Revision Package: OMB 0923-0040

NCEH/ATSDR Exposure Investigations (EI)

Sections A and B

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Section A: Justification

Attachments

A. Justification

The following justification and attachments for the information collection request (ICR) identified as OMB No. 0923-0040 is a revision of the ICR by the same OMB number previously approved in November 2009 and first approved in July 2006. The revisions made in this package are re-wording and some additions to the Chemical Exposure Questions.

The total annualized burden hour estimate for this ICR is slightly decreased to reflect a decrease in the number of EIs requiring a questionnaire each year (i.e., reduction from 10-15 to 7). The new burden hour estimate is now 350 hours instead of 375.

Beginning in 1995, ATSDR has completed 246 EIs. Since ATSDR's July 26, 2006 OMB approval of NCEH/ATSDR Exposure Investigations, we have begun or completed work on 37 EIs; 26 were environmental sampling only, 6 biomedical only, and 5 involved both environmental and biomedical sampling. As a result of ATSDR conducting the 246 EIs, one or more of the following outcomes took place at each location (EI Internal Database):

- Health Education for reduction or elimination of exposure (34% of EIs)
- Expanded sampling to identify the extent of exposure/contamination (32%)
- Physician education for prevention or identification of adverse health effects (4%)
- Further investigation or applied research (7%)
- Provided individual EI participant's a better understanding of their exposure
- (i.e., provided biological results) (41%)
- Provided, arranged, or recommended health education to reduce stress caused by fear of pollution (11%)

For all EIs, final documents are prepared and made available to the participants and the community.

1. Circumstances Making the Collection of Information Necessary

The Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH) [hereafter ATSDR will represent both ATSDR and NCEH] are seeking an revision to our OMB approval for Exposure Investigations (EIs) [OMB NO:0923-0040, Expiration Date 11/30/2012]. EIs are an approach developed by ATSDR that employ targeted biologic and environmental sampling to *determine whether people are or have been exposed to unusual levels of pollutants at specific locations* (e.g., where people live, spend leisure time, or anywhere they might come into contact with contaminants under investigation). This time-critical service is authorized by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (Attachment 1).

Background

The purpose of EIs is to provide a public health service to communities. ATSDR uses EIs to fill a data gap that is essential for evaluating community exposure pathways and determining if a

health hazard is present. The exposure investigation team conducts point of human-contact sampling (environmental, biological, biomonitoring, and/or food samples) focused on areas where exposures are expected to be high. Environmental exposure investigations include ambient air, personal air, indoor air, dust, soil, sediment, biota, ground water, and surface water sampling. Depending on individual site characteristics, the sampling period may vary from days to several months. Biologic exposure investigations include blood and urine sampling for exposure biomarkers. Most Exposure Investigations are completed over a period of several months and are a one-time occurrence.

Exposure investigations must meet four criteria. They are

1. Can an exposed population be identified?
2. Does a data gap exist that affects the ability to determine if a health hazard exists?
3. Can an exposure investigation be designed that will address this data gap?
4. Will the EI results impact the public health decision for the site?

An exposure investigation is not a study. Rather, it is a biased attempt to identify individuals most highly exposed and sample their exposure. Our results are a public health service to provide individual exposure information to the participants and are not generalizable to other populations.

Generally, exposure investigations range in cost from $2,000 to $100,000 each. For the past several years, our entire extramural yearly budget has been approximately $300,000.

The Exposure Investigation team is a multidisciplinary group of 6-8 scientists with expertise in environmental health science and engineering, industrial hygiene, epidemiology, toxicology, and medicine. After the team develops and conducts an investigation, they evaluate the results and communicate their public health findings and recommendations to the community. If exposures are found at levels that might cause health concerns, the following may be recommended:

1. reduction or elimination of exposure,
2. expanded sampling to identify the extent of exposure/contamination,
3. prevention or identification of adverse health effects, and
4. further applied research

ATSDR's EI reports are used by public health professionals, environmental risk managers, and other decision makers to determine if current conditions warrant additional sampling or intervention to minimize or eliminate human exposure. They can also be useful in determining the source and extent of the exposures. After an environmental cleanup or other intervention to reduce exposure is completed, EIs can be useful in assessing the effectiveness of those actions. For past and future exposures, EIs can use exposure-dose reconstruction analysis (environmental sampling information and computer models) to estimate the contaminant levels that people may have been exposed to in the past or may be exposed to in the future.

