Supporting Statement Part A

Assessment of Chemical Exposures (ACE) Investigations

OMB Control No: 0923-0051 (Expiration Date: 02/28/2021)

Reinstatement with Change

Generic Clearance

April 2021

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Part A. Justification

Goal of the study: The goal of the Assessment of Chemical Exposures (ACE) Investigations is to perform rapid epidemiological assessments after acute environmental incidents.

Intended use of the resulting data: Information obtained by ACE Investigations will characterize the exposures and health symptoms of the potentially exposed group. Additionally, the data will guide public health and emergency response activities. Finally, ACE will assess and provide feedback on emergency response procedures to local authorities when requested.

Methods to be used to collect: Sampling methods can vary depending on the needs of the requesting agency and number of people involved. ACE Investigations can use convenience sampling or random sampling by individuals or household (depending on which survey that requesting agency wants to use). Also medical chart abstractions could occur.

Subpopulation to be studied: ACE Investigations vary between different incidents. Subpopulations to be studied would be determined by the requesting agency. It may include the community, workers or first responders.

How data will be analyzed: Descriptive statistics (frequencies, means, and ranges), bivariate and multivariate analyses

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 the "Assessment of Chemical Exposures (ACE) Investigations" (OMB Control No. 0923-0051; expiration date: 02/28/2021), which has been approved since 2015, and again in 2018, to allow ATSDR to respond to acute chemical release incidents. Three investigations (Appendix A) have been completed during the past seven years. These investigations demonstrate that during an environmental incident with acute health effects, immediate action by ATSDR is necessary to assist partners to minimize or prevent harm to the public. ATSDR seeks to continue this Generic ICR to ensure that the agency is poised to mobilize quickly when urgent epidemiologic support is requested by our partners.

The current ICR is a reinstatement with change, which requests to expand the ACE Investigation scope, based on stakeholder feedback. We would like to expand the ICR to include additional types of environmental incidents affecting the community, which fall under the jurisdiction of ATSDR, and, at times, our partners in the Center for Disease Control and Prevention's (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.

Proposed revisions to methods include the addition of a new eligibility screener, modifying current surveys to include the expanded scope of eligible incidents, removal of one form which was never used, and implementing direct data entry using handheld devices in the field rather than using hardcopy forms. We also added optional mental health screeners, streamlined surveys where possible, and adjusted the number of responses and the time burden for several forms.

These changes result in a net annual increase of 1,920 responses and 227 burden hours per year over the next three years. We are now requesting an annualized total of 3,210 responses and 818 burden hours. Details of the proposed revisions are found in Section A.15.

The 60-day Federal Register Notice was published on February 24, 2021 (Attachment 2) and is further discussed in Section A.8.

A.1. Circumstances Making the Collection of Information Necessary

Supporting effective epidemiologic investigations is an important way that ATSDR serves to protect the health of the public. When an environmental incident happens that affects the community, a rapid assessment and timely application of public health actions are fundamental to the overall mission of ATSDR. ATSDR is authorized to conduct investigations of chemical releases under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986. Under CERCLA, ATSDR works closely with the U.S. Environmental Protection Agency (EPA) to evaluate the presence and nature of hazardous substances at specific sites and the levels at which these substances may pose a threat to human health. For other types of environmental disasters, ACE Investigations are authorized under the Public Health Service Act (42 USC Sec. 301 [241]), as the team often includes staff from Centers for Disease Control and Prevention (CDC) centers, institutes, or offices. The authorizing legislation is shown in Attachment 1.

For an ACE Investigation to occur, the following criteria must be met:

1. ACE Investigations will be undertaken at the request of, and in collaboration with, the state, regional, local, or tribal health department (the requesting agency) where the environmental incident occurred.

2. ACE Investigations will be carried out in the event of acute environmental incidents, including, but not limited to, acute chemical releases, radiological and nuclear incidents, explosions, and natural disasters, which can cause serious mental or physical health effects. An event must involve:
    a. an environmental incident with the potential to cause acute human health effects, and/or;
    b. reports of acute mental or physical health effects in the community (including the public, workers, and responders) consistent with an environmental incident.

3. ACE Investigations will be non-research public health responses:

a. designed to prevent or control adverse mental and physical health effects and reduce risk in the requesting agency's jurisdiction, and
b. may be used to improve the requesting agency's public health response.

