52.203–12 [Amended]

66. Amend section 52.203–12 by removing from the clause heading "(Sep 2007)" and adding "(Date)" in its place; and removing from paragraphs (g)(1) and (g)(3) "$100,000" and adding "$150,000" in its place.

52.204–8 [Amended]

67. Amend section 52.204–8 by removing from the provision heading "(Feb 2009)" and adding "(Date)" in its place; and removing from paragraph (c)(1)(ii) "$100,000" and adding "$150,000" in its place.

52.212–3 [Amended]

68. Amend section 52.212–3 by removing from the provision heading "(Aug 2009)" and adding "(Date)" in its place; and removing from paragraph (e) "$100,000" and adding "$150,000" in its place.

52.212–5 [Amended]

69. Amend section 52.212–5 by—

a. Removing from the clause heading "(Dec 2009)" and adding "(Date)" in its place;

b. Removing from paragraph (b)(11)(i) "(Apr 2008)" and adding "(Date)" in its place;

c. Removing from paragraph (b)(24) "(Jun 1998)" and adding "(Date)" in its place;

d. Removing from paragraph (e)(1)(ii) "$550,000" and adding "$650,000" in its place, and removing "$1,000,000" and adding "$1.5 million" in its place;

e. Removing from paragraph (e)(1)(vi) "(Jun 1998)" and adding "(Date)" in its place; and

f. In Alternate II by—

1. Removing from the Alternate heading "(Dec 2009)" and adding "(Date)" in its place;

2. Removing from paragraph (e)(1)(ii)(C) "$550,000" and adding "$650,000" in its place, and removing "$1,000,000" and adding "$1.5 million" in its place; and

3. Removing from paragraph (e)(1)(ii)(F) "(June 1998)" and adding "(Date)" in its place.

52.213–4 [Amended]

70. Amend section 52.213–4 by—

a. Removing from the clause heading "(Dec 2009)" and adding "(Date)" in its place;

b. Removing from paragraph (a)(2)(vi) "(Dec 2009)" and adding "(Date)" in its place;

c. Removing from paragraph (b)(1)(ii) "(Dec 1996)" and adding "(Date)" in its place, and removing "$10,000" and adding "$15,000" in its place; and

d. Removing from paragraph (b)(1)(iv) "(June 1998)" and adding "(Date)" in its place, and removing "$10,000" and adding "$15,000" in its place.

52.219–9 [Amended]

71. Amend section 52.219–9 by—

a. Removing from the clause heading "(Apr 2008)" and adding "(Date)" in its place;

b. Removing from paragraph (d)(9) "$550,000" and adding "$650,000" in its place, and removing "$1,000,000" and adding "$1.5 million" in its place;

c. Removing from the introductory text of paragraph (d)(11)(iii) "$100,000" and adding "$150,000" in its place; and

d. Removing from paragraph (l)(2)(i)(C) "$550,000" and adding "$650,000" in its place, and removing "$1,000,000" and adding "$1.5 million" in its place.

52.222–20 [Amended]

72. Amend section 52.222–20 by removing from the clause heading "(Dec 1996)" and adding "(Date)" in its place; and removing from the introductory paragraph "$10,000" and adding "$15,000" in its place.

52.222–36 [Amended]

73. Amend section 52.222–36 by removing from the clause heading "(Jun 1998)" and adding "(Date)" in its place; and removing from paragraph (d) "$10,000" and adding "$15,000" in its place.

52.225–8 [Amended]

74. Amend section 52.225–8 by removing from the clause heading "(Feb 2000)" and adding "(Date)" in its place; and removing from the introductory texts of paragraphs (c)(1) and (j)(2) "$10,000" and adding "$15,000" in its place.

52.228–15 [Amended]

75. Amend section 52.228–15 by removing from the clause heading "(Nov 2006)" and adding "(Date)" in its place; and removing from the introductory text of paragraph (b) "$100,000" and adding "$150,000" in its place.

52.244–6 [Amended]

76. Amend section 52.244–6 by—

a. Removing from the clause heading "(Dec 2009)" and adding "(Date)" in its place;

b. Removing from paragraph (c)(1)(iii) "$550,000" and adding "$650,000" in its place, and removing "$1,000,000" and adding "$1.5 million" in its place; and

c. Removing from paragraph (c)(1)(vi) "(Jun 1998)" and adding "(Date)" in its place.

52.248–1 [Amended]

77. Amend section 52.248–1 by removing from the clause heading "(Feb 2000)" and adding "(Date)" in its place; and removing from paragraph (l) "$100,000" and adding "$150,000" in its place.

52.248–3 [Amended]

78. Amend section 52.248–3 by removing from the clause heading "(Sep 2006)" and adding "(Date)" in its place; and removing from paragraph (h) "$55,000" and adding "$65,000" in its place.

[FR Doc. 2010–2318 Filed 2–3–10; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST–2010–0026]

RIN 2105–AD95

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Transportation is proposing to amend certain provisions of its drug testing procedures dealing with laboratory testing of urine specimens. Some of the proposed changes will also affect the roles and standards applying to collectors and Medical Review Officers. The proposed changes are intended to create consistency with new requirements established by the U.S. Department of Health and Human Services Mandatory Guidelines.

DATES: Comments to the notice of proposed rulemaking should be submitted by April 5, 2010. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave., SE., West Building Ground Floor Room W12–140, Washington, DC 20590–0001;
- *Hand Delivery:* West Building Ground Floor, Room W–12–140 1200 New Jersey Ave., SE., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329;

Instructions: You must include the agency name and docket number DOT–OST—or the Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comments. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided

FOR FURTHER INFORMATION CONTACT: Mark Snider, Senior Policy Advisor (S–1), Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Ave., SE., Washington, DC 20590; telephone number 202–366–3784 (voice), 202–366–3897 (fax), or *mark.snider@dot.gov* (e-mail).

SUPPLEMENTARY INFORMATION:

Purpose

In its final rule of December 2000 [65 FR 79562, Dec. 19, 2000], the U.S. Department of Transportation (DOT) made significant changes to the drug testing rules to include making specimen validity testing (SVT) mandatory for the transportation industry contingent upon U.S. Department of Health and Human Services (HHS) publishing its Mandatory Guidelines on SVT. In late 2001, the DOT amended part 40 [66 FR 41944, Aug. 9, 2001] to remove the mandatory requirement because HHS had not finalized its Mandatory Guidelines regarding SVT. We said that SVT would remain authorized but not required.