Two examples of how the results of the EI have been used to impact legislation are provided below:

Example 1: Excel Dairy, MN – Concentrated Animal Feed Operation (CAFO)

- Nearby residents complained of odor & symptoms (e.g., eye and throat irritation, headache, nausea)
- Conducted emergency sampling of Hydrogen Sulfide (H_2S) outdoor air – some H_2S levels were higher than emergency response guidelines (>400 exceedances of MN standard)
- Determined exposure to emissions from the waste lagoons are a *Public Health Hazard* for individuals living nearby (30 to 40 people)
- State environmental agency continued air monitoring of emissions from the facility
- The USEPA and the Minnesota Attorney General's office used ATSDR's EI data to support enforcement actions against the dairy
- Those actions results in the dairy's closure while the dairy operators sought ways to reduce the emissions (e.g., apply permanent covers for manure lagoons and eliminate land manure applications)
- As a result, MN businesses must comply with ambient air standards for 9 contaminants at their property line
- ATSDR provided congressional briefing on CAFOs

http://www.health.state.mn.us/divs/eh/hazardous/sites/marshall/exceldairy/exceldairyhcfull.pdf

Example 2: Penn Tex Resources, IL – Oil Field

- Nearby residents complained of H_2S emissions
- Sampled H_2S in outdoor and indoor air in community
- 2,000 – 3,000 people directly affected
- Peak H_2S levels in community ranged from 53 to 1,500 ppb; many were above acute Minimum Risk Level (MRL) of 70 parts per billion (ppb)
- Determined two large areas were at increased risk of respiratory and neurological health impacts
- U.S. Attorney brought civil action pursuant to the Clean Air Act
- A Consent Decree was signed in April 2007
- Engineering remedies were implemented
- The State of Illinois changed laws for oil well fields
- EPA awarded ATSDR staff the Gold Medal

http://www.atsdr.cdc.gov/HAC/pha/PennTex_HC_3-19-08/PennTex_HC_3-19-08.pdf
http://regulations.vlex.com/vid/consent-judgments-penntex-illinois-26944001

In order to continue this necessary public health function, ATSDR is requesting a revision to our current approval. The revision will allow us to continue without delay the collection of time-dependent (i.e., soon after a chemical has been released from a source and before the chemical passes through or is eliminated from the body) environmental and biomedical samples so that

public health officials can take action. Several questions have been added and a few modified for clarity and for improved readability but these changes are not substantive. Without the approval of the revision, this necessary public health activity must cease.

Privacy Impact Assessment

All of ATSDR's biomedical assessments and some of the environmental investigations involve participants. ATSDR provides the participants with information on the EI process and what it can and cannot determine. After providing the participants this information, ATSDR asks for their consent to participate in the EI. Participation is completely voluntary; participants can stop participation in the EI at any time.

Overview of the Data Collection System

To assist in interpreting the sampling results, ATSDR generally uses face-to-face interviews to ask situation-specific questions about the participant's exposure to chemicals. Although some of our questionnaire responses are entered on paper, where practical, we load the questionnaire onto a laptop and record the answers electronically. ATSDR computers comply with the HHS Standard 2008-0007.001S for encryption. We generally interview people in their homes or workplaces.

Collecting identifying information is necessary to facilitate personal contact with participants, to obtain their consent to participate, and to provide them their results. Although personal identifiers may be kept for up to 5 years, ATSDR uses the information only to contact respondents. Data is treated in a private manner, unless otherwise compelled by law.

For this revision request, some minor non-substantive changes were made to the participant questions; these changes to the OMB approved questionnaire were done to clarify, to ask for more specificity, or to divide one question into an additional question to better generate the information needed for public health professionals and the general public.

Items of Information to be Collected

ATSDR collects contact information (e.g., name, address, phone number, email address) to provide the participant with their individual results. General information, which includes height, weight, age/date of birth, race, gender, etc., may also be collected primarily on biomedical investigations to assist with results interpretation. We would also ask for a biological specimen for those investigations.

