

# **Pandemics, Natural Disasters, and other Interruption of Service Events: Contingency Planning Considerations for Mycobacteriology Testing**

CSTLTS Generic Information Collection Request  
OMB No. 0920-0879

## **Supporting Statement – Section A**

Submitted:

**Program Official/Project Officer**

Stephanie P. Johnston, MS  
Research Microbiologist/Team Lead  
Laboratory Branch  
Division of Tuberculosis Elimination  
Centers for Disease Control and Prevention  
1600 Clifton, N.E., MS H17-4  
Atlanta, GA 30329  
Phone: (404) 639-5019  
Fax: (404) 639-1287  
Email: sip5@cdc.gov

# Table of Contents

Table of Contents.....	2
Section A – Justification.....	3
1. Circumstances Making the Collection of Information Necessary.....	3
2. Purpose and Use of the Information Collection.....	6
3. Use of Improved Information Technology and Burden Reduction.....	6
4. Efforts to Identify Duplication and Use of Similar Information.....	6
5. Impact on Small Businesses or Other Small Entities.....	7
6. Consequences of Collecting the Information Less Frequently .....	7
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	7
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	7
9. Explanation of Any Payment or Gift to Respondents.....	7
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	7
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	8
12. Estimates of Annualized Burden Hours and Costs.....	8
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	9
14. Annualized Cost to the Government.....	9
15. Explanation for Program Changes or Adjustments.....	10
16. Plans for Tabulation and Publication and Project Time Schedule.....	10
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	11
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	11
LIST OF ATTACHMENTS – Section A.....	11
REFERENCE LIST .....	11

- **Purpose of the data collection:** To assess availability of public health laboratory (PHL) continuity of operations plans (COOPs), specifically mycobacteriology laboratory COOPs and the processes in place for the continuation of mycobacteriology testing services in case of interruption in service events. Determine if PHL officials and mycobacteriology supervisors implemented COOPs in response to interruption of service events, if modifications to COOPs following these events were made and lessons learned from these events
- **Intended use of the resulting data:** Information regarding COOPs and their availability for mycobacteriology laboratory testing along with lessons learned from PHL interruption of service events will be shared among partners and peers to emphasize the importance of COOPs and planning for any impact of mycobacteriology testing services.
- **Methods to be used to collect data:** Respondents will be emailed a link to a CDC REDCap data collection instrument with instructions to input data online. Respondents will also be invited to participate in focus group discussions to collect more in-depth qualitative data and share lessons learned with CDC and PHL colleagues.
- **Respondent Universe:** There will be a total of 58 respondents for the questionnaire and up to 58 respondents for focus group discussions. The total number of potential responses for both the questionnaire and focus groups will be 116.
- **How data will be analyzed:** Data will be downloaded to Excel and SPSS and descriptive statistics will be used to analyze and summarize results.

## Section A – Justification

### 1. Circumstances Making the Collection of Information Necessary

#### Background

This information collection is being conducted using OMB No. 0920-0879 “Information Collections to Advance State, Tribal, Local and Territorial Governmental Agency System Performance, Capacity, and Program Delivery” nicknamed the “CSTLTS Generic.” The respondent universe for this information collection aligns with that of the CSTLTS Generic. Data will be collected from a total of 58 respondents across state and local public health laboratories (PHL) supported in part through a Centers for Disease Control and Prevention (CDC) Division of Tuberculosis Elimination (DTBE) and Laboratory Strengthening Cooperative Agreement (CoAg). Respondents acting in their official capacities include PHL mycobacteriology supervisors or their designees (**Attachment A**—CoAg PHLs and Mycobacteriology supervisors or designees).

