CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* and Non-tuberculous Mycobacteria Drug Susceptibility Testing (OMB Control No. 0920-0600)

Request for Revision
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CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* and Non-tuberculous Mycobacteria Drug Susceptibility Testing (OMB Control No. 0920-0600)

Request for Revision

CDC is requesting OMB approval for a revision of the currently approved data collection, the CDC MPEP for *Mycobacterium tuberculosis* and Non-tuberculous Mycobacteria Drug Susceptibility Testing. In this request, CDC is requesting approval for the following revisions:

- Deleting the burden for international labs from the 2006 submission. International laboratories are no longer participating in this MPEP program (-165 hours)
- Decreasing the number of domestic laboratories participating in this program (-33 respondents; -33 burden hours)
- Added back the Laboratory Practices Questionnaire (LPQ). The LPQ was originally included and approved in CDC's 2001 submission. It was not included in the 2006 submission (+33 hours).
- Rounding up the burden for the Enrollment Form and Change Form (+1 hour each for a total of +2 hours).
- Streamlined the Results Form to an online data collection and deleting all hardcopy forms (no change in burden hours)

This information collection request is currently approved for 165 hours. However in preparing this request, CDC has discovered a calculation error in the previous submission. The annualized burden for the previous submission should have been 330 hours, not the 166 hours currently approved. This 2010 submission is requesting OMB approval for a total of 167 hours or an increase of 2 hours over the current approval. The increase can be attributed to rounding up the burden for the Enrollment Form and Change Form. This icr is scheduled to expire March 31, 2010. CDC is requesting a 3 year approval to collect data.

A. Justification

1. Circumstances Making the Collection of Information Necessary

As part of the continuing effort to assess and monitor the quality and effectiveness of laboratory testing systems which support public health objectives of tuberculosis treatment programs, the Centers for Disease Control and Prevention (CDC) evaluates the performance and practices of domestic public health laboratories and international laboratories which have public health responsibilities. These laboratories must have the approval of their National Tuberculosis Program for drug susceptibility testing of *Mycobacterium tuberculosis* (*M. tuberculosis)* and other selected non-tuberculous Mycobacteria (NTM). This voluntary performance evaluation program assesses the reproducibility of test results and the practices reported by clinical and public health

laboratories twice a year through the use of an online data entry website (Attachment 4c: General Instructions and Results Worksheet) and a set of clinical mycobacterial culture strains. The Laboratory Practices Questionnaire (LPQ) (Attachment 6) is administered every other year (biennially) to assess laboratory practices, methods, and procedures. New participants are enrolled using the Enrollment Form (Attachment 3a) and laboratories can update their facility information using the Information Change Form (Attachment 5). All information will be collected electronically.

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.

From 1985 to 1992, the increase in the number of cases of tuberculosis was accompanied by increasing numbers of *M. tuberculosis* found to be resistant to one or more of the primary drugs used for treatment. This pattern of resistance has added significantly to the cost and duration of treatment while reducing the efficacy of therapy. These issues continue to challenge TB control programs in the U.S. 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. Mycobacteriology 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.

Since the 1992 TB resurgence peaked in the U.S., the number of TB cases reported annually has decreased. In 2008, a total of 12,898 incident tuberculosis (TB) cases were reported in the U.S.; the TB rate declined 3.8% from 2007 to 4.2 cases per 100,000 population.

This study is authorized under the Public Health Service Act, (42 USC 241) Section 301. A copy is included in the attachments. (Attachment 1)

Privacy Impact Assessment

The information is filed and retrieved by the MTB/NTM DST identification number (TPEP). The number is linked to the name of the organization which is a testing site. The Privacy Act does not apply to those organizations that are enrolled in MPEP. While the names of persons completing the forms are requested, no other personal identifiers are collected other than their title. Respondents are speaking in their roles as staff knowledgeable of performance testing and laboratory practices at their testing site.

