



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment

Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer at (240) 276-0361.

Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs Federal Drug Testing Custody and Control Form (CCF) (OMB No. 0930-0158) and National Laboratory Certification Program (NLCP) Information Collection Tools - Revision

SAMHSA will request OMB approval for revision of the Federal Drug Testing Custody and Control Form (CCF) for federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) dated October 12, 2023 (88 FR 70768) and using Oral Fluid (OFMG) dated October 12, 2023 (88 FR 70814), and OMB approval for information provided by test facilities (laboratories and Instrumented Initial Test Facilities, IITFs) for the National Laboratory Certification Program (NLCP).

The CCF is used by all federal agencies and by employers regulated by the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) to document the collection and chain of custody of a urine or oral fluid specimen at the collection site, for HHS-certified test facilities to document chain of custody and report results, and for Medical Review Officers (MROs) to document and report a verified result. SAMHSA allows the use of the CCF as a paper or electronic form.

The current OMB-approved CCF has an August 31, 2026 expiration date. SAMHSA has resubmitted the CCF with revisions to the form for OMB approval. During 60-day public comment, 7 commenters submitted comments on the proposed changes to the CCF. Commenters

were comprised of individuals, organizations, and private sector companies. All comments were reviewed and taken into consideration in preparation of the revised CCF. The issues and concerns raised in the public comments are set out at www.reginfo.gov/public/do/PRAMain.

The revisions are listed below:

Copies 1-5

Revised Step 1

1. Removed drug analytes and checkboxes from Item F and changed “Drug Tests to be Performed” to “Other tests to be performed (specify):”.

Copy 1

Revised Step 4

1. Moved the “Split Specimen Device Expiration Date” field to the right.

Copies 2-5

Revised Step 5

1. Lengthened the email address line and moved it to the right.
2. Replaced the 2 date fields for “Daytime Phone No.” and “Evening Phone No.” with a single field “Phone No.” and moved it to the left.
3. Moved the “Date of Birth” field to the left, reworded as “Birthdate” and moved the text under the line.

Laboratories and IITFs seeking HHS certification under the NLCP must complete and submit the NLCP application form. The NLCP application form has been updated in accordance with the current UrMG and OFMG. The revisions enable provision of information for analytes in the Authorized Testing Panels now published separately from the Mandatory Guidelines, and enable applicant test facilities to submit information on new technologies/instruments.

Prior to an inspection, an HHS-certified laboratory or IITF is required to submit specific information regarding its procedures. Collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the testing procedures before arriving for the onsite inspection. The NLCP information checklist has been updated in accordance with the current UrMG and OFMG. The revisions enable provision of information for analytes in the Authorized Testing Panels now published separately from the Mandatory Guidelines, and enable certified test facilities to submit information on new technologies/instruments.

The annual total burden estimates for the CCF, the NLCP application, the NLCP information checklist, and the NLCP recordkeeping requirements are shown in the following table.

Form/Respondent	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden per Response (hours)	Annual Burden (hours)	Hourly Wage Rate (\$)	Total Cost (\$)³
Custody and Control Form¹:							
Donor	6,726,610	1	6,726,610	0.08	538,129	25	13,453,225
Collector	6,726,610	1	6,726,610	0.07	470,683	15	7,060,245
Laboratory	6,726,610	1	6,726,610	0.05	336,331	35	11,771,585
IITF	1	0	0	0.05	0	35	0
Medical Review Officer	6,726,610	1	6,726,610	0.05	336,331	150	50,449,650
NLCP Application Form²:							
Laboratory	20	1	20	3	60	35	2,100
IITF	0	0	0	3	0	35	0
Sections B and C - NLCP Information Checklist:							
Laboratory	19	1	19	1	19	35	665
IITF	1	1	1	1	1	35	35
Record Keeping:							
Laboratory	19	1	19	250	4,750	35	166,250
IITF	0	0	0	250	0	35	0
Total	6,726,669		26,906,499		1,687,529		82,946,625

¹Note: The time it takes each respondent (i.e., donor, collector, laboratory, IITF, and MRO) to complete the Federal CCF is based on an average estimated number of minutes it would take each respondent to complete their designated section of the form or regulated entities (e.g. HHS, DOT, and NRC).

¹Note: The above number of responses is based on an estimate of the total number of specimens collected annually (approximately 150,000 federal agency specimens; 6,500,000 DOT regulated specimens, and 145,000 NRC regulated specimens).

²Note: The estimate of 20 applications per year is based on requests for a laboratory application (urine or oral fluid) or IITF application in the past year (i.e., at the time of these calculations) .

²Note: *The estimate of three burden hours to complete the application has not changed.*

³Note: *At the time of these calculations, there were 18 certified laboratories and one certified IITF undergoing 2 maintenance inspections each year, and 1 applicant laboratory.*

³Note: *The wage rates listed for each respondent are based on estimated average hourly wages for the individuals performing these tasks.*

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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