

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Proposed Revisions to Federal Drug Testing Custody and Control Form

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of Proposed Revisions to the Federal Custody and Control Form.

SUMMARY: The Department of Health and Human Services (HHS) establishes the standards for Federal workplace drug testing programs under authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301 and Executive Order No. 12564. As required, HHS published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** on April 11, 1988 (53 FR 11979). The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), on November 13, 1998 (63 FR 63483), on April 13, 2004 (69 FR 19644) and on November 25, 2008 (73 FR 71858) with an effective date of May 1, 2010 (correct effective date published on December 10, 2008; 73 FR 75122). The Guidelines establish comprehensive standards for all aspects of the Federal workplace drug testing program, including the requirement for all urine specimens to be collected using chain of custody procedures to document specimen integrity and security from the time of collection until receipt by the “test facility.” To ensure uniformity among all Federal agency workplace drug testing programs and procedures, the Guidelines require agencies to use an Office of Management and Budget (OMB) approved Federal Custody and Control Form (Federal CCF) for their programs. Additionally, the Department of Transportation (DOT) requires its regulated industries to use the Federal CCF.

The current Federal CCF is a five-part form that consists of the following copies: Copy 1—Laboratory Copy, with the tamper-evident specimen bottle seal(s)/label(s) that are attached to the bottom of Copy 1, Copy 2—Medical Review Officer (MRO) Copy, Copy 3—Collector Copy, Copy 4—Employer Copy, and Copy 5—Donor Copy. The reverse side of each copy has a Public Burden Statement. The reverse side of Copy 5 also has a Privacy Act Statement (for Federal employees only) and instructions for completing the Federal

CCF. The current Federal CCF has been approved for use by OMB until September 1, 2012 for all Federal agency and federally-regulated drug testing programs that must comply with the Guidelines.

In the latest revision to the Guidelines, dated November 25, 2008 (73 FR 71858 with an effective date of May 1, 2010), the new regulations will permit the certification of Instrumented Initial Test Facilities (IITF) and will expand the drug testing profile to include new drug analytes: methylenedioxymethamphetamine (MDMA) commonly known as “ecstasy,” methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA) which are close chemical analogues of MDMA. These new regulatory actions will require that the Federal CCF be modified to accommodate the new rule changes.

This notice provides proposed changes to the current Federal CCF. It incorporates changes in accordance with the latest revisions to the Guidelines (published November 25, 2008; 73 FR 71858; effective May 1, 2010) and recommendations developed in a collaborative effort involving HHS and DOT. The proposed form is provided in Appendix A.

DATES: Written comments on the proposed draft should be submitted by January 19, 2010.

ADDRESSES: Written comments should be addressed to Robert L. Stephenson II, M.P.H., Director, Division of Workplace Programs (DWP), Center for Substance Abuse Prevention (CSAP), 1 Choke Cherry Road, Room 2–1035, Rockville, MD 20857. The public may also send comments by e-mail to charles.lodico@samhsa.hhs.gov. All comments received will be posted without change to <http://www.drugfreeworkplace.gov>.

FOR FURTHER INFORMATION CONTACT:

Charles LoDico, M.S., D–ABFT, Drug Testing Team, DWP, CSAP, 1 Choke Cherry Road, Room 2–1039, Rockville, MD 20857, telephone (240) 276–2600, fax (240) 276–2610, or e-mail: charles.lodico@samhsa.hhs.gov.

Discussion

SAMHSA is proposing several major changes to the Federal CCF. The first major change is to revise Copy 1 to permit use by IITFs, in addition to laboratories. This is in accordance with the latest revisions to the Guidelines (published November 25, 2008; effective May 1, 2010), which allow certification of IITFs to perform federally-regulated drug testing. A chain of custody section

was added in Step 4 of Copy 1 for the IITF to document receipt of the specimen and, as needed, to document subsequent transfer of the specimen to an HHS-certified laboratory for testing. The second major change is to add the new drug analytes required by the revised Guidelines to the Primary Specimen Report section in Step 5a of Copy 1. The new drug analytes are MDMA, MDA and MDEA. The third major change is to discontinue recording split specimen test results on Copy 1 of the Federal CCF. Instead, Step 5b of Copy 1 will be used to identify the split testing laboratory (i.e., laboratory name, city, and State), to indicate that the split specimen was tested, and to refer to a separate laboratory report for the split specimen test results. The fourth major change is to revise the MRO reporting sections on Copy 2 for primary specimens (Step 6) and for split specimens (Step 7), to facilitate reporting in accordance with the Guidelines and DOT Regulations. Revisions to Copy 2, Step 6 include the addition of lines for the MRO to specify positive drug analyte(s), to specify the adulterant/reason for reporting a specimen as adulterated, and to report other reasons for reporting a Refusal to Test (in addition to Adulteration and Substitution). Revisions to Copy 2, Step 7 include the addition of lines for the MRO to specify drug analyte(s), substitution, or adulteration for “Reconfirmed” or “Failed to Reconfirm” split specimens, and the addition of a checkbox to report a cancelled test.