Overview of the Data Collection System

When laboratories complete the Enrollment Form (attachment 3a) and enroll in the MTB/NTM DST, they are assigned a login number (TPEP) (attachment 3c, Acceptance

Letter) and sent a program description via email (attachment 3b). The TPEP number and password are required for electronic data entry. Before survey samples are mailed to the laboratory, an advance email pre-shipment letter (attachment 4a) and a Laboratory Information Change Form (attachment 5) are sent to participants to inform them of the expected date for receiving the culture shipment (survey samples) and to capture any changes in laboratory contact information. Cultures are sent to the laboratories along with a shipment letter containing the laboratory password (attachment 4b), instructions for handling the culture isolates and for reporting testing results online for the shipment (attachment 4c). Testing results and demographic information are collected from respondents through the CDC MPEP online website for *M. tuberculosis* and non-tuberculosis susceptibility testing. The password and TPEP number are also required for entering data for the Laboratory Practices Questionnaire (attachment 6). On the results entry site, CDC MPEP staff post a case history for the NTM isolate (attachment 4d). If laboratories have not responded to either the survey samples or the LPQ, they are contacted by email (attachment 4.e.i.) or by telephone (attachment 4.e.ii.) one to two weeks before the deadline. Only online results are accepted. Thirty days after the deadline, CDC MTB/NTM staff sends an electronic copy of the preliminary report (attachment 4f). Approximately 60 days after the deadline, the results of the data collected are analyzed and the aggregate report letter (attachment 4g) is emailed to all enrollees and the complete aggregated report will be posted on the CDC MPEP Home Page at http://wwwn.cdc.gov/mpep/mtbds.aspx. An example Final Aggregate Report is found in Attachment 4.i.

Data collected for the sample survey and the laboratory practices questionnaire are stored as SAS files (or equivalent) data sets and imported into Excel files with a unique identifier. The CDC information technology (IT) contractors de-link the facility name and identification number. The laboratory/facility classification information for all data sets resides in the CDC mainframe computer.

Hard copies of the results worksheets may be provided to assist laboratory personnel with the data entry. The results of the hard copy worksheets are not returned to the CDC. All data is treated in a secure manner and will not be 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. All information collections (both the Results Worksheet and LPQ) are web-based. The information collected will be maintained at the CDC for at least 10 years.

Items of Information to be Collected

The information collected consists of laboratory demographic information about the testing facility, the susceptibility testing results, and laboratory practices information associated with laboratory standards, guidelines, and testing methods. No individually identifiable information is to be collected.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The CDC MPEP maintains a home page with program information. The website information is not directed at children under 13 years of age.

2. Purpose and Use of Information Collection

Over the past 5 years, despite the fact that the number of cases of TB has slightly declined in the U.S. population, the number of domestic laboratories participating in the MTB/NTM DST Program enrollment has remained stable. Information collected from participants via the website are compiled, analyzed, and distributed in aggregate form (Attachment 4g: Aggregate Report Letter) or posted on the MPEP Homepage (Attachment 4i) that laboratories can use as a self-assessment tool to help improve and maintain the skills of laboratory participants in susceptibility testing of TB and selected non-tuberculous Mycobacteria. 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. Data from this program will be used by CDC and other public health organizations to measure reproducibility of susceptibility test results performed with various test procedures in the U.S. These results will be used to determine areas of need for training while monitoring reagents and test methodologies to improve the quality of susceptibility testing of *M. tuberculosis* and other Mycobacteria.

Because of the importance of accurate and timely test results for the success of TB surveillance, prevention, and treatment programs, the CDC has maintained an active role in the assurance of high quality laboratory testing. The MTB/NTM DST Program fulfills part of this role by monitoring the level of performance and practices among public health and private sector laboratories within the U.S. Information obtained on susceptibility testing practices and procedures help to determine variables related to good performance, assessing areas for training and development of practice standards. By providing a performance evaluation program to assess the ability of the laboratories to test for drug resistant *M. tuberculosis* and selected strains of NTM, laboratories also have a self-assessment tool to aid in optimizing their skills in susceptibility testing.

The MTB/NTM DST is a voluntary self-assessment non-statistical data collection program.

Privacy Impact Assessment Information

No sensitive information will be collected. This data collection will have little or no effect on the respondent's privacy. No IIF is being collected.

3. Use of Improved Information Technology and Burden Reduction

To reduce the burden on each laboratory participant, CDC has provided online access to the enrollment, questionnaire, and testing results through the CDC internet webpage at (http://wwwn.cdc.gov/mpep/mtbds/login.aspx). Submission of all information is 100% web-based. A toll-free phone number is 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 Mycobacteriology does not specifically survey the same technical personnel or provide similar testing and feedback on *M. tuberculosis*/NTM susceptibility testing.

