



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-20EC; Docket No. CDC-2019-0115]

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Enterprise Laboratory Information Management System which is a system used to record specimen metadata and patient data related to test order requests submitted by external partners (state public health laboratories, International organizations,

federal institutions, hospitals, doctor's offices, etc.) to the CDC Infectious Diseases testing laboratories.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0115 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

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

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

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffery M. Zirger, of the Information Collection Review Office, Centers for Disease

Control and Prevention, 1600 Clifton Road, N.E., MS-D74,
Atlanta, Georgia 30329; phone: 404-639-7570; E-mail:
omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

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

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Enterprise Laboratory Information Management System (ELIMS) - Existing Collection in Use without an OMB Control Number - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

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's 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. CDC requests approval for 2,047 annual burden hours. There is no cost to respondents other than their time.

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) |
|---|---|-----------------------|------------------------------------|--|-------------------------|
| Medical Assistant, Doctor's Office/Hospital | <i>CDC Specimen Submission 50.34 Form</i> | 2,000 | 3 | 5/60 | 480 |
| 19-1042 Medical | <i>CDC Specimen</i> | 98 | 193 | 5/60 | 1,513 |

| | | | | | |
|---|--|----|----|-------|-------|
| Scientists, Except Epidemiologists, State Public Health Lab | <i>Submission 50.34 Form</i> | | | | |
| Medical Assistant, Doctor's Office/Hospital | <i>Global File Accessioning Template</i> | 15 | 11 | 20/60 | 54 |
| Total | | | | | 2,047 |

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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