4162-20 - P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning the opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276-0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs (OMB No. 0930-0158) - Extension

SAMHSA will request OMB approval for extension 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. In March 2025, SAMHSA was notified of a potential issue with the current Federal CCF. Most hardcopy paper CCFs are provided as a 5-part form using carbonless paper. When expiration dates for primary/single and split specimen oral fluid collection devices were handwritten in Step 4 on Copy 1, the annotations covered some donor information in Step 5 on Copies 2 – 5. SAMHSA notified certified test facilities of the issue and approved some laboratory requests for modifications.

SAMHSA plans to submit the CCF with the following revisions for OMB approval:

Copies 2-5

Revised Step 5

1. Shorten the email address line
2. Replace the 2 date fields for ““Daytime Phone No.” and “Evening Phone No.” with a single field “Phone No.”
3. Move the “Date of Birth” field to the left.

Laboratories and IITFs seeking HHS certification under the NLCP must complete and submit the NLCP application form. The 3 NLCP Applications (i.e., for urine laboratories, for urine instrumented initial test facilities [IITFs], and for oral fluid laboratories) have 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 and certified 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 changes enable provision of information for analytes in the Authorized Testing Panels now published separately from the Mandatory Guidelines and enable applicant and 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 Form[1]:							
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 Form[2]:							
Laboratory	20	1	20	3	60	35	2,100
IITF	0	0	0	3	0	35	0

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]
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		1,686,304		82,903,755

[1]Note: 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).

[1]Note: 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).

[2]Note: 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).

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

[3]Note: 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.

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

Send comments to SAMHSA Reports Clearance Officer, Room 15-E-57-A,

5600 Fishers Lane, Rockville, MD 20857 ***OR*** e-mail a copy to **samhsapra@samhsa.hhs.gov**.

Written comments should be received by [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE FEDERAL REGISTER].

Alicia Broadus,
Reports Clearance Officer.

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