

**Office of the Secretary**

**49 CFR Part 40**

**[Docket DOT-OST-2010-0161]**

**RIN 2105-AE03**

**Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Federal Drug Testing Custody and Control Form; Technical Amendment**

**AGENCY:** Office of the Secretary, DOT

**ACTION:** Interim Final Rule

**SUMMARY:** The Department of Health and Human Services recently issued a new Federal Drug Testing Custody and Control Form for use in both the Federal employee and Department of Transportation drug testing programs. In order to accommodate the form's use within our transportation industry program, the Department is making a few necessary regulation changes in order for collectors, laboratories, and Medical Review Officers to know how to use the new form. The form's use is authorized beginning October 1, 2010. The Department is also making

a technical amendment to its drug testing procedures. The purpose of the technical amendment is to add a provision of the rule which was inadvertently omitted from the final rule in August 2010.

**DATES:** The rule is effective October 1, 2010. Comments to this interim final rule should be submitted by **[Insert date 30 days after date of publication]**. 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 W12-140, 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-2010-0161 or the Regulatory Identification Number (2105-AE03) 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:** Bohdan Baczara, U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, SE, Washington, DC 20590; 202-366-3784 (voice), 202-366-3897 (fax), or [bohdan.baczara@dot.gov](mailto:bohdan.baczara@dot.gov) (e-mail).

## **SUPPLEMENTARY INFORMATION:**

### **Background**

All urine specimens collected under the Department of Transportation (DOT) drug testing regulation, 49 CFR Part 40, must be collected using chain-of-custody procedures that incorporate the use of the Federal Drug Testing Custody and Control Form (CCF) promulgated by the Department of Health and Human Services (HHS). On November 17, 2009, HHS published a proposal to revise the CCF. [74 FR 59196] All the comments submitted were thoroughly reviewed by HHS and taken into consideration in fashioning the new CCF. The Department worked closely with HHS on the new CCF. Recently, HHS announced the new CCF in the Federal Register [75 FR 41488] which has an effective date of October 1, 2010.

The following items in the revised CCF are worth noting for the DOT transportation industry drug testing program:

(1) In Step 1 of the CCF, the Federal testing authorities – HHS; DOT; and Nuclear Regulatory Commission (NRC) – are noted, with further specificity for the DOT Agencies – Federal Motor Carrier Safety Administration (FMCSA); Federal Aviation Administration (FAA); Federal Railroad Administration (FRA); Federal Transit Administration (FTA); Pipeline

and Hazardous Materials Safety Administration (PHMSA); and the United States Coast Guard (USCG)<sup>1</sup> – also noted;

(2) In Step 5A on Copy 1 of the CCF, the new drug analytes MDMA, MDA, and MDEA are added, as are “Δ9-THCA” after “Marijuana Metabolite” and “BZE” after “Cocaine Metabolite” to specify the drug analytes;

(3) In Step 6 on Copy 2 of the CCF, a line has been included on which the Medical Review Officer (MRO) would write the drug for which a positive result is verified, and a new line item “other” was added to assist the MRO in documenting other “refusal to test” situations – for example, when there is no legitimate medical explanation for the employee providing an insufficient amount of urine;

(4) In Step 7 on Copy 2 of the CCF, a box has been added for the MRO to check if the split specimen is reported as cancelled; and

(5) On the reverse side of Copy 5 – the “Donor Copy” – of the CCF, are the revised instructions for completing the CCF.

Because HHS sought and received comments on the form and its use, we seek only to receive comments on the actual implementation of the new CCF, and not on the form itself.

In addition, the technical amendment is intended to address an omission which has been called to our attention since the publication of the Department’s final rule in August 2010 [75 FR 49850] which was intended to create consistency with many of the new drug testing requirements established by HHS. Specifically, the HHS Guidelines require laboratories to report the concentration of the drug or drug metabolite for a positive result to the MRO. This

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<sup>1</sup> For purposes of following the requirements of 49 CFR Part 40, “DOT, The Department, DOT Agency” is defined, at 40.3, to include the United States Coast Guard.

was omitted from our rule text in the section that directs what laboratories are to report and how they are to report it. We have amended the rule text to reflect this requirement.

