Request for Revision to an Approved Information Collection

CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* Drug Susceptibility Testing

(OMB Control No. 0920-0600)
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Supporting Statement A

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- **Goal of the study**: The goal of the study is collect and analyze the performance and practices of all known clinical and public health laboratories in the United States that perform drug susceptibility testing of isolates belonging to the *Mycobacterium tuberculosis* complex (MTBC), a genetically related group of Mycobacterium species that can cause tuberculosis in humans.
- **Intended use of the resulting data**: Data will be used to monitor the quality and effectiveness of laboratory testing systems which support public health objectives of tuberculosis treatment programs. Information collected from participants is compiled, analyzed, and reported in a form laboratories can use as a self-assessment tool to maintain the skills for drug susceptibility testing of MTBC. The results are also used to determine areas of need for training while monitoring reagents and test methodologies.
- **Methods to be used to collect:** Data will be collected from purposive sample of staff from public health laboratories performing drug susceptibility testing of MTBC. Data will be collected online using a survey instrument that will be completed by a laboratory representative.
- **The subpopulation to be studied:** Subpopulations to be studied consist of comparison of data inputted by staff from clinical laboratories classified as public health, hospital, or independent (non-hospital based).
- **How data will be analyzed:** This data collection does not use statistical methods. Data is analyzed by tabulating and comparing results from various test methodologies and associated practice variables.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a revision to an approved information collection 0920-0600 (expiration date 03/31/2019) entitled, "*CDC Model Performance for Mycobacterium tuberculosis Drug Susceptibility Testing,*" for a period of 3 years. Revision of this information consists of a modification of the Participant Biosafety Compliance Letter of Agreement, the Instructions to Participants , the MPEP Mycobacterium tuberculosis Results Worksheet, the addition of a MPEP Mycobacterium tuberculosis Minimum Inhibitory Concentration (MIC) Results form and a reduction in request for burden hours from 156 hours to 129 hours due to fewer laboratories participating in the program.

The CDC Model Performance Evaluation Program (MPEP) is an educational self-assessment tool in which five isolates of *Mycobacterium tuberculosis* complex (MTBC) are sent from CDC to participating laboratories biannually for staff to monitor their ability to determine drug resistance among the isolates. The MTBC is a genetically related group of Mycobacterium species that can cause tuberculosis in humans. The report produced from testing information

received includes results for a subset of laboratories performing drug susceptibility tests (DST) for MTBC in the United States. MPEP is a voluntary self-assessment and non-statistical data collection program, and the report reflects data received from participating laboratory personnel. The aggregate report is prepared in a format that will allow laboratory personnel to compare their DST results with those obtained by other participants using the same methods and drugs, for each isolate.

The MPEP was established to analyze the performance and practices of all known clinical and public health laboratories in the United States that perform drug susceptibility testing of isolates belonging to the *Mycobacterium tuberculosis* complex (MTBC), a genetically related group of Mycobacterium species that can cause tuberculosis in humans. MPEP is a voluntary self-assessment and non-statistical data collection program. The approval of this revision will allow CDC to continue receiving essential data to assess and monitor the quality and effectiveness of laboratory testing systems, which support public health objectives of tuberculosis treatment programs.

The data collected over the previous three-year period enabled CDC to correlate testing practices with performance and to use this information to design training modules targeted to participants encouraging the adaptation of advanced testing methods. The requested revision of this data collection will allow CDC to evaluate the effectiveness of these training modules by continually monitoring laboratory performance. CDC is requesting several changes to the ICR, which are explained in Section 15 on page 9 of this supporting statement and in *Explanation of Changes* **(Attachment 3)**.

Tuberculosis (TB) is a continuing public health problem despite the declining number of cases in the United States over the past few years. Although there has been an overall decrease in the number of cases in the U.S, rates still remain high among foreign-born persons, prisoners, the homeless populations, and individuals infected with HIV in major metropolitan areas. Adequate TB control depends on rapid isolation and identification of the etiologic agent, *M. tuberculosis*, and confirmation of the appropriate therapeutic regimen by anti-tuberculosis drug susceptibility testing. With this information, the necessary infection control procedures and contact tracing can be initiated, and informed decisions can be made regarding therapy. Public health laboratories play a key role in reducing tuberculosis transmission. Competent staff, adequate test procedures, and facilities for thorough evaluations of clinical specimens are critical in reducing TB transmissions.

