Data Calls for the Laboratory Response Network

Request for Revision of OMB Control No. 0920-0881 (Expiring 3/31/17)

Supporting Statement A

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Contact:
Lee Samuel
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS C-12
Atlanta, Georgia 30333
Phone: (404) 718-1616

Email: llj3@cdc.gov

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List of Attachments

Goal: The goal of the survey is to collect information about laboratory capabilities, equipment or personnel.
Intended Use of resulting data: The information gathered will assist the LRN Program Office in decisions about testing platforms used by LRN members thereby shaping the scope of emerging infectious disease responses.
Methods: Surveys will be conducted by email with LRN Helpdesk or through online survey tools.
Subpopulation to be studied: Laboratory Response Network members
How the data will be analyzed: The data collected from the survey will be used to shape incident response plans and assay development strategies based on specific equipment possessed by the majority of LRN member laboratories.

A. Justification

l. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is submitting a request for a three (3) year revision for OMB Control No. 0920-0881, an existing collection conducted by Laboratory Response Network (LRN), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). Although the LRN Program Office at CDC has an extensive database of information regarding all network members, LRN Special Data Calls are sometimes needed to address issues concerning the response capabilities of member facilities for priority threat agents or to assess the network's ability to respond to new emerging threats. This is a generic clearance that is necessary for any impromptu data calls that are needed.

In the last three years, two generic information collections have been conducted. In 2014, when there was an Ebola case in the U.S., LRN contacted their member laboratories asking how many would be willing to perform an Ebola virus assay (Attachment 4). The information collected resulted in the LRN deploying a new assay to its members.

Again, in 2015, it became necessary for LRN to survey our laboratories to find out if they had a specific laboratory instrument (Attachment 5). The information was used to help the LRN program office determine if new procedures should be written.

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 (Attachment 1), which outlined national anti-terrorism policies and assigned specific missions to Federal Departments and agencies. The Administration has stated that it is the policy of the United States to use all appropriate means, to deter, defeat, and respond to all terrorist attacks on our territory and resources, both with people and facilities. 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 facility information to the LRN Program Office at CDC as well as test results for real samples or proficiency tests. LRN laboratories participate in Proficiency Testing Challenges, Exercises and Validation Studies each year. The Frequency of the data collection will be conducted twice a year. LRN information collection is covered by OMB control no. 0920-0852.

CDC may conduct a Special Data Call to obtain additional information from LRN laboratories regarding biological or chemical terrorism preparedness. Special Data Calls may be conducted via broadcast email that asks respondents to send information via email to the LRN Help Desk or through online survey tools (i.e. Survey Monkey) which require respondents to go to a web link and answer a series of questions (Attachment 3).

Data collection for this project is authorized under the Public Health Service Act, (42 USC 241) Section 301. A copy is included in the attachments (Attachment 1a).

2. Purpose and Use of Information Collection

The LRN has used the generic 0920-0881 only twice since 2014. However, it is important to indicate that a lack of use should not be a signal for a lack of need. Emerging infections and outbreaks are not predictable and the LRN program is requesting an extension for OMB 0920-0881 to perform critical data calls of LRN member laboratories should the circumstance arise.

One instance occurred in 2014 with the Ebola case in the U.S. LRN members were asked via broadcast email if their facilities were willing and able to conduct Ebola testing (see attachment 4). This led to emergency deployment of a new Ebola assay for LRN members. It's critical for the LRN to know which labs have equipment to support an agent specific assay during an emergency. Also, during the two years between Biennial Requalification, CDC may need to obtain additional information from the LRN laboratories to better understand or quantify the network's preparedness. Surveying participating labs during this time is critical.

Collecting information through Special Data Calls is necessary for the CDC to make critical program decisions. For example, in 2015, we asked members via broadcast email how many facilities had a specific version of an instrument (see attachment 5). The information was used to help the LRN program office determine if new procedures should be written and made available to members to support the instrument in question.

The LRN program office within the Division of Preparedness and Emerging Infections (DPEI) at CDC will maintain this ICR and review any versions of data requests using this ICR approval for CDC. The LRN Program Office will be responsible for ensuring the generic ICRs are submitted with a mini-supporting statement under the generic ICR's OMB number.

3. Use of Improved Information Technology and Burden Reduction
Special Data Calls are conducted using email or survey tools which can be accessed using any web browser. All information is reported electronically. Thus, 100% of information is collected electronically. CDC only collects the minimum information necessary for the purposes of maintaining the operations of the LRN.