## **Implementation Guidance**

DOT- regulated employers and their service agents are authorized to begin use of the new CCF on October 1, 2010. However, we recognize there will be large supplies of old CCFs available after the start date. To avoid wasting the old forms, the Department will permit use of the old CCF until September 30, 2011. After this date, collectors and laboratories are not to use any of the old CCFs in the DOT testing program. The rule text has been changed to reflect this one-full-year transition period from old CCF to new CCF.

However, when the old CCF is used on or before September 30, 2011, the collector will need to write in the specific DOT Agency under which the specimen is collected and must do so in the remarks section in Step 2 on Copy 1 of the CCF. This DOT Agency designation is a new feature in the new CCF. So, if an old CCF is used and the employee's specimen is collected under, for example, authority of the FMCSA regulation, the collector will write in "DOT – FMCSA" in the remarks section in Step 2 of the CCF.

Likewise, when an old CCF is used on or before September 30, 2011, before transmitting a confirmed positive drug test for MDMA, MDA, or MDEA, as appropriate, to the MRO, the laboratory – in addition to checking the "positive" box – must write in the specific MDMA, MDA, or MDEA analyte in the "Remarks" section in Step 5-A of Copy 1 of the CCF.

Like now, use of a CCF past its expiration date will not be a fatal flaw. Use of the old CCF after September 30, 2011, must be corrected using the procedures at § 40.205(b)(2).

Regarding the completion of the new Step 1-D of the CCF, the Department would like to emphasize that neither the employer nor the collector should find it difficult to complete this new data item. DOT- regulated employers and their Consortium/Third Party Administrators (C/TPAs) currently provide the collector and the collection site with specific instructions – the test reason, whether the test is to be conducted under direct observation, the MRO name and address, and employee information (e.g., name and SSN or ID number), among others. Adding one additional data element to what is already provided by employers or their C/TPAs to collectors should not prove significantly difficult. An employer and its C/TPA should be readily aware of the DOT Agency regulating the employee’s safety-sensitive duties. We have added a new § 40.14 to put into one place the items that employers and their C/TPAs have been routinely providing collectors, and if they have not been doing so, the information they should have always been providing collectors, in addition to this new requirement for DOT Agency designations.

If the information in Step 1-D of the CCF is not completed, the laboratory will not delay testing the specimen and reporting the confirmed result to the MRO. Similarly, the MRO will not delay the medical review process and reporting the verified result to the employer. The Department believes the laboratory and MRO should note that the testing authority box was not checked and continue with processing, testing, verifying, and reporting the specimen result, as appropriate. To reduce the potential failure of the collector to check the appropriate box in Step 1-D, the Department will permit the checkmark to be pre-printed in the appropriate box prior to the collection. We amended our rule text to reflect these situations.

As more of the DOT Agencies go toward having employee drug testing violations reported to them, these designations will prove invaluable to the process.

Regarding Step 6 of Copy 2 of the CCF, HHS provided more space for identifying the positive drug(s) and a new line item “Other” was added to assist the MRO in documenting other “Refusal to Test” situations – for example, when there is no legitimate medical explanation for the employee providing an insufficient amount of urine. In Step 7 of Copy 2 of the CCF, HHS added a box for “Test Cancelled” for the MRO to check when a test is cancelled if a split specimen fails to reconfirm. We amended our rule text to reflect these modifications. As a reminder to MROs, the “Test Cancelled” box should only be used when the split fails to reconfirm for all the results verified and reported for the primary specimen.

In light of the modifications HHS made to Step 7 of Copy 2 of the CCF, we have taken this opportunity to incorporate into § 40.187(f) rule text on how MROs are to document split specimen results. It is our understanding that MROs have been completing this section correctly even though the rule text did not instruct the MRO to check the “Reconfirmed” and/or “Failed to Reconfirm” boxes. The amendment to § 40.187(f) makes this a requirement.

On the back of Copy 5 – the “Donor Copy” – of the CCF, the instructions to the collector on completing the CCF are revised and updated.

## **Regulatory Analyses and Notices**

### Authority

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 54101 *et seq.*) and the Department of Transportation Act (49 U.S.C. 322).