On April 13, 2004, 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 the requirements that laboratories modify substituted specimen and diluted specimen testing and reporting criteria. HHS revised laboratory requirements for adulterated specimen testing. HHS also required each Federal agency to conduct SVT to determine if urine specimens collected under HHS Federal Workplace Drug Testing Programs have been adulterated or substituted.

In an interim final rule (IFR) [69 FR 64865, Nov. 9, 2004], the DOT changed a number of items in its regulation to make part 40 and the HHS Mandatory Guidelines consistent. We did this to avoid conflicting requirements that implementation of both rules would have had on laboratories and Medical Review Officers (MROs).

In the 2004 IFR, we indicated that we intended to fully address all aspects of the HHS changes to their Mandatory Guidelines in a future DOT notice of proposed rulemaking (NPRM). In an NPRM [70 FR 62276, Oct. 31, 2005], the DOT sought comments to include SVT mandatory for the transportation industry, and the instructions that were given to MROs, laboratories, and employers with respect to adulterated, substituted, diluted, and invalid drug testing results. In a final rulemaking [73 FR 35961, Jun. 25, 2008] the DOT finalized these requirements to include making SVT mandatory for the transportation industry.

On November 25, 2008, HHS issued a Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Revisions to Mandatory Guidelines) [73 FR 71858, Nov 28, 2008]. The HHS revised some of their requirements for collecting and testing urine specimens, initiated requirements for the certification of Instrumented Initial Test Facilities (IITFs), and expanded upon the roles of and standards for collectors and MROs.

We are issuing this notice of proposed rulemaking to offer changes to 49 CFR Part 40 in an effort to create consistency with this latest set of requirements established by HHS.

Principal Policy Issues

Harmonization With HHS

In this NPRM we are seeking to harmonize our proposals for laboratories, collectors, MROs, and employers with the new requirements contained in the revised HHS Mandatory Guidelines. Here are the most noteworthy of the coordinated proposals:

1. We propose to modify some of our definitions and add a few new definitions in order to make them consistent with the HHS Mandatory Guidelines definitions.

2. We propose to allow DOT employers to choose between a full service laboratory and an IITF. An IITF would only be able to provide results to employers for negative and negative dilute specimens, as well as specimens they reject for testing. All other specimens would be forwarded to an HHS certified laboratory.

3. We propose to modify regulations to add IITFs to the laboratory section of this regulation and spell-out how an IITF should perform urine testing. An ITTF could conduct Initial Tests and SVT for all DOT employer programs. When an IITF discovers a non-negative drug test result, it will have to forward that result to a full service laboratory to perform a full analysis of the specimen and report the results to the employer's MRO.

4. The DOT is also proposing to adopt the following HHS laboratory testing requirements:

- Conduct Initial Testing for Methylenedioxymethamphetamine (MDMA);
- Conduct Confirmatory Testing for MDMA, Methylenedioxyamphetamine (MDA), and Methylenedioxyethylamphetamine (MDEA);
- Conduct Initial Testing for 6–Acetylmorphines.
- Lower the Initial Test and Confirmatory Test cutoff concentrations for Amphetamines; and
- Lower the Initial Test and Confirmatory Test cutoff concentrations for Cocaine.

We would note here that past experience has shown that DOT has never deviated from HHS on laboratory testing matters—the drugs for which we test, the specimens we test, specimen validity testing values, initial and confirmatory cutoff values, and laboratory testing processes and procedures, among others. Also, DOT is required by the Omnibus Transportation Employee Testing Act of 1991 to adhere with the HHS on these important laboratory testing matters.

5. We are also proposing to amend Appendix B so that IITFs will be required to report semi-annual test reports to employers, as appropriate. Appendix C would also be modified to require IITFs to report semi-annual test data to the DOT.

6. Finally, the HHS Mandatory Guidelines will require that nationally-recognized MRO certification entities or subspecialty boards for medical practitioners in the field of medical review must have their qualifications, training programs, and examinations approved by HHS on an annual basis. The DOT is seeking comment on whether part 40 should require these groups to be approved. Would the DOT program be better served if we sought a shared approval process with the HHS? In addition, the DOT is seeking comments on whether part 40, at 49 CFR Part 40.121(d), should be amended by removing the requirement that MROs must complete 12 Continuing Education Units (CEUs) pertaining to DOT and MRO practices every three years, and instead require MROs to be recertified every five years by an MRO certification board or subspecialty board. We believe this is a cost neutral proposition, and may even prove less costly because many MROs obtain both the 12 CEUs every 3 years and the MRO recertification every 5 years.

While we have sought to harmonize our proposed regulations with the new

HHS requirements, there remain some for which we have not proposed changes to some of our longstanding procedures. For items left unchanged in the HHS Guidelines from previous iterations, we believe there is no need to address them again. We have found that our procedures have worked well within and for the transportation industries. In addition, we must consider program costs and the value added in adopting some of the new HHS Mandatory Guidelines procedures.

For example, the DOT does not propose to require observers to receive advanced formalized training to learn about the steps necessary to perform a direct observation collection (DO collection). The current process of having a qualified and trained collector provide immediate, precise, and relevant instructions to an observer at the time of a DO collection is very appropriate and has been for years. That way, the Department can be assured that the requisite instructions are provided each time that a DO collection is required, no matter how many, or few, an observer has already accomplished. In addition, the costs associated with formally training observers (and the resulting limitation on available observers) do not outweigh any minimal benefits to arguably be obtained by training observers in advance instead of providing timely and relevant instructions on site at the time of the DO collection. The DOT is not aware of any cases where it was not effective to have the qualified and trained collector instruct the observer at the time the DO collection is to occur, and to do so each time a DO collection is required.

Also, the DOT does not propose to change our longstanding regulatory position that a collector need not obtain prior approval from collection site supervisor before performing a DO collection. Requiring collectors to get approval from collection site supervisors would create difficult logistical issues that would complicate the process. There are numerous instances where the collector is alone or does not have immediate access to a collection site supervisor. In fact, the collector may be the site supervisor. Many collections occur off-site or in the middle of the night where and when supervisors would not be available, and requiring consultation with an unavailable supervisor would prove onerous and serve only to delay unnecessarily the DO process. We believe the collectors should continue to make these DO collection decisions and to continue basing those decision upon the clear requirements set forth in part 40.

