

**Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention
Division of Workplace Programs**

Subject: Guidance for Using the 2010 Federal Custody and Control Form (CCF)

Date: October 1, 2010

Table of Contents

1. When can a federally regulated program begin using the 2010 Federal CCF?	2
2. Can the 2000 Federal CCF be used after October 1, 2010?.....	2
3. Where can a sample proof of the 2010 Federal CCF be viewed?.....	2
4. What statements must appear on the back of each copy of the new Federal CCF? ...	2
5. Can the 2010 Federal CCF be modified?	5
6. Has the HHS Urine Specimen Collection Handbook been revised for use with the 2010 Federal CCF?	6
7. Has the HHS MRO Manual been revised for use with the 2010 Federal CCF?.....	6
8. Does a laboratory need to change its Standard Operating Procedure (SOP) manual for the 2010 Federal CCF?	6
9. How does a test facility (IITF or laboratory) document specimen receipt using the 2010 Federal CCF?	6
10. How does a test facility (IITF or laboratory) report primary specimen results to MROs using the 2010 Federal CCF?.....	7
11. How does a laboratory report split (Bottle B) specimen results to MROs using the 2010 Federal CCF?	7
12. What are tamper-evident labels/seals?.....	7
13. How does an MRO report a verified result to the employer when using the 2010 Federal CCF?	8

1. When can a federally regulated program begin using the 2010 Federal CCF?

The Office of Management and Budget (OMB) has approved the use of the new 2010 Federal CCF beginning October 1, 2010.

2. Can the 2000 Federal CCF be used after October 1, 2010?

Yes. The 2000 Federal CCF was published in the Federal Register on June 23, 2000 (65 FR 39155) with an effective date of August 1, 2000. To allow for depletion of existing supplies of the 2000 Federal CCF, OMB permitted the use of this Federal CCF in Federal workplace drug testing programs through September 30, 2011. Therefore, for one (1) year after the implementation of the revised 2010 Federal CCF on October 1, 2010, regulated specimens may be collected, tested, and reported using the 2000 Federal CCF.

From October 1, 2010 through September 30, 2011, Federal agencies may use either Federal CCF for their workplace drug testing programs.

As of October 1, 2011, the 2010 Federal CCF will be the only Federal CCF permitted for regulated specimens. If a regulated specimen is received at a test facility accompanied by the 2000 Federal CCF after September 30, 2011, the test facility (IITF or laboratory) must treat this as a correctable discrepancy.

3. Where can a sample proof of the 2010 Federal CCF be viewed?

A sample of the 2010 Federal CCF is available on the SAMHSA website (<http://www.workplace.samhsa.gov/>). Additionally, OMB (Reginfo.gov) has a sample proof available on the RegInfo.gov website: http://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201007-0930-002&icID=193835.

4. What statements must appear on the back of each copy of the new Federal CCF?

(a) **The Public Burden Statement** 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 4)

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.

(b) The following statements must be printed on the back of Copy 5: **Instructions for Completing the Federal Drug Testing Custody and Control Form, Privacy Act Statement (For Federal Employees Only)**, and **The Public Burden Statement**.

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

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.

5. Can the 2010 Federal CCF be modified?

Yes. 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 Federal CCF. These minor changes in appearance are permitted since they do not significantly impact the required format.

The following is a list of acceptable differences and modifications when printing the Federal CCF:

1. The OMB number may appear either vertically or horizontally in the upper right hand corner of the form.
2. The name and address of the test facility and the unique specimen identification number at the top of the form and on the specimen bottle label(s)/seal(s) may be printed during the original printing and form assembly process or added by overprinting after the form is assembled.
3. Preprinting and/or overprinting the employer name and address, MRO name and address, and collection site information is permitted.
4. The spaces for the employer name and address, MRO name and address, and the collection site address may have lines.
5. The unique specimen identification number at the top of the form and on the tamper-evident label(s)/seal(s) may be either a bar code with an associated human-readable number or a human-readable number only.
6. A test facility does not need to assign and record a separate accession number in the space at the top of the form if it uses the unique specimen identification number to track the specimen after receipt. When this is the case, the form may be printed without the words ACCESSION NO. appearing on the top of the form.
7. The size of each check box may vary slightly.
8. The font size and style used for letters may vary to enhance readability.
9. The exact location for each item on the printed form may vary slightly from the location indicated on the Federal CCF.
10. The data entry/information fields may be highlighted using different colors to show where the collector, donor, and test facility would be providing information. The colors used to highlight the fields may be different for different fields but must not prevent making clear facsimiles and photocopies of the information that is printed or handwritten in those fields.
11. The space for the donor's SSN or Employee I.D. No. may have combs, boxes, or a single line.
12. The legend at the bottom of Copies 2 through 5 may be printed using different colors, or a different color stripe may be printed at the bottom of Copies 2 through 5. To ensure consistency and correct distribution of the copies, if

different color stripes or legends are used at the bottom of each copy, the following colors must be used: MRO Copy - pink, Collector Copy - yellow, Employer Copy - blue, Donor Copy - green.

