

# NCEH DLS Laboratory Quality Assurance Programs

OMB Control No. 0920- NEW

Existing Information Collection in Use without an OMB  
Control Number

Supporting Statement Part A –  
Justification

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## Part A. Justification

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**Goal of the program:** Accuracy and reliability of laboratory tests is important to identify and to monitor exposures and health biomarkers, which in turn improves diagnosis and treatment. Laboratories that conduct biomonitoring or test for certain environmental or nutritional chemicals participate in quality assurance (QA) activities for many reasons: to assess internal test performance, calibrate methods to standards among other laboratories, receive certification of proficiency to comply with certain regulations, or simply improve quality. Participation may help a laboratory to verify the accuracy of their methods and results or ensure accurate and consistent test results across multiple laboratories.

**Intended use of the resulting data:** Offering a range of programs under the QA umbrella, the Division of Laboratory Sciences (DLS) provides quality control (QC) samples and technical assistance (TA) to laboratories to improve analytical accuracy and reliability of tests. Data produced by laboratories participating in a DLS QA program are used to:

- Determine which analytes/samples to ship to the laboratory participant(s)
- Provide laboratory participants with a statistical report that evaluates the performance (quality and accuracy) of their analysis
- Understand laboratory participant instrumentation, calibrators and reagents and overall capability in order to provide TA and troubleshoot analytical problems
- Maintain measurement data to verify calibrations, compare various laboratory methods (in the case of standardization or external quality assessment programs), and document continued laboratory proficiency

**Methods to be used to collect:** Data will be collected electronically via email and online forms; data reporting forms are returned to DLS via Excel templates, PDFs, or web platforms.

**Respondent population:** Laboratories that participate in the various programs are domestic and international and can include public health laboratories, research laboratories, commercial laboratories, and diagnostic test manufacturers. They can be associated with medical schools, hospital systems, state health departments, universities/academic institutions, ministries of health, nonprofit organizations.

**How data will be analyzed:** Statistical tools, like SAS, are used to perform analytics of laboratories' test results (i.e. simple descriptive analysis, over-time data among laboratories).

### A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) National Center for Environmental Health (NCEH) seeks a three-year Paperwork Reduction Act (PRA) clearance for an existing information

collection in use without an OMB Control Number for the Division of Laboratory Science (DLS) laboratory quality assurance (QA) programs.

Laboratory QA encompasses a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods, instrumentation, analytes, source materials, and the volume of specimens tested.

The CDC DLS QA programs operate out of multiple laboratories within the Division. They establish the 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 program that fits their needs (i.e.: external quality assurance/performance assessment, proficiency testing, accuracy-based monitoring, or standardization/harmonization). After the laboratories receive DLS QA samples and perform their measurements, they return test results to DLS. DLS then evaluates the data using statistical methods and reports back to the laboratories on their analytical performance. Laboratories may receive additional technical assistance (TA)/troubleshooting to improve their method performance as needed. DLS programs are offered at different frequencies.

There are thirteen (13) DLS QA programs conducted by the following five DLS branches. These programs provide materials and test result analysis to laboratories for the purpose of improving and/or standardizing test performance.

- Clinical Chemistry Branch
  - **Accuracy-based Laboratory Monitoring Programs (AMP)**
  - **Lipid Standardization Program (LSP) for Clinical Biomarkers**
  - **Cholesterol Reference Method Laboratory Network (CRMLN)**
  - **Hormone Standardization (HoST) Program**
  - **Vitamin D Standardization Certification Program (VDSCP)**
- Nutrition Biomarkers Branch
  - **Vitamin A Laboratory - External Quality Assurance (VITAL-EQA)**
  - **Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay (MBA)**
  - **Quality Assurance Method Performance Verification (MPV) for Micronutrients**
- Organic Analytical Toxicology Branch
  - **Biomonitoring Quality Assurance Support Program (BQASP)**
- Inorganic Radiation and Analytical Toxicology Branch
  - **Proficiency in Arsenic Speciation (PAsS) Program**
  - **Ensuring the Quality of Urinary Iodine Procedures (EQUIP)**
  - **Lead and Multielement Proficiency (LAMP) Testing Program**
- Newborn Screening and Molecular Biology Branch

## o Newborn Screening and Quality Assurance Program (NSQAP)

All thirteen (13) CDC quality assurance programs help improve the accuracy and reliability of tests performed by laboratories in patient care, research, commercial and public health settings. They also help to make measurement results among research studies and among clinical laboratories more comparable.

