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

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Supporting Statement A

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Overview

Goals of the study: The goal of the study is to collect and analyze the performance and practices of 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. The TB Model Performance Evaluation Program (MPEP) assesses the ability of laboratories to test for drug resistant MTBC strains, providing laboratories a self-assessment tool to aid in optimizing their skills in susceptibility testing.

Intended use: The information obtained from the laboratories on susceptibility practices and procedures is used to monitor the quality and effectiveness of laboratory testing systems which support public health objectives of tuberculosis treatment programs. Additionally, data will help inform continuous program improvement related to good performance, training needs, and the development of practice standards. Information collected from participants is compiled, analyzed, and developed into an aggregated, de-identified report that laboratories can use as a self-assessment tool to maintain the skills for accurate and reliable drug susceptibility testing of MTBC.

Methods to be used to collect data: Data will be collected from staff of participating 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 survey has routing and logic built-in to limit burden for the majority of participating laboratories that perform testing of antituberculosis drugs.

The subpopulation to be studied: Subpopulations to be studied consist of representative staff from laboratories classified as public health, hospital, independent/reference (non-hospital based), federal, or other.

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. Analyzed data will be presented in aggregated, de-identified reports for participant comparison.

Section A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests an extension to the currently approved information collection 0920-0600 (expiration date 09/30/2025) entitled, "CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* Drug Susceptibility Testing," for a period of 3 years. Non-substantive changes of this information consist of modifications to the project title, online data collection instrument to update molecular testing method choices to reflect current testing options, and MPEP Results worksheet to consolidate four molecular results into one, improving usability and flexibility, per the request of our participants.

Background

Tuberculosis (TB) is a continuing public health problem. The overall number of cases, and associated incidence rate, in the United States has increased over the past few years. High rates are reported among non-U.S.-born persons, correctional populations, people experiencing homelessness, and individuals reported to have diabetes. Adequate TB control depends on rapid isolation and identification of the etiologic agent, *M. tuberculosis* complex, and confirmation of the appropriate therapeutic regimen by antituberculosis drug susceptibility testing (DST). 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 testing evaluations of clinical specimens are critical in reducing TB transmission.

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. 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 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 laboratories. The final report is prepared in a format that will allow laboratory personnel to compare their DST results with those obtained by other participating laboratories using the same method(s) and drugs, for each isolate.

MPEP was established to analyze the performance and practices of clinical and public health laboratories in the United States that perform DST of MTBC isolates. By providing a performance evaluation program to assess the ability of the laboratories to test for drug resistant isolates of MTBC, participating laboratories have a self-assessment tool to aid in optimizing their skills and education in susceptibility testing.

Data collection from CDC MPEP for *Mycobacterium tuberculosis* DST has been useful in identifying gaps in detection of certain drug resistance by current susceptibility testing, in developing educational trainings/webinars, and in assisting laboratories in assessment of their testing practices.

The approval of this extension 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. CDC is requesting non-substantive changes to the ICR, which are explained in Section 15 on page 17 of this supporting statement and in Explanation of Changes (**Attachment 3**).

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 isolates of MTBC to the participating laboratories. Data (test results of isolates) are collected from staff of participating laboratories classified as public health, hospital, independent/reference (non-hospital based), federal, or other to analyze the performance and practices of clinical and public health laboratories in the United States that perform DST of MTBC isolates. Since statistical methods are not utilized, no sampling is employed. Upon signing of a Participant Biosafety Compliance Agreement (**Attachment 5**) by an authorized laboratory 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 in a survey collection instrument (**Attachment 4**). Before survey samples are mailed to the laboratory, a Pre-shipment Email (**Attachment 6**) is sent to participants to inform them of the expected date for receiving the MPEP isolate shipment. The Pre-shipment Email also contains a request to notify CDC of any changes in laboratory contact information. Isolates are sent to the laboratories along with an Instructions to Participants Letter (**Attachment 7**), MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment 8**), and MPEP *Mycobacterium tuberculosis* Minimum Inhibitory Concentration (MIC) Form (**Attachment 9**). The Instructions to Participants contains information on handling the isolates and for reporting DST results online using the survey instrument. All testing results data must be entered online via a link provided to the respondents.

Background information concerning the classification of each participating laboratory and their DST methods are also collected. Participants who have not input their results two weeks prior to the deadline are notified by a Reminder Email (**Attachment 10**). Roughly two weeks after the result entry deadline, an Expected Results Report (**Attachment 11**) is sent to participating laboratories. Approximately four months after the deadline, the results of the data collected are analyzed into a report. A Final Report Letter (**Attachment 12**) is emailed to all enrollees with a pdf version and link to the Final

Report (**Attachment 13)**, also posted on the CDC MPEP Reports Page at https://www.cdc.gov/tb/php/laboratory-information/model-performance-evaluation-program.html.

