



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-26-1389]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “NCEH DLS Laboratory Quality Assurance Programs” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on October 2, 2025 to obtain comments from the public and affected agencies. CDC received one public comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

NCEH DLS Quality Assurance Programs (OMB Control No. 0920-1389, Exp. 3/31/2026) - Revision - National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this information collection is general purpose statistics. There are two points of information collection for participation in any of the DLS QA and standardization programs. The first is an enrollment/sample request form and the second is a result reporting form. For programs with multiple rounds of QA each year (when CDC sends materials to a participating laboratory to use in their quality assurance testing), one enrollment form is collected for each year or just one time at onset of request/participation and a result reporting form is returned to CDC for each panel of samples sent and tested.

The collection of general laboratory information upon enrollment application occurs via email, web-inquiry, or pdf form and includes information such as lab name or identifier, shipping address, assay information, and analytes of interest. The request/enrollment form will assist the

CDC QA and standardization programs to develop and ship desired materials for laboratories' QA and standardization activities.

Participant data submission forms (some provided to participants with some pre-populated information from the enrollment form) request information on measurement results and assay characteristics (test instrument and configuration/assay description, calibrators, and reagent information), as well as sample result information (date of analysis, values), and laboratory activities (expertise, relevant research, providing reference materials to other laboratories). The collection of laboratory results following participant receipt and use of CDC quality control materials allows the CDC QA program to provide each laboratory participant with statistical reports that evaluate the performance of their analyses and methods. These reports are provided back to participating laboratories to adjust and improve their tests, and to provide expertise and TA as needed.

CDC also uses the results to assess and monitor trends of laboratory measurements over time, thus contributing to the reliability and consistency of high-quality laboratory testing for analytes of significant public health and clinical decision-making.

DLS provides laboratory support that improves the detection, diagnosis, treatment, and prevention of environmental, tobacco-related, nutritional, newborn, selected chronic, and infectious diseases. CDC's DLS Laboratory QA and Standardization Programs support these efforts by improving the analytical accuracy and reliability of high priority tests used in patient care, research, and public health. A key component of quality assurance for laboratory testing is monitoring and evaluating the performance of tests in clinical, research, commercial, and public health laboratories. Some of the programs, like Accuracy-based Laboratory Monitoring Programs (AMP) for Clinical Biomarkers, include established assessment of analytical accuracy of measurements among participating laboratories over time, while other programs provide information about the analytical performance of a laboratory at a point in time. The QA

programs in DLS are foundational services provided to meet CDC and DLS objectives and have received funding and support for years, and for some, decades.

This is a Revision request for a currently approved collection, under OMB Control No. 0920-1389. Additionally, changes have been made to the estimated burden and cost table to reflect updated average hourly wage.

Clinical Chemistry Branch (CCB): Programs have been consolidated to limit redundancies in efforts and enhance paper reduction. These changes are editorial in nature and do not impact the total burden on the public. Based on feedback from program respondents, the term “Enrollment Forms” will be changed to “Request Form,” as not all requests are from program participants.

Clinical Chemistry Branch (CCB) – Clinical Standardization Programs

- Accuracy-based Laboratory Monitoring Programs (AMP), covering Lipid Standardization Program (LSP) and AMP for Clinical Biomarkers
- Reference Laboratory Networks for Lipids and Other Chronic Disease Biomarkers, covering Cholesterol Reference Method Laboratory Network (CRMLN) and Hormone Reference Networks)
- Chronic Disease Standardization Programs for Clinical Biomarkers, covering Hormone Standardization (HoST) Programs and Vitamin D Standardization Certification Program (VDSCP)

Additional changes are made to the burden table to reflect the number of additional participants for the different programs under the CCB Clinical Standardization Programs.

NBB: Changes were made to the burden table to reflect the number of respondents based on historical data for the number of participants in the two NBB MPV programs and a change in frequency of reporting. The MPV reports are now reported once a year rather than quarterly. The average burden per response was adjusted to account for 1 form submission per year and the total burden hours and total respondent costs were adjusted accordingly. The only change to the

VITAL-EQA program entailed the correction of a previous rounding error (12.5 and 22.5 should have been rounded to 13 and 23). The cost to the government table was updated to reflect respondent updates and personnel changes. The cost to government for the start-up and survey kits was removed because they are not part of the MPV Folate MBA QA program and require no data collection.

CDC has estimated the annualized burden for these 11 programs to be 6,428 hours per year. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Accuracy-based Laboratory Monitoring Programs (AMP) for Lipids and Other Chronic Disease Biomarkers				
CCB AMP for Chronic Disease Biomarkers				
Academic/ University Research Lab	AMP Enrollment Section on Data Submission Form	10	1	25/60
	AMP Data Submission Form	10	4	45/60
Private Research Lab	AMP Enrollment Section on Data Submission Form	10	1	25/60
	AMP Data Submission Form	10	4	45/60
Routine Clinical Lab	AMP Enrollment Section on Data Submission Form	20	1	25/60
	AMP Data Submission Form	20	4	45/60
CCB AMP for Lipid Standardization Program (LSP)				
Academic/ University Research Lab	LSP Enrollment Section on Data Submission Form	20	1	25/60
	LSP Data Submission Form	20	4	45/60
Private Research Lab	LSP Enrollment Section on Data Submission Form	10	1	25/60
	LSP Data Submission Form	10	4	45/60