Collectively, these programs improve the quality of laboratory tests that measure environmental exposures and chronic disease biomarkers (including nutritional indicators and hormones) to better inform critical patient care and public health decisions for an expansive host of health outcomes such as rare heritable disorders in newborns, endocrine disorders, maternal health and risk of birth defects, bone, kidney and cardiovascular disease, cancers (including breast cancer), diabetes, thyroid and hormone dysregulation.

[ISO 17511:2020](#) (In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples) states “A manufacturer shall document the complete calibration hierarchy and identify the highest metrological reference to which the resulting measured quantity values are traceable, in conformance with the requirements set out in this document”. DLS operates several reference methods that are considered the ‘highest metrological reference’ (i.e., HDL-Cholesterol). Furthermore, the standard requires that manufacturers “shall validate a claim of metrological traceability of the value assigned to the IVD MD calibrator.” According to this ISO standard, this is achieved by “participation in EQA, proficiency testing (PT), or other inter-laboratory comparison schemes that utilize commutable test samples, with target values preferably assigned by a reference materials program (RMP) (when available) or a harmonization protocol" or “Method comparison studies on a set of human samples, comparing to a higher order RMP”. Several DLS QA programs are the only standardization programs world-wide that allow for validation of metrological traceability. Therefore, DLS standardization programs help laboratories and manufacturers achieve metrological traceability requirements, which are also a requirement stated in [ISO 17025](#).

In the US, as part of their routine work, clinical testing labs are required by 42 CFR Chapter 4 Subchapter G Subpart H §493 to participate in proficiency testing for non-waived testing. Additionally, [Subpart K, §493.1236\(c\)\(1\)](#) states that: “(c) At least twice annually, the laboratory must verify the accuracy of the following: (1) Any test or procedure it performs that is not included in subpart I of this part”. Internationally, as part of routine laboratory operation, participation in proficiency testing is a requirement of ISO/IEC 17025 7.7.2 a) participation in proficiency testing programs b) participation in interlaboratory comparisons other than proficiency testing. A similar requirement exists for labs accredited to [ISO 15189](#) (clause 5.6.3.1 of this international standard requires participation in a proficiency testing program).

Authorizing legislation comes from [Section 301 of the Public Health Service Act \(42 U.S.C.241\)](#). Additionally, the section of the federal regulations titled “Standards and Certification:

Laboratory Requirements” is issued by the Centers for Medicare & Medicaid Services (CMS) to enact the [Clinical Laboratory Improvement Act \(CLIA\) of 1988](#) passed by Congress. For most international laboratories and U.S. laboratories operating internationally, it is a requirement to be compliant with International Organization for Standardization (ISO). ISO is an independent, non-governmental, international organization comprised of standards experts from 165 countries. The FDA lists ISO 17511 as a recognized standard that test manufacturers demonstrate compliance with when submitting for FDA clearance. The Electronic Code of Federal Regulations (eCFR) Title 42, chapter 4, subchapter G, subpart H and K set requirements for laboratory PT and QA for non-waived testing. All authorizing legislation are included in **Attachment 1** and all published regulations and standards, required or voluntary, are included in **Attachment 1a**.

CDC has estimated the annualized time burden for these thirteen (13) programs to be 6,513 hours per year. The annualized number of responses are estimated as 10,804 submissions to NCEH DLS.

The 60-day Federal Register Notice was published on December 27, 2021 (**Attachment 2**) and is further discussed in Section A.8.

## A.2. Purpose and Use of the Information Collection

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 programs. The first is an enrollment 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 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 enrollment form will assist the CDC QA program to develop and ship desired materials for laboratories’ QA 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 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.