5. Impact on Small Businesses or Other Small Entities

To reduce the burden on laboratories, two different shipment panels are offered. A limited panel of isolates will be shipped to laboratories that only perform primary drug testing on M. tuberculosis and a panel containing non-tuberculous Mycobacteria will be shipped for testing upon request. All results will be entered though a web-based application system. The system allows laboratories to skip questions that do not pertain to their normal routine performance. Laboratories are only expected to report information for the level of testing they perform routinely. Therefore, each laboratory's voluntary participation imposes no additional record keeping. None of the laboratories participating in this data collection would be considered small businesses or small entities.

6. Consequences of Collecting the Information Less Frequently

Laboratories will receive, test, and record data on select *M. tuberculosis* isolates 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 to ensure a period of time sufficient for resolving any proficiency issues in the laboratory. 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 will be captured at this time. There are no legal obstacles to reduce the burden. The laboratory practices questionnaire will only be conducted every other year.

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

The information collection activity fully complies with Guidelines 5 CFR 1320.5. No special circumstances are planned or intended for the respondents.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published on June 18, 2009, vol. 74 No. 116, pp. 28939-28940 (Attachment 2). There were no public comments.

B. In development of the survey questions, CDC solicited the feedback from the following personnel in reviewing the Results Worksheets and LPQ within the past year (March-June 2009):

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These individuals provided minor semantic changes to both forms that were incorporated into the forms.

9. Explanations of Any Payment or Gift to Respondents

There will be no compensation offered for participation in the program.

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this information collection request and has determined that the Privacy Act is not applicable. Respondents are domestic laboratories that perform *M. tuberculosis* susceptibility testing. 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 processing registration forms for the MTB/NTM DST. Laboratories that wish to enroll must do so through a web-based Enrollment Form. CDC reviews the Enrollment Form for completeness and assigns a unique identification number (TPEP number) to the participant. CDC's contractor maintains the records that link the unique TPEP ID number to the respondent organization's name.

Participants are required to submit data online by using an assigned a unique log-in ID and password. The CDC IT staff has access to respondent names and the information that links a respondent's name to the corresponding TPEP number. However, CDC program staff have only routine access to response information that is coded by the TPEP number. This system safeguards respondent privacy and allows CDC staff to conduct primary analyses only on de-identified data.

The TPEP number is associated with laboratory performance records only. The Laboratory TPEP number link to the master laboratory identification number link is stored in a separate data set. The CDC IT staff uses this master laboratory identification number to link the laboratory TPEP 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 IT staff. CDC program staff must send a written request to the CDC IT staff, should it become necessary to identify the laboratory.

Response data is primarily filed and retrieved by the TPEP number. The master copy of the data base is to be maintained by CDC IT staff and resides on the MS SQL Server 2005. The facilities of the TOP SECRET mainframe security package are used to restrict access to the data to designated CDC program personnel. The IT staff is 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 data base, with one copy transferred to a secure, off-site facility. In addition, backups are made after major updates to the data base 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 can not 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.

Privacy Impact Assessment Information

Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

A. The information will be filed and retrieved by the MTB/NTM DST (TPEP) identification number. The number is linked to the name of the organization which is a testing site. The Privacy Act does not apply to organizations. While names of persons completing the form is requested, no other personally identified information is collected other than their title. They will be speaking in their roles as staff knowledgeable of performance testing and laboratory practices.

B. Not applicable. Only test results will be collected for use in an aggregate report. Facilities reporting results will not be identified in the reports and no personal information from the individual submitting results will be collected.

C. No respondent consent is required. This is a voluntary program.

D. This is a voluntary program as stated in the announcement, the program brochure, and in the final aggregate reports.

11. Justification for 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. One hundred thirty-two (132) laboratories (respondents) will receive the Results Worksheet twice a year. Respondents are asked to complete the Enrollment Form when they join the program. CDC asks respondents to supply program changes via the Information Change Form.

In this submission, CDC is requesting approval for domestic laboratory participants only; the 2006 submission included 165 international laboratories. In addition, CDC is decreasing the number of domestic laboratory participants from 165 in the 2006 submission to 132 in this submission. In this submission, CDC is also adding back the Laboratory Practice Questionnaire (LPQ). The LPQ was originally included in the 2001 submission but was not included in subsequent submissions. CDC would like to bring this data collection back in order to learn about laboratory practice in participating laboratories. The LPQ will be administered to participating laboratories every other year. Finally, CDC is rounding up the burden for the Enrollment Form and Information Change Form to 1 hour each. The burden for each form is actually 0.33 hours each. CDC feels that rounding up the burden will more accurately reflect the burden to respondents.