4. ACE Investigations will be restricted to domestic incidents and responses under ATSDR's and its partners authorizing legislation(s) (Attachment 1).

5. ACE Investigations data collection will be completed within 90 days after OMB approval.

ATSDR continues to request a 5-day approval, or within 72 or 24 hours if urgently needed. ACE Investigation teams must have the ability to rapidly choose data collection tools and methods immediately after they determine the scope of the problem and appropriate actions. They have a standing set of screener, consent, and survey forms that can be rapidly adapted to use the applicable questions (Appendices B–H). This will allow ATSDR to maintain critical mission function by working with partners throughout the nation and providing health protection and health equity.

The ACE Investigations Generic ICR can be used by ATSDR and CDC personnel responding to a request for assistance that is within the scope of this ICR. Team members on any given investigation could include ATSDR and CDC staff and contractors such as Epidemic Intelligence Service Officers and trainees such as CDC Experience Fellows, Epi-Elective Students, and Medical Toxicology Fellows, and may include staff from state, local, or tribal health agencies.

A.2. Purpose and Use of the Information Collection

The purpose of this Generic ICR is to conduct rapid assessments after an acute environmental incident, in partnership with the requesting agency. ATSDR will provide tools, technical expertise, laboratory and mapping support, and personnel support to the health departments. When existing data sources fail to provide enough information for the implementation of effective response, and to strengthen prevention efforts for such incidents, new data must be collected. The information obtained from ACE Investigations will be used to:

- immediately identify a group of potentially exposed people following an acute environmental incident,
- characterize the exposures and health symptoms of the potentially exposed people,
- guide public health and emergency response activities using the data gathered, and
- assess and provide feedback on emergency response procedures to local authorities when requested.

The primary purpose of each ACE Investigation is to respond to an environmental emergency and rapidly collect sufficient information to control and minimize public harm. Information collection during these investigations will also help guide response and strengthen prevention efforts in that locality. ACE Investigations will be conducted in the days or weeks following an acute environmental incident with the intent to gather data to inform the public health response and identify areas of the response that could be improved in future mass casualty environmental incidents in the jurisdiction.

This Generic ICR is for a rapid assessment of potential exposure and the health status of persons in the area of the acute environmental incident and a review of the response to the incident. It is not designed to be a study of the health effects associated with that particular type of environmental incident or to produce generalizable information (ATSDR will not have before and after health status data). Having a generic mechanism in place will facilitate a faster processing and clearance of information collection assistance requested by ATSDR partners. Summarized below are the accomplishments of this Generic ICR since the initial PRA clearance on 03/31/2015. A revision ICR was approved in 2018, but ATSDR has not conduct an ACE Investigation under this Generic ICR since that time. ATSDR wishes to keep this Generic ICR open in the event that another ACE Investigation is necessary.

1. Methyl bromide exposure at a condominium resort, U.S. Virgin Islands, 2015 (under OMB No. 0923-0051)
   Requesting agency: U.S. Virgin Islands Department of Health
   Methods: Identified persons who were potentially exposed to methyl bromide (n= 37); interviewed potentially exposed persons including pest control company personnel, emergency responders, condominium staff members, and resort residents, vacationers, and visitors.
   Usefulness of the results: Raised awareness for pest control companies that methyl bromide is banned in homes and other residential settings. For clinicians raised awareness about the toxicologic syndrome that exposure to methyl bromide can cause. Created awareness of the importance of immediately notifying first responders when they have been in contact with contaminated patients.

2. Flint Rash Investigation, Michigan 2016 (under OMB No. 0923-0051)
   Requesting agency: Michigan Department of Health and Human Services (MDHHS)
   Methods: Interviews were conducted from a convenience sample of rash referrals. Dermatological medical charts were reviewed. Water samples from homes were provided.
   Usefulness of the results: When the city was using water from the Flint River, there were large swings in chlorine, pH and hardness. These swings are one possible explanation for the eczema-related rashes. A factsheet was developed about the Rash study, what to do if they still have a rash, who to contact, and stress management. Participants were referred for a free dermatologist screening if desired.

3. Flint Rash Dermatology Follow-up, Michigan 2016 (under OMB No. 0923-0051)
   Requesting agency: Michigan Department of Health and Human Services (MDHHS)
   Methods: Follow-up interviews with people who sought care from dermatologists.
   Usefulness of the results: 40 follow-up interviews were conducted and provided valuable information to improve the ongoing exam and referral processes.