Information collection forms for each program:

- Accuracy-based Laboratory Monitoring Programs (AMP)
  - **Attachment 3a: AMP Enrollment and Data Submission Form**
- Lipid Standardization Program (LSP) for Clinical Biomarkers
  - **Attachment 3b: LSP Enrollment and Data Submission Form**
- Cholesterol Reference Method Laboratory Network (CRMLN)
  - **Attachment 3c: CRMLN Data Submission Form**
  - **Attachment 3c-I: CRMLN Recruitment Webpage**
- Hormone Standardization (HoST)
  - **Attachment 3d: HoSt and VDSCP Enrollment and Data Submission Form**
- Vitamin D Standardization Certification Program (VDSCP)
  - **Attachment 3e: HoSt and VDSCP Enrollment and Data Submission Form**
- Vitamin A Laboratory – External Quality Assurance (VITAL-EQA)
  - **Attachment 3f: VITAL-EQA Enrollment Form International**
  - **Attachment 3f-I: VITAL-EQA Enrollment Form Domestic**
  - **Attachment 3f-II: VITAL-EQA Data Submission Form CRP**
  - **Attachment 3f-II: VITAL-EQA Data Submission Form Ferritin**
  - **Attachment 3f-II: VITAL-EQA Data Submission Form Folate**
  - **Attachment 3f-II: VITAL-EQA Data Submission Form sTfR**
  - **Attachment 3f-II: VITAL-EQA Data Submission Form Vit A**
  - **Attachment 3f-II: VITAL-EQA Data Submission Form Vit B12**
  - **Attachment 3f-II: VITAL-EQA Data Submission Form Vit D**
- Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay
  - **Attachment 3g: MPV Folate MBA Enrollment and Data Submission Form**

- Quality Assurance Method Performance Verification (MPV) for Micronutrients
  - **Attachment 3h: MPV Micronutrients Enrollment and Data Submission Form**
- Biomonitoring Quality Assurance Support Program (BQASP)
  - **Attachment 3i: BQASP Recruitment Email**
  - **Attachment 3i-I: BQASP Data Submission Form Cotinine**
  - **Attachment 3i-I: BQASP Data Submission Form PAH**
  - **Attachment 3i-I: BQASP Data Submission Form Perchlorate**
  - **Attachment 3i-I: BQASP Data Submission Form Pesticides**
  - **Attachment 3i-I: BQASP Data Submission Form PFAS**
  - **Attachment 3i-I: BQASP Data Submission Form Phenols**
  - **Attachment 3i-I: BQASP Data Submission Form Phthalates**
- Proficiency in Arsenic Speciation (PAsS) Program
  - **Attachment 3j: PAsS Enrollment Form**
  - **Attachment 3j-I: PAsS Data Submission Form**
- Ensuring the Quality of Urinary Iodine Procedures (EQUIP)
  - **Attachment 3k: EQUIP Enrollment Form**
  - **Attachment 3k-I: EQUIP Data Submission Form**
- Lead and Multielement Proficiency (LAMP) Testing Program
  - **Attachment 3l: LAMP Enrollment Form**
  - **Attachment 3l-I: LAMP Data Submission Form**
- Newborn Screening Quality Assurance Program (NSQAP)
  - **Attachment 3m: NSQAP Enrollment Form**
  - **Attachment 3m-I: NSQAP Data Submission Portal QC**
  - **Attachment 3m-II: NSQAP Data Submission Portal Biochemical PT**
  - **Attachment 3m-III: NSQAP Data Submission Portal Molecular PT**

### A.3. Use of Improved Information Technology and Burden Reduction

All (100%) data collection forms (**Attachment 3a-3m**) are electronic as most laboratorians have access to a computer either at work or at home. In the case of programs in which a participating laboratory receives all analytes included in the program as a result of participation, the enrollment and data submission forms are rolled into one form to reduce the number of forms. In the case of programs in which laboratory participants may select which samples/panels they would like to receive, data submission forms are available by analyte so the respondent only receives the forms pertinent to their analyte selection. For BQASP and VITAL-EQA programs where multiple panels of analytes can be selected, a different analyst from the participating laboratory may perform the analysis for each panel, indicating the need for separate reporting forms.

