**Justification for Change Request**

**Purpose**

CDC is requesting OMB approval for a non-substantial change request to OMB 0920-0600 Model Performance Evaluation Program for Mycobacterium tuberculosis/non-tuberculosis Mycobacteria Drug Susceptibility Testing Program. These are minor changes that include:

(1) additional choices that a participant can select from in answering 2 of the questions (Question #7 and Question #8) on the MTBC Results Worksheet that accompanies the *M. tuberculosis* (TB) isolates. Two (2) of the additional choices list specific molecular methods, so with these additions, we can delete the current choice for a generic molecular method with instructions to write-in the specific molecular method. Modifying these choices should minimize the events in which a participant must write in a testing methodology, and also simplify analysis.

(2) revising text in Question #8 from “If your laboratory uses more than one method for testing this shipment’s isolate…” to “If your laboratory uses more than one method for testing routine samples…”; and to change the wording from “primary method (not confirmatory)..” to “initial method.” These revisions would clarify the intent of the question and provide more accurate information.

(3) clarifying in Question #9 that the selection for ‘not applicable’ means that the laboratory does not use the method in question. Previously, a few participants made a selection for how they obtained their media, as well as selecting ‘not applicable.’

(4) correcting our address to account for a new Mailstop as a result of CDC’s reorganization.

**Previously Approved Questions**

Below are Questions #7 and #8 that were approved in October 2010, showing the way they are worded, and the options from which a participant can select in answering the questions:

7. What method(s) was used in your laboratory to perform drug susceptibility testing on the MTBC isolates **in this shipment**? **(Please blacken all that apply.)**

* Agar Proportion (Middlebrook 7H10)
* Agar Proportion (Middlebrook 7H11)
* Radiometric (BACTEC)
* VersaTREK Myco
* MGIT System
* Lowenstein Jensen (LJ) proportion method
* Molecular Method (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8. If your laboratory uses more than one method for testing this shipment’s isolates for first-line drugs for MTBC susceptibility, please indicate **the primary method (NOT confirmatory method)** that isused. **(Please blacken only one circle.)**

* Agar Proportion (Middlebrook 7H10)
* Agar Proportion (Middlebrook 7H11)
* Radiometric (BACTEC)
* VersaTREK Myco
* MGIT System
* Lowenstein Jensen (LJ) proportion method
* Molecular Method (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

9. If you use Middlebrook 7H10 or 7H11 media as either an initial or secondary method of MTBC drug susceptibility testing, your media is: **(Please blacken all that apply.)**

* purchased “commercially-prepared” containing anti-tuberculosis drugs
* prepared in-house with disks containing anti-tuberculosis drugs
* prepared in-house by reconstituting and adding anti-tuberculosis drugs
* Not Applicable

**Modified Questions**

We are requesting to modify the questions to read (revisions highlighted):

7. What method(s) was used in your laboratory to perform drug susceptibility testing on the MTBC isolates **in this shipment**? **(Please blacken all that apply.)**

* Agar Proportion (Middlebrook 7H10)
* Agar Proportion (Middlebrook 7H11)
* Genotype MTBDRplus (Hain Lifescience)
* Genotype MTBDRsl (Hain Lifescience)
* Lowenstein Jensen (LJ) proportion method
* MGIT System
* Radiometric (BACTEC 460)
* VersaTREK Myco
* XPERT MTB/RIF (Cepheid)
* Laboratory Developed Test (LDT) (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8. If your laboratory uses more than one method for testing routine samples for first-line drugs for MTBC susceptibility, please indicate the **initial method** that is used. **(Please blacken only one circle.)**

* Agar Proportion (Middlebrook 7H10)
* Agar Proportion (Middlebrook 7H11)
* Genotype MTBDRplus (Hain Lifescience)
* Genotype MTBDRsl (Hain Lifescience)
* Lowenstein Jensen (LJ) proportion method
* MGIT System
* Radiometric (BACTEC 460)
* VersaTREK Myco
* XPERT MTB/RIF (Cepheid)
* Laboratory Developed Test (LDT) (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

9. If you use Middlebrook 7H10 or 7H11 media as either an initial or secondary method of MTBC drug susceptibility testing, your media is: **(Please blacken all that apply.)**

* purchased “commercially-prepared” containing anti-tuberculosis drugs
* prepared in-house with disks containing anti-tuberculosis drugs
* prepared in-house by reconstituting and adding anti-tuberculosis drugs
* Not Applicable – We do not use Middlebrook media