

Dated: November 5, 1999.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Federal Drug Testing Custody and Control Form

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

ACTION: Notice of proposed revision.

SUMMARY: The Department of Health and Human Services (HHS) establishes the standards for Federal workplace drug testing programs under authority of Public Law 100-71 and Executive Order No. 12564. As a result of the Executive Order and Public Law, HHS published the Mandatory Guidelines for Federal Workplace Drug Testing Programs in the **Federal Register** on April 11, 1988 (53 FR 11979), which were revised on June 9, 1994 (59 FR 29908), to establish comprehensive standards for all aspects of the Federal workplace drug testing program. The Mandatory Guidelines require all urine specimens to be collected using chain of custody procedures to document the integrity and security of the specimen from the time of collection until receipt by the laboratory. To ensure uniformity among all Federal agency workplace drug testing programs, the Mandatory Guidelines require agencies to use an Office of Management and Budget (OMB) approved Federal drug testing custody and control form (Federal CCF) for their programs. Additionally, the Department of Transportation (DOT) has required its regulated industries to use the Federal CCF. The current Federal CCF has been approved for use by OMB until July 31, 2000, for all Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines.

The current Federal CCF is a seven-part form that consists of the following copies: Copy 1 (Original—Must Accompany Specimen to Laboratory (White)), Copy 2 (Second Original—Must Accompany Specimen to Laboratory (White)), Copy 3 (Split Specimen—Must Accompany Split Specimen to Laboratory (White)), Copy 4 (Medical Review Officer Copy (Pink)), Copy 5 (Donor Copy (Green)), Copy 6 (Collector Copy (Yellow)), and Copy 7 (Employer Copy (Blue)). The reverse

side of copies 1, 2, 3, 4, 5, and 6 have a Paperwork Reduction Act Notice statement, the reverse side of Copy 5 has a Privacy Act Statement (for Federal employees only), and the reverse side of Copy 7 has instructions for completing the CCF. Additionally, the tamper-evident specimen bottle seal(s)/label(s) are attached to the right side of Copy 1.

This notice provides proposed changes to the current Federal CCF. It incorporates changes based on the HHS and DOT experiences during the past several years as well as many of the recommendations developed by industry representatives (*i.e.*, users and suppliers of the Federal CCF) at two working group meetings held in January and March 1999. The Substance Abuse and Mental Health Services Administration (SAMHSA) believes the proposed changes will make the Federal CCF easier to use and will more accurately reflect the collection process and how results are reported by the drug testing laboratories. The proposed form is provided in Appendix A.

DATES: Written comments on the proposed draft should be submitted by January 14, 2000.

ADDRESSES: Written comments should be addressed to Robert L. Stephenson II, M.P.H., Director (Acting), Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Walter F. Vogl, Ph.D., Drug Testing Section, Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, tel. (301) 443-6014, fax (301) 443-3031, or email: wvogl@samhsa.gov.

Discussion

SAMHSA is proposing the following major changes to the Federal CCF. The first major change is to make the revised Federal CCF a six-part form by eliminating the split specimen copy (current Copy 3). Since the split specimen copy is used only when the split specimen is tested (*i.e.*, less than approximately 5 percent of split specimens are tested), it would be more efficient to have the second laboratory report the split specimen test result on Copy 1. For those instances when the split specimen is tested, the primary laboratory will need to make a photocopy of Copy 1 of the Federal CCF and send it along with the split specimen to the second laboratory. Although this procedure requires the primary laboratory to make a photocopy, SAMHSA believes saving the costs for printing a separate split

specimen copy for each Federal CCF outweighs the costs associated with the few times that Copy 1 will need to be photocopied by the primary laboratory. In addition, eliminating the split specimen copy will help make the information that appears on later pages more legible.