Also, we will not propose to change the duration of the paperwork retention requirement for collectors. HHS will require collectors to keep Copy 3 for two years. The DOT believes the current 30 days is sufficient in the DOT program. Retention for 30 days has proven a sufficient amount of time in which ensure that a CCF copy with the employee's signature would be available to the MRO's CCF copy were not available. Requiring document retention for three years would greatly increase the paperwork burden without any added safety or efficiency benefit.

Under the revised HHS Mandatory Guidelines, Federal agencies will be required to audit 5 percent or a maximum of 50 of their collection sites. DOT believes that creating a parallel requirement for transportation industry employers would be very expensive to employers in the DOT program in terms of time and resources, with few efficiency and/or safety benefits. The DOT would anticipate seeing more effective monitoring by the collection site parent organizations in an effort to ensure employers that sites under their organization umbrellas, with which employers are contracting, are properly conducting collections. The DOT Agencies and United States Coast Guard also provide on-site audits and inspections of collection sites. They have also increased their efforts to include mock collections and more clandestine inspections. All of these provide added oversight to determine whether collection site personnel are properly performing collections and whether collection sites adhere to the DOT's security and integrity requirements.

The revised HHS Mandatory Guidelines will require at least 3 percent blind specimen testing, compared to DOT's current 1 percent. We believe our current requirements represent a good balance between considerations of reducing burdens and maintaining an effective check upon laboratory performance. We have had few if any laboratory accuracy problems over the history of the program, and we believe that we can continue to ensure that this pattern continues while reducing burdens and costs on participants. Coupled with the HHS requirements and the additional proficiency testing required for laboratory certification, the blinds submitted via the DOT requirements are quite ample.

The new HHS Mandatory Guidelines require MROs to retain records for two years. The current DOT regulations currently require that MROs to follow the employer's recordkeeping requirements, one year for negative results and 5 years for non-negative results. The DOT is comfortable with the existing provision, but seeks comments about what types of MRO records should be covered under the record keeping requirements. Is it normal practice for an MRO to include in his or her paperwork personal notes and conversations with laboratory personnel? What other types of records would MROs normally be required to keep as part of this paperwork requirement? The DOT would like for MROs to provide comment upon what they believe are records DOT inspectors or auditors could expect to see when reviewing MROs records as part of the overall compliance audit of a DOT-regulated employer.

In addition, we propose to limit IITF and MRO relationships similar to the limits placed upon laboratory and MRO relationships. We are also proposing that MROs treat MDMA positives like any other Schedule I drug for which we test: MROs must not accept an assertion that there is a legitimate medical explanation for the presence of MDMA in a specimen.

Section-by-Section NPRM Issues

1. *Index Changes*—We would modify some existing section headings and add new section headings in order to reflect regulation text changes. All told, 39 sections of our regulation are proposed to be modified or added.

2. *Definition changes*—In order to align our definitions section (§ 40.3) more closely with definitions contained in the HHS Mandatory Guidelines, we propose to modify some of our existing definitions and add some new ones. We revised the definitions of "adulterated specimen," "blind specimen or blind performance test specimen," "cancelled test," "confirmatory drug test," "confirmatory validity test," "initial drug test (also known as a screening drug test," "invalid result," "laboratory," "limit of detection (LOD)," "performance testing (PT) sample," "primary specimen," and "split specimen." We also added several new definitions.

3. *Appendix Items*—At Appendix B, we propose to modify the semi-annual laboratory report to employers so that it will have the same information required by the HHS Mandatory Guidelines. The report will also require laboratories to report the number of positive results for MDMA. We also provide additional clarification to IITFs about what data they should report and how they are to report it to employers. The proposed changes, while not dramatic, will help laboratories and IITFs avoid needing

two different report formats, one for DOT and one for HHS.

At Appendix C, we provide clarification to IITFs about what data they should report and how they are to report it to the DOT on a semi-annual basis.

Other Issues

The Department is aware that HHS is preparing an NPRM which will propose changes to the current Federal Drug Testing Custody and Control Form (CCF). If changes are adopted by HHS, they would likely have some impact upon the DOT procedural requirements for collectors, laboratories, and MRO's. When the HHS rule on the revised CCF is published, the Department will make necessary changes to part 40.

Some individuals have recently raised issues about screening and confirmation of 6–AM at 10 ng/mL without the need show the presence of morphine in the specimen. If there are factual, evidence-based concerns, we would like to hear them. If there are such valid concerns, are there viable laboratory testing resolutions to the issue? Or must the regulation provide additional instruction to MROs about how to deal with a positive heroin result? What would that instruction be?

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).

This rule is not significant for purposes of Executive Order 12866 or the DOT's regulatory policies and procedures. It proposes modifications to our overall part 40 procedures and is intended only to further align our laboratory procedures and processes, as well as a few collection and MRO procedures, with those requirements that are being directed by the HHS Guidelines which were considered non-significant. Their economic effects will be negligible for DOT regulated employers. Consequently, the DOT certifies, under the Regulatory Flexibility Act, this rule will not have a significant economic impact on a substantial number of small entities.

We would note that all HHS-certified laboratories must have the capability to accurately test for MDMA in order to pass certification requirements of the National Laboratory Certification Program. In addition, Federal Agency employee testing programs will have to test for MDMA, as well as amphetamine and cocaine at the new cutoffs. Our harmonizing on these matters will only bring clarity and consistency to the efforts of the Federal testing programs, programs that are internal to the Federal Government and those that are regulated by the Federal Government.

HHS has estimated that there may be 10% more users of amphetamine and cocaine identified using the lowered cutoffs and testing for new drugs. HHS says the incidence and prevalence of amphetamines and cocaine use is very low. Our data supports this fact. From July 1, 2008 through June 30, 2009, the DOT's regulated-transportation industry program had 14,440 amphetamine positive and 15,675 cocaine positive laboratory results in the 5,444,255 total test results reported. These relatively small numbers mean that MRO review costs and burdens resulting from additional requirements in the proposed rule should be minimal.