### Administrative Procedure Act

The Department has determined this rule may be issued without a prior opportunity for notice and comment because providing prior notice and comment would be unnecessary, impracticable, or contrary to the public interest. This rule will authorize DOT-regulated employers to use the CCF beginning October 1, 2010. Providing an opportunity for prior notice and comment would be unnecessary, and would seem redundant, because the public already had an opportunity to comment and did provide comments to HHS on the proposed CCF. In their Notice of Proposed Revisions to the Federal Custody and Control Form, HHS stated that the CCF is used for the Federal workplace drug testing program but also pointed out that "...the Department of Transportation (DOT) requires its regulated industries to use the Federal CCF." [74 FR 59196] Because many of the commenters were transportation industry employers, C/TPAs, and associations, we are confident they understood that the new CCF would be used in the DOT-regulated program. And, because the DOT utilizes the CCF for our drug testing program, the DOT and HHS collaborated in preparing the final CCF.

Providing an opportunity for prior notice and comment would be impracticable because there is such a short time frame from when HHS published the new CCF [75 FR 41488] to its October 1, 2010 effective date. In addition, this Interim Final Rule makes minor procedural amendments to its rule text to merely reflect the changes to the revised CCF and a technical amendment to correct an inadvertent oversight from a prior rulemaking. For these reasons, the Department finds there is good cause to make the rule effective immediately.

### Executive Order 12866 and Regulatory Flexibility Act

This Interim Final Rule is not significant for purposes of Executive Order 12866 or the DOT's regulatory policies and procedures. The rule makes minor procedural amendments to its rule text to merely reflect the changes to the revised CCF and a technical amendment to correct an inadvertent oversight. The use of the revised CCF does not increase costs on regulated parties because it authorizes regulated employers to continue using the old CCF for an additional twelve months, until September 30, 2011. After this date, the revised CCF must be used. This allows employers to use their current supply of old CCFs rather than discarding them. The rule will impose no new burdens on any parties. While small entities are among those who may use the revised CCF, the Department certifies, under the Regulatory Flexibility Act, that this rule does not have a significant economic impact on a substantial number of small entities.

**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 September 20, 2010, AT WASHINGTON D.C.**

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Ray LaHood,  
Secretary of Transportation

For reasons discussed in the preamble, the Department of Transportation amends Title 49 of the Code of Federal Regulations, Part 40, 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:** 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 et seq.

2. A new § 40.14 is added, to read as follows:

**§ 40.14 What collection information must employers provide to collectors?**

As an employer, or an employer's service agent – for example a C/TPA, you must ensure the collector has the following information when conducting a urine specimen collection for you:

- (a) Full name of the employee being tested.
- (b) Employee SSN or ID number.
- (c) Laboratory name and address (can be pre-printed on the CCF).
- (d) Employer name, address, phone number, and fax number (can be pre-printed on the CCF at Step 1-A).
- (e) DER information required at § 40.35 of this part.
- (f) MRO name, address, phone number, and fax number (can be pre-printed on the CCF at Step 1-B).

(g) The DOT Agency which regulates the employee's safety-sensitive duties (the checkmark can pre-printed in the appropriate box on the CCF at Step 1-D).

(h) Test reason, as appropriate: Pre-employment; Random; Reasonable Suspicion/Reasonable Cause; Post-Accident; Return-to-Duty; and Follow-up.

(i) Whether the test is to be observed or not (see § 40.67 of this part).

(j) (Optional) C/TPA name, address, phone, and fax number (can be pre-printed on the CCF).

3. In § 40.23, paragraph (f)(4) is revised, to read as follows:

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

\* \* \* \* \*

(f) \* \* \*

(4) You must instruct the collector to note on the CCF the same reason (e.g., random test, post-accident test) and DOT Agency (e.g., check DOT and FMCSA) as for the original collection.

\* \* \* \* \*

4. In § 40.45, revise paragraphs (b) and (c)(3), 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 CCF to conduct a DOT urine collection. As a laboratory, C/TPA or other party that provides CCFs to employers, collection sites, or other customers, you must not provide copies of an expired CCF to these participants.

You must also affirmatively notify these participants that they must not use an expired CCF (e.g., that after September 30, 2011, they may not use an expired CCF for DOT urine collections).

(c) \* \* \*

(3) As an employer, in Step 1-D of the CCF you may preprint the box for the DOT Agency under whose authority the test will occur.

