

for Disease Control and Prevention (CDC).

Background and Brief Description

Under the Public Health Service Act (42 United States Code 264), and under 42 Code of Federal Regulations (CFR) 71.4 and 71.5, CDC can order air carriers and maritime vessels arriving from another country to submit a certain information related to passengers and crew that CDC believes were exposed to co-traveler infected with a communicable disease of public health concern.

Stopping a communicable disease outbreak—whether it is naturally occurring or intentionally caused—requires the use of the most rapid and effective public health tools available. Basic public health practices, such as collaborating with airlines in the identification and notification of potentially exposed contacts, are critical tools in the fight against the introduction, transmission, and spread

of communicable diseases in the United States.

The collection of pertinent contact information enables Quarantine Public Health Officers in CDC's Division of Global Migration and Quarantine (DGMQ) to notify state and local health departments in order for them to make contact with individuals who may have been exposed to a contagious person during travel and identify appropriate next steps.

In the event that there is a confirmed case of communicable disease of public health concern aboard an aircraft or maritime vessel, CDC collects manifest information for those passengers and crew at risk for exposure. This specific manifest information collection differs depending on the communicable disease that is confirmed during air or maritime travel. CDC then uses this passenger and crew manifest information to coordinate with state and local health departments so they can follow-up with residents who live or are

currently located in their jurisdiction. In general, state and local health departments are responsible for the contact investigations. In rare cases, CDC may use the manifest data to perform the contact investigation directly. In either case, CDC works with state and local health departments to ensure individuals are contacted and provided appropriate public health follow-up.

CDC estimates that for each traveler manifest ordered, airlines require approximately six hours to review the order, search their records, and send those records to CDC. There is no cost to respondents other than their time perform these actions. The total estimated hourly burden to respondents as a result of this information collection is 600 hours per year. While CDC has included maritime conveyance manifest orders in the public health rationale for this information collection, these orders are rare and are not included in the burden table.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International TB Manifest Template.	51	1	360/60	306
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International Non-TB Manifest Template.	49	1	360/60	294
Total	600

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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 February 21, 2020.

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 NE, 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 Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: 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 50–1,000 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 Scientists, Except Epidemiologists, State Public Health Lab.	<i>CDC Specimen Submission 50.34 Form.</i>	98	193	5/60	1,513
Medical Assistant, Doctor's Office/Hospital	<i>Global File Accessioning Template.</i>	15	11	20/60	54
Total	2,047

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