**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. 03/31/2019**

**Supporting Statement B**

**October 30, 2018**

**Contact:**

Mitchell A. Yakrus

Project Officer

Laboratory Branch

Division of Tuberculosis Elimination

**National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention**

Centers for Disease Control and Prevention

1600 Clifton Road, N.E., MS F08

Atlanta, Georgia 30333

Phone: (404) 639-1288

Fax: (404) 639-1287

Email: [may2@cdc.gov](mailto:may2@cdc.gov)

(OMB Control No. 0920-0600)

Table of Contents

Section

B. Collections of Information Employing Statistical Method

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with No Response
4. Tests of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

**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 Model Performance Evaluation Program (MPEP) identification number 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 4**) by an authorized representative, the laboratory will be enrolled in MPEP and assigned a MPEP number. The MPEP number is needed for participants to enter data online. Before survey samples are mailed to the laboratory, an advance *Pre-shipment Email* (**Attachment 5**) 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 6**) and the *MPEP Mycobacterium tuberculosis Results Worksheet* (**Attachment 7**). *The Instructions to Participants Letter* contains information on handling the culture isolates and for reporting DST results online using the survey instrument (**Attachment 8**). 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 *Reminder Email* (**Attachment 10**) or by telephone (**Attachment 11**).

**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 12**) 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.