

CDC is requesting OMB approval for a revision of the currently approved data collection, the CDC MPEP for *Mycobacterium tuberculosis* and Nontuberculous Mycobacteria Drug Susceptibility Testing. CDC is requesting approval for the following changes:

- Changing the title of the data collection to “ CDC Model Performance Evaluation (MPEP) for *Mycobacterium tuberculosis* Drug Susceptibility Testing” to reflect that nontuberculous mycobacteria are no longer included in the test package
- Replacement of Laboratory Enrollment Form with a Participant Biosafety Compliance Letter of Agreement (Attachment D)
- Revision of the Pre-shipment Email (Attachment E)
- Addition of Instructions to Participants Letter (Attachment F)
- Revision of the MPEP *M. tuberculosis* Results Worksheet (Attachment G)
- Entering survey results online using a modified data collection instrument created with Snap Surveys® software (Attachment H)
- Modification of Reminder Email (Attachment I)
- Modification of Reminder Telephone Script (Attachment J)
- Modification of the Aggregate Report Letter (Attachment K)
- Replace example of Complete Final Aggregate Report with an example of a Final Aggregate Report (Attachment L)
- Removal of the Laboratory Program Description, Shipment and Password letter/email, Case History Form-NTM supplemental Information, Preliminary Report for Sample Shipment, Analysis of Performance Evaluation, and the Laboratory Information Change Form.
- The new software used to create the survey instrument generates a more user friendly format than the prior data collection instrument, thereby reducing burden. Also, the reduction in the number of participating laboratories from 96 to 93 reduces the burden hours from 167 to 156.

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. Implementation of this program under this information collection has been transferred from the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) to National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). NCEZID lacked resources and subject matter expertise to continue management of the program. In addition, evaluation of laboratory programs performing testing on isolates of MTBC is a mission within NCHHSTP.

Justification for Changes

The mission of NCHHSTP does not include the evaluation of tests performed on isolates of nontuberculous mycobacteria. Isolates of nontuberculous mycobacteria are no longer included in shipments to U.S. laboratories participating in MPEP. Therefore, CDC is requesting removal of the words “and nontuberculous mycobacteria” from the title of the data collection.

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. The current Laboratory Enrollment Form is not suitable for this purpose. Therefore, CDC is requesting that as a condition to participate in MPEP, an authorized representative for each laboratory wishing to receive isolates of MTBC sign a Participant Biosafety Compliance Letter of Agreement (Attachment D).

The transfer of MPEP from NCEZID to NCHHSTP has necessitated that participants be notified of changes to management of the program and how their test results will be collected. Therefore, CDC is requesting that each laboratory that agrees to participate in MPEP be sent a revised Pre-shipment Email (Attachment E) and revised Instructions to Participants Letter (Attachment F) containing new contact information and directions for inputting results.

NCHHSTP will use a new data collection instrument to collect DST results online from participating laboratories. In order to prepare results prior to online entry, CDC is requesting that participants be sent a revised MPEP *M. tuberculosis* Results Worksheet (Attachment G).

CDC is requesting approval of modified data collection instrument created using Snap Surveys® software (Attachment H) for participants to input their DST results online. In the opinion of CDC, the format of this instrument is more user-friendly than software used to create the prior data collection instrument.

CDC is requesting modification of the Reminder Email (Attachment I), the Reminder Telephone Scrip (Attachment J), and the Aggregate Report Letter (Attachment K), due to the changes in management resulting from the transfer of MPEP from NCEZID to NCHHSTP.

CDC is requesting replacement on an example of a Complete Final Aggregate Report with an example of a Final Aggregate Report (Attachment L)

CDC is requesting removal of the Laboratory Program Description, Shipment and Password letter/email, Case History Form-NTM supplemental Information, Preliminary Report for Sample Shipment, Analysis of Performance Evaluation, and the Laboratory Information Change Form.

In the opinion of CDC, the above requested changes will not result in an increase in burden hours on respondents.

Detailed form change explanations are shown in Table 1.

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

Form Name and Number	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
3. Laboratory Enrollment Form documents				
a. Laboratory Enrollment Form	N	Attachment D : Participant Biosafety Compliance Letter of Agreement	Y	Enrollment information requested in Attachment 3a from previous submission is now requested using Attachment D.
b. Program Description	N	N	Y	Attachment 3b no longer sent to participants.
c. Acceptance Letter	N	Attachment D : Participant Biosafety Compliance Letter of Agreement	Y	Attachment 3c from previous submission is replaced with Attachment D.
4. Results Worksheet documents				
a. Pre-shipment Letter/email	N	Attachment E: Pre-shipment Email	Y	Attachment 4a from previous submission replaced with a modified Pre-shipment Email (Attachment E)
b. Shipment and Password Letter/email	N	N	Y	Attachment 4b no longer sent to participants
c. General Instructions for Handling Culture Isolates and Test Results Worksheet	N	Attachment F: Instructions for Participants Attachment G: MPEP M. tuberculosis worksheet	Y	Instructions and results worksheet provided to participants in Attachment 4c from previous submission replaced with Instructions to Participants (Attachment F) and a modified MPEP M. tuberculosis worksheet (Attachment G)
d. Case History Form-NTM Supplemental Information	N	N	Y	Attachment 4d no longer sent to participants
e. Non-Responder notices i. Reminder email ii. Reminder telephone script	N	Attachment I:Reminder Email Attachment J:Reminder Telephone Script	Y	Non-responder notices (Attachment 4e) from previous submission replaced with modified Reminder Email (Attachment I) and modified Reminder Telephone Script (Attachment J)
f. Preliminary Report for Sample Shipment	N	N	Y	Attachment 4f no longer sent to participants
g. Aggregate Report Letter	N	Attachment K: Aggregate Report Letter	Y	Attachment 4g from previous submission replaced by a modified Aggregate Report Letter (Attachment K)
h. Analysis of Performance Evaluation	N	N	Y	Attachment 4h no longer sent to participants
i. Complete Final Aggregate	N	Attachment L: Final	Y	An example of a Complete Final Aggregate Report

Form Name and Number	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
Report (example)		Aggregate Report		(Attachment 4i) from previous submission replaced with an example of a Final Aggregate Report (Attachment L)
5. Laboratory Information Change Form	N	N	Y	Attachment 5 no longer sent to participants
6. Laboratory Practices Questionnaire (LPQ)	N	Attachment H: Survey Instrument Web-shots	Y	Attachment 6 from previous submission replaced with an online survey instrument (Attachment H)