U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: *1/21/26*

Title:	NCEH DLS Laboratory Quality Assurance Programs
Project Id:	0900f3eb81ddfba9
Accession #:	NCEH-DLSPB-9/30/21-dfba9
Project Contact:	Alfonsina De Leon Salazar
Organization:	NCEH/ATSDR/DLS
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	10/01/2021
Estimated Completion Date:	10/01/2024
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1389
Source System #:	2021-0086
OMB Discontinuation Date:	

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Quality Assurance / Improvement	9/17/25	Flores_Sharon (fil4) CIO HSC
PRA: **PRA Applies**		9/17/25	Flores_Sharon (fil4) CIO OMB / PRA
ICRO: **PRA Applies**	OMB Approval date: 5/1/23 OMB Expiration date: 5/31/26	9/19/25	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Date Needed: 11/30/2021

Priority Justification:

CDC Priority Area for this Project: Not selected

Determination Start Date: 11/16/21

Description: The CDC DLS QA and standardization programs operate out of multiple laboratories within the Division. 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). 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.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Submitted through IMS Clearance Matrix: Not selected

Primary Scientific Priority: Not selected

Secondary Scientific Priority (s):	Not selected
Task Force Responsible:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	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.
Objective:	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.
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	No
Activities or Tasks:	All Work Onsite at CDC Facilities
Target Populations to be Included/Represented:	Other - Not Applicable
Tags/Keywords:	DLS 2021-0086
CDC's Role:	CDC is the sole institution conducting activity
Method Categories:	QA/QI
	There are eleven (11) 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 # Clinical Standardization Programs o Accuracy-based Laboratory Monitoring Programs (AMP), covering Lipid Standardization Program (LSP) and AMP for Clinical Biomarkers o Reference Laboratory Networks for Lipids and Other Chronic Disease Biomarkers, covering Cholesterol Reference Method Laboratory Network (CRMLN) and Hormone Reference Networks) o Chronic

Methods:	Disease Standardization Programs for Clinical Biomarkers, covering Hormone Standardization (HoST) Programs and Vitamin D Standardization Certification Program (VDSCP) # Nutrition Biomarkers Branch o Vitamin A Laboratory # External Quality Assurance (VITAL-EQA) o Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay (MBA) o Quality Assurance Method Performance Verification (MPV) for Micronutrients # Organic Analytical Toxicology Branch o Biomonitoring Quality Assurance Support Program (BQASP) # Inorganic and Radiation Analytical Toxicology Branch o Proficiency in Arsenic Speciation (PAsS) Program o Ensuring the Quality of Urinary Iodine Procedures (EQUIP) o Lead and Multielement Proficiency (LAMP) Testing Program # Newborn Screening and Molecular Biology Branch o Newborn Screening and Quality Assurance Program (NSQAP) All eleven (11) CDC quality assurance and standardization 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.
Collection of Info, Data or Biospecimen:	Data will be collected electronically via email and online forms; data reporting forms are returned to DLS via Excel templates, PDFs, or web platforms. 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.
Expected Use of Findings/Results and their impact:	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.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Funding Intramural	Project Funding and Partners				1762845.00

HSC Review

HSC Attributes

Quality Assurance / Improvement	Yes

Regulation and Policy

Do you anticipate this project will require review by a CDC IRB or HRPO?	No
Estimated number of study participants	

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects	
Do you anticipate this project will be exempt research or non-exempt research	

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPAA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Will you be working with an outside Organization or Institution? No

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	CITI Good Laboratory Practice Exp. Date	Staff Role	Email	Phone	Organization
Linde Parcels	08/29 /2026	06/26/2027		12/01/2026		Project Officer		404-498-5892	DLS POLICY BRANCH
Yan Ding	06/26 /2026	06/26/2027		12/01/2026		Project Officer		770-488-7934	DIVISION OF LABORATORY SCIENCES

Data

DMP

Proposed Data Collection Start Date: 9/30/21

Proposed Data Collection End Date: 9/30/24

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - QA/QC

Public Access Justification: 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).

How Access Will Be Provided for Data: Project data is not public health data

Plans for Archival and Long Term Preservation: Data will be archived per Federal records retention standards.

Spatiality

Spatiality (Geographic Locations) yet to be added .....

