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

Supporting Statement A

Request for Revision
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53. (OMB Control No. 0920-0600)

54.
55. **A. Justification**
56.

1. Circumstances Making the Collection of Information Necessary

57.
58. The Centers for Disease Control and Prevention requests a revision to approved data collection 0920-0600 (expiration date 05/31/2013) entitled, "*CDC MPEP for Mycobacterium tuberculosis and Nontuberculous Mycobacteria Drug Susceptibility Testing*," for a period of 3 years. 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 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 non-statistical data collection program.
59. Implementation of this program under this information collection has been transferred from the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) to National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). The title of the ICR is being changed from "*CDC MPEP for Mycobacterium tuberculosis and Nontuberculous Mycobacteria Drug Susceptibility Testing"* to "*CDC Model Performance Evaluation (MPEP) for Mycobacterium tuberculosis Drug Susceptibility Testing*" As a result of this programmatic change, CDC is requesting several revisions to the ICR which are explained in Section 15 on page 9 of this supporting statement and in **Attachment C**.
60.
61. 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.

62. 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.

63. Since the 1992 TB resurgence peaked in the U.S., the number of TB cases reported annually has decreased. 11,182 TB cases were reported to CDC from the 50 states and the District of Columbia (DC) for 2010, representing a 3.1% decrease from 2009. In 2010, the TB case rate declined from 3.8 to 3.6 per 100,000 persons, representing a 3.8% decrease from 2009.
64.
65. 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**)
66.
67. <u>Privacy Impact Assessment</u>
68. The information is filed and retrieved by the Tuberculosis Performance Evaluation Program (TPEP) Number. 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.
69.

70. Overview of the Data Collection System 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 E**) 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 an Instructions to Participants Letter (**Attachment F**) and a MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment G**). 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 H**). Background information concerning the classification of each participating laboratory and their DST methods will also be collected. All information must be entered online at **http://www.snapsurveys.com/swh/surveylogin.asp?k=135817325450**. Participants who have not input their results two weeks prior to the deadline will be notified by email (**Attachment I**) or by telephone (**Attachment J**). Approximately 60 days after the deadline, the results of the data collected are analyzed and an aggregate report letter (**Attachment K**) 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 of the Final Aggregate Report is found in **Attachment L**.
71.
72. 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.
73.
74. Items of Information to be Collected
75. The information collected consists of laboratory demographic information about the testing facility, the DST results, and laboratory practices information associated with laboratory standards, guidelines, and testing methods. No individually identifiable information is to be collected.
76.
77. Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age
78. The CDC MPEP maintains a home page with program information. The website information is not directed at children less than 13 years of age.
79.
80.
81. **2. Purpose and Use of Information Collection**
82. 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 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 MTBC.

83. 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. 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 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.
84.
85. Privacy Impact Assessment Information
86. 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.
87.
88. **3. Use of Improved Information Technology and Burden Reduction**
89. To reduce the burden on each laboratory participant, CDC has provided online access for entering laboratory information and testing results through an internet webpage at **http://www.snapsurveys.com/swh/surveylogin.asp?k=135817325450**. 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.
90.
91. **4. Efforts to Identify Duplication and Use of Similar Information**
92. 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 MTBC susceptibility testing.
93. **5. Impact on Small Businesses or Other Small Entities**
94. 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. 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 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. 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

100. 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

The 60-day Federal Register Notice was published Friday, January 18, 2013, Vol. 78, No. 13 pages 4148-4149 (see **Attachment B**). No public comments were received.

9. Explanations of Any Payment or Gift to Respondents

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

108. 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 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. Laboratories that wish to enroll must do so by completing and signing a Participant Biosafety Compliance Letter of Agreement (**Attachment A**). CDC assigns a unique identification number (TPEP number) to each enrolled participant. CDC maintains the records that link the unique TPEP number to the respondent organization's name.

Participants are required to submit data online by using their assigned TPEP number. The CDC staff has access to respondent names and the information that links a respondent's name to the corresponding TPEP number. However, CDC program staff has 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.

114. 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 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 staff.

115.

116. Response data is primarily filed and retrieved by the TPEP 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 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 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.

117.

118. 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.

119.

120.

121. <u>Privacy Impact Assessment Information</u>

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

123.

124. A. The information will be filed and retrieved by the 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.

125.

126. 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.

127.

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

129.

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

131. **11. Justification for Sensitive Questions**

132. 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.

133.

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

135. A. Ninety-three (93) respondents will be asked to complete the Participant Biosafety Compliance Letter of Agreement (**Attachment D)** in order to join the program. Each participant will need to complete an MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment G**) and enter results online using the survey instrument (**Attachment A)**. These forms need to be completed for each test shipment. Two shipments are sent annually. There is a reduction in the number of participating laboratories from 96 to 93 which reduces burden hours from 167 to 156

136.

137. In this submission, CDC is requesting approval for 156 burden hours.

138.

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

140. Type of Respondent	141. Form Name	142. No. of Respondents	143. No. of Responses per Respondent	144. Average Burden per Response 145. (in hours)	146. Total Burden Hours
147. Domestic Laboratories 148.	149. Participant Biosafety Compliance Letter of Agreement 150.	151. 93	152. 2	153. 5/60	154. 16
	156. MPEP *Mycobacterium tuberculosis* Results Worksheet	157. 93	158. 2	159. 30/60	160. 93
	162. Online Survey	163. 93	164. 2	165. 15/60	166. 47

140. Type of Respondent	141. Form Name	142. No. of Respondents	143. No. of Responses per Respondent	144. Average Burden per Response 145. (in hours)	146. Total Burden Hours
	Instrument				
167. Total	168.	169. 93	170. 6	171.	172. 156

173.

