

2. Program Personnel (25 percent)

The extent to which the application has described the qualifications, experience, and commitment of the principal investigator (or project director) and his/her ability to devote adequate time and effort to provide effective leadership.

3. Applicant Capability and Coordination Efforts (25 percent)

The extent to which the application has described:

(a) the capability of the applicant's administrative structure to foster successful scientific and administrative management of the program;

(b) the capability of the applicant to demonstrate an appropriate plan for interaction with the community; and

(c) the level of collaboration needed to conduct the program; and demonstrate that an advisory group can be established at the onset of the project.

4. Program Budget—(not scored)

The extent to which the budget is reasonable, clearly justified, and consistent with intended use of cooperative agreement/grant funds.

5. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of—

1. Annual progress report;
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the announcement in the application kit.

- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-18 Cost Recovery—ATSDR
- AR-19 Third Party Agreements—ATSDR

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 104 (i)(5)(A) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980 as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 [42 U.S.C. 9604 (i)(5)(9A), and (15)] and U.S. Senate Report 106-410. The Catalog of Federal Domestic Assistance number is 93.161.

J. Where To Obtain Additional Information

This and other ATSDR announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Nelda Y. Godfrey, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: 770-488-2722, Email address: nag9@cdc.gov

For program technical assistance, contact: Leslie C. Campbell, Environmental Health Scientist, Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, MS E-32, Atlanta, GA 30333, Telephone number: 404-498-0473, Email address: lcampbell@cdc.gov

or

William Cibulas, Chief, Research Implementation Branch, Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, MS E-29, Atlanta, GA 30333, Telephone number: 404-498-0715, Email address: wcibulas@cdc.gov.

Dated: June 26, 2001.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-41-01]

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 the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

National Exposure Registry—Extension—(OMB No. 0923-0006) Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC). The Agency for Toxic Substances and Disease Registry (ATSDR) is mandated pursuant to the 1980 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and its 1986 Amendments, the Superfund Amendments and Re-authorization Act (SARA), to establish and maintain a national registry of persons who have been exposed to hazardous substances in the environment and a national registry of persons with illnesses or health problems resulting from such exposure. ATSDR created the National Exposure Registry (NER) as a result of this legislation in an effort to provide scientific information about potential adverse health effects people develop as a result of low-level, long-term exposure to hazardous substances.

The National Exposure Registry is a program that collects, maintains, and analyzes information obtained from participants (called registrants) whose exposure to selected toxic substances at specific geographic areas in the United States was documented. Relevant health data and demographic information are also included in the NER database. The NER databases furnish the information needed to generate appropriate and valid hypothesis for future activities such as epidemiologic studies. The NER also serves as a mechanism for longitudinal health investigations that follow registrants over time to ascertain

adverse health effects and latency periods.

The NER is currently composed of four sub-registries of persons known to have been exposed to specific chemicals: 1,1,1,-Trichloroethane (TCA), Trichloroethylene (TCE), 2,3,7,8-tetrachlorodibenzo-p-dioxin (dioxin), and benzene. In 2001, the NER will establish a new asbestos subregistry.

Participants in each subregistry are interviewed initially with a baseline

questionnaire. An identical follow-up telephone questionnaire is administered to participants every three years until the criteria for terminating a specific subregistry have been met. The annual number of participants varies greatly from year to year. Two factors influencing the number of respondents per year are the number of subregistry updates that are scheduled and whether a new subregistry will be established.

The addition of the new asbestos subregistry is expected to add approximately 6,000 persons to the NER. This increase is reflected in the following estimated burden table.

The following table is annualized to reflect one new subregistry (asbestos) and five updates for the requested three-year extension of OMB No. 0923-0006. The estimated annualized burden is 3,053 hours.

Respondents	Number of responses	Responses per respondent	Avg. burden per response (in hours)
One New Subregistry	2,000	1	30/60
Five Updates	4,927	1	25/60

Dated: June 25, 2001.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-40-01]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Project

Model Performance Evaluation Program for Retroviral and AIDS-Related Testing—Revision—OMB No. 0920-0274 Public Health Practice Program Office (PHPPPO), Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention Model Performance Evaluation Program (MPEP) currently assesses the performance of laboratories that test for human immunodeficiency virus type 1 (HIV-1) antibody, human T-lymphotropic virus types I and II

(HTLV-I/II) antibody, perform CD4 T-cell testing or T-lymphocyte immunophenotyping (TLI) by flow cytometry or alternate methods, perform HIV-1 ribonucleic acid (RNA) determinations (viral load), and test for HIV-1 p24 antigen through the use of mailed sample panels. The CDC MPEP is proposing to use annual data collection documents to gain updated information on the characteristics of testing laboratories and their testing practices.

Two data collection instruments, or survey questionnaires will be used. The first data collection instrument will be concerned with laboratories that perform HIV-1 antibody (Ab) testing, HTLV-I/II Ab testing, HIV-1 viral RNA determinations, and HIV-1 p24 antigen (Ag) testing. Laboratories enrolled in the MPEP will be mailed a survey questionnaire and be asked to complete the sections pertinent to their laboratory's testing. The survey instrument will collect demographic information related to laboratory type, primary purpose for testing, types of specimens tested, minimum education requirements of testing personnel, laboratory director, and laboratory supervisor, and training required of testing personnel. The demographic section will be followed by more specific sections related directly to HIV-1 Ab testing, HTLV-I/II Ab testing, HIV-1 RNA, and HIV-1 p24 Ag testing. Included in the latter sections will be questions related to the types of tests performed, the algorithm of testing, how test results are interpreted, how results are reported, how specimens may be rejected for testing, if some testing is referred to other laboratories, and what quality control and quality assurance procedures are conducted by the laboratory. Similarly, the TLI survey questionnaire will also collect

demographic information about each laboratory, as well as, the type(s) of flow cytometer used, educational and training requirements of testing personnel, the types of monoclonal antibodies used in testing, how specimens are received, prepared, and stored, how test results are recorded and reported to the test requestor, and what quality control and quality assurance procedures are practiced.

Information collected through the use of these instruments will enable CDC to determine if laboratories are conforming to published recommendations and guidelines, whether education and training requirements of testing personnel are conforming to current legislative requirements, and whether problems in testing can be identified through the collection of information. Information collected through the survey instruments will then be compared statistically with the performance evaluation results reported by the enrolled laboratories to determine if characteristics of laboratories that perform well can be distinguished from laboratories not performing as well. Upon enrolling in the MPEP, participants are assigned an MPEP number used to report testing results and survey questionnaire responses allowing the individual responses of each laboratory participant to be treated in confidence. When participants respond to the surveys by sending CDC completed questionnaires, the collected information is developed into aggregate reports. A copy of the completed report is provided to each participating laboratory. Total annual burden for this data collection is 941 hours.