This information collection activity is authorized under *the Public Health Service Act, (42 USC 241) Section 301* (**Attachment 1**).

2. Purpose and Use of Information Collection

CDC sends test culture of strains of Mycobacterium tuberculosis complex (MTBC) to the testing labs. Data (test results of isolates) are collected from participating staff from clinical laboratories classified as public health, hospital, or independent (non-hospital based), to analyze the performance and practices of all known clinical and public health laboratories in the United States that perform drug susceptibility testing (DST) of isolates belonging to the Mycobacterium

tuberculosis complex (MTBC). Since statistical methods are not utilized, no sampling is employed. Upon signing of the *Participant Biosafety Compliance Letter of Agreement* (**Attachment 4**) by an authorized representative once per year in January, each laboratory is enrolled in MPEP and assigned a MPEP number. The MPEP number is used by participants to enter data online. Before survey samples are mailed to the laboratory, an advance *Pre-shipment Email* (**Attachment 5**) is sent to participants to inform them of the expected date for receiving the culture shipment. The *Pre-shipment Email* will also contain a request to notify CDC of any changes in Laboratory contact information. Cultures are sent to the laboratories along with *Instructions to Participants Letter* (**Attachment 6**) and *MPEP Mycobacterium tuberculosis Results Worksheet* **(Attachment 7**). The Instructions to Participants contains information on handling the culture isolates and for reporting drug susceptibility test (DST) results online using the *Survey Instrumen*t (**Attachment 8)**. All testing results data must be entered online at http://MPEP.formstack.com/forms/mpep_1. However, included as a change for this revision (**Attachment 3**), participants that additionally use the Sensititre® procedure to perform DST will enter their minimal inhibitory concentration results manually using a *MPEP Mycobacterium tuberculosis Minimum Inhibitory Concentration (MIC) Form* (**Attachment 9**) and email the results to TBMPEP@cdc.gov.

Background information concerning the classification of each participating laboratory and their DST methods are also be collected. Each participant is sent a link to enter all information online. Participants who have not input their results two weeks prior to the deadline are notified by a *Reminder Email* (**Attachment 10**) or by telephone using a *Reminder Telephone Script* (**Attachment 11**). Approximately 60 days after the deadline, the results of the data collected are analyzed and an *Aggregate Report Letter* (**Attachment 12**) is emailed to all enrollees and a link to the completed aggregated report is posted on the CDC MPEP Home Page at http://www.cdc.gov/tb/topic/Laboratory/mpep/default.htm. An example of the *Final Aggregate Report* is found in **Attachment 13**.

Data collected are stored as SAS files (or equivalent) data sets and imported into Excel files with a unique identifier. All data are treated in a secure manner and not released with identifiers, unless compelled by law or unless CDC project staff requests re-linking in order to facilitate communication with a site that is experiencing a high rate of inaccurate results. The information collected will be maintained at the CDC for at least 10 years.

Information collected from participants is compiled, analyzed, and reported in an aggregate form laboratories can use as a self-assessment tool to maintain the skills for drug susceptibility testing of MTBC. The challenge culture strains are sent twice yearly. If data from the challenge culture strains are not collected and analyzed, laboratories may not have the ability to detect susceptibility testing and quality control problems, and therefore not correct the problem.

CDC and other public health organizations use the information from this collection to measure reproducibility of susceptibility test results performed with various test procedures in the U.S. These results are used to determine areas of need for training while monitoring reagents and test methodologies to improve the quality of susceptibility testing of MTBC. Because of the importance of accurate and timely test results for the success of TB surveillance, prevention, and treatment programs, the CDC maintains an active role in the assurance of high quality laboratory

testing. MPEP fulfills part of this role by monitoring the level of performance and practices among public health and private sector laboratories within the U.S. By providing a performance evaluation program to assess the ability of the laboratories to test for drug resistant isolates of MTBC, laboratories also have a self-assessment tool to aid in optimizing their skills in susceptibility testing. As previously stated, MPEP is a voluntary self-assessment non-statistical data collection program.