Data collected are stored as Excel files and converted to R (or equivalent) data sets 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 participating laboratories is compiled, analyzed, and reported in an aggregate report that laboratories can use as a self-assessment tool to maintain the skills needed for DST of MTBC. The challenge isolate strains are sent twice yearly. If data from the challenge isolate strains are not collected and analyzed, laboratories may not have the ability to detect problems related to susceptibility testing and quality control, 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 United States. These results are used to determine needed areas of training while monitoring 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, 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 United States. 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.

In 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 the program and to provide customer feedback to improve service delivery. Forty-nine MPEP participants responded to the survey request with responding laboratories very appreciative of MPEP and overwhelmingly considering it an important part of their quality management program. Respondents indicated that participation in MPEP increased their laboratory's confidence in their ability to detect drug-resistant TB with the Final Report (**Attachment 13**) used in a variety of ways including education, resource for future TB cases, and review of isolates with unexpected DST results.

Exhibit 2.1 Overview of MPEP Process

MPEP Process

1. Laboratories complete and sign a participant biosafety compliance agreement annually and send it to CDC via email to TBMPEP@cdc.gov.
2. CDC assigns the participating laboratory an MPEP number, which is needed for participants to enter data (testing results) online in a survey instrument.
3. CDC sends a pre-shipment email to participating laboratories to inform them of the expected date to receive the isolate shipment from CDC. The participants should notify CDC of any changes in laboratory contact information.
4. CDC sends MTBC isolates to the laboratories with instructions for handling, manual worksheets to assist with data entry, and a deadline for submitting results.
5. CDC electronically sends each participant a link to enter results online. A reminder email is sent two weeks prior to the deadline.
6. Once the data has been collected and analyzed, CDC sends by email, an expected results report and then a final report to all MPEP participating laboratories. The report is also posted online on the CDC TB MPEP reports webpage (https://www.cdc.gov/tb/php/laboratory-information/model-performance-evaluation-program.html).

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 participating laboratories. An 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. Since all results are entered though a web-based collection instrument, the system allows laboratories to skip questions that do not pertain to their testing practices. Laboratories report only information for the level of testing performed routinely. Therefore, each laboratory's voluntary participation imposes no additional record keeping.

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.

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. 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 in the Federal Register on 06/16/2025, Volume 90, Number 114, Pages 25295–25296 (**Attachment 2)**. The notice was titled, “CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis Drug Susceptibility Testing” and closed on 08/15/2025. The CDC received no public comments.

9. Explanation 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 is currently assessing this package for applicability of 5 U.S.C. § 552a 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 participating laboratories in MPEP. CDC assigns a unique identification number (MPEP number) to each enrolled participating laboratory. CDC maintains the records that link the unique MPEP number to the laboratory's name.

Participants are required to submit data online by using their assigned MPEP number. Data is collected from staff of participating laboratories performing DST of MTBC. The Participant Biosafety Compliance Agreement (**Attachment 5**) 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 agreement back to CDC, the responding email address will be captured. Data collected from the online survey instrument will include growth-based drug susceptibility results and molecular test results obtained from testing performed on the isolates the facility received from CDC. The Pre-shipment Email (**Attachment 6**) will be used to request the contact and address information, which includes name, participant site, address, city, state, zip code, phone, fax number, and email address. Limited CDC staff have 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 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 CDC staff.

Response data is primarily filed and retrieved by the MPEP number. The master copy of the database is maintained by CDC staff and access to the data is restricted to designated CDC program personnel only. 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 this voluntary self-assessment.

12. Estimates of Annualized Burden Hours and Costs

Estimated Annualized Burden Hours

Seventy (70) respondents will be asked to complete a Participant Biosafety Compliance Agreement (**Attachment 5**) to join the program. This agreement is completed once annually and is estimated to take five minutes to complete for a total of six burden hours. Each of the 70 participants will need to complete a MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment 8**) and enter results online using the survey instrument. These forms need to be completed for each test shipment, for which there are two biannual shipments. This is expected to take 30 minutes for each shipment for a total of 70 burden hours. The Online Survey Instrument (**Attachment 4**) is completed by each of the 70 participants, two times annually and is expected to take 15 minutes each for a total of 35 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.

CDC is requesting approval for 113 burden hours. The burden is reduced by 16 hours from the previous submission due to the reduction in the number of respondents.

