Assessment of the Tuberculosis Laboratory Aggregate Report

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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- **Goal of the study:** To evaluate the utility and impact of the Centers for Disease Control and Prevention (CDC) Division of Tuberculosis Elimination's (DTBE) Tuberculosis Laboratory Aggregate Report and collect feedback from stakeholders to improve content of future editions.
- **Intended use of the resulting data:** Information collected will be used by the Laboratory Branch to improve the distribution methods and content of the Aggregate Report to be more useful to state, local, and tribal program objectives in future iterations. In addition, this assessment will inform guidance, resource development, and technical assistance activities of the Laboratory Branch.
- **Methods to be used to collect**: A web-based assessment will be used to collect data from respondents.
- **The subpopulation to be studied**: The respondent universe includes 58 (50 states, 7 cities, and Puerto Rico) state, local, and territorial TB Public Health Laboratory (PHL) supervisors located in laboratories funded under the CDC DTBE Tuberculosis Elimination and Laboratory Strengthening Cooperative Agreement.
- **How data will be analyzed:** Descriptive statistical analyses will be conducted on responses to multiple-choice questions and qualitative analyses on responses to open-ended questions.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This data information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information aligns with that of the O2C2. Information will be collected from 58 (50 states, 7 cities, and Puerto Rico) state, local, and territorial Tuberculosis (TB) Public Health Laboratory (PHL) Supervisors (or their designees), located in laboratories funded under the Centers for Disease Control and Prevention (CDC) Division of Tuberculosis Elimination (DTBE) Tuberculosis Elimination and Laboratory Strengthening Cooperative Agreement, acting in their official capacities. A listing of these laboratories can be found in **Attachment A–Public Health Laboratories.**

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health services of:

☐ 1. Monitoring health status to identify community health problems
☐ 2. Diagnosing and investigating health problems and health hazards in the community
☐ 3. Informing, educating, and empowering people about health issues
☐ 4. Mobilizing community partnerships to identify and solve health problems
☒ 5. Development of policies and plans that support individual and community health efforts

☐ 6. Enforcement of laws and regulations that protect health and ensure safety
☐ 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
☐ 8. Assuring a competent public health and personal health care workforce
☒ 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
☐ 10. Research for new insights and innovative solutions to health problems [1]

Tuberculosis (TB) is one of the world's deadliest diseases. According to CDC statistics for 2014 (http://www.cdc.gov/tb/statistics/default.htm), one third of the world's population is infected with TB with 9.6 million people sick with TB and 1.5 million TB-related deaths reported worldwide. A total of 9,421 TB cases (a rate of 2.96 cases per 100,000 persons) were reported in the United States in 2014. Additionally, TB is a leading cause of death in people who are infected with HIV.

The CDC, Division of Tuberculosis Elimination (DTBE) is the lead Federal Agency for TB prevention and control funding, resource coordination, and development of national TB strategies and policies. As such, DTBE has pursued federal involvement in funding essential elements in state and local TB programs through a Cooperative Agreement (CoAg). The primary responsibility for designing and carrying out TB laboratory activities rests with state and local public health departments, not the Federal Government. The CoAg is intended to complement ongoing TB laboratory services and activities at the state and local level. It is not the intent of the CoAg to replace or reduce state and local support for TB control activities and responsibilities.

DTBE distributes TB CoAg funds to PHLs based on data-driven funding formulas to align funding with changing TB epidemiology in the United States. The laboratory workload formula is designed to ensure high-quality laboratory testing with rapid turnaround time (TAT) of results for each jurisdiction. In addition, TB CoAg funding aids PHLs with implementation of new methods and technologies as an integral component of TB control efforts. Furthermore, CDC's support and guidance of CoAg recipients, representing health departments from states, territories, and several large cities, helps to ensure that efforts to prevent and control the transmission of *Mycobacterium tuberculosis* in the United States will continue to be successful in an effort to meet Healthy People 2020 objectives (http://intranet.cdc.gov/od/ppeo/healthyPeople/). As required by the CoAg, participating PHLs must self-report on an annual basis to CDC the following cumulative workload data:

- Clinical specimens received for testing to detect TB
- Patients for whom a specimen was submitted
- Patients who were culture positive for *Mycobacterium tuberculosis* complex (MTBC)
- Patients for whom a reference isolate was submitted
- Patients with a reference isolate identified as MTBC
- Patients for whom drug susceptibility testing (DST) was performed
- Patients tested for TB using nucleic acid amplification testing (NAAT) or other rapid test
- Patients NAAT positive for MTBC
- Number of Interferon Gamma Release Assays (IGRAs) performed

Each PHL is also required to report percent turnaround time data for each of the following indicators:

- Specimen receipt within one day, two days, and three days of collection
- Acid-fast smear within one day of specimen receipt
- Identification (ID) of MTBC within 21 days of specimen receipt
- DST performed within 17 days of ID of MTBC

In addition, PHLs are required to report methods used to ID and perform DST of MTBC.

