DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-21-0051]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled “Assessment of Chemical Exposures (ACE) Investigations” to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on 02/24/2021 to obtain comments from the public and affected agencies. ATSDR received no comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR 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
Assessment of Chemical Exposures (ACE) Investigations (OMB Control No. 0923-0051, Exp. 02/28/2021) – Reinstatement with Change – 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 Paperwork Reduction Act (PRA) clearance for the generic clearance information collection request (Generic ICR) titled “Assessment of Chemical Exposures (ACE) Investigations” (OMB Control No. 0923-0051; Exp. Date 02/28/2021). This request is a Reinstatement with Change.

ATSDR conducts ACE Investigations to assist state and local health departments after acute environmental incidents. ATSDR has successfully completed five investigations to date using this valuable mechanism, and would like to continue these impactful information collections. A summary of recent information collections approved under this tool includes the following:

- During 2015, in U.S. Virgin Islands there was a methyl bromide exposure incident at a condominium resort severely injuring a family and causing symptoms in the first responders to the incident. ATSDR interviewed all potentially exposed persons who stayed or worked at the resort to look for signs of exposure. Under
this ACE investigation, ATSDR raised awareness among pest control companies that methyl bromide is currently prohibited in homes and other residential settings. Additionally, ATSDR raised awareness among clinicians about the toxicologic syndrome caused by exposure to methyl bromide and the importance of notifying first responders immediately when they have encountered contaminated patients.

- During 2016, the ACE Team conducted a rash investigation in Flint, Michigan. Persons who were exposed to Flint municipal water and had current or worsening rashes were surveyed and referred to free dermatologist screening if desired. Findings revealed that when the city was using water from the Flint River, there were large swings in chorine, pH, and hardness, which could be one possible explanation for the eczema-related rashes.

- During 2016, the ACE Team also conducted a follow-up investigation for people who were referred to a dermatologist in the first Flint investigation. The follow-up interviews resulted in improvements in medical exam and referral processes that were still on-going at the time.

The ACE Investigations have focused on performing rapid epidemiological assessments to assist state, regional, local, or
tribal health departments (the requesting agencies) to respond to, or prepare for acute chemical releases. The main objectives for performing these rapid assessments are to:

- Characterize exposure and acute health effects of the affected community to inform health officials and the community;
- Identify needs (i.e., medical, mental health, and basic) of those exposed during the incidents to aid in planning interventions in the community;
- Determine the sequence of events responsible for the incident so that actions can be taken to prevent future incidents;
- Assess the impact of the incidents on the emergency response and health services use and share lessons learned for use in hospital, local, and state planning for environmental incidents; and
- Identify cohorts that may be followed and assessed for persistent health effects resulting from environmental releases.

Because each incident is different, it is not possible to predict in advance exactly what type of, or how many respondents will be consented and interviewed to effectively evaluate the incident. Respondents typically include, but are not limited to, emergency responders such as police, fire, hazardous material technicians, emergency medical services, and personnel at
hospitals where patients from the incident were treated. Incidents may occur at businesses or in the community setting; therefore, respondents may also include business owners, managers, workers, customers, community residents, and those passing through the affected area.

The multidisciplinary ACE Team consisting of staff from ATSDR, the Centers for Disease Control and Prevention (CDC), and the requesting agencies will be collecting data. ATSDR has developed a series of draft survey forms to be quickly tailored in the field to meet the goals of the investigation. ATSDR collections will be administered based on time permitted and urgency. For example, it is preferable to administer the General Survey to as many respondents as possible. However, if there are time constraints, the shorter Household Survey or the Epidemiologic Contact Assessment Symptom Exposure (Epi CASE) Survey (proposed to replace the former ACE Short Form), may be administered instead. The individual surveys collect information about exposure, acute health effects, health services use, medical history, needs resulting from the incident, communication during the release, health impact on children, and demographic data. Hospital personnel are asked about the surge, response and communication, decontamination, and lessons learned.

Depending on the situation, data can be collected by face-to-face interviews, telephone interviews, written surveys, mailed surveys, or on-line surveys. Medical charts may also be
reviewed. In rare situations, an investigation might involve collection of clinical specimens.

ATSDR is proposing to increase the utility of this Generic ICR in response to stakeholder requests. We would like to expand the ACE toolkit to be more inclusive of other types of environmental incidents affecting the community which fall under ATSDR’s mandate and, at times, the mandates of our partners in the CDC’s National Center for Environmental Health (NCEH) and the National Center for Occupational Safety and Health (NIOSH). In addition to acute chemical releases, we propose to include radiological and nuclear incidents, explosions, natural disasters, and other environmental incidents.

We propose revisions to select information collection forms, which will be deployed using handheld devices whenever possible to reduce burden, and to adjust the number of responses and time per response for several forms. A new brief Eligibility Screener (1,000 responses per year; 33 hours) will be added prior to administering consent for our General and Household Surveys. The Epi CASE Survey replaces the ACE Short Form, which has been modified for the expanded scope of eligible incidents requested (1,000 responses per year; 250 hours). To reduce time burden, there will be new field data entry screens and deletion of unused questions for the General Survey (800 responses per year; 373 hours), the Household Survey (120 responses per year; 20 hours) and for the Hospital Survey (40 responses per year; 17 hours). There will be two optional short Mental Health Screeners
added to the General Survey. One screener measures both acute stress disorder and major depressive disorder, and the other one is strictly focused on generalized anxiety disorder. We are retaining the Medical Chart Abstraction Form (250 responses per year; 125 hours) but are removing the Veterinary Chart Abstraction Form as it has not been used in the past.

ATSDR anticipates up to four ACE investigations per year. We are requesting approval for 3,210 annual responses (increase of 1,920 responses per year) and for 818 annual hours (increase of 227 hours per year). Participation in ACE investigations is voluntary and there are no anticipated costs to respondents other than their time.

Estimated Annualized Burden Hours

<table>
<thead>
<tr>
<th>Type of Respondents</th>
<th>Form Name</th>
<th>Number of Respondents</th>
<th>Number of Responses per Respondent</th>
<th>Average Burden per Response (in hours)</th>
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</thead>
<tbody>
<tr>
<td>Residents, first responders, business owners, employees, customers</td>
<td>Eligibility Screener</td>
<td>1,000</td>
<td>1</td>
<td>2/60</td>
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<tr>
<td></td>
<td>Epi CASE Survey</td>
<td>1,000</td>
<td>1</td>
<td>15/60</td>
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<tr>
<td></td>
<td>General Survey</td>
<td>800</td>
<td>1</td>
<td>28/60</td>
</tr>
<tr>
<td>Residents</td>
<td>Household Survey</td>
<td>120</td>
<td>1</td>
<td>10/60</td>
</tr>
<tr>
<td>Hospital staff</td>
<td>Hospital Survey</td>
<td>40</td>
<td>1</td>
<td>25/60</td>
</tr>
<tr>
<td>Staff from state, local, or tribal health agencies</td>
<td>Medical Chart Abstraction Form</td>
<td>25</td>
<td>10</td>
<td>30/60</td>
</tr>
</tbody>
</table>
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[FR Doc. 2021-11146 Filed: 5/25/2021 8:45 am; Publication Date: 5/26/2021]