Supporting Statement Part A

Assessment of Chemical Exposures (ACE) Investigations

OMB Control No: 0923-0051 (Expiration Date: 10/31/2024)

Revision

Generic Clearance

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Point of Contact:
Maureen F. Orr, MS
Team Lead, Surveillance Team
Environmental Health Surveillance Branch
Division of Toxicology and Human Health Sciences
Agency for Toxic Substances and Disease Registry (ATDSR)
4770 Buford Hwy NE, MS 106-5
Atlanta, GA 30341
Phone: 770-488-3806
Email: mco0@cdc.gov

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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.. 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: 10/31/2024), which has been approved since 2015, 2018, and 2021 to allow ATSDR to respond to acute chemical release incidents. Three investigations (Appendix A) have been completed using this ICR. 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 continuation with revision, which requests to modify and add questions and add some modules to the general survey (Appendix E), based on coordination with stakeholders. New modules were developed in coordination with outside subject matter experts for pets, livestock, responders, and community resilience.

The children's (age < 18) questions will now be answered by adults; previously adolescents 13-17 were allowed to answer the general survey with a parent's consent, but this is too complicated in the field.

We have modified the race and ethnicity questions to fit new OMB standards.

The surveys now have some open-ended questions for qualitative analysis.

In our previous submission we had deleted the pet section and the responder section was much smaller but with the CDC One Health initiative there has been a resurgence of interest in animal health, so we worked with CDC One Health and also a state veterinarian and EIS officer to develop short pet and livestock health modules.

There has also been interest from NIOSH and other groups in responder health impacts from these disasters, so we worked with NIOSH to build out responder questions into a separate module. Lastly, we have seen that open-ended questions allow people to give more insights into their health and wellbeing. OMB has supported their use.

We have become more familiar with the science of interpreting qualitative data, so we have built an optional qualitative module for people who want to provide more insight. We are using community resilience constructs for this module and developed it in coordination with the CDC Office of Readiness and Response. This will be offered as an optional module at the end of the General survey. We also interspersed some qualitative questions throughout the survey including for physical and mental health, and communications.

We have added questions on functional disabilities at the request of, and in coordination with, the CDC National Center for Birth Defects and Disabilities and the CDC At-Risk Task Force.

We have worked with CDC At-Risk Task force and several CDC physicians to develop a set of questions on maternal and child health that could be used for follow-up surveys.

We did research and found simpler mental health screeners than we had previously, for potentially associated conditions including one for depression, one for anxiety and one for PTSD.

Lastly, with the ease of self-administered online surveys using QR codes or links and more people being familiar with them during COVID, we would like to include online data collection as a new option to allow for substantially more responses in a shorter time period. This necessitated slight wording changes to the questions so that the questions could be either interviewer or self-administered. We felt that most of these changes allowed us to coordinate data with CDC/ATSDR and other federal data collection efforts.

The Epi CASE survey (Appendix D) now has the symptom checker show card integrated into the form rather than being separate. We would like for Epi CASE to have an online self-administration option as well, so removing a separate showcard and some wording modification were needed. The categories of symptoms are now consistent with the General survey. We modified to the new OMB standards for race/ethnicity.

The Medical chart form (Appendix G) was modified with the OMB standards for race/ethnicity, and the functional disabilities were added to it as well. A medical toxicology fellow, and the At-Risk task force who are familiar with chart reviews made some other suggested edits.

We decided to retire the household survey (Former Appendix F) as it is logistically difficult to administer and analyze.

There were no changes to the hospital survey (Appendix F).

We adjusted the number of responses and the time burden for several forms.

These changes result in a net annual increase of responses and 690 burden hours per year over the next three years. We are now requesting an annualized total of 4,815 responses and 1,508 burden hours. Details of the proposed revisions are found in Section A.15.

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 chemical incidents happen 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 have been undertaken at the request of, and in collaboration with public health authorities, including state, regional, local, or tribal health departments where the environmental incident occurred. We are requesting to expand to include other Federal public health agencies as a requesting agency.

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–G). 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, tribal or other federal public 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 agencies. 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.

