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 New Federal Custody and Control Form

Date: June 23, 2000

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

OMB has approved the use of the new Federal CCF beginning August 1, 2000.

2. Can the current Federal CCF be used after its July 31, 2000, expiration date?

Yes. OMB is permitting the current Federal CCF to be used until supplies are exhausted, but not beyond July 31, 2001. After that date, copies of the "old" Federal CCF should be discarded.

3. Can a Federal agency/employer delay using the new Federal CCF?

Since the current Federal CCF can be used until July 31, 2001, the use of the new Federal CCF may be delayed until such time that collectors, certified laboratories, and Medical Review Officers are prepared to implement the use of the new form. However, the new Federal CCF must be implemented before July 31, 2001 (i.e., the extended expiration date for the current Federal CCF).

4. Where can the new Federal CCF be obtained?

A sample of the new Federal CCF is available on the SAMHSA website (http://workplace.samhsa.gov).

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

(a) The following Paperwork Reduction Act Notice must be printed on the back of **Copy 1, 2, 3, and 4**:

Paperwork Reduction Act Notice (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information, including the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information is estimated for each respondent to average: 5 minutes/donor; 4 minutes/collector; 3 minutes/laboratory; and 3 minutes/Medical Review Officer. Federal employees may send comments regarding these burden estimates, or any other

aspect of this collection of information, including suggestions for reducing the burden, to the SAMHSA Reports Clearance Officer, Paperwork Reduction Project (0930-0158), Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. 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.

(b) The following Instructions, Privacy Act Statement, and Paperwork Reduction Act Notice must be printed on the back of **Copy 5**:

Instructions for Completing the Federal Drug Testing Custody and Control Form

A Collector ensures that the name and address of the drug testing laboratory appear on the top of the CCF and the Specimen I.D. number on the top of the CCF matches the Specimen I.D. number on the labels/seals.

B. Collector provides the required information in STEP 1 on the CCF. The collector provides a remark in STEP 2 if the donor refuses to provide his/her SSN or Employee I.D. number.

C. Collector gives a collection container to the donor for providing a specimen.

D. After the donor gives the specimen to the collector, the collector checks the temperature of specimen within 4 minutes and marks the appropriate temperature box in STEP 2 on the CCF. The collector provides a remark if the temperature is outside the acceptable range.

E. Collector checks the split or single specimen collection box. If no specimen is collected, that box is checked and a remark is provided. If it is an observed collection, that box is checked and a remark is provided. If no specimen is collected, Copy 1 is discarded and the remaining copies are distributed as required.

F. Donor watches the collector pouring the specimen from the collection container into the specimen bottle(s), placing the cap(s) on the specimen bottle(s), and affixing the label(s)/seal(s) on the specimen bottle(s).

G. Collector dates the specimen bottle label(s) after they are placed on the specimen bottle(s).

H. Donor initials the specimen bottle label(s) after the label(s) have been placed on the specimen bottle(s).

I. Collector turns to Copy 2 (MRO Copy) and instructs the donor to read the certification statement in STEP 5 and to sign, print name, date, provide phone numbers, and date of birth after reading the certification statement. If the donor refuses to sign the certification statement, the collector provides a remark in STEP 2 on Copy 1.

J. Collector completes STEP 4 (i.e., provides signature, printed name, date, time of collection, and name of delivery service), immediately places the sealed specimen bottle(s) and Copy 1 of the CCF in a leak-proof plastic bag, releases specimen package to the delivery service, and distributes the other copies as required.

Privacy Act Statement: (For Federal Employees Only)

Submission of the information on the attached form is voluntary. However, incomplete

submission of the 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. § 3301 (2), 5 U.S.C. § 7301, and Section 503 of Public Law 100-71, 5 U.S.C. § 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 specimen provided for urinalysis testing for illegal drugs. If you refuse to indicate your SSN, a substitute number or other identifier will be assigned, as required, to process the specimen.

In the event laboratory analysis determines the presence of one or more illegal drugs in the specimen you provide, you will be contacted by an agency Medical Review Officer (MRO). The MRO will determine whether there is a legitimate medical explanation for the drug(s) identified by urinalysis.

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6. Can the new Federal CCF be modified?