All forms are either electronic fillable PDF or web-based, online forms or electronic fillable XLSX forms with multiple picklist-enabled data fields to enforce the use of standardized values to promote efficiency and consistency in the collection of information for an analyte or panel of analytes being tested. In the case of NSQAP, reporting occurs through a web portal and online data submission (**Attachment 3m**). In all cases, CDC collects the minimum information necessary for the purposes of providing a statistical and qualitative performance report back to participants based on their analysis and laboratory practices.

## A.4. Efforts to Identify Duplication and Use of Similar Information

No other similar system or method of data collection exists at CDC. External quality assurance programs and reference materials may be provided by this agency or other organizations for other clinical, diagnostic, infectious disease, or other tests not covered by DLS's 13 QA programs.

Laboratories must achieve a standard of practice that ensures safety and quality laboratory science. [Clinical Laboratory Improvement Amendments \(CLIA\) of 1988](#) and ISO standards (**Attachments 1 and 1a**) are examples of the regulations and quality standards laboratories need to meet to obtain certification or accreditation. Many laboratories use proficiency testing (PT) materials from commercial PT programs not only to meet these requirements, but also as an internal mechanism for quality improvement. In the case of newborn screening, however, CDC provides the only comprehensive source of PT materials for newborn screening QA regulations. Additionally, laboratories may develop internal quality control standards as part of their quality assurance plans. CDC's laboratory quality assurance programs provide higher order reference samples by characterizing its QA materials using internationally recognized, highly accurate, precise, and specific laboratory methods. CDC provides QA for designated reference laboratories that supply other labs with assessment materials. CDC also develops standards for commercial laboratories, test manufacturers, vendors, and clinical and academic laboratories and offers this service as a voluntary and free or low-cost program to receive quality control materials for analytes that may not be readily available or offered by other vendors or reference laboratories and that cannot be made in-house.

## A.5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses. Respondents submitting reports to CDC are domestic and/or international laboratories and can include academic or public health laboratories, state or local governmental laboratories, clinical laboratories, commercial

laboratories, and diagnostic test manufacturers. The questions have been held to the absolute minimum required for the intended use of the data/information. Participation in these quality assurance programs is voluntary, unless required by state or jurisdictional laboratory performance bylaws.

## A.6. Consequences of Collecting the Information Less Frequently

The participants will respond to the information collection at differing frequencies depending on the program and the measurements being made. Laboratories will receive, test, and record data on select analytes either quarterly, biannually, or annually. These regular intervals for shipment and data collection provide laboratories with the opportunity to assess their performance and to maintain proficient and quality measurements with acceptable accuracy over time. Each DLS QA program collects information at the frequency needed to maintain acceptable accuracy for particular analyte(s). There are no technical or legal obstacles to reducing burden.

## A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5. No special circumstances are planned or intended for the respondents.

## A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A) A 60-day Federal Register Notice was published in the *Federal Register* on December 27, 2021, Volume 086, page numbers 73280-73283 (**Attachment 2**).

CDC received four non-substantive comments and replied with a standard CDC response to one commenter who provided contact information. (**Attachment 2a**).

B) No consultations outside of CDC occurred.

## A.9. Explanation of Any Payment or Gift to Respondents

No payments, gifts, or incentives will be provided for participation in this collection. CDC provides TA upon request to participating laboratories whose performance needs improvement, as shown by CDC's performance report.

## A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

On 02/28/2022, the Office of the CDC Chief Privacy Officer reviewed this submission and determined that the Privacy Act does not apply. A Privacy Impact Assessment is included with this submission (**Attachment 4**).

Information in Identifiable Form (IIF) categories included in this data collection are the names, phone numbers, and email addresses of laboratory personnel. Individuals responding to this request are doing so as part of their job. The primary purpose for IFF collection is to distribute lab results and certificates of the proficiency testing. Individuals may opt-out of providing their information. However, they will not be able to use the system if they opt-out. Individuals may contact the program using the email or phone number on the website if they believe their information has been inappropriately obtained, used, or disclosed, or that the information is inaccurate. The program will respond to the concerns and correct the issues.

The least privilege model is applied. Managers can only view PII for CDC employees who report to them within each module. Managers can only access PII after having the managerial group permission associated to their account by the system business steward. PII in the system will be retained according to the Scientific and Research Project Records, Records Control Schedule, 3. Minor Research Records. Records are maintained at least six years, but no longer than ten years, after the retirement of the system—depending upon program need for scientific, legal, or business reference—then they are deleted/destroyed.

