

Supporting Statement Part A

Assessment of Chemical Exposures (ACE) Investigations

OMB Control No: 0923-0051 (Expiration Date: 03/31/2018)

Revision

Generic Clearance

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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 mass-scale toxic chemical releases.

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.

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) revision for the generic clearance information collection request (Generic ICR) titled the “Assessment of Chemical Exposures (ACE) Investigations,” OMB Control No: 0923-0051; expiration Date: 03/31/2018) which are conducted in response to acute chemical release incidents. PRA revision approval for this impactful information collection needs to be in place prior to expiration in **03/31/2018**.

The current request for PRA clearance is a revision which involves minor modifications to Appendix C detailed below:

- a) Change in the title of the former (Appendix C) Rapid Response Registry to ACE Short Form. We are renaming the form previously titled the Rapid Response Registry Form as the ACE Short Form. This revision better describes the use of the ACE Short Form in time-limited investigations where longer surveys are not possible. We do not use the form to establish registries.
- b) Deletion of question # 33, which best describes the level of health insurance (you have/ registrant has)? and question # 34, please give me the name of your health insurance plan from the form. We are removing two insurance questions from the ACE Short Form, as

they are not currently asked in the longer surveys. There are no changes to the requested burden hours.

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 a toxic substance spill or chemical emergency happens, 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. In addition, 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.

In order 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 release occurred.
2. ACE investigations will be carried out in the event of an acute chemical release of toxic substances, which can cause serious health effects. An event must involve:
 - a. the release of a toxic substance at levels that may cause acute human health effects
 - b. reports of people with acute health effects consistent with health effects of the chemical listed on reference materials (ATSDR Toxicological Profiles, Material Safety Data Sheet, etc.).
3. ACE investigations will be nonresearch public health responses:
 - a. designed to prevent or control disease or injury 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 CERCLA.
5. ACE investigations will be completed within 90 days after OMB approval.

ACE investigations PRA clearance was obtained in 2015. Three investigations (Appendix A) have been completed during the past three years. These investigations demonstrate that during a chemical release with acute health effects, immediate action by ATSDR is necessary to assist

partners to minimize or prevent public harm to the public. ATSDR seeks a revision for this Generic ICR to ensure that the agency is poised to mobilize quickly when urgent epidemiologic support is requested by our partners. Therefore, ATSDR requests 5-day approval, or within 72 or 24 hours if 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 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.

A.2. Purpose and Use of the Information Collection

The purpose of this Generic ICR is to conduct rapid assessments after a toxic release incident has occurred, in partnership with the requesting agency. ATSDR will provide tools, technical expertise, laboratory 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 chemical release;
- 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.

ACE investigations will be conducted in the days or weeks following an acute chemical release 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 chemical 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 acute chemical releases and a review of the response to the incident. It is not designed to be a study of the health effects associated with the release of chemicals 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 PRA clearance in 03/31/2015:

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. The data analysis work is ongoing and results will be shared when they are available.

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

Since ACE investigations collect information in response to an emergency situation, most data will be collected by in-person interviews and with hardcopy forms (Appendix B–G). Generally, there will not be sufficient time to develop, test, and launch an electronic survey, and not all potential respondents will have internet access. In addition, in investigations where a community survey is needed, obtaining contact information for the households selected for interview would necessitate knocking on doors; consequently, it is more practical to administer the survey when talking to the individual.

In all ACE investigations, the number of questions posed will be held to the minimum required to collect the data needed by the requesting agency. For example questions referring to the symptoms will be limited to those deemed by ATSDR toxicology staff to have reference in the literature as being related, 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 3.

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 the incident is ongoing. National Institute for Occupational Safety and Health (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 a chemical release occurs 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 conducted under OMB No. 0923-0051, 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 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 a chemical 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 chemical 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 chemical exposures.
- 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 3) describing the release and the planned response.

- Data collection for ACE investigation will be conducted using standing set of surveys (Appendices B – G), if the time duration for collecting data using a survey is expected to exceed (> 30 mins), a justification for the burden will be provided.
- Each request for ACE investigation GenIC request will also include a complete Supporting Statement B.
- 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 (i.e. 24 hours is requested.) If a 72 or 24 hour approval is requested, an explanation will be provided which describes the public health need. If a 72 or 24 hour time frame will be requested, an email (Attachment 4) will be sent to OMB to provide as much advance warning as possible that the request is being prepared. 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 5) to the Information Collection Request Liaison (ICRL).
- 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. 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 5) 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 NCEH/ATSDR OMB PRA Contact serves in the role of the ICRL. The ICRL oversees the clearance process for individual GenICs. Information about the Generic ICR and how to submit a GenIC is distributed to ATSDR program officials (Steps for Conducting an ACE Investigation, Attachment 6). 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.

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 3) and Supporting Statement B serves as the GenIC package for each ACE investigation.

