



This document is scheduled to be published in the Federal Register on 12/16/2015 and available online at <http://federalregister.gov/a/2015-31581>, and on FDsys.gov

Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry (ATSDR),
Centers for Disease Control and Prevention (CDC)

[30Day-16-0048]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: 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

ATSDR Exposure Investigations (EIs) (OMB Control No. 0923-0048, Expiration Date 5/31/2016) - Extension - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year extension of this generic

clearance to allow the agency to conduct exposure investigations (EIs), through methods developed by ATSDR. After a chemical release or suspected release into the environment, EIs are usually requested by officials of a state health agency, county health departments, the Environmental Protection Agency (EPA), the general public, and ATSDR staff.

EI results are used by public health professionals, environmental risk managers, and other decision makers to determine if current conditions warrant intervention strategies to minimize or eliminate human exposure. For example, three of the EIs that ATSDR conducted in the past three years include the Colorado Smelter (CO - blood lead and urine arsenic), ASARCO Hayden Smelter Site (AZ - blood lead and urine arsenic), and Decatur (AL - perfluorochemicals [PFCs] in serum).

Example 1: Colorado Smelter Blood Lead and Urine Arsenic Sampling, CO

The site is a former smelter located in Pueblo, Colorado. Past sampling found elevated levels of lead and arsenic in residential soils and a slag pile associated with the smelter. ATSDR sampled blood lead levels (BLLs) in children and adults and found seven children that had BLLs near or exceeding the

level of 5 micrograms per deciliter (mg/dL) (a level identified by ATSDR as a level of concern for lead effects in children). One adult had an elevated level of arsenic in their urine. Speciation of the sample determined that it was primarily organic arsenic, probably resulting from eating seafood.

- The local health department conducted a Healthy Homes Inspection for these families having children with elevated BLLs and ATSDR recommended that the children follow up with their primary care provider.
- On June 10, 2014, the local health department obtained a six year grant from the EPA Region 8 to conduct health education, BLL screening, assist in the coordination of developmental and cognitive evaluations in affected children from a designated area of Pueblo, and conduct other public health actions/investigations as stipulated in the grant.
- On December 11, 2014, EPA listed the Colorado Smelter site on the National Priority List (NPL).

Example 2: ASARCO Hayden Smelter Site, AZ

The community is located in the vicinity of the ASARCO Hayden Smelter, which has been operating for 100 years as a copper ore processor. The processing has resulted in lead and arsenic contamination in the surrounding residential area and in

tailing piles used for recreation. Limited sampling of the community in the past found elevated BLLs and arsenic in urine. Based on community concerns, EPA requested that ATSDR conduct an EI to assess potential exposure of the community to lead and arsenic.

- In April, 2015, ATSDR collected 83 BLL and 58 urine arsenic samples from the community.
- Participants have been notified of their results and the EI report is being prepared.

Example 3: Perfluorochemical Serum Sampling, Decatur, AL

Perfluorochemicals (PFC) are a class of organofluorine compounds that are used in a variety of industrial and consumer products including fire-fighting foams; personal care and cleaning products; and oil, stain, grease, and water repellent coatings. These coatings are used on carpet, textiles, leather, "non-stick" cookware, and paper wrappers used on fast food items. As a result, United States (U.S.) general population exposure to PFCs is common.

In 2007, PFCs were released by a chemical manufacturer near Decatur, AL, and impacted environmental media in the area. In 2010, ATSDR conducted an EI to assess exposure of residents to PFCs in blood. PFCs were found in the serum of people that regularly used the public water system in the area as their

primary drinking water source.

Recommendations of the EI included continued monitoring for PFCs in the public water supply and continued biological PFC testing in the community to determine if PFCs in the community had been reduced.

Based on the results of the 2010 EI, ATSDR is preparing to conduct another EI at the site in 2016 (approved by OMB on 8/10/2015), including biological sampling of serum and urine to:

- Compare individuals' current serum PFC concentrations with their 2010 serum PFC concentrations.
- Compare individuals' serum PFC concentrations to the national population reference values (NHANES 2011-2012).
- Calculate the biological half-life for each PFC species using paired blood and urine PFC concentrations to improve the understanding of the pharmacokinetic behavior of these compounds in humans.
- Evaluate the potential existence of non-drinking water PFC exposure pathways through physiologically-based pharmacokinetic (PBPK) modeling.

All of ATSDR's targeted biological assessments (e.g., urine, blood) and some of the environmental investigations (e.g., air, water, soil, or food sampling)

involve participants to determine whether they are or have been exposed to unusual levels of pollutants at specific locations (e.g., where people live, spend leisure time, or anywhere they might come into contact with contaminants under investigation).

Questionnaires, appropriate to the specific contaminant, are generally needed in about half of the EIs (at most approximately 12 per year) to assist in interpreting the biological or environmental sampling results. ATSDR collects contact information (e.g., name, address, phone number) to provide the participant with their individual results. ATSDR also collects information on other possible confounding sources of chemical(s) exposure such as medicines taken, foods eaten, hobbies, jobs, etc. In addition, ATSDR asks questions on recreational or occupational activities that could increase a participant's exposure potential. That information represents an individual's exposure history.

The number of questions can vary depending on the number of chemicals being investigated, the route of exposure (e.g., breathing, eating, touching), and number of other sources of the chemical(s) (e.g., products used,

jobs). We use approximately 12-20 questions about the pertinent environmental exposures per investigation. Typically, the number of participants in an individual EI ranges from 10 to 100. Participation is completely voluntary, and there are no costs to participants other than their time. Based on a maximum of 12 EIs per year and 100 participants each, the estimated annualized burden hours are 600.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Exposure Investigation Participants	Chemical Exposure Questions	1,200	1	30/60

Leroy A. Richardson,
 Chief, Information Collection Review Office,
 Office of Scientific Integrity,
 Office of the Associate Director for
 Science,
 Office of the Director,
 Centers for Disease Control and Prevention.

[FR Doc. 2015-31581 Filed: 12/15/2015 8:45 am; Publication Date: 12/16/2015]