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 service(s) of

1. Assess and monitor population health status, factors that influence health, and community needs and assets

- 2. Investigate, diagnose, and address health problems and hazards affecting the population
- 3. Communicate effectively to inform and educate people about health, factors that influence it, and how to improve it
- 4. Strengthen, support, and mobilize communities and partnerships to improve health
- 5. Create, champion, and implement policies, plans, and laws that impact health
- 6. Utilize legal and regulatory actions designed to improve and protect the public's health
- 7. Assure an effective system that enables equitable access to the individual services and care needed to be healthy
- 8. Build and support a diverse and skilled public health workforce
- 9. Improve and innovate public health functions through ongoing evaluation, research, and continuous quality improvement
- 10. Build and maintain a strong organizational infrastructure for public health<sup>1</sup>

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis*. There were 8,916 cases of TB in the United States in 2019 from 60 jurisdictions (states, cities and US territories) that report TB data to CDC (<https://www.cdc.gov/tb/statistics/default.htm>). Mycobacteriology laboratories in PHLs perform acid-fast bacilli smear, growth-based culture, nucleic acid amplification testing, identification procedures and drug susceptibility testing to identify mycobacteria and determine susceptibility to drugs needed to initiate appropriate patient treatment. For TB, these testing services are essential. Continuity of operations plans (COOPs) are in place within PHLs to establish policy and guidance to ensure critical testing services continue. The depth of COOPs in PHLs and the inclusion of mycobacteriology laboratory services is not well-known.

The purpose of this data collection is to learn the availability of PHL mycobacteriology COOPs and processes in place for the continuation of mycobacteriology testing services in case of interruption in service events. The respondent universe will be state, local and territorial PHL mycobacteriology supervisors, or their designees supported in part by the CDC TB Elimination and Laboratory Cooperative Agreement. Respondents will be asked about implementation of COOPs in response to past interruption in service events and COOP modifications after these events. This information along with lessons learned from PHL mycobacteriology interruption of service events will be shared among partners and peers to emphasize the importance of COOPs and planning for events that may impact mycobacteriology testing services.

## **Overview of the Information Collection System**

### **REDCap Survey**

Data will be collected from 58 state, local and territorial PHL mycobacteriology supervisors or their designees via a web-based data collection instrument (**see Attachment B— Data Collection Instrument: Word Version and Attachment C—Data Collection Instrument: Web Shots**). The data collection instrument will be designed within CDC REDCap. The instrument will be used to gather information from state, local and territorial PHL mycobacteriology supervisors or their designees regarding the availability of PHL and mycobacteriology COOPs

and the processes in place for the continuity of mycobacteriology testing services in case of interruption in service events. The information collection instrument was pilot tested by nine public health professionals. Feedback from this group was used to refine questions (as needed), ensure accurate programming and skip patterns and establish estimated time required to complete the information collection instrument.

### **Focus Group Discussions**

Once data is collected using the online information collection instrument and analyzed, up to 58 state, local and territorial PHL mycobacteriology supervisors or their designees will be selected for focus groups to share lessons learned from interruption in service events and to describe in greater detail any COOP changes after these events, specifically in regards to mycobacteriology testing. Questions asked during focus groups will be not be duplicative of the information requested through the data collection instrument and are designed to add rich context to initial questionnaire responses. This qualitative approach will be used to gain an in-depth understanding of how interruption in service events impacted PHL COOPs specifically for the mycobacteriology laboratory and how COOPs were modified after these types of events. Participants will informally share their experiences and ideas to inform best practices and recommendations for other jurisdictions. Participants will be grouped together for discussions based on experiencing similar types of events. A virtual platform will be selected to conduct each focus group using a script with questions to stimulate discussion among the participants (See **Attachment D** — Focus Group Virtual Platform Discussions Script). A prototype of the script was reviewed and modified by five public health officials. A two-hour time limit was selected to account for adequate response time for participants in each group.