In the DOT-regulated industries, more positive results should not impose a significant economic impact or burdens on testing laboratories. The Department has obtained information on costs for MDMA and 6–AM testing at 11 laboratories representing about 3.6 million DOT tests, approximately 67 percent of the 5,444,255 tests mentioned above for the July 2008—June 2009 period. Because the cost per test varies among laboratories (from a low of $0.06 per MDMA or 6–AM test to a high of $1.27 per test for MDMA tests and $2.27 per test for 6–AM tests), appearing to depend in part on the volume of tests at each laboratory, the Department calculated a weighted average cost per test for the industry. Given the number of tests conducted by each laboratory, MDMA tests would have cost a weighted average of $0.09 per test; 6–AM tests would have a weighted average cost of $0.26 per test. The actual dollar cost of the tests at the 11 laboratories would have been $392,125 for MDMA, $569,024 for 6–AM, and $961,419 combined. Extrapolating the weighted average costs per test to the 100 percent of the DOT tests would result in an estimated cost of $489,982 for MDMA tests, $871,081 for 6–AM tests, and $1,361,063 combined.

We have concluded that this rule is not significant for purposes of Executive Order 12866 or the DOT's regulatory policies and procedures. In addition to its low costs, it proposes modifications to our overall part 40 procedures and is intended only to further align our laboratory procedures and processes, as well as some collection and MRO procedures, in order to harmonize DOT procedures with requirements that are being directed by HHS Mandatory Guidelines, which were themselves deemed to be non-significant rules.

List of Subjects in 49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

Issued this 20th day of January 2010 at Washington, DC.

Ray LaHood,

Secretary of Transportation.

For reasons discussed in the preamble, the Department of Transportation proposes to amend part 40 of Title 49 Code of Federal Regulations, as follows:

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

1. 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.*

2. Section 40.3 is amended as follows:

A. Revise the definitions of *Adulterated specimen, Blind Specimen or blind performance test specimen, Cancelled test, Confirmatory drug test, Initial drug test, Invalid result, Laboratory, and Limit of Detection.*

B. Add definitions of Alternate Responsible Technician, Certifying Scientist (CS), Certifying Technician (CT), Instrumented Initial Test Facility (IITF), Limit of Quantitation, Negative result, Positive result, Reconfirmed, Rejected for testing, Responsible Person (RP), Responsible Technician (RT), and Split specimen collection in alphabetical order.

The revisions and additions read as follows:

§ 40.3 What do the terms used in this regulation mean?

* * * * *

Adulterated specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

* * * * *

Alternate Responsible Technician. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified IITF when the responsible

technician is unable to fill these obligations.

* * * * *

Blind Specimen or blind performance test specimen. A specimen submitted to an HHS-certified laboratory or an HHS-certified IITF for quality control testing purposes, with a fictitious identifier, so that the laboratory or IITF cannot distinguish it from an employee specimen.

* * * * *

Cancelled test. The result reported by the MRO to the employer when a specimen has been reported to the MRO as invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable error exists in the forensic records.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of any test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, negative/dilute, and rejected for testing results reported by a laboratory or IITF.

* * * * *

Confirmatory drug test. A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify the presence of a specific drug or drug metabolite.

* * * * *

Initial drug test. The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

* * * * *

Instrumented Initial Test Facility (IITF). A permanent location where initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician. Any U.S. IITF certified by HHS under the National Laboratory Certification Program as meeting the IITF minimum standards of Subpart I of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; or, in the case of foreign laboratories, an IITF approved for participation by DOT under this part. (The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs are available on the Internet at *http://www.health.org/workpl.htm* or from the Division of Workplace Programs, 1 Choke Cherry Road, Room 2–1035, Rockville, MD 20857).

* * * * *

Invalid result. The result reported by an HHS-certified laboratory in accordance with the criteria established in HHS Guidelines when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory testing, reporting of results, and recordkeeping is performed under the supervision of a responsible person. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the laboratory minimum standards of Subpart I of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part.

Limit of Detection. The lowest concentration at which a measurand can be identified, but (for quantitative assays) the concentration cannot be accurately calculated.

* * * * *

Limit of Quantitation. For quantitative assays, the lowest concentration at which the identity and concentration of the measurand can be accurately established.

* * * * *

Negative result. The result reported by an HHS-certified laboratory or an HHS-certified IITF to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class and the specimen is a valid specimen.

* * * * *

Positive result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentration.

* * * * *

Reconfirmed. The result reported for a split specimen when the second laboratory is able to corroborate the original result reported for the primary specimen.

* * * * *

Rejected for testing. The result reported by an HHS-certified laboratory or HHS-certified IITF when no tests are performed for a specimen because of a fatal flaw or a correctable flaw that is not corrected.

Responsible Person (RP). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory.

Responsible Technician (RT). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified IITF.

* * * * *

Split specimen collection. A collection in which the urine collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

* * * * *

3. In § 40.13, paragraph (c) is revised, to read as follows:

§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?

* * * * *

(c) Except as provided in paragraph (d) of this section, you must not perform any tests on DOT urine or breath specimens other than those specifically authorized by this part or DOT agency regulations. For example, you must not test a DOT urine specimen for additional drugs; and a laboratory or IITF is prohibited from making a DOT urine specimen available for a DNA test or other types of specimen identity testing.

* * * * *

4. Section 40.27 is revised, to read as follows:

§ 40.27 May an employer require an employee to sign a consent or release in connection with the DOT drug and alcohol testing program?

No, as an employer, you must not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory or IITF testing, MRO and SAP services).

5. In § 40. 41, paragraph (c) is revised, to read as follows:

§ 40.41 Where does a urine collection for a DOT drug test take place?

* * * * *

(c) If you are operating a collection site, you must have all necessary personnel, materials, equipment, facilities and supervision to provide for the collection, temporary storage, and shipping of urine specimens to a laboratory or IITF, and a suitable clean surface for writing.

* * * * *

6. In § 40.45, paragraphs (b) and (d) are revised, to read as follows:

§ 40.45 What form is used to document a DOT urine collection?

* * * * *

(b) You must not use a non-Federal form or an expired Federal form to

conduct a DOT urine collection. As a laboratory or IITF, C/TPA or other party that provides CCFs to employers, collection sites, or other customers, you must not provide copies of an expired Federal form to these participants. You must also notify these participants that they must not use an expired Federal form.