If an incident sent people to the hospitals, like a toxic gas cloud or explosion might, then App F Hospital Survey can be used to survey hospital staff involved, usually in a group at a convenient time to minimize disruption. The Hospital Survey consent is used for those staff.

The Eligibility Screener is always used prior to App E General Survey or App D Epi CASE. It attempts to determine whether someone was in the area of interest during the time of exposure, usually with a map and a frame of reference. If they were not the area they immediately released and if they were in the area they are asked if they want to take the survey and are consented with the consent form for that survey.

App D Epi CASE is used when there is a large-scale environmental incident that causes a massive disruption, for example the World Trade Center collapse and a large radiation incident. In this instance, you want to get very basic information about exposure and health effects and needs and enough information to recontact people to get additional information or share resources at a later time. The sheer size of these incidents may require the collection of the last 5 of the social security number to eliminate duplicates. However, this is always at the discretion of the requesting locality.

App E General Survey is used where there is time to collect more thorough information. Usually in a less chaotic incident. However, please note, it is not the intention to ask every question or answer choice. These will be tailored down to the actual incident and information needs of the requestor. An example of when the General survey might be used is in a a water contamination incident where people are allowed to stay in their homes, but are provided bottled water.

As part of the General Survey there may be a desire to collect medical records to better understand treatments. This is when the Medical Chart consent form is used to request the charts and the App G medical chart form to abstract the charts. In the rare instance when there is a biological marker that is still able to be measured, for example a persistent organic pollutant, the individual can consent to the biological testing and that consent will allow us to collect and test their blood, urine, or saliva.

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 and 2021 but ATSDR has not conducted an ACE Investigation under this Generic ICR since that time. However, our ACE data collection tools are available on our ATSDR website for health agencies to use or request technical assistance with, so we wish 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

ACE Investigations collect information in response to an emergency environmental incident. We would like to offer a combination on survey administration methods to efficiently gather this information. Online surveys which can be quickly distributed through posted or distributed links or QR codes allow people the ease taking the survey on their schedule and devices. Some people's circumstances require in-person interviews, in this case we prefer direct entry into handheld devices for quicker analysis. If 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.

The survey samples (Appendix D-G) include the universe of all potential questions that may be asked. They are a questions bank intended 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 the requestor does not think that responder or pet health impacts were an issue in the incident, those modules can be deleted. If data collection using a survey is expected to be longer than 60 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, tribal or other federal health agency and after consultation with our external partners, ATSDR and CDC decide to organize and deploy a team. The team is 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 – G). If the time duration for collecting data using a survey is expected to exceed 60 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* Vol. 89, No. 122 on Tuesday, June 25, 2024 pages 53103-53105 (Attachment 2).
   One response was received (Attachment 2a) and responded to (Attachment 2b).
B. In 2023 and 2024, ATSDR specifically sought input on the questions for the Responder Module of the General Survey (Appendix E). We reached out to both internal and external partners for input.

Name	Agency
Chad Dowell	NIOSH
Cherie F. Estill	NIOSH
Sophia Chiu	NIOSH
Christina (Tina) Lawson	NIOSH
Carissa Rocheleau	NIOSH
Jim Collins	NIOSH
Thomas Cunningham	NIOSH
Courtney Dewart	Ohio ODH
Kristin Dickerson	Ohio ODH
Laurel Harduar-Morano	PA DOH
Sharon Watkins	PA DOH
Remy Babich	PA DOH
Vidisha Parasram	NIOSH
Dallas Shi	NIOSH

In 2021 through 2023 we sought input for the pet and livestock questions from the CDC One Health program and a state epidemiologist.

Name	Agency
Casey Barton Bahravesh	CDC\DDID
Natalie Wendling	CDC\DDID
Kate Varela	CDC\DDID
Rochelle Medford	CDC\DDID
Betsy Schroder	PA Dept Health
Emily Dulcey	CDC\PHIC

In 2023 and 2024 we consulted with subject matter experts at the CDC in maternal and child health, mental health, and in disabilities at the request of the CDC At-Risk taskforce to develop related questions.

