scientist, for example the Responsible Person (RP), may discuss invalids with the MRO. This commenter supported having the MRO talk with ''a certifying scientist.''

DOT Response

The rule continues to require laboratories to contact the MRO prior to reporting an invalid result, a requirement which mirrors the current HHS Mandatory Guidelines. The fact that some laboratories may not be following this requirement is not sufficient reason to suspend or disregard this procedure. The HHS identifies 12 separate criteria for identifying a specimen as invalid. Of these 12, the first three do not require laboratory contact with MROs. It is entirely possible that many of the invalid results fall under these three criteria and may explain the reason that contact between the laboratories and the MROs appears lacking. These three criteria are:

1. Inconsistent creatinine concentration and specific gravity results;

2. The pH is greater than or equal to 3 and less than 4.5, or greater than or equal to 9 and less than 11; or

3. The nitrite concentration is greater than or equal to 200 mcg/mL, but less than 500 mcg/mL.

As indicated before, some laboratory testing methodologies may differ. If the invalid result is related to the criteria listed in the HHS Mandatory Guidelines—under sections 2.4(7), (iv) through (xii), the MRO and laboratory might conclude it is beneficial to conduct another test at a different laboratory to obtain a result that is not invalid. This would require a certifying scientist and the MRO to discuss the benefit of sending the specimen to another laboratory and to determine which laboratory would be able to conduct the appropriate test.

A few commenters requested that DOT specify whether the MRO or a certifying scientist would make the determination to send a specimen to another laboratory. The DOT believes this is a mutual decision to be made by both the MRO and a certifying scientist.

Regarding payment for additional testing, the DOT's position is similar to our stance on paying for split specimen testing. Regardless of who pays or how, it is the employer's responsibility to ensure that procedures are in place to accomplish the additional testing. We believe the cost of any additional tests would be less than the subsequent cost of recollecting under direct observation when the first laboratory reported the result as invalid.

One commenter said that the NPRM's reference to the MRO's conferring with ''the certifying scientist'' should remain ''a certifying scientist''—as it is in the current rule text. We agree, and our regulation reflects this.

HHS Blind Specimen Certification Criteria

The DOT proposed to adopt the HHS blind specimen certification criteria. HHS provides technical oversight to the laboratories, and quality control is part of that very important oversight. We did not receive comments regarding this proposal. Therefore, the DOT has adopted the HHS criteria for blind specimen certification.

Recollection Under Direct Observation When Creatinine Is in the 2–5 mg/dL Range

The DOT proposed adopting the 2004 IFR's approach to the treatment of negative-dilute specimens with creatinine in the 2–5 mg/dL range, which requires recollection under direct observation. The DOT requested comments about continuing this requirement. The majority of commenters supported the proposal to require recollections under direct observation for negative-dilute results with creatinine in the 2–5 mg/dL range.

Several commenters indicated that there was an increase in positive results from the directly observed recollections, while others stated the results were mostly negative. Most of these commenters provided anecdotal information. However, one commenter's data showed that a significant number

of the directly observed recollections produced non-negative results.

DOT Response

The DOT will continue to require the MRO to direct employers to conduct immediate recollections under direct observation when the original specimen is reported with a creatinine concentration in the 2–5 mg/dL range. We think the number of non-negatives produced during directly observed recollections is significant and justifies continuing the recollection requirement.

Although a few individuals claim the ability to produce urine specimens with this concentration of creatinine, there has been no conclusive evidence that this is a common occurrence. Concentration of creatinine at these levels is not the norm. In the interest of public safety, the DOT believes that a recollection under direct observation is a reasonable requirement.

HHS Requirement That an MRO Report a Negative Result When a Medical Explanation for a Substituted Specimen Appears Legitimate

The DOT proposed not adopting the HHS MRO Manual guidance for an MRO to report a negative result if the MRO believed there was a legitimate medical explanation for the substituted specimen. There were no comments related to this item.

DOT Response

Under part 40, the MRO will continue to have the ability to verify substituted specimens with medical explanations as cancelled tests. Because there are virtually no medical explanations for substituted results, the MRO must continue to report to DOT the medical basis for canceling the test.

Section-by-Section Discussion

The following part of the preamble discusses each of the final rule's sections, including responses to comments on each section.

Index

The DOT proposed to modify some existing section headings and add two new section headings to reflect regulation text changes. Seven section headings have been modified or added. Two commenters responded to this proposal and both supported it.

Section 40.3 What do the terms in this regulation mean?

In order to align more closely the definitions in § 40.3 with definitions contained in the HHS Mandatory Guidelines, the DOT proposed modifying some existing definitions and adding several new ones.

Commenters supported this proposal and responded by making suggested additions or changes to this section. Several commenters, especially MROs, recommended adoption of the term ''hyperdilute'' or ''superdilute'' to distinguish references to those negative-dilute specimens with creatinine concentrations in the 2–5 mg/dL range. They recommended that positive specimens the MROs downgrade to negatives be recollected if they are dilute with creatinine concentrations in the 2–5 mg/dL range. Additionally, the terms ''cancelled-invalid'' and ''confirmatory creatinine and specific gravity tests'' are used in the text. Commenters asked if these should be included in the definitions.

The DOT will modify eight definitions and add five new ones. We will include a definition of the term ''aliquot'' as defined in the HHS Mandatory Guidelines. For the term ''Oxidizing adulterant'' we did provide HHS' examples of these agents.

We will not use of the term ''hyperdilute'' or ''superdilute'' to describe a dilute specimen with creatinine concentrations in the 2–5 mg/dL range. Laboratories do not report specimens with creatinine concentrations in the 2–5 mg/dL range as ''hyperdilute'' or ''superdilute'' but rather as dilute with a numerical value. To require the use of this term in the reporting process would require laboratories to change their reporting format and the DOT will not direct them to do that.

Additionally, some MROs may think that the use of this term would somehow make it easier for them to report these results to the designated employer representative (DER). However, even if we adopted this term, the DERs would still have to be told that the reason for the test result being ''hyperdilute'' or ''superdilute'' is that the creatinine concentration fell in the 2–5 mg/dL range. The DOT does not think that adding a different name to a test result would in any way improve laboratory and MRO procedures.

We also proposed to use the term ''cancelled-invalid'' in the NPRM. However, we will not include this term in the text since laboratories will not report tests as being ''cancelled-invalid.'' In addition, current requirements call for the MRO to check the cancelled box on the Federal Drug Testing Custody and Control Form (CCF) and, on the remarks line, write that the reason is an invalid result. We think this is sufficiently clear in describing the test outcome. We will not add another term to the current lexicon of drug testing results. We use the term ''cancelled'' in the rule text rather than ''cancelled-invalid.''

One commenter asked if a definition should be developed to describe what is meant by a confirmatory creatinine and specific gravity test. The DOT believes that the terms ''confirmatory creatinine test'' and ''confirmatory specific gravity test'' are self-explanatory and do not need more specific definitions. A confirmatory specimen validity test is just that, a test on a separate aliquot to confirm the results of an initial specimen validity test.

Section 40.89 What is specimen validity testing, and are laboratories required to conduct it?

