



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day-16-0850]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

## **Proposed Project**

### Background and Brief Description

Laboratory Response Network, (OMB Control Number 0920-0850, expires April 30, 2016) - Extension - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

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 threats and other public health emergencies.

When Federal, State and local public health laboratories voluntarily join the LRN, 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. Complete testing capability information is required in order for the LRN Program Office to determine the ability of the Network to respond to a biological or chemical threat event. The sensitivity of all information associated with the LRN requires the LRN Program Office to obtain personal information about all individuals accessing the LRN Web site. In addition, the LRN Program Office must be able to contact all laboratory personnel during an event so each laboratory staff member that obtains

access to the restricted LRN Web site 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 at CDC using a CDC developed software tool called the LRN Results Messenger. This information is essential for surveillance of anomalies, to support response to an event that may involve multiple agencies and to manage limited resources. LRN Laboratories must also participate in and report results for Proficiency Testing Challenges or Validation Studies. LRN Laboratories participate in multiple Proficiency Testing Challenges, Exercises and/or Validation Studies every year consisting of five to 500 simulated samples provided by the LRN Program Office. It is necessary to conduct such challenges in order to verify the testing capability of the LRN Laboratories. The rarity of biological or chemical agents perceived to be of bioterrorism concern prevents some LRN Laboratories from maintaining proficiency as a result of day-to-day testing. Simulated samples are therefore distributed to ensure proficiency across the LRN. The results obtained from testing these simulated samples must also be entered into Results Messenger for evaluation by the LRN Program Office.

During a surge event resulting from a bioterrorism or chemical terrorism attack, LRN Laboratories are also required to

submit all testing results using LRN Results Messenger. The LRN Program Office requires these results in order to track the progression of a bioterrorism event and respond in the most efficient and effective way possible and for data sharing with other Federal partners involved in the response. The number of samples tested during a response to a possible event could range from 10,000 to more than 500,000 samples depending on the length and breadth of the event. Since there is potentially a large range in the number of samples for a surge event, CDC estimates the annualized burden for this event will be 2,250,000 hours or 625 responses per respondent.

The requalification occurred between October 24, 2014 and November 7, 2014. We had 122 domestic LRN labs tasked with completing the requalification. We had a 90% response rate.

We conducted LRN proficiency testing (PT). The purpose of PT is to simulate real samples for labs that would not have regularly performed some of the LRN procedures. Having the ability to conduct LRN PTs under OMB approval has led to improved laboratory performance and better preparedness. In FY13, the PT passing rate was 89%, which improved to 96% in FY14 and 97% in FY15.

There is no cost to the respondents other than their time. The total estimated annualized burden is 2,382,300 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Average Number of Responses per Respondent	Average Burden Per Response (hours)
Public Health Laboratories	Biennial Requalification	150	1	2
Public Health Laboratories	General Surveillance Testing Results	150	25	24
Public Health Laboratories	Proficiency Testing/ Validation Testing Results	150	5	56
Public Health Laboratories	Surge Event Testing Results	150	625	24

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