Reference Laboratories Customer Satisfaction Information Collection: 2014

OSTLTS Generic Information Collection Request

OMB No. 0920-0879

Supporting Statement – Section A

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Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This data collection is being conducted using the Generic Information Collection mechanism 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).

In 2012 CDC's Infectious Disease laboratories conducted the first OMB approved questionnaire to determine if the services provided were meeting the needs of our public health laboratories. This initiative was undertaken for two reasons: 1) to continually improve our laboratories services to our customers, the public health laboratories, and 2) to periodically review our laboratory performance as required by the Centers for Medicare and Medicaid Services (CMS) to comply with the Clinical Laboratory Improvement Amendment (CLIA). Data was collected from 55 state and territorial public health laboratories in February 2012 to ask what aspects of our reference laboratory services are being carried out effectively and what areas need improvement.

Results from the 2012 data collection were analyzed and compiled into a 10 page report that was distributed to the Office of Infectious Diseases, the Infectious Diseases Center Directors and their Division Directors and Branch Chiefs. (**See Attachment A- Customer Satisfaction Assessment of the CDC Infectious Diseases Reference Laboratories Report, July 2012**).The 2012 CDC Infectious Diseases Reference Laboratories Customer Satisfaction Assessment indicated that the knowledge and technical services CDC Infectious Diseases (ID) Laboratories provide are invaluable to the Public Health Laboratories. The responses provided several key areas where process improvements could be made. These include 1) a directory of tests available from CDC laboratories, 2) contact information for the subject matter experts who perform testing, and 3)an estimated turnaround time for test results and faster receipt of test results.

Based on the 2012 assessment, several process improvements were completed in the last two years.

- The CDC Infectious Diseases Test Directory was released in February 2013. This test directory lists all tests offered by the ID laboratories and includes information on specimen submission, methods performed, subject matter experts contact information, and expected turnaround times.
- The new Adobe downloadable specimen submission form electronically linked to orderable tests was implemented February 2013.

- In April 2013, CDC ID laboratories utilizing StarLIMS software began sending final test results as encrypted PDF reports in password protected email, which reduced the delivery time from a week to hours.

The 2014 information collection will capture data on the overall performance of the CDC Infectious Diseases Reference Laboratories and assess whether these improvements have met the needs of our customers, the public health laboratories. The CDC infectious diseases laboratory testing is performed in 28 branches across the Agency. Laboratories are located in Atlanta, Georgia; Fort Collins, Colorado; Anchorage, Alaska; and San Juan, Puerto Rico and are located in four infectious diseases centers. A detailed list of laboratories is included in (**Attachment B: List of CDC Infectious Disease Reference Laboratories)**. This data collection permits feedback for the services provided by the infectious diseases laboratories in lieu of having 28 individual data collections sent to the public health laboratories to complete.

Overview of the Data Collection System – The data collection system consists of a short web-based questionnaire to query 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. The link to the data collection instrument will be sent by email to each Laboratory Director individually. The questions are displayed in **(Attachment C – Data Collection Instrument- (web screen shots) and Attachment D - Data Collection Instrument (Word version))**.

Items of Information to be Collected –
It is comprised of 10 short, check-box questions. Six of the general questions are identical to the ones used in 2012 so that we can use the same metrics to gauge improvement. Three of the questions target the recent process improvements requested by our customers. The last question asks laboratories to identify service areas where more improvements are needed.

All 10 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. Six questions ask customers to rate the timeliness, accessibility, convenience of our CDC services and forms used to submit samples to CDC and receive test reports. Three of the questions target the recent process improvements that were made in response to our customers. These ask for feedback on the Test Directory, new specimen submission form, and electronic reporting of patient results. The last question asks laboratories to identify service areas where future improvements are needed.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age – No website content will be directed at children.

1.1 Privacy Impact Assessment

No sensitive information is being collected by the instrument. Responses are not linked to any personally identifying information. The proposed data collection will have no effect on respondent privacy. Respondents are participating in their official capacity as health officials in state, district, or territorial departments of health. All responses will be stored in a password-protected, secure database accessible only by authorized CDC.