The second major change is locating the specimen bottle seal(s)/label(s) on the bottom of Copy 1 rather than attaching them to the right side of the form. This change will eliminate the need to have special and expensive wide carriage printers and equipment to handle the automatic processing of the Federal CCF and will standardize the storage and handling requirements to match those for other documents. We believe this change will increase the number of suppliers printing the Federal CCF, will reduce the cost to print the Federal CCF, and reduce the cost of the forms for the user.

The third major change involves simplifying the chain of custody step by requiring the collector to only sign the form once. SAMHSA believes the current requirement for the collector to sign the form three times can be replaced by using one signature because the certification statement signed by the collector clearly describes that the collector had possession of the specimen from the time collector received the specimen from the donor until the collector released the specimen for shipment to the laboratory.

The fourth major change is to provide additional choices for the laboratory to report specimen test results. The current form uses "Test Not Performed" to report anything other than a negative or positive result. SAMHSA believes it is more appropriate to provide choices on the form that accurately reflect the handling and reporting of specimen test results, such as, invalid result, adulterated, substituted, or rejected for testing.

The fifth major change is to include a new step on Copy 1 to allow the secondary laboratory to document a result for the split specimen (Bottle B). This change ensures that the primary specimen and split specimen laboratory test results are recorded on the same copy that is provided to the Medical Review Officer if the split specimen is tested.

The sixth major change is placing the Medical Review Officer steps for the primary and split specimens on Copy 2. This change permits the MRO to record the determination for both the primary specimen and the split specimen (if tested) on the same copy (Copy 2).

Appendix A presents the required format and appearance for each copy of

the 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 "check" box appearing 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 varies slightly from the location indicated on the sample provided in Appendix A. These minor changes in appearance are permitted since they do not 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 SSN 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 these highlighted fields. Other required information (e.g., the name and address of the testing laboratory, 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 six-part printed form after it is assembled.

A detailed discussion of other proposed changes is as follows:

Copy 1

Copy 1 (Laboratory Copy) 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 OMB Number that must appear in the upper right hand corner (the OMB Number may be placed vertical or horizontal), the name and street address of the laboratory that will receive and test the specimen, a unique preprinted specimen identification number (it may be a bar code with an associated human readable number or only a human readable number), space for the laboratory to assign an accession number after the specimen is received, and any other information (e.g., accounting) the laboratory or user of the form may want to document on the form. There are no restrictions on the font size used for the information appearing in this one inch space.

Step 1 is completed by the collector or employer representative. The employer name and address, the acronym of the Federal Agency under which the specimen is being collected

and tested (e.g., DOD, DOI, FRA, FAA), and the MRO name and address may be preprinted or handwritten. The collector will normally enter the donor's social security number after verifying the donor's identity. The collector also marks the appropriate box to indicate the reason for the test and the appropriate box for the drug tests to be performed. The collector then enters the information required for the collection site. This step is essentially the same as for the current Federal CCF except the collection site information has been moved from step 5 on the current form to step 1 on this proposed form.

Step 2 is completed by the collector after receiving the specimen from the donor and measuring the temperature of the specimen. As on the current form, this step requires the collector to mark the appropriate box to indicate if the temperature of the specimen was within the required temperature range; but also requires the collector to indicate whether it is a single or split specimen collection, to indicate if no specimen was collected and why, or to indicate if it was an observed collection and why. SAMHSA believes the additional information is needed to ensure that the collector documents why a specimen was not collected or the reason an observed collection was conducted.

Step 3, as on the current form, instructs the collector to seal the specimen bottle(s), have the donor initial the bottle seal(s), and then instruct the donor to complete step 5 on the MRO copy (Copy 3). This is essentially the same instruction that appears on the current form.

