DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-25-0600]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* Drug Susceptibility Testing" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on June 16, 2025, to obtain comments from the public and affected agencies. CDC received no public comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* Drug Susceptibility Testing (OMB Control No. 0920-0600, Exp. 9/30/2025) – Extension - National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting an Extension of a currently approved information collection from participants in the CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* Drug Susceptibility Testing for a period of three years. Extension of this information will not require changes in the scope of the project. As part of the Extension, CDC is requesting a non-substantive change to the 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.

Tuberculosis (TB) is a continuing public health problem. The overall number of cases, and associated incidence rate, in the United States has increased over the past several years. High rates are reported among non-U.S.-born persons, correctional populations, people experiencing homelessness, and individuals reported to have diabetes. To reach the goal of eliminating TB, this data collection is designed to monitor and evaluate performance and practices among U.S. laboratories performing *M. tuberculosis* susceptibility testing.

Participation in this program is one way in which laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results. By providing an evaluation program to assess the ability of laboratories to test for drug resistant *M. tuberculosis* strains, this provides laboratories a self-assessment tool to aid in optimizing their skills in susceptibility testing. The information obtained from the laboratories on susceptibility practices and procedures is used to inform continuous program improvement related to good performance, training needs, and the development of practice standards.

Participants in this program include domestic clinical and public health laboratories. Data collection from laboratory participants occurs twice per year. The data collected in this program will include the susceptibility test results of primary and secondary drugs, drug concentrations, and test methods performed by laboratories on a set of performance evaluation isolates. The performance evaluation isolates are sent to participating laboratories twice each year. Participants also report laboratory demographic data such as laboratory type and the number of drug susceptibility tests performed annually. Over the past three years, six final MPEP reports have been distributed and published with an average of 58 participants per MPEP isolate shipment. All state public health laboratories that perform *Mycobacterium tuberculosis* drug

susceptibility testing participated in MPEP, along with approximately seven hospital, seven independent/reference, and two federal laboratories; these participating laboratories represent geographical and laboratory type variation. Drug susceptibility testing results met consensus for 73% or 22 isolates of the six panels with five isolates each (30) for first-line drugs, highlighting challenges that laboratories experience with current testing practices and methods. MPEP continues to select isolates with both common and challenging resistance patterns for educational value.

CDC is requesting OMB approval for 113 burden hours, a reduction of 16 burden hours due to the reduction in the number of respondents. There is no cost to respondents to participate other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (hours)
Domestic Laboratory	Online Survey Instrument Webshots	70	2	15/60
	Participant Biosafety Compliance Agreement	70	1	5/60
	MPEP *Mycobacterium tuberculosis* Results Worksheet	70	2	30/60
	MPEP *Mycobacterium tuberculosis* Minimum Inhibitory Concentration (MIC) Results Form	4	2	15/60

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