



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-20-0051; Docket No. ATSDR-2020-0005]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Assessment of Chemical Exposures (ACE) Investigations." The purpose of ACE Investigations is to focus on performing rapid epidemiological assessments to assist state, regional, local, or tribal health departments (the requesting agencies) to respond to or prepare for acute environmental incidents.

DATES: ATSDR must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2020-0005 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

Assessment of Chemical Exposures (ACE) Investigations (OMB Control No. 0923-0051, Exp. 03/31/2021) – Revision – 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 Revision of "Assessment of Chemical Exposures (ACE) Investigations" information collection request (ICR) (OMB Control No. 0923-0051; Expiration Date 03/31/2021). 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. ATSDR would like to continue these impactful information collections. A brief 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 chlorine, 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, and 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 quickly tailored series of draft survey forms used in the field to collect data that will 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 former ACE Short Form, now modified as the Epidemiologic Contact Assessment Symptom Exposure (Epi CASE) Survey, 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 collected by face-to-face interviews, telephone interviews, written surveys, mailed surveys, or on-line surveys can be collected. Medical charts may also be considered for review. 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 and 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 (900 responses per year; 30 hours) will be added prior to administering consent for our surveys. The Epi CASE Survey, formerly the ACE Short Form, 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; 333 hours), the Household Survey (120 responses per year; 20 hours) and for the Hospital Survey (40 responses per year; 17 hours). 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 3,110 annual responses (increase of 1,820 responses per year) and for 775 annual hours (increase of 184 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

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
Residents, first responders, business owners, employees, customers	Eligibility Screener	900	1	2/60	30
	Epi CASE Survey	1,000	1	15/60	250
	General Survey	800	1	25/60	333
Residents	Household Survey	120	1	10/60	20
Hospital staff	Hospital Survey	40	1	25/60	17
Staff from state, local, or tribal health agencies	Medical Chart Abstraction Form	25	10	30/60	125
Total					775

Jeffrey M. Zirger,

Lead,

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Office of Scientific Integrity,

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Centers for Disease Control and Prevention.

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