ATSDR asks participants questions about recreational or occupational activities that could increase their exposure potential to the contaminants under investigation. In addition, ATSDR collects information on other possible sources of chemical(s) exposure such as medicines taken, foods eaten, hobbies and jobs done, etc. That information represents their individual exposure history.

The information necessary to evaluate exposure and its impacts varies from investigation to investigation. The questionnaire information is used to broadly address the exposure situation and to adequately interpret our sampling and modeling results. For each individual exposure investigation, we choose a set of questions appropriate for the specific chemical(s) and activities of concern.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

There are no web sites related to Exposure Investigations for children under 13 years of age.

2. Purpose and Use of Information Collection

Public health officials, risk managers, and the public use EI results to make decisions concerning exposure to a hazardous substance(s). EI sampling, modeling results, and questionnaire information taken together, not only allow us to determine if current conditions warrant intervention, but help determine the most appropriate intervention strategies or where to target additional sampling. Further, without the EI questionnaire information, interventions by public health officials and risk managers could be delayed in cases of out-of-normal range laboratory results, while reasons for the higher results are ascertained. If there were ongoing exposures, those exposures could be unnecessarily prolonged.

Privacy Impact Assessment Information

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. We do not use the information to generalize or represent population-based data. EIs are intended to be a public health service –not research.

ATSDR has conducted an average of 14 EIs nationwide each year since 1995. The majority of EIs (more than 52%) involve only environmental sampling (e.g., air, water, soil, or food), 29% biomedical (e.g., urine, blood, hair samples), and 16% involve both. Standard air modeling to augment environmental data was conducted in a small percentage (3%) of EIs. The number of participants in an individual EI generally ranges from 10 to 100. Questionnaires are needed in less than half of the EIs per year.

In deciding where and from whom to gather information, ATSDR considers the following:

- Can we test the most highly exposed?
- Will an exposure history questionnaire help us identify the best test population?
- Does the test population need/want to protect their confidentiality as the “identified” or “tested” population?
- Can we identify sensitive populations or should we exclude children and other sensitive populations? For example, it is not good public health practice to collect the required sample (70 ml blood) for dioxins from a small child, pregnant woman, or an anemic person.
- If we do pre- and post-testing to check intervention effectiveness, how will participants be selected if the original participants are not available?

A questionnaire is generally administered in a face-to-face interview with potentially exposed participants, but could occasionally be administered by phone or mail. Only those questions pertaining to a specific contaminant exposure route are asked in an investigation. In addition, only questions needed to determine the extent of exposure in a particular situation are asked. With these data, we can assess the presence or absence of a specific exposure and estimate how long and how frequently people have had contact with the chemical(s) of interest. The questionnaire responses also provide data about exposure to other sources of the chemical(s).

General contact information (name, address, phone number, email) and comparison information on physical attributes (height, weight, age, race, gender) can account for approximately 20 questions per investigation. Some of this information is investigation-specific; not all of this data is collected for every investigation.

ATSDR also asks approximately 12-20 questions per investigation that are pertinent to environmental exposure. This number can vary depending on the number of chemicals being investigated, the route of exposure (breathing, eating, touching), and number of other sources of the chemical(s) (e.g., products used, jobs done).

Topic areas for the questions shown in Attachment 3 include the following:

General Information: name, address, phone number, email, height, weight, age, race, ethnicity, gender

Media specific: Air (indoor/outdoor), Water (water source, plumbing), Soil, and Food (gardening, fish, game, domestic animals (e.g., chickens))

Other sources: Occupational, Hobbies, Household chemical uses and house construction characteristics, Lifestyle (e.g., smoking), Medicines and/or health conditions, and Foods

Once we conduct an EI, we match the unique answers given by participants with their laboratory results or environmental samples to determine whether intervention is needed on an individual level. The information collection is therefore *inherently person- or location-specific*.

Data are treated in a confidential manner; access to computer files is password-protected and access is limited to authorized EI personnel. All staff working on the project agrees to safeguard the data and not to make unauthorized disclosures. Published reports may present responses in aggregate form and no individuals are identified by name.