The DOT will make SVT mandatory by removing the option to conduct SVT and adding text requiring SVT. This proposal had a majority of favorable comments. Specific discussion of this item is listed under Principal Policy Issues.

Section 40.95 What are the adulterant cutoff concentrations for initial and confirmation tests?

Section 40.96 What criteria do laboratories use to establish that a specimen is invalid?

The DOT proposed adding two tables (one at the existing § 40.95, the other at a new § 40.96) to inform MROs and others about the cutoffs and the procedures HHS directs laboratories to use in reporting adulterated and invalid test results. We sought comments on whether this information would be helpful to MROs and others, or would have too much information and be too complicated to add value.

Most commenters supported the proposal to include two tables related to adulterant and invalid testing cutoffs. The DOT, however, did not include these tables because we are concerned that including such tables could provide information useful in developing adulterants to circumvent the testing process. Moreover, the inclusion of these tables would not clarify for laboratories what they are currently required to report by the HHS Mandatory Guidelines nor would it add to the effectiveness of the MRO verification process. Since the cutoff levels are mandated by the HHS, duplicating them in the rule text does not add any value or streamline the overall procedures required by part 40. Therefore, we have indicated in the rule text that laboratories will be required to use cutoff levels for adulterated and

invalid urine specimens that are directed by the HHS.

One commenter stated that an invalid report due to abnormal pH is reported only as ''abnormal pH'' per HHS direction. For the MRO to find out if it was abnormally high or low, the MRO must contact the laboratory. The commenter suggested that DOT direct laboratories to report either high pH or low pH or the actual pH numbers. This would be consistent with § 40.96(d) which directs laboratories to report the reason a test is invalid and would remove the need for the MRO to call the laboratory on these results.

We agree with the comment that the use of the term abnormal pH creates a requirement for the MRO to contact the laboratory, and we will therefore, direct laboratories to report the actual numerical value for pH.

Finally, one commenter suggested that we clearly point out that the confirmation test is one that uses a different chemical methodology than the initial test on a second aliquot of the specimen. The definition of ''confirmatory validity test'' clearly states that a confirmation test is performed on a different aliquot of the original specimen.

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

Laboratories are reporting and MROs are reviewing a variety of test results, including multiple test results for the same testing event. The DOT proposed using categories to make it easier to understand what laboratories and MROs are to report.

Of the commenters who responded to this proposal, some addressed only the question of categories, while others addressed issues related to multiple reporting. Several commenters agreed that understanding the myriad of results is a difficult situation and supported the DOT's attempt to simplify it through the use of identifying categories.

Some concerns centered on the complexities of reporting multiple results of two separate collections from the same collection event. These commenters were troubled about how the overall process would work—for example, if two CCFs were produced on a collection, what would the MRO do with them and how would the MRO report the results? Additionally, the issue of cost per test to the employer was raised and the difficulty of billing with no documentation (i.e., no CCF for the test not reported). In any situation where the tests are reported negative and non-negative—in any order of collection—commenters agreed that the non-negative test should be the result of record reported by the MRO for the testing event. These MRO issues are addressed in the discussion of § 40.162.

Some commenters supported the use of categories and some did not. A number believed that laboratories would not use the categories, but would continue to use specific test results because these are more descriptive and useful. A commenter felt that the terms ''negative'' and ''non-negative'' are very simple and descriptive and much more useful than a category list.

The DOT never intended for laboratories to report results as ''Category 1'' or ''Category 2'' or ''Category 3.'' In the NPRM, we merely said that a laboratory's specimen testing result would fall into one of three distinct and separate categories—negative; non-negative; and rejected for testing—and we described them as Categories 1 through 3. We agree with those commenters who said this delineation made it easier for them to understand that the results reported would fall into one of those three categories. Therefore, we will keep the three separate categories for results being reported with the understanding that laboratories are not to report a result as being in a specific category (i.e., Category 1, Category 2, or Category 3; or non-negative), but must report a specific result.

Section 40.133 Under what circumstances may the MRO verify a test result as positive, or as a refusal to test because of adulteration or substitution, or as cancelled because the specimen was invalid, without interviewing the employee?

MROs have situations in which neither they nor the employers are able to contact employees to complete the interview process for invalid results. The DOT proposed to modify § 40.133 so that invalids would be handled parallel to part 40's directives on positive, adulterated, and substituted specimens when the employee cannot be interviewed. Four commenters responded to this proposal, and all supported the proposed procedure for resolving invalid test results without interviewing the employee. Based on the comments, the DOT will adopt the proposal in § 40.133 with one modification: To refer to this result as a cancelled test due to an invalid result, instead of a cancelled-invalid.

Section 40.159 What does the MRO do when a drug test is invalid?

The DOT made a number of proposals trying to close the potential endless loop of observed collections that could result when the specimen result of a directly observed recollection, following a first invalid (and in some cases, a second or third observed collection), is again invalid.

If the second invalid result was for the same reason as the first invalid, we proposed having the MRO cancel the test. One commenter wished to call this a negative test. The DOT believes it would be inappropriate for the MRO to call this a negative test. Therefore, we will have the MRO cancel the test if the observed recollection is invalid for the same reason as the first invalid. This is consistent with the HHS guidance to MROs. In addition, in § 40.160 (see below), we have provided a way for MROs to obtain negative results for invalids when employees require negative results for pre-employment, return-to-duty, and follow-up testing.

If the second invalid result was for a different reason than the first invalid, the DOT proposed having the MRO verify the result as a refusal to test. We did this to harmonize with the HHS guidance to MROs. We also proposed adding this to the list of refusals at § 40.191.

Many of the commenters said that calling this an automatic refusal to test is problematic—especially if this were allowed without MRO review. The DOT agrees with these commenters. We have decided not to adopt the proposal to add this to the list of refusals at § 40.191. We will consider this an invalid result requiring another immediate recollection under direct observation—and we will not require the MRO to first contact the employee to discuss the result.

The DOT also proposed that when the MRO reports multiple non-negative results and one of them is invalid, the MRO would not be required to report an ''invalid result'' if the MRO verified any of the other non-negative results—for example, a positive result. A number of commenters supported this proposal, but one did not understand what DOT wanted the MRO to do about the invalid result.

The DOT believes that § 40.159(f) is clear: When the MRO verifies multiple non-negative results and one of them is invalid, the MRO would report all but the invalid result. The invalid result simply will not be reported and the test would not be cancelled because there would actually be at least one reportable non-negative result. For instance, if a laboratory reported a test result as being positive for phencyclidine (PCP) and invalid, the MRO would conduct an MRO review for both the PCP positive and the invalid. The MRO would verify the PCP positive and report it to the employer. Even if the employee had no

medical explanation for the invalid result, the MRO would not report it to the employer unless the employee requests to have his or her split specimen tested for PCP and the split fails to reconfirm. The MRO would then cancel both tests, report them to the DER, and direct an immediate recollection under direct observation because the primary specimen had also been invalid. The same would hold true for invalid specimens whose splits failed to reconfirm for adulterants and substitutions.

We also proposed to have MROs contact collection sites to confirm that collectors had properly observed the collections. We agree with the majority of commenters who said that having MROs confirm that collections had been directly observed is labor intensive and of little value, especially if CCFs indicate that observed collections were conducted. Therefore, we will not require the MRO to contact the collector.

