Laboratory Response Network

Existing Data Collection in use without an OMB Control Number
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CDC is requesting OMB approval of an existing data collection in use without an OMB Control Number. CDC discovered this data collection during a review of a Request for Contract. CDC is requesting a 3 year approval to collect data and will include this data collection as an existing data collection in use without an OMB Control Number during the next Information Collection Budget submission.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 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. 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 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 for evaluation by CDC.

During a surge event resulting from a bioterrorism or chemical terrorism attack, LRN Laboratories must submit all testing results using LRN Results Messenger. CDC uses these results in order to track the progression of a bioterrorism event, respond in the most efficient and effective way possible, and shares this data 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 has estimated the annualized burden for this event will be 3,000,000 hours or 625 responses per respondent.

This data collection 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

Data is collected via two primary avenues, the program LRN Results Messenger 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. 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.

Items of Information to be Collected

An LRN laboratory must provide its testing capabilities, physical and shipping addresses, 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.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The LRN Website is not directed at children less than 13 years of age.

2. Purpose and Use of Information Collection

The information collected in the Biennial Requalification is utilized on a daily basis by both CDC and LRN member laboratories. Details of the laboratories' testing capabilities are an indication of the capability of the network as a whole. CDC uses the testing capabilities entered by laboratories to determine participation in LRN Proficiency Testing challenges. The responsible parties' contact information provided in the Biennial Requalification ensures up-to-date contact information for accurate and efficient communications between CDC and the laboratories. The shipping addresses are necessary for the shipment of PT Challenges and the shipment of reagents ordered via the LRN Website. The physical address of the LRN laboratories is utilized for mapping laboratories in a Lab Referral Directory.

LRN member laboratories also have access to the testing capability information entered during the Biennial Requalification and can use this information to search for a laboratory with a certain testing capability within a certain area relative to their location in order to refer samples for additional testing.

General Surveillance Testing Results are collected constantly so CDC can evaluate and track potential events and outbreaks on a continual basis. General Testing Results also provide CDC with data about workload and affectivity of the LRN when reviewed over periods of time or reviewed retrospectively.

LRN laboratories are required to submit of Proficiency Testing or Validation Testing Results approximately once a month. The results of this testing provides both the LRN Laboratories and CDC with information about actual capability and preparedness of the LRN. Performance during Proficiency Testing Challenges can influence a laboratory's status as an LRN laboratory. Because biological and chemical terrorism events have been rare, Proficiency Testing Challenges and Validation Testing ensure the effectiveness of the LRN.

Surge Event Testing Results are those results entered by LRN laboratories during an actual biological or chemical terrorism event or a naturally occurring outbreak. The quantity of samples for which results would be reported have the potential to be drastically larger than the number reported during General Surveillance. Data must be reported during an event in order for CDC and HHS to track the progression of an event or outbreak. If CDC did not have this reporting, CDC would not be able to efficiently and effectively allot its limited resources.

<u>Privacy Impact Assessment Information</u>

Information in Identifiable Form categories included in this data collection are the names, date and month of birth, phone numbers, and email addresses of laboratory personnel. The date and month of birth are collected as a security precaution. If a user forgets his or her password to log in to the LRN Website, he or she is prompted to verify their identity by entering his or her before the password is reset. This information is not shared with any other party. It is necessary to have contact information for laboratory personnel with access to the LRN Website because CDC needs to be able to contact all LRN members during an event or outbreak. All LRN laboratories are able to view the contact

information of each member laboratory director so that laboratories can refer samples to one another. Shipping addresses are available via the LRN Referral Directory. This information may be shared internally at CDC during events or with Subject Matter Experts during Proficiency Testing Challenges.

3. Use of Improved Information Technology and Burden Reduction

Biennial Requalification are conducted using the LRN Website which can be accessed using any web browser. All information is reported electronically. General Surveillance Testing, Proficiency Testing/Validation Testing, and Surge Event Testing Results are submitted using the LRN Results Messenger program. Thus, 100% of information is collected electronically. CDC only collects the minimum information necessary for the purposes of maintaining 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.

