

**CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* and
Nontuberculous Mycobacteria Drug Susceptibility Testing**

Attachment B

60-day Federal Register Notice

Name	CAS
1. Trichloroethylene (UPDATE) ..	79-01-6
2. Tetrachloroethylene (UP- DATE).	127-18-4
3. Hydrogen sulfide/Carbonyl sulfide (UPDATE).	7783-06-4 463-58-1
4. Glutaraldehyde (NEW)	111-30-8
5. Parathion (NEW)	56-38-2

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9601 *et seq.*) amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) with regard to hazardous substances that are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the Priority List of Hazardous Substances (www.atsdr.cdc.gov/SPL). This list names 275 hazardous substances that pose the most significant potential threat to human health as determined by ATSDR and EPA. The availability of the revised list of the 275 priority substances was announced in the **Federal Register** on November 3, 2011 (76 FR 68193). For prior versions of the list of substances, see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332); October 21, 1999 (64 FR 56792); October 25, 2001 (66 FR 54014); November 7, 2003 (68 FR 63098); December 7, 2005 (70 FR 70284); and March 6, 2008 (73 FR 12178).

Notice of the availability of drafts of these five toxicological profiles for public review and comment will be published in the **Federal Register** on or about October 17, 2013, with notice of a 90-day public comment period for each profile, starting from the actual release date. Following the close of the comment period, chemical-specific comments will be addressed, and, where appropriate, changes will be incorporated into each profile.

FOR FURTHER INFORMATION CONTACT: Commander Jessilyn B. Taylor, Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, 1600

Clifton Road NE., Mail Stop F-57, Atlanta, GA 30333, telephone 770-488-3313.

Dated: January 11, 2013.

Ken Rose,

Director, Office of Policy Planning and Evaluation, National Center for Environmental Health.

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BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-0600]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Ron Otten, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis and Nontuberculous Mycobacteria Drug Susceptibility Testing OMB #0920-0600 (exp. 5/31/2013),—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of the continuing effort to support domestic public health objectives for treatment of tuberculosis (TB), prevention of multi-drug resistance, and surveillance programs, CDC is requesting approval from the Office of Management and Budget to continue data collection from participants in the Model Performance Evaluation Program for Mycobacterium tuberculosis and Non-tuberculous Mycobacterium Drug Susceptibility Testing. This revision request includes (a) 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; (b) replacement of Laboratory Enrollment Form with a Participant Biosafety Compliance Letter of Agreement; (c) revision of the Pre-shipment Email; (d) addition of Instructions to Participants Letter; (e) revision of the MPEP M. tuberculosis Results Worksheet; (f) entering survey results online using a modified data collection instrument; (g) modification of Reminder Email; (h) modification of Reminder Telephone Script; and (i) modification of the Aggregate Report Letter.

While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, prisoners, homeless populations, and individuals infected with HIV in major metropolitan areas. To reach the goal of eliminating TB, the Model Performance Evaluation Program for Mycobacterium tuberculosis and Non-tuberculous Mycobacterium Drug Susceptibility Testing is used to monitor and evaluate performance and practices among national laboratories performing M. tuberculosis susceptibility testing. Participation in this program is one way laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results.

By providing an evaluation program to assess the ability of the laboratories to test for drug resistant M. tuberculosis strains, laboratories also have 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 establish variables related to good performance, assessing training needs, and aid with 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 (PE) samples. The PE samples are sent to participants twice a year. Participants also report demographic data such as laboratory

type and the number of tests performed annually.

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 (in hours)	Total burden hours
Domestic Laboratory	Participant Biosafety Compliance Letter of Agreement.	93	2	5/60	16
	MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet.	93	2	30/60	93
	Online Survey Instrument	93	2	15/60	47
Total	0	156

Dated: January 14, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0488]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Restriction on Interstate Travel of Persons (OMB Control No. 0920-0488, Exp. 3/31/2013)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention is requesting OMB approval for a revision of the information collection, “Restriction on Interstate Travel of Persons” (OMB Control No. 0920-0488).

This information collection request is scheduled to expire on March 31, 2013. CDC is authorized to collect this information under 42 CFR 70.5 (Certain communicable diseases; special requirements). This regulation requires that any person who is in the communicable period for cholera, plague, smallpox, typhus, or yellow fever or having been exposed to any such disease is in the incubation period thereof, to apply for and receive a permit from the Surgeon General or his authorized representative in order to travel from one State or possession to another.

CDC is requesting changes to the forms used within this information

collection. The changes involve splitting the current form into two separate forms based on the type of respondent: an ill traveler, or the master of a vessel or conveyance engaged in interstate travel. CDC is also adding the option of electronic reporting of illness.

Control of disease transmission within the States is considered to be the province of state and local health authorities, with Federal assistance being sought by those authorities on a cooperative basis without application of Federal regulations. The regulations in 42 Part 70 were developed to facilitate Federal action in the event of large outbreaks requiring a coordinated effort involving several states, or in the event of inadequate local control. While it is not known whether, or to what extent situations may arise in which these regulations would be invoked, contingency planning for domestic emergency preparedness is now commonplace. Should these situations arise, CDC will use the reporting and recordkeeping requirements contained in the regulations to carry out quarantine responsibilities as required by law. The total number of burden hours requested for this collection is 3,701.

There is no cost to respondents other than their time.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Traveler	42 CFR 70.3 Application to the State of destination for a permit.	2,000	1	15/60
Attending physician	42 CFR 70.3 Copy of material submitted by applicant and permit issued by State health authority.	2,000	1	15/60
State health authority	42 CFR 70.3 Copy of material submitted by applicant and permit issued by State health authority.	8	250	6/60