Finally, if the employee admits to using drugs to the MRO during the invalid result interview, the MRO must report the admission to the DER for additional action under applicable DOT Agency and United States Coast Guard regulations.

Section 40.160 What does the MRO do when a valid test result cannot be produced and a negative result is required?

The DOT proposed adding a new § 40.160 to address procedures when a negative result is required but a valid test result cannot be produced because of an individual's legitimate, albeit rare, medical condition.

In such rare circumstances, we will require the MRO to determine if there is clinical evidence that the individual is an illicit drug user. The evaluation requirements in this section will be parallel to existing requirements at § 40.195—when a permanent or long-term medical condition precludes the employee from providing a sufficient amount of urine and a negative result is needed. If the medical evaluation reveals no clinical evidence of drug use, the MRO would report the result to the employer as a negative test with written notations regarding the medical examination. The same procedures would be used when the primary specimen is reported as invalid and the individual has a legitimate medical explanation.

The DOT also requested comments about findings of illicit drug use during these medical evaluations. Currently, a finding of illicit drug use during the medical evaluation under § 40.195 causes the test to be cancelled. We asked for comments on whether the DOT should continue to require cancellation or treat such findings as positive test results.

Most commenters stated that findings of illicit drug use during the medical evaluation should be considered a positive result. Two commenters felt they should be reported as a refusal. One commenter stated that if the examination discloses evidence of current illicit drug use, this should be reported as a positive result. Another commenter was concerned that this evaluation may identify past drug use and may not provide the employee with due process. One commenter stated that a blood test would be far superior to a medical examination in determining evidence of substance abuse.

Although a number of these commenters believe that a finding of illegal drug use during the medical evaluation should be considered a positive or a refusal, the DOT will require that in these cases, MROs will cancel the test, parallel to the existing procedures for insufficient urine in § 40.195. The Omnibus Transportation Employees Testing Act of 1991 provides only one way to determine that an employee has tested positive for illicit drug use—a drug test confirmed by an HHS-certified laboratory using HHS scientific and testing protocols and verified by an MRO. Therefore, we will continue to cancel these results if there are medical signs and symptoms of illicit drug use. The individual will not be able to perform safety-sensitive duties because a negative result is needed. The MROs, under their authority at § 40.327, must continue to report safety and medical qualification concerns to appropriate parties, such as the employer and the physician or health care provider responsible for determining medical qualifications of the employee.

In response to the commenter who thought a blood test far superior to a medical examination for determining substance abuse, we would remind everyone that as part of this medical evaluation, the evaluating physician may conduct other testing to determine whether the employee shows clinical evidence of drug abuse, including, but not limited to, blood testing.

Section 40.162 What must MROs do with multiple verified results for the same testing event?

The DOT requested comments to proposed procedures addressing how the MRO would report multiple verified results from one testing event—either multiple results from a single specimen or multiple results from more than one specimen collected during one event. Regarding multiple results from more than one specimen, we asked if it was sensible to require collectors to continue to send two separate specimen collections (*e.g.*, a specimen that showed signs of tampering and the subsequent observed collection) to laboratories. In other words, should we continue requiring collectors to send the observed collection but not the specimen that appeared to show signs of tampering?

Most commenters appreciated the fact that DOT had articulated what MROs are to report after verifying multiple results for the same testing event. Some commenters correctly noted some of the problems associated with multiple specimens collected during the same testing event. For example, these multiple specimens pose administrative difficulties: Tying together two collections and two laboratory results and simultaneously reporting the two verified results. In addition, some commenters noted that testing a second specimen imposes additional cost. None of the comments included credible evidence to show that the results of the observed collections were always non-negative.

Therefore, we will continue to require that collectors send both the specimen suspected of adulteration or substitution and the directly observed specimen on for laboratory testing. At § 40.67(f), collectors are already directed to identify and link both specimens in the Remarks section of the CCFs. When the collector follows the required procedures, and the MRO reviews the MRO copies of CCFs before reporting results, the MRO will know that the specimen appeared to show signs of tampering and that specimen is connected to another specimen taken under direct observation. MROs should have procedures in place to identify and connect these linked specimens.

We will modify the section to authorize MROs to ''hold'' the result of the first laboratory specimen result received if it is negative until the MRO receives the result of a second specimen. If the first result is non-negative, the MRO reports it immediately. The MRO would then follow the required reporting procedures.

Section 40.171 How does an employee request a test of a split specimen?

The DOT proposed amending § 40.171 to state clearly that there is no split specimen testing for an invalid result. This is consistent with current part 40 split request procedures and with the

HHS MRO Manual. Most commenters who responded to this item supported it. We will retain it as written in the NPRM.

Section 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

Section 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

Section 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

These sections concern the DOT's decision to provide authorization for the split laboratory to send the split specimen or an aliquot of it to another HHS-certified laboratory if the split fails to reconfirm the primary specimen's results. The DOT proposed amending §§ 40.177, 40.179, and 40.181 so that a provision currently contained only in § 40.177 for drug testing would be added to the adulterated and substituted split sections. The DOT sought comment on whether providing authorization to the split laboratory would be sufficient, or whether we should require laboratories to send the split specimen or an aliquot.

Several commenters opposed making it mandatory to send the specimen to another laboratory but believed that providing authorization to do so would be sufficient. One commenter wondered if the term ''you may'' send a specimen to a third laboratory would become ''routine'' practice and something that all laboratories would then do. This commenter recommended that Laboratory B send the split to a third laboratory only under special circumstances that are documented and have been discussed with the MRO.

The DOT has amended §§ 40.177, 40.179, and 40.181. We continue to authorize the split laboratory to send the split specimen or an aliquot of it to another HHS-certified laboratory to reconfirm the presence of drugs/drug metabolites. We also authorize the same for adulterated specimens. Because the testing procedures for identifying substituted specimens are the same at each laboratory, there would be no reason to send the split to a third laboratory if it failed to reconfirm at a second laboratory.

We will not require a discussion between the MRO and laboratory. The longstanding requirements at § 40.177 on sending the split specimen to another laboratory, which did not make MRO discussion with the laboratory mandatory, have not appeared to cause problems. We agree with the commenter who said that sending split specimens to a third laboratory should not be routine. Therefore, a split specimen should only be sent to a second laboratory when it is likely that doing so will confirm the criteria that were reported in the primary specimen.

Several commenters asked for clarification of § 40.181(b), which stated, ''if the test fails to reconfirm the validity criteria reported in the primary specimen, the second laboratory may transmit the specimen or an aliquot to another HHS-certified laboratory that has the capability to conduct another reconfirmation test.'' These commenters asked whether ''another reconfirmation test'' is a requirement to conduct a different, more specific, test method.

With regard to the language proposed in the NPRM at 40.181(b), we are removing the paragraph because all laboratories use the same confirmation methodologies for creatinine and specific gravity.