13. Reference mark(s) may be used to position the form in a printer to overprint information in the correct location or to optically scan the information in the various fields.
14. The size of the two tamper-evident labels/seals may vary but must be at least $\frac{3}{4}$ inch wide placed within the space provided at the bottom of Copy 1.
15. The color of the preprinted information on the "A" specimen bottle label/seal may be different than the color of the preprinted information on the "B" specimen bottle label/seal.
16. The form may include a designated space for a collector identification number (e.g., as assigned by a collector training organization) in Step 4 beside the collector's signature or printed name.

6. Has the HHS Urine Specimen Collection Handbook been revised for use with the 2010 Federal CCF?

Yes. The HHS Collection Handbook has been revised to reflect changes in the Federal CCF and how the collector completes the form. The revised handbook is available on the SAMHSA website (<http://www.workplace.samhsa.gov>).

7. Has the HHS MRO Manual been revised for use with the 2010 Federal CCF?

Yes. The HHS MRO Manual has been revised to reflect changes in the Federal CCF and how laboratories will be reporting results. The revised manual is available on the SAMHSA website (<http://www.workplace.samhsa.gov>).

8. Does a laboratory need to change its Standard Operating Procedure (SOP) manual for the 2010 Federal CCF?

A certified laboratory will need to change all sections, where appropriate, that refer to the 2010 Federal CCF. Since the laboratory will continue receiving "old" forms (2000 Federal CCF), the SOP manual will need to have sections applicable to both forms until October 1, 2011, when the 2000 Federal CCF is no longer approved for use. At that time, the laboratory must have procedures to handle specimens submitted with the outdated form as having a recoverable discrepancy.

9. How does a test facility (IITF or laboratory) document specimen receipt using the 2010 Federal CCF?

The test facility that receives the specimen package from the collection site continues the specimen's chain of custody by completing the appropriate chain of custody entries in Step 4 (i.e., "Received at Lab or IITF). In addition to signing and printing his or her name, the accessioner records the receipt date, marks the appropriate checkbox to document the condition of the primary specimen seal, and releases custody of the specimen (e.g., to a storage area). When forwarding a specimen to a laboratory, an IITF

sends both the original Federal CCF (Copy 1) and an IITF Supplemental CCF with the specimen. The laboratory documents specimen receipt using the IITF Supplemental CCF. The laboratory accessioner continues the specimen chain of custody and documents the condition of the primary specimen bottle seal (i.e., the seal placed on the opened bottle by the IITF) on this form.

10. How does a test facility (IITF or laboratory) report primary specimen results to MROs using the 2010 Federal CCF?

A test facility may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF (Copy 1) for all results to the MRO. For negative results, a test facility may report results using only a computer-generated electronic report, provided the report contains sufficient information to ensure that the test result is properly associated with the MRO copy (Copy 2) of the Federal CCF. For “rejected for testing” results, IITFs and laboratories must send the copy of the completed Federal CCF (Copy 1). For all positive, substituted, adulterated, and invalid results, a laboratory must send the copy of the completed Federal CCF (Copy 1). For all specimens received from an IITF, a laboratory must also send a legible image or copy of the completed IITF Supplemental CCF that was received with the specimen.

11. How does a laboratory report split (Bottle B) specimen results to MROs using the 2010 Federal CCF?

The laboratory that tested and reported the primary specimen (Lab A) will have sent a copy of the Federal CCF (Copy 1) to the split testing laboratory (Lab B) with the split specimen. For all split specimen results, the split testing laboratory must complete Step 5b of the Federal CCF (i.e., annotate the laboratory name and address, mark the appropriate result checkbox(es), and include the certifying scientist signature, printed name and certification date). The laboratory must also complete a laboratory Split Specimen Report Form and include a reference to this separate laboratory report in the Reason line in Step 5b of Copy 1. The laboratory sends a legible image or copy of the completed Federal CCF (Copy 1) and Split Specimen Report Form to the MRO.

12. What are tamper-evident labels/seals?

Once applied to a specimen bottle, tamper-evident labels/seals cannot be removed and replaced without visible evidence that tampering has occurred. It is the responsibility of the supplier of the specimen bottle labels/seals to ensure that they are tamper-evident. The two tamper-evident labels/seals must be at least ¾-inch wide, placed within the space provided at the bottom of Copy 1 of the 2010 Federal CCF.

13. How does an MRO report a verified result to the employer when using the 2010 Federal CCF?

An MRO may report all verified results (for primary and split specimens) to the agency/employer by:

1. Faxing the completed Copy 2;
2. Transmitting a scanned image of the completed Copy 2; or
3. Faxing a separate report using a letter/memorandum format.

An MRO must send to the agency/employer a hard copy of either the completed Copy 2 or the separate letter/memorandum report for all tests reported as positive or as a refusal to test because the specimen was adulterated or substituted.

The result sections on the MRO Copy (Copy 2) of the 2010 Federal CCF (Step 6 for the primary specimen and Step 7 for the split specimen) are formatted in accordance with MRO reporting requirements in the HHS Mandatory Guidelines and in DOT Regulations (49 CFR Part 40). To complete the Federal CCF, the MRO marks the appropriate checkbox(es) for the verified result and records information in the designated spaces to specify the test results (i.e., drug analytes, substitution, adulteration). The MRO includes any explanatory comments on the "Remarks" line.