A desired outcome from the proposed Federal CCF revision process was to maintain the same form size (8.5 inch by 11 inch) as the current Federal CCF. The content and format was redrawn for conciseness, to conserve space, and to allow for the needed additional content while maintaining the overall familiarity to which collectors, laboratories and MROs were accustomed to using.

Appendix A presents the required format and appearance for each copy of the proposed Federal CCF. SAMHSA recognizes that suppliers use different hardware and software to print forms and minor differences in appearance will occur. For example, the size of each checkbox on the form may be different, the font sizes and styles used for letters may be different, or the exact location of an item on a printed form may vary slightly from the location indicated on the sample provided in Appendix A. These minor changes in appearance are permitted since they do not significantly impact on the required format. Other changes permitted on the printed copies

include highlighting data entry/information fields where the collector and donor would be providing information and using combs/boxes (rather than a single line) for the donor's identification, to facilitate using optical readers for transferring that information. The colors used to highlight the fields may be different for different fields but must not prevent making clear photocopies of the information that is printed or handwritten in the highlighted fields. Other required information (e.g., the name and address of the test facility, the specimen identification number appearing on the top of the form and on the specimen bottle seal(s)/label(s)) may be printed on the Federal CCF during the original printing and assembly process or added by overprinting the five-part printed form after assembly.

A detailed discussion of other proposed changes follows:

Copy 1

To reflect use of the Federal CCF by IITFs as well as laboratories, Copy 1 has been redesignated as the Test Facility Copy (changed from Laboratory Copy). As on the current form, Copy 1 has a one-inch space at the top of the page reserved for: the title of the form ("Federal Custody and Control Form") that must be printed along the top edge, the name and street address of the test facility, the unique preprinted specimen identification number (i.e., a barcode with an associated human readable number or only a human readable number), the test facility accession number (if used), and other information (e.g., accounting) that the test facility or user of the Federal CCF may want to include. There are no restrictions on the font size used for the information appearing in this one-inch space. Also as on the current form, the OMB number must be included, either vertically or horizontally, in the upper right-hand corner.

The collector or employer representative completes Step 1. The items in Step 1(a), (b), and (c) are essentially the same as on the current Federal CCF. Step 1(d) is a new proposed item to list the acronyms for the Federal testing authority under which the specimen is being collected. The new Step 1(d) would read as follows: D. "Specify Testing Authority: HHS, NRC, DOT—Specify DOT Agency: FMCSA, FAA, FRA, FTA, PHMSA, USCG" with a checkbox beside each agency name.

The DOT-regulated testing program applies to more than 6 million individuals. Some of the DOT agencies and the United States Coast Guard

(USCG) have or anticipate having reporting requirements for test results. For example, the Federal Aviation Administration (FAA) requires the reporting of test results for pilots and mechanics, while the USCG requires the reporting of test results for mariners. We also expect other DOT agencies (e.g., FMCSA) may in the future require the identification of the "testing authority" in reporting of positive and refusal to test results which will be entered into a database. Identifying the Federal testing authority will facilitate reporting results to DOT agencies when their regulations require it and will assist HHS in identifying the Federal testing authority when it receives laboratory data. The information identifying the specific Federal testing authority captured on the Federal CCF will make it simpler for the entity reporting the result to the DOT agency (usually the employer or other program participant) to gather the information to satisfy the DOT agency reporting requirement. Knowing which data belongs to HHS, NRC, the USCG and the DOT agencies will prove helpful to each of these entities.

The collector or employer should not find it difficult or impossible to complete this new step. HHS and DOT experience is that employers and Consortium/Third Party Administration (C/TPA) currently provide specific instructions to the collector or collection site in order to conduct the collection. For example, C/TPA would provide the name of the employer, the date of the collection, the test reason, whether the test is to be conducted under direct observation, and employee information (e.g., name and ID number). Therefore, we would expect the employers and C/TPAs to simply add another data element to what they already provide. In the event the information in Step 1(d) is not completed the test facility must not hold up processing, or testing the specimen. Similarly, the MRO must not hold up reporting a verified result. We believe this is something the test facility or MRO should just note and continue with processing, testing, and reporting of the specimen result.

Step 1(e) contains the item "Reason for Test," with the reasons consolidated on a single line to conserve space on the proposed Federal CCF. Items in Steps 1(f) and (g) are essentially the same as on the current Federal CCF.

The collector completes Step 2 after he/she has received the specimen from the donor and has read the temperature of the specimen. The changes proposed for Step 2 are intended to gain more space on the proposed Federal CCF and

to allow more space for the collector's Remarks. One proposed change is to move the instructions for Step 2 [i.e., "(make remarks when appropriate)" and "Collector reads specimen temperature within 4 minutes"] to the same line as "Completed by Collector." Another proposed change is to revise the sentence "Is temperature between 90° and 100°F?" to "Temperature between 90° and 100°F?" This will reduce the space required for the three sections in Step 2 [i.e., for recording specimen temperature (Yes/No, Enter Remark) and collection type (Split/Single/None Provided, Enter Remark), and to indicate an observed collection (Observed, Enter Remark)]. We are proposing to increase the space for collector comments in the "Remarks" section to allow additional explanation and to improve legibility of handwritten remarks.

