



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-0850]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Laboratory Response Network to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on October 4, 2018 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) 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;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) 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 submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Laboratory Response Network (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 three year extension without change to the data collection plan or tools. The only change is a decrease in annual burden hours from 2,382,300 to 2,064,660. 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 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 November 7, 2016 and December 12, 2016. We had 130 domestic LRN labs tasked with completing the requalification, and 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

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Public health laboratories	Biennial Requalification	130	1	2
	General Surveillance Testing Results	130	25	24
	Proficiency Testing/ Validation Testing Results	130	5	56
	Surge Event Testing Results	130	625	24

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