We intend § 40.179(b) to provide an option for using another laboratory to make it more likely to reconfirm the adulterated criteria reported for the primary specimen. In writing § 40.179(b), we used the language currently at § 40.177 that addresses the use of another laboratory to confirm the split specimen. We are retaining the word ''another'' in § 40.179(b), to require the second split laboratory to use a different confirmation test than the one used by the first split laboratory. In the case of pH, all laboratories use the same test methodologies, so this would not apply to pH. However, for other adulterants, we think another confirmation test would be suitable if it is likely to confirm the adulteration criteria reported in the primary specimen. If the first split laboratory is unable to confirm the adulteration criteria of the specimen, a second split laboratory, using a different confirmation procedure, may be able to confirm the test result. Therefore, the DOT will retain most of the specific language proposed in the NPRM at § 40.179(b).

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

The DOT proposed to divide the split results into five distinct categories to make it easier for MROs to understand their responsibilities in cases where they receive any of the more complicated split result possibilities. The majority of commenters supported this proposal. One commenter suggested that these categories would lend themselves to a table.

The DOT will retain the five categories of split results as proposed in the NPRM. We will not include a table, since the description of the five categories in the rule text is specific and self-explanatory.

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

The DOT did not propose any changes to the employer policy providing the option for recollection of negative-dilute specimens at § 40.197(b)(2), although we added additional rule text to clarify procedures. Several commenters supported this. One commenter suggested that the rules for dilute specimens should be more rigorous. Another commenter suggested that if the DOT believes it appropriate to recollect a negative dilute, the DOT should require that all results of this type be recollected without giving the employer a choice in the matter.

The DOT will not make any changes in this area, other than to revise paragraph § 40.197(c)(3), re-designate paragraph (c)(4) as (c)(5), and add paragraph (c)(4). Negative specimens that are also dilute will continue to be viewed as negative specimens, but with the option for employer policies to determine if there is to be a recollection. This is in keeping with the current regulation for which there have been no significant issues raised.

Section 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

The DOT proposed changes for splits that are reported as invalid. Commenters who responded to this item supported the proposed rule language. We also proposed changes for a situation in which there is no split laboratory available to test the split specimen. One commenter, an MRO, supported this proposal. We will amend this section by revising paragraphs (c), (d), and (e) and maintain the changes as proposed in the NPRM.

Section 40.207 This section was amended by changing the references in the paragraph.

Appendices

Appendix B

As proposed, the DOT will modify the semi-annual laboratory report to employers so that it has the same information required by the HHS Mandatory Guidelines. The three proposed changes, while not dramatic, will help laboratories avoid following different report formats for DOT and HHS.

Appendix C

As discussed earlier, we will also add Appendix C requiring laboratories to provide the Department semi-annual data about their DOT-mandated testing.

Appendix D

We will also modify Appendix D to show DOT's new mailing address and electronic-entry address.

Appendix F

DOT will also amend some Appendix F citations to accurately reflect text changes.

Comments Related to Other NPRM Issues and Questions

The DOT asked a number of other questions related to several issues. Most of these have been addressed in other portions of the preamble. The following issues were not addressed and are discussed below:

We wanted to know if it would be appropriate to require that observers check for realistic-looking prosthetic devices by having employees lower their pants and underwear just before observed collections take place.

Most commenters did not support this proposal on the basis that it was too invasive and that most observers can be trained in ensuring that the urine specimen actually comes from the individual. One commenter indicated that if there is any suspicion during collection, one method that could be used was a one-handed collection (for males) since most devices have a valve that needs to be released and this cannot be done if the donor is holding the collection cup in one hand (with the other hand behind his back).

One association said this proposal would be totally inappropriate since most of their members are female. One TPA and one MRO stated that checks for prosthetic devices should be allowed, but not mandatory, since trained collectors should be expected to know when these checks are needed. Another association supported this proposal and indicated that the Olympic model could be used, where the donors raise their shirts to the chest line and lower their underwear to the knees for initial inspections.

We are also aware that the Omnibus Employee Testing Act of 1991 directed the DOT to utilize procedures that ''promoted, to the maximum extent practicable, individual privacy in the collection of specimen samples.'' We believe that, with the current proliferation of adulteration products, checking for devices prior to observed collections provide individual privacy ''to the maximum extent practicable.'' In the early 1990's, adulteration was not a significant problem and the current wide variety of products for adulteration of urine were not available. However, because these products and various mechanical devices are now readily available to individuals who want to adulterate or substitute their urine specimen during a drug testing collection, we believe that the measure of what is the maximum extent of privacy has shifted somewhat. Checking for devices prior to observed collections is the most effective way to ensure the integrity of the testing process while providing individual privacy as much as practicable.

We would also point out that employees who may be required to undergo a directly observed collection have provided reasons to necessitate this procedure by providing specimens that: Showed signs of tampering; were invalid with no legitimate medical explanation for the result; or demonstrated a negative and dilute specimen with creatinine concentration in the 2 to 5 mg/dL range, which made the specimen suspect of adulteration or tampering. Some of these employees may have already violated the testing regulations and are having a return-to-duty or follow-up test.

Based on these facts, the DOT will require employees who are undergoing directly observed collections to raise their shirts, blouses, or dresses/skirts, as appropriate, above the waist and lower their pants and underpants to show the observer, by turning around, that they do not have a prosthetic device on their person. After this is done, they may return their clothing to its proper position and contribute a specimen in such manner that the observer can see the urine exiting directly from the individual into the collection container, as required under current regulations. We will also require direct observation collections for all return-to-duty and follow-up drug tests. We are amending § 40.67 to reflect this procedure and this requirement for return-to-duty and follow-up drug tests.

We also asked for comments regarding the consequence when a realistic-looking prosthetic device is found.

Eight commenters responded. Seven commenters indicated that this should definitely be treated as a refusal to test. One association stated that this should be considered on a case-by-case basis and that the collector should request the donor to remove the device and then proceed with the collection. If the donor fails to remove the device, the collector should document this as a refusal to test.

The DOT agrees with the majority of commenters that the use of realistic-looking prosthetic devices to circumvent the urine specimen collection process is a significant and grievous action, in most cases related to an individual attempting to hide drug use; and it is a deliberate attempt to thwart the testing process. We believe that this action is no different than an individual refusing to cooperate or participate in a specimen collection process. The end result of failure to cooperate is a refusal to test. We believe trying to subvert the collection process using a prosthetic device is as serious an offense and will consider this as a refusal to test. We said so in the July 2006 Questions and Answers guidance; and we will add it to the list in Section 40.191 as constituting a refusing to test.

Also, in the July 2006 Questions and Answers that appear on our Web site, we added to the examples of refusals to test at the collection site an individual refusing to wash his or her hands and an individual admitting to adulterating or substituting a specimen. We will add these two examples to the list in Section 40.191 as constituting a refusal to test. In addition, we will add an employee's refusal to allow the observer to check for devices prior to undergoing an observed collection.

Editorial Comments

There were 17 comments (some duplicates) that addressed editorial changes and included typographical errors. We appreciate these comments and included most of them.

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 45101 *et seq.*) and the Department of Transportation Act (49 U.S.C. 322).

Executive Order 12866

This rule has been designated as significant by the Office of Management and Budget for purposes of Executive Order 12866 or the DOT's regulatory policies and procedures, because of potential policy interest to Congress, affected industries, and the public. It is a modification to our overall part 40 procedures and is intended to further align our laboratory and MRO procedures with those requirements that are being directed by HHS. Their economic effects will be very small. Consequently, the DOT certifies, under the Regulatory Flexibility Act, that this rule will not have a significant

economic impact on a substantial number of small entities.