Step 4 is a totally revised chain of custody step that is initiated by the collector and then completed by the laboratory after the specimen is accessioned by the laboratory. This step requires the collector to only sign the form once to certify that the specimen was collected, labeled, sealed, and released for shipment to the laboratory in accordance with Federal requirements. SAMHSA believes that one collector signature is sufficient to document the chain of custody from the time the collector receives the specimen from the donor and prepares the specimen bottle(s) and Federal CCF for shipment to the laboratory. The collector is also required to note the time of the collection, the date of collection, and the specific name of the delivery service to whom the specimen is released for shipment to the laboratory. This is the same information that is required on the current Federal CCF, but the format has changed. Since there is no requirement for couriers, express carriers, or postal service

personnel to document chain of custody for the specimens during transit because they do not have access to the specimen(s) or the Federal CCF, chain of custody annotations resume when the shipping container/package is opened and an individual at the laboratory has access to the specimen bottle(s) and the Federal CCF. We consider this individual to be the accessioner, and he or she is required to document the condition of the primary specimen bottle seal, sign the Federal CCF, print his/her name, the date the specimen was accessioned, and then to whom the specimen was released. The entry for the "Specimen Bottle(s) Released To" may include transfer to temporary storage or transfer to another individual. After this transfer, chain of custody of the specimen bottle(s) is documented by the laboratory on an internal chain of custody form.

Step 5(a) is completed by the laboratory to document the test results on the primary specimen. This step has been expanded compared to the current Federal CCF to allow the laboratory to more easily report a specimen for which there may have been an invalid result, the specimen was adulterated or substituted, or rejected for testing. An additional box has been included for 6-acetylmorphine since the required testing for this analyte began December 1, 1998.

Step 5(b) has been added for reporting the split specimen result if the split specimen is tested. This new step gives the secondary laboratory an area to report the result for the split specimen, a line to indicate the laboratory's name and address, a certification statement, and a space for the secondary laboratory's certifying scientist to sign and date the form.

The bottom area of copy 1 is reserved for the tamper-evident specimen bottle seal(s)/label(s). There must be two labels (i.e., one marked with the letter "A" to designate the primary specimen and the other marked with the letter "B" to designate the split specimen) to accommodate collecting split specimens and each must have the same preprinted specimen identification number that appears at the top of the Federal CCF. Each label must also have a place for the collector to annotate the date of the collection and a place for the donor to initial each label after it is placed on the specimen bottle. If a single specimen collection procedure is used, the second label (i.e., the "B" label) is discarded by the collector.

Copy 2

Copy 2 (Laboratory Copy) is similar to Copy 1 except that step 5(b) and the

space where the labels are located has been replaced with step 6 (Medical Officer Review step used to make a determination on the primary specimen) and step 7 (Medical Officer Review step used to make a determination on the split specimen). Step 6 has been changed from the current Federal CCF to allow the MRO to record a "Refusal To Test" when the primary specimen is "Adulterated" or "Substituted." Step 7 is used to record the determination for the split specimen (if tested).

Copy 3

Copy 3 (Medical Review Officer Copy) is the same format as Copy 2 except that step 5(a) has been replaced with step 5. This step 5 on Copy 3 is completed by the donor after the specimen bottle(s) are sealed, initialed by the donor, and dated. The donor is required to read the certification statement, provide a signature, printed name, date of collection, daytime phone number, evening phone number, and date of birth. This information will be used by the Medical Review Officer to contact the donor for results that require donor contact before making a determination. Additionally, Copy 3 must have a pink border (approximately 1/4 inch width) rather than using a pink sheet of paper to allow easy photocopying, if needed.

Copy 4, Copy 5, Copy 6

Copy 4 (Collector Copy), Copy 5 (Donor Copy), and Copy 6 (Employer

Copy) are exactly the same as Copy 3 with the following exceptions. Copy 4 must have a yellow border, Copy 5 must have a green border, and Copy 6 must have a blue border. These borders will allow photocopying, if necessary. As with Copy 3, the color borders should be approximately 1/4 inch width.

Paperwork Reduction Act Notice

The Paperwork Reduction Act Notice in Appendix A must appear on all Federal government forms that place a reporting burden on gathering information. This notice is the same as that appearing on the current OMB approved Federal CCF; however, SAMHSA is specifically interested in receiving comments for the estimated average times it will take the collector to complete the form, the donor to complete the form, the laboratory to complete the form, and the Medical Review Officer to complete the form. Please assume that completing the form will include reviewing printed information and/or reading certification statements.