3. Use of Improved Information Technology and Burden Reduction

To reduce the burden on people being interviewed, ATSDR created a list of reviewed and approved questions so that investigators can choose the pertinent questions for their investigation. Having a predetermined set to choose from in various situations keeps the number of questions asked to a minimum. Generally, ATSDR interviews people in their homes or workplaces either in person or over the phone. Where practical, we will load the questionnaire onto a laptop and record the answers electronically into the site-specific questionnaire as we are interviewing the participants. The use of electronic data collection as compared to paper

collection has steadily increased with time. Any data on laptops will be encrypted in accordance with information systems security requirements for safeguarding personally identifiable information. That information is stored in a secure database along with the laboratory and/or modeling results.

Several procedures may be used to sign up participants for the EI, such as newsletters or recruitment posters. Usually, the participants are targeted for inclusion in the EI and initial contact is made with potential participants through mail or phone.

4. Efforts to Identify Duplication and Use of Similar Information

ATSDR determined through literature and internet searches, discussions with other public health and environmental professionals, and attendance at meetings that other agencies are asking or have asked similar questions. *However, their questions and resulting data are being used for population-based research and modeling, policy setting, or behavioral change through education.* Since our information collection is *inherently person- or location-specific,* we cannot use the results of national probability surveys. Again, the intent of the EI is not to generalize information to represent population based data, but to match the unique answers given by participants with their laboratory results or environmental samples to determine whether individual intervention is needed. We have, however, found some of the questions from other federal agencies' surveys useful and included them in our chemical exposure questions.

Below is a list of the agencies that we determined are asking similar questions. A detailed list of the similar questions from those agencies is in Attachment 4: Environmental Exposure Questions from EPA and CDC.

NHAP=EPA National Human Activity Pattern Survey (NHAPS) - This EPA survey was a two-year probability-based telephone survey (n = 9,386) of exposure-related human activities in the United States. The primary purpose of NHAPS was to provide comprehensive and current exposure information over broad geographical and temporal scales, particularly for use in probabilistic population exposure models. NHAPS was conducted on a virtually daily basis from late September 1992 through September 1994. [http://eetd.lbl.gov/IED/viaq/pubs/LBNL-47713.pdf]

NHEXAS=EPA National Human Exposure Assessment Survey – In the early 1990's, EPA initiated this population-based pilot study of the exposure of over 500 people in three areas of the U.S. to metals, pesticides, volatile organic compounds, and other toxic chemicals. Measurements were made of the air people breathed, the foods and beverages they consumed, and the soil and dust in/near their home. Chemicals in their blood and urine were measured. The participants also completed questionnaires to help identify possible sources of exposures and to characterize activities that might contribute to exposure. The purpose of NHEXAS is to evaluate comprehensive human exposure to multiple chemicals on a community and regional scale. Ultimately, the EPA anticipates that the information gained from NHEXAS will help individuals, communities, states, the EPA, and other organizations understand the greatest health risks from various chemicals and decide whether steps to reduce those risks are needed. [http://www.epa.gov/heasd/edrb/nhexas.html]

NHANES = National Health and Nutrition Examination Survey – Teams of doctors, dentists, nutritionists, and health technicians go out to communities across the United States for the National Health and Nutrition Examination Survey (NHANES), which is updated annually. Since the early 1990s, CDC has surveyed approximately 5,000 people /year. Data from direct examination, testing, and measurement of national samples of the civilian noninstitutionalized population provide the basis for (1) estimates of the medically defined prevalence of specific diseases in the United States and the distribution of the population with respect to physical, physiological, and psychological characteristics and (2) analysis of relationships among the various measurements without reference to an explicit finite universe of persons. For example:

- Growth Charts - How is my baby growing? How does my child compare with other children the same age?
- Cholesterol - What about cholesterol? How do I know if that is too high?
- Lead in Gasoline - measures the amount of lead reduction in people's blood after lead was removed from gasoline.
- Osteoporosis - measures the density of participant's bones.
- Environmental smoke - The last NHANES found that nearly 9 out of 10 nonsmoking Americans were exposed to smoke either at home or on the job.
- Obesity- Today, more than half of the adults in the U.S. are overweight, and the number of overweight children and teens has doubled in the past decade. This has led public health experts to look for ways to improve both diet and fitness.
- Changes in Food/Diet- NHANES helps monitor whether these new foods and dietary changes actually are in the best interest of our health. What vitamins and minerals belong in our food and diet?
- Immunizations - The National Health and Nutrition Examination Survey has turned up important information about the extent of hepatitis B infections, and led to the recommendation that all infants and children be vaccinated against it. While we think of babies and children as the primary target for immunizations, the survey also has alerted doctors to the importance of tetanus shots for older people.