5. Impact on Small Businesses or Other Small Entities

There is no impact on small businesses or other small entities. 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

Biennial Requalification is required in order ensure laboratory capability and contact information is accurate and up-to-date. General Surveillance Testing Results must be submitted on a continual basis to CDC to ensure adequate surveillance. Proficiency Testing/Validation Testing is conducted approximately every month in order to assure competency of the laboratories. This testing also helps to confirm preparedness of the network and identify potential testing issues. Surge Event Testing Results are submitted during a biological or chemical terrorism event or natural outbreak, the occurrence of which is unpredictable. CDC would use these results to track the progression and breadth of the event.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

An LRN laboratory is required to report testing results to CDC whenever it tests a suspected sample using reagents and procedures provided by the LRN Program Office. Since such suspect samples may be received by a laboratory on a daily basis or yearly basis, the frequency of submitting General Surveillance Testing Results may exceed a quarterly basis. CDC requires the submission of all results for surveillance purposes. Negative results could still indicate attempted acts of biological or chemical terrorism, therefore the collection of even negative results is instrumental in maintaining national security. Proficiency Testing/Validation Testing is required on a monthly basis to verify the proficiency and preparedness of the LRN. Proficiency Testing requires this frequency because of the number of agents of concern for biological or chemical terrorism. These testing results are submitted to CDC so that weaknesses can be identified and addressed.

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 March 23, 2009 (Vol. 74, No. 54, page 12132) (Attachment 3). No comments were received from the public.

B. The Association of Public Health Laboratories (APHL) was the CDC's primary source of input in 1999 during the creation of the biological division of the LRN. APHL represented the stakeholders in the LRN since a majority of the LRN laboratories are public health laboratories belonging to APHL. Feedback is provided by APHL and other LRN partners during annual partnership meetings. An LRN National Meeting is held biennially to which all LRN members are invited to attend. Bimonthly, a conference call is held by the LRN Program Office during which defined topics are presented by the Program Office and questions can be proposed by listening LRN members. Additionally, for the Biological division of the LRN, a working group composed of representatives from a variety of laboratories within the LRB meets at least three times a year in order for the LRN Program Office to obtain feedback on predefined issues as well as on the LRN in general. LRN members are also encouraged to provide feedback and pose questions to the LRN Helpdesk at any time.

LRN Founding Partners (Meets in Feb and August every year)

Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
Contact: Chris Mangal, 240.485.2769, chris.mangal@aphl.org

Federal Bureau of Investigation
2501 Investigation Parkway
Quantico, VA 22135
Contact: Doug Anders, Phone: 703-632-7919, Douglas.Anders@ic.fbi.gov

Department of Defense
US Army Medical Command
Fort Sam Houston, Texas 78234
Contact: Bill Nauschuetz, PhD LTC (ret), (210) 221-3755,
william.nauschuetz@us.army.mil

Operational Working Group (This group meets 3 times a year, dates vary with member schedules)

Members:
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Quantico, VA 22135
Phone: 703-632-7919; Email: Douglas.Anders@ic.fbi.gov

9. Explanations of Any Payment or Gift to Respondents
Not Applicable

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.

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B. The LRN Website, where all laboratory information is entered and stored, is certified by VeriSign SSL Certification. Access to website is limited to LRN members, partners and CDC staff and is password protected. All passwords are stored and encrypted. The LRN website establishes an encrypted link between a web server and a browser. In addition, many security checks have been implemented which would prevent Structured Query Language (SQL) database injection. SQL injection is a code injection technique that exploits a security vulnerability occurring in the database layer of an application. The system also prevents hackings such as cross site scripting (Cross-site scripting (XSS) is a type of computer security vulnerability typically found in web applications which enable malicious attackers to inject client-side script into web pages viewed by other users).

The LRN Results Messenger/Viewer where all laboratory test results are stored is maintained in a database behind CDC firewall. LRN Results Messenger/Viewer, like all Federal systems, has undergone an extensive Certification and Accreditation security review process by the Office of the Chief Information Security Officer (OCISO)/CDC to ensure that any vulnerabilities to electronic threats are mitigated appropriately to limit unauthorized access.

Access to the LRN Results Viewer is strictly limited to only those persons authorized by the LRN Program Office. These persons must obtain a special electronic certificate with dual protection passwords that is used for authentication and access to the Results Viewer. Within authorized user access, data is further restricted by the role of the user. LRN Program Office select staff are authorized access to all data. LRN laboratory users are can only access data from their laboratory and are restricted from access to all other data in the Results Viewer. The submitting lab has the option to share results with other facilities of their choice.