Routine Clinical Lab	LSP Enrollment Section on Data Submission Form	60	1	25/60
	LSP Data Submission Form	60	4	45/60
Reference Laboratory Network Programs for Lipid and Hormone				
Reference Network Laboratories	CRMLN Enrollment Webpage	20	1	10/60
	CRMLN Data Submission Form	20	2	2
CCB Chronic Disease Standardization Programs for Clinical Biomarkers				
CCB Hormone Standardization (HoST) Programs				
Assay Manufacturers	HoSt Enrollment Section on Data Submission Form	60	1	30/60
	HoSt Data Submission Form	60	4	1
(LDT) Lab Developed Tests Manufacturers	HoSt Enrollment Section on Data Submission Form	50	1	30/60
	HoSt Data Submission Form	50	4	1
End-user/ Labs	HoSt Enrollment Section on Data Submission Form	30	1	30/60
	HoSt Data Submission Form	30	4	1
CCB Vitamin D Standardization Certification Program (VDSCP)				
Assay Manufacturers	VDSCP Enrollment Section on Data Submission Form	60	1	30/60
	VDSCP Data Submission Form	60	4	1
(LDT) Lab Developed Tests Manufacturers	VDSCP Enrollment Section on Data Submission Form	50	1	30/60
	VDSCP Data Submission Form	50	4	1
End-user/ Labs	VDSCP Enrollment Section on Data Submission Form	30	1	30/60
	VDSCP Data Submission Form	30	4	1
NBB Vitamin A Laboratory – External Quality Assurance (VITAL-EQA)				
Academic/ University Research Lab	VITAL-EQA Enrollment Form National	30	1	25/60

	VITAL-EQA Data Submission Form	30	2	45/60
Government/ Ministry of Health Lab	VITAL-EQA Enrollment Form International	30	1	25/60
	VITAL-EQA Data Submission Form	30	2	45/60
Private Research Lab	VITAL-EQA Enrollment Form	15	1	25/60
	VITAL-EQA Data Submission Form	15	2	45/60
Clinical Lab	VITAL-EQA Enrollment Form	15	1	25/60
	VITAL-EQA Data Submission Form	15	2	45/60
NBB Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay (MBA)				
Academic/ University Research Lab	MPV Folate MBA Enrollment Section on Data Submission Form	10	1	25/60
	MPV Folate MBA Data Submission Form	10	1	90/60
Government/ Ministry of Health Lab	MPV Folate MBA Enrollment Section on Data Submission Form	10	1	25/60
	MPV Folate MBA Data Submission Form	10	1	90/60
Private Research Lab	MPV Folate MBA Enrollment Section on Data Submission Form	2	1	25/60
	MPV Folate MBA Data Submission Form	2	1	90/60
Clinical Public Health Lab	MPV Folate MBA Enrollment Section on Data Submission Form	2	1	25/60
	MPV Folate MBA Data Submission Form	2	1	90/60
NBB Quality Assurance Method Performance Verification (MPV) for Micronutrients				
Academic/ University Research Lab	MPV Micronutrients Enrollment	15	1	25/60

	Section on Data Submission Form			
	MPV Micronutrients Data Submission Form	15	1	90/60
Government/ Ministry of Health Lab	MPV Micronutrients Enrollment Section on Data Submission Form	15	1	25/60
	MPV Micronutrients Data Submission Form	15	1	90/60
Private Research Lab	MPV Micronutrients Enrollment Section on Data Submission Form	7	1	25/60
	MPV Micronutrients Data Submission Form	7	1	90/60
Clinical Public Health Lab	MPV Micronutrients Enrollment Section on Data Submission Form	7	1	25/60
	MPV Micronutrients Data Submission Form	7	1	90/60
OATB Biomonitoring Quality Assurance Support Program (BQASP)				
State Public Health Labs	BQASP Enrollment Email	10	1	5/60
	BQASP Data Submission Form	10	1	45/60
IRATB Proficiency in Arsenic Speciation (PAsS) Program				
Public Health Labs	PAsS Enrollment Form	28	1	10/60
	PAsS Data Submission Form	28	4	10/60
IRATB Ensuring the Quality of Urinary Iodine Procedures (EQUIP)				
Public Health Labs	EQUIP Enrollment Form	240	1	10/60
	EQUIP Data Submission Form	240	3	10/60
IRATB Lead and Multielement Proficiency (LAMP) Testing Program				
Public Health Labs	LAMP Enrollment Form	226	1	10/60

	LAMP Data Submission Form	226	4	10/60
NSMBB Newborn Screening and Quality Assurance Program (NSQAP)				
Domestic NBS Labs	NSQAP Enrollment Form	3	1	10/60
	NSQAP Data Submission Portal Quality Control (QC)	78	2	45/60
	NSQAP Data Submission Portal Biochemical (Proficiency Testing) PT	78	3	45/60
	NSQAP Data Submission Portal Molecular PT	78	3	45/60
International NBS Labs	NSQAP Enrollment Form	44	1	10/60
	NSQAP Data Submission Portal QC	568	2	45/60
	NSQAP Data Submission Portal Biochemical PT	568	3	45/60
	NSQAP Data Submission Portal Molecular PT	568	3	45/60
NBS Test Manufacturers	NSQAP Enrollment Form	3	1	10/60
	NSQAP Data Submission Portal QC	18	2	45/60
	NSQAP Data Submission Portal Biochemical PT	18	3	45/60
	NSQAP Data Submission Portal Molecular PT	4	3	45/60

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