174.

175. 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.

176.

177. Table A12b. Estimated Annualized Burden Hours

178. Type of Respondent	179. Total Burden Hours	180. Hourly Wage Rate	181. Total Respondent Costs
182. Microbiologist	183. 156	184. $31.69	185. $4,943.64

186.

187.

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

189. None.

190. 14. Annualized Cost to the Government

191. The estimated annual cost to the government, $65,560, 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.

192.

193. Annualized Cost to the Government

194. Expense Type	195. Expense Explanation	196. Cost
197. Direct Cost to the Federal Government	198. CDC Project Officer (30% effort GS-13, $105,449)	199. $31,634.70
200. Direct Cost to the Federal Government	201. Data Management 202. (30% effort,	203. $21,570.30

194. Expense Type	195. Expense Explanation	196. Cost
	GS-12, $71,901)	
204. Direct Cost to Federal Government	205. Laboratory Support 206. (10% effort, GS-12, 93,470)	207. $9,163.00
208. Direct Cost to Federal Government	209. culture slants, shipping containers, shipping costs	210. $3,192
211. Total	212.	213. 065,560

214.

215.

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

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

- Transfer of the ICR from the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) to National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). NCEZID lacked resources and subject matter expertise to continue management of the program. In addition, evaluation of laboratory programs performing testing on isolates of MTBC is a mission within NCHHSTP.
- Changing the title of the data collection to "CDC Model Performance Evaluation (MPEP) for *Mycobacterium tuberculosis* Drug Susceptibility Testing" to reflect that nontuberculous mycobacteria are no longer included in the test package.
- Replacement of Laboratory Enrollment Form with a Participant Biosafety Compliance Letter of Agreement (Attachment D). CDC needs to document that laboratories participating in MPEP are equipped with the necessary biosafety facilities and practices to work with isolates of MTBC and acknowledge the potential risks associated with manipulation of live cultures of MTBC. The current Laboratory Enrollment Form is not suitable for this purpose.
- Revision of the Pre-shipment Email (Attachment E). The transfer of MPEP from NCEZID to NCHHSTP has necessitated that participants be notified of changes to management of the program.
- Addition of an Instructions to Participants Letter (Attachment F). The transfer of MPEP from NCEZID to NCHHSTP has necessitated that participants be instructed on new procedures for submitting results online.
- Revision of the MPEP *M. tuberculosis* Results Worksheet (Attachment G). A revised worksheet is needed for participants to record their results prior to online entry.
- Entering results online using a modified survey instrument created with Snap Surveys® software (Attachment H). In the opinion of CDC, the format of this instrument is more user-friendly for entering results than the prior data collection instrument.
- Modification of Reminder Email (Attachment I) to reflect changes in CDC contact information due to transfer of MPEP from NCEZID to NCHHSTP.
- Modification of Reminder Telephone Script (Attachment J) to reflect changes in CDC contact information.

- Modification of the Aggregate Report Letter (Attachment K) to reflect changes in CDC contact information.
- Reduction in the number of participating laboratories from 96 to 93 and reduction in burden hours from 167 to 155 (Table A.12A)

218.

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

220. 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

221. http://wwwn.cdc.gov/mpep/mtbds.aspx.

222. This information will assist in determining guidelines to improve *M. tuberculosis* susceptibility testing.

223.

224.

225. **A. 16.1 Project Time Schedule**	
226. **Activity**	**227.** **Time Schedule**
228. Enrollment using Participant Biosafety Compliance Letter of Agreement	**229.** March and September (or 2-3 months after OMB approval)
230. Shipment of Cultures with Instructions for Participants	**231.** May and November (or 3-4 months after OMB approval)
232. Data Entry by Respondents	**233.** May and November (3-4 months after OMB approval)
234. Preliminary Reports to Respondents	**235.** June and December (or 4-5 months after OMB approval)
236. Analysis of Aggregate Data	**237.** June and December (or 4-5 months after OMB approval)
238. Final Report to Respondents	**239.** July and January (or 5-6 months after OMB approval)

240.

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

242. Approval is not requested to not display OMB expiration date.

243.

244. **18. Exceptions for Certification for Paperwork Reduction Act Submissions**

245. There are no exceptions to the certification.

246. **Statistical Methods**

247.

248. **B. Collections of Information Employing Statistical Methods**

249.

250. This data collection does not use statistical methods.

251.

252. Laboratories enroll in the program via the Enrollment Form and are assigned an identification (TPEP) number. The TPEP number is required for electronic data entry. An advance Pre-shipment Email is sent to participants to inform them of the expected date for receiving the culture shipment 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 laboratory information are collected from respondents through an online website. If laboratories have not entered DST results one to two weeks before the deadline, they are contacted by email or by telephone. Only online results are accepted. Aggregate data are derived from the testing results of the various methods provided to CDC by each of the laboratories. CDC compiles the test results in graph and table form to prepare aggregate reports. Results compiled from participating laboratories include the total volume of MTBC isolates tested, the distribution of susceptibility methods used for testing, test media used for susceptibility testing, antituberculous drugs used for testing, and susceptibility results for each of the MTBC test isolates. Thirty days after the deadline, CDC staff will send 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. The aggregate report allows participants to compare their results with others at a national level and improve testing quality through self-evaluation. The CDC uses test results to identify potential testing problems and to consult with participants to incorporate procedures to eliminate them.

253.