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	Landing Page URL	Direct Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	09/19/2025	NOA 0920-1398 (2023)	Notice of Action	NOA 0920-1398_2023.pdf
Current	De Leon Salazar_Alfonsina (wvg4) Project Contact	09/16/2025	0920-1389 Collection Instruments	Other	0920-1389 60D collection instruments.zip
Current	De Leon Salazar_Alfonsina (wvg4) Project Contact	09/16/2025	0920-1389 SSA + 60D FRN + 60D template	Other	0920-1389 60D FRN + SSA.zip
	Zirger_Jeffrey (wtj5) ICRO Reviewer	03/21/2023	NOA 0920-1389 (2023)	Notice of Action	NOA 0920-1389_2023.pdf
	Davis_Stephanie I. (sgd8) PRA Reviewer	03/21/2023	Notice of Action	Notice of Action	NOA 0920-1389.pdf
	Davis_Stephanie I. (sgd8) PRA Reviewer	08/29/2022	30D ICR Files to ICRO 20220829	Paperwork Reduction Act Form	30D ICR Files to ICRO 20220829.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	08/29/2022	Worksheets 1 Rows 1-34 to ICRO 20220829; please note there are security issues with ICRO's Worksheet 1; edits could not be saved; therefore, we are delivering a Word document with screenshots.	Paperwork Reduction Act Form	Worksheets 1 Rows 1-34 to ICRO 20220829.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	08/29/2022	Worksheets Rows 35-70 20220829	Paperwork Reduction Act Form	Worksheets Rows 35-70 20220829.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	08/19/2022	30D ICR files	Paperwork Reduction Act Form	30D ICR Files.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	08/19/2022	Worksheet 2's for Rows 35-70	Paperwork Reduction Act Form	Worksheets Rows 35-70.zip
	Davis_Stephanie		Worksheet 1 and Worksheet 2's		

	Davis_Stephanie I. (sgd8) PRA Reviewer	08/19/2022	Worksheet 1 and Worksheet 2 3 for Rows 1-34. Worksheet 1 could not be edited and saved securely.	Paperwork Reduction Act Form	Worksheets 1 Rows 1-34.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	08/19/2022	Burden Table Calculations (Excel and Word document)	Other	Excel Calcs.zip
	Parcels_Linde (oqj1) PRA Reviewer	08/16/2022	Zipfile 3 of Worksheets. This includes new calculations, requested edits, and new worksheets for new rows of NSQAP program per revision conversation in late April.	Paperwork Reduction Act Form	Rev ICR Wrksht II Rows 35-70.zip
	Parcels_Linde (oqj1) PRA Reviewer	08/16/2022	Zipfile of ICR files revised per requested edits. Contains 30 day FRN, publication wrksht, privacy act checklist, list of attachments, SSA, SSB, authorizing leg, regs and standards, 60 day FRN, public comment responses.	Paperwork Reduction Act Form	Rev ICR 1.zip
	Parcels_Linde (oqj1) PRA Reviewer	08/16/2022	Zipfile 3 of Worksheets. This includes Wrksht I and Wrksht II Rows 1-35 with updated data per latest avg salary and OMB calculation style and other requested edits for titling and att references.	Paperwork Reduction Act Form	Rev ICR Wrksht I & Wrksht II Rows 1-35.zip
	Parcels_Linde (oqj1) PRA Reviewer	08/16/2022	Zipfile 2 of Attachment 3-5 with revised edits as requested. This includes all survey instruments /data collection forms, Att 4 - PIA, and Att 5 Non-Research Determination.	Paperwork Reduction Act Form	Rev ICR Attachments 3-5.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	04/15/2022	Zipfile 2 of Worksheets	Paperwork Reduction Act Form	OS Rev Wrksht 2.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	04/15/2022	Zipfile 3 of Worksheets	Paperwork Reduction Act Form	OS Rev Wrksht 3.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	04/15/2022	Zipfile 4 of Worksheets	Paperwork Reduction Act Form	OS Rev Wrksht 4.zip
	Davis_Stephanie I. (sgd8)	04/15/2022	Zipfile of ICR files	Paperwork Reduction Act Form	OS Rev ICR 1.zip