Table 12.A: Estimates of Annualized Burden Hours

Type of Respondent	Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hours)	Total Burden (hours)
Domestic Laboratory	Online Survey Instrument (**Attachment 4**)	70	2	15/60	35

	Participant Biosafety Compliance Agreement (**Attachment 5**)	70	1	5/60	6
	MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment 8**)	70	2	30/60	70
	MPEP Minimum Inhibitory Concentration (MIC) Results Form (**Attachment 9**)	4	2	15/60	2
Total Annualized Burden					113

Estimated Annualized Cost to Respondents

Based on U.S. Department of Labor data, an average hourly wage of $44.89 for Microbiologists is estimated for all 70 respondents. Table 12.B shows estimated cost information.

Note: The hourly rate was determined by using data obtained from the U.S. Department of Labor, Bureau of Labor Statistics: http://www.bls.gov/oes/current/oes_nat.htm

Table 12.B: Estimates of Annualized Costs

Type of Respondent	Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hours)	Hourly Wage ($44.89)
Domestic Laboratory (Microbiologist)	Online Survey Instrument (**Attachment 4**)	70	2	15/60	35x$44.89= $1,571.15
	Participant Biosafety Compliance Agreement (**Attachment 5**)	70	1	5/60	5.83x $44.89= $261.71
	MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment 8**)	70	2	30/60	70x$44.89= $3,142.30
	MPEP Minimum	4	2	15/60	2x$44.89=

	Inhibitory Concentration (MIC) Results Form (**Attachment 9**)				$89.78
Total Annualized Cost					$5,064.94

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

No additional costs are anticipated with this data collection. There will be no direct costs to the respondents other than their time to participate in each data collection.

14. Annualized Cost to the Federal Government

The annualized cost to the government is $105,003. The cost of this project for the three years is estimated to be $315,009. The annualized cost is summarized in Exhibit 14.A.

The personnel related to the MPEP data collection include a Quality Manager at the GS-13 level, Health Scientist at the GS-13 level, and Laboratory Support at the GS-13 and GS-12 levels. Additional costs include culture slants, Category A shipping containers, and shipping costs.

Exhibit 14.A. Annualized Cost to the Federal Government

Expense Type	Expense Explanation			Annual Costs (dollars)
Direct Costs to the Federal Government	Personnel			
	Quality Manager (GS-13)	30%	$115,157	$34,547
	Data Management (GS-13)	30%	$133,732	$40,120
	Laboratory Support (GS-12)	5%	$114,026	$5,710
	Laboratory Support (GS-13)	10%	$133,732	$13,373
Direct Costs to the Federal Government	Supplies			
	Culture slants, Category A shipping containers			$4,653
Direct Costs to the Federal Government	Other			
	Shipping costs			$6,600
Total Cost to the Federal Government				$105,003

*Salary estimates were obtained from the U.S. Office of Personnel Management salary scale at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2025/general-schedule/

15. Explanation for Program Changes or Adjustments

This is a request for an extension of the currently approved data collection. In this request, CDC is requesting approval for the following non-substantive changes:

- Change to the project title of the data collection to "CDC Model Performance Evaluation (MPEP) for Mycobacterium tuberculosis Drug Susceptibility Testing" from "CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis and Nontuberculous Mycobacteria Drug Susceptibility Testing" to reflect that nontuberculous mycobacteria are no longer included in the program.
- Modification of the MPEP Online Survey Instrument (**Attachment 4**) to update molecular testing method choices to reflect current testing options and improve survey usability and flexibility, per the request of participants.
- Modification of the MPEP Results Worksheet (**Attachment 8**) to consolidate collection of molecular testing results for ofloxacin, ciprofloxacin, moxifloxacin, and levofloxacin separately to Fluoroquinolones (moxifloxacin, levofloxacin, ofloxacin).
- Addition of Expected Results Report (**Attachment 11**) to provide participating laboratories a preliminary report prior to the development of the Final Report.

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 growth-based and molecular methods. The data is published as an aggregate report and distributed by email as a PDF to

participating laboratories. Data is also posted on the CDC MPEP website at:

https://www.cdc.gov/tb/php/laboratory-information/model-performance-evaluation-program.html.

Exhibit 16.A. MPEP Project Time Schedule

Activities	Time Schedule
Enrollment using Participant Biosafety Compliance Agreement	January
Shipment of Isolates with Instructions for Participants	February and August
Data Entry by Respondents	April/May and October/November
Analysis of Aggregate Data	June/July and December/January
Final Report to Participating Laboratories	August and February

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

Display of the OMB expiration date is appropriate for this collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.