The system's Security Plan defines the process for handling security incidents. The system's team and the Office of the Chief Information Security Officer (OCISO) share the responsibilities for event monitoring and incident response. The team will direct reports of suspicious security or adverse privacy-related events to the NCEH/ATSDR Information Systems Security officer (ISSO), CDC helpdesk, or to the CDC Incident Response team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

## A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

### Institutional Review Board (IRB)

Each Quality Assurance program has been reviewed by NCEH/ATSDR Office of Science as non-research activity (**Attachment 5**).

### Justification for Sensitive Questions

DLS QA programs do not have questions of sensitive nature (I.e. individual identifiers such as race, medical history or patient information related to laboratory samples.). CDC does not disclose participating laboratory performance results, unless in aggregate of all participant results to demonstrate consistency and reliability between laboratories and reports back to each respondent individually.

## A.12. Estimates of Annualized Burden Hours and Costs

The estimated annualized burden hours were determined as follows. The respondents are participating laboratories that are represented by an individual laboratory analyst who would record the data from their testing results in the supplied data submission form(s). Depending on the program, the average burden per response for the enrollment and data submission forms was determined to be five minutes up to two (2) hours through firsthand experience in testing usability/data entry of forms. The number of respondents fluctuates minimally each year and an average number of participants per program was estimated by each program based on previous years' participation and trends in participation rate since the inception of each program. CDC has estimated the annualized burden for these thirteen (13) programs to be 6,513 hours per year. The annualized number of responses are estimated as 10,804 submissions to NCEH DLS per year.

See "**List of Attachments**" for corresponding forms in the tables below.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
CCB Accuracy-based Laboratory Monitoring Programs (AMP)					
Academic/ University	AMP Enrollment Section on Data Submission Form	10	1	25/60	4
Research Lab	AMP Data Submission Form	10	4	45/60	30

Private Research Lab	AMP Enrollment Section on Data Submission Form	3	1	25/60	1
	AMP Data Submission Form	3	4	45/60	9
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 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	7	1	25/60	3
	LSP Data Submission Form	7	4	45/60	21
Routine Clinical Lab	LSP Enrollment Section on Data Submission Form	40	1	25/60	17
	LSP Data Submission Form	40	4	45/60	120
CCB Cholesterol Reference Method Laboratory Network (CRMLN)					
CRMLN Network Laboratories	CRMLN Enrollment Webpage	15	1	10/60	2
	CRMLN Data Submission Form	15	2	2	60
CCB Hormone Standardization (HoSt) Program					
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	40	1	30/60	20
	HoSt Data Submission Form	40	4	1	160
End-user/ Labs	HoSt Enrollment Section on Data Submission Form	20	1	30/60	10
	HoSt Data Submission Form	20	4	1	80
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	40	1	30/60	20
	VDSCP Data Submission Form	40	4	1	160
End-user/ Labs	VDSCP Enrollment Section on Data Submission Form	20	1	30/60	10
	VDSCP Data Submission Form	20	4	1	80
NBB Vitamin A Laboratory – External Quality Assurance (VITAL-EQA)					
Academic/ University Research Lab	VITAL-EQA Enrollment Form National	30	1	25/60	12
	VITAL-EQA Data Submission Form	30	2	45/60	45
Government/ Ministry of Health Lab	VITAL-EQA Enrollment Form International	30	1	25/60	12
	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	15	1	25/60	6
	MPV Folate MBA Data Submission Form	15	4	45/60	45
Government/ Ministry of Health Lab	MPV Folate MBA Enrollment Section on Data Submission Form	15	1	25/60	6
	MPV Folate MBA Data Submission Form	15	4	45/60	45
Private Research Lab	MPV Folate MBA Enrollment Section on Data Submission Form	5	1	25/60	2
	MPV Folate MBA Data Submission Form	5	4	45/60	15
Clinical Public Health Lab	MPV Folate MBA Enrollment Section on Data Submission Form	5	1	25/60	2
	MPV Folate MBA Data Submission Form	5	4	45/60	15
NBB Quality Assurance Method Performance Verification (MPV) for Micronutrients					
Academic/ University Research Lab	MPV Micronutrients Enrollment Section on Data Submission Form	20	1	25/60	8
	MPV Micronutrients Data Submission Form	20	4	45/60	60
Government/ Ministry of Health Lab	MPV Micronutrients Enrollment Section on Data Submission Form	20	1	25/60	8
	MPV Micronutrients Data Submission Form	20	4	45/60	60
Private Research Lab	MPV Micronutrients Enrollment Section on Data Submission Form	10	1	25/60	4
	MPV Micronutrients Data Submission Form	10	4	45/60	30
Clinical Public Health Lab	MPV Micronutrients Enrollment Section on Data Submission Form	10	1	25/60	4
	MPV Micronutrients Data Submission Form	10	4	45/60	30
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	71	3	45/60	160