Privacy Act Statement

The Privacy Act Statement in Appendix A must appear on the back of the donor copy (Copy 4). It applies to all donors who are Federal employees. It is the same statement that appears on the current Federal CCF.

Tamper-Evident Labels

The size of the two tamper-evident seal(s)/label(s) may vary, but must be placed within the space provided at the bottom of Copy 1. It is also the responsibility of the supplier of the specimen bottle seal(s)/label(s) to ensure that they are tamper-evident. Tamper-evident is defined as a seal/label that cannot be removed from the specimen bottle after 5 minutes contact with the specimen bottle. SAMHSA believes this single requirement is sufficient to ensure that the seal(s)/label(s) provided with the Federal CCF are tamper-evident; however, we invite comments to recommend other specifications/requirements that should be considered.

Availability of CCF

The proposed Federal CCF, once approved by OMB, will be available on the SAMHSA website as an electronic file (using several different formats) that can be downloaded. Photocopies will also be available from the Division of Workplace Programs. SAMHSA believes making the Federal CCF available using this approach will ensure that the form is readily available from different sources.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

BILLING CODE 4162-20-P

Appendix A

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM



1234567

1234567

SPECIMEN ID NO.

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

Form section for Step 1 containing fields A through G: Employer Name, Agency, MRO Name, Donor SSN, Reason for Test, Drug Tests, and Collection Business Information.

STEP 2: COMPLETED BY COLLECTOR

Form section for Step 2 containing fields for specimen temperature and collection type (Single, Split, None Provided, Observed).

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 3 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

Form section for Step 4 containing Remarks, Signature of Collector, Time of Collection, and Received at Laboratory fields.

STEP 5a: PRIMARY SPECIMEN TEST RESULTS - COMPLETED BY PRIMARY LABORATORY

Form section for Step 5a containing test result options (Negative, Positive, Rejected, etc.) and Remarks.

STEP 5b: SPLIT SPECIMEN TEST RESULTS - (IF TESTED) COMPLETED BY SECONDARY LABORATORY

Form section for Step 5b containing Laboratory Name, Address, and Signature of Certifying Scientist.

Bottom section of the form containing two specimen bottle seal labels with barcode, ID number, and instructions to place over the cap.

OMB No. 1234-5678

PRESS HARD - YOU ARE MAKING MULTIPLE COPIES

Back of Copy 1*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 16-106, 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.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO.

1234567

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No.		B. Agency	C. MRO Name, Address, Phone and Fax No.	
D. Donor SSN or Employee I.D. No.				
E. Reason for Test: <input type="checkbox"/> Random <input type="checkbox"/> Pre-employment <input type="checkbox"/> Reasonable Suspicion <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 Business Information:				
Collection Business Name		Collection Business Phone No.		Collection Business Fax No.
Address		City		State Zip

OMB No. 1234-5678

STEP 2: COMPLETED BY COLLECTOR

Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? <input type="checkbox"/> Yes <input type="checkbox"/> No, enter remarks in Step 4 below	Specimen Collection: <input type="checkbox"/> Single <input type="checkbox"/> Split <input type="checkbox"/> None Provided (Enter Remarks Below) <input type="checkbox"/> Observed (Enter Remarks Below)
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STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 3 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

REMARKS: _____
I certify that the specimen given to me by the donor identified in the certification section on Copy 3 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

<input checked="" type="checkbox"/> Signature of Collector	Time of Collection _____ AM PM	SPECIMEN BOTTLE(S) RELEASED TO: Name of Delivery Service Transferring Specimen to Lab
(PRINT) Collector's Name (First, MI, Last)	Date (Mo./Day/Yr.)	
<input checked="" type="checkbox"/> Signature of Accessioner		RECEIVED AT LABORATORY
(PRINT) Accessioner's Name (First, MI, Last)	Date (Mo./Day/Yr.)	Primary Specimen Bottle Seal Intact <input type="checkbox"/> Yes <input type="checkbox"/> No, enter remarks below
		SPECIMEN BOTTLE(S) RELEASED TO:

