CDC Infectious Diseases Reference Laboratories Customer Satisfaction Survey

OSTLTS Generic Information Collection Request

OMB No. 0920-0879

Supporting Statement – Section A

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Program Official/Project Officer

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Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

When CDC had its 2010 inspection by the Centers for Medicaid and Medicare Services (CMS) to determine the laboratories' compliance with the Clinical Laboratory Improvement Amendment (CLIA), it was noted that our CDC reference laboratories failed to do this effectively (**Attachment A**). In order to provide more optimal customer service to our state, territorial, local, and tribal public health laboratories we must ask them what aspects of our reference laboratory services are being carried out effectively and what areas of improvement are needed. The combined responses from the public health laboratories will determine how CDC reference laboratories uses its resources and conducts its continuing process improvement efforts in the coming years.

This Customer Satisfaction Survey is being done to meet the needs of our CLIA-certified CDC reference laboratories. One of the important elements for laboratory certification is obtaining response from the laboratories' "customers" to determine if services are appropriate. The state and territorial public health laboratories are our "customers". This proposed survey will significantly reduce the burden to the state and territorial public health laboratories since there will be only one survey to complete. Instead of each of our 25 lab branches sending independent surveys to the public health laboratories, the Laboratory Quality Management Program at CDC has designed a common survey that will capture data on the overall performance of the CDC Infectious Diseases Reference Laboratories. This is the first time that the state and territorial public health laboratories have been solicited for their comments on what we can improve and what we are doing well in our reference laboratories. Input from our "customers" is critical in this time of scarce resources. We must understand what is most important to the public health laboratories. CDC should not delete something that they need, and we must improve on services that are not meeting the requirements of our "customers".

The CDC infectious diseases laboratory testing is performed in 27 branches across the Agency (Table 1). Laboratories are located in Atlanta, Georgia, Fort Collins, Colorado, Anchorage, Alaska, and Puerto Rico. The type of reference testing is reflected in the name of the laboratory branch listed in the table. Not all laboratory activities fall under the CLIA regulations, only testing performed on live human subjects where the test results are reported back to the patient's individual chart for the diagnosis, treatment or assessment of the patient's health.

Table 1: CDC infectious diseases laboratory testing branches across the Agency

CENTER	LABORATORY BRANCH NAME
CGH	Parasitic Diseases Branch
NCBDDD	Laboratory Research Branch, Division of Blood Disorders
NCEZID	Arboviral Diseases Branch
NCEZID	Bacterial Diseases Branch
NCEZID	Bacterial Special Pathogens
NCEZID	Chronic Viral Diseases Branch
NCEZID	Clinical and Environmental Microbiology Branch
NCEZID	Enteric Diseases Laboratory Branch
NCEZID	Infectious Diseases Pathology Branch
NCEZID	Laboratory Preparedness and Response Branch
NCEZID	Mycotic Diseases Branch
NCEZID	Poxvirus and Rabies Branch
NCEZID	Rickettsial Zoonoses Branch
NCEZID	Arctic Investigations Branch
NCEZID	Dengue Branch
NCEZID	Special Pathogen Lab
NCEZID	Specimen Management Branch
NCHHSTP	Laboratory Branch, Division of HIV/AIDS Prevention-Surveillance and Epidemiology
NCHHSTP	Laboratory Branch, Division of Tuberculosis Elimination
NCHHSTP	Laboratory Branch, Division of Viral Hepatitis
NCHHSTP	Laboratory Reference and Research Branch, Division of STD Prevention
NCIRD	Gastroenteritis and Respiratory Viruses Laboratory Branch
NCIRD	Measles, Mumps, Rubella, Herpes viruses Laboratory
NCIRD	Meningitis and Vaccine Preventable Diseases Branch
NCIRD	Polio and Picornavirus Laboratory Branch
NCIRD	Respiratory Diseases Branch
NCIRD	Viral Surveillance & Diagnosis

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of the OSC. Data will be collected from U.S. Public Health Laboratory Directors or their designee acting in their official capacities.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

1.1 Privacy Impact Assessment

Overview of the Data Collection System – The data collection system consists of a web-based questionnaire (**see Attachment B – Survey Instrument: MS Word version and Attachment C– Survey Instrument: Web version**) designed to survey the Laboratory Directors of the 50 State Public Health Laboratories, the District of Columbia, and four territories regarding the services provided by the CDC Infectious Diseases Reference Laboratories for the identification, antimicrobial susceptibility testing, and typing of bacterial, fungal, viral, and parasitic isolates/specimens.. The data collection instrument will be administered as a web-based survey. The survey was pilot tested by several in-house CDC personnel and one representative from the Association of Public Health Laboratories (APHL). Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the survey.

Items of Information to be Collected – There are a total of 9 questions on the survey. There are 6 check- box questions to gauge the level of satisfaction with a service component ranging from very poor to very good on a 4 point scale. There are three open-ended questions asking the respondent to list the 3 most important things to improve CDC's service, two things that are we are doing well, and a place to request an additional service not currently provided. All questions are designed to receive input on CDC's Infectious Diseases Reference Laboratories current ability to perform diagnostic testing and report results with appropriate consultation and ease for the public health laboratories who submit the specimens and isolates.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age – The data collection system involves using a web-based survey. Respondents will be sent a link directing them to the online survey only (i.e., not a website). No website content will be directed at children.

