

**Requesting Laboratory Input to Identify Gaps in Preparedness
for Testing Environmental Samples Following a Biological
Threat Event**

**Request for Approval for Data Call/Questionnaire
0920-0881 Gen IC**

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List of Attachments

1. Questionnaire: Requesting Laboratory Input to Create Select Agent Webinar

- Goal of the study
- The goal of the study is to identify gaps in preparedness for testing environmental samples following a biological threat event.
- Intended use of the resulting data
- The data will be used to try and determine which laboratories are prepared for and can receive proficiency test samples in the near future.
- Methods to be used to collect
- Questionnaires and 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. 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)
- Subpopulation to be studied
- LRN members
- How data will be analyzed
- Data will be collected and analyzed using Survey Monkey. Data will be analyzed to see which laboratories are prepared for and can receive proficiency test samples in the near future.

Supporting Statement

A. Justification

I. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is submitting a request to survey LRN laboratories to identify gaps in preparedness for testing environmental samples following a biological threat event. The LRN program currently does not have information about equipment and consumables for specific methods. We are trying to determine which laboratories are prepared and can receive proficiency test samples in the near future. In addition, we have a new method under development that requires the same equipment and materials and we are trying to gauge the number of laboratories that will be able to use this method

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 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 1).

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

Items of Information to be Collected

The full list of questions (SurveyMonkey) is attached (Attachment 1).

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 identifying gaps in preparedness for testing environmental samples following a biological threat event

3. Use of Improved Information Technology and Burden Reduction

This data call will be conducted using email or survey tools (SurveyMonkey) 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 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.

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. Personal identifiable information will be collected for this data call. Questionnaires and 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. 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).

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 10 hours. A participant responding to the questions is estimated to take 20 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	30	1	20/60	10
Total					10

B. 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	10	\$27.31	\$273.10
Total	10		\$273.10

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 2015 General Pay of a CDC ORISE Fellow. Approximately 5 hours will be needed for: the creation of data questions, creating the survey online, distributing the survey, collecting and analyzing the results. Then setting up subsequent follow-up calls regarding answers on equipment inventory and the calls themselves. No other expense will be incurred for this collection

Expense Type	Expense Explanation	Annual Cost (dollars)
Direct Cost to the Federal Government	CDC Orise Fellow (5 hr)	\$152.97
TOTAL COST TO THE GOVERNMENT		\$152.97

15. Explanation for Program Changes or Adjustments

This is a new Gen IC.

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