	Biochemical (Proficiency Testing) PT				
	NSQAP Data Submission Portal Molecular PT	71	3	45/60	160
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
<b>Total</b>					<b>6,513</b>

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Occupational Employment and Wage Estimates United States website for laboratory technician occupations. Based on May 2021 DOL data, an average hourly wage of \$27.36 ([Clinical Laboratory Technologists and Technicians \(bls.gov\)](https://www.bls.gov)) is estimated for the respondents. The following table shows estimated burden and cost information.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
<b>CCB Accuracy-based Laboratory Monitoring Programs (AMP)</b>				
Academic/ University Research Lab	AMP Enrollment Section on Data Submission Form	4	\$27.36	\$109.44
	AMP Data Submission Form	30	\$27.36	\$820.80
Private Research Lab	AMP Enrollment Section on Data Submission Form	1	\$27.36	\$27.36
	AMP Data Submission Form	9	\$27.36	\$246.24
Routine Clinical Lab	AMP Enrollment Section on Data Submission Form	8	\$27.36	\$218.88
	AMP Data Submission Form	60	\$27.36	\$1,641.60
<b>CCB Lipid Standardization Program (LSP)</b>				
Academic/ University Research Lab	LSP Enrollment Section on Data Submission Form	8	\$27.36	\$218.88
	LSP Data Submission Form	60	\$27.36	\$1,641.60
Private Research Lab	LSP Enrollment Section on Data Submission Form	3	\$27.36	\$82.08
	LSP Data Submission Form	21	\$27.36	\$574.56
Routine Clinical Lab	LSP Enrollment Section on Data Submission Form	17	\$27.36	\$465.12

	LSP Data Submission Form	120	\$27.36	\$3,283.20
<b>CCB Cholesterol Reference Method Laboratory Network (CRMLN)</b>				
CRMLN Network Laboratories	CRMLN Enrollment Email	3	\$27.36	\$82.08
	CRMLN Data Submission Form	60	\$27.36	\$1,641.60
<b>CCB Hormone Standardization (HoSt) Program</b>				
Assay Manufacturers	HoSt Enrollment Section on Data Submission Form	30	\$27.36	\$820.80
	HoSt Data Submission Form	240	\$27.36	\$6,566.40
(LDT) Lab Developed Tests	HoSt Enrollment Section on Data Submission Form	20	\$27.36	\$547.20
	HoSt Data Submission Form	160	\$27.36	\$4,377.60
End-user/ Labs	HoSt Enrollment Section on Data Submission Form	10	\$27.36	\$273.60
	HoSt Data Submission Form	80	\$27.36	\$2,188.80
<b>CCB Vitamin D Standardization Certification Program (VDSCP)</b>				
Assay Manufacturers	VDSCP Enrollment Section on Data Submission Form	30	\$27.36	\$820.80
	VDSCP Data Submission Form	240	\$27.36	\$6,566.40
(LDT) Lab Developed Tests	VDSCP Enrollment Section on Data Submission Form	20	\$27.36	\$547.20
	VDSCP Data Submission Form	160	\$27.36	\$4,377.60
End-user/ Labs	VDSCP Enrollment Section on Data Submission Form	10	\$27.36	\$273.60
	VDSCP Data Submission Form	80	\$27.36	\$2,188.80
<b>NBB Vitamin A Laboratory - External Quality Assurance (VITAL-EQA)</b>				
Academic/ University Research Lab	VITAL-EQA Enrollment Form	13	\$27.36	\$355.68
	VITAL-EQA Data Submission Form	45	\$27.36	\$1,231.20
Government/ Ministry of Health Lab	VITAL-EQA Enrollment Form International	13	\$27.36	\$355.68
	VITAL-EQA Data Submission Form	45	\$27.36	\$1,231.20
Private Research Lab	VITAL-EQA Enrollment Form	6	\$27.36	\$164.16
	VITAL-EQA Data Submission Form	22	\$27.36	\$601.92
Clinical Lab	VITAL-EQA Enrollment Form	6	\$27.36	\$164.16
	VITAL-EQA Data Submission Form	22	\$27.36	\$601.92
<b>NBB Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay (MBA)</b>				
Academic/ University Research Lab	MPV Folate MBA Enrollment Section on Data Submission Form	6	\$27.36	\$164.16
	MPV Folate MBA Data Submission Form	45	\$27.36	\$1,231.20
Government/ Ministry of Health Lab	MPV Folate MBA Enrollment Section on Data Submission Form	6	\$27.36	\$164.16