In the 2000 part 40 final rule, we estimated that approximately 80% of industry specimens were being tested for SVT and that the costs associated with making SVT mandatory would be about $1.4 million annually—for the 20% that we estimated were not being tested. One commenter misinterpreted our data, thinking that the cost was for testing of the current 80%, and asked for clarification of how the DOT arrived at these figures. Another commenter questioned the accuracy of our more current information, pointing out that at the time the NPRM was published, complete data for 2005 were not available.

The HHS laboratory data for 2006 are available and show the actual number of Federal tests performed was 7.54 million—7.32 million of which were DOT tests. An estimated 98 to 99% of these DOT tests were tested for SVT. The number of tests not being tested for SVT in 2006 is estimated to be 200,000.

A review of laboratory costs for SVT from a number of HHS-certified laboratories indicated an average additional cost of 75 cents to $1.25 per specimen. Using the 2006 data, the cost of SVT would then only increase the cost of DOT-mandated testing by about $200,000. This figure is far less than the $1.4 million amount estimated and approved for SVT in the 2000 final rule. Information on SVT from the DOT Federal employee drug testing program and from another Federal agency's program revealed that they experienced no increased laboratory costs for drug testing when they implemented SVT.

The DOT believes that $200,000 is a reasonable cost for the mandatory SVT and should have minimal impact on employers. In fact, it is far less than the 2000 final rule estimate for mandatory SVT.

Executive Order 12372 (Intergovernmental Review)

Executive Order 12372 requires intergovernmental consultation with state and local officials that would provide the non-Federal funds for, or that would be directly affected by, proposed Federal financial assistance or direct Federal development. The rule would not affect state and local entities in a way that would warrant such consultation.

Unfunded Mandates Reform Act of 1995

This rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (2 U.S.C. § 1532).

Executive Order 13132 (Federalism)

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This notice does not include requirements that (1) has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government, (2) imposes substantial direct compliance costs on State and local governments, or (3) preempts state law. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

Executive Order 13084

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Because none of the provisions of the rule would significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13084 do not apply.

Paperwork Reduction Act

DOT invites public comment about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below. We will subsequently publish a **Federal Register** notice concerning this proposed collection. We would add a requirement that all HHS-certified laboratories provide testing data to the DOT on a semi-annual basis. This is data readily available in laboratory computer systems—information they provide routinely to HHS. They provide similar company-specific information to employers on a semi-annual basis. We estimate that these semi-annual reports to DOT will take a total of six hours for all the laboratories to complete, at a cost of approximately $162 to all laboratories, or less than $4 annually for each laboratory.

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.

Dated: June 11, 2008.

Mary E. Peters,

Secretary of Transportation.

49 CFR Subtitle A—Authority and Issuance

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

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

■ 1–2. The authority citation for 49 CFR Part 40 continues to read as follows:

Authority: 40 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

■ 3. Section 40.3 is amended by revising the definitions of ''adulterated specimen,'' ''confirmation (or confirmatory) drug test,'' ''confirmation (or confirmatory) validity test,'' ''dilute specimen,'' ''initial drug test,'' ''initial validity test,'' ''invalid result,'' and ''substituted specimen'' and adding definitions for ''aliquot,'' ''limit of detection,'' ''non-negative specimen,'' ''oxidizing adulterant,'' and ''screening test'' in alphabetical order, all to read as follows:

§ 40.3 What do the terms in this regulation mean?

* * * * *

Adulterated specimen. A urine specimen containing a substance that is not a normal constituent or containing an endogenous substance at a concentration that is not a normal physiological concentration.

* * * * *

Aliquot. A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

* * * * *

Confirmatory drug test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (Gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine).

Confirmatory validity test. A second test performed on a different aliquot of the original urine specimen to further support a validity test result.

* * * * *

Dilute specimen. A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

* * * * *

Initial drug test (also known as a Screening drug test). An immunoassay test to eliminate ''negative'' urine specimens from further consideration and to identify the presumptively positive specimens that require confirmation or further testing.

Initial validity test. The first test used to determine if a urine specimen is adulterated, diluted, or substituted.

Invalid result. The result reported by a laboratory for a urine specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

* * * * *

Limit of Detection (LOD). The lowest concentration at which an analyte can be reliably shown to be present under defined conditions.

* * * * *

Non-negative specimen. A urine specimen that is reported as adulterated, substituted, positive (for drug(s) or drug metabolite(s)), and/or invalid.

* * * * *

Oxidizing adulterant. A substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drug or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

* * * * *

Screening drug test. See Initial drug test definition above.

* * * * *

Substituted specimen. A urine specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine.

* * * * *

■ 4. Section 40.23 is amended by revising paragraph (f) introductory text and adding paragraph (f)(5), to read as follows:

§ 40.23 What actions do employers take after receiving verified test results?

* * * * *

(f) As an employer who receives a drug test result indicating that the employee's urine specimen test was cancelled because it was invalid and that a second collection must take place under direct observation—

* * * * *

(5) You must ensure that the collector conducts the collection under direct observation.

* * * * *

■ 5. Section 40.67 is amended by revising paragraph b); redesignating paragraphs (i), (j), (k), (l), and (m) as (j), (k), (l), (m), and (n) respectively, and adding a new paragraph (i) to read as follows:

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

* * * * *

(b) As an employer, you must direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.

* * * * *

(i) As the observer, you must request the employee to raise his or her shirt, blouse, or dress/skirt, as appropriate, above the waist; and lower clothing and underpants to show you, by turning around, that they do not have a prosthetic device. After you have determined that the employee does not have such a device, you may permit the employee to return clothing to its proper position for observed urination.

* * * * *

■ 6. Section 40.83 is amended by revising paragraph (g)(2) to read as follows:

§ 40.83 How do laboratories process incoming specimens?

* * * * *

(g) * * *

(2) If the problem(s) is not corrected, you must reject the test and report the result in accordance with § 40.97(a)(3).

* * * * *

■ 7–8. Section 40.89 is amended by revising paragraph (b) to read as follows:

§ 40.89 What is validity testing, and are laboratories required to conduct it?

* * * * *

(b) As a laboratory, you must conduct validity testing.

■ 9. Section 40.95 is revised to read as follows:

§ 40.95 What are the adulterant cutoff concentrations for initial and confirmation tests?

(a) As a laboratory, you must use the cutoff concentrations for the initial and confirmation adulterant testing as required by the HHS Mandatory Guidelines and you must use two separate aliquots—one for the initial test and another for the confirmation test.

(b) As a laboratory, you must report results at or above the cutoffs (or for pH, at or above or below the values, as appropriate) as adulterated and provide the numerical value that supports the adulterated result.

■ 10. A new section 40.96 is added to read as follows:

§ 40.96 What criteria do laboratories use to establish that a specimen is invalid?

(a) As a laboratory, you must use the invalid test result criteria for the initial and confirmation testing as required by the HHS Mandatory Guidelines, and you must use two separate aliquots—one for the initial test and another for the confirmation test.

