**ASARCO Smelter Exposure Investigation**

ATSDR Exposure Investigations (EI) Generic Information Collection Request

OMB No. 0923-0048

Expiration Date: 05/31/2016

**Supporting Statement Part A**

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Science Support Branch (SSB)

Division of Community and Health Investigations (DCHI)

Agency for Toxic Substances and Disease Registry (ATSDR)

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4. ASARCO Smelter EI Questionnaire
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# A. Justification

## A.1 Circumstances Making the Collection of Information Necessary

This data collection is being conducted using the Generic Information Collection mechanism of the Agency for Toxic Substances an Disease Registry (ATSDR) Exposure Investigations (EIs) – OMB No. 0923-0048 expiration date. 5/31/2016. The data collection for the **A**merican **S**melting **a**nd **R**efining **Co**mpany (ASARCO) Smelter EI aligns with the agency’s mission.

The data collection is authorized by 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.

**ATSDR Public Health Assessment Process and the Role of the Exposure Investigation**

The ASARCO Smelter site has operated for over 100 years and continues to operate at the present time, producing copper from copper sulfide ore. The ASARCO smelter is a large complex of approximately 200 acres at the eastern end of the town. Two large emission stacks dominate the horizon. One is about 1,000 feet tall and the other is 250 feet tall. The historic and current smelting process emits lead, arsenic, copper, sulfur dioxide, particulate matter, and other materials into the air. Some of these substances have been deposited in soil across the area.

Two communities, Hayden and Winkelman, AZ, are located near the smelter. Hayden has been identified as having high concentrations of lead and arsenic in the soil. All of Hayden is located next to or within ½ mile of the smelter site. Winkelman is located between ¼ and 1 ½ miles from the smelter site. In addition, a large slag pile (smelter residue) is located on the edge of the ASARCO complex, approximately ½ mile from the main school in the community. The slag area currently has a fence around the area but is still accessible to children in the community and may be an attractive play area for them. Much of the housing in the two communities was built in the early 1900s; therefore, contact with degraded lead paint is another pathway for exposure to lead.

The ATSDR Division of Community Health and Investigation (DCHI), along with Arizona Department of Environmental Quality (ADEQ) and the Arizona Department of Health Services (ADHS) conducted a public health assessment (PHA)[[1]](#footnote-1) at the ASARCO Smelter Site in 2002. The PHA process concluded that exposure to sulfur dioxide occasionally posed a short term public health hazard to sensitive asthmatics.

In 2008, a Phase I evaluation was completed by the US Environmental Protection Agency (EPA) that focused on non-residential soils and air. Elevated levels of lead and arsenic were found in soil in the industrial area as well as in a large slag pile. Maximum Levels of contamination in non-residential soils were 1230 mg/kg (ppm) of lead and 1720 mg/kg (ppm) of arsenic. Maximum levels of contamination in the slag pile were 468 mg/kg (ppm) of lead and 361 mg/kg (ppm) of arsenic.

Air monitoring conducted during the Phase I reported elevated levels of lead (maximum of 0.8 µg/m3), arsenic (maximum of 0.19 µg/m3), cadmium (maximum of 0.035 µg/m3) and chromium (maximum of 0.007 µg/m3) in the area. The level of arsenic found in Hayden’s air is about 60 times above the levels expected in an area unaffected by smelting activities. Lead levels in local air sometimes exceed the EPA’s National Ambient Air Quality Standard (NAAQS) for lead (0.15 µg/m3). In 2012, ambient air monitoring in the area found that three-month rolling average lead levels ranged from 0.07 µg/m3 to 0.20 µg/m3, exceeding EPA’s NAAQS on several occasions. In April 2014, EPA proposed to redesignate the Hayden area in Arizona, which encompasses portions of southern Gila and eastern Pinal Counties, from “unclassifiable” to “nonattainment” for the 2008 National Ambient Air Quality Standard for lead.

