Enterprise Laboratory Information Management System

Request for OMB approval of an Existing Collection in Use without an OMB Control Number

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Supporting Statement A

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- **Goal of the study:** To record specimen metadata and patient data related to test order requests submitted by external partners (state public health laboratories (SPHLs), International organizations, federal institutions, hospitals, doctor's offices, etc.) to the CDC Infectious Diseases testing laboratories.
- **Intended use of the resulting data:** The collected specimen and patient data are used to help determine the appropriate testing that will be performed by the CDC testing laboratories.
- **Methods to be used to collect:** 1.) *CDC Specimen Submission Form 50.34 v3.3.3* and 2.) *Global File Accessioning Template v4.7*.
- **The subpopulation to be studied:** None.
- **How data will be analyzed:** The data will be analyzed based on the type of test order requested, external partner location, accompanying patient history, and epidemiological information provided.

1. Circumstances Making the Collection of Information Necessary

This is an existing collection in use without an OMB control number. The Centers for Disease Control and Prevention (CDC) is requesting approval for three years.

The CDC Infectious Disease (ID) Laboratories launched a major laboratory informatics project in 2004 to implement a single interoperable Laboratory Information Management System (LIMS), in all infectious diseases specimen-testing laboratories. The project was initiated to resolve challenges in data sharing across laboratories that were encountered during the 2001 anthrax response. Over 90 CDC laboratories were identified as needing to use the common LIMS.

Today the Enterprise Laboratory Information Management System (ELIMS) is a web-based system that Infectious Diseases laboratorians use to accession specimen data, patient information, record results, report data, and manage other laboratory data and documentation. EILMS supports clinical, research, outbreak, and other relevant response work through managing multiple aspects of laboratory informatics. ELIMS's organizational objectives seek to improve laboratory capacity and capabilities.

Authorizing legislation (Attachment 1) comes from Section 301 of the Public Health Service Act (42 U.S.C. 241).

2. Purpose and Use of Information Collection

The collection of specimen information designated for testing by the CDC occurs on a regular and recurring basis (multiple times per day) using an electronic PDF file called the *CDC Specimen Submission 50.34 Form* or an electronic XSLX file called the *Global File Accessioning Template*.

Hospitals, doctor offices, medical clinics, commercial testing labs, universities, state public health laboratories, U.S. federal institutions and foreign institutions use the *CDC Specimen Submission Form 50.34* when submitting a single specimen to CDC Infectious Diseases laboratories for testing. The *CDC Specimen Submission 50.34 Form* consists of over 200 data entry fields (of which five are mandatory

fields that must be completed by the submitter) that captures information about the specimen being sent to the CDC for testing. The type of data captured on the *50.34 Form* identifies the origin of the specimen (human, animal, food, environmental, medical device or biologic), CDC test order name/code, specimen information, patient information (as applicable), animal information (as applicable) information about the submitting organization requesting the testing, patient history (as applicable), owner information and animal history (as applicable) and epidemiological information. The collection of this type of data is pertinent in ensuring a specimen's testing results are linked to the correct patient and the final test reports are delivered to the appropriate submitting organization to aid in making proper health-related decisions related to the patient. Furthermore, the data provided on this form may be used by the CDC to identify sources of potential outbreaks and other public-health related events. When the form is filled out, a user in the submitting organization prints a hard copy of it that will be included in the specimen's shipping package sent to the CDC. The printed form has barcodes on it that allow the CDC testing laboratory to scan its data directly into ELIMS where the specimen's testing lifecycle is tracked and managed.

Likewise, the *Global File Accessioning Template* records the same data as the *50.34 Form* but provides the capability to submit information for a batch of specimens (typically 50-1000 specimens per batch) to a specific CDC laboratory for testing. The CDC testing laboratory electronically uploads the *Global File Accessioning Template* into ELIMS where the batch of specimens are then logged and are ready to be tracked through their respective testing and reporting workflow.

3. Use of Improved Information Technology and Burden Reduction

The collection of information related to the use of the *CDC Specimen Submission 50.34 Form* and the *Global File Accessioning Template* involve the use of Improved Information Technology to reduce the burden in the collection of information and utilize existing data exchange capabilities available in the LIMS.

- *CDC Specimen Submission 50.34 Form*
  - Is an electronic fillable PDF form with multiple picklist-enabled data fields that enforce the use of standardized values to promote efficiency, consistency, and quality in the collection of information for a single specimen.
  - Utilizes barcode data encoding technology that allows for fast and accurate electronic transfer of information from the paper copy of the form into the LIMS.
- *Global File Accessioning Template*
  - Is an electronic fillable XLSX file with multiple picklist-enabled data fields that enforce the use of standardized values to promote efficiency, consistency, and quality in the collection of information for a large batch of specimens.
  - Data in the XLSX file is electronically uploaded quickly and accurately into the LIMS.

4. Efforts to Identify Duplication and Use of Similar Information

No other similar system or method of data collection exists at CDC.

5. Impact on Small Businesses or Other Small Entities

Currently, both the *CDC Specimen Submission 50.34 Form and Global File Accessioning Template* require a minimum number of mandatory data fields to be completed in order to submit a specimen to the CDC for testing.

