

**CDC Model Performance Evaluation Program (MPEP) for
Mycobacterium tuberculosis Drug Susceptibility Testing
(OMB Control No. 0920-0600)
Exp. 05/31/2016**

Request for Nonmaterial/Nonsubstantive Change to an Approved Information Collection

Modified Supporting Statement

November 4, 2013

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

54.

55. **A. Justification**

56.

57. **Circumstances Making the Collection of Information Necessary**

58.

59. The Centers for Disease Control and Prevention (CDC) requests nonmaterial/non-substantive changes to approved information collection 0920-0600 (expiration date 05/31/2016) entitled, “*CDC Model Performance for Mycobacterium tuberculosis Drug Susceptibility Testing.*” These changes are not significant to the scope of the study, methodology or information collection instruments. There is no change in burden on the respondents. Changes to the data collection are explained in Section 15 on page 9 of this supporting statement.

60.

61. 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.

62.

63. 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.

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. Privacy Impact Assessment

68. The information is filed and retrieved by the MTB 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.
- 69.
70. Overview of the Data Collection System Respondents will use a modified MPEP *M. tuberculosis* Worksheet (Attachment C) to record their drug susceptibility test results in preparation to entering data online using a modified survey instrument (**Attachment D**) 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.
71. 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.
- 72.
73. Items of Information to be Collected
74. 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.
- 75.
76. Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age
77. The CDC MPEP maintains a home page with program information. The website information is not directed at children less than 13 years of age.
- 78.
- 79.
80. **2. Purpose and Use of Information Collection**
81. 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.

82. 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.

83.

84. Privacy Impact Assessment Information

85. 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.

86.

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

88. 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.

89.

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

91. 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.

92.

93. **5. Impact on Small Businesses or Other Small Entities**

94. To reduce the burden on laboratories all results will be entered through 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.

95.

96. **6. Consequences of Collecting the Information Less Frequently**

97. 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.

98.

99. 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.

101.

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

103. 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.

104.

105. 9. Explanations of Any Payment or Gift to Respondents

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

107.

108. 10. Assurance of Confidentiality Provided to Respondents

109. 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.

110.

111. 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.

112.

113. 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.

114. 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.

115.

116. 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.

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. Privacy Impact Assessment Information

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 MPEP 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.

132. **11. Justification for Sensitive Questions**

133. 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.

134.

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

136. A. Ninety-three (93) respondents will be asked to complete a Participant Biosafety Compliance Letter of Agreement in order to join the program. Each participant will need to complete the modified MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment C**) and enter results online using the modified survey instrument (**Attachment D**). These forms need to be completed for each test shipment. Two shipments are sent annually. .

137.

138. In this submission, the burden has not changed. CDC is requesting approval for 156 burden hours.

139.

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

141. Type of Respondent	142. Form Name	143. No. of Respondents	144. No. of Responses per Respondent	145. Average Burden per Response 146. (in hours)	147. Total Burden Hours
148. Domestic Laboratories 149.	150. Participant Biosafety Compliance Letter of Agreement	152. 93	153. 2	154. 5/60	155. 16
	151. MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet	158. 93	159. 2	160. 30/60	161. 94
	163. Online Survey Instrument	164. 93	165. 2	166. 15/60	167. 46
168. Total	169.	170. 93	171. 6	172.	173. 156

174.

175.

176. 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>.

177.

178. Table A12b. Estimated Annualized Burden Hours

179. Type of Respondent	180. Total Burden Hours	181. Hourly Wage Rate	182. Total Respondent Costs
183. Micro biologist	184. 156	185. \$31.69	186. \$4,943.64

187.

188.

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

190. None.

191.

192. **14. Annualized Cost to the Government**

193. 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.

194.

195.

196.

197.

198. Annualized Cost to the Government

199. Expense Type	200. Expense Explanation	201. Cost
202. Direct Cost to the Federal Government	203. CDC Project Officer (30% effort GS-13, \$105,449)	204. \$31,634.70
205. Direct Cost to the Federal Government	206. Data Management (30% effort, GS-12, \$71,901)	208. \$21,570.30
209. Direct Cost to Federal Government	210. Laboratory Support (10% effort, GS-12, 93,470)	212. \$9,163.00
213. Direct Cost to Federal Government	214. culture slants, shipping containers, shipping costs	215. \$3,192
216. Total	217.	218. 065,560

219.

220.

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

222. This is a request for a change to a currently approved data collection. In this request, CDC is requesting approval for the following changes:
- Entering results online using a modified survey instrument (**Attachment D**) using ADOBE® FormsCentral (<https://www.adobe.com/formscentral/en/home.html>) software. In the opinion of CDC, the format of this instrument is more user-friendly for entering results than the prior data collection instrument created using Snap® Surveys (<http://www.snapsurveys.com>) software.
 - Respondents will no longer need to report test concentrations of antituberculosis drugs used for drug susceptibility testing of MTBC isolates.
 - Respondents entering results online will now be required to enter their contact email address. ADOBE® FormsCentral will read this field and send copy of responses back to submitter for record keeping purposes.
 - Modification of the MPEP *M. tuberculosis* Results Worksheet (**Attachment C**) for participants to record their results prior to online entry to reflect that concentrations of antituberculosis drugs used for testing against MTBC isolates will no longer be reported.

223.

224. In the opinion of CDC, the above changes will not result in no change in burden for respondents.

225.

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

227. 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

228. <http://wwwn.cdc.gov/mpep/mtbds.aspx>.

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

230.

231.

232. A. 16.1 Project Time Schedule	
233. Activity	234. Time Schedule
235. Enrollment using Participant Biosafety Compliance Letter of Agreement	236. March and September (or 2-3 months after OMB approval)
237. Shipment of Cultures with Instructions for Participants	238. May and November (or 3-4 months after OMB approval)
239. Data Entry by Respondents	240. May and November (3-4 months after OMB approval)
241. Preliminary Reports to Respondents	242. June and December (or 4-5 months after OMB approval)
243. Analysis of Aggregate Data	244. June and December (or 4-5 months after OMB approval)
245. Final Report to Respondents	246. July and January (or 5-6 months after OMB approval)

- 247.
248. **17. Reason(s) Display of OMB Expiration Date is Inappropriate**
249. Approval is not requested to not display OMB expiration date.
- 250.
251. **18. Exceptions for Certification for Paperwork Reduction Act Submissions**
252. There are no exceptions to the certification.
253. **Statistical Methods**
- 254.
255. **B. Collections of Information Employing Statistical Methods**
256. This data collection does not use statistical methods.
257. Laboratories enroll in the program via the Enrollment Form and are assigned an identification (MPEP) number. The MPEP 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://www.cdc.gov/tb/topic/Laboratory/mpep/default.htm>. 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.