* * * * *

(d) Under no circumstances may the CCF transmit personal identifying information about an employee (other than a social security number (SSN) or other employee identification (ID number)) to a laboratory or IITF.

* * * * *

7. Section 40.51 is revised, to read as follows:

§ 40.51 What materials are used to send urine specimens to the laboratory or IITF?

(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory or IITF.

(b) You are not required to use a shipping container if a laboratory or IITF courier hand-delivers the specimens from the collection site to the laboratory or IITF.

8. In § 40.73, paragraphs (a)(2), (a)(8)(iii), and (b) are revised, to read as follows:

§ 40.73 How is the collection process completed?

(a) * * *

(2) Complete the chain of custody on the CCF (Step 4) by printing your name (**Note:** You may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory or IITF,

(8) * * *

(iii) If a laboratory or IITF courier hand-delivers the specimens from the collection site to the laboratory or IITF, prepare the sealed plastic bag for shipment as directed by the courier service.

* * * * *

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory or IITF as quickly as possible, but in any case within 24 hours or during the next business day.

9. In § 40.81, the section heading and paragraphs (b) through (d) are revised, and paragraphs (e) and (f) are added, to read as follows:

§ 40.81 What laboratories or IITFs may be used for DOT drug testing?

* * * * *

(b) As an IITF located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the NLCP for initial testing required under this part.

(c) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory verification standards, or deemed your laboratory or IITF fully equivalent to a laboratory meeting HHS laboratory certification standards for testing required under this part; or

(2) The DOT, based on a written recommendation from HHS, has recognized a Canadian or Mexican certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your laboratory under those equivalent standards and procedures.

(d) As an IITF located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your IITF as meeting HHS laboratory verification standards, or deemed your laboratory or IITF fully equivalent to a laboratory meeting HHS laboratory certification standards for testing required under this part; or

(2) The DOT, based on a written recommendation from HHS, has recognized a Canadian or Mexican certifying organization as having equivalent IITF certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your IITF under those equivalent standards and procedures.

(e) As a laboratory or IITF participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.

(f) If DOT determines that you are in noncompliance with this part, you could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to you, you are ineligible to participate in the DOT drug testing program even if you continue to meet the requirements of paragraph (a), (b), (c), or (d) of this section.

10. In § 40.83, the section heading, the introductory text, and paragraphs (h)(1)(i), (h)(1)(iii), (h)(1)(iv), (h)(2), and (i) are revised, to read as follows:

§ 40.83 How do laboratories or IITFs process incoming specimens?

As the laboratory or IITF, you must do the following when you receive a DOT specimen from a collection site:

(a) You are authorized to receive only copy (1) of the CCF. You are not authorized to receive other copies of the CCF nor any copies of the alcohol testing form.

* * * * *

(h) * * *

(1) * * *

(i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory or IITF testing; or

(ii) * * *

(iii) The laboratory or IITF opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory or IITF believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory or IITF testing; or

(iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory or IITF believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing.

(2) In situations outlined in paragraph (h)(1) of this section, the laboratory or IITF shall mark through the "A" and write "B," then initial and date the change. A corresponding change shall be made to the other bottle by marking through the "B" and writing "A," and initialing and dating the change.

(i) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory or IITF internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

11. A new § 40.84 is added, to read as follows:

§ 40.84 How do laboratories process and test specimens received from an IITF?

(a) As a laboratory, you must process each specimen received from an IITF you must do so following the appropriate procedures outlined in the HHS Mandatory Guidelines.

(b) You must test each specimen received from an IITF in the same manner as if it had not been previously tested.

12. Section 40.85 is revised, to read as follows:

§ 40.85 For what drugs do laboratories or IITFs test?

As a laboratory or IITF, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test "DOT specimens" for any other drugs.

(a) Marijuana metabolites.

(b) Cocaine metabolites.

(c) Amphetamines.

(d) Opiate metabolites.

(e) Phencyclidine (PCP).

13. Section 40.87 is revised, to read as follows:

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

(a) As a laboratory, you must use the Initial Test and Confirmatory Test cutoff concentrations displayed in the following table. As an IITF, you must use the Initial Test cutoff concentrations displayed in the following table. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Initial test analyte	Initial test cutoff concentration	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites	50 ng/mL	THCA [1]	15 ng/mL.
Cocaine metabolites	150 ng/mL	Benzoylecgonine	100 ng/mL.
Opiate metabolites:			
Codeine/Morphine [2]	2000 ng/mL	Codeine	2000 ng/mL.
		Morphine	2000 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamines: [3]			
AMP/MAMP [4]	500 ng/mL	Amphetamine	250 ng/mL.
		Methamphetamine [5]	250 ng/mL.
MDMA [6]	500 ng/mL	MDMA	250 ng/mL.
		MDA [7]	250 ng/mL.
		MDEA [8]	250 ng/mL.

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).
[2] Morphine is the target analyte for codeine/morphine testing.
[3] Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.
[4] Methamphetamine is the target analyte for amphetamine/methamphetamine testing.
[5] To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.
[6] Methylenedioxymethamphetamine (MDMA).
[7] Methylenedioxyamphetamine (MDA).
[8] Methylenedioxyethylamphetamine (MDEA).

(b) As a laboratory or IITF, on an initial drug test you must report a result below the cutoff concentration as negative.

(c) If the result is at or above the cutoff concentration:

(1) As a laboratory, you must conduct a confirmation test.

(2) As an IITF, you must forward the specimen and its split to an HHS-certified laboratory; and you must do so following the appropriate procedures outlined in the HHS Mandatory Guidelines.

(d) As a laboratory, on a confirmation drug test you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(e) As a laboratory, you must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

14. In § 40.89, the section heading and paragraph (b) are revised, to read as follows:

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

* * * * *

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

15. Section 40.91 is revised to read as follows:

§ 40.91 What validity tests must laboratories and IITFs conduct on primary specimens?

As a laboratory or IITF, when you conduct validity testing under § 40.89, you must conduct it in accordance with the requirements of this section; and you must ensure that the following specimen validity tests are conducted on each specimen:

(a) You must determine the creatinine concentration on every specimen;

(b) You must determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;

(c) You must determine the pH on every specimen; and

(d) You must perform one or more specimen validity tests for oxidizing adulterants on every specimen.