- For the *CDC Specimen Submission 50.34 Form* these fields are *Specimen Origin, Test Order Name, Specimen source (type*), and *Institutional e-mail*.
- For the *Global File Accessioning Template* these fields are *Package ID, CDC Sample Identifier (CSID), CDC Unique Identifier (CUID), Origin (specimen),* and *Test order name.*

Questions and data requirements for these two forms have been held to the absolute minimum required for the intended use of the information.

6. Consequences of Collecting the Information Less Frequently

The frequency of data collection for both the *CDC Specimen Submission 50.34 Form and Global File Accessioning Template* must occur on a daily basis in order to meet the operational requirements of health care institutions who are attempting to diagnose diseases and make patient health care decisions based on specimen testing performed by the CDC.

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

This request fully complies with the regulation 5 CFR 1320.5.

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 23, 2019, vol. 84, No. 246, pp. 70550-70551 (Attachment 2). CDC did receive public comments related to this notice**.** (Attachment 2a)

B. No consultations outside of CDC occurred.

9. Explanation of Any Payment or Gift to Respondents

No payments, gifts, or incentives will be provided for participation in this collection.

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

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) reviewed this submission and determined that the Privacy Act does apply.

The applicable statement of records notice (SORN) 09-20-0106, Specimen Handling for Testing and Related Data, Federal Register: November 24, 1986 Volume 51, Number 226, Pages 42464-42465

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

An IRB was never conducted for the CDC Specimen Submission 50.34 Form and the Global File Accessioning Template, which have been operational since 2011 and 2005, respectively. Furthermore, CDC officials have confirmed via email that the ELIMS system (of which the 50.34 Form and GFAT are components under) "… is not a research program, and that the information is not collected for research purposes." *Attachment 5*

Sensitive information is collected in these forms as it relates to a patient's symptoms, underlying illnesses/ infections and other noted health conditions. This information is necessary to help the CDC determine the type of testing needed to confirm the presence of a suspected disease.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Responders using the *CDC Specimen Submission 50.34 Form* and *Global File Accessioning Template* typically include medical assistants at doctor's offices and hospitals as well as medical scientists at State Public Health Laboratories. The burden was calculated using ELIMS database information for specimens submitted to the CDC using the *CDC Specimen Submission 50.34 Form* and the number of specimen batches submitted using the *Global File Accessioning Template* for a period of 12 months.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Medical Assistant, Doctor's Office/Hospital	*CDC Specimen Submission 50.34 Form*	2,000	3	5/60	500
19-1042 Medical Scientists, Except Epidemiologists, State Public Health Lab	*CDC Specimen Submission 50.34 Form*	98	193	5/60	1576
Medical Assistant, Doctor's Office/Hospital	*Global File Accessioning Template*	15	11	20/60	55
Total					2131

B. Estimated Annualized Burden Costs

The annualized cost to respondents were based upon mean hourly wage rates for medical assistants and medical scientists information published on the *Bureau of Labor Statistics-May 2018 National Occupational Employment and Wage Estimates* website, https://www.bls.gov/oes/current/oes_nat.htm.

United States

Type of Respondent	Form Name	Total Burden Hours	Mean Hourly Wage Rate	Total Respondent Costs
31-9092 Medical Assistant, Doctor's Office/Hospital	*CDC Specimen Submission 50.34 Form*	500	$16.61	$8,305
19-1042 Medical Scientists, Except Epidemiologists, State Public Health Lab	*CDC Specimen Submission 50.34 Form*	1576	$46.36	$73,063
31-9092 Medical Assistant, Doctor's Office/Hospital	*Global File Accessioning Template*	55	$16.61	$914
Total				$82,282

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

The average annualized cost to the Federal Government to collect this information is $132,062. The federal government personnel cost estimate is based on using two resource types The first resource is a CDC laboratorian (GS-13) who is responsible for barcode scanning 25,170 (annual total count) *CDC Specimen Submission 50.34 Forms* into ELIMS at an average time of 12 seconds per form which calculates to 84 hours for all 25,170 forms. The CDC laboratorian (GS-13) is also responsible for preparing and uploading 3,234 *Global File Accessioning Templates* into ELIMS at an average time of 20 minutes per template. The total time for processing 3,234 templates is 1,078 hours.

The second resource type is an IT Specialist (contractor) that provides up to 600 hours annually to provide on-going production support as well as requirements identification, design, development, testing and deployment of new content to both the *CDC Specimen Submission 50.34 Form* and *Global File Accessioning Template*. The average hourly rate cost to the government for an IT Specialist to support these activities is $122.00

Exhibit A.14.1. Government Costs

		Percent Time	Total ($)
Federal Government	CDC Laboratorian (GS-13) (using the annual 2,087-hour divisor for federal employees)	56%	$58,862
Personnel Costs	IT Specialist (contractor) (using the annual 1,960-hour divisor for contract staff)	31%	$73,200
Total Annualized Cost to Government			$132,062

15. Explanation for Program Changes or Adjustments

This is a request for OMB approval of an Existing Collection in Use without an OMB Control Number.

16. Plans for Tabulation and Publication and Project Time Schedule

ELIMS data collection is ongoing and continuous. There are no plans to publish findings.

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

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Authorizing Legislation
2. 60-Day FRN

2a. Public Comments

3. Information Collection instruments
    a. CDC Specimen Submission Form 50.34 v3.3.3
    b. Global File Accessioning Template v4.7
4. Privacy Impact Assessment
5. IRB Email