From March to April 2018, CDC conducted an assessment of MPEP under genIC "Collection of Qualitative Feedback on Agency Service Delivery", OMB Control No. 0920-1027. MPEP participants were invited to complete an online survey to measure how they value of the program and to receive customer feedback to improve service delivery. Forty-nine participants in MPEP responded to the survey request. Overall, responding laboratories were very appreciative of MPEP and overwhelmingly considered it is an important part of their quality management program. Respondents indicated that participation in MPEP increases their laboratory's confidence in their ability to detect drug-resistant TB. Laboratories reported using the *Final Aggregate Report* (**Attachment 13**) in a variety of ways including education, reference material for future TB cases, and review of isolates with unexpected DST results. Ninety-five percent of respondents reported being amenable to receiving isolates that are resistant to at least rifampin and isoniazid (i.e., multi-drug resistant TB) as part of MPEP in future shipments.

Exhibit 2.1 Overview of MPEP Process

MPEP Process

1. Laboratories complete and sign a participant compliance letter annually and send it to CDC via email to TBMPEP@cdc.gov.
    a. Participant Biosafety Compliance Letter of Agreement(https://www.cdc.gov/tb/topic/laboratory/mpep/pdf/MLB.pdf)
2. CDC assigns the participating laboratory an MPEP number, which is needed for participants to enter data (testing results) online.
3. CDC sends a pre-shipment email to participating laboratories to inform them of the expected date to receive the culture shipment from CDC. The participants should notify CDC of any changes in laboratory contact information.
4. CDC sends MTBC cultures to the laboratories with instructions for handling, a manual worksheet, and a deadline for submitting results.
5. CDC sends each participant a link to enter results online. Participants who have not input their results two weeks prior to the deadline will be notified by email or telephone.
6. Once the data has been collected and analyzed, CDC sends by email a final aggregate report to all MPEP enrollees. The report is also posted online on the CDC TB MPEP reports(https://www.cdc.gov/tb/topic/laboratory/mpep/reports.htm) webpage.

3. Use of Improved Information Technology and Burden Reduction

To reduce the burden on each laboratory participant, CDC has provided online access for entering laboratory information and testing results. Submission of all information is 100% web-based for all participants except for an estimated four laboratories that also perform DST using Sensititre. Laboratories performing Sensititre will need to manually complete a *MPEP*

Mycobacterium tuberculosis Minimum Inhibitory Concentration Results Form (**Attachment 9**) and submit their results to CDC by email. A MPEP dedicated phone number (404-639-4013) and email address (TBMPEP@CDC.GOV) are available to provide technical assistance to program participants during the data entry periods.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has taken steps to ensure that the information collected on laboratory susceptibility testing practices and challenge strains are not duplicated or otherwise accessible from any other source. To do so, CDC communicates with Association of Public Health Laboratories (APHL), and American Public Health Association (APHA), and maintains a panel of external experts to ensure that there is no duplication of information requested in this program. Any information collection that is currently conducted either internally or externally in the area of TB does not specifically survey the same technical personnel or provide similar testing and feedback on MTBC susceptibility testing.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses. None of the laboratories participating in this data collection are considered small entities. To reduce the burden on laboratories all results are entered though a web-based application system. The system allows laboratories to skip questions that do not pertain to their normal routine performance. Laboratories report only information for the level of testing they perform routinely. Therefore, each laboratory's voluntary participation imposes no additional record keeping.

6. Consequences of Collecting the Information Less Frequently

Laboratories will receive, test, and record data on select isolates of MTBC twice yearly. This semi-annual shipment and data collection system allows laboratories the opportunity to maintain proficiency in detecting drug resistance while providing the necessary feedback for resolving any proficiency issues in the laboratory. Collecting data less frequently will negatively affect maintenance of laboratory proficiency. Semi-annual shipments and data collection allows laboratories entering the program to participate at least once during their entry year. Changes in laboratory guidelines and practices are captured at this time. There are no technical or legal obstacles to reduce the burden.

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

No special circumstances are planned or intended for the respondents. 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 60-day federal register notice to solicit public comments was published on August 28, 2018, Volume 83, Number 167, Pages 43876–43877 (**Attachment 2**). One non-substantive anonymous public comment was received (**Attchment 2a)**.

No individuals outside the Agency were consulted on either the data collection or analysis associated with this collection activity.