4. Efforts to Identify Duplication and Use of Similar Information
There is no similar data collection conducted either within the Federal government or privately. There is no overlap or duplication of specific projects. NCEZID has verified through RegInfo.gov that there are no other federal generic collections that duplicate the data collection in this request.

5. Impact on Small Businesses or Other Small Entities
This data collection will not involve small businesses. Respondents are other Federal, state, or local governmental laboratories. The data requested has been held to the absolute minimum required for its intended use.

6. Consequences of Collecting the Information Less Frequently
There are no legal obstacles to reduce the burden. Special Data Calls are conducted semiannually when additional information is required by CDC to evaluate and ensure the preparedness of the network.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
A. A 60-day Federal Register Notice was published in the *Federal Register* on 11/17/2016, Vol. 81, No. 222, pp. 81146-81147 (Attachment 2). One public comment was received (Attachment 2a). However, because there was no return mailing address, no response was sent.

B. No one was consulted on this collection.

9. Explanations of Any Payment or Gift to Respondents
There will be no remuneration for participants.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
This information collection request has been reviewed by NCEZID who has determined that the Privacy Act does not apply. Individuals responding to this request are doing so as part of their job. Although participation in the Laboratory Response Network is voluntary, member laboratories are required to provide information as a condition of membership.

Privacy Impact Assessment

Overview of the Data Collection System
Special Data Calls may be conducted via broadcast email that asks respondents to send information via email to the LRN help desk or through online survey tools (i.e. Survey Monkey) which require respondents to go to web link and answer a series of questions. CDC will not receive any personally identifiable information. The types of information collection activities included in this generic package are: questionnaires that are provided to members through email communications or online survey tools (i.e Survey Monkey).

Items of Information to be collected
Special data calls are unique and hard to predict the level of detail of the questions that may be asked of network members. Some example questions that will most likely be used are included in Attachment 3.

Identification of Websites and Website Content Directed at Children Under 13 Years of Age
Under no circumstances will CDC sponsored data collection, websites or internet content directed at children under the age of 13.

Personal identifiable information is collected as a condition of membership in the LRN as a mechanism to maintain communication with members. The collection of personal identifiable information to maintain communication with members was approved in OMB 0920-0850, The Laboratory Response Network. Examples of personal identifiable information would include work phone number and address and birthday and birth month.

Information that is collected from LRN members is restricted to program staff. Individuals outside of the program that request access to data must provide justification to see data and sign nondisclosure agreements. Data is contained electronically on program staff personal computers that are password protected.

Respondent consent is not needed for special data calls. LRN member laboratories have the option to respond or decline response.

If a special data call should require mandatory response from all members, the LRN program office would indicate that requirement when the special data call is announced.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions
Justification for Sensitive Questions
LRN does not have questions of sensitive nature (i.e. individual identifiers such as race, medical history or patient information related to laboratory samples).

Institutional Review Board (IRB)
This information collection was reviewed by NCEZID's Human Subjects Advisor who determined that the project does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (attachment 6)

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The number of respondents has decreased from 150 to 136 in the past three years thereby reducing the estimated annualized response burden for data collections under the generic clearance to 68 hours. A participant responding to the questions is estimated to take 30 minutes. We may ask for information about new equipment purchases or staff trained on a particular procedure.

Exhibit A.12.A Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden Per Response (in hours)	Total Burden Hours
Public Health Laboratorians	Special Data Call	136	1	30/60	68
Total					**68**

Estimated Annualized Burden Cost

The estimated annualized costs were determined by using the 2016 General Schedule Pay Tables for a GS-11, Step 5 scientist.

Exhibit A.12.B Estimated Annualized Burden Cost

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Public Health Laboratorians	68	$33.64	$2,287.52
Total	**68**		$2,287.52

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

CDC does not anticipate providing start up or other related costs to private entities.

14. Annualized Cost to the Government

Estimated annualized costs were determined by using the 2016 General Schedule Pay Tables for a GS-11, Step 7 scientist. No other expense will be incurred for this collection.

Expense Type	Expense Explanation	Annual Cost (dollars)
Direct Cost to the Federal Government	CDC Health Scientist	$74,346.00
TOTAL COST TO THE GOVERNMENT		**$74,246.00**

15. Explanation for Program Changes or Adjustments

In the last three years, we have used this generic only twice so we reduced the burden for this submission from 75 to 68 hours. The number of LRN members decreased from 150

to 136 members, thereby reducing the number of respondents, while the responses per respondent remains at 1.

16. Plans for Tabulation and Publication and Project Time Schedule
There are no plans for publication of this data. The data is used for surveillance of possible terror events and public health emergences and to assess competencies of LRN member laboratories.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submission
There are no exceptions to the certification