A.3. Use of Improved Information Technology and Burden Reduction

Since ACE Investigations collect information in response to an emergency environmental incident, in-person interviews with direct entry into handheld devices is preferred. When in-person direct entry is not possible in-person interviews with hardcopy forms with centralized data entry or phone interviews with direct data entry are possible (Appendix B–H). In addition, in

investigations where a community survey is needed, we will work with the state and locals and ATSDR geographers to try to locate potential households to interview ahead of time.

The survey samples (Appendix D-H) include the universe of all potential questions that may be asked. They are meant to be tailored down to fit the individual incident. For example, questions referring to the symptoms will be limited to those deemed related in the literature to the incident at hand, plus one unrelated symptom to test reliability. If data collection using a survey is expected to be longer than 30 minutes, then a justification for this burden will be provided in Attachment 3a.

A.4. Efforts to Identify Duplication and Use of Similar Information

Investigations conducted under this Generic ICR will be designed in collaboration with other CDC programs and other federal agencies, as well as state, regional, local, or tribal health authorities so that redundant data collection is avoided and the utility of the data collected are maximized. ATSDR investigators will work within the response framework if an incident is ongoing. NIOSH teams will be involved when releases involve a workplace or potentially exposed emergency responders. As part of the planning process for each investigation, ATSDR will identify whether there are existing data on environmental monitoring, exposure, and health effects.

A.5. Impact on Small Businesses or Other Small Entities

Every effort will be made to minimize the burden on small businesses. If the incident occurs at or is due to actions of employees of a small business, the investigation will involve interviewing business owners, managers, and workers. In addition, if incidents occur close enough to a business to potentially expose workers or customers, then these individuals may be interviewed. The information collected from a small business will be the minimum required to meet the needs of the requesting agency.

Based on the past ACE Investigations, we estimate that up to 10 percent of the total burden hours will be incurred by small businesses over the next three years.

A.6. Consequences of Collecting the Information Less Frequently

Each ACE Investigation will be a one-time generic information collection (GenIC) undertaken immediately after an emergency incident. If it is determined that ACE team should collect information beyond the approved 90-day data collection period, it will be processed separately under a new GenIC or different ICR. There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

In order to respond to the needs of the population potentially exposed during an acute environmental incident, data needs to be collected within hours or days of the request. Because of

the need to rapidly obtain information to appropriately respond to the urgent public health need, data collection will usually be completed within 90 days.

To comply with the regulation 5 CFR 1320.5 and at the same time ensure that public health data are collected in a timely manner to assist partners in responding to environmental emergencies, ACE Investigations will adhere to the following timeline and processes:

- At the request of the state, regional, local, or tribal health department and after consultation with our external partners, ATSDR and CDC decide to organize and deploy a team to provide assistance to our partners in assessing potential community exposures and the frequency of health effects potentially associated with such environmental exposures.

- The NCEH/ATSDR PRA Contact serves in the role of the ICRL. The ICRL oversees the clearance process for individual GenICs.

- The CDC Information Collection Request Office (ICRO), United States (US) Department of Health and Human Services, and the Office of Management and Budget Office of Information and Regulatory Affairs (OIRA) desk officers are notified of the ACE Investigation immediately via e-mail from ATSDR followed by receipt of the GenIC "Request for Assessment of Chemical Exposures (ACE) Investigation" Form (Attachment 3a) describing the incident and the planned response.

- Each ACE Investigation GenIC request is closely reviewed by the ICRL based on the predefined set of criteria (the "scope") of the ACE Investigations Generic ICR. The "Request for Assessment of Chemical Exposures Investigation" (Attachment 3a) and Supporting Statement B serves as the GenIC package for each ACE Investigation. Data collection for ACE Investigation will be conducted with the reduced versions of surveys (Appendices D – H). if the time duration for collecting data using a survey is expected to exceed 30 minutes, a justification for the burden will be provided.

- The OMB-OIRA Desk Officer responds with approval or comments on the proposed ACE Investigation within 5 days of receipt of the request unless a shorter time frame is requested. If a 72- or 24-hour approval is requested, a justification will be provided in an email which describes the public health need (Attachment 3b) and will provide as much advance warning as possible about the request. OMB may provide approval and comments orally (followed by e-mail for written documentation) or e-mail directly. This may occur before the GenIC request is submitted and received by OMB through the official ICR tracking system.

