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

Attachment 3
Explanation of Changes

Attachment 3: Explanation of Changes OMB #0920-0600

CDC is requesting OMB approval for an extension of the currently approved data collection entitled "*CDC Model Performance for Mycobacterium tuberculosis Drug Susceptibility Testing,*" including approval for the following non-substantive changes:

- Change to the project title of the data collection to "CDC Model Performance Evaluation (MPEP) for *Mycobacterium tuberculosis* Drug Susceptibility Testing" from "CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* and Nontuberculous Mycobacteria Drug Susceptibility Testing" to reflect that nontuberculous mycobacteria are no longer included in the program.
- Modification of the MPEP Online Survey Instrument (**Attachment 4**) to update molecular testing method choices to reflect current testing options and improve survey usability and flexibility, per the request of participants.
- Modification of the MPEP Results Worksheet (**Attachment 8**) to consolidate collection of molecular testing results for ofloxacin, ciprofloxacin, moxifloxacin, and levofloxacin separately to Fluoroquinolones (moxifloxacin, levofloxacin, ofloxacin).
- Addition of Expected Results Report (**Attachment 11**) to provide participating laboratories a preliminary report prior to the development of the Final Report.

Background

Established in 1994, the CDC Model Performance Evaluation Program (MPEP) has been used to analyze the performance and practices of clinical and public health laboratories in the United States that perform drug susceptibility testing of isolates belonging to the *Mycobacterium tuberculosis* complex (MTBC) using biosafety level 3 (BSL3) or BSL2 with BSL3 practices. This voluntary program assesses the reproducibility of drug susceptibility test (DST) results reported by laboratories from a panel of five MTBC isolates shipped twice a year.

Justification for Changes

CDC is requesting approval for a project title change. The proposed updated project title would remove 'Nontuberculous Mycobacteria' from the title, as this group of mycobacteria are no longer included in the program.

CDC is requesting approval for modification of the MPEP online data collection instrument **(Attachment 4).** These non-substantive changes include an update to the molecular testing method choices and improved survey usability and flexibility. The molecular testing method choices include the addition of next generation targeted DNA sequencing and the opportunity to specify the specific manufacturer for next generation targeted DNA sequencing and whole genome sequencing. Additionally, the usability has been improved by grouping data collection for molecular testing in one section and consolidating the collection of molecular results for four drugs (ofloxacin, ciprofloxacin, moxifloxacin, and levofloxacin) into one collection [Fluoroquinolones (moxifloxacin, levofloxacin, ofloxacin)]. Per feedback received from participating laboratories, flexibility has been improved to allow respondents to submit data for multiple growth-based DST or molecular methods in one entry. These non-substantive changes will allow collection of more current testing practices and streamline result entry for participating laboratories. These changes and the reduction in number of participants has reduced the total burden hours from the previous version of the online data collection instrument.

CDC is requesting approval for modification of the MPEP Results Worksheet (**Attachment 8**) to consolidate data collection of molecular results for four drugs (ofloxacin, ciprofloxacin, moxifloxacin, and levofloxacin) into one collection [Fluoroquinolones (moxifloxacin, levofloxacin, ofloxacin)]. This will streamline molecular result entry for participating laboratories that perform this testing. This change and the reduction in number of participants has reduced the total burden hours from the previous version of the MPEP Results Worksheet.

CDC is requesting approval of an Expected Results Report **(Attachment 11)**. The Expected Results Report is a preliminary report with expected growth-based DST and molecular results. Inclusion of this report allows participating laboratories to begin their self-evaluation while the Final Report is being developed.

Table 1. CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* Drug Susceptibility Testing
OMB Control No. 0920-0600
Explanation of Form Changes

Form Name	Still being Used **Y/N**	Replaced by another form if so which new form replaces this one (Attachment #)	OK to delete form **Y/N**	Comments
Online Survey Instrument Webshots (**Attachment 4**)	Y		N	Update molecular testing method choices to reflect current testing options and improve survey usability and flexibility, per the request of participants
MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment 8**)	Y		N	Consolidate data collection of four drugs (ofloxacin, ciprofloxacin, moxifloxacin, and levofloxacin) into one collection [Fluoroquinolones (moxifloxacin, levofloxacin, ofloxacin)]
Expected Results Report (**Attachment 11)**				New form to provide participating laboratories a preliminary report of expected results prior to the development of the Final Report