

## **Data Calls for the Laboratory Response Network**

**Request for OMB Approval of an Existing Data Collection in use without an OMB  
Control Number (Generic Clearance)**

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2. Public Health Service Act (42 USC 241) Section 301
3. 60 Day Federal Register Notice
4. LRN Data Elements
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**Data Calls for the Laboratory Response Network  
Existing Data Collection in use without an OMB Control Number  
(Generic Collection)**

**Supporting Statement**

**A. Justification**

**I. Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention (CDC) is submitting a request for three (3) year approval for an Existing Collection in use without an OMB Control Number (Generic Clearance) information 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. CDC discovered this data collection during a review of a Request for Contract.

**Background**

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. 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 on line survey tools (i.e. Survey Monkey) which require respondents to go to a web link and answer a series of questions (Attachment 4).

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 2).

### **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 (Attachment 5).

#### **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.

## **2. Purpose and Use of Information Collection**

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. A Special Data Call would be conducted by CDC in this situation to obtain the necessary information. For example in 2009, we asked members via broadcast email how many facilities had a specific version of an instrument? 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 Master ICR's OMB number.

### **Privacy Impact Assessment**

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 under OMB 0920-0850.

## **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**

No small businesses will be involved in this data collection. 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 June 17, 2010, Vol. 75, No. 116, pp 34451 -34452 (Attachment 3). No comments were received from the public.

This was a presidential decision directive which validates and reaffirms the CDC's responsibility for this counterterrorism project.

#### **9. Explanations of Any Payment or Gift to Respondents**

There will be no remuneration for participants.

#### **10. Assurance of Confidentiality Provided to Respondents**

This information collection request has been reviewed by CDC's Information Collection Review Office 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**

A. This information collection request has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), and 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.

B. 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.

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

D. 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. 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)

**12. Estimated of Annualized Burden Hours and Costs**

**A. Estimated Annualized Burden Hours**

The annualized response burden for data collections under this generic clearance is estimated at 400 hours. Exhibit A.12.A. provides details about how this estimate was calculated. A participant responding to the questions is estimated to take 30 minutes.

**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	200	4	30/60	400
<b>Total</b>					<b>400</b>

**Estimated Annualized Burden Cost**

The estimated annualized costs were determined by using the 2010 General Schedule Pay Tables for a GS-11, Step 5 scientist.

**Exhibit A.12.A** Estimated Annualized Burden Cost

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Public Health Laboratorians	400	\$27.31	\$10,924
<b>Total</b>	<b>400</b>		<b>\$10,924</b>

**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 Federal Government**

Estimated annualized costs were determined by using the 2010 General Schedule Pay Tables for a GS-11, Step 7 scientist. No other expense will be incurred for this collection.

<b>Expense Type</b>	<b>Expense Explanation</b>	<b>Annual Cost (dollars)</b>
Direct Cost to the Federal Government	CDC Health Scientist	\$118,750.00
<b>TOTAL COST TO THE GOVERNMENT</b>		<b>\$118, 750.00</b>

**15. Explanation for Program Changes or Adjustments**

This is a request for approval of an Existing Collection in use without an OMB control number for special data calls. This is a request for generic clearance.

**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 emergencies and to assess competencies of LRN member laboratories.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

No exemption from display of expiration date is being requested.

**18. Exceptions for Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification

**B. Collections of Information Employing Statistical Methods**

The Laboratory Response Network’s (LRN) 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. This collection of information does not employ statistical methods.

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. Twice a year, CDC may conduct a Special Data Call to obtain additional information from LRN laboratories regarding biological or chemical terrorism preparedness. Special Data Calls are conducted using email communications and survey tools (i.e. Survey Monkey).

**1. Respondent Universe and Sampling Methods**

Respondents include members of the Laboratory Response Network. Expected response rate as determined by previous data collections is 80% or better. No statistical methods are used to determine the sampling group for respondents.

## **2. Procedures for the Collection of Information**

No statistical methods are employed for the collection of information. Individuals at the LRN Program will assess if data exists in current database on LRN website. If additional information is needed a questionnaire will be developed and method for distribution (i.e. email, survey tool) will be determined. An announcement will be sent to all members by email requesting their response to the special data call and detailed instructions on how and when to respond. LRN Program office will review data collected and contact members that have not responded as needed. Data will be compile and summarized and used internally at CDC for public health and program decisions.

## **3. Methods to Maximize Response Rates and Deal with No Response**

If limited responses to a special data call are received from LRN member laboratories the LRN Program office at CDC will extend the deadline to respond and send another announcement of the data call and the need for the information by broadcast email. No responses after second announcement will be followed up by a maximum of two personal phone calls to the Lab Director of the LRN member laboratory.

## **4. Tests of Procedures or Methods to be Undertaken**

If a tool such as Survey Monkey is used to collect data it will be tested by individuals within and external to CDC/LRN Program office to assure functionality exists and questions are clear. More extensive questionnaires may be piloted with 8-10 LRN member laboratories before requesting all members to respond.

## **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

No individuals consulted are consulted on statistical aspects or the design of the data collection.