DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–25–1389; Docket No. CDC–2025–0586]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled NCEH DLS Laboratory Quality Assurance Programs. The Division of Laboratory Science (DLS) provides quality assurance in the form of quality control samples and technical assistance to laboratories to improve analytical accuracy and reliability of tests, allowing CDC to assess performance.

DATES: CDC must receive written comments on or before December 1, 2025.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2025–0586 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

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 CDC Division of Laboratory Science (DLS) Quality Assurance (QA) and standardization programs operate out of multiple laboratories. They establish baseline measurements and provide calibration and/or QC samples that laboratories around the world rely on to develop and improve methods with acceptable levels of accuracy and reliability and, in some cases, meet certain required certifications or accreditation. Laboratories use DLS-developed samples to test the quality and accuracy of their methods/assays. Participating laboratories enroll in the DLS QA and standardization program that fits their needs (i.e.: external quality assurance/performance assessment, proficiency testing, accuracy-based monitoring, or standardization/harmonization).

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. CDC requests the following changes to the activities and estimated burden associated with the data collection:

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. 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.

Nutrition Biomarkers Branch (NBB): Changes are 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 correction to burden in the VITAL–EQA program.

CDC requests OMB approval for an estimated 6,674 annual burden hours. There is no additional cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden 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	4
	AMP Data Submission Form	10	4	45/60	30
Private Research Lab	AMP Enrollment Section on Data Submission Form	10	1	25/60	4
	AMP Data Submission Form	10	4	45/60	30
Routine Clinical Lab	AMP Enrollment Section on Data Submission Form	20	1	25/60	8
	AMP Data Submission Form	20	4	45/60	60
CCB AMP for Lipid Standardization Program (LSP)					
Academic/University Research Lab.	LSP Enrollment Section on Data Submission Form	20	1	25/60	8
	LSP Data Submission Form	20	4	45/60	60
Private Research Lab	LSP Enrollment Section on Data Submission Form	10	1	25/60	4
	LSP Data Submission Form	10	4	45/60	30
Routine Clinical Lab	LSP Enrollment Section on Data Submission Form	60	1	25/60	25
	LSP Data Submission Form	60	4	45/60	180
Reference Laboratory Network Programs for Lipid and Hormone					
Reference Network Laboratories.	CRMLN Enrollment Webpage	20	1	10/60	3
	CRMLN Data Submission Form	20	2	2	80
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	30
	HoSt Data Submission Form	60	4	1	240
(LDT) Lab Developed Tests Manufacturers.	HoSt Enrollment Section on Data Submission Form	50	1	30/60	25
	HoSt Data Submission Form	50	4	1	200
End-user/Labs	HoSt Enrollment Section on Data Submission Form	30	1	30/60	15
	HoSt Data Submission Form	30	4	1	120
CCB Vitamin D Standardization Certification Program (VDSCP)					
Assay Manufacturers	VDSCP Enrollment Section on Data Submission Form	60	1	30/60	30
	VDSCP Data Submission Form	60	4	1	240
(LDT) Lab Developed Tests Manufacturers.	VDSCP Enrollment Section on Data Submission Form	50	1	30/60	25
	VDSCP Data Submission Form	50	4	1	200
End-user/Labs	VDSCP Enrollment Section on Data Submission Form	30	1	30/60	15
	VDSCP Data Submission Form	30	4	1	120

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
NBB Vitamin A Laboratory—External Quality Assurance (VITAL–EQA)					
Academic/University Research Lab.	VITAL–EQA Enrollment Form National	30	1	25/60	13
	VITAL–EQA Data Submission Form	30	2	45/60	45
Government/Ministry of Health Lab.	VITAL–EQA Enrollment Form International	30	1	25/60	13
	VITAL–EQA Data Submission Form	30	2	45/60	45
Private Research Lab	VITAL–EQA Enrollment Form	15	1	25/60	6
	VITAL–EQA Data Submission Form	15	2	45/60	22
Clinical Lab	VITAL–EQA Enrollment Form	15	1	25/60	6
	VITAL–EQA Data Submission Form	15	2	45/60	22
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	4
	MPV Folate MBA Data Submission Form	10	1	45/60	30
Government/Ministry of Health Lab.	MPV Folate MBA Enrollment Section on Data Submission Form.	10	1	25/60	4
	MPV Folate MBA Data Submission Form	10	1	45/60	30
Private Research Lab	MPV Folate MBA Enrollment Section on Data Submission Form.	2	1	25/60	1
	MPV Folate MBA Data Submission Form	2	1	45/60	6
Clinical Public Health Lab	MPV Folate MBA Enrollment Section on Data Submission Form.	2	1	25/60	1
	MPV Folate MBA Data Submission Form	2	1	45/60	6
NBB Quality Assurance Method Performance Verification (MPV) for Micronutrients					
Academic/University Research Lab.	MPV Micronutrients Enrollment Section on Data Submission Form.	15	1	25/60	6
	MPV Micronutrients Data Submission Form	15	1	45/60	45
Government/Ministry of Health Lab.	MPV Micronutrients Enrollment Section on Data Submission Form.	15	1	25/60	6
	MPV Micronutrients Data Submission Form	15	1	45/60	45
Private Research Lab	MPV Micronutrients Enrollment Section on Data Submission Form.	7	1	25/60	3
	MPV Micronutrients Data Submission Form	7	1	45/60	21
Clinical Public Health Lab	MPV Micronutrients Enrollment Section on Data Submission Form.	7	1	25/60	3
	MPV Micronutrients Data Submission Form	7	1	45/60	21
OATB Biomonitoring Quality Assurance Support Program (BQASP)					
State Public Health Labs	BQASP Enrollment Email	10	1	5/60	1
	BQASP Data Submission Form	10	1	45/60	8
IRATB Proficiency in Arsenic Speciation (PAsS) Program					
Public Health Labs	PAsS Enrollment Form	28	1	10/60	5
	PAsS Data Submission Form	28	4	10/60	19
IRATB Ensuring the Quality of Urinary Iodine Procedures (EQUIP)					
Public Health Labs	EQUIP Enrollment Form	240	1	10/60	40
	EQUIP Data Submission Form	240	3	10/60	120
IRATB Lead and Multielement Proficiency (LAMP) Testing Program					
Public Health Labs	LAMP Enrollment Form	226	1	10/60	38
	LAMP Data Submission Form	226	4	10/60	151
NSMBB Newborn Screening and Quality Assurance Program (NSQAP)					
Domestic NBS Labs	NSQAP Enrollment Form	71	1	10/60	12
	NSQAP Data Submission Portal Quality Control (QC)	71	2	45/60	106
	NSQAP Data Submission Portal Biochemical (Proficiency Testing) PT.	71	3	45/60	160
	NSQAP Data Submission Portal Molecular PT	71	3	45/60	160