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

ATSDR previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on August 30, 2017, Volume 82, Number 167, Page 41263 to obtain comments from the public and affected agencies. ATSDR did not receive comments related to the 60-day notice.

Below is a list of individuals and groups outside of the agency who were consulted in 2010 to obtain their views on the availability of data, the clarity of instructions and information, and the completeness of the ACE protocol.

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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

This Generic ICR has been reviewed by the NCEH/ATSDR OMB PRA Contact who determined that the Privacy Act applies to this information collection. The applicable System of Records Notice (SORN) is ATSDR's SORN 09-19-0001. 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.

During the field investigation, the following IIF may be collected when necessary: name, date of birth, address, phone number, housing unit latitude and longitude, medical information and notes, clinical specimens, employment status, and email address. 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. Other data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

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

- Location/exposure
- Health status
- Injuries from fire/explosion
- Medical care and treatments received after the incident
- Occupational history and exposure to chemicals at work
- Medical history
- Emergency response
- Communication during the release
- Current needs
- Other people and pets present with the respondent at the time of the release
- Demographic and contact information

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

- Surge
- Response
- Decontamination
- Lessons learned

Appendices F-G - During medical and veterinary 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 laboratory at the CDC's National Center for Environmental Health (NCEH). ATSDR will not store clinical samples for future research; any unused samples will be discarded at the completion of the testing.

After the field investigation ends, ATSDR will not have access to IIF with the exception of: housing unit latitude and longitude, medical information and notes, and employment status. All records and specimens shared with ATSDR and the NCEH laboratory will be coded with respondent ID number only. These coded data and specimens will be de-identified for ATSDR's further use and a nondisclosure form will ensure that ATSDR will not have access to the identity of the individuals whose specimens were tested. 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.

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. Some of the questions asked will be personal and talking about them with a stranger could make the respondent uncomfortable. These include medical history, medications taken, symptoms experienced, and health care received after the incident.

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.

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

Name	Medical Information and Notes
Date of Birth	Biological Specimens
Mailing Address	Email Addresses
Phone Numbers	Employment Status

As previously stated, all records, including name, contact information, and other IIF, belong to the requesting agency and will reside on its own established record system. The requesting agency will retain the link between the IIF and the respondent ID according to its own record schedule. 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 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, surveys are stored in a locked Pelican case.

Only de-identified data in an appropriate format (e.g., Epi-Info, Excel, or SAS) are brought back to ATSDR to perform data analysis. Similarly, only de-identified clinical specimens are sent to NCEH for laboratory analysis. All de-identified records received from the requesting agency and maintained by ATSDR after the investigation will be subject to the ATSDR CRCS, B-371, which contains authorized disposition instructions for administrative and program records. ATSDR will not retain the link between the IIF and the respondent ID number.

Respondents will be asked to consent to take part in an investigation of the incident. During the consent process, respondents in ACE investigations will be told that their participation is voluntary and they may refuse to answer any of the questions. Respondents will be fully informed of the potential risks and benefits of their participation and that their privacy will be protected to the extent allowed by law. Respondents will be informed that no penalties will occur if they wish not to respond to the information collection as a whole or to any specific questions. The mode in which consent is obtained from participants will vary by the investigation and will be customized per the requirements of the inviting agency. A sample of the consent forms for ACE investigations is attached (Attachment 7).

The primary purpose of each ACE investigation is to respond to a chemical 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. The new information obtained from ACE investigations will be used to:

- immediately identify a group of potentially exposed people following an acute chemical release,
- 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 local population, and therefore the respondents, will vary in locale and demographics from investigation to investigation. Respondents selected for ACE investigations will include those in the geographic area during chemical incidents, responders to the incident, and others involved in the incident. These will typically include, but are not limited to:

1. adults and adolescents (14–17 years of age) living, working, or traveling in the area of a chemical incident;
2. first responders such as members of the fire department, police department, hazardous materials team, and emergency medical services;
3. parents or guardians of children that were present in the area of a chemical incident;
4. staff at hospitals where patients were treated; and
5. pet owners or veterinarians

Depending on the situation and the needs of the requesting agency, different types of data collections may be required in an investigation. The methods used to collect data may include but are not limited to face-to-face interviews, telephone interviews, secure on-line surveys, respondent-administered pen-and-paper surveys that are either mailed or delivered in-person, and medical and veterinary chart abstractions.

ATSDR has developed a decision tree (Appendix H) and a series of draft survey forms that can be quickly tailored (Appendices B–G). Not all survey questions will be asked on every investigation. Rather, ATSDR will use the minimum number of questions that will obtain the needed data to address the needs of the requesting agency, consistent with the scope of this ICR.