Step 3 instructs the collector to seal the specimen bottle(s), the donor to initial the bottle seal(s), and the donor to then complete Step 5 on Copy 2 (the MRO copy). These are the same instructions as on the current Federal CCF.

Step 4 is the chain of custody section initiated by the collector and completed by the test facility. The major changes proposed for Step 4 are to permit use of the Federal CCF by IITFs, as well as by laboratories, in accordance with the revised Guidelines. We are also proposing format changes to improve legibility of handwritten entries and facilitate form completion, while allowing all required information to be included. In the collector's chain of custody section, we propose to enlarge the block for the collector's signature while reducing the width of the "Specimen Bottle(s) Released to:" block. We also propose changing "Initiated by Collector and Completed by Laboratory" to "Initiated by Collector and Completed by Test Facility". The "Received at IITF" chain of custody section includes lines/checkboxes for the accessioner at the IITF to sign and print his/her name on the Federal CCF, record the date of specimen receipt, document the name and address of the IITF (if different from that printed on the Federal CCF), document the condition of the primary specimen bottle seal, and document the transfer of specimen custody. If a specimen received at the IITF cannot be reported (i.e., as rejected for testing, negative, or negative and dilute), the remaining specimen will be resealed using tamper-evident tape and forwarded to an HHS-certified laboratory for testing. This handling will be documented in the "Transfer from IITF to Lab" section of

the proposed Federal CCF. The laboratory chain of custody section in Step 4 is essentially the same as on the current Federal CCF. We are proposing changes similar to those for the collector's chain of custody section: to enlarge the block for the laboratory accessioner's signature while reducing the width of both the "Specimen Bottle(s) Released to:" block and the block for documenting condition of the primary specimen bottle seal.

Step 5(a) is completed by the test facility to report the test results of the primary specimen. Changes are proposed for this section in accordance with the revised Guidelines, including: changing "Primary Specimen Test Results—Completed by Primary Laboratory" to "Primary Specimen Report—Completed by Test Facility"; adding the new drug analytes (MDMA, MDA, and MDEA); changing "Test Lab (if different from above)" to "Test Facility (if different from above)"; and changing "Certifying Scientist" to "Certifying Technician/Scientist" on both signature and printed name lines. In addition, for clarity and to facilitate form completion, we propose to reposition drug/metabolite names and checkboxes, and to change the term "Rejected for Testing" to "Rejected." We also propose to add "Δ9-THCA" after "Marijuana Metabolite" and "BZE" after "Cocaine Metabolite" to specify the drug analytes.

We are proposing major changes to Step 5(b) of the current Federal CCF to accommodate the additional information needed on Copy 1 to address revised Guidelines requirements as described above. Laboratories will no longer record split specimen test results on Copy 1 of the proposed Federal CCF and be moved to Copy 2 (Medical Review Officer Copy). This change is justified by National Laboratory Certification Program (NLCP) data obtained from HHS-certified laboratories in 2008. These data indicate that only 0.07% of federally-regulated split specimens were tested (i.e., 3.7% of the total reported positives). Also, in many cases, the "Remarks" line of the current Federal CCF is insufficient to document all required comments for reporting split specimen test results. Laboratories often use a separate laboratory report to report split specimen results to the MRO. Therefore, in Step 5(b) of the proposed Federal CCF, the split laboratory will record its name and location (city and State), indicate that the split specimen was tested, and reference the separate laboratory report for the split specimen test results.

At the bottom of Copy 1, we propose to reduce the area available for tamper-evident labels/seals to conserve space. The proposed Federal CCF in Appendix A shows two 1/2-inch wide labels (i.e., reduced from 3/4-inch on the current Federal CCF). The reduced size is sufficient for the required specimen identification number and should not affect the legibility of information printed on the labels/seals. We are also proposing to change the designation "Copy 1—Laboratory" printed on the bottom of Copy 1 to "Copy 1—Test Facility Copy".

Copy 2

Steps 1 through 4 of Copy 2 (Medical Review Officer Copy) will be the same as Steps 1 through 4 of Copy 1 (Test Facility Copy) through the collector chain of custody section. The changes to the proposed Federal CCF begin in Step 4 of Copy 2. We propose to delete the "Received at Lab" section in Step 4 of Copy 2 of the current Federal CCF. The collector separates the copies of the Federal CCF and sends Copy 1 to the test facility with the specimen. At that time, the test facility resumes chain of custody documentation. Therefore, chain of custody sections beyond the collector section are not completed on Copies 2 through 5.