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
International NBS Labs	NSQAP Enrollment Form	568	1	10/60	95
	NSQAP Data Submission Portal QC	568	2	45/60	852
	NSQAP Data Submission Portal Biochemical PT	568	3	45/60	1,278
	NSQAP Data Submission Portal Molecular PT	568	3	45/60	1,278
NBS Test Manufacturers	NSQAP Enrollment Form	32	1	10/60	5
	NSQAP Data Submission Portal QC	32	2	45/60	48
	NSQAP Data Submission Portal Biochemical PT	32	3	45/60	72
	NSQAP Data Submission Portal Molecular PT	32	3	45/60	72
Total	.....	.....	.....	.....	6,674

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Lead Exposure and Prevention Advisory Committee

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS), is soliciting nominations for membership on the Lead Exposure and Prevention Advisory Committee (LEPAC). The LEPAC is composed of not more than 15 members that are Federal and non-Federal experts in fields associated with lead screening, the prevention of lead exposure, and services for individuals and communities affected by lead exposure.

DATES: Nominations for membership on the LEPAC must be received no later than October 31, 2025. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be emailed to *LEPAC@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Paul Allwood, Ph.D., M.P.H., Designated Federal Officer, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, Atlanta, GA 30341. Telephone: (770) 488–6774, *PAllwood@cdc.gov.*

SUPPLEMENTARY INFORMATION: Nominations are being sought for individuals with expertise in the fields of epidemiology, toxicology, mental health, pediatrics, early childhood education, special education, diet and nutrition, and environmental health. Members may be invited to serve for three-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of Lead Exposure and Prevention Advisory Committee (LEPAC) objectives.

The members of this Committee are selected by the Secretary of the Department of Health and Human Services (HHS). The Committee's objective is to advise the Secretary, HHS and the Director, Centers for Disease Control and Prevention (CDC)/ Administrator, Agency for Toxic Substances and Disease Registry on a range of activities to include: (1) review of Federal programs and services available to individuals and communities exposed to lead; (2) review of the current research on lead exposure to identify additional research needs; (3) review of and identification of best practices, or the need for best practices regarding lead screening and the prevention of lead exposure; (4) identification of effective services, including services relating to healthcare, education, and nutrition for individuals and communities affected by lead exposure and lead poisoning, including in consultation with, as appropriate, the lead exposure registry as established in Public Law 114–322 Section 2203(b) (42 U.S.C. 300j–27); and (5) undertaking of any other review or activities that the Secretary determines to be appropriate.

Annually as determined necessary by the Secretary or as required by Congress, the Committee shall submit a report to include: (1) an evaluation of the effectiveness of the Federal programs and services available to individuals and communities exposed to lead; (2) an evaluation of additional lead exposure research needs; (3) an assessment of any effective screening methods or best practices used or developed to prevent or screen for lead exposure; (4) input and recommendations for improved access to effective services relating to health care, education, or nutrition for individuals and communities impacted by lead exposure; and (5) any other recommendations for communities affected by lead exposure, as appropriate.

At least half of the committee will consist of Federal representatives from a range of agencies that may include the Department of Housing and Urban Development; the Environmental Protection Agency; the Consumer Product Safety Commission; the Centers for Medicare and Medicaid Services; the Health Resources and Services Administration; the Food and Drug Administration; the U.S. Department of Agriculture; the Occupational Safety and Health Administration; the National Institute of Environmental Health Sciences; the U.S. Geological Survey; and such additional Federal, state, tribal, and local public and private officials as the Secretary deems necessary for the Committee to carry out its function. The rest of the Committee will consist of non-Federal members. Only non-Federal members are being solicited with this announcement.

Department of Health and Human Services (HHS) policy stipulates that committee membership be balanced in terms of points of view represented and the committee's function. Appointments shall be made free from discrimination