2. Purpose and Use of the Information Collection

The purpose for this data collection is to assess system performance and program delivery based on process improvements suggested during the 2012 data collection and to determine if future process improvements are needed. In 2014 we want to ask the same public health laboratories if we have met their needs and where potential areas should be improved.

Responses to the 2014 data collection will be analyzed to determine the success of the performance improvements made since the 2012 assessment. Three of the questions specifically ask to rate the new Laboratory Test Directory, the electronic submission form, and receipt of patient reports via secure email. The final question provides opportunities to request additional improvements in these three areas, as well as the new Laboratory Website and new Laboratory Help Desk that were created in response to the 2012 assessment. To ascertain a comprehensive overview of customer satisfaction, six of the questions from 2012 are the same in 2014, in order to compare ratings utilizing the same metrics.

Information gathered through this data collection will be analyzed and collated into a report that will be shared with the CDC Infectious Diseases Reference Laboratories and CDC Center and Division Leadership to enable the Laboratory Quality Management Program to prioritize changes and work on new processes to improve their performance. This information will contribute to the strategic plan for CDC's Infectious Diseases Laboratory Quality Management Program for 2014-2016.

<u>2.1 Privacy Impact Assessment</u>

No sensitive information is being collected by the instrument. Responses are not linked to any personally identifying information. The proposed data collection will have no effect on respondent privacy. Respondents are participating in their official capacity as health officials in state, district, or territorial departments of health. All responses will be stored in a password-protected, secure database accessible only by authorized CDC. 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 brief invitation letter will be emailed directly to the State Public Health Laboratory Directors with a link to the questions. The collection instrument was designed to collect the minimum information necessary for the purposes of this project.

4. **Efforts to Identify Duplication and Use of Similar Information**
   According to the Association of Public Health Laboratories (APHL) and CDC, this information has been systematically collected once from the State Public Health Laboratories in 2012 using our data collection instrument.

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's reference laboratories would not have timely feedback of the weakness and strengths of the services they provide to the public health laboratories
   - CDC's reference laboratories would not know if the performance improvements enacted as a result of the 2012 data collection were successful
   - Limited resources (personnel and financial) would be spent less effectively
   - CDC's reference laboratories would not meet the CLIA requirement to assessment 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 information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

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 data collection instrument by three health scientists. The average time to complete the data collection including time for reviewing instructions, gathering needed information and completing the questions, was approximately five minutes. Based on these results, the estimated time range for actual respondents to complete the data collection 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 Assessment 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

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 Directors	55	1	10/60	9	42.00	$378.00
TOTALS	**55**	**1**		**9**		**$378.00**

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 data collection.

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 Assessment 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 (Title 42)	28	74.00	2072.00
Estimated Total Cost of Information Collection			**3712.00**

15. Explanation for Program Changes or Adjustments

No program changes or adjustments are anticipated for 2014.

16. Plans for Tabulation and Publication and Project Time Schedule

Our Health Scientist in the Laboratory Quality Management Program will verify the data for completeness and clarity and collate the responses into a composite report. The report will highlight the success of 2012 performance improvements, new items for improvement, and compare overall service ratings for 2014 to those in 2012 prior to the performance improvements. The final report will be cleared by the Director of the Laboratory Quality Management Program and shared with Center Associate Directors for Laboratory Science and Branch Chiefs overseeing CDC's Infectious Diseases Reference Laboratories located in the four infectious diseases centers at CDC.

Project Time Schedule

Action	**Timeline**
Data collection instrument 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 data collection instrument sent
Data validation	1 week after data collection closes
Data analysis	1 month after results are available
Report generated and shared	2 months after results are available

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

Attachment A - Customer Satisfaction Report, July 2012

Attachment B - CDC Infectious Diseases Laboratories Listed by Center and Branch

Attachment C - Data Collection Instrument (Web version)

Attachment D- Data Collection Instrument (Word version)