2. Purpose and Use of the Information Collection

The state and territorial public health laboratories are being solicited for their input on what improvements CDC's infectious diseases reference laboratories should make in order to use our resources wisely and meet the expanding needs of the public health laboratories.

Information gathered through this survey will be shared with the CDC Infectious Diseases Reference Laboratories and CDC Center and Division Leadership to enable laboratories to prioritize changes and work on new processes to improve their performance. This information will inform the strategic plan objectives for the Laboratory Quality Improvement Program to institute and track key activities for the 2012-2014.

2.1 Privacy Impact Assessment

We are asking for the name, position and city and state of a contact person who may or may not be the person who filled out the survey. The contact information will only be used to reach the person if we need to clarify their written response. If the survey response describes problems to be resolved, it will be important for CDC laboratories to understand if issues are related to geographical location of the public health lab or other characteristics. Every public health laboratory is unique and has its own testing constraints, lab information system and public health priorities. The survey information will not be as helpful if it is supplied anonymously. The data is intended to be used as an aggregate of all 55 responses to inform our CDC Infectious Diseases Reference Laboratories where we can improve. The CDC laboratory staff will not see the individual responses from each state.

3. **Use of Improved Information Technology and Burden Reduction**
Data will be collected via a web-based questionnaire on Survey Monkey allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents. The short survey will be emailed directly to the State Public Health Laboratory Directors with a link to the survey. The survey was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 9 survey questions).

4. **Efforts to Identify Duplication and Use of Similar Information**
According to the Association of Public Health Laboratories (APHL) and CDC, this information has never been systematically collected from the State Public Health Laboratories. This information does not exist in any formal document.

5. **Impact on Small Businesses or Other Small Entities**
No small businesses will be involved in this data collection.

6. **Consequences of Collecting the Information Less Frequently**
Without this data:
    - CDC reference laboratories would not have timely feedback of the weakness and strengths of the services they provide to the public health laboratories
    - Limited resources (personnel and financial) would be spent less effectively
    - CDC's reference laboratories would not meet the CLIA requirement to survey our "customers" to make process improvements. We risk being cited by CMS in not complying with the full intent of the CLIA regulations.
    - CDC would miss an excellent opportunity to strengthen relationships between the federal laboratories and the state, tribal, local and territorial public health laboratories to fulfill their public health mission.

7. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**
There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

8. **Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 22, 2010, Vol. 75, No. 204; pp. 65353-54. Two comments were received from the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO).

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. **Explanation of Any Payment or Gift to Respondents**

CDC will not provide payments or gifts to respondents.

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

The Privacy Act does not apply to this data collection. Employees of state and local public health agencies will be speaking from their official roles and will not be asked, nor will they provide individually identifiable information.

This data collection is not research involving human subjects.

11. **Justification for Sensitive Questions**

No information will be collected that is of personal or sensitive nature.

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

The estimate for burden hours is based on a pilot test of the survey instrument by four public health professionals. In the pilot test, the average time to complete the survey including time for reviewing instructions, gathering needed information and completing the survey, was approximately five minutes. Based on these results, the estimated time range for actual respondents to complete the survey is 5-10 minutes, factoring in time for some Laboratory Directors to consult with other employees before completing the form. For the purposes of estimating burden hours, the upper limit of this range (i.e., 10 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf).

Based on DOL data, an average hourly wage of $42 is estimated for all 55 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents – PSR Survey

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State and Territorial Public Health Laboratory Director	55	1	10/60	9	42.00	378
TOTALS	**55**	**1**		**9**		**378**

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

There will be no direct costs to the respondents other than their time to participate in each survey.

14. Annualized Cost to the Government

There are no equipment or overhead costs. Contractors are not being used to support this data collection. The only cost to the federal government would be the salary of CDC staff supporting the data collection activities and associated tasks.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf).

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Lab Quality Management Health Scientist (GS-13)	40	41.00	1640.00
Lab Quality Management Director (Sr. Service Fellow)	28	74.00	2072.00
Estimated Total Cost of Information Collection			**3712.00**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The data will be collated by our Health Scientist in the Laboratory Quality Management Program, verified for completeness and clarity of response. A composite "report card" will be created to gauge the overall responses for the 6 checklist questions. The report will highlight the items for improvement, key services we are doing well, and any new testing services we should consider offering. The final report will be cleared by the Director of the Laboratory Quality Management Program and shared with CDC's Emerging and Zoonotic Infectious Diseases Science Office Leadership. Center Associate Directors for Laboratory Science and Branch Chiefs overseeing CDC's Infectious Diseases Reference Laboratories will receive the final report.

Project Time Schedule

Action	**Timeline**
Survey to be sent	1 month following OMB approval
Data collection	1 month to complete
Reminders sent	1 week after date due
Final collection of data	2 months after survey sent
Data validation	1 week
Data analysis	1 month
Report generated and shared	2 months

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

Attachment A- CMS letter to Dr. Turgeon dated October 26, 2010

Attachment B- Word version of survey OMB Formatted CDC Customer Survey

Attachment C- Web version of survey (Survey Monkey) at the following URL:

http://www.surveymonkey.com/s/Z6FJ2V5