

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

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 B

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B. Collections of Information Employing Statistical Methods

This data collection does not use statistical methods but this section of the submission will be used to describe how the data are collected.

All information is filed and retrieved by using a MTB DST identification number (TPEP) assigned to each participant. The number is linked to the name of the organization which is a testing site. 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.

1. Respondent Universe and Sampling Methods

Data are collected from representatives of participating laboratories to analyze the performance and practices of all known clinical and public health laboratories in the United States that perform drug susceptibility testing (DST) of isolates belonging to the *Mycobacterium tuberculosis* complex (MTBC). Since statistical methods are not utilized, no sampling is employed.

2. Procedures for the Collection of Information

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 an Instructions to Participants Letter (**Attachment G**) and the MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment E**). The Instructions to Participants contains information on handling the culture isolates and for reporting DST results online using the 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.

3. Methods to Maximize Response Rates and Deal with No Response

Participants who have not input their results two weeks prior to the collection deadline will be notified by email (**Attachment H**) or by telephone (**Attachment I**).

4. Tests of Procedures or Methods to be Undertaken

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. 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. An aggregate report letter (**Attachment J**) 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>. 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.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Since this ICR does not employ statistical methods, no individuals were consulted on statistical aspects of either the data collection or analysis.