### **Items of Information to be Collected**

#### **REDCap Survey**

The data collection instrument consists of 54 questions of various types, including dichotomous (yes/no), multiple response and open-ended. An effort was made to limit the number of questions and questions requiring a narrative response by including skip logic to send respondents to a future point in the survey based on how they answer a question. Most respondents will answer less questions as they will only be routed to questions concerning type of interruption of service event selected. The instrument will collect data on the following:

- Availability of PHL COOPs
- Classification of types of past interruption in service events and duration
- Availability of COOPs addressing testing services for mycobacteriology before and after interruption of service events

#### **Focus Group Discussions**

The Focus Group Virtual Platform Discussions Script consists of 5 main questions on specific topics designed to engage and encourage an open-ended discussion among participants grouped by those experiencing a particular type of event. Qualitative data will be collected on:

- Detailed descriptions of interruption of service events selected in questionnaire and their specific impacts on mycobacteriology testing services

- Description of lessons learned after the type of event that impacted mycobacteriology testing services
- Revisions made to COOPs after the type of event that impacted mycobacteriology testing services
- Description of best practices shared among mycobacteriology colleagues to prepare for a future event
- Other suggestions from the group for mycobacteriology laboratories encountering interruption in service events

## **2. Purpose and Use of the Information Collection**

The purpose of this data collection is to learn the availability of PHL mycobacteriology COOPs and processes in place for the continuation of mycobacteriology testing services in case of interruption in service events. The respondent universe will be state, local and territorial PHL mycobacteriology supervisors, or their designees supported in part by the CDC TB Elimination and Laboratory Cooperative Agreement. Respondents will be asked about implementation of COOPs in response to past interruption in service events and COOP modifications after these events. This information along with lessons learned from PHL mycobacteriology interruption of service events will be shared among partners and peers to emphasize the importance of COOPs and planning for events that may impact mycobacteriology testing services.

## **3. Use of Improved Information Technology and Burden Reduction**

### **REDCAP Survey**

Data will be collected via a web-based questionnaire. This method was chosen to reduce the overall burden on respondents by allowing respondents to complete and submit their responses electronically. The data collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to a maximum of 54 questions and skip logic to send respondents to a future point in the survey based on how they answer a question).

### **Focus Group Discussions**

Data will be collected using a virtual platform (Zoom, Skype, or Teams Meeting). This method was chosen to reduce the overall burden on respondents by eliminating the time and cost to travel to a specific location. Data collection was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 5 discussion questions).

## **4. Efforts to Identify Duplication and Use of Similar Information**

A literature review was conducted to ensure the requested information for collection was not duplicated or otherwise accessible from any other source. Any information collection currently conducted concerning COOPs is not related to the area of mycobacteriology nor has information been sought from PHL mycobacteriology supervisors or their designees.

**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 data collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Determine if PHLs have COOPs in place to continue mycobacteriology laboratory services in case of interruption of service events
- Categorize the types, frequencies, and lengths of interruption of service events in PHLs
- Communicate lessons learned from past events to PHL partners and encourage identification of referral laboratories in their COOPs for mycobacterial testing

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances with this data 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 CSTLTS Generic Information Collection Service (CSTLTS Generic) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on May 21, 2020, Vol. 85, No. 99, pp 30962-30963. 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**

The Privacy Act does not apply to this data collection. STLT governmental staff and / or delegates will be speaking from their official roles.

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

No information will be collected that are of personal or sensitive nature. This data collection is not research involving human subjects.

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

The estimate of burden hours for the survey instrument is based on a pilot test by nine public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information, and completing the instrument, was approximately 7 minutes (range: 5 –10 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 10 minutes) is used.

The estimate of burden hours for conducting focus groups is based on a review of the focus group script by five public health officials. The time for conducting and completing discussion of the scripted questions was approximately 90 minutes (range 60–120 minutes). For purposes of estimating burden hours, the upper limit of this range (i.e., 120 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 who are employed in the medical and diagnostic laboratories industry.

[http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm). Based on DOL data, an average hourly wage of \$58.80 is estimated for all 58 respondents.

To account for potential increases due to the COVID-19 response, the hourly wage rate has been doubled to \$117.60 to account for fringe benefits and overhead (<https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis>). Table A-12 shows estimated burden and cost information.

There will be a total of 58 respondents for the questionnaire and up to 58 respondents for focus group discussions. The total number of potential responses for both the questionnaire and focus groups will be 116.