	MPV Folate MBA Data Submission Form	45	\$27.36	\$1,231.20
Private Research Lab	MPV Folate MBA Enrollment Section on Data Submission Form	2	\$27.36	\$54.72
	MPV Folate MBA Data Submission Form	15	\$27.36	\$410.40
Clinical Public Health Lab	MPV Folate MBA Enrollment Section on Data Submission Form	2	\$27.36	\$54.72
	MPV Folate MBA Data Submission Form	15	\$27.36	\$410.40
<b>NBB Quality Assurance Method Performance Verification (MPV) for Micronutrients</b>				
Academic/ University Research Lab	MPV Micronutrients Enrollment Section on Data Submission Form	8	\$27.36	\$218.88
	MPV Micronutrients Data Submission Form	60	\$27.36	\$1,641.60
Government/ Ministry of Health Lab	MPV Micronutrients Enrollment Section on Data Submission Form	8	\$27.36	\$218.88
	MPV Micronutrients Data Submission Form	60	\$27.36	\$1,641.60
Private Research Lab	MPV Micronutrients Enrollment Section on Data Submission Form	4	\$27.36	\$109.44
	MPV Micronutrients Data Submission Form	30	\$27.36	\$820.80
Clinical Public Health Lab	MPV Micronutrients Enrollment Section on Data Submission Form	4	\$27.36	\$109.44
	MPV Micronutrients Data Submission Form	30	\$27.36	\$820.80
<b>OATB Biomonitoring Quality Assurance Support Program (BQASP)</b>				
State Public Health Labs	BQASP Enrollment Email	1	\$27.36	\$27.36
	BQASP Data Submission Form	8	\$27.36	\$218.88
<b>IRATB Proficiency in Arsenic Speciation (PAsS) Program</b>				
Public Health Labs	PAsS Enrollment Form	5	\$27.36	\$136.80
	PAsS Data Submission Form	19	\$27.36	\$519.84
<b>IRATB Ensuring the Quality of Urinary Iodine Procedures (EQUIP)</b>				
Public Health Labs	EQUIP Enrollment Form	40	\$27.36	\$1,094.40
	EQUIP Data Submission Form	120	\$27.36	\$3,283.20
<b>IRATB Lead and Multielement Proficiency (LAMP) Testing Program</b>				
Public Health Labs	LAMP Enrollment Form	39	\$27.36	\$1,067.04
	LAMP Data Submission Form	154	\$27.36	\$4,213.44
<b>NSMBB Newborn Screening and Quality Assurance Program (NSQAP)</b>				
Domestic NBS Labs	NSQAP Enrollment Form	12	\$27.36	\$328.32
	NSQAP Data Submission Portal QC	107	\$27.36	\$2,927.52