Residents in the area have also been shown to be exposed to low levels of arsenic in their municipal drinking water (3.6 to 5 ug/L), obtained from area groundwater. These levels are below the Maximum Contaminant Level (MCL) but may contribute to total arsenic exposure in residents. Lead was not detected in the drinking water samples. EPA is not aware of any private wells in the area used for domestic purposes.

In 2008, ASARCO, EPA and ADEQ agreed to complete residential cleanup of 266 homes in the area for lead, arsenic and copper. ASARCO is currently conducting a Phase II remedial investigation under the direction of EPA that focuses on air, non-residential soils, groundwater, surface water and sediment.

Testing of blood lead levels in children and arsenic in urine have been reported in the past, but are not sufficient to determine the extent of human exposures in the community. ADHS estimates that less than 50% of children living in Hayden and Winkelman have received blood lead screening between 2003 and 2012. The most recent testing for arsenic in urine occurred in 1999 when the University of Arizona and ADHS conducted a blood lead and urinary arsenic study in the community (with ASARCO funding). Fourteen children were tested for blood lead levels using a finger stick capillary blood screening method. Results ranged from non-detect to 9µg/dL and averaged 3.6µg/dL (detection limit of 1 µg/dl).

The lack of information on blood lead levels and urine arsenic levels is a concern to community members, EPA, ADHS, ADEQ and ATSDR given that contamination is known to exist in environmental media in the area around the smelter. In 2014, EPA requested ATSDR conduct this exposure investigation to assist in determining whether residents in the Hayden and Winkelman communities are being exposed to lead and arsenic in the environment.

**The Exposure Investigation Criteria and Recommendation Process**

Four criteria must be met for the EI to be approved and conducted. The criteria 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 EI be designed that will address this data gap?
4. Will the EI results impact the public health decision for the site?

If the answers to these questions indicate that an EI would allow ATSDR to make a better-informed public health call, the DCHI EI Team may conduct agency-led EIs. For the ASARCO Smelter, the responses to the four questions (provided below) indicated that an EI is warranted at the site.

The EI Team from the DCHI Science Support Branch (SSB) and the ATSDR Region 9 Office will lead the investigation, evaluate the results, and communicate their public health findings and recommendations to the community (further discussed in Section A.2)

**ASARCO Smelter Exposure Investigation**

The four questions used to establish whether it was appropriate to conduct an EI for the ASARCO Smelter site were as follows:

1. *Can an exposed population be identified?*

Yes. Based on the ATSDR PHA and the EPA Phase I remedial investigation, an exposure area can be defined. Hayden and Winkelman are small, isolated towns located very close to the smelter site. While all residents of these towns are potentially exposed to lead, arsenic, and other contaminants, geographic and environmental data suggest that Hayden residents are likely more highly exposed. All children (preschool – high school) in Hayden and Winkelman attend school at the same campus in Winkelman. Population estimates for both towns indicate that approximately 486 children and women of child bearing age reside in these two communities.

1. *Does a data gap exist that affects one’s ability to decide whether a public health hazard exists?*

Yes. Little is known about current lead and arsenic exposures in this community. ATSDR/ADHS completed a PHA in 2002, concluding that short term sulfur dioxide exposures may pose health risks. However, since then, EPA has revised the lead and sulfur dioxide NAAQS and the Centers for Disease Control and Prevention (CDC) has instituted the 5µg/dl blood lead reference value (<http://www.cdc.gov/nceh/lead/publications/LeadandPregnancy2010.pdf>).

EPA collected much additional environmental data during the Phase I remedial investigation that followed the publication of the PHA and a Phase II evaluation is in progress. Blood lead and urine arsenic levels available are not sufficient to fully characterize whether exposure to these contaminants has occurred in these communities. Additional sampling will allow this data gap to be filled.

1. *Can an Exposure Investigation be developed that addresses this data gap?*

Yes. Lead and arsenic exposures are measurable through blood and urine respectively. Results of the EPA remedial investigation processes have provided information on the extent of contamination from the site. The addresses of residents in this area are already available from prior EPA residential soil testing. Lead and arsenic are the primary contaminants of concern identified to date, permitting clear conclusions about the current status of site contamination on the population.

