

**Supporting Statement of the Request for
OMB Review and Approval of
Assessment of Chemical Exposures (ACE) Investigations**

0923-NEW

Generic Clearance

(Part B: Collections of Information Employing Statistical Methods)

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Point of Contact:

Mary Anne Duncan, DVM, MPH
Epidemiologist, Surveillance Team
Environmental Health Surveillance Branch
Division of Toxicology and Human Health Sciences
Agency for Toxic Substances and Disease Registry
4770 Buford Hwy NE, MS F-58
Atlanta, GA 30341
Phone: 770-488-3668
Email: maduncan@cdc.gov

Table of Contents

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Method
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Nonresponse
4. Tests of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Attachments

- A. Authorizing Legislation
- B. 60-Day Federal Register Notice
- C. *ACE Morbidity and Mortality Weekly Report* Article
- D. Request for Assessment of Chemical Exposures (ACE) Investigation
- E. ACE Investigation GenIC Advance Notification Email
- F. ACE Investigations Burden Memo
- G. Steps for Conducting an ACE Investigation
- H. Consent Forms (sample)
- I. NCEH-ATSDR Research Determination

Appendices

- 1. Past ACE Investigations
- 2. General Survey (sample)
- 3. Rapid Response Registry Form (sample)
- 4. Household Survey (sample)
- 5. Hospital Survey (sample)
- 6. Medical Chart Abstraction Form (sample)
- 7. Veterinary Chart Abstraction Form (sample)
- 8. Decision Tree for ACE Investigations

B. Collections of Information Employing Statistical Methods

As indicated in Part A, the scope of ACE investigations 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 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.

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., household 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 a chemical spill. Extensive health history and prior exposure surveys necessary primarily for investigating longer term health effects should be submitted as part of a stand alone ICR that includes the goal, design (e.g., prospective cohort study), and methods the follow up.

It is expected that ACE 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 within 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 be 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 household survey.

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 F) to the Information Collection Request Liaison (ICRL).

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 a chemical release.

Respondents selected for ACE investigations will include those in the area of the release, responders to the incident, and others involved in the incident. These may include, but are not limited to:

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

The respondent types are not mutually exclusive, as the adults may be parents, pet owners, or 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, 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 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.

Appendix 8 contains a decision tree for statistical methods to be employed during an investigation. Appendix 1 lists the different sampling methods that were employed on previous ACE investigations, which were selected based on the situation.

2. Procedures for the Collection of Information

Depending on the situation and the needs of the requesting agency, most investigations will involve collecting information from multiple types of respondents and using multiple forms.

After informed consent (Attachment H) is administered, interviews with exposed persons and first responders will be conducted as soon as possible after the incident. The preferred mode of data collection is face-to-face interviews using paper surveys; when this is not practical given time and personnel limitations, data may be collected by the other modes including telephone interviews secure on-line surveys, respondent-administered pen-and-paper surveys that are either mailed or delivered in-person. Medical and veterinary chart abstractions and testing of clinical specimens may also be employed. ATSDR has developed a series of sample survey forms that can be quickly tailored in the field (Appendices 2–7). They are administered based on the time available and urgency. A CDC medical toxicologist is consulted to determine symptoms that could be related to exposure to the chemical that was released to include on the survey that is administered.

- It is preferable to administer the comprehensive general survey to as many respondents as possible (Appendix 2). However, if there are time constraints, the shorter Rapid Response Registry Form (Appendix 3) or the household survey (Appendix 4) may be administered instead.
- Personnel at hospitals may be interviewed to gather information on the level of care required by patients, about decontamination if it was performed, and on communication about the release (Appendix 5). All persons who identify themselves as having a lead role in the response may be interviewed.
- Medical chart abstractions may be used to learn additional information about the health status of the population that sought medical care after the incident (e.g., medical diagnoses, symptoms, and length of hospitalization) (Appendix 6). If health status data from pets is needed to supplement the human data, veterinary chart abstractions may also be done (Appendix 7).

- 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 F) and placed into the library of forms by the Information Collection Request Liaison (ICRL).
- 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. This information will inform the extent of the exposure.

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. Appendix 1 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.

3. Methods to Maximize Response Rates and Deal with Nonresponse

In past investigations (under OMB No. 0920-0008), the participation rates have usually been high because individuals exposed in a chemical incident are generally concerned about potential health effects and are willing to volunteer information about the incident. In the case of the general survey, the proportion of individuals that agreed to be interviewed was 100% of those who could be contacted in a past investigation. 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 will not know the actual number of responders who worked the incident, we will not know the size of the respondent universe from which our respondents arise. The response rates from past ACE investigations are shown in Appendix 1.

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.

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.

4. Tests of Procedures or Methods to be Undertaken

The ACE surveys 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.

ATSDR staff revised the hospital survey and medical chart abstraction form after lessons learned during previous ACE investigations. The household survey and veterinary chart abstraction form were added to the ACE toolkit in 2014.

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 (AEGs). <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.