STEP 5a: PRIMARY SPECIMEN TEST RESULTS - COMPLETED BY PRIMARY LABORATORY

NEGATIVE POSITIVE for: Marijuana Metabolite Codeine Amphetamine ADULTERATED

REJECTED FOR TESTING Cocaine Metabolite Morphine Methamphetamine SUBSTITUTED

PCP 6-Acetylmorphine INVALID RESULT

REMARKS _____

TEST LAB (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 Scientist (PRINT) Certifying Scientist's Name (First, MI, Last) Date (Mo./Day/Yr.)

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

Negative Positive Test Cancelled Refusal To Test because: Adulterated Substituted

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 determination/verification for the split specimen (if tested) is:

RECONFIRMED FAILED TO RECONFIRM - REASON _____

Signature of Medical Review Officer (PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo./Day/Yr.)

COPY 2 - LABORATORY COPY

Back of Copy 2*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 16-106, 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.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO.

1234567

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No.		B. Agency	C. MRO Name, Address, Phone and Fax No.	
D. Donor SSN or Employee I.D. No.				
E. Reason for Test: <input type="checkbox"/> Random <input type="checkbox"/> Pre-employment <input type="checkbox"/> Reasonable Suspicion <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 Business Information:				
Collection Business Name	Collection Business Phone No.	Collection Business Fax No.		
Address	City	State	Zip	

OMB No. 1234-5678

STEP 2: COMPLETED BY COLLECTOR

Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? <input type="checkbox"/> Yes <input type="checkbox"/> No, enter remarks in Step 4 below	Specimen Collection: <input type="checkbox"/> Single <input type="checkbox"/> Split <input type="checkbox"/> None Provided (Enter Remarks Below) <input type="checkbox"/> Observed (Enter Remarks Below)
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STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 3 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

REMARKS: _____
I certify that the specimen given to me by the donor identified in the certification section on Copy 3 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

<input checked="" type="checkbox"/> Signature of Collector	Time of Collection _____ AM PM	SPECIMEN BOTTLE(S) RELEASED TO: Name of Delivery Service Transferring Specimen to Lab
(PRINT) Collector's Name (First, MI, Last)	Date (Mo./Day/Yr.)	
RECEIVED AT LABORATORY	Primary Specimen Bottle Seal Intact	SPECIMEN BOTTLE(S) RELEASED TO:
<input checked="" type="checkbox"/> Signature of Accessioner	Date (Mo./Day/Yr.)	<input type="checkbox"/> Yes <input type="checkbox"/> No, enter remarks below
(PRINT) Accessioner's Name (First, MI, Last)		

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.

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will 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 4). —DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 4 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

Negative Positive Test Cancelled Refusal To Test because:
 Adulterated Substituted

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 determination/verification for the split specimen (if tested) is:

RECONFIRMED FAILED TO RECONFIRM - REASON _____

Signature of Medical Review Officer _____ (PRINT) Medical Review Officer's Name (First, MI, Last) _____ Date (Mo./Day/Yr.) _____

COPY 3 - MEDICAL REVIEW OFFICER COPY

Back of Copy 3*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 16-106, 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.

Back of Copy 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 16-106, 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.

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 your removal from 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 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.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO.

