Requesting Laboratory Input to Support Ebola Response

Request for Approval for Data Call/Questionnaire

September 3, 2014

0920-0881
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Supporting Statement

A. Justification

l. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is submitting a request to survey LRN laboratories for information regarding automated extraction equipment. This information is highly critical and will be used to assess, support, and plan CDC Ebola Response.

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, 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 a. CDC may conduct a Special Data Call to obtain additional information from LRN laboratories regarding biological or chemical terrorism preparedness. Special Data Calls will be conducted via broadcast email that asks respondents to send information via email to the LRN Help Desk. The email will contain a series of questions (Attachment 1).

Data collection for this project is authorized under the Public Health Service Act, (42 USC 241) Section 301.

Privacy Impact Assessment

Overview of the Data Collection System

Questionnaires and Special Data Calls may be conducted via broadcast email that asks respondents to send information via email to the LRN help desk. The type of information

collection activity included in this generic package is a questionnaire that is provided to members through email communications.

Items of Information to be Collected
The full list of questions is below:

> **Subject**: Request for Information Regarding Automated Extraction Equipment
>
> **LRN Broadcast Email To**: All LRN Laboratories Testing for Biological Threat Agents
> Good Morning,
> The LRN needs your assistance. Please indicate if your laboratory has any of the automated extraction instruments listed here and if so, please indicate how many of each you possess. Additionally, if your facility has any of this equipment, please indicate what version of software you have. Please send your replies to LRN@cdc.gov by COB Friday, August 29, 2014. Thank you for your time.
> Kindest Regards,
> LRN Program Office
>
> 1. KingFisher mL Magnetic Particle Processor, Thermo Scientific catalog# 5400050
> 2. KingFisher Duo, Thermo Scientific catalog # 5400100
> 3. Dynal Bead Retriever, Life Technologies catalog #15950

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

The upcoming questionnaire will aid in planning CDC Ebola response.

Privacy Impact Assessment

Personal identifiable information may be collected for this data call. The collection will specifically be for lab instruments and software, but those who operate or purchase the instrument may be identified.

3. Use of Improved Information Technology and Burden Reduction

This data call will be conducted using broadcast email which can be accessed using any web browser. All information is reported electronically. Thus, 100% of information is collected electronically. CDC will collect the minimum information necessary for the purposes planning this future webinar.

4. Efforts to Identify Duplication and Use of Similar Information
There is no duplication or use of similar data collection 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.

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 12/2/2013, Vol. 78, No. 231, pp. 72087. No comments were received from the public.

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. Assurance of Confidentiality Provided to 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 requested to provide information to improve program activities at CDC.

Privacy Impact Assessment

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.

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 annualized response burden for data collections under this generic clearance is estimated at 75 hours. A participant responding to the questions was best estimated to take approximately 30 minutes. This conclusion is drawn from the idea that the representative would have to review their lab equipment and provide specifics on the software versions. In some cases it may require manual checking of the equipment to find this information. 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	150	1	30/60	75
Total					**75**

Estimated Annualized Burden Cost

The estimated annualized costs were determined by using the 2013 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	75	$27.31	$2,048.25
Total	**75**		**$2,048.25**

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 2013 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	$118,750.00
TOTAL COST TO THE GOVERNMENT		**$118, 750.00**

15. Explanation for Program Changes or Adjustments
There are no changes since the last submission.

16. Plans for Tabulation and Publication and Project Time Schedule
There are no plans for publication of this data.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
No exemption from display of expiration date is being requested.

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