The collector instructs the donor to read the donor certification statement in Step 5 of Copy 2 and to complete the entries (signature, printed name, date, daytime telephone number, evening telephone number, and date of birth) in this section. The MRO uses this information to contact the donor as necessary during the verification process. We propose to revise the instructions to the donor at the bottom of the section to be consistent with current Guidelines requirements. The current statement "Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you * * *" will be changed to "After the Medical Review Officer receives the test results for the specimen identified by this form, he/she may contact you * * *." Also, for clarity and ease of viewing, we propose to bold the lines on the proposed Federal CCF above and below Step 5 to provide visual separation of the section completed by the donor and the rest of the form.

Step 6 on Copy 2 is used by the MRO to report the primary specimen test results to the employer after completing the verification. The proposed changes to this section are intended to facilitate form completion in accordance with MRO reporting requirements in the

Guidelines and in DOT Regulations. The proposed changes include: changing the term "determination/verification" to "verification", repositioning results and checkboxes, adding a line after "Positive" for the MRO to specify the positive drug analyte(s), adding a line after "Adulterated" for the MRO to specify the adulterant/reason, adding "Other" under the "Refusal to Test" grouping to allow additional reasons for this result, and adding another "Remarks" line for the MRO's explanatory comments.

Step 7 is used by the MRO to report the split specimen test results to the employer after completing the verification. The proposed changes to this section are intended to facilitate form completion in accordance with MRO reporting requirements in the Guidelines and in DOT Regulations. The proposed changes include: changing the term "determination/verification" to "verification", adding a line after "Reconfirmed" for the MRO to specify the reconfirmed test results (i.e., drug analytes, substitution, adulteration), adding the result and checkbox to report "Test Cancelled", adding a line after "Failed to Reconfirm" for the MRO to specify the test results that were not reconfirmed (i.e., drug analytes, substitution, adulteration), and adding another "Remarks" line for the MRO's explanatory comments.

Copy 3, Copy 4, Copy 5

Copy 3 (Collector Copy), Copy 4 (Employer Copy), and Copy 5 (Donor Copy) will be the same as Copy 2 (Medical Review Officer Copy).

Instructions for Completing the Federal Custody and Control Form

As on the current Federal CCF, instructions for completing the form are included on the back of Copy 5 (Donor Copy). The purpose of these instructions is to provide the donor with an overview of the specimen collection process. We propose to revise and update the instructions for clarity and for consistency with the revised Guidelines.

Public Burden Statement

The Public Burden Statement in Appendix A must appear on all Federal Government forms that place a reporting burden on gathering information. This statement must be included on the back of each copy of the Federal CCF (i.e., Copies 1 through 5). The reporting address in this notice has been updated on the proposed revised Federal CCF and the word "laboratory" has been changed to "test facility". Otherwise, the statement is the same as the

“Paperwork Reduction Act Notice” on the current OMB-approved Federal CCF. However, SAMHSA is interested in receiving public comments concerning the estimated average times for the collector, the donor, the test facility, and the MRO to complete the form. Individuals commenting on these topics should include in their estimates the time to review, print information, and/or read certification statements on the form.

Privacy Act Statement

The Privacy Act Statement in Appendix A must appear on the back of Copy 5 (Donor Copy). It applies to all donors who are Federal employees. The statement is the same as that on the current Federal CCF.

Tamper-Evident Labels/Seals

The size of the two tamper-evident labels/seals may vary, but they must be placed within the space provided at the bottom of Copy 1. It is the responsibility of the supplier of the specimen bottle labels/seals to ensure that they are tamper-evident. Tamper-evident tape is a tape that is placed on a specimen bottle which cannot be removed and be replaced without visible evidence that tampering has occurred. SAMHSA believes this single requirement is sufficient to ensure that the labels/seals provided with the Federal CCF are tamper-evident; however, comments are welcome on recommending other specifications/requirements that should be considered.

Availability of the Federal CCF

The proposed Federal CCF, once approved by OMB, will be available on the SAMHSA Web site at <http://www.drugfreeworkplace.gov/as> an electronic file (using several different formats) that can be downloaded. Photocopies will also be available from the Division of Workplace Programs (DWP). SAMHSA believes making the Federal CCF available using this approach will ensure that the form is readily available from different sources.

Elaine Parry,

*Director, Office of Program Services,
SAMHSA.*

APPENDIX A—Federal Drug Testing Custody and Control Forms

BILLING CODE 4162-20-P

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM



SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

ACCESSION NO.

A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone No. and Fax No. C. Donor SSN or Employee I.D. No. D. Specify Testing Authority: HHS, NRC, DOT, FMCSA, FAA, FRA, FTA, PHMSA, USCG. E. Reason for Test: Pre-employment, Random, Reasonable Suspicion/Cause, Post Accident, Return to Duty, Follow-up, Other. F. Drug Tests to be Performed: THC, COC, PCP, OPI, AMP, THC & COC Only, Other. G. Collection Site Address. Collector Phone No. Collector Fax No.