1234567

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No.		B. Agency	C. MRO Name, Address, Phone and Fax No.	
D. Donor SSN or Employee I.D. No.				
E. Reason for Test: <input type="checkbox"/> Random <input type="checkbox"/> Pre-employment <input type="checkbox"/> Reasonable Suspicion <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 Business Information:				
Collection Business Name	Collection Business Phone No.	Collection Business Fax No.		
Address	City	State	Zip	

OMB No. 1234-5678

STEP 2: COMPLETED BY COLLECTOR

Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? <input type="checkbox"/> Yes <input type="checkbox"/> No, enter remarks in Step 4 below	Specimen Collection: <input type="checkbox"/> Single <input type="checkbox"/> Split <input type="checkbox"/> None Provided (Enter Remarks Below) <input type="checkbox"/> Observed (Enter Remarks Below)
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STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 3 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

REMARKS:
I certify that the specimen given to me by the donor identified in the certification section on Copy 3 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

<input checked="" type="checkbox"/> Signature of Collector	Time of Collection <input type="checkbox"/> AM <input type="checkbox"/> PM	SPECIMEN BOTTLE(S) RELEASED TO: Name of Delivery Service Transferring Specimen to Lab
(PRINT) Collector's Name (First, MI, Last)	Date (Mo./Day/Yr.)	
<input checked="" type="checkbox"/> Signature of Accessioner	Date (Mo./Day/Yr.)	RECEIVED AT LABORATORY
(PRINT) Accessioner's Name (First, MI, Last)	Date (Mo./Day/Yr.)	Primary Specimen Bottle Seal Intact <input type="checkbox"/> Yes <input type="checkbox"/> No, enter remarks below
		SPECIMEN BOTTLE(S) RELEASED TO:

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.

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will 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 4). —DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 4 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

Negative Positive Test Cancelled Refusal To Test because: Adulterated Substituted

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 determination/verification for the split specimen (if tested) is:

RECONFIRMED FAILED TO RECONFIRM - REASON _____

Signature of Medical Review Officer (PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo./Day/Yr.)

COPY 5 - COLLECTOR COPY

Back of Copy 5*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 16-106, 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.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO.

1234567

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No.	B. Agency	C. MRO Name, Address, Phone and Fax No.
D. Donor SSN or Employee I.D. No.		
E. Reason for Test: <input type="checkbox"/> Random <input type="checkbox"/> Pre-employment <input type="checkbox"/> Reasonable Suspicion <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 Business Information:		
Collection Business Name	Collection Business Phone No.	Collection Business Fax No.
Address	City	State Zip

OMB No. 1234-5678

STEP 2: COMPLETED BY COLLECTOR

Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? <input type="checkbox"/> Yes <input type="checkbox"/> No, enter remarks in Step 4 below	Specimen Collection: <input type="checkbox"/> Single <input type="checkbox"/> Split <input type="checkbox"/> None Provided (Enter Remarks Below) <input type="checkbox"/> Observed (Enter Remarks Below)
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STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 3 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

REMARKS:
I certify that the specimen given to me by the donor identified in the certification section on Copy 3 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

<input checked="" type="checkbox"/> _____ Signature of Collector	Time of Collection ____/____/____ AM PM	SPECIMEN BOTTLE(S) RELEASED TO: _____ Name of Delivery Service Transferring Specimen to Lab
(PRINT) Collector's Name (First, MI, Last)	Date (Mo./Day/Yr.)	
RECEIVED AT LABORATORY		SPECIMEN BOTTLE(S) RELEASED TO:
<input checked="" type="checkbox"/> _____ Signature of Accessioner	Date (Mo./Day/Yr.)	Primary Specimen Bottle Seal Intact <input type="checkbox"/> Yes <input type="checkbox"/> No, enter remarks below
(PRINT) Accessioner's Name (First, MI, Last)	Date (Mo./Day/Yr.)	

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.

<input checked="" type="checkbox"/> _____ 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.