(b) As a laboratory, for a specimen having an invalid result for one of the reasons outlined in the HHS Mandatory Guidelines, you must contact the MRO to discuss whether sending the specimen to another HHS certified laboratory for testing would be useful in being able to report a positive or adulterated result.

(c) As a laboratory, you must report invalid results in accordance with the invalid test result criteria as required by the HHS Guidelines and provide the numerical value that supports the invalid result, where appropriate, such as pH.

(d) As a laboratory, you must report the reason a test result is invalid.

11. Section 40.97 is amended by adding the words, ''and Rejected for Testing'' between ''Non-negative'' and ''results'' in paragraph (b)(2) and by revising paragraph (a) to read as follows:

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

(a) As a laboratory, you must report the results for each primary specimen. The result of a primary specimen will fall into one of the following three categories. However, as a laboratory, you must report the actual results (and not the categories):

(1) Category 1: Negative Results. As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as appropriate:

(i) Negative, or

(ii) Negative-dilute, with numerical values for creatinine and specific gravity.

(2) Category 2: Non-negative Results. As a laboratory, when you find a specimen to be non-negative, you must report the test result as being one or more of the following, as appropriate:

(i) Positive, with drug(s)/metabolite(s) noted;

(ii) Positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for creatinine and specific gravity;

(iii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remark(s);

(iv) Substituted, with confirmatory test values for creatinine and specific gravity; or

(v) Invalid result, with remark(s). Laboratories will report actual values for pH results.

(3) Category 3: Rejected for Testing. As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).

* * * * *

■ 12. Section 40.103 is amended by removing the word ''blank'' and adding in its place the word ''negative'' in paragraph (c) introductory text, by revising paragraphs (c)(1) through (5), and removing paragraph (c)(6) to read as follows:

§ 40.103 What are the requirements for submitting blind specimens to a laboratory?

* * * * *

(c) * * *

(1) All negative, positive, adulterated, and substituted blind specimens you submit must be certified by the supplier and must have supplier-provided expiration dates.

(2) Negative specimens must be certified by immunoassay and GC/MS to contain no drugs.

(3) Drug positive blind specimens must be certified by immunoassay and GC/MS to contain a drug(s)/metabolite(s) between 1.5 and 2 times the initial drug test cutoff concentration.

(4) Adulterated blind specimens must be certified to be adulterated with a specific adulterant using appropriate confirmatory validity test(s).

(5) Substituted blind specimens must be certified for creatinine concentration and specific gravity to satisfy the criteria for a substituted specimen using confirmatory creatinine and specific gravity tests, respectively.

* * * * *

■ 13. Section 40.105(c) is revised to read as follows:

§ 40.105 What happens if the laboratory reports a result different from that expected for a blind specimen?

* * * * *

(c) If the unexpected result is a false positive, adulterated, or substituted result, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy. You must also notify ODAPC of the discrepancy by telephone (202–366–3784) or e-mail (addresses are listed on the ODAPC Web site, *http://www.dot.gov/ost/dapc*). ODAPC will notify HHS who will take appropriate action.

■ 14. Section 40.111 is amended by adding a new paragraph (d) to read as follows:

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

* * * * *

(d) As a laboratory, you must transmit an aggregate statistical summary of the data listed in Appendix C to this part to DOT on a semi-annual basis. The summary must be sent by January 31 of each year for July 1 through December 31 of the prior year; it must be sent by July 31 of each year for January 1 through June 30 of the current year.

■ 15. Section 40.129 is amended by revising the section heading and paragraph (a)(5) to read as follows:

§ 40.129 What are the MRO's functions in reviewing laboratory confirmed non-negative drug test results?

(a) * * *

(5) Verify the test result, consistent with the requirements of §§ 40.135 through 40.145, 40.159, and 40.160, as:

(i) Negative; or

(ii) Cancelled; or

(iii) Positive, and/or refusal to test because of adulteration or substitution.

* * * * *

■ 16. Section 40.131 is amended by revising the section heading to read as follows:

§ 40.131 How does the MRO or DER notify an employee of the verification process after receiving laboratory confirmed non-negative drug test results?

* * * * *

■ 17. Section 40.133 is amended by revising the section heading, redesignating paragraphs (b) and (c) as (c) and (d), respectively, revising them, and adding new paragraph (b) to read as follows:

§ 40.133 Without interviewing the employee, under what circumstances may the MRO verify a test result as positive, or as a refusal to test because of adulteration or substitution, or as cancelled because the test was invalid?

* * * * *

(b) As the MRO, you may verify an invalid test result as cancelled (with instructions to recollect immediately under direct observation) without interviewing the employee, as provided at § 40.159:

(1) If the employee expressly declines the opportunity to discuss the test with you;

(2) If the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee; or

(3) If neither you nor the DER, after making and documenting all reasonable efforts, has been able to contact the employee within ten days of the date on which you received the confirmed invalid test result from the laboratory.

(c) As the MRO, after you verify a test result as a positive or as a refusal to test under this section, you must document the date and time and reason, following the instructions in § 40.163. For a cancelled test due to an invalid result under this section, you must follow the instructions in § 40.159(a)(5).

(d) As the MRO, after you have verified a test result under this section and reported the result to the DER, you must allow the employee to present information to you within 60 days of the verification to document that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/or DER in the times provided. On the basis of such information, you may reopen the verification, allowing the employee to present information concerning whether there is a legitimate medical explanation of the confirmed test result.

■ 18. Section 40.149(a) introductory text and (a)(1) are revised to read as follows:

§ 40.149 May the MRO change a verified drug test result?

(a) As the MRO, you may change a verified test result only in the following situations:

(1) When you have reopened a verification that was done without an interview with an employee (see § 40.133(d)).

* * * * *

■ 19. Section 40.155 is amended by adding paragraph (d) to read as follows:

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

* * * * *

(d) If the employee's recollection under direct observation, in paragraph (c) of this section, results in another negative-dilute, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF documentation shows that the recollection was directly observed as required, report this result to the DER as a negative-dilute result.

(3) If CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that

there must be an immediate recollection under direct observation.

■ 20. Section 40.159 is amended by revising paragraphs (a)(1) through (3), adding paragraph (a)(4)(iii), and adding paragraphs (d) through (g) to read as follows:

§ 40.159 What does the MRO do when a drug test is invalid?

(a) * * *

(1) Discuss the laboratory results with a certifying scientist to determine if the primary specimen should be tested at another HHS certified laboratory. If the laboratory did not contact you as required by §§ 40.91(e) and 40.96(c), you must contact the laboratory.

(2) If you and the laboratory have determined that no further testing is necessary, contact the employee and inform the employee that the specimen was invalid. In contacting the employee, use the procedures set forth in § 40.131.

(3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you must determine if the employee has a medical explanation for the invalid result. You must inquire about the medications the employee may have taken.

(4) * * *

(iii) If a negative test result is required and the medical explanation concerns a situation in which the employee has a permanent or long-term medical condition that precludes him or her from providing a valid specimen, as the MRO, you must follow the procedures outlined at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

* * * * *

(d) If the employee admits to using a drug, you must, on the same day, write and sign your own statement of what the employee told you. You must then report that admission to the DER for appropriate action under DOT Agency regulations. This test will be reported as cancelled with the reason noted.