C. Not Applicable

D. Requesting access to the LRN Website and becoming an LRN Member is a voluntary act. No individual is mandated to join the LRN. By requesting access to the LRN Website and agreeing to the stipulations of being an LRN Member, an individual or laboratory is voluntarily providing all requested information to the LRN Program Office. Data collected on the website is accessed by the LRN Program Office at CDC and used to characterize response capabilities of the network for planning purposes and responding to congressional inquiries. Laboratory test results collected by the LRN Results Messenger is accessed by LRN Program office and provided as needed to CDC medical epidemiologists and subject matter experts for outbreak response with consent of submitting laboratory.

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. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The estimated annualized burden hours were determined as follows. There are 200 laboratories in the LRN. A "respondent" refers to a single LRN Laboratory. Since the Biennial Requalification is conducted every other year, the average number of Responses per Respondent is one. The Average Burden per Response for the Biennial Requalification was determined to be two hours through firsthand experience. Since this is an existing collection in use without an OMB control number, the data on hand was utilized in estimating the Average Number of Responses per Respondent for the General Surveillance Testing Results. The Average Burden per Response was determined by reviewing the testing protocols utilized by the laboratories to determine the average length of time required to complete testing on a sample. The number of samples sent per Proficiency Testing/Validation Testing challenge varies significantly, an average of 5 was chosen since Proficiency Testing challenges generally include 5 samples. The length of time given to complete a Proficiency Testing/Validation Testing challenge also varies significantly, an average of 6 business days, or 56 hours was approximated as the burden time per sample. The Average Number of Responses per Respondent for Surge Event Testing Results is based on the assumptions that a large scale event is occurring on a national level so all LRN Laboratories are being utilized to their capacity. Similar to the Average Burden per Response for General Surveillance Testing Results, the Average Burden per Response for Surge Event Testing Results is also extrapolated from the testing protocols utilized by laboratories.

Respondents	Forms	Number of Respondents	Average Number of Responses per Respondent	Average Burden Per Response (hours)	Total Burden Hours
Public Health Laboratories	Biennial Requalification	100	1	2	200

Public Health Laboratories	General Surveillance Testing Results	200	25	24	120,000
Public Health Laboratories	Proficiency Testing/ Validation Testing Results	200	5	56	56,000
Public Health Laboratories	Surge Event Testing Results	200	625	24	3,000,000
Total		200			3,176,200

B. Estimated Annualized Costs

The estimated annualized costs were determined by using the 2009 General Schedule Pay Tables for a GS-11, Step 5 scientist.

Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Public Health Laboratorians	3,176,200	$26.90	$85,439.780

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

None

14. Annualized Cost to the Government

Expense Type	Expense Explanation	Cost (dollars)
Direct Cost to the Federal Government	CDC Health Scientist	118,750.00
Contractor and other expenses	Results Messenger/Laboratory Information Management Systems Integration Project (LIMSi) development, maintenance and implementation.	4,200,000.00
	LRN Website development and maintenance	600,000.00
	LRN PT Program – sample production and shipment	350,000.00
	Contractor – PT Program	45,000.00

Expense Type	Expense Explanation	Cost (dollars)
	logistical support	
	Total	5,313,750.00

15. Explanation for Program Changes or Adjustments

This is a request for approval of an existing data collection without an OMB Control Number. CDC will report this PRA violation in its FY 2010 Information Collection Budget report.

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

Not Applicable

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. 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 CDC to 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. In addition, CDC must be able to contact all laboratory personnel during an event so each laboratory staff member that obtains access to the restricted LRN Website must provide his or her contact information to the LRN Program Office.

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List of Attachments

1. **Presidential Decision Directive 39**

2. **Public Health Service Act (42 USC 241) Section 301**

3. **60 Day Federal Register Notice**

4. **LRN Data Elements**
   - **a. Biennial Requalification Data Elements**
   - **b. General Surveillance Testing Data Elements**
   - **c. Proficiency Testing/Validation Testing Results Data Elements**
   - **d. Surge Event Testing Results Data Elements**