Self-reported data from PHLs are compiled, analyzed, and published as a TB Laboratory Aggregate Report by the Laboratory Branch (LB) in DTBE. The report serves as a tool for PHLs to assess local benchmarks and to make peer comparisons using national workload averages and TAT benchmarks. Data in the report are stratified by workload volume to allow more specific comparisons among laboratories. DTBE/LB objectives are to provide clear and relevant information in the TB Laboratory Aggregate Report that PHLs can use to document program accomplishments and to increase awareness of a program's impact. Information from the report can serve as evidence to substantiate change within specific activities such as methodologies, protocols, or staffing in an effort to improve laboratory services.

The purpose of this information collection is to assess the utility and impact of the TB Laboratory Aggregate Report and collect information from stakeholders to improve content of future editions. Information will be collected from 58 Public Health Laboratory (PHL) supervisors (or their designees) using a web-based assessment. The assessment will collect information from respondents regarding: 1) how respondents received the Aggregate report, 2) perceptions of the content of the Aggregate Report; 3) how the information in the Aggregate Report is used to assess the performance of the laboratory's activities; 4) how the information in the Aggregate Report is used to justify and implement changes to the laboratory programs; and 5) suggestions for types of additional information to include in future editions of the Aggregate Report.

The information collected will be used by the Laboratory Branch to improve the distribution methods and content of the Aggregate Report to be more useful to state, local, and tribal program objectives in future iterations. In addition, this assessment will inform guidance, resource development, and technical assistance activities of the Laboratory Branch.

Overview of the Information Collection System

Information will be collected from a total of 58 (50 states, 7 cities, and Puerto Rico) state, local, and territorial Tuberculosis (TB) Public Health Laboratory (PHL) supervisors, or their designees, via a web-based questionnaire (see **Attachments B—Instrument: Word version** and **Attachment C—Instrument: Web version**). The web-based instrument will measure how the respondents received the report, the ease of interpreting the report data, how the information was used by respondents to measure the relative performance of their laboratories compared to peer data, and

how data was used to justify changes within their laboratories. This method was chosen to allow respondents to complete and submit their responses electronically, reducing the overall burden. The information collection instrument was pilot tested by 9 randomly selected TB PHL Supervisors. 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 information collection instrument.

Items of Information to be Collected

The web-based information collection instrument (see **Attachments B—Instrument: Word version** and **Attachment C—Instrument: Web version**) will assess the utility and impact of the TB Laboratory Aggregate Report. The instrument consists of a total of 11 questions. Question types include multiple choice and open ended. In an effort to minimize response burden, the instrument was designed with particular focus on streamlining questions to allow for skipping questions based on responses to previous questions. Also, an effort was made to limit questions requiring narrative responses from respondents whenever possible.

The instrument will be used to collect the following information:

- How PHL TB Supervisors or their designees received the Tuberculosis Laboratory Aggregate Report
- If PHL TB Supervisors or their designees used the data and information provided in the TB Laboratory Aggregate Report to compare relative performance of their laboratory with other laboratories
- To what degree PHL TB Supervisors or their designees found information, such as tables and figures in the report, easy to interpret
- If PHL TB Supervisors or their designees used information in the report to either support or request changes in program areas such as staffing, methodology, protocols, equipment, and services.
- If PHL TB Supervisors or their designees used the Aggregate Report to document their laboratory's accomplishments.
- If PHL TB Supervisors or their designees used the Aggregate Report to increase awareness of their laboratory program.
- If PHL TB Supervisors or their designees found the information in the Aggregate Report either too technical or too basic for their program needs.
- If PHL TB Supervisors or their designees considered the Aggregate Report to be a primary source of information regarding identification and drug susceptibility testing of TB specimens. What information PHL TB Supervisors or their designees would like to be in included in future editions of the Aggregate Report.
- If PHL TB Supervisors would agree that the Aggregate Report should use the names of state and city laboratories when reporting turnaround time data.
- How important PHL TB Supervisors consider the information in the Aggregate Report to their laboratory program
- The volume of TB clinical specimens tested in calendar year 2015 for each PHL participating in the assessment.