Name	Agency
Jessica Meeker	CDC\NCCDPHP
Rebecca Leeb	CDC\NCBDD
Cristen McArdle	CDC\NCEH
Asha Choudhury	CDC\PHIC
Rebecca Hall	CDC\NCCPPHP
Joe Holbrook Romeo Galang	CDC\NCBDD CDC\NCCDPHP

In 2023 to 2024 we had a workgroup dedicated to developing a quantitative and qualitative question bank for the community resilience constructs. This module of the survey will be last and optional for those who want to provide additional insights into the impacts of the incident. It is suggested that the survey developer choose 1 quantitative and one qualitative question from the question bank for each construct. Additionally, several qualitative questions were interspersed with the existing quantitative questions to get a fuller picture of how people's physical health and mental health were affected and to understand what they thought were problems with the response. The responses to these questions will be rated by multiple reviewers with a codebook of themes that arise and an interrater reliability statistic will be calculated either manually or with a software product.

Name	Agency
Mary Leinhos	CDC\ORR
Vidisha Parasram	CDC\NIOSH
Valerie Madera Garcia	CDC\NCHHSTP

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

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

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. A privacy impact assessment (Attachment 5) was conducted.

The following IIF Categories apply to this information collection

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, or other federal public health agencies) 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.

In summary, for Surveys in Appendix D, E 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
- Maternal and child health
- Functional disability
- 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 F - Personnel at responding health care facilities may be asked about the:

- Surge
- Response
- Decontamination
- Lessons learned

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

- Patient demographics and contact information
- Visit information
- Medical history
- Functional disability
- 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. Attachment 3e 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. The ACE Investigation team will use encrypted computers and flash drives to enter and transfer any survey and medical chart abstraction data collected on tablets or desktops. All ATSDR computers comply with the HHS Standard 2008-0007.001S for encryption. In the field when not in use, any hardcopy surveys are stored in a locked Pelican case.

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. The CDC data use agreement template, Attachment 4C will be completed and signed with the requesting agency representative for all investigations where ATSDR will receive deidentified data.

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 CDC STARS project determination summary 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, functional disability, 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.

A.12. Estimates of Annualized Burden Hours and Costs

ATSDR anticipates there will be up to 3 investigations in the next iteration of the three-year approval (one 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, 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. With the addition of the ability to self-administer the survey online, we expect more participants. For a total of 1,508 burden hours.

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	2,500	1	2/60	83
	Epi CASE Survey	1,000	1	17/60	283
	General Survey	1,000	1	60/60	1000
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		4,565			1,508

There will be no anticipated costs to respondents other than time. The May 2023 U.S. median national wage for all occupations is $23.11 (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 ($41.38) 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 $39.13. With an annual respondent burden of 1,508 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	2,500	1	2/60	$23.11	$770.33
	Epi CASE Survey	1,000	1	17/60	$23.11	$6,547.83
	General Survey	1,000	1	60/60	$23.11	$23,110.0
Hospital staff	Hospital Survey	40	1	25/60	$41.38	$689.67
Staff from state, local, or tribal health agencies	Medical Chart Abstraction Form	25	10	30/60	$39.13	$4,891.25
Total		4,565				$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

There are no overhead costs. The cost factors considered are related to routine procedures of the investigators in planning investigations; design database, preparation, printing, and distribution of surveys; 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 2024 ($50.12) (available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/) On average, CDC staff and contractors contribute 1000 hours per ACE Investigation, with one per year for a total cost for staff of $50,120. Travel to the site and meals and incidental expenses (M&IE) for 10 staff per incidents at roughly $1,000 per person equates to $10,000. The total annualized cost to the government of this data collection is $60,120.

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	1000	$50.12	1	$50,120
Travel				$10,000
Total Cost per Year				$60,120

A.15. Explanation for Program Changes or Adjustments

Adding modules and questions in coordination with CDC subject matter experts

Based on CDC stakeholders' feedback, ATSDR is proposing to increase the utility of the ACE toolkit by expanding the ACE general survey to include new questions and modules, mainly for maternal and child health, responder health, One health (pets and livestock), and functional disability. Additionally with the recognition of the importance of qualitative surveys, we have developed qualitative questions to be interspersed in the general survey and a separated elective module for people wanting to provide a more in-depth response to gain more insights on the effects of these incidents. ATSDR has found no other toolkits like ACE Investigations to do epidemiologic assessments for these other types of incidents. Additionally, with the advent of COVID has come more community acceptability for online surveys and we want to take advantage of that to bolster our survey numbers in large incidents.