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes. Temperature between 90° and 100° F? Yes No, Enter Remark. Collection: Split, Single, None Provided, Enter Remark, Observed, Enter Remark. REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy) STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements. Signature of Collector. Date (Mo/Day/Yr). Time of Collection. Name of Delivery Service. SPECIMEN BOTTLE(S) RELEASED TO:

RECEIVED AT IITF: Signature of Accessioner. IITF Name and Address (if not above). Primary Specimen Bottle Seal Intact YES NO. If NO, Enter remark in Step 5A. Name of Delivery Service. SPECIMEN BOTTLE(S) RELEASED TO:

TRANSFER FROM IITF TO LAB. I certify that the specimen identified on this form was handled using chain of custody procedures and resealed in accordance with applicable Federal requirements. Signature. (PRINT) Name (First, MI, Last). Date (Mo/Day/Yr). Name of Delivery Service. SPECIMEN BOTTLE(S) RELEASED TO:

RECEIVED AT LAB: Signature of Accessioner. Primary Specimen Bottle Seal Intact YES NO. If NO, Enter remark in Step 5A. Name of Delivery Service. SPECIMEN BOTTLE(S) RELEASED TO:

STEP 5A: PRIMARY SPECIMEN REPORT - COMPLETED BY TEST FACILITY. NEGATIVE, POSITIVE for: Marijuana Metabolite (Δ9-THCA), 6-Acetylmorphine, Methamphetamine, MDMA, DILUTE, Cocaine Metabolite (BZE), Morphine, Amphetamine, MDA, REJECTED, ADULTERATED, SUBSTITUTED, INVALID RESULT, PCP, Codeins, MDEA. REMARKS: Test Facility (if different from above): I certify that the specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements. Signature of Certifying Technician/Scientist. (PRINT) Certifying Technician/Scientist's Name (First, MI, Last). Date (Mo/Day/Yr).

STEP 5B: COMPLETED BY SPLIT TESTING LABORATORY. SPLIT SPECIMEN TESTED; SEE LABORATORY REPORT. Split Testing Laboratory (Name, City, State)

Specimen bottle seal area with barcode, specimen ID NO. (A and B), 'PLACE OVER CAP' instructions, and donor initials/signature lines.

COPY 1 - TEST FACILITY COPY

Public Burden Statement

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it

displays a currently valid OMB control number. The OMB control number for this project is 0930-0158. Public reporting burden for this collection of information is estimated to average 5

minutes/donor, 4 minutes/collector, 3 minutes/test facility and 3 minutes/Medical Review Officer. Send comments regarding this burden estimate or any other aspect of this

OMB No. 0930-0158 PRESS HARD - YOU ARE MAKING MULTIPLE COPIES

collection information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 1

Choke Cherry Road, Room 7-1044, Rockville, Maryland 20857.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE		ACCESSION NO.	
A. Employer Name, Address, I.D. No.		B. MRO Name, Address, Phone No. and Fax No.	
C. Donor SSN or Employee I.D. No. _____			
D. Specify Testing Authority: <input type="checkbox"/> HHS <input type="checkbox"/> NRC <input type="checkbox"/> DOT - Specify DOT Agency: <input type="checkbox"/> FMCSA <input type="checkbox"/> FAA <input type="checkbox"/> FRA <input type="checkbox"/> FTA <input type="checkbox"/> PHMSA <input type="checkbox"/> USCG			
E. Reason for Test: <input type="checkbox"/> Pre-employment <input type="checkbox"/> Random <input type="checkbox"/> Reasonable Suspicion/Cause <input type="checkbox"/> Post Accident <input type="checkbox"/> Return to Duty <input type="checkbox"/> Follow-up <input type="checkbox"/> Other (specify) _____			
F. Drug Tests to be Performed: <input type="checkbox"/> THC, COC, PCP, OPI, AMP <input type="checkbox"/> THC & COC Only <input type="checkbox"/> Other (specify) _____			
G. Collection Site Address: _____			
		Collector Phone No. _____	
		Collector Fax No. _____	
STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes.			
Temperature between 90° and 100° F? <input type="checkbox"/> Yes <input type="checkbox"/> No, Enter Remark _____			
Collector: <input type="checkbox"/> Split <input type="checkbox"/> Single <input type="checkbox"/> None Provided, Enter Remark _____ <input type="checkbox"/> Observed, Enter Remark _____			
REMARKS			
STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)			
STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY			
I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.		SPECIMEN BOTTLE(S) RELEASED TO:	
X _____ Signature of Collector		AM _____ PM _____	
(PRINT) Collector's Name (First, MI, Last)		Date (Mo/Day/Yr)	
		Time of Collection	
		Name of Delivery Service	
STEP 5: COMPLETED BY DONOR			
I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.			
X _____ Signature of Donor			
		(PRINT) Donor's Name (First, MI, Last)	
		Date (Mo/Day/Yr)	
Daytime Phone No. () _____		Evening Phone No. () _____	
		Date of Birth (Mo/Day/Yr)	
After the Medical Review Officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). -- DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.			
STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN			
In accordance with applicable Federal requirements, my verification is:			
<input type="checkbox"/> NEGATIVE <input type="checkbox"/> POSITIVE for: _____			
<input type="checkbox"/> DILUTE			
<input type="checkbox"/> REFUSAL TO TEST because - check reason(s) below:		<input type="checkbox"/> TEST CANCELLED	
<input type="checkbox"/> ADULTERATED (adulterant/reason): _____			
<input type="checkbox"/> SUBSTITUTED			
<input type="checkbox"/> OTHER: _____			
REMARKS: _____			
X _____ Signature of Medical Review Officer			
		(PRINT) Medical Review Officer's Name (First, MI, Last)	
		Date (Mo/Day/Yr)	
STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN			
In accordance with applicable Federal requirements, my verification for the split specimen (if tested) is:			
<input type="checkbox"/> RECONFIRMED for: _____		<input type="checkbox"/> TEST CANCELLED	
<input type="checkbox"/> FAILED TO RECONFIRM for: _____			
REMARKS: _____			
X _____ Signature of Medical Review Officer			
		(PRINT) Medical Review Officer's Name (First, MI, Last)	
		Date (Mo/Day/Yr)	

