Supporting Statement B

Assessment of Chemical Exposures (ACE) Investigations

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

Revision of a currently approved collection

Generic Clearance

September 2024

Point of Contact:
Maureen Orr, MS
Team Lead, Surveillance Team
Registries and Surveillance Section
Office of Innovation and Analytics
Agency for Toxic Substances and Disease Registry (ATSDR)
4770 Buford Hwy NE, MS 106-5
Atlanta, GA 30341
Phone: 770-488-3806
Email: mco0@cdc.gov

Table of Contents

B. Collections of Information Employing Statistical Methods

As indicated in Part A, the scope of ACE Investigations in this revision information collection request (ICR) is to collect information to be used for one or more of the purposes listed below.

- immediately identify a group of potentially exposed people following acute environmental incidents, including, but not limited to, acute chemical releases, radiological and nuclear incidents, explosions, and natural disasters,
- 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.

This umbrella Part B provides a general description of the methods that will be used to achieve these purposes, however, the Part B submitted for each GenIC will describe the specific goal(s) of the collection instruments and how the specific data being collected facilitate achieving the specific goals. Each submission will justify the need for the IC (e.g., general survey, biospecimens, hospital records etc.) being used in the context of the overall goal of the ACE Investigation. Because it is outside the scope of this ICR to develop an extensive baseline for longer-term follow up, questionnaires should focus specifically on information that is necessary to characterize exposure, interpret health symptom reports, and otherwise document the immediate wake of an environmental incident. Extensive health history and prior exposure surveys necessary primarily for investigating longer term health effects should be submitted as part of a standalone ICR that includes the goal, design (e.g., prospective cohort study), and methods the follow up.

It is expected that ACE Investigation data collection instruments will need to be refined in the field (e.g., questions that are not being understood may be dropped, wording may be changed, or additional items may be added to record abstractions or based upon field experience).

The Part B submitted for each GenIC will describe:

1. the geographic, demographic, and/or institutional characteristics the population to be studied (e.g., all people who were within 5 miles of the spill location within the first 8 hours after the event, or all patients admitted to hospitals with 25 miles of the spill, or all responders who participated within the first 24 hours);
2. the sampling frame (e.g., the roster of activated personnel from the fire department or national guard or hospital billing records associated with acute care visits within 10 days of the spill);
3. the sampling type (e.g., convenience, census, systematic, etc.) and the extent to which the sampling is intended to be generalizable (and if so, to what population it would generalized);
4. the specific sampling method, including any screening and/or stratification to be done; and

5. the sample size goals, even if the goal is simply to maximize the number of households surveyed or the records abstracted (if this is the basis of the sample size estimate, state the driving parameters (e.g., times since exposure or staffing resources available).

Multiple ACE components can be submitted to OMB in the same Gen IC request, but a request for clearance for any given component of a response should not be submitted to OMB until all of these study parameters identified here have been determined. As such, it is possible that any given response would entail submission of multiple ICs. For instance, ATSDR may not have the information to define the hospital records follow up until later in the project, and thus their first submission may only be for the general survey or a 6-month follow-up survey may be conducted.

At the completion of each ACE Investigation, the investigators will submit a report of any changes to the sampling and recruitment methods, as well as the actual respondent characteristics and numbers, the final information collection instruments, and associated burden using the "ACE Investigations Burden Memo" form (Attachment 3c) to the Information Collection Request Liaison (ICRL).

B.1. Respondent Universe and Sampling Methods

The Agency for Toxic Substances and Disease Registry (ATSDR)/Centers for Disease Control and Prevention (CDC), in partnership with the state, regional, local, or tribal health department (the requesting agency), will identify the respondent universe for each ACE Investigation in order to perform a rapid assessment of the extent of the potential exposure and potentially related health effects of the community after an acute environmental incident.

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 area of the incident, responders to the incident, and others involved in the incident. These may include, but are not limited to:

- adults living, working, or traveling in the area of an acute environmental incident,
- first responders such as members of the fire department, police department, hazardous materials team, and emergency medical services,
- parents or guardians of minor children that were present in the area of an acute environmental incident, and
- staff at hospitals where patients were treated

The respondent types are not mutually exclusive, as the adults may be both parents and staff at hospitals, for example.

Sampling and recruitment methods will vary based on the goals of the investigation, number of potential respondents, the geographic range of the chemical release, available resources, and other data sources that are available. The ACE team will be in the field after investigating an incident usually up to 90 days if the circumstances require. The investigation will generally include multiple components (i.e. general survey, hospital survey, and medical chart abstraction), data entry/cleaning, and preliminary analysis. The type of sampling and number of persons

interviewed will depend on the geographic area of the release and the size of the affected population.

