Request for Extension to an Approved Information Collection

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

(OMB Control No. 0920-0600)
Exp. 05/31/2016

Supporting Statement A

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CDC Model Performance Evaluation Program (MPEP) for
Mycobacterium tuberculosis Drug Susceptibility Testing
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30. **A. Justification**

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- **Goal of the study** : Study was designed 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).
- **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.
- **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.
- **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.

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58. 1. Circumstances Making the Collection of Information Necessary

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60. The Centers for Disease Control and Prevention (CDC) requests an extension for three years to approved information collection 0920-0600 (expiration date 05/31/2016) entitled, "*CDC Model Performance for Mycobacterium tuberculosis Drug Susceptibility Testing*." Extension of this information will not require changes in the scope of the study, methodology, information collection instruments, and burden on the respondents.

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62. Extension of this information collection will continue to provide essential data required by CDC to assess and monitor the quality and effectiveness of laboratory testing systems which support public health objectives of tuberculosis treatment programs. The CDC Model Performance Evaluation Program (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). MPEP is a voluntary self-assessment and non-statistical data collection program. 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. Extension of data collection will allow CDC to

evaluate the effectiveness of these training modules by continually monitoring laboratory performance.

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65. 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.

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67. This information collection activity is authorized under the Public Health Service Act, (42 USC 241) Section 301. A copy is included in the attachments. (**Attachment A**)

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69. 2. Purpose and Use of Information Collection

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71. Upon signing of the Participant Biosafety Compliance Letter of Agreement (**Attachment D**) by an authorized representative, the laboratory will be enrolled in MPEP and assigned a TPEP number. The TPEP number is needed for participants to enter data online. Before survey samples are mailed to the laboratory, an advance Pre-shipment Email (**Attachment F**) 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 G**) and MPEP Mycobacterium tuberculosis Results Worksheet **(Attachment E**). The Instructions to Participants contains information on handling the culture isolates and for reporting drug susceptibility test (DST) results online using the survey instrument (**Attachment C)**. All data must be entered online at https://adobeformscentral.com/?f=-OE0XxQcK8H-bBka5ibeWg. Background information concerning the classification of each participating laboratory and their DST methods will also be collected. Each participant will be sent a link to enter all information online. Participants who have not input their results two weeks prior to the deadline will be notified by email (**Attachment H**) or by telephone (**Attachment I**). Approximately 60 days after the deadline, the results of the data collected are analyzed and an aggregate report letter (**Attachment J**) is emailed to all enrollees and a link to the completed aggregated report will be 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 K**.

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73. Data must be entered online (http://MPEP.formstack.com/forms/mpep_1) using a survey instrument (**Attachment C**). Background information concerning the classification of

each participating laboratory and their DST methods will also be collected. Each participant will be sent a link to enter all information online. 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. All data are 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. The information collected will be maintained at the CDC for at least 10 years.

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75. 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.

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77. Data from this information collection has been 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 have been 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 has maintained 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.

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

80. 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. 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.

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

83. 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 would be considered small entities. To reduce the burden on laboratories 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.

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 to ensure a period of time sufficient 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 will be 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 November 17, 2015, Volume 80, Number 221, Pages 71802– 71803 (**Attachment B**). No public comments were received.

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 CDC NCHHSTP PRA Coordinator has reviewed this information collection request and has determined that the Privacy Act is not applicable. 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. 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 data base is to be maintained by CDC staff that restricts access to the data to designated CDC program personnel. CDC 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 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

<u>IRB Approval</u>

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

119.
120. Sensitive Questions
121. 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.
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123. **12. Estimates of Annualized Burden Hours and Costs**
124. A. Ninety-three (93) respondents will be asked to complete a Participant Biosafety Compliance Letter of Agreement **(Attachment D**) in order to join the program. Each participant will need to complete a MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment E**) and enter results online using the survey instrument. These forms need to be completed for each test shipment. Two shipments are sent annually. .
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126. In this submission, the burden has not changed. CDC is requesting approval for 156 burden hours.

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128. Table A.12A. Estimate of Annualized Burden Hours

129. Type of Respondent	130. Form Name	131. No. of Respondents	132. No. of Responses per Respondent	133. Average Burden per Response 134. (in hours)	135. Total Burden Hours
136. Domestic Laboratories 137.	138. Participant Biosafety Compliance Letter of Agreement 139.	140. 93	141. 2	142. 5/60	143. 16
	145. MPEP *Mycobacterium tuberculosis* Results Worksheet	146. 93	147. 2	148. 30/60	149. 93
	151. Online Survey Instrument	152. 93	153. 2	154. 15/60	155. 47

129. Type of Respondent	130. Form Name	131. No. of Respondents	132. No. of Responses per Respondent	133. Average Burden per Response 134. (in hours)	135. Total Burden Hours
156. Total	157.	158. 93	159. 6	160.	161. 156

162.

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164. 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.

165.

166. Table A12b. Estimated Annualized Burden Hours

167. Type of Respondent	168. Total Burden Hours	169. Hourly Wage Rate	170. Total Respondent Costs
171. Microbiologist	172. 156	173. $36.79	174. $5,739.24

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

178. None.

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180. 14. Annualized Cost to the Government

181. The estimated annual cost to the government, $70,537.20, 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.

182.

183. Annualized Cost to the Government

184. Expense Type	185. Expense Explanation	186. Cost
187. Direct Cost to the Federal Government	188. CDC Project Officer (30% effort GS-13, $109,383)	189. $32,814.90
190. Direct Cost to	191. Data	193. $23,238.30

184. Expense Type	185. Expense Explanation	186. Cost
the Federal Government	Management 192. (30% effort, GS-12, $77,461)	
194. Direct Cost to Federal Government	195. Laboratory Support 196. (10% effort, GS-13, 100,748)	197. $10,074.00
198. Direct Cost to Federal Government	199. culture slants, shipping containers, shipping costs	200. 4,410.00
201. Total	202.	203. 070,537.20

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206. 15. Explanation for Program Changes or Adjustments

207. This extension request does not require any program changes or adjustments. The burden has not changed from the burden shown in the current inventory.

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

210. Laboratories are surveyed twice a year. 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 MPEP website at

211. http://wwwn.cdc.gov/mpep/mtbds.aspx. This information will assist in determining guidelines to improve *M. tuberculosis* susceptibility testing.

212.

213. A. 16.1 Project Time Schedule	
214. Activity	**215. Time Schedule**
216. Enrollment using Participant Biosafety Compliance Letter of Agreement	**217.** March and September (or 2-3 months after OMB approval)
218. Shipment of Cultures with Instructions for Participants	**219.** May and November (or 3-4 months after OMB approval)
220. Data Entry by Respondents	**221.** May and November (3-4 months after OMB approval)
222. Preliminary Reports to Respondents	**223.** June and December (or 4-5 months after OMB approval)
224. Analysis of Aggregate Data	**225.** June and December (or 4-5 months after OMB approval)
226. Final Report to Respondents	**227.** July and January (or 5-6 months after OMB approval)

228.

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

230. 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.