BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-0850; Docket No. CDC-2018-0088]

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 Laboratory Response Network to maintain an integrated national and international network of laboratories that can respond to suspected acts of biological, chemical, or radiological terrorism and other public health emergencies.

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-2018-0088 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 Jeffrey M. Zirger, 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

Laboratory Response Network Information Collection (OMB Control No. 0920-0850, Exp. Date: 4/30/2019) - Extension – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a 3-year extension without change to the data collection plan or tools for Laboratory Response Network (OMB Control No. 0920-0850, Exp. Date: April 30, 2019). The only change is a decrease in the estimated burden from 2,382,300 to 2,064,660 annual hours. The decrease is due to a decrease in the number of LRN member laboratories from 150 to 130 laboratories.

The Laboratory Response Network (LRN) was established by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to federal departments and agencies. The LRN's mission is to maintain an integrated national and international network of

laboratories that can respond to suspected acts of biological, chemical, or radiological terrorism and other public health emergencies.

Federal, state and local public health laboratories join the LRN voluntarily. When laboratories join, they assume specific responsibilities and are required to provide information to the LRN Program Office at CDC. Each laboratory must submit and maintain complete information regarding the testing capabilities of the laboratory. Biennially, laboratories are required to review, verify and update their testing capability information. This information is needed so that the LRN Program Office can determine the ability of the Network to respond to a biological or chemical terrorism event. The sensitivity of all information associated with the LRN requires that CDC obtain personal information about all individuals accessing the LRN Website. Since CDC must be able to contact all laboratory personnel during an event, each laboratory staff member who obtains access to the restricted LRN Website must provide his or her contact information to the LRN Program Office.

As a requirement of membership, LRN laboratories must report all biological and chemical testing results to the LRN Program using a CDC developed software tool called the LRN Results Messenger, or through the laboratory information

management system (LIMS) which CDC refers to as Data Integration. CDC supplies this software to LRN laboratories at no charge. This information obtained from LRN laboratories is essential for surveillance of anomalies, to support response to an event that may involve multiple agencies, and to manage limited resources.

LRN laboratories are also required to participate in Proficiency Testing Challenges or Validation Studies and report their results to CDC. LRN laboratories participate in multiple Proficiency Testing Challenges, Exercises and/or Validation Studies every year. These activities consist of 5-500 simulated samples provided by CDC. These challenges are necessary to verify the testing capability of the LRN laboratories. Because biological or chemical agents perceived to be of bioterrorism concern can occur rarely, some LRN laboratories may not be maintaining proficiency in certain testing methods as a result of day-to-day testing. Thus, simulated samples are distributed to ensure proficiency across LRN member laboratories. LRN laboratories also enter the results of these simulated samples into the LRN Results Messenger or through Data Integration for evaluation by CDC.

During a surge event resulting from a bioterrorism or chemical terrorism attack, or during an emerging infectious disease outbreak, LRN Laboratories must submit all testing

results using LRN Results Messenger or through Data Integration. CDC uses these results in order to track the progression of a bioterrorism event, responds in the most efficient and effective way possible, and shares this data with other Federal partners involved in the response.

Data is collected via two primary avenues, the program LRN Results Messenger or through Data Integration and the LRN Website. Laboratories belonging to the Laboratory Response Network utilize the CDC developed software tool LRN Results Messenger to submit testing results to CDC. Data Integration through the Laboratory Information Management System Integration (LIMSi) is an effort parallel to the LRN Results Messenger, which will ultimately allow laboratories to submit data to CDC using their own data collection systems. Results include details about the type and source of samples as well as the tests performed and the numerical and empirical results of those tests. The LRN Website is used by laboratories to provide their complete testing capabilities to CDC. All individuals who use the LRN Website must provide their contact information to the LRN Program Office during registration.

An LRN laboratory must provide its testing capabilities, physical and shipping addresses, United States Department of Agriculture (USDA) and Select Agent Permits, and specified responsible individuals' names, phone numbers and email

addresses. After registering with the LRN Website, a user must provide his/her first and last name, work phone number, alternate phone number, email address, and month and day of birth. During reporting of results, sample details, tests performed, results obtained, and conclusions of tests are required.

Accomplishments during the last three years include the requalification of labs. The requalification occurred between October 24, 2014 and November 7, 2016 and December 12, 2016. We had 130 domestic LRN labs tasked with completing the requalification. We had a 96% response rate. The LRN website has remained the same, and has only undergone routine maintenance since 2015 to keep it in working order. This data collection is authorized under the Public Health Service Act, (42 USC 241) Section 301. CDC has estimated the annualized burden for this project to be 2,064,660 hours, a decrease of 317,640 hours per year. There is no cost to respondents other than the time to participate.

Estimated Annualized Burden Hours

Respondents	Forms	Number of Respondents	Average Number of Responses per Respondent	Average Burden Per Response (hours)	Total Burden Hours

Public Health Laboratories	Biennial Requalification	130	1	2	260
	General Surveillance Testing Results	130	25	24	78,000
	Proficiency Testing/ Validation Testing Results	130	5	56	36,400
	Surge Event Testing Results	130	625	24	1,950,000
				Total	2,064,660

Jeffrey M. Zirger,

Acting Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

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