- At the completion of the ACE Investigation, the investigators submit the final data collection instrument(s) and associated burden using the "ACE Investigations Burden Memo" Form (Attachment 3c) to the Information Collection Request Liaison (ICRL).

- All final data collection instruments conducted under this Generic ICR and the updated burden numbers based on data collected via the "ACE Investigations Burden Memo" (Attachment 3c) will be submitted to OMB quarterly as a non-substantive change to the Generic ICR , unless no ACE Investigations are conducted during a given quarter.

- The public record for this ICR will include a library of data collection instruments that have been used in the past or are likely to be used. The ICRL will maintain the library of data collection forms that may be accessed by ATSDR programs initiating new investigations. Upon the completion of an approved ACE Investigation, the ICRL will place the data collection instrument(s) into the library.

- Information about the Generic ICR and how to submit a GenIC is distributed to ATSDR program officials (Steps for Conducting an ACE Investigation, (Attachment 3d).

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on 02/24/2021, Vol. 86, No. 35, pp. 11296-8 (Attachment 2). ATSDR received no public comments related to this notice.

B. In 2018 and 2019, ATSDR specifically sought input on the former ACE Short Form now named the Epidemiologic Contact Assessment Symptom Exposure (Epi CASE) Survey (Appendix D). We reached out to both internal and external partners for input.

Table A.8.B.1. 2018-2019 ATSDR External Consultations

Name	Title	Affiliation	Phone	Email
Vinicius Antao, MD, MSc, PhD	Senior Director, Health Outcomes Strategy	Hospital for Special Surgery	212-774-7398	antaov@hss.edu
Wendy Kaye, PhD	Epidemiologist	McKing Consulting	404-660-7571	WKaye@cdc.gov
Michael Heuman, MS	CEO	Heuman Health Consulting	503-880-2226	heumannhealth@gmail.com
Melissa Powell, MS	Manager, Surveillance & Epidemiology	Oregon State DOH	971-673-1222	MELISSA.E.POWELL@dhsoha.state.or.us
Tom Garcia, MS	Epidemiologist	Minnesota State DOH	612-704-0761	tom.garcia@state.mn.us
Behrooz Behbod, PhD	Epidemiologist	Public Health England, Chilton, Oxfordshire, England	+44-786-036-6406	bbehbod@gmail.com

External persons consulted on the conversion of the ACE short form to the new Epi CASE.

Table A.8.B.2. 2018-2019 Consultations with other CDC/ATSDR Programs

Name	Title	Affiliation	Phone	Email

Patrick Breysse, PhD	NCEH/ATSDR Director	CDC/NCEH	770-488-0604	PBreysse@cdc.gov
Daniel Sosin, MD	CDC OPHPR Deputy Director	CDC/OPHPR	404-639-7985	dms8@cdc.gov
Arthur Chang, MD	Chief Medical Officer	CDC/NCEH	770-488-1470	AChang@cdc.gov
Ekta Choudhary, PhD, MPH, MS	Senior Service Fellow	CDC/NCEH	770-488-3825	gnr0@cdc.gov
Tesfaye Bayleyegn, MD	Senior Service Fellow	CDC/NCEH	770-488-3476	bvy7@cdc.gov
Armin Ansari, PhD	Physical Scientist	CDC/NCEH	770-488-3654	asa4@cdc.gov
Joshua Schier, MD	Medical Officer/Toxicologist	CDC/NCEH	770-488-3401	are8@cdc.gov
Renee Funk, DVM, MPH, MBA	NCEH/ATSDR Deputy Director	CDC/NCEH	770-488-2499	rjf8@cdc.gov
Sherry Burrer, DVM, MPH	Epidemiologist	CDC/ NIOSH	770-498-2025	hhf8@cdc.gov
Jill Shugart, BS, MSPH	Public Health Advisor	CDC/NIOSH	770-498-2559	ahe8@cdc.gov
Geoffrey Calvert, MD, MPH	Medical Officer	CDC/NIOSH	513-841-4448	jac6@cdc.gov
Amy Schnall, MPH, BA, CPH	Epidemiologist	CDC/NCEH	770-488-3422	ghu5@cdc.gov
Lina Balluz, ScD, MPH, BS	DTHHS ADS	ATSDR	770-488-3998	lib7@cdc.gov
Stephanie Davis, BS, MSPH	Epidemiologist	CDC/NCEH	770-488-3676	sqd8@cdc.gov
Alisha Etheredge, MS, MPH, BS	Public Health Analyst	CDC/NCEH	770-488-7884	epq5@cdc.gov
Padmaja Vempaty, MPH, MSW	Health Scientist	CDC/NCEH	770-488-3963	dmy6@cdc.gov
Megan Reynolds, MDiv, MPH	Health Scientist	CDC/NCBDDD	770-498-0607	xah6@cdc.gov
Caroline Cusack	Epidemiologist	ATSDR	770-488-3813	cyc9@cdc.gov
Timothy Dignam, MPH, PhD, MS	Health Scientist	CDC/NCEH	770-488-3622	ted9@cdc.gov
Pamela Tucker, MD	Medical Officer	ATSDR	770-488-3458	pgt0@cdc.gov
Charlton Coles, MD	Behavioral Scientist	ATSDR	770-488-3345	fzn3@cdc.gov
Benjamin Gerhardstein, MPH	Regional Representative	ATSDR	415-947-4316	fty9@cdc.gov
The first 19 CDC/ATSDR staff consulted in the conversion of the ACE short form to Epi CASE. The last 3 CDC/ATSDR ATSDR staff assisted in the identification of the 2 mental health screeners for the ACE				