(e) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for the same reason as reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed as required, document that the employee had another specimen with an invalid result for the same reason.

(3) Follow the recording and reporting procedures at (a)(4)(i) and (ii) of this section.

(4) If a negative result is required (i.e., pre-employment, return-to-duty, or follow-up tests), follow the procedures at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

(5) If the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(f) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for a different reason than that reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed as required, document that the employee had another specimen with an invalid result for a different reason.

(3) As the MRO, you should not contact the employee to discuss the result, but rather direct the DER to conduct an immediate recollection under direct observation without prior notification to the employee.

(4) If the CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(g) If, as the MRO, you receive a laboratory invalid result in conjunction with a positive, adulterated, and/or substituted result and you verify any of those results as being a positive and/or refusal to test, you do not report the invalid result unless the split specimen fails to reconfirm the result(s) of the primary specimen.

■ 21. Section 40.160 is added to read as follows:

§ 40.160 What does the MRO do when a valid test result cannot be produced and a negative result is required?

(a) If a valid test result cannot be produced and a negative result is required, (under § 40.159 (a)(5)(iii) and (e)(4)), as the MRO, you must determine if there is clinical evidence that the individual is currently an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation. In addition, if appropriate, you may also consult with the employee's physician to gather information you need to reach this determination.

(b) If you do not personally conduct the medical evaluation, as the MRO, you must ensure that one is conducted by a licensed physician acceptable to you.

(c) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (e.g., blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

(d) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report this to the employer as a negative test result with written notations regarding the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and for the determination that no signs and symptoms of drug use exist.

(1) Check ''Negative'' (Step 6) on the CCF.

(2) Sign and date the CCF.

(e) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding the results of the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purpose of an actual negative test result (i.e., the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test result is needed for that purpose).

■ 22. Section 40.162 is added to read as follows:

§ 40.162 What must MROs do with multiple verified results for the same testing event?

(a) If the testing event is one in which there was one specimen collection with multiple verified non-negative results, as the MRO, you must report them all to the DER. For example, if you verified the specimen as being positive for marijuana and cocaine and as being a refusal to test because the specimen was also adulterated, as the MRO, you should report the positives and the refusal to the DER.

(b) If the testing event was one in which two separate specimen collections (e.g., a specimen out of temperature range and the subsequent observed collection) were sent to the laboratory, as the MRO, you must:

(1) If both specimens were verified negative, report the result as negative.

(2) If either of the specimens was verified negative and the other was verified as one or more non-negative(s), report the non-negative result(s) only. For example, if you verified one specimen as negative and the other as a refusal to test because the second specimen was substituted, as the MRO you should report only the refusal to the DER.

(i) If the first specimen is reported as negative, but the result of the second specimen has not been reported by the laboratory, as the MRO, you should hold—not report—the result of the first specimen until the result of the second specimen is received.

(ii) If the first specimen is reported as non-negative, as the MRO, you should report the result immediately and not wait to receive the result of the second specimen.

(3) If both specimens were verified non-negative, report all of the non-negative results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, as the MRO, you should report the positive and the refusal results to the DER.

(c) As an exception to paragraphs (a) and (b) of this section, as the MRO, you must follow procedures at § 40.159(f) when any verified non-negative result is also invalid.

■ 23. Section 40.171 is amended by revising paragraph (a) to read as follows:

§ 40.171 How does an employee request a test of a split specimen?

(a) As an employee, when the MRO has notified you that you have a verified positive drug test and/or refusal to test because of adulteration or substitution, you have 72 hours from the time of notification to request a test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen. There is no split specimen testing for an invalid result.

* * * * *

■ 24. Section 40.177 is amended by revising paragraph (d) to read as follows:

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

* * * * *

(d) In addition, if the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

■ 25. Section 40.179 is revised to read as follows:

§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

(a) As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the confirmatory test for the adulterant and using criteria in § 40.95 and confirmatory cutoff levels required by the HHS Mandatory Guidelines.

(b) In addition, if the test fails to reconfirm the adulterant result reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

■ 26. Section 40.181 is revised to read as follows:

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing the split specimen, you must test the split specimen using the confirmatory tests for creatinine and specific gravity, and using the confirmatory criteria set forth in § 40.93(b).

■ 27. Section 40.183 amended by revising paragraph (a), removing paragraph (b), and re-designating paragraph (c) as paragraph (b).

§ 40.183 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the ''Reconfirmed'' box and/or the ''Failed to Reconfirm'' box (Step 5(b)) on Copy 1 of the CCF, as appropriate, and by providing clarifying remarks using current HHS Mandatory Guidelines requirements.

* * * * *

■ 28. Section 40.187 is revised to read as follows:

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

As the MRO, the split specimen laboratory results you receive will fall into five categories. You must take the following action, as appropriate, when a laboratory reports split specimen results to you.

(a) *Category 1:* The laboratory reconfirmed one or more of the primary specimen results. As the MRO, you must report to the DER and the employee the result(s) that was/were reconfirmed.

(1) In the case of a reconfirmed positive test(s) for drug(s) or drug metabolite(s), the positive is the final result.

(2) In the case of a reconfirmed adulterated or substituted result, the refusal to test is the final result.

(3) In the case of a combination positive and refusal to test results, the final result is both positive and refusal to test.

(b) *Category 2:* The laboratory failed to reconfirm all of the primary specimen results because, as appropriate, drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/or substitution criteria were not met. As the MRO, you must report to the DER and the employee that the test must be cancelled.

(1) As the MRO, you must inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In a case where the split failed to reconfirm because the substitution criteria were not met and the split specimen creatinine concentration was equal to or greater than 2mg/dL but less than or equal to 5mg/dL, as the MRO, you must, in addition to step (b)(1) of this paragraph, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) In a case where the split failed to reconfirm and the primary specimen's result was also invalid, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(c) *Category 3:* The laboratory failed to reconfirm all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted.

(1) In the case where the laboratory failed to reconfirm all of the primary specimen results and the split was reported as invalid, as the MRO, you must:

(i) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation.

(ii) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(iii) Inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In the case where the laboratory failed to reconfirm any of the primary specimen results, and the split was reported as adulterated and/or substituted, as the MRO, you must:

(i) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated and/or substituted, as appropriate.

(ii) Follow the procedures of § 40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration and/or substitution, as appropriate.

(iii) If you determine that there is a legitimate medical explanation for the adulterated and/or substituted test result, report to the DER and the employee that the test must be cancelled; and inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(iv) If you determine that there is not a legitimate medical explanation for the adulterated and/or substituted test result, you must take the following steps:

(A) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen is also present in the primary specimen and/or to determine if the primary specimen meets appropriate substitution criteria.

(B) Except when the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of §§ 40.153, 40.171, 40.173, 40.179, 40.181, and 40.185, as appropriate.

(C) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen and/or to determine that the primary specimen meets appropriate substitution criteria, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF.

(D) If the test of the primary specimen reconfirms the adulteration and/or substitution finding of the split specimen, as the MRO you must report the result as a refusal to test as provided in paragraph (a)(2) of this section.