(e) If a specimen exhibits abnormal physical characteristics (*e.g.,* unusual odor or color, semi-solid characteristics), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of standards, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

(f) As a laboratory, if you determine that the specimen is invalid and HHS Guidelines direct you to contact the MRO, you must contact the MRO and together decide if testing the primary specimen by another HHS certified laboratory would be useful in being able to report a positive or adulterated test result.

(g) As an IITF, if you determine that a specimen is adulterated, substituted, or invalid you must forward that specimen and its split to a HHS certified laboratory.

16. A new § 40.92 is added to read as follows:

§ 40.92 What specimen validity test criteria must be met in order for an IITF to send specimens to an HHS-certified laboratory?

(a) As an IITF, you must forward specimens to an HHS-certified laboratory when the creatinine test result is equal to or less than 5.0 mg/dL or when the screening specific gravity test result is less than 1.002.

(b) As an IITF, you must forward specimens to an HHS-certified

laboratory when the pH is less than 4.5 or equal to or greater than 9.0.

(c) As an IITF, your must forward specimens to an HHS-certified laboratory when the nitrite concentration is equal to or greater than 200 mcg/mL must be forwarded to an HHS-certified laboratory.

(d) As an IITF, you must forward specimens to an HHS-certified laboratory if the oxidizing adulterant result is equal to or greater than the cutoff.

(e) As an IITF, you must forward specimens to an HHS-certified laboratory in accordance with the invalid test result criteria required by the HHS Guidelines.

17. A new § 40.98 is added to read as follows:

§ 40.98 What do IITFs report and how do they report it?

(a) As an IITF, you may only report negative results and rejected for testing results.

(b) When a specimen is found to be negative, you must report the test result as being one of the following:

(1) Negative, or

(2) Negative-dilute, with numerical values for creatinine and specific gravity. The creatinine values must be greater than 5 mg/dL but less than 20 mg/dL; and the specific gravity values must be equal to or greater than 1.002 but less than 1.003.

(c) As an IITF, you must report the results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (*e.g.,* C/TPA).

(1) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF which has been signed by the certifying technician, or you may provide the IITF results report electronically (*i.e.,* computer data file).

(i) If you elect to provide electronically the IITF results report, you must include the following elements, as a minimum, in the report format:

(A) IITF name and address;

(B) Employer's name (you may include I.D. or account number);

(C) Medical review officer's name;

(D) Specimen I.D. number;

(E) Donor's SSN or employee I.D. number, if provided;

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) Date received at the IITF;

(J) Certifying Technician's name;

(K) Date Certifying Technician released the results;

(L) Results (*i.e.,* Negative, Negative-Dilute (with values for creatinine and specific gravity), or Rejected for Testing (with reason).

(ii) [Reserved]

(2) [Reserved]

(d) As an IITF, any primary specimen that tested positive, adulterated, substituted, or invalid you must forward the remaining specimen and split specimen to a HHS certified laboratory, following the procedures outlined in the HHS Mandatory Guidelines.

18. A new § 40.100 is added to read as follows

§ 40.100 How long must an IITF retain a specimen?

A specimen that is negative, negative-dilute, or rejected for testing is discarded.

19. Section 40.101 is revised, to read as follows:

§ 40.101 What relationship may a laboratory or IITF have with an MRO?

(a) As a laboratory or IITF, you must not enter into any relationship with an MRO that creates a conflict of interest or the appearance of a conflict of interest with the MRO's responsibilities for the employer. You must not derive any financial benefit by having an employer use a specific MRO.

(b) The following are examples of relationships between laboratories or IITFs and MROs that the Department regards as creating conflicts of interest, or the appearance of such conflicts. This following list of examples is not intended to be exclusive or exhaustive:

(1) The laboratory or IITF employs an MRO who reviews test results produced by the laboratory or IITF;

(2) The laboratory or IITF has a contract or retainer with the MRO for the review of test results produced by the laboratory or IITF;

(3) The laboratory or IITF designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory or ITTF gives the employer a discount or other incentive to use a particular MRO;

(5) The laboratory or IITF has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory or IITF; or

(6) The laboratory or IITF permits an MRO, or an MRO's organization, to have a financial interest in the laboratory or IITF.

20. In § 40.103, the section heading, paragraphs (a) and (b), paragraph (c) introductory text, paragraph (d) introductory text, and paragraph (d)(1) are revised, to read as follows:

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

(a) As an employer or C/TPA with an aggregate of 2000 or more DOT-covered employees, you must send blind specimens to laboratories or IITFs you use. If you have an aggregate of fewer than 2000 DOT-covered employees, you are not required to provide blind specimens.

(b) To each laboratory or IITF to which you send at least 100 specimens in a year, you must transmit a number of blind specimen's equivalent to one percent of the specimens you send to that laboratory or IITF, up to a maximum of 50 blind specimens in each quarter (*i.e.,* January–March, April–June, July–September, October–December). As a C/TPA, you must apply this percentage to the total number of DOT-covered employees' specimens you send to the laboratory or IITF. Your blind specimen submissions must be evenly spread throughout the year. The following examples illustrate how this requirement works:

Example 1 to Paragraph (b). You send 2500 specimens to Lab or IITF X in Year 1. In this case, you would send 25 blind specimens to Lab or IITF X in Year 1. To meet the even distribution requirement, you would send 6 in each of three quarters and 7 in the other.

Example 2 to Paragraph (b). You send 2000 specimens to Lab or IITF X and 1000 specimens to Lab or IITF Y in Year 1. In this case, you would send 20 blind specimens to Lab or IITF X and 10 to Lab or IITF Y in Year 1. The even distribution requirement would apply in a similar way to that described in Example 1.

Example 3 to Paragraph (b). Same as Example 2, except that you also send 20 specimens to Lab or IITF Z. In this case, you would send blind specimens to Labs or IITFs X and Y as in Example 2. You would not have to send any blind specimens to Lab or IITF Z, because you sent fewer than 100 specimens to Lab or IITF Z.