general survey.

There were no unresolved problems with either external of internal consultants.

When we conduct ACE investigations the surveys are modified and tested and we receive feedback. We used this to help us modify the surveys.

A.9. Explanation of Any Payment or Gift to Respondents

Respondents will receive no gift or payment for their participation in any information collections.

A.10. Assurance of Confidentiality Provided to Respondents

On 02/03/2021, this Generic ICR was reviewed by the CDC Chief Privacy Officer who determined that the Privacy Act applies to this information collection (Attachment 5a). The applicable System of Records Notice (SORN) is ATSDR's SORN 09-19-0001 titled "Records of Persons Exposed or Potentially Exposed to Hazardous or Toxic Substances."

Data are collected in collaboration with, or at the request of, the state, regional, local, or tribal health department. Respondents are assigned an ID number to serve as a link between their identity and their response data or their specimens. Information in identifiable form (IIF) may be collected from or about the respondents affected by the incident only when essential to support objectives of the ACE Investigation.

The following IIF Categories apply to this information collection (Appendices B-F, H):

Name	Medical Information and Notes
Date of Birth	Biological Specimens
Mailing Address	Email Addresses
Housing Unit Latitude and Longitude	Employment Status
Phone Numbers	Social Media Accounts
Social Security Number	

All records, including IIF, belong to the requesting agency and will reside on its own established record system. The requesting agency will retain the linking IIF according to its own record schedule. The requesting agency (i.e. local or state health department) may use the respondents' names and contact information to provide individual assistance or to follow-up to assess persistent or delayed health effects consistent with the chemicals released during the incident. Any release of IIF will be done in accordance with the statutes, rules, procedures, and discretion of the requesting agency. Other data will also be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

Appendices B–F - In summary, the library of potential data collection topics in addition to IIF, may include information on:

- Location/exposure

- Health status
- Injuries
- Medical care and treatments received after the incident
- Occupation
- Medical history
- Emergency response
- Communication during the release
- Current basic needs
- Other people present with the respondent at the time of the release
- Demographic and contact information

Appendix G - Personnel at responding health care facilities may be asked about the:

- Surge
- Response
- Decontamination
- Lessons learned

Appendix H - During medical chart abstraction, information may be collected on:

- Patient demographics and contact information
- Visit information
- Medical history
- Decontamination
- Signs and symptoms
- Medical tests and imaging
- Treatment

In some investigations, clinical samples, either blood or urine, may be collected to test for the chemical(s) or metabolites of interest. The laboratory testing may be performed at a state facility or the CDC's NCEH laboratory. ATSDR will not store clinical samples for future research; any unused samples will be discarded at the completion of the testing. Appendix I demonstrates the typical decisions that the ACE investigation team uses to select the forms to be employed at each investigation.

ACE field procedures for ATSDR and CDC investigators are outlined in Attachments 4a and 4b. During an ACE Investigation, local health authority policies and procedures for data storage and security will be followed (Attachment 4c). The ACE Investigation team will use encrypted computers and flash drives to enter and transfer the survey and medical chart abstraction data. All ATSDR computers comply with the HHS Standard 2008-0007.001S for encryption. In the field when not in use, hardcopy surveys are stored in a locked Pelican case.