(OMB approval #0920-0237) [http://www.cdc.gov/nchs/nhanes/nhanes2009-2010/questexam09_10.htm]

The first *National Report on Human Exposure to Environmental Chemicals* was issued in March 2001, and presented exposure data for 27 chemicals from NHANES 1999. The *Second Report*, released in January 2003, presents biomonitoring exposure data for 116 environmental chemicals (including the 27 in the first *Report*) for the noninstitutionalized, civilian U.S. population over the 2-year period 1999-2000. The *Second Report* also presents exposure data for the U.S. population divided into age, gender, and race/ethnicity groups. This *Third Report,* released July 21, 2005, presents first-time exposure information for the U.S. population for 38 of the 148 chemicals included in the *Report*. The *Fourth Report*, released in 2009, presents data for 212 chemicals. The *Fourth Report* includes the findings from nationally representative samples for 1999-2004. http://www.cdc.gov/exposurereport/

5. Impact on Small Businesses or Other Small Entities

Every effort is made to minimize the burden on all participants in EIs. Very few of our EIs have involved small businesses. On occasion, ATSDR has asked for participation from employees and

attendees of daycare facilities and schools. Participation in an EI is voluntary and ATSDR strives to keep our questions to the minimum needed to interpret our results.

6. Consequences of Collecting the Information Less Frequently

The vast majority of EIs are a one time sampling or modeling event related to a specific exposure situation. At times, the results of the first sampling event require that we collect additional samples (either environmental or biomedical). Participants in EIs are generally asked one set of questions per sampling event. If we need to conduct additional sampling (e.g., to assess the effectiveness of an intervention), we would request that the participants answer another questionnaire.

If ATSDR determines that a long-term study is needed, ATSDR would obtain a separate OMB clearance in order to specifically conduct that study.

There are no legal obstacles to reduce the burden.

7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5

There should be no special circumstances with EI data collection. The data collection fully complies with the guidelines of 5 CFR 1320.5.

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. 77, No. 61 on Thursday, March 29, 2012 (Attachment 2).

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

Sharon Lee, Division of Environmental & Occupational Disease Control,
CA Dept of Health Services
& Facilitator of the Interstate Chemical Terrorism Workgroup
1515 Clay St., Suite 1901
Oakland CA 94612
Phone (510) 622-4478
Lee, Sharon (DHS-EHIB) [SSeidel@dhs.ca.gov]
– ATSDR solicited comments through her from the Interstate Chemical Terrorism Workgroup and requested information on other surveys. More than 30 state representatives reviewed the chemical exposure questions. ATSDR received oral and written comments from 10 representatives and added questions from other surveys. (2006)

Laura Fenster, PhD., Epidemiologist
Occupational Health Branch
CA Dept of Health Services

1515 Clay St., Suite 1901
Oakland CA 94612
Phone (510) 622-4448
Fenster, Laura (DHS-DEODC-OHB) [LFenster@dhs.ca.gov]
- reviewed the chemical exposure questions and provided comments. She also provided information on other surveys and ATSDR incorporated some of the questions into the chemical exposure questions. (2006)

Bruce Bernard, M.D., M.P.H.
Medical Section Chief
Hazard Evaluations and Technical Assistance Branch
Div of Surveillance, Hazard Evaluations & Field Studies
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)
4676 Columbia Parkway R-10
Cincinnati, Ohio 45226
Phone (513) 841-4589
BPB4@CDC.GOV
– provided review of portions of the package pertaining to occupational exposure. (2006)

9. Explanation of any Payment or Gift to Respondents

Participants will not receive payments or other tokens of appreciation for their participation in an EI.

10. Assurance of Confidentiality Provided to Respondents

Institutional Review Board

Federal Regulations for Protection of Human Subjects (45 CFR 46) do not apply to this project because it is not research. The regulations state that "research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge". EIs are not systematic investigations, nor are they designed to develop or contribute to generalizable knowledge. However ATSDR does require that participants in EIs be fully informed of the potential risks and benefits of their participation and that the privacy of the participants information be protected. All EIs are reviewed by the NCEH-ATSDR Human Subjects Coordinator who is designated to make a human subjects research/non-research determinations. (See Attachment 6. Example of a Determination).