2. Purpose and Use of the Information Collection

The purpose of this information collection is to assess the utility and impact of the TB Laboratory Aggregate Report and collect data from stakeholders for incorporating improvements to future editions. Information will be collected from 58 TB Public Health Laboratory (PHL) supervisors (or their designees) including 50 states, 7 cities, and Puerto Rico. The assessment will collect information from respondents regarding: 1) how respondents received the Aggregate report, 2) perceptions of the content of the Aggregate Report; 3) how the information in the Aggregate Report is used to evaluate the performance of the laboratory's activities; 4) how the information in the Aggregate Report is used to justify and implement changes to the laboratory programs; and 5) suggestions for types of additional information to include in future editions of the Aggregate Report.

The information collected will be used by the Laboratory Branch to improve the distribution methods and content of the Aggregate Report to be more useful to state, local, and tribal program objectives in future iterations. In addition, this assessment will inform guidance, resource development, and technical assistance activities of the Laboratory Branch.

3. Use of Improved Information Technology and Burden Reduction

Information will be collected via a web-based questionnaire allowing respondents to complete and submit responses electronically. This method was chosen to reduce the overall burden on respondents. The data collection instrument was designed to collect minimum information necessary for the purposes of this project (i.e., limited to 11 questions). Further, skip patterns were incorporated to allow for streamlining responses and the reduction of burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is the first attempt to gather feedback from stakeholders concerning the impact and utility of the TB Laboratory Aggregate Report. This data will be used to prepare an aggregate report that will be made available to all stakeholders. Prior to developing this information collection, DTBE's LB conducted a literature review to confirm no similar reports or assessments of information provided by the Tuberculosis Laboratory Aggregate Report existed and that this effort is not duplicative.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time information collection. There are no legal obstacles to reduce the burden. If data are not collected, CDC/DTBE/LB will be unable to:

- Collect input from respondents regarding perceptions of the aggregate report, how the information within the report is being used, and suggestions for improvement.
- Improve future editions of the Aggregate Report to provide continued support to CDC/DTBE/LB CoAg funded PHLs including:
    - Distribution methods
    - Content used to measure relative performance of TB laboratory services
    - Content used to support program changes to decrease delays in reporting of TB test results to health care providers
- Develop guidance, resource development, and technical assistance activities for state, local, and tribal TB PHLs.

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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

STLT governmental staff will be speaking from their official roles. CDC will not collect any individually identifiable information (IIF). All information gathered from participants will be kept secure to ensure protection of information.

This information collection is not research involving human subjects.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

No information will be collected that are 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 information collection instrument by 9 randomly selected TB PHL Supervisors. In the pilot test, average time to complete the instrument including time for reviewing instructions, gathering needed information, and completing the instrument, was approximately 10 minutes (range: 10 to 15 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 15 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for Medical and Health Service Managers (http://www.bls.gov/oes/current/oes_nat.htm). Based on DOL data, an average hourly wage of $57.11 is estimated for all 58 respondents. Table A-12 shows estimated burden and cost information.

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

Information collection Instrument: Form Name	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
Tuberculosis Laboratory Aggregate Report Assessment	Public Health Laboratory TB Supervisors or their designees	58	1	15/60	15	$57.11	$857
	TOTALS	**58**	**1**		**15**		**$857**

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 the information collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff. The total estimated cost to the federal government is $6,623.30. Table A-14 describes how this cost estimate was calculated.

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

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Microbiologist (GS-13) Instrument development, pilot testing, OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation	100 hours	$50.69	$5,069.00
Microbiologist, Team lead (GS-14) Instrument development, pilot testing, OMB package preparation, summary report preparation	30 hours	$51.81	$1,554.30
Estimated Total Cost of Information Collection			**$6,623.30**

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Once the 3-week information collection period has closed, results of the assessment will be coded and entered into a secure database, maintained by CDC, for further analysis by DTBE/LB. Quantitative data analysis and descriptive statistics will be achieved through input into SPSS according to variables aligned with response choices. Qualitative analysis of open-ended responses will be achieved by coding responses into categories that can be analyzed quantitatively. Upon completion of data analysis, CDC will utilize the de-identified data to compile a report summarizing the results and for presentation to appropriate DTBE staff. A final aggregate report will be prepared for distribution to cooperative agreement grantees.

Project Time Schedule:

- ✓ Design questionnaire ..... (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan ..... (COMPLETE)
- ✓ Pilot test questionnaire ..... (COMPLETE)
- ✓ Prepare OMB package ..... (COMPLETE)
- ✓ Submit OMB package ..... (COMPLETE)
- ❑ OMB approval ..... (TBD)
- ❑ Conduct assessment ..... (Assessment open 3 weeks)
- ❑ Code, enter, and analyze data..... (4 weeks)
- ❑ Prepare reports ..... (4 weeks)
- ❑ Disseminate results/reports ..... (4 weeks)

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.

A. **Attachment A- Public Health Laboratories**
B. **Attachment B- Instrument: Word version**
C. **Attachment C- Instrument: Web version**