- If possible, we will attempt to interview all potentially exposed persons.
- If there is a mass incident, we may allow for persons in the affected area to self-administer the survey via the Web.
- If in person survey methods are preferred, and more persons are exposed than can be interviewed within approximately a two-week period, sampling may be employed; if a sampling strategy is employed, a statistician will be consulted. Sampling methods may include, but are not limited to:
    - simple random sampling,
    - stratified random sampling,
    - two-stage cluster sampling, and
    - convenience sampling.

Attachment 3E contains a decision tree for statistical methods to be employed during an investigation. Appendix A lists the different sampling methods that were employed on previous ACE Investigations, which were selected based on the situation.

B.2. Procedures for the Collection of Information

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, in-person surveys using handheld devices, respondent-administered pen-and-paper surveys that are either mailed or delivered in-person, and medical chart abstractions.

ATSDR has developed a decision tree (Attachment 3E) and a series of draft consent and 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.

- To streamline the interviewing process, an Eligibility Screener (Appendix B) will identify eligible persons.

- Eligible persons will be asked to consent to take part in an investigation of the incident (Appendix C). 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.

- The survey of persons in the area of the environmental incident is usually the largest component of an ACE Investigation, using the shorter Epidemiologic Contact Assessment Symptom Exposure (Epi CASE) Survey (Appendix D) or the more extensive General Survey (Appendix E), time permitting. If the data needed by the requesting agency can be obtained without a survey, for example, by reviewing medical charts (Appendix G), 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 a decision will be made if ATSDR will include workplace exposures or 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 F – Hospital Survey).

- The ACE Investigation team may use the Medical Chart Abstraction Form to collect more detailed patient information (Appendix G).

- Testing of clinical samples may be performed if:

    - a test exists for the substance exposed to, and

    - the 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.

- If forms are translated and administered in a language other than English, the translated forms will be submitted by the investigators with the completed "ACE Investigation Burden Memo" form (Attachment 3c) and placed into the library of forms by the Information Collection Request Liaison (ICRL).

In general, the interviewers for ACE Investigations are trained public health professionals who conduct interviews regularly. Prior to beginning interviews, staff are oriented to the consent procedures and the forms, sample selection techniques (if applicable), and procedures. Quality control procedures will be implemented in each ACE Investigation to the extent possible given the rapid nature of the data collection to collect high quality data.

Because of the acute nature of the chemical events or releases to be investigated, each generic information collection (GenIC) is anticipated to be a one-time information collection. Investigation will extend for up to 90 days; examples include returning to review medical charts a month or two after the incident when all patients have been discharged from the hospital and laboratory and imaging reports will have had time to be included in the charts or allowing additional time for participants to return a mailed survey. If a follow-up request is received and accepted by ATSDR, a new GenIC will be submitted to outline the new scope of the requesting agency's needs.

- Estimation procedure

The lead Epidemic Intelligence Service Officer (EISO) or team lead from the requesting agency has the primary responsibility for the data analysis. Statistical analysis will be conducted in consultation with a statistician/data analyst from the requesting organization, CDC, or ATSDR. Descriptive statistics (including frequencies, means, and ranges) will be calculated to describe the demographics of the respondents and their potential exposure levels. Frequencies will be calculated for the reported acute signs/ symptoms indicative of exposure, types of medical care received, decontamination, method of transport for medical care, effectiveness of communications and needs of respondents. Additional bivariate and multivariate analyses may be conducted as needed to identify risk factors for injuries or for more severe outcomes to improve preparedness and response for future chemical releases. Content analysis using structured inter-rater reliability methods will be used for open ended questions, software designed for this type of analysis may be used. Appendix A contains a description of the different analysis performed on data from past ACE Investigations and how the findings were used to improve public health response.

- Unusual problems requiring specialized sampling procedures

  ATSDR does not expect unusual problems requiring specialized sampling.