9. Explanations of Any Payment or Gift to Respondents

There will be no payments or tokens of appreciation offered for participation.

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

The Privacy Officer for CDC / ATSDR has assessed this package for applicability of 5 U.S.C. § 552a and has determined that the Privacy Act does apply to the information collection **(Attachment 14).** Respondents are domestic laboratories that perform susceptibility testing on isolates of MTBC. Although data collection forms request the name of the individual who completes the form on behalf of the respondent laboratory, the individual is responding in their role as an official contact for the laboratory, and does not provide personal information. The Privacy Act does not apply to organizations.

CDC is responsible for enrolling participants for MPEP. CDC assigns a unique identification number (MPEP number) to each enrolled participant. CDC maintains the records that link the unique MPEP number to the respondent organization's name.

Participants are required to submit data online by using their assigned MPEP number. Data will be collected from a purposive sample of staff from public health laboratories performing drug susceptibility testing of MTBC. The *Participant Biosafety Compliance Letter of Agreement* (**Attachment 4)** is used to collect the name, city and state of the facility, the name and business title of the person completing form, and because the person completing the form emails the letter back to CDC, the responding email address will be captured. Data collected from the online survey instrument will include the conventional drug susceptibility results and the molecular test results obtained from testing performed on the isolates the facility received from CDC. *The Pre-shipment Email* (**Attachment 4**) will be used to request the Contact and Address Information, which includes the name, participant site, address, city, state, zip code, phone, fax number and email address. The CDC staff has access to respondent names and the information that links a respondent's name to the corresponding MPEP number. However, CDC program staff has only routine access to response information that is coded by the MPEP number. This system safeguards respondent privacy and allows CDC staff to conduct primary analyses only on de-identified data.

The MPEP number is associated with laboratory performance records only. The Laboratory MPEP number link to the master laboratory identification number link is stored in a separate data set. The CDC staff uses this master laboratory identification number to link the laboratory MPEP number to the laboratory address for the purpose of connecting files and creating aggregate reports for distribution to participant laboratories, as needed. All report generation which requires the use of the laboratory identity is the responsibility of the CDC staff.

Response data is primarily filed and retrieved by the MPEP number. The master copy of the database is maintained by CDC staff that restricts access to the data to designated CDC program personnel. CDC IT staff are responsible for ensuring that adequate backup and recovery procedures are in place to ensure that accidental or natural occurrences will not result in loss of project data. These procedures, as a minimum, include regular generation of two (2) backup

copies of the database, with one copy transferred to a secure, off-site facility. In addition, backups are made after major updates to the database are performed.

The data collection procedures allow CDC to conduct primary analyses on the data. However, since CDC offers consultation for the participant laboratories, CDC maintains the capability to re-link identification information, if an individual laboratory seeks CDC's help in resolving testing problems. While CDC does not anticipate the re-linking of identifiers to be a regular occurrence, one cannot be certain how a given test will perform in laboratories. CDC envisions that the re-linking function will persist only for the brief length of time needed to address the performance issues raised by the inquiring participant laboratory of high public health impact associated with any given survey.

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

IRB Approval

The appropriate CDC/ATSDR official has determined that this information collection activity is not human subjects research and therefore does not require IRB approval.

Sensitive Questions

It is not the intent of this program to collect sensitive information. Some laboratories may view their laboratory performance data as sensitive. The data de-identification procedures (described above in Section 10.) were instituted to encourage laboratories to participate in voluntary self-assessment.

12. Estimates of Annualized Burden Hours and Costs

A. Eighty (80) respondents will be asked to complete a *Participant Biosafety Compliance Letter of Agreement* **(Attachment 4**) in order to join the program. This letter is completed once and is estimated to take five minutes to complete for a total of seven burden hours. Each of the 80 participants will need to complete a *MPEP Mycobacterium tuberculosis Results Worksheet (***Attachment7**) and enter results online using the survey instrument. These forms need to be completed for each test shipment, for which there are two annual shipments. This is expected to take 30 minutes for each shipment for a total of 80 burden hours. The *Online Survey Instrument (***Attachment 8***)* is completed by each of the 80 participants, 2 times annually and is expected to take 15 minutes each for a total 40 burden hours. The *Minimum Inhibitory Concentration (MIC) Results Form* (**Attachment 9**) is completed by four participants two times a year taking 15 minutes each for a total of two burden hours annually.