Table A.12A. Estimate of Annualized Burden Hours

Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Enrollment Form	4	1	5/60	1
Information Change Form	4	1	5/60	1
Results Worksheet	132	2	30/60	132
Laboratory Practices Questionnaire	66	1	30/60	33
Total	206			167

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 www.bls.gov.

Table A12b. Estimated Annualized Burden Hours

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Microbiologist	167	$31.00	$5,177.00

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

None.

14. Annualized Cost to the Government

The estimated annual contractor cost to the government is shown in the table below for 2 shipments of testing challenges per year. This cost includes wages for staff hours involved in preparation of culture slants, shipping, and overhead expenses for the performance evaluation program. All of the work mentioned above is performed by the contractor with a cost plus fixed-fee contract. The contract is a one-year contract with 4 option years.

Annualized Cost to the Government

Expense Type	Expense Explanation	Cost
Direct Cost to the Federal Government	CDC Project Officer (50% effort GS-13 $94,877)	$47,385.00
Direct Cost to the Federal Government	Clerical (25% effort, GS-7, $39,687)	9,921.75
Contractor Cost	Cost plus fixed-fee	$187,188.00
Total		$244,494.75

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:

- Deleting the burden for international labs from the 2006 submission. International laboratories are no longer participating in this MPEP program (-165 hours)
- Decreasing the number of domestic laboratories participating in this program (-33 respondents; -33 burden hours)
- Added back the Laboratory Practices Questionnaire (LPQ). The LPQ was originally included and approved in CDC's 2001 submission. It was not included in the 2006 submission (+33 hours).
- Rounding up the burden for the Enrollment Form and Change Form (+1 hour each for a total of +2 hours).

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16. Plans for Tabulation and Publication and Project Time Schedule

Laboratories are surveyed twice a year using the Results Worksheet and once every other year using the Laboratory Practices Questionnaire. Data is 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 TPEP 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**
Letters to Respondents	June and December (or 2-3 months after OMB approval)
Results Form worksheets Delivery	January and July (or 3-4 months after OMB approval)
Data Entry by Respondents	January and July (3-4 months after OMB approval)
Preliminary Reports to Respondents	March and September (or 4-5 months after OMB approval)
Analysis of Aggregate Data	April and October (or 4-5 months after OMB approval)
Final Report to Respondents	May and November
Laboratory practice Questionnaire	April (once every year) (or 1-2 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.

B. Collections of Information Employing Statistical Methods

This data collection does not use statistical methods.

Laboratories enroll in the program via the Enrollment Form and are assigned a login number (TPEP) and sent a program description via email. The TPEP number and password are required for electronic data entry. An advance email pre-shipment letter and a Laboratory Information Change Form are sent to participants to inform them of the expected date for receiving the culture shipment (survey samples) and to capture any changes in laboratory contact information. Cultures are sent to the laboratories along with a shipment letter containing the laboratory password, instructions for handling the culture isolates and for reporting testing results online for the shipment. Testing results and demographic information are collected from respondents through the CDC MPEP online website for *M. tuberculosis* and non-tuberculosis susceptibility testing. The password and TPEP number are also required for entering data for the Laboratory Practices Questionnaire which collects laboratory practice information from participants every other year. On the results entry site, CDC MPEP staff post a case history for the NTM isolate. If laboratories have not responded to either the survey samples or the LPQ, they are contacted by email or by telephone one to two weeks before the deadline. Only online results are accepted. Thirty days after the deadline, CDC MTB/NTM staff sends an electronic copy of the preliminary report. Approximately 60 days after the deadline, the results of the data collected are analyzed and the aggregate report letter is emailed to all enrollees and the complete aggregated report will be posted on the CDC MPEP Home Page at http://wwwn.cdc.gov/mpep/mtbds.aspx.

List of Attachments

1. Authorizing Legislation
2. 60 day Federal Register Notice
3. Laboratory Enrollment Form documents
    a. Laboratory Enrollment Form
    b. Program Description
    c. Acceptance Letter
4. Results Worksheet documents
    a. Pre-shipment Letter/email
    b. Shipment and Password Letter/email
    c. General Instruction for Handling Culture Isolates and Test Results Worksheet
    d. Case History Form – NTM Supplemental Information (example)
    e. Non-Responder notices
        i. Reminder email
        ii. Reminder telephone script
    f. Preliminary Report for Sample Shipment
    g. Aggregate Report Letter
    h. Analysis of Performance Evaluation Results (example)
    i. Complete Final Aggregate Report (example)
5. Laboratory Information Change Form
6. Laboratory Practice Questionnaire (LPQ)