COPY 2 - MEDICAL REVIEW OFFICER COPY

Public Burden Statement

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a

collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0158. Public

reporting burden for this collection of information is estimated to average 5 minutes/donor, 4 minutes/collector, 3 minutes/test facility and 3 minutes/

Medical Review Officer. Send comments regarding this burden estimate or any other aspect of this

collection information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 1

Choke Cherry Road, Room 7-1044, Rockville, Maryland 20857.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE. A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone No. and Fax No. C. Donor SSN or Employee I.D. No. D. Specify Testing Authority: HHS, NRC, DOT, FMCSA, FAA, FRA, FTA, PHMSA, USCG. E. Reason for Test: Pre-employment, Random, Reasonable Suspicion/Cause, Post Accident, Return to Duty, Follow-up, Other. F. Drug Tests to be Performed: THC, COC, PCR, OPI, AMP, THC & COC Only, Other. G. Collection Site Address: Collector Phone No., Collector Fax No.

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes. Temperature between 90° and 100° F? Yes No, Enter Remark. Collection: Split Single None Provided, Enter Remark Observed, Enter Remark. REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy). STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY. I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements. SIGNATURE OF COLLECTOR, Date (Mo/Day/Yr), Time of Collection, Name of Delivery Service.

STEP 5: COMPLETED BY DONOR. I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct. SIGNATURE OF DONOR, (PRINT) Donor's Name (First, M, Last), Date (Mo/Day/Yr), Daytime Phone No., Evening Phone No., Date of Birth.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN. In accordance with applicable Federal requirements, my verification is: NEGATIVE POSITIVE for: DILUTE. REFUSAL TO TEST because - check reason(s) below: ADULTERATED (adulterant/reason): SUBSTITUTED OTHER: TEST CANCELLED. REMARKS: SIGNATURE OF MEDICAL REVIEW OFFICER, (PRINT) Medical Review Officer's Name (First, M, Last), Date (Mo/Day/Yr).

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN. In accordance with applicable Federal requirements, my verification for the split specimen (if tested) is: RECONFIRMED for: TEST CANCELLED. FAILED TO RECONFIRM for: REMARKS: SIGNATURE OF MEDICAL REVIEW OFFICER, (PRINT) Medical Review Officer's Name (First, M, Last), Date (Mo/Day/Yr).

COPY 3 - COLLECTOR COPY

Public Burden Statement

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a

collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0158. Public

reporting burden for this collection of information is estimated to average 5 minutes/donor, 4 minutes/collector, 3 minutes/test facility and 3 minutes/

Medical Review Officer. Send comments regarding this burden estimate or any other aspect of this