Yes. The following is a list of acceptable differences and modifications when printing the new 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 testing laboratory and the unique specimen identification number at the top of the form and on the specimen bottle seal(s)/label(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 seal(s)/label(s) may be either a bar code with an associated human readable number or only a human readable number.

(6) A laboratory does not need to assign and record a separate laboratory accession number in the one inch 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 "LAB 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 sample form provided in Appendix A.

(10) The data entry/information fields may be highlighted using different colors to show where the collector, donor, and laboratory 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 these 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) A 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 seals/labels may vary, but must be placed within the space provided at the bottom of Copy 1.

(15) The color of the preprinted information on the "A" specimen bottle tamper-evident seal/label may be different than the color of the preprinted information on the "B"specimen bottle tamper-evident seal/label.

7. Has the HHS Collection Handbook changed for use with the new Federal CCF?

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://workplace.samhsa.gov).

8. Has the HHS MRO Manual changed for use with the new Federal CCF?

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://workplace.samhsa.gov).

9. Does a laboratory need to change its SOP manual for the new Federal CCF?

A certified laboratory will need to change all sections, where appropriate, that refer to the new Federal CCF. Since the laboratory will continue receiving "old" forms, the SOP manual will need to have sections applicable to both forms until the "old" forms are no longer used.

10. How does a laboratory report results to MROs when using the new Federal CCF?

A laboratory may transmit all results (negative and non-negative) to MROs by either faxing the completed Copy 1 or transmitting a scanned image of the completed Copy 1 by computer. Each method used must be designed to ensure the confidentiality of the information, the security of the data transmission, and limit access to any data transmission, storage, and retrieval system. For **all non-negative** results, the laboratory must send a hard copy of the completed Copy 1.

11. What does "Rejected for Testing" mean on the new Federal CCF?

"Rejected for Testing" means that the laboratory did not conduct any tests (i.e., either drug or validity tests) on the specimen or the collector was unable to provide a memorandum to correct/recover a discrepancy. An appropriate remark must be indicated on the "Remarks" line stating why the specimen was not tested.

12. What does "Invalid Result" mean on the new Federal CCF?

"Invalid Result" means that valid initial drug test results could not be obtained or an unknown substance interfered with the confirmatory test. An appropriate remark must be indicated on the "Remarks" line stating why the "Invalid result" was reported.

13. What problems will always result in a laboratory not testing a specimen?

The following problems are considered to be fatal flaws (i.e., cannot be recovered/ corrected) and the laboratory must report a "Rejected for Testing" result:

(1) The specimen I.D. number on the specimen bottle label(s)/seal(s) received by the laboratory does not match the specimen I.D. number on the Federal CCF;

(2) The tamper-evident seal on the primary specimen is received broken;

(3) There is no printed collector's name and no collector signature; or

(4) There is insufficient volume of specimen in the primary specimen bottle unless the

split specimen bottle has sufficient volume of specimen and can be re-designated as the primary specimen.

14. What problems will result in a laboratory not reporting a drug test result unless the problem is corrected?

(a) The following problems are considered to be correctable/recoverable:

(1) The collector's signature is missing but the collector's printed name is provided;

(2) Specimen temperature box is not marked; or

(3) Donor SSN or employee I.D. number was not provided and no comment is provided on the "Remarks" line.

(b) If the collector cannot provide a memorandum to correct/recover the error, the laboratory must report a "Rejected for Testing" result and provide an appropriate comment on the "Remarks" line.

15. What types of errors/omissions do not affect the testing and reporting of a result by a laboratory?

(a) The following errors/omissions are considered insignificant, do not need to be corrected/recovered, and do not affect the scientific or legal supportability of the test result:

(1) The specimen is delivered to the laboratory by a delivery service different from the one noted by the collector on the CCF;

(2) The collector phone number or fax number is missing;

(3) A misspelled word appears on the Federal CCF (e.g., employer name is misspelled, street name is misspelled); or

(4) An address is incomplete (e.g., employer zip code is missing).

(b) This list and examples are not all inclusive.

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

(a) An MRO may report all verified (negative and non-negative) results to the agency/employer by:

(1) Faxing a completed Copy 2;

(2) Transmitting a scanned image of a completed Copy 2; or

(3) Faxing a separate report using a letter/memorandum format.

(b) 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 non-negative results.