- Any use of periodic (less frequent than annual) data collection cycles to reduce burden

  The purpose of the data collection is to investigate acute chemical releases. Periodic data collection will generally not be employed. Because data collection must occur quickly after an incident in order to inform the public health response, data collection will be completed within 90 days. In the rare cases that a follow-up investigation will be performed, a separate GenIC will be submitted.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

For investigations (under OMB No. 0923-0051), the participation rates have usually been high because individuals exposed in an acute environmental incident are generally concerned about potential health effects and are willing to volunteer information about the incident. Response rate varies depending on with tool we use. For example, in an investigation (Michigan 2016) we used a convenience sample using the general survey and the response rate was 90.9%. However, we have observed that it may be difficult to locate potentially exposed individuals that we wish to interview; they may have left the area due to an evacuation, be out of work recovering from the exposure, or not be at home during the time household interviews are conducted. In some situations, such as when we may interview a convenience sample or allow exposed people to self identify and complete the survey themselves online. The response rates in ACE Investigations are shown in Appendix A.

The ACE team will engage in several activities described below to maximize response rates. For releases occurring at workplaces, we often partner with the state health department, occupational health authorities, or NIOSH; this partnership facilitates our interviews with workers.

In order to continue to yield a high response rate, appointments will be made to speak with hospital personnel, responders, or businesses, which will be scheduled at their convenience. To improve participation in community surveys, a description of the survey may be advertised to the community by local authorities. In community surveys, if the first attempt to reach prospective respondents is unsuccessful, repeat visits to their homes, telephone calls, or letters may be employed in an attempt to gain their participation. If telephone surveys are used, toll-free numbers will be arranged for individuals to return calls. For mailed surveys, stamped self-addressed envelopes will be mailed with the survey. For on-line surveys, we may also supplement with in-person or telephone surveys in the target area, particularly in low computer use populations.

Before collecting information, investigators inform respondents that participation is voluntary, that respondents are not personally identified in any published reports of the study, and that their privacy will be protected to the extent allowed by law.

B.4. Tests of Procedures or Methods to be Undertaken

The surveys used in ACE Investigations were originally developed in 2010, based on surveys used to investigate earlier chemical incidents (conducted under 0920-0008 OMB approval). They were used in the field to investigate three incidents, then, in 2011, the general survey was revised to improve clarity and ease of use and pilot tested by a contractor. The ACE surveys received approval under the Generic ICR OMB No. 0923-0051 in 2015 and again in 2018 and 2021. The renewed and new forms were used in the field to investigation three incidents. Additional bivariate and multivariate analyses may be conducted as needed to identify risk factors for injuries or for more severe outcomes to improve preparedness and response for future chemical releases. Content analysis using structured inter-rater reliability methods will be used for open ended questions, software designed for this type of analysis may be used.

In 2024, revisions to methods include restricting the General survey to adults, making the child questions a module with the addition of new modules responders, pets and livestock, and a community resilience questions bank. We have added questions on functional disabilities, maternal and child health for follow-up surveys, and qualitative questions for physical and mental health and opinions on the response. We incorporated the Epi CASE symptom checker showcard into the Epi CASE survey making it longer but easier to follow. We removed the Household survey which was complicated to analyze and not being requested. We modified the General survey and Epi CASE survey so that they could be self-administered online. This made it possible to collect data from many more people than done previously particularly during a mass incident. The Medical chart abstraction form now has the race/ethnicity questions updated to the OMB standard, functional disability questions were added, and a subject matter expert reviewed the form and suggested some minor changes. The Hospital survey remained unchanged.

B. 5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The investigators leading the ACE Investigation field responses and analyzing the data will be trained in biostatistics and epidemiology. Investigators will collaborate extensively with health officials of the state or local health department requesting assistance throughout the process of data collection and analysis. All investigations will be supervised by ATSDR and CDC's experienced epidemiologists. Additional statistical resources will be available at both ATSDR and CDC.

Because the investigations will be public health responses and not planned research studies, the analysis is largely descriptive. Statisticians will be consulted if sampling or a more complicated analysis is needed.

References

1. EPA (Environmental Protection Agency). Acute Exposure Guideline Levels (AEGLs). http://www.epa.gov/opptintr/aegl/index.htm. EPA: Washington, DC, 2010. Accessed on April, 1, 2014.

2. NOAA (National Oceanic and Atmospheric Administration. Emergency Response Planning Guidelines developed by the American Industrial Hygiene Association (AIHA). http://response.restoration.noaa.gov/oil-and-chemical-spills/chemical-spills/resources/emergency-response-planning-guidelines-erpgs.html. Accessed on April, 1, 2014.

3. Centers for Disease Control and Prevention (CDC). Community Assessment for Public Health Emergency Response (CASPER) Toolkit: Second edition. Atlanta (GA): CDC; 2012. http://www.cdc.gov/nceh/hsb/disaster/casper.htm. Accessed on April, 1, 2014.