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will 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 4). —DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 4 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

Negative Positive Test Cancelled Refusal To Test because:
 Adulterated Substituted

REMARKS _____

<input checked="" type="checkbox"/> _____ Signature of Medical Review Officer	(PRINT) Medical Review Officer's Name (First, MI, Last)	Date (Mo./Day/Yr.)
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STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN

In accordance with applicable Federal requirements, my determination/verification for the split specimen (if tested) is:

RECONFIRMED FAILED TO RECONFIRM - REASON _____

<input checked="" type="checkbox"/> _____ Signature of Medical Review Officer	(PRINT) Medical Review Officer's Name (First, MI, Last)	Date (Mo./Day/Yr.)
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COPY 6 - EMPLOYER COPY

Back of Copy 6

Instructions for Completing the Federal Drug Testing Custody and Control Form

Note: Use ballpoint pen, press hard, and check *all* copies for legibility.

Procedure:

1. Collector ensures that the name and address of the drug testing laboratory appear on the top of the form and that the preprinted Specimen I.D. number on the top of the form is identical to the preprinted Specimen I.D. number appearing on the specimen bottle labels/seals.

2. Collector ensures the required information is provided in STEP 1 on the CCF.

Note: If the donor refuses to provide his/her SSN or Employee I.D. number, the collector must provide an appropriate comment on the REMARKS line in STEP 4.

3. Collector gives the collection container/specimen bottle to the donor for providing a specimen.

4. Upon receiving the specimen from the donor, the collector checks the temperature of specimen within 4 minutes.

5. Collector marks appropriate temperature box (if outside the temperature range, provides a remark in STEP 4).

6. Collector marks the appropriate box to indicate whether it is a single or split specimen collection. If no specimen is collected, the box is checked and a remark is provided in STEP 4. If it is an observed collection, the box is checked and a remark is provided in STEP 4.

Note: If no specimen is collected, Copies 1 and 2 are discarded, but the remaining copies are distributed as indicated below.

7. Collector secures cap(s) on specimen bottle(s) and affixes seal(s).

8. Collector dates the specimen bottle label(s).

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

10. Collector turns to Copy 3 (MRO Copy—pink border) and instructs the donor to read the certification statement in STEP 5 (Copy 3) and to sign, print name, date, provide phone numbers, and date of birth after reading the certification statement.

Note: If the donor refuses to sign the certification statement, the collector must provide an appropriate comment on the REMARKS line in STEP 4 on Copy 1.

11. Collector completes STEP 4 (*i.e.*, provides signature, printed name, date, time of collection, and specific name of delivery service).

Note: Collector records any comments concerning the collection on the REMARKS line in STEP 4.

12. Collector immediately places and seals the specimen bottle(s) and Copy 1 and Copy 2 of the CCF in an appropriate leak-proof plastic bag.

Note: If the plastic bag containing the specimen bottle(s) is not immediately placed in a shipping container and sealed because several collections will be placed in the same shipping container, the Collector must maintain visual control of the specimens or place them in secured temporary storage.

13. Collector sends Copy 3 to the MRO, gives Copy 4 to the donor, retains Copy 5, and sends Copy 6 to the Employer.

[FR Doc. 99-29609 Filed 11-12-99; 8:45 am]
BILLING CODE 4162-20-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4441-N-53]

Submission for OMB Review: Builder's Certification of Plans, Specifications, and Site

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting comments on the subject proposal.

DATES: *Comments Due Date:* December 15, 1999. Comments should refer to the proposal by name (2502-0496) and/or OMB Control Number.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal, and should be sent to: Joseph F. Lackey, Jr. HUD Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503 (202) 395-7316.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management

Officer, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708-2374 (This is not a toll-free number) or e-mail to Wayne_Eddins@HUD.gov. Copies of the available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: the Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Builder's Certification of Plans, Specifications, and Site.

OMB Approval Number: 2502-0496.

Form Number: HUD-92541.

Description of the need for the Information and its proposed use: HUD requires the builder to complete the certification (Form HUD-92541) that notes any adverse site and location factors on the property, including flood plains, so that HUD does not insure a mortgage on property that poses a risk to health or safety of the occupant.

Respondents: Business or Other-For-Profit.

Frequency of Submission: On Occasion.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Information Collection	800		82		.25		16,400