Example 4 to Paragraph (b). You are a C/TPA sending 2000 specimens to Lab or IITF X in Year 1. These 2000 specimens represent 200 small employers who have an average of 10 covered employees each. In this case you—not the individual employers—send 20 blind specimens to Lab or IITF X in Year 1, again ensuring even distribution. The individual employers you represent are not required to provide any blind specimens on their own.

Example 5 to Paragraph (b). You are a large C/TPA that sends 40,000 specimens to Lab or IITF Y in Year 1. One percent of that figure is 400. However, the 50 blind specimen per quarter "cap" means that you need send only 50 blind specimens per quarter, rather than the 100 per quarter you would have to send to meet the one percent rate. Your annual total would be 200, rather than 400, blind specimens.

(c) Approximately 75 percent of the specimens you submit must be negative

(*i.e.,* containing no drugs, nor adulterated or substituted). Approximately 15 percent must be positive for one or more of the five drugs involved in DOT tests, and approximately 10 percent must either be adulterated with a substance cited in HHS guidance or substituted (*i.e.,* having specific gravity and creatinine meeting the criteria of § 40.93(b)).

* * * * *

(d) You must ensure that each blind specimen is indistinguishable to the laboratory or IITF from a normal specimen.

(1) You must submit blind specimens to the laboratory or IITF using the same channels (*e.g.,* via a regular collection site) through which employees' specimens are sent to the laboratory or IITF.

* * * * *

21. In § 40.105, the section heading and paragraphs (b) and (c) are revised, to read as follows:

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

* * * * *

(b) If the unexpected result is a false negative, you must provide the laboratory or IITF with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory or IITF to determine the reason for the discrepancy.

(c) If the unexpected result is a false positive, adulterated, or substituted result, you must provide the laboratory or IITF with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory or IITF 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.

22. Section 40.107 is revised, to read as follows:

§ 40.107 Who may inspect laboratories or IITFs?

As a laboratory or IITF, you must permit an inspection, with or without prior notice, by ODAPC, a DOT agency, or a DOT-regulated employer that contracts with the laboratory or IITF for drug testing under the DOT drug testing program, or the designee of such an employer.

23. Section 40.109 is revised, to read as follows:

§ 40.109 What documentation must the laboratory or IITF keep and for how long?

(a) As a laboratory or IITF, you must retain all records pertaining to each employee urine specimen for a minimum of two years.

(b) As a laboratory or IITF, you must also keep for two years employer-specific data required in § 40.111.

(c) Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain the records for an additional period of time (*e.g.,* for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the records at the end of the two-year period.

24. Section 40.111 is revised, to read as follows:

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

(a) As a laboratory or IITF, you must transmit an aggregate statistical summary, by employer, of the data listed in Appendix B to this part to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is likely that information about an employee's test result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) The summary must be sent by January 20 of each year for July 1 through December 31 of the prior year.

(4) The summary must also be sent by July 20 of each year for January 1 through June 30 of the current year.

(b) When the employer requests a summary in response to an inspection, audit, or review by a DOT agency, you must provide it unless the employer had fewer than five aggregate test results. In that case, you must send the employer a report indicating that not enough testing was conducted to warrant a summary. You may transmit the summary or report by hard copy, fax, or other electronic means.

(c) You must also release information to appropriate parties as provided in §§ 40.329 and 40.331.

(d) As a laboratory or IITF, 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.

25. Section 40.113 is revised, to read as follows:

§ 40.113 Where is other information concerning laboratories or IITFs found in this regulation?

You can find more information concerning laboratories in several sections of this part:

26. In § 40.123, paragraph (b)(1) is revised, to read as follows:

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

* * * * *

(b) * * *

(1) Ensuring the review of the CCF on all specimen collections for the purposes of determining whether there is a problem that may cause a test to be cancelled (see §§ 40.199–40.203). As an MRO, you are not required to review laboratory or IITF internal chain of custody documentation. No one is permitted to cancel a test because you have not reviewed this documentation;

* * * * *

27. Section 40.125 is revised, to read as follows:

§ 40.125 What relationship may an MRO have with a laboratory or IITF?

As an MRO, you must not enter into any relationship with an employer's laboratory or IITF that creates a conflict of interest or the appearance of a conflict of interest with your responsibilities to that employer. You must not derive any financial benefit by having an employer use a specific laboratory or IITF. For examples of relationships between laboratories and MROs that the Department views as creating a conflict of interest or the appearance of such a conflict, see § 40.101(b).

28. In § 40.127, the introductory text and paragraphs (b), (c)(2), (d), (g) introductory text, and (g)(3) to read as follows:

§ 40.127 What are the MRO's functions in reviewing negative test results?

As the MRO, you must do the following with respect to negative drug test results you receive from a laboratory or IITF, prior to verifying the result and releasing it to the DER:

* * * * *

(b) Review the negative laboratory or IITF test result and ensure that it is consistent with the information contained on the CCF.

(c) * * *

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF or the electronic laboratory or IITF results report that conveys the negative laboratory test result.

(d) If the copy of the documentation provided to you by the collector or laboratory or IITF appears unclear, you must request that the collector or laboratory or IITF send you a legible copy.

* * * * *

(g) Staff under your direct, personal supervision may perform the administrative functions of this section for you, but only you can cancel a test. If you cancel a laboratory or IITF-confirmed negative result, check the "Test Cancelled" box (Step 6) on Copy 2 of the CCF, make appropriate annotation in the "Remarks" line, provide your name, and sign, initial or stamp and date the verification statement.

* * * * *

(3) Your review must, as a minimum, include the CCF, negative laboratory or IITF test result, any accompanying corrective documents, and the report sent to the employer. You must correct any errors that you discover. You must take action as necessary to ensure compliance by your staff with this part and document your corrective action. You must attest to the quality assurance review by initialing the CCFs that you review.

* * * * *

29. In § 40.151, paragraph (g) is revised, to read as follows:

§ 40.151 What are MROs prohibited from doing as part of the verification process?

* * * * *

(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP, 6–AM, or MDMA in a specimen. There are no legitimate medical explanations for the presence of these substances

* * * * *

30. In § 40.155, paragraph (a) is revised, to read as follows:

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

(a) When the laboratory or IITF reports that a specimen is dilute, you must, as the MRO, report to the DER that the specimen, in addition to being negative or positive, is dilute.