In this submission, the burden has been reduced from the previous submission due to fewer laboratories from 93 to 80, participating in the program. CDC is requesting approval for 129 burden hours.

Table A.12A. Estimate of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Domestic Laboratories	Participant Biosafety Compliance Letter of Agreement (Attachment 4)	80	1	5/60	7
	MPEP *Mycobacterium tuberculosis* Results Worksheet (Attachment 7)	80	2	30/60	80
	Online Survey Instrument (Attachment 8)	80	2	15/60	40
	Minimum Inhibitory Concentration (MIC) Results Form (Attachment 9)	4	2	15/60	2
Total					129

B. The average hourly wage shown below in Table A12.B for respondents is based on salary ranges for laboratory staff wages in U.S. dollars. The average hourly rate for respondents participating in this survey was obtained from the Bureau of Labor Statistics, National Compensation Survey found at http://www.bls.gov/oes/current/oes191022.htm.

Table A12b. Estimated Annualized Burden Hours

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Microbiologist	129	$36.95	$4766.55

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

None.

14. Annualized Cost to the Government

Funding is being made available through the operating budget of the CDC TB Laboratory Branch. The estimated annual cost to the government, $76,772.90 is shown in the table below for two shipments of testing challenges per year. This cost includes wages for staff hours for data analysis, preparation of reports, and preparation and shipping of culture slants for the program.

Annualized Cost to the Government

Expense Type	Expense Explanation	Cost
Direct Cost to the Federal Government	CDC Project Officer (30% effort GS-13, $117,028)	$35,108.40
Direct Cost to the Federal Government	Data Management (30% effort, GS-12, $88,325)	$26,497.50
Direct Cost to Federal Government	Laboratory Support (10% effort, GS-13, 107,569)	$10,756.90
Direct Cost to Federal Government	culture slants, shipping containers, shipping costs	4,410.00
Total		076,772.90

15. Explanation for Program Changes or Adjustments

This is a request for a revision of a currently approved data collection. In this request, CDC is requesting approval for the following revisions:

- Modification of the *Participant Biosafety Compliance Letter of Agreement* (**Attachment 4**) to contain language to ensure that participants understand and comply with biosafety guidelines using quality management system practices.
- Modification of *Instructions to Participants Letter* (**Attachment 6**) to include detailed instructions for online data entry of DST results.
- Modification of *MPEP Mycobacterium tuberculosis Results Worksheet* (**Attachment 7**) to include fields for entering methods used for conventional and molecular DST.
- Addition of a *MPEP Mycobacterium tuberculosis Minimum Inhibitory Concentration (MIC) Results form* (**Attachment 9**) for laboratories performing this procedure to enter results manually and submit by email to TBMPEP@cdc.gov.
- Reduction in request for burden hours from 156 hours to 129 hours due to fewer laboratories participating in the program compared to the previous submission request. Previously there were 93 laboratories, compared to the 80 currently.

16. Plans for Tabulation and Publication and Project Time Schedule

Laboratories will be surveyed twice a year. Data will be analyzed by tabulating and comparing results from various test methodologies and associated practice variables. Analysis also includes compiling and collating a variety of methods and drug concentrations. The data is published as an aggregate report and distributed by email to participating laboratories in pdf files. Data is also posted on the CDC MPEP website at http://wwwn.cdc.gov/mpep/mtbds.aspx. This information will assist in determining guidelines to improve *M. tuberculosis* susceptibility testing.

A. 16.1 Project Time Schedule	
Activity	**Time Schedule**
Enrollment using Participant Biosafety Compliance Letter of Agreement	January (or 2-3 months after OMB approval)
Shipment of Cultures with Instructions for Participants	April and October (or 3-4 months after OMB approval)
Data Entry by Respondents	April and October (3-4 months after OMB

	approval)
Preliminary Reports to Respondents	May and November (or 4-5 months after OMB approval)
Analysis of Aggregate Data	May and November (or 4-5 months after OMB approval)
Final Report to Respondents	January and July(9-10 months after OMB approval)

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

Approval is not requested to not display OMB expiration date.

18. Exceptions for Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.