ACE has an approved Privacy Impact Assessment (Attachment 5a.) The Epi CASE survey (Appendix D) has the most personally identifying data because it is meant to capture persons who were affected by an environmental disaster rather soon after the incident and there may be a need to recontact them to get or share more information at a later time. The state has the option of collecting Social Security Number, or a part of it. On 02/05/2021, the CDC Chief Privacy Officer approved the collection of Social Security Number (Attachment 5b). There is a training manual that describes how to protect the data (Attachment 5c).

After the ACE Investigation team completes its field data collection, the requesting agency will have the discretion to share de-identified data labeled only with respondent ID with ATSDR for continued support with statistical analysis and report writing. Only de-identified data in an appropriate format (e.g., Epi-Info, Excel, or SAS) are brought back to ATSDR to perform data analysis.

ATSDR will not have access to IIF with the exception of: housing unit latitude and longitude, medical information and notes, and employment status. ATSDR will not retain the link between the respondent's direct identity (e.g., name, date of birth, address, phone number, email address) and the respondent ID number. A nondisclosure form will ensure that ATSDR will not have access to the identity of the individuals whose data are shared and whose specimens were tested.

Only de-identified clinical specimens are sent to NCEH for laboratory analysis. If clinical testing is performed by the NCEH laboratory, ATSDR will send the de-identified test results to the requesting agency. Because ATSDR will not have names and contact information, the requesting agency will be encouraged to send individual results and reports to the respondent.

All de-identified records maintained by ATSDR after the investigation will be subject to the ATSDR Comprehensive Record Control Schedule (CRCS), B-371, which contains authorized disposition instructions for administrative and program records. ATSDR is legally required to maintain its program-related records in accordance with CRCS disposition instructions. These retention periods have a direct impact on completing Freedom of Information Act requests.

If there is a data security breach, there would be a likely effect on the respondent's privacy; however, every effort will be taken to prevent accidental disclosure. Laboratories have procedures to protect privacy. Survey data will be safeguarded to protect privacy in the field and in the office; paper surveys will be kept in a locked location, computer files will be password-protected, and access will be limited to the personnel working on the investigation.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The Federal Regulations for Protection of Human Subjects (45 CFR 46) state, "research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

ACE Investigations will be undertaken to identify, characterize, and solve an immediate public health problem and the knowledge gained will directly benefit the affected community. Although the ACE Investigations will use systematic methods, they will not be designed to develop or contribute to generalizable knowledge and will not be research investigations. Human subjects review by an Institutional Review Board (IRB) will not be required. The NCEH/ATSDR research determination is attached (Attachment 6).

Some of the ACE Investigation respondents may find some of the questions asked during an investigation to be sensitive, such as social security number, medical conditions, pregnancy status, or race/ethnicity. Respondents will be informed that the data will be collected in response to the environmental incident and that the information they provide may help authorities understand the health effects and may be used to help the community and learn how to better prepare for future disasters. The respondent will be informed that his or her response is voluntary (Appendix C).

Social security numbers will be collected for the mass disaster situations where there may be multiple people with the same name. It is up to the jurisdiction where the incident occurred about how many digits of a social security number they think they will need. The training manuals carefully discusses data security issues.

A.12. Estimates of Annualized Burden Hours and Costs

ATSDR anticipates there will be up to 12 investigations in the next iteration of the three-year approval (four per year). Although in the past approval period, this clearance has not been used, we believe the number requested gives ATSDR flexibility to do more investigations, especially Epi CASE, when there is a need. In past ACE Investigations, the number of respondents surveyed has ranged from about 30-715, with an average of about 300 respondents per investigation.

Table A.12.1. 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	1000	1	2/60	33
	Epi CASE Survey	1,000	1	15/60	250
	General Survey	800	1	28/60	373
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		2,985			818

There will be no anticipated costs to respondents other than time. The May 2020 U.S. median national wage for all occupations is $20.17 (available at http://www.bls.gov/oes/current/oes_nat.htm#00-0000). This wage is assumed for general respondents because of the variety of types expected. Registered nurses are often the persons interviewed at hospitals, so their median hourly wage ($36.22) is used to represent the hospital staff wages. The medical chart review will be done by the epidemiologists from state, local, or tribal health agencies at a median wage rate of $35.84. With an annual respondent burden of 818

hours, the overall annual cost of respondents' time for the proposed collection will be a maximum of $18,732.03 .

