

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 the Participant Biosafety Compliance Letter of Agreement (**Attachment 4**) to contain language to ensure that participants understand and comply with biosafety guidelines using quality management system practices.
- Modification of Instructions to Participants Letter (**Attachment 6**) to include detailed instructions for online data entry of DST results.
- Modification of the MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment 7**) to include fields for entering methods used for conventional and molecular DST.
- Request for approval of a MPEP *Mycobacterium tuberculosis* Minimum Inhibitory Concentration (MIC) Results Form (**Attachment 9**) for laboratories that perform Sensititre DST to record MIC results.

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 needs to document that laboratories participating in MPEP are equipped with the necessary biosafety facilities and practices to work with isolates of MTBC and acknowledge the potential risks associated with manipulation of live cultures of MTBC. Participants must also agree to comply with biosafety guidelines using quality management system practices. CDC is requesting approval for a modified The Participant Biosafety Compliance Letter of Agreement (**Attachment 4**) to contain language regarding participant compliance to quality management practices. (Attachment D).

CDC is requesting approval of a modified Instructions to Participants Letter (**Attachment 6**). The modified letter contains additional instructions to participants to ensure that a separate survey should be filled out for each conventional drug susceptibility method.

CDC is requesting approval for modification of the MPEP *Mycobacterium tuberculosis* Results Worksheet (**Attachment 7**). The new worksheet contains fields for participants to enter what method they used to perform conventional and molecular DST. This modification should improve data entry online and record keeping by participants.

CDC is requesting approval of a MPEP *Mycobacterium tuberculosis* Minimum Inhibitory Concentration (MIC) Results Form (**Attachment 9**) for laboratories that perform Sensititre DST to record MIC results. The Survey Instrument (**Attachment 8**) for entering DST results using other methods does not contain fields for entering MICs. Participants that perform Sensititre will manually record their DST results on the form and submit them by email to TBMPEP@cdc.gov.

CDC is requesting less burden hours for this revision due to fewer laboratories participating in MPEP. Burden hours requested have decreased from 156 hours to 129 hours due to the reduction of participant sites from 93 to 80 laboratories.

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
Participant Biosafety Compliance Letter of Agreement	N	Participant Biosafety Compliance Letter of Agreement (Attachment 4)	Y	Participant Biosafety Compliance Letter of Agreement (Attachment D) from previous submission replaced with modified Participant Biosafety Compliance Letter of Agreement (Attachment 4)
Instructions to Participants	N	Instructions to participants Letter (Attachment 6)	Y	Instructions to Participants (Attachment G) from previous submission replaced with modified Instructions to Participants Letter (Attachment 6)
MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet	N	MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet (Attachment 7)	Y	MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet (Attachment E) from previous submission replaced with modified MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet (Attachment 7)