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

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Supporting Statement B

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Section B. Justification

This data collection does not use statistical methods; this section of the submission will be used to describe how the data are collected. All information is filed and retrieved by using a Model Performance Evaluation Program (MPEP) identification number assigned to each participant. The number is linked to the name of the organization, which is a laboratory testing site. While the names of persons completing the forms are requested, no other personal identifiers are collected other than their title and email address. Respondents are speaking in their roles as staff knowledgeable of performance of testing and laboratory practices at their testing site.

1. Respondent Universe and Sampling Methods

Data are collected from representatives of participating laboratories classified as public health, hospital, independent/reference (non-hospital based), federal, or other to analyze the performance and practices of 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 of the Collection of Information

Upon signing of the *Participant Biosafety Compliance Agreement* (**Attachment 5**) by an authorized laboratory representative, the laboratory will be enrolled in MPEP and assigned an MPEP number. The MPEP number is needed for participants to enter data into an *Online Survey Instrument* (**Attachment 4**). Before survey isolates are mailed to the laboratory, a *Pre-shipment Email* (**Attachment 6**) is sent to participants to inform them of the expected date for receiving the isolates shipment. The *Pre-shipment Email* will also contain a request to notify CDC of any changes in laboratory contact information. Isolates are sent to the laboratories along with an *Instructions to Participants Letter* (**Attachment 7**), the *MPEP Mycobacterium tuberculosis Results Worksheet* (**Attachment 8**), and *MPEP Mycobacterium tuberculosis Minimum Inhibitory Concentration (MIC) Form* (**Attachment 9**). The *Instructions to Participants Letter* contains information on

handling the isolates and for reporting DST results online using the survey instrument. Background information concerning the classification of each participating laboratory, and their DST methods will also be collected. All testing results data must be entered online via a link provided to the respondents.

3. Methods to Maximize Response Rates and Deal with Nonresponse

A *Reminder Email* (**Attachment 10**) is sent two weeks prior to the collection deadline. Roughly two weeks after the result entry deadline, an *Expected Results Report* (**Attachment 11**) is sent to participating laboratories, allowing them to begin their self-evaluation while the Final Report is being developed.

4. Tests of Procedures or Methods to be Undertaken

Data collected for the DST results and the laboratory practices are stored as SAS file (or equivalent) data sets and imported into Excel files with a unique identifier. Information collected from participating laboratories is compiled, analyzed, and reported in an aggregate report that laboratories can use as a self-assessment tool to maintain the skills needed for DST of MTBC. A *Final Report Letter* (**Attachment 12**) is emailed to all enrollees with a pdf version and link to the *Final Report* (**Attachment 13**), also posted on the CDC MPEP Reports Page at https://www.cdc.gov/tb/php/laboratory-information/model-performance-evaluation-program.html.

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 United States.

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.

Data analysis will be performed by:

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