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



<b>Data collection Instrument: Form Name</b>	<b>Type of Respondent</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Costs</b>
Continuity of Operations Plan (COOP) Questionnaire	Mycobacteriology supervisors or their designees	58	1	10 / 60	10	\$117.60	\$1,176
Focus Group Virtual Platform Discussions Script	Mycobacteriology supervisors or their designees	58	1	120/60	116	\$117.60	\$13,642
	<b>TOTALS</b>	<b>116</b>	<b>1</b>		<b>126</b>		<b>\$14,818</b>

**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. The only cost to the federal government would be the salary of CDC staff to develop the data collection instrument, collect data, perform data analysis, and conduct focus group discussions. The total estimated cost to the federal government is \$ 59,059.90. Table A-14 describes how this cost estimate was calculated.

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

<b>Staff (FTE)</b>	<b>Average Hours per Collection</b>	<b>Average Hourly Rate</b>	<b>Total Average Cost</b>
<b>Microbiologist – GS-13, Step 10.</b> Instrument development, pilot testing, OMB package preparation, data collection, data coding and entry, quality control, data analysis, conduct focus groups, report preparation	450	\$ 59.87/hour	\$26,941.50
<b>Microbiologist – GS-12, Step 7.</b> Instrument development, pilot testing, OMB package preparation, data collection, data coding and entry, quality control, data	330	\$46.48/ hour	\$15,338.40

analysis, conduct focus groups, report preparation			
<b>Microbiologist – GS-14, Step 8; Team Lead. Laboratory Capacity Team</b> Instrument development, pilot testing, OMB package preparation, data analysis, conduct focus groups, report preparation	250	\$67.12/hour	\$16,780.00
<b>Estimated Total Cost of Information Collection</b>			<b>\$59,059.90</b>

**15. Explanation for Program Changes or Adjustments**

This is a new data collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Quantitative data collected using the online questionnaire will be downloaded from CDC REDCap to Excel and SPSS for data cleaning and analysis. All data will be stored on an encrypted and password-protected server maintained by CDC. Quantitative analysis will be used to assess the availability of PHL, specifically mycobacteriology, COOPs and processes in place for the continuity of mycobacteriology testing services in case of interruption in service events.

For qualitative data collected using the **Focus Group Virtual Platform Discussions Script (Attachment D)**, electronic files for all recordings, transcripts and interviewer notes from focus groups will be maintained on encrypted and password protected CDC computer servers and computers in compliance with requirements for data security. Qualitative data will be coded and analyzed using SPSS. Coded qualitative data files will be linked with the quantitative analytical file to support mixed-method analyses by using unique study identifiers assigned to each qualitative and quantitative observation.

Findings from the analyses will expand information regarding COOPs and availability for continuation of mycobacteriology laboratory testing in response to interruption of service events. Lessons learned from PHL interruption of service events will be shared among partners and peers to emphasize the importance of COOPs and planning for any impact of mycobacteriology testing services. Data collected during the assessments will be shared only in aggregate form. No IIF will be distributed.

Project Time Schedule

- ✓ Design instrument ..... (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan ..... (COMPLETE)

- ✓ Pilot test instrument ..... (COMPLETE)
- ✓ Prepare OMB package ..... (COMPLETE)
- ✓ Submit OMB package ..... (COMPLETE)
- OMB approval ..... (TBD)
- Conduct data collection ..... (Assessment open 6 weeks)
- Code data, conduct quality control and analyze data..... (8 weeks)
- Prepare summary report(s) ..... (8 weeks)
- Focus Groups ..... (16 weeks)
- Disseminate results/reports ..... (16 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 – CoAg PHLs and Mycobacteriology supervisors or designees**
- B. Attachment B – Instrument: Word Version**
- C. Attachment C – Instrument: Web Version**
- D. Attachment D – Focus Group Virtual Platform Discussions Script**

**REFERENCE LIST**

1. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services." Available at <http://www.cdc.gov/nphpsp/essentialservices.html>. Accessed on 8/14/14.