Privacy Impact Assessment Information

A. This submission has been reviewed by the NCEH-ATSDR Privacy Officer and it has been determined that the Privacy Act is applicable. The applicable System of Records Notice (SORN) is ATSDR's broad SORN covering the majority of investigations involving personally identifiable information conducted by the Agency, 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Hazardous or Toxic Substances."

B. Identifying information such as name, address, phone number and email are collected. Although personal identifiers may be kept for up to 5 years, ATSDR uses the information only to contact respondents. Identifying information is necessary to facilitate the personal contact with respondents to conduct the questionnaire, to obtain consent to participate (Attachment 5), and to provide them their results. All identifying information is kept with the ATSDR investigators.

Data are treated in a private manner, unless otherwise compelled by law. The paper document containing personal identifiers are kept in locked file cabinets at CDC/ATSDR. Access to computer files is password-protected and access is limited to authorized EI personnel. All staff working on the project agree to safeguard the data and not to make unauthorized disclosures. Any data on laptops will be encrypted in accordance with information systems security requirements for safeguarding personally identifiable information. Data are safeguarded in accordance with applicable statutes. Responses in published reports are presented in aggregate form and no individuals are identified by name.

C. Respondent Consent

Although EIs are not systematic investigations, all participants will be informed of the potential risks and benefits in participation and will be asked to consent as participants in an EI

D. Voluntary Nature

Respondents are told that their participation in the EI is voluntary and they may refuse to answer any of the questions.

11. Justification for Sensitive Questions

ATSDR sometimes gathers information about individual characteristics (e.g., gender, age, weight, ethnicity, and race) to assist with interpretation for biomedical samples. For example, if ethnicity and race information is collected, the individual's laboratory results are compared to similar ethnicity and race results in the *National Report on Human Exposure to Environmental Chemicals* (see citation above). Beyond that, generally, questions of a sensitive nature are not asked. Occasionally, we may need to ask questions on drug and medication use to assist us in interpreting an individual's laboratory results. ATSDR may also ask questions pertaining to recent or current pregnancy status for one of two reasons: 1) Inclusion in the EI – pregnancy makes a woman and her unborn child more vulnerable to the effects of some chemicals (e.g., lead) or 2) Exclusion in the EI- some blood tests require a large quantity of blood. For example it is generally not reasonable to collect a 70 ml blood sample for dioxins from a small child, pregnant woman, or an anemic person.

Social security numbers are not needed or requested.

12. Estimates of Annualized Burden Hours and Costs

A. Estimates of Annualized Burden Hours

Typically, ATSDR conducts no more than 7 EIs nationwide each year requiring a questionnaire. Generally, the number of participants per investigation ranges from 10 to 100. Therefore, we estimate that the maximum total number of respondents annually is 700 (7x100). Generally, we ask the questions once.

The time burden per respondent is estimated at 30 minutes. A typical questionnaire may include up to 20 general questions taking less than 30 seconds each to respond and 20 more in-depth exposure specific questions requiring less than one minute each. This estimate is consistent with our results from EIs conducted in the past few years. The total estimated annual burden hours are 350.

Estimated Annualized Burden Hours

Type of Respondents	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (In Hours)
EI participants	700	1	30/60	350

B. Annualized Cost to Respondents

Using a rate of $21.35/hr, the annualized cost to respondents for the hour burdens for the collection of information is $7,472.50. The hourly wage rate is based on the U.S. Department of Labor, Bureau of Labor Statistics' most current statistics [May 2010 National Occupational Employment and Wage Estimates United States, last updated April 6, 2011].

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	No. Responses per Respondent	Hourly Wage Rate	Total Respondent Costs
EI participants	350	1	$21.35	$7,472.50

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

There will be no other costs to respondents.

14. Annualized Cost to the Federal Government

Costs for ATSDR personnel and cooperative agreement state personnel were estimated based on experience with previous EI activities.

