international laboratories in partnership with the United Nations Office on Drugs and Crimes (UNODC). The CDC vendor will bulk ship these kits to UNODC for international distribution, or the vendor may direct ship these kits to select international laboratories upon UNODC request.

Over the past three years, CDC has received 1,472 requests from interested laboratories (approximately 490 requests per year) and has distributed 3,007 TOM Kits*. Based on this experience and with the addition of EDP Kits, we anticipate that up to 600 domestic laboratories will request test kits per year. Given that each application will take six minutes, the annual time burden for 600 domestic laboratories will be 60 hours.

We will add 30 additional annual burden hours for the international distribution of test kits. We estimate that 300 international partner laboratories will apply for test kits per year with UNODC, assuming the same six minutes per application. The UNODC will compile and report this information to CDC twice a year (15 burden hours per response).

We estimate a total time burden of 90 hours per year, which is a decrease of 30 hours over the previously approved 120 hours. There is no cost to the respondents other than their time to participate.

** TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services.*

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
U.S. Federal Laboratories	Test Kit Application and Questions for U.S. Laboratories (online).	200	1	6/60	20
State, Local, and Tribal Government Laboratories.	Test Kit Application and Questions for U.S. Laboratories (online).	200	1	6/60	20
Private or Not-for-Profit U.S. Institutions.	Test Kit Application and Questions for U.S. Laboratories (online).	200	1	6/60	20
United Nations Office on Drugs and Crimes (UNODC).	Test Kit Distribution Report for International Laboratories.	1	2	15	30
Total	.....	.....	.....	.....	90

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, 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

[30Day–22–22AW]

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 December 27, 2021, to obtain comments from the public and affected agencies. CDC received four non-substantive comments 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—Existing Collection in Use Without an OMB Control Number—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Laboratory quality assurance (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 Centers for Disease Control and Prevention (CDC),

National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS) QA programs operate out of multiple laboratories within the Division. They establish the baseline measurements and provide calibration and/or quality control (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 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 (CCB)
  - 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 (NBB)
  - 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 (OATB)
  - Biomonitoring Quality Assurance Support Program (BQASP)
- Inorganic Radiation and Analytical Toxicology Branch (IRATB)
  - 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 (NSMBB)
  - Newborn Screening and Quality Assurance Program (NSQAP)

All 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.

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 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 time burden for these 13 programs to be 6,513 hours per year. The annualized number of responses are estimated as 10,804 submissions to NCEH DLS. NCEH is requesting a three-year Paperwork Reduction (PRA) Act Clearance. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent (in hours)	Average burden per response (in hours)
CCB Accuracy-Based Laboratory Monitoring Programs (AMP)				
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 ...	3	1	25/60
	AMP Data Submission Form	3	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 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	7	1	25/60
	LSP Data Submission Form	7	4	45/60
Routine Clinical Lab	LSP Enrollment Section on Data Submission Form	40	1	25/60
	LSP Data Submission Form	40	4	45/60
CCB Cholesterol Reference Method Laboratory Network (CRMLN)				
CRMLN Network Laboratories	CRMLN Enrollment Webpage	15	1	10/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent (in hours)	Average burden per response (in hours)
	CRMLN Data Submission Form	15	2	2
CCB Hormone Standardization (HoST) Program				
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	40	1	30/60
	HoSt Data Submission Form	40	4	1
End-user/Labs	HoSt Enrollment Section on Data Submission Form	20	1	30/60
	HoSt Data Submission Form	20	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	40	1	30/60
	VDSCP Data Submission Form	40	4	1
End-user/Labs	VDSCP Enrollment Section on Data Submission Form	20	1	30/60
	VDSCP Data Submission Form	20	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 National	15	1	25/60
	VITAL–EQA Data Submission Form	15	2	45/60
Clinical Lab	VITAL–EQA Enrollment Form National	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.	15	1	25/60
	MPV Folate MBA Data Submission Form	15	4	45/60
Government/Ministry of Health Lab	MPV Folate MBA Enrollment Section on Data Submission Form.	15	1	25/60
	MPV Folate MBA Data Submission Form	15	4	45/60
Private Research Lab	MPV Folate MBA Enrollment Section on Data Submission Form.	5	1	25/60
	MPV Folate MBA Data Submission Form	5	4	45/60
Clinical Public Health Lab	MPV Folate MBA Enrollment Section on Data Submission Form.	5	1	25/60
	MPV Folate MBA Data Submission Form	5	4	45/60
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
	MPV Micronutrients Data Submission Form	20	4	45/60
Government/Ministry of Health Lab	MPV Micronutrients Enrollment Section on Data Submission Form.	20	1	25/60
	MPV Micronutrients Data Submission Form	20	4	45/60
Private Research Lab	MPV Micronutrients Enrollment Section on Data Submission Form.	10	1	25/60
	MPV Micronutrients Data Submission Form	10	4	45/60
Clinical Public Health Lab	MPV Micronutrients Enrollment Section on Data Submission Form.	10	1	25/60
	MPV Micronutrients Data Submission Form	10	4	45/60
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

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent (in hours)	Average burden per response (in hours)
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	71	1	10/60
	NSQAP Data Submission Portal Quality Control (QC)	71	2	45/60
	NSQAP Data Submission Portal Biochemical (Proficiency Testing) PT.	71	3	45/60
	NSQAP Data Submission Portal Molecular PT	71	3	45/60
International NBS Labs	NSQAP Enrollment Form	568	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	32	1	10/60
	NSQAP Data Submission Portal QC	32	2	45/60
	NSQAP Data Submission Portal Biochemical PT	32	3	45/60
	NSQAP Data Submission Portal Molecular PT	32	3	45/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, 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

[30Day–22–22FC]

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 ''Assessing the Capacity of Vector Management Programs in the United States to Provide Comprehensive Community-level Tick Management Services'' 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 May 13, 2022 to obtain comments from the public and affected agencies. CDC did not receive comments 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: 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

Assessing the Capacity of Vector Management Programs in the U.S. to Provide Comprehensive Community-level Tick Management Services—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).