collection information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 1

Choke Cherry Road, Room 7-1044, Rockville, Maryland 20857.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE		ACCESSION NO.	
A. Employer Name, Address, I.D. No.		B. MRO Name, Address, Phone No. and Fax No.	
C. Donor SSN or Employee I.D. No. _____			
D. Specify Testing Authority: <input type="checkbox"/> HHS <input type="checkbox"/> NRC <input type="checkbox"/> DOT - Specify DOT Agency: <input type="checkbox"/> FMCSA <input type="checkbox"/> FAA <input type="checkbox"/> FRA <input type="checkbox"/> FTA <input type="checkbox"/> PHMSA <input type="checkbox"/> USCG			
E. Reason for Test: <input type="checkbox"/> Pre-employment <input type="checkbox"/> Random <input type="checkbox"/> Reasonable Suspicion/Cause <input type="checkbox"/> Post Accident <input type="checkbox"/> Return to Duty <input type="checkbox"/> Follow-up <input type="checkbox"/> Other (specify) _____			
F. Drug Tests to be Performed: <input type="checkbox"/> THC, COC, PCR, OPI, AMP <input type="checkbox"/> THC & COC Only <input type="checkbox"/> Other (specify) _____			
G. Collection Site Address: _____			
		Collector Phone No. _____	
		Collector Fax No. _____	
STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes.			
Temperature between 90° and 100° F? <input type="checkbox"/> Yes <input type="checkbox"/> No, Enter Remark _____			
Collection: <input type="checkbox"/> Split <input type="checkbox"/> Single <input type="checkbox"/> None Provided, Enter Remark _____ <input type="checkbox"/> Observed, Enter Remark _____			
REMARKS _____			
STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)			
STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY			
I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.			SPECIMEN BOTTLE(S) RELEASED TO:
X _____ Signature of Collector			
Date (Mo/Day/Yr) _____			AM PM
Time of Collection _____			Name of Delivery Service _____
STEP 5: COMPLETED BY DONOR			
I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.			
X _____ Signature of Donor			
(PRINT) Donor's Name (First, MI, Last) _____		Date (Mo/Day/Yr) _____	
Daytime Phone No. () _____		Evening Phone No. () _____	
Date of Birth _____ (Mo/Day/Yr)			
After the Medical Review Officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). - DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.			
STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN			
In accordance with applicable Federal requirements, my verification is:			
<input type="checkbox"/> NEGATIVE <input type="checkbox"/> POSITIVE for: _____			
<input type="checkbox"/> DILUTE			
<input type="checkbox"/> REFUSAL TO TEST because - check reason(s) below: <input type="checkbox"/> TEST CANCELLED			
<input type="checkbox"/> ADULTERATED (adulterant/reason): _____			
<input type="checkbox"/> SUBSTITUTED			
<input type="checkbox"/> OTHER: _____			
REMARKS: _____			
X _____ Signature of Medical Review Officer			
(PRINT) Medical Review Officer's Name (First, MI, Last) _____		Date (Mo/Day/Yr) _____	
STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN			
In accordance with applicable Federal requirements, my verification for the split specimen (if tested) is:			
<input type="checkbox"/> RECONFIRMED for: _____ <input type="checkbox"/> TEST CANCELLED			
<input type="checkbox"/> FAILED TO RECONFIRM for: _____			
REMARKS: _____			
X _____ Signature of Medical Review Officer			
(PRINT) Medical Review Officer's Name (First, MI, Last) _____		Date (Mo/Day/Yr) _____	

COPY 4 - EMPLOYER COPY

Public Burden Statement

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reporting burden for this collection of information is estimated to average 5 minutes/donor, 4 minutes/collector, 3 minutes/test facility and 3 minutes/

Medical Review Officer. Send comments regarding this burden estimate or any other aspect of this

collection information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 1

Choke Cherry Road, Room 7-1044, Rockville, Maryland 20857.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE. A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone No. and Fax No. C. Donor SSN or Employee I.D. No. D. Specify Testing Authority: HHS, NRC, DOT, FMCSA, FAA, FRA, FTA, PHMSA, USCG. E. Reason for Test: Pre-employment, Random, Reasonable Suspicion/Cause, Post Accident, Return to Duty, Follow-up, Other. F. Drug Tests to be Performed: THC, COC, PCP, OPI, AMP, THC & COC Only, Other. G. Collection Site Address. Collector Phone No. Collector Fax No.

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes. Temperature between 90P and 100P F? Yes No, Enter Remark. Collection: Split, Single, None Provided, Enter Remark, Observed, Enter Remark. REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy). STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY. I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements. Signature of Collector, Date (Mo/Day/Yr), Time of Collection, Name of Delivery Service.

STEP 5: COMPLETED BY DONOR. I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct. Signature of Donor, (PRINT) Donor's Name (First, MI, Last), Date (Mo/Day/Yr), Daytime Phone No., Evening Phone No., Date of Birth (Mo/Day/Yr). After the Medical Review Officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). - DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN. In accordance with applicable Federal requirements, my verification is: NEGATIVE, POSITIVE for: DILUTE, REFUSAL TO TEST because - check reason(s) below: ADULTERATED (adulterant/reason): SUBSTITUTED, OTHER: TEST CANCELLED. REMARKS: Signature of Medical Review Officer, (PRINT) Medical Review Officer's Name (First, MI, Last), Date (Mo/Day/Yr).

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN. In accordance with applicable Federal requirements, my verification for the split specimen (if tested) is: RECONFIRMED for: TEST CANCELLED, FAILED TO RECONFIRM for: REMARKS: Signature of Medical Review Officer, (PRINT) Medical Review Officer's Name (First, MI, Last), Date (Mo/Day/Yr).