Modification of Information Collection Forms and Methods

Revisions also include making the Epi CASE symptom questions and the general survey symptom questions comparable. We removed the household survey for simplicity. We added a possibility of doing online self-administration of surveys which is more convenient for some people and saves a lot of federal resources while bolstering response numbers. We modified some questions to make them easier to self-administer. We 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	*Eligibility Screener* – slight wording changes to make easier to self-administer online This form is to decrease some recruitment burden and to more efficiently eliminate ineligible people before consent. The person is shown a map of the area of the incident and asked 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	*ACE Consent Forms* – Slight wording changes, removed household survey consent.
.	*Epi CASE Survey –Epidemiologic Contact Assessment Symptom Exposure (Epi CASE)* for use when time is of the essence and an emergency has just happened. A short survey is needed to gather brief symptom and exposure data and a way to recontact them later. There is a place to record social security number, driver's license or other form of ID so that the health agency will be better able to locate people if they need to recontact them later. The level of information collected will be up to the requesting health 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 changed the symptom showcard to incorporate symptoms categories into the survey. This will ease its use in an emergency situation and online use, when showcards may not be easy to access. It also makes it more systematic and easier to report on and analyze. If it is conducted online there is the opportunity to collect data from a greater number of people. This increased the average time of the survey to 7 minutes and the number of respondents increased to 1,000.
Appx E (former Appx B)	The General survey will now be for adults 18+ (previously adolescents could answer for themselves) and have modules at the end for people who have minor children, pets, livestock or who are responders. We have modified the race and ethnicity questions to fit OMB standards. We added short pet and livestock health modules a responder module. We have built an optional qualitative module using community resilience constructs in coordination with the CDC Office of Readiness and Response. This will be offered as an optional module We added at the end of the General survey for people who want to provide additional thoughts on the incident. We added a question bank to draw from if the requester wants to include qualitative questions, it is built to measure community resilience; it will be optional for the respondent. We also added open-ended qualitative type questions throughout the survey including for physical and mental health, and communications. We have added questions on functional disabilities and a set of questions on maternal and child health that could be used for follow-up surveys. We did research and found simpler mental health screeners than we had previously, for potentially associated conditions including one for depression, one for anxiety and one for PTSD. Lastly, we would like to offer an option of allowing online self-administration, which will allow for the collection of substantially more responses. This

	necessitated slight wording changes to the questions so that the questions could be interviewer or self-administered. This increased the average time of the survey to 60 minutes and the number of respondents increased to 1,000.
Former Appx F-Removed	*Household Survey* – Discontinued
Appx F (former appendix G)	*Hospital Survey* -No changes
Appx G (former appendix H)	*Medical Chart Abstraction Form* – minimal changes by SME, edited race/ethnicity questions to OMB standards, added functional disability questions. No change to time or respondents.

Revised Number of Responses and Time Burden in 2024

These changes result in a net annual increase of 1,580 responses and 690 burden hours per year over the next three years.

Table A.15.2. Summary of Revision Impacts, 2021 to 2024.

Form Number		Form Name	Number of Responses			Average Burden per Response (in hr)		Total Burden (in hr)		
2021	2024		2021	2024	Δ	2021	2024	2021	2024	Δ
Appx B	Appx B	Eligibility Screener	1000	2500	+1500	2/60	2/60	33	83	+50
Appx D	Appx D	Epi CASE Survey	1000	1000	+0	15/60	17/60	250	283	+33
Appx E	Appx E	General Survey	800	1000	+200	28/60	60/60	373	1000	+627
Appx F	n/a	Household Survey	120	0	-120	10/60	n/a	20	0	-20
Appx G	Appx F	Hospital Survey	40	40	0	25/60	25/60	17	17	0
Appx H	Appx G	Medical Chart Abstraction Form	250	250	0	30/60	30/60	125	125	0
		Total	3210	4790	**+1580**	---	---	818	1508	**+690**

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 in the field at the end of the field investigation or virtually soon after. 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.