\* \* \* \* \*

5. In § 40.63, paragraph (e) is revised, to read as follows:

**§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?**

\* \* \* \* \*

(e) You must pay careful attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute). If you detect such conduct, you must require that a collection take place immediately under direct observation (see §40.67) and complete Step 2 by noting the conduct in the “Remarks” line of the CCF and the fact that the collection was observed by checking the “Observed” box. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

6. In § 40.83, paragraph (a) is revised, to read as follows:

**§ 40.83 How do laboratories process incoming specimens?**

\* \* \* \* \*

(a) You are authorized to receive only Copy 1 of the CCF. You are not authorized to receive other copies of the CCF or any copies of the alcohol testing form.

\* \* \* \* \*

7. In §40.97, paragraphs (a)(2)(i) and (ii), and (e)(1) are revised, to read as follows:

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

(a) \* \* \*

(2) \* \* \*

(i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s).

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

\* \* \* \* \*

(e) \* \* \*

(1) You must provide quantitative values for confirmed positive drug test results to the MRO.

\* \* \* \* \*

8. In §40.129, paragraph (c) is revised, to read as follows:

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

\* \* \* \* \*

(c) With respect to verified positive test results, place a checkmark in the “Positive” box in Step 6 on Copy 2 of the CCF, indicate the drug(s)/metabolite(s) verified positive, and sign and date the verification statement.

\* \* \* \* \*

9. In §40.163:

- a. Paragraph (c)(8) is amended by removing “and”.
- b. Paragraph (c)(9) is amended by removing the period at the end and adding “; and” in its place.
- c. Paragraph (c)(10) is added.

The addition reads as follows:

**§ 40.163 How does the MRO report drug test results?**

\* \* \* \* \*

(c) \* \* \*

(10) The DOT Agency, if noted on the CCF.

\* \* \* \* \*

10. In §40.187, paragraph (f) is revised to read as follows:

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

\* \* \* \* \*

(f) For all split specimen results, as the MRO you must in Step 7 of Copy 2 of the CCF:

- (1) Report split specimen test results by checking the “Reconfirmed” box and/or the “Failed to Reconfirm” box, or the “Test Cancelled” box, as appropriate.

(2), Enter your name, sign, and date.

(3) 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.

11. In §40.191, paragraph (d)(2) is revised, to read as follows:

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

\* \* \* \* \*

(d)\* \* \*

(2) As the MRO, you must note the refusal by checking the “Refusal to Test” box in Step 6 on Copy 2 of the CCF, checking whether the specimen was adulterated or substituted and, if adulterated, noting the adulterant/reason. If there was another reason for the refusal, check “Other” in Step 6 on Copy 2 of the CCF, and note the reason next to the “Other” box and on the “Remarks” lines, as needed. You must then sign and date the CCF.

\* \* \* \* \*

12. In §40.193, paragraph (d)(2)(i) is revised, to read as follows:

**§ 40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?**

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(i) Check the “Refusal to Test” box and “Other” box in Step 6 on Copy 2 of the CCF and note the reason next to the “Other” box and on the “Remarks” lines, as needed.

\* \* \* \* \*

13. In §40.203, paragraphs (d)(2) and (d)(3) are revised, to read as follows:

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

\* \* \* \* \*

(d) \* \* \*

(2) The certifying scientist's signature is omitted on Copy 1 of the CCF for a positive, adulterated, substituted, or invalid test result.

(3) The collector uses a non-Federal form or an expired CCF 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. During the period of October 1, 2010 – September 30, 2011, you are not required to cancel a test because of the use of an expired CCF. Beginning October 1, 2011, if the problem is not corrected, you must cancel the test.

14. In §40.209, paragraphs (b)(1) 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?**

\* \* \* \* \*

(b) \* \* \*

(1) A minor administrative mistake (e.g., the omission of the employee's middle initial, a transposition of numbers in the employee's social security number, the omission of the DOT Agency in Step 1-D of the CCF.)

\* \* \* \* \*

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

\* \* \* \* \*

15. In §40.355, paragraph (1) is revised, to read as follows:

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

\* \* \* \* \*

(1) In transmitting documents to laboratories, you must ensure that you send to the laboratory that conducts testing only Copy 1 of the CCF. You must not transmit other copies of the CCF or any ATFs to the laboratory.

\* \* \* \* \*

[FR Doc. 2010-24038 Filed 09/24/2010 at 8:45 am; Publication Date: 09/27/2010]