

**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 a revision of the currently approved data collection entitled *CDC Model Performance for Mycobacterium tuberculosis Drug Susceptibility Testing*,” including approval for the following changes:

- Modification of Instructions to Participants Letter (**Attachment 6**) to clarify detailed instructions for online data entry of DST results.
- Modification of the MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment 7**) to include additional antituberculosis drugs.
- Transition to new online data entry instrument (**Attachment 8**).
- Modification of the MPEP *Mycobacterium tuberculosis* Minimum Inhibitory Concentration Results Worksheet (**Attachment 9**) to include additional antituberculosis drugs.
- Removal of Reminder Telephone Script (**previously Attachment 11**).
- Modification of Aggregate Report Letter (**previously Attachment 12**) to remove information and include updated MPEP Reports webpage URL.

Background

Established in 1994, the CDC Model Performance Evaluation Program (MPEP) has been used 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) 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 MTBC isolates shipped twice a year.

Justification for Changes

CDC is requesting approval of a modified Instructions to Participants Letter (**Attachment 6**). The modified letter includes an updated online data entry webpage link and removal of language that a separate survey should be filled out for each growth-based drug susceptibility method. The new online data entry instrument allows for more than one growth-based method to be entered at one time.

CDC is requesting approval for modification of the MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment 7**). The worksheet is used to assist in data entry online and record-keeping by participants. Additional antituberculosis drugs have been added for growth-based and molecular sections.

CDC is requesting approval for the use of a new online data collection instrument (**Attachment 8**). The new instrument provides the same functionality as the previous instrument but does not require annual purchase, incorporates improved routing, and allows respondents to enter multiple methods in one submission. Previously only one growth-based and one molecular method were able to be entered at a time; the new instrument allows respondents to enter up to two growth-based DST methods and two molecular methods in one submission.

CDC is requesting approval for modification of the MPEP *Mycobacterium tuberculosis* Minimum Inhibitory Concentration (MIC) Results Worksheet (**Attachment 9**). The worksheet is used to assist in data entry online and record-keeping by participants performing Sensititre MIC drug susceptibility testing. Additional antituberculosis drugs have been added.

CDC is requesting approval for removal of the Reminder Telephone Script (**previously Attachment 11**). Reminders are sent by email to all contacts simultaneously for the participating laboratory.

CDC is requesting approval for modification of the Aggregate Report Letter (**previously Attachment 12**). Duplicate information was removed and MPEP Reports webpage link, where reports are posted, was updated.

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
Instructions to participants Letter (Attachment 6)	Y		N	Modified Instructions to Participants Letter (Attachment 6) with clarifying details
MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet (Attachment 7)	Y		N	Modified MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet (Attachment 7) to include additional antituberculosis drugs.
Survey Instrument Web Shots (Attachment 8)	N	Survey Instrument Webshots (Attachment 8)	Y	Transition to new data collection instrument to reduce costs and allow for improved efficiency as respondents submit results.
MPEP <i>Mycobacterium tuberculosis</i> Minimum Inhibitory Concentration Results Worksheet (Attachment 9)	Y		N	Modified MPEP <i>Mycobacterium tuberculosis</i> Minimum Inhibitory Concentration Results Worksheet (Attachment 9) to include additional antituberculosis drugs.
Reminder Telephone Script (Attachment 11)	N		Y	Reminders are sent via email to all contacts for the participating laboratory at one time, rather than by telephone.
Aggregate Report Letter (Attachment 12)	N	Aggregate Report Letter (Attachment 11)	Y	Duplicate information was removed and MPEP Reports webpage link was updated.