(E) If the test of the primary specimen fails to reconfirm the adulteration and/or substitution finding of the split specimen, as the MRO you must cancel the test, following procedures in paragraph (b) of this section.

(d) *Category 4:* The laboratory failed to reconfirm one or more but not all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted. As the MRO, in the case where the laboratory reconfirmed one or more of the primary specimen result(s), you must follow procedures in paragraph (a) of this section and:

(1) Report that the split was also reported as being invalid, adulterated, and/or substituted (as appropriate).

(2) Inform the DER to take action only on the reconfirmed result(s).

(e) *Category 5:* The split specimen was not available for testing or there was no split laboratory available to test the specimen. As the MRO, you must:

(1) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation;

(2) Direct the DER to ensure the immediate recollection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection; and

(3) Notify ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(f) For all split specimen results, as the MRO you must:

(1) Enter your name, sign, and date (Step 7) of Copy 2 of the CCF.

(2) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see § 40.163) to the employer and keep a copy for your records. Transmit the document as provided in § 40.167.

■ 29. Section 40.191 is amended by revising paragraph (a)(8) and adding paragraphs (a)(9), (10) and (11) to read as follows:

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

(a) * * *

(8) Fail to cooperate with any part of the testing process (e.g., refuse to empty pockets when directed by the collector, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector).

(9) For an observed collection, fail to follow the observer's instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process.

(10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process.

(11) Admit to the collector or MRO that you adulterated or substituted the specimen.

* * * * *

■ 30. Section 40.197 is amended by revising paragraph (c)(3), redesignating paragraph (c)(4) as (c)(5), and adding new paragraph (c)(4) to read as follows:

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

* * * * *

(c) * * *

(3) If the result of the test you directed the employee to take under paragraph (b)(1) 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.

(4) If the result of the test you directed the employee to take under paragraph (b)(2) 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.

* * * * *

■ 31. Section 40.201 is amended by revising paragraphs (c), (d), and (e) to read as follows:

§ 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

* * * * *

(c) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results because the drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/or substitution criteria were not met. You must follow the applicable procedures in § 40.187(b)—no recollection is required in this case, unless the split specimen creatinine concentration for a substituted primary specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/dL, or the primary specimen had an invalid result which was not reported to the DER. Both these cases require recollection under direct observation.

(d) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results, and that the split specimen was invalid. You must follow the procedures in § 40.187(c)(1)—recollection under direct observation is required in this case.

(e) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results because the split specimen was not available for testing or there was no split laboratory available to test the specimen. You must

follow the applicable procedures in § 40.187(e)—recollection under direct observation is required in this case.

* * * * *

§ 40.207 [Amended]

■ 32. Section 40.207 is amended by removing, in paragraph (a)(3), the reference to ''40.187(b)'' and adding in its place ''40.187(b)(2), (c)(1), and (e)''.

■ 33. Appendix B to Part 40 is revised to read as follows:

Appendix B to Part 40—DOT Drug Testing Semi-Annual Laboratory Report to Employers

The following items are required on each report:
Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
Employer Identification: (name; may include Billing Code or ID code)
C/TPA Identification: (where applicable; name and address)
1. Specimen Results Reported (total number) By Type of Test
(a) Pre-employment (number)
(b) Post-Accident (number)
(c) Random (number)
(d) Reasonable Suspicion/Cause (number)
(e) Return-to-Duty (number)
(f) Follow-up (number)
(g) Type of Test Not Noted on CCF (number)
2. Specimens Reported
(a) Negative (number)
(b) Negative and Dilute (number)
3. Specimens Reported as Rejected for Testing (total number)
By Reason
(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)
4. Specimens Reported as Positive (total number) By Drug
(a) Marijuana Metabolite (number)
(b) Cocaine Metabolite (number)
(c) Opiates (number)
(1) Codeine (number)
(2) Morphine (number)
(3) 6-AM (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
5. Adulterated (number)
6. Substituted (number)
7. Invalid Result (number)

■ 34. Appendix C to Part 40 is added to read as follows:

Appendix C to Part 40—DOT Drug Testing Semi-Annual Laboratory Report to DOT

Mail, fax, or e-mail to: U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62–300, 1200 New Jersey Avenue, SE., Washington, DC 20590, Fax: (202) 366–3897, E-mail: *ODAPCWebMail@dot.gov*.

The following items are required on each report:
Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
1. DOT Specimen Results Reported (number)
2. Negative Results Reported (number)
3. Rejected for Testing Reported (number) By Reason (number)
4. Positive Results Reported (number) By Drug (number)
5. Adulterated Results Reported (number) By Reason (number)
6. Substituted Results Reported (number)
7. Invalid Results Reported (number) By Reason (number)

■ 35. Appendix D to Part 40 is revised to read as follows:

Appendix D to Part 40—Report Format: Split Specimen Failure To Reconfirm

Mail, fax, or submit electronically to: U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62–300, 1200 New Jersey Avenue, SE., Washington, DC 20590, Fax: (202) 366–3897, Submit Electronically: *http://www.dot.gov/ost/dapc/mro_split.html*.

The following items are required on each report:

1. MRO name, address, phone number, and fax number.
2. Collection site name, address, and phone number.
3. Date of collection.
4. Specimen I.D. number.
5. Laboratory accession number.
6. Primary specimen laboratory name, address, and phone number.
7. Date result reported or certified by primary laboratory.
8. Split specimen laboratory name, address, and phone number.
9. Date split specimen result reported or certified by split specimen laboratory.
10. Primary specimen results (e.g., name of drug, adulterant) in the primary specimen.
11. Reason for split specimen failure-to-reconfirm result (e.g., drug or adulterant not present, specimen invalid, split not collected, insufficient volume).
12. Actions taken by the MRO (e.g., notified employer of failure to reconfirm and requirement for recollection).
13. Additional information explaining the reason for cancellation.
14. Name of individual submitting the report (if not the MRO).

Appendix F to Part 40 [Amended]

■ 36. Appendix F to Part 40 is amended by removing the references to § 40.187(a)–(f) and adding in its place § 40.187(a) through (e).

[FR Doc. E8–14218 Filed 6–24–08; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 385 and 395

[Docket No. FMCSA–2004–19608]

RIN 2126–AB14

Hours of Service of Drivers; Availability of Supplemental Documents

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of availability of supplemental documents.

SUMMARY: This notice advises the public that FMCSA is placing in the public docket four additional documents concerning hours of service (HOS) for commercial motor vehicle (CMV) drivers. FMCSA published an interim final rule (IFR) on this issue on December 17, 2007. The Agency now dockets the supplemental documents.

ADDRESSES: You may submit comments, identified by docket number FMCSA–2004–19608, by one of the following methods: Internet, facsimile, regular mail, or hand delivery. Please do not submit the same comments by more than one method. FMCSA encourages use of the Federal eRulemaking portal. It provides the most efficient and timely method of receiving and processing your comments.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility; U.S. Department of Transportation; 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.
- *Hand Delivery:* Ground floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number (FMCSA–2004–19608) or Regulatory Identification Number (RIN 2126–AB14) for this action. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Refer to the Privacy Act heading at *http://www.regulations.gov* for further information.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the