For the past 3 years, the annual budget for EIs has been $960,000. This includes: FTEs (including benefits), contractors, travel, per diem, and laboratory, supply, and equipment costs. We expect the budget to remain unchanged for the next three years.

15. Explanation for Program Changes or Adjustments

The burden hours have decreased from 375 hours in the current inventory to 350 hours as a result of a decrease in the number of EIs requiring a questionnaire each year.

16. Plans for Tabulation and Publication and Project Time Schedule

A.16-1 Project Time Schedule

Activity	**Time Schedule**
Start of data collection	1 month after OMB approval
Field work	1-36 months after OMB approval
Analysis	2-36 months after OMB approval
Respond to participants	2-36 months after OMB approval
Written Report	3-36 months after OMB approval

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

We are not requesting an exemption to the display of the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for Paperwork Reduction Act.

B. Collections of Information Employing Statistical Methods

Although no statistical methodology is used for the investigations, we will use this section of the submission to describe how the data are collected.

1. Respondent Universe and Sampling Methods

Since ATSDR does not use the questionnaire results to generalize or estimate the total exposed population, the respondent universe and statistical methods for determining sample size are not a factor. ATSDR does, however, need to know the potential size of the population to be sampled and since many EIs are location-based, we estimate the potential respondent universe based on street maps and census information.

2. Procedures for the Collection of Information

A questionnaire (developed from the list in Attachment 3) is administered either in person or over the phone. Several procedures may be used to sign up participants, such as newsletters or recruitment posters. The principal investigator, or team, is identified by name along with qualifications or experience in conducting similar EIs.

The EI team may also recruit participants at public availability meetings. Based on ATSDR's experience recruiting and interviewing subjects for investigations, the response rate is close to 100%.

Quality Control Procedures

Prior to the interviews, the EI team is trained on the site-specific questionnaire (e.g., the purpose of each question, how to capture answers, place for comments, etc.). Once developed, the site-specific questionnaire is not changed unless the team discovers an important addition needed from the chemical exposure questions or a subtraction. Participants are re-interviewed if a question is added from the chemical exposure questions. The site-specific questionnaire and individual's answers are stored in a secure database or locked filing cabinet.

Each participant is given information regarding the name of the EI, a telephone number to answer questions, and the address of the ATSDR website where they can find more information about the EI, if applicable. Each participant receives a copy of their personal results.

3. Methods to Maximize Response Rates and Deal with Non-Response

An EI is usually requested by officials of a state health agency, county health departments, the EPA, the general public and ATSDR staff in order to address community health concerns. To evaluate potential exposure, ATSDR is generally looking for participants that are the most highly exposed . We identify them through a location or an activity that they engage in. If activity based (e.g., fishing, working, etc.) we may need to contact people to encourage their participation.

Ours is not a response rate as the term is typically used in research or evaluation to show the legitimacy of a study. We invite people to participate in our sampling based on who would likely be most exposed. Generally, we look for 10-100 participants in the most exposed category. Getting participants has not been a problem since communities have been requesting the sampling before we arrive. Since our goal for participation is a wide range and participants usually request the sampling, we usually have close to a 100% response rate. However, because we are interpreting each individual's response to his or her specific exposure and not attempting to determine population level exposures, we can interpret results without 100% participation.

4. Tests of Procedures or Methods to Be Undertaken

Although some modifications to the questions in Attachment 3 – Chemical Exposure Questions – were necessary for improved readability, we did not making substantive changes. (See Comparison in Attachment 7) The current data collection instrument (Attachment 3 – Chemical Exposure Questions) was modified from previous similar exposure investigations, and from questions administered by other agencies; some of which have gone through OMB clearance. See page 5 of this Supporting Statement or Attachment 3.

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

Statistical calculations are not used to determine participation in Exposure Investigations. Rather, all the community residents with the greatest likelihood of exposure are asked to participate**.**

The primary and secondary contacts for this data collection are the following:

Primary:
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List of Attachments

Attachment 1. Authorizing Legislation – CERCLA
Attachment 2. 60 Day Federal Register Notice
Attachment 3. Revised Chemical Exposure Questions
Attachment 4. Environmental Exposure Questions from EPA and CDC
Attachment 5. Example Consent Form
Attachment 6. Example of Human Subjects Research Determination