* * * * *

31. In § 40.161, the introductory text is revised, to read as follows:

§ 40.161 What does the MRO do when a drug test specimen is rejected for testing?

As the MRO, when the laboratory or IITF reports that the specimen is rejected for testing (*e.g.,* because of a fatal or uncorrected flaw), you must do the following:

* * * * *

32. In § 40.203, paragraphs (a) and (d)(3) are revised, to read as follows:

§ 40.203 What problems cause a drug test to be cancelled unless they are corrected?

(a) As the MRO, when a laboratory or IITF discovers a "correctable flaw" during its processing of incoming specimens (see § 40.83), the laboratory or IITF will attempt to correct it. If the laboratory or IITF is unsuccessful in this attempt, it will report to you that the specimen has been "Rejected for Testing" (with the reason stated).

* * * * *

(d) * * *

(3) The collector uses a non-Federal form or an expired Federal form for the test. This flaw may be corrected through the procedure set forth in § 40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures of this part in an HHS-certified laboratory or IITF. If the problem is not corrected, you must cancel the test.

33. In § 40.205, paragraphs (b) introductory text and (b)(2) are revised, to read as follows:

§ 40.205 How are drug test problems corrected?

* * * * *

(b) If, as a collector, laboratory or IITF, MRO, employer, or other person implementing these drug testing regulations, you become aware of a problem that can be corrected (*see* § 40.203), but which has not already been corrected under paragraph (a) of this section, you must take all practicable action to correct the problem so that the test is not cancelled.

* * * * *

(2) If the problem is the use of a non-Federal form or an expired Federal form, you must provide a signed statement (*i.e.,* a memorandum for the record). It must state that the incorrect form contains all the information needed for a valid DOT drug test, and that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond your control. The statement must also list the steps you have taken to prevent future use of non-Federal forms or expired Federal forms for DOT tests. For this flaw to be corrected, the test of the specimen must have occurred at a HHS-certified laboratory or IITF where it was tested consistent with the requirements of this part. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

* * * * *

34. In § 40.208, paragraph (a) is revised, to read as follows:

§ 40.208 What problem requires corrective action but does not result in the cancellation of a test?

(a) If, as a laboratory or IITF, collector, employer, or other person implementing the DOT drug testing program, you become aware that the specimen temperature on the CCF was not checked and the "Remarks" line did not contain an entry regarding the temperature being out of range, you must take corrective action, including securing a memorandum for the record explaining the problem and taking appropriate action to ensure that the problem does not recur.

* * * * *

35. In § 40.209, the section heading and paragraphs (a) and (b)(9) are revised, to read as follows:

§ 40.209 What procedural problems do not result in the cancellation of a test and do not require corrective action?

(a) As a collector, laboratory or IITF, MRO, employer or other person administering the drug testing process, you must document any errors in the testing process of which you become aware, even if they are not considered problems that will cause a test to be cancelled as listed in this subpart. Decision about the ultimate impact of these errors will be determined by other administrative or legal proceeding, subject to limitation of paragraph (b) of this section.

(b) * * *

(9) Personal identifying information is inadvertently contained on the CCF (*e.g.,* the employee signs his or her name on the laboratory or IITF copy 1); or

* * * * *

36. In § 40.329, the section heading and paragraph (b) are revised, to read as follows:

§ 40.329 What information must laboratories, MROs, and other service agents release to employees?

* * * * *

(b) As a laboratory or IITF, you must provide, within 10 business days of receiving a written request from an employee, and made through the MRO, the records relating to the results of the employee's drug test (*i.e.,* laboratory or IITF) report and data package). You may charge no more than the cost of preparation and reproduction for copies of these records.

* * * * *

37. In § 40.355, the introductory text, paragraphs (a) through (c), and paragraph (l) are revised, to read as follows:

§ 40.355 What limitations apply to the activities of service agents?

As a service agent, you are subject to the following limitations concerning your activities in the DOT drug and alcohol testing program.

(a) You must not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory or IITF testing, MRO, and SAP services). No one may do so on behalf of a service agent.

(b) You must not act as an intermediary in the transmission of drug test results from the laboratory or IITF to the MRO. That is, the laboratory or IITF must not send results to you, with you in turn sending them to the MRO for verification. For example, a practice in which the laboratory or IITF transmits results to your computer system, and you then assign the results to a particular MRO is not permitted.

(c) You must not transmit drug test results directly from the laboratory or IITF to the employer (by electronic or other means) or to a service agent who forwards them to the employer. All confirmed laboratory or IITF results must be processed by the MRO before they are released to any other party.

* * * * *

(l) In transmitting documents to laboratories or IITFs, you must ensure that you send to the laboratory or IITF that conducts testing only the laboratory copy of the CCF. You must not transmit other copies of the CCF or any ATFs to the laboratory or IITF.

* * * * *

38. Appendix B is revised, to read as follows:

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

Laboratory Report to Employer

The following items are required on each laboratory 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 Test Reason:
  (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)
  (3) MDMA (number)
  (4) MDA (number)
  (5) MDEA (number)
5. Adulterated (number)
6. Substituted (number)
7. Invalid Result (number)

IITF Report to Employer

The following items are required on each IITF report:

Reporting Period: (inclusive dates)
IITF 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 Test Reason:
  (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. Number of specimens forwarded to an HHS-certified laboratory for additional drug testing and/or specimen validity testing.

39. Appendix C is revised, to read as follows:

Appendix C to Part 40—DOT Drug Testing Semi-Annual Laboratory or IITF 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 laboratory report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
1. DOT Specimen Results Reported (number)
2. Negative Results Reported (number)
  Negative (number)
  Negative-Dilute (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)

The following items are required on each IITF report:

Reporting Period: (inclusive dates)
IITF Identification: (name and address)
1. DOT Specimen Results Reported (number)
2. Negative Results Reported (number)
  Negative (number)
  Negative-Dilute (number)
3. Rejected for Testing Reported (number)
  By Reason (number)
4. Specimens forwarded to an HHS-certified laboratory for additional testing (number)
  For Drugs (number)
  For SVT (number)

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

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RIN 1018–AW63

Endangered and Threatened Wildlife and Plants; Establishment of a Nonessential Experimental Population of Sonoran Pronghorn in Southwestern Arizona

AGENCY: Fish and Wildlife Service, Interior.