	NSQAP Data Submission Portal Biochemical PT	160	\$27.36	\$4,377.60
	NSQAP Data Submission Portal Molecular PT	160	\$27.36	\$4,377.60
International NBS Labs	NSQAP Enrollment Form	95	\$27.36	\$2,599.20
	NSQAP Data Submission Portal QC	852	\$27.36	\$23,310.72
	NSQAP Data Submission Portal Biochemical PT	1278	\$27.36	\$34,966.08
	NSQAP Data Submission Portal Molecular PT	1278	\$27.36	\$34,966.08
NBS Test Manufacturers	NSQAP Enrollment Form	5	\$27.36	\$136.80
	NSQAP Data Submission Portal QC	48	\$27.36	\$1,313.28
	NSQAP Data Submission Portal Biochemical PT	72	\$27.36	\$1,969.92
	NSQAP Data Submission Portal Molecular PT	72	\$27.36	\$1,969.92
<b>Total</b>				<b>\$178,414.56</b>

### A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

None. Participating laboratories will not incur additional costs to participate in DLS Quality Assurance programs as laboratory staff and instrumentation needed to participate are in place as part of their routine laboratory work.

### A.14. Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Cost (dollars)
AMP, HOST/VDSCP, LSP, CRMLN		
Direct Cost to the Federal Government	CDC Project Manager (GS-12 equivalent) ~60% of time	\$48,256
	CDC Health Scientist Project Oversight (GS-14 equivalent) ~25% of time	\$31,200
	Five (5) CDC Lab Analyst/Technicians - technical assistance, sample development, shipment, data collection, analysis, reporting (GS-12) ~25% of time each	\$482,664
VITAL-EQA		
Direct Cost to the Federal Government	CDC Health Scientist	\$52,300
	QA Program - sample production	\$18,000
	QA Program - sample shipment	\$25,000
MVP Folate MBA		

Direct Cost to the Federal Government	CDC Health Scientist – Start Up Kit Development	\$34,550
	CDC Health Scientist – Survey Kit Development	\$34,550
	QA Program – Sample Production for Start Up Kit	\$38,760
	QA Program – Sample Production for Survey Kit	\$11,240
	QA Program – Shipment for Start Up Kit	\$4,800
	QA Program – Shipment for Survey Kit	\$4,400
	CDC Health Scientist – Folate MVP Coordination	\$34,550
	CDC Health Scientist – Folate MVP sample production & shipment	\$45,080
MPV Micronutrient		
Direct Cost to the Federal Government	CDC Health Scientist	\$34,550
	QA Program – sample production	\$65,520
	QA Program – shipment	\$12,600
BQASP		
Direct Cost to the Federal Government	Project oversight (GS-14, 40-h @ \$62.30/hour)	\$2,492
	QA Program – sample production, analysis, reporting (GS-12, 700-h @ \$50.85/hour)	\$35,595
	Lab Analyst/tech: technical assistance, coordination of shipment (GS 11/12, 24-h @ \$42.43)	\$1,015
PAsS		
Direct Cost to the Federal Government	CDC Health Scientist	\$56,111
	QA Program – sample production and shipment	\$5,000
EQUIP		
Direct Cost to the Federal Government	CDC Health Scientist	\$56,111
	QA Program – sample production and shipment	\$7,500
LAMP		
Direct Cost to the Federal Government	CDC Health Scientist	\$56,111
	QA Program – sample production and shipment (WSLH LAMP contract)	\$49,000
NSQAP		
Direct Cost to the Federal Government	Two (2) CDC Health Scientists – Program Management and Analyst (GS-13/14)	\$211,795
	Five (5) CDC Laboratory Analysts/Technicians (GS-12) Dried Blood Spot Preparation ~50% of time	\$204,095
	QA Program – DBS, QC materials, PT materials shipment	\$100,000
<b>Total</b>		<b>\$1,762,845</b>

Cost was estimated by determining the support staff time to develop and prepare materials, offer TA, and generate reports based on the standard number of participating laboratories and analytes and include operational overhead such as program management, equipment use and maintenance, supplies needed to develop QA materials and costs to ship materials to participating laboratories.

## A.15. Explanation for Program Changes or Adjustments

This is an existing data collection without approval and therefore a new information collection request.

## A.16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for publication of this data. The data is used to provide performance reports to individual laboratory participants and for surveillance of laboratory performance/quality assurance over time (for laboratories that participate routinely).

## A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

## A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.