	[illegible] (3gd8) PRA Reviewer	04/13/2022	Zipfile of ICR files	Paperwork Reduction Act Form	OS Rev ICR 1.zip
	Parcels_Linde (oqj1) Project Contact	04/08/2022	Wrksht2 Row 35-67	Paperwork Reduction Act Form	Wrksht2 Row 35-67.zip
	Parcels_Linde (oqj1) Project Contact	04/08/2022	Worksheet 2 for each line of burden table (This compressed file is for rows 1-34)	Paperwork Reduction Act Form	Wrksht2 Row 1-34.zip
	Parcels_Linde (oqj1) Project Contact	04/08/2022	0 - FRN_PblctnRqstWrksht_DLS QA.pdf	Paperwork Reduction Act Form	0 - FRN_PblctnRqstWrksht_DLS QA.pdf
	Parcels_Linde (oqj1) Project Contact	04/08/2022	0 - Privacy Act Checklist_DLS QA. docx	Paperwork Reduction Act Form	0 - Privacy Act Checklist_DLS QA.docx
	Parcels_Linde (oqj1) Project Contact	04/08/2022	1 - List of Attachments DLS QA. docx	Paperwork Reduction Act Form	1 - List of Attachments DLS QA.docx
	Parcels_Linde (oqj1) Project Contact	04/08/2022	1 - SSA DLS Lab QA Programs	Paperwork Reduction Act Form	1 - SSA DLS Lab QA Programs.docx
	Parcels_Linde (oqj1) Project Contact	04/08/2022	1 - SSB DLS Lab QA Programs	Paperwork Reduction Act Form	1 - SSB DLS Lab QA Programs.docx
	Parcels_Linde (oqj1) Project Contact	04/08/2022	Att 3 Data Collection Instruments	Data Collection Form	Att 3 Data Collection Instruments.zip
	Parcels_Linde (oqj1) Project Contact	04/08/2022	Att 4 PIA DLS QA.pdf	Paperwork Reduction Act Form	Att 4 PIA DLS QA.pdf
	Parcels_Linde (oqj1) Project Contact	04/08/2022	Att 1 Authorizing Legislation	Other	Att 1 Authorizing Legislation.pdf
	Parcels_Linde (oqj1) Project Contact	04/08/2022	Att 1a Regulations and Standards. pdf	Other	Att 1a Regulations and Standards.pdf
	Parcels_Linde (oqj1) Project Contact	04/08/2022	Att 2 Published 60 Day Notice 2021-28033.pdf	Paperwork Reduction Act Form	Att 2 Published 60 Day Notice 2021-28033.pdf

	Parcels_Linde (oqj1) Project Contact	04/08/2022	Att 2a Public Comments & Program Responses .docx	Other	Att 2a Public Comments & Program Responses .docx
	Parcels_Linde (oqj1) Project Contact	04/08/2022	Att 5 Non-Research Determination. PNG	Other	Att 5 Non-Research Determination.PNG
	Parcels_Linde (oqj1) Project Contact	04/08/2022	0 - 30_Day_FRN_DLS QA Programs	Paperwork Reduction Act Form	0 - 30_Day_FRN_DLS QA Programs.docx
	Parcels_Linde (oqj1) Project Contact	04/08/2022	Wrksht1 DLS Lab QA Programs. pdf	Paperwork Reduction Act Form	Wrksht1 DLS Lab QA Programs.pdf
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	11/16/2021	Package for request to publish 60-day FRN for this new ICR.	Paperwork Reduction Act Form	60D DLS QA Pgms to ICRO.zip
	Parcels_Linde (oqj1) CIO HSC	11/02/2021	NCEH DLS Quality Assurance Programs 60 Day FRN Request Form	Paperwork Reduction Act Form	0 - 60-day FRN Publication Request Form_DLS QA Programs_rev 11.2.docx
	Parcels_Linde (oqj1) CIO HSC	11/02/2021	60 Day FRN requests inclusion of zipped file of data collection instruments. File name lengths and standard OMB PRA Approval language adhere to attachment guidelines.	Other	Data Collection Instruments Abbreviated.zip
	Parcels_Linde (oqj1) CIO HSC	11/02/2021	NCEH DLS QA Programs 60 Day FRN	Paperwork Reduction Act Form	0 - 60-day_FRN_DLS Quality Assurance Programs rev OS rev DLS 11.2.docx
	Davis_Stephanie I. (sgd8) CIO HSC	10/04/2021	draft 60D FRN with OS comments; focus on reformatting the burden table	Other	0 - 60-day_FRN_DLS Quality Assurance Programs rev OS.docx
	Davis_Stephanie I. (sgd8) CIO HSC	10/04/2021	OS Guide for Attachment Preparation for PRA clearance	Other	1-1 NCEH-ATSDR Guide to Attachment Preparation with Privacy Act Statement.docx
	Parcels_Linde (oqj1) Project Contact	09/30/2021	Zipped file of main data collection instrument(s) as required for inclusion with the 60-day FRN for OMB PRA approval of DLS Quality Assurance Programs	Other-Data Collection Instruments - 60 day FRN DLS QA Programs	Data Collection Instruments.zip
	Parcels_Linde				

	Parcels_Linde (oqj1) Project Contact	09/30/2021	60-day FRN DLS Quality Assurance Programs	Paperwork Reduction Act Form	0 - 60-day_FRN_DLS Quality Assurance Programs.docx
	Parcels_Linde (oqj1) Project Contact	09/30/2021	60-day FRN Publication Request Form for DLS Quality Assurance Programs	Paperwork Reduction Act Form	0 - 60-day FRN Publication Request Form_DLS QA Programs.docx