BILLING CODE 4162-20-C

Instructions for Completing the Federal Drug Testing Custody and Control Form

When Making Entries Use Black or Blue Ink Pen and Press Firmly

Collector ensures that the name and address of the HHS-certified Instrumented Initial Test Facility (IITF) or HHS-certified laboratory are on the top of the Federal CCF and the Specimen identification (I.D.) Number on the top of the Federal CCF matches the Specimen I.D. number on the label(s)/seal(s).

STEP 1:

- Collector ensures that the required information is in STEP 1. Collector enters a remark in STEP 2 if donor refuses to provide his/her SSN or Employee I.D. number.
- Collector gives collection container to Donor and instructs Donor to provide a specimen. Collector notes any unusual behavior or appearance of Donor in the remarks line STEP 2. If the Donor's conduct at any time during the collection process clearly indicates an attempt to tamper with the specimen, Collector notes the conduct in the remarks line in STEP 2 and takes action as required.

STEP 2:

- Collector checks specimen temperature within 4 minutes after receiving the specimen from Donor, and marks the appropriate temperature box in STEP 2. If the temperature is outside the acceptable range, Collector enters a remark in STEP 2 and takes action as required.

- Collector inspects the specimen and notes any unusual findings in the remarks line in STEP 2 and takes action as required. Any specimen with unusual physical characteristics (e.g., unusual color, presence of foreign objects or material, unusual odor) cannot be sent to an IITF and must be sent to an HHS-certified laboratory for testing, as required.

- Collector determines the volume of specimen in the collection container. If the volume is acceptable, Collector proceeds with the collection. If the volume is less than required by the Federal Agency, Collector takes action as required, and enters remarks in STEP 2. If no specimen is collected by the end of the collection process, Collector checks the *None Provided* box, enters a remark in STEP 2, discards Copy 1, and distributes remaining copies as required.

- Collector checks the Split or Single specimen collection box. If the collection is observed, Collector checks the Observed box and enters a remark in STEP 2.

STEP 3:

- Donor watches Collector pour the specimen from the collection container into the specimen bottle(s), place the cap(s) on the specimen bottle(s), and affix the label(s)/seal(s) on the specimen bottle(s).

- Collector dates the specimen bottle label(s) after placement on the specimen bottle(s).

- Donor initials the specimen bottle label(s) after placement on the specimen bottle(s).

- Collector turns to Copy 2 (Medical Review Officer Copy) and instructs the Donor to read and complete the certification statement in STEP 5 (signature, printed name, date, phone numbers, and date of birth). If Donor refuses to sign the certification statement, Collector enters a remark in STEP 2 on Copy 1.

STEP 4:

- Collector completes STEP 4 on Copy 1 (signature, printed name, date, time of collection, and name of delivery service), places the sealed specimen bottle(s) and Copy 1 in a leak-proof plastic bag, seals the bag, prepares the specimen package for shipment, and distributes the remaining CCF copies as required.

Privacy Act Statement: (For Federal Employees Only)

Submission of the requested information on the attached form is voluntary. However, incomplete submission of the requested information, refusal to provide a urine specimen, or substitution or adulteration of a specimen may result in delay or denial of your application for employment/appointment or may result in removal from the Federal service or other disciplinary action.

The authority for obtaining the urine specimen and identifying information contained herein is Executive Order 12564 ("Drug-Free Federal Workplace"), 5 U.S.C. Sec. 3301 (2), 5 U.S.C. Sec. 7301, and Section 503 of Public Law 100-71, 5 U.S.C. Sec. 7301 note. Under provisions of Executive Order 12564 and 5 U.S.C. 7301, test results may only be disclosed to agency officials on a need-to-know basis. This may include the agency Medical Review Officer, the administrator of the Employee Assistance Program, and a supervisor with authority to take adverse personnel action. This information may also be disclosed to a court where necessary to defend against a challenge to an adverse personnel action.

Submission of your SSN is not required by law and is voluntary. Your refusal to furnish your number will not result in the denial of any right, benefit,

or privilege provided by law. Your SSN is solicited, pursuant to Executive Order 9397, for purposes of associating information in agency files relating to you and for purposes of identifying the urine specimen provided for testing for the presence of illegal drugs. If you refuse to indicate your SSN, a substitute number or other identifier will be assigned, as required, to process the specimen.

Public Burden Statement

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0158. Public reporting burden for this collection of information is estimated to average 5 minutes/donor, 4 minutes/collector, 3 minutes/test facility and 3 minutes/Medical Review Officer. Send comments regarding this burden estimate or any other aspect of this collection information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 1 Choke Cherry Road, Room 7-1044, Rockville, Maryland 20857.

[FR Doc. E9-27371 Filed 11-16-09; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2009-N-0664]

Thermal Aspects of Radio Frequency Exposure; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Thermal Aspects of Radio Frequency Exposure." The purpose of the workshop is to discuss thermal sensitivity and heating effects of different tissues.

Date and Time: The public workshop will be held on January 11 and 12, 2010, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Victoria Wagman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6581, FAX: 301-796-5428, e-mail: victoria.wagman@fda.hhs.gov.