Table A.12.2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Hourly Wage Rate	Total Respondent Cost
Residents, first responders, business owners, employees, customers	Eligibility Screener	1000	1	2/60	$20.17	$672.33
	Epi CASE Survey	1,000	1	15/60	$20.17	$5,042.50
	General Survey	800	1	28/60	$20.17	$7,530.13
Residents	Household Survey	120	1	10/60	$20.17	$403.40
Hospital staff	Hospital Survey	40	1	25/60	$36.22	$603.67
Staff from state, local, or tribal health agencies	Medical Chart Abstraction Form	25	10	30/60	$35.84	$4,480.00
Total						$18,732.03

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no other total annual cost burden to respondents or record keepers.

A.14. Annualized Cost to the Federal Government

Tablets were purchased for data entry for $2,789. There are no overhead costs. The cost factors considered are related to routine procedures of the investigators in planning investigations; design, preparation, printing, and distribution of questionnaires; and editing, coding, tabulation, analysis, and presentation of the information. The annual cost is estimated based on the U.S. national average hourly wage for GS-14 Step 1 epidemiologists in 2020 ($54.42) (available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/). On average, CDC staff and contractors contribute 300 hours per ACE Investigation, with four per year that equates to for a total cost for staff of $65,304. Travel to the site and meals and incidental expenses (M&IE) for 4 staff per incidents at roughly $1,000 per person equates to $16,000. The total annualized cost to the government of this data collection is $84,903.

Table A.14.1. Estimated Annualized Burden Costs to the Government

Staff, Fellows or Contractors	Average Hours per ACE Investigation	Hourly Wage Rate	Number of ACE Investigations Annually	Total Annualized Costs
GS14 Step 1 Epidemiologists	300	$54.42	4	$65,304
Travel				$16,000
3 tablets				$2,789
Total Cost per Year				$84,903

A.15. Explanation for Program Changes or Adjustments

Expanding the Scope of Environmental Incidents

Several states, including California, Kentucky and Illinois voluntarily implemented the ACE toolkit. Based on these stakeholders' feedback, ATSDR is proposing to increase the utility and efficiency of the ACE toolkit by expanding ACE Investigations to include not only acute chemical exposures, but also radiological and nuclear incidents, explosions, natural disasters, and other types of environmental incidents. ATSDR has found no other toolkits like ACE Investigations to do epidemiologic assessments for these other types of incidents.

Modification of Information Collection Forms and Methods

Revisions also include the addition of a new eligibility screener, modifying current surveys to include the expanded scope of eligible incidents, removal of one form which was never used, and implementing direct data entry using handheld devices in the field rather than using hardcopy forms. We also streamlined surveys where possible and adjusted the number of responses and the time burden for several forms.

Form Number	Form Name and Narrative
Appx A	*Summary of ACE Investigations* – no change
Appx B (new form)	*Eligibility Screener* – We added this form to decrease some recruitment burden and to more efficiently eliminate ineligible people before consent. We show the person a map of the area of the incident and ask if he/she was in that area during the time of concern. If the person was not, then we will thank him/her and end the recruitment. If he/she is eligible, we will consent that person and conduct the appropriate survey. The time per response is 2 minutes.
Appx C (former Att7)	*ACE Consent Forms* – We generalized the type of emergency incident to allow acute chemical exposures, radiological and nuclear incidents, explosions, natural disasters, and other types of environmental incidents.
Appx D (former Appx C "ACE Short	*Epi CASE Survey* – The former *ACE Short Form* is renamed to *Epidemiologic Contact Assessment Symptom Exposure (Epi CASE)* to better fit its purpose. We anticipate the Epi CASE Survey will be useful for the expanded scope of environmental emergencies. This is