- The survey of persons in the area of the toxic substance release is usually the largest component of an ACE investigation, using the general survey (Appendix B), the shorter

ACE short form (Appendix C), or household survey (Appendix D), time permitting. If the data needed by the requesting agency can be obtained without a survey, for example, by reviewing medical charts, the survey will not be done. In some investigations, the ACE team will collaborate with another agency in the investigation, such as CDC's NIOSH for workplace exposures, and that agency will perform a survey under their own authority.

- Staff of hospitals receiving potentially exposed patients may be surveyed to capture their experiences with the mass casualty event (Appendix E).
- The ACE investigation team may use the Medical Chart Abstraction Form to collect more detailed patient information (Appendix F). If data about potential exposure to pets is needed to supplement human data, veterinary chart abstractions may also be performed (Appendix G).
- Testing of clinical samples may be performed if:
 - a test exists for the toxic substance that was released, and
 - the toxic substance or its metabolite is still detectable in the blood or urine at the time of the request.

However at no time will any samples be retained by ATSDR after the test is completed. The data will inform the extent of potential exposure.

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.

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.

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. 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.

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 8). The body of data gathered from multiple ACE investigations may be used for education and training to prepare for future incidents.

Identifying information such as name, address, phone number, and email will be collected to facilitate personal contact with respondents. The ACE investigation team will use the information in the field only to contact and track respondents. All respondents will be asked to consent to take part in an investigation of the incident. During the consent process, respondents in ACE investigations will be told that their participation is voluntary and they may refuse to answer any of the questions. Respondents will be fully informed of the potential risks and benefits of their participation and that their privacy will be protected to the extent allowed by law. Respondents will be informed that no penalties will occur if they wish not to respond to the information collection as a whole or to any specific questions.

A.11. 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 9).

Some of the ACE investigation respondents may find some of the questions asked during an investigation to be sensitive, such as medical conditions, pregnancy status, or race/ethnicity. Respondents will be informed that the data will be collected in response to the chemical incident and that the information they provide may help authorities understand the health effects of chemical releases 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 (Attachment 7). Social security numbers will not be needed and will not be collected.

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. Although in the past approval period, this clearance has been used to conduct only three ACE Investigations, we believe the number requested gives ATSDR flexibility to do more investigations, especially follow-ups, 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. Surveys have ranged from 15-64 minutes, with an average approaching 30 minutes per respondent. Therefore, total estimated burden will be around 1,773 hours, or 591 burden hours per year. For ACE investigations, respondents to surveys and interviews will incur reporting burden; the staff from state, local, or tribal health agencies, will incur recordkeeping burden if they work with ATSDR and CDC staff on medical and veterinary chart abstractions.

Table A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden Hours
Residents, first responders, business owners, employees, customers	General Survey	800	1	30/60	400
	ACE Short Form	50	1	7/60	6
Residents	Household Survey	120	1	15/60	30
Hospital staff	Hospital Survey	40	1	30/60	20
Staff from state, local, or tribal health agencies	Medical Chart Abstraction Form	250	1	30/60	125
	Veterinary Chart Abstraction Form	30	1	20/60	10
Total					591

There will be no anticipated costs to respondents other than time. The 2012 U.S. median national wage for all occupations is \$16.71(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 hourly wage (\$33.13) is used to represent the hospital staff wages. The medical and veterinary chart review will be done by the epidemiologists from state, local, or tribal health agencies at a wage rate of \$34.33. With an annual respondent burden of 591 hours, the overall annual cost of respondents' time for the proposed collection will be a maximum of \$12, 582.71.

Table B. Estimated Annualized Burden Costs

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Respondents	436	\$16.71	\$7,285.56
Hospital Staff	20	\$33.13	\$662.60
Staff from state, local, or tribal health agencies	135	\$34.33	\$ 4,634.55
Total			\$ 12,582.71

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 equipment or 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 epidemiologists in 2012 (\$34.33) (available at http://www.bls.gov/oes/current/oes_nat.htm#00-0000). On average, CDC staff and contractors contribute 300 hours per ACE investigation, for a total annualized cost to the Government of \$41,196.

Table C. 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
Epidemiologists	300	\$34.33	4	\$41,196.00

A.15. Explanation for Program Changes or Adjustments

The current request for PRA clearance is a revision which involves minor modifications to Appendix C detailed below:

- a) Change in the title of the former (Appendix C) Rapid Response Registry to ACE Short Form. We are renaming the form previously titled the Rapid Response Registry Form as the ACE Short Form. This revision better describes the use of the ACE Short Form in time-limited investigations where longer surveys are not possible. We do not use the form to establish registries.
- b) Deletion of question # 33, which best describes the level of health insurance (you have/ registrant has)? and question # 34, please give me the name of your health insurance plan from the form. We are removing two insurance questions from the ACE Short Form, as they are not currently asked in the longer surveys. There are no changes to the requested burden hours.

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 a chemical 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.

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.