Form")	meant to be applied when time is of the essence and an emergency has just happened. A short survey is needed to gather symptom and exposure data and a way to recontact them later. We have added a place to record social security number, driver's license or other form of ID so that the state or local health department will be better able to locate people if they need to recontact them later. The level of information collected will be up to the state and local authorities since they keep the records there. The applicable laws in their jurisdiction will govern how this information is collected and stored and used. Our training guidance stresses the importance of protecting this information. We updated the contact information so that one of the contacts address/phone/email has been replaced with social media accounts which is a better way to locate people. We added a systematic symptom showcard to make symptoms easier to report on and analyze. We added a question for a radiological incident to determine affected people. We anticipate this short form will potentially be used in large radiological incidents; therefore, we requested an increase in the number of respondents from 50 to 1000. We added a place to record information on affected children in an adult's care during the incident. Children were not previously captured. Adding the extra questions results in an 8-minute increase to the survey from 7 to 15 minutes.
Appx E (former Appx B)	*General Survey* – We received feedback that the survey is too lengthy (54 pages). We removed several sections and questions that have not been asked or analyzed in the past and simplified some very complicated questions. We deleted the pet related questions. It is now 37 pages. We developed a pick list of potential symptoms organized by type (used with Epi CASE also). This is a more organized and complete list than previously used. Also, we have added an optional mental health screener module to the symptoms section. This is for incidents where there is a high concern for mental health impacts and there are resources available to address them. These are well accepted non copyright tools with good validity and sensitivity and are very short (3 minutes) We deleted module letters and just left names because it becomes confusing when you drop or reorder modules. Survey time is reduced from 30 minutes to 28 minutes
Appx F (former Appx D)	*Household Survey* – Several questions were deleted or edited to streamline the form, resulting in a 5-minute decrease for the survey
Appx G (former Appx E)	*Hospital Survey* – Several questions were deleted or edited to streamline the form, resulting in a 5-minute decrease for the survey
Appx H (former Appx F)	*Medical Chart Abstraction Form* – Several questions were combined and several were added for no net change in time
Removed (former Appx G)	*Veterinary Chart Abstraction Form* – The previous veterinary records abstraction form took 20 minutes. This form was removed because it was not used in the past.
Appx I (former Appx H)	*Decision Tree for ACE Investigations* – no change

Revised Number of Responses and Time Burden in 2021

These changes result in a net annual increase of 1,920 responses and 227 burden hours per year over the next three years.

Table A.15.2. Summary of Revision Impacts, 2018 to 2021.

Form Number		Form Name	Number of Responses			Average Burden per Response (in hr)		Total Burden (in hr)		
2018	2021		2018	2021	Δ	2018	2021	2018	2021	Δ

n/a	Appx B	Eligibility Screener (new in 2021)	n/a	1000	+1000	n/a	2/60	n/a	33	+33
Appx C	Appx D	Epi CASE Survey (former 2018 ACE Short Form)	50	1,000	+950	7/60	15/60	6	250	+244
Appx B	Appx E	General Survey	800	800	0	30/60	28/60	400	373	-27
Appx D	Appx F	Household Survey	120	120	0	15/60	10/60	30	20	-10
Appx E	Appx G	Hospital Survey	40	40	0	30/60	25/60	20	17	-3
Appx F	Appx H	Medical Chart Abstraction Form	250	250	0	30/60	30/60	125	125	0
Appx G	n/a	Veterinary Chart Abstraction Form (removed)	30	n/a	-30	20/60	n/a	10	n/a	-10
		Total	1,290	3,210	**+1,920**	---	---	591	818	**+227**

A.16. Plans for Tabulation and Publication and Project Time Schedule

The epidemiologic data collected in each ACE Investigation provides information necessary for an effective public health response to an environmental incident with adverse health consequences. Therefore, it is critical to collect data as soon as possible after the release. The duration of each ACE Investigation varies; data collection will usually be completed within 90 days of the incident. If it is determined an investigation will extend beyond 90 days, the lead investigator will submit a new GenIC.

For each ACE Investigation, the lead investigator is responsible for developing an analysis plan and conducting the data analysis. Preliminary findings are generally provided to the inviting agency at the end of the field investigation or on a conference call the following week. A preliminary report summarizing the early findings of the investigation is written by the lead investigator and provided to CDC. Any publication of data derived from an ACE Investigation is subject to review by the requesting agency, ATSDR, CDC, and other collaborating federal agencies.

ATSDR will prepare a written report that summarizes the overall findings. No personal identifiers will be included in the report. The report will be available to the public and to other federal, state, and local environmental and public health agencies. Findings of the investigation will include summary data only and may be reported as state or local agency reports, *Morbidity and Mortality Weekly Report* or journal articles, media reports, and presentations to the community, responders, and to public health practitioners at local, regional, and national conferences. A sample of published material from an ACE Investigation is attached (Attachment 7). The body of data gathered from multiple ACE Investigations may be used for education and training to prepare for future incidents.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.