The state health department has voiced support for ATSDR to conduct this EI and has offered their partnership, increasing the likelihood of a successful turnout and appropriate health education follow up.

1. *Would the Exposure Investigation results impact public health decision-making?*

Yes. First and foremost, in this EI the presence of a single participant with an elevated level of blood lead or urine arsenic in a population that should not have any elevated levels present constitutes a significant exposure. If the EI indicates that exposures are significant, ADHS and the ATSDR Regional Office can design a suitable health education and outreach effort. In addition, the EPA would be able to make more informed decisions about clean-up priorities. The community has already expressed interest in further evaluation of their risk of exposure and evidence of exposure to the contaminants of concern is paramount. ADHS is prepared to follow up with families and local physicians, consistent with regulations that protect health information privacy.

Once the EI data collection and analysis is complete, if indicated, the ATSDR Team may conduct a public availability session for participants in the EI and for the community as a whole to discuss recommendations to reduce exposure and potential health concerns related to the contaminants. ATSDR will also make recommendations as needed for exposure reduction to the EPA and appropriate state environmental agencies and other federal, state and local agencies as indicated. Exposure reduction recommendations may lead to enforcement decisions by EPA such as removing contaminated soil in residential areas and restricting access to the contaminated slag piles.

A full EI Final Report is also completed and made available to the public and to all partners once all samples and data have been collected and analyzed. The final report includes the following:

* Summary of the investigation and background history of the site
* Purpose of the Investigation
* Methods used
* Results of the Investigation
* Discussion of the Results
* Conclusions
* Recommendations
* References
* Appendices related to the Investigation

Additional sections may be included as needed based on the requirements of the Investigation. An example of a past EI Final Report is included as Attachment 7.

## A.2. Purpose and Use of Information Collection

The goal of the EI is to determine whether area contamination from historical smelting operations is resulting in community members being exposed to lead and arsenic in soil and air at levels of health concern. If this is the case, ATSDR will make recommendations people can take to reduce their exposures and will recommend contaminant mitigation to the appropriate government agencies [e.g., EPA and its state equivalent]. If exposures are found at levels that might cause health concerns, ATSDR may recommend the following:

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.

Data from ATSDR’s ASARCO Smelter EI report may also be used by public health professionals, environmental risk managers, and other decision makers in determining the source and extent of the exposures.

ATSDR will produce this needed information to support public health action. Further, ATSDR expects to use these findings to improve our understanding of the public health impacts posed by environmental contaminants so that public health interventions may be implemented as quickly as possible. The results of this EI are not intended to be generalized and are applicable only to the participants.

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. 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 to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. 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.

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

ATSDR will conduct computer-assisted personal interviews (CAPIs) with the participants at the blood collection location. The results of the interview will be recorded in the Rapid Data Collector (RDC), an NCEH/ATSDR information system that enables scientists and epidemiologists to rapidly collect data while in the field. The information will be recorded electronically on a laptop computer.

## A.4. Efforts to Identify Duplication and Use of Similar Information

In the Hayden area, adequate lead and arsenic testing has not been completed in the community:

*Children:* No large-scale testing in children in the neighborhoods surrounding the ASARCO Smelter site has been completed. Only a small fraction of children from the surrounding communities near the former smelter and slag pile were tested for blood lead and urine arsenic by the University of Arizona and the ADHS. This previous testing was done using screening methods that do not have the laboratory precision being proposed in this EI.

*Pregnant women:* Testing of pregnant women in the neighboring areas for lead or arsenic has not been completed. Epidemiological and experimental evidence suggests that lead is a potent developmental toxicant. Recent epidemiologic cohort studies suggest that prenatal lead exposure, even with maternal blood lead level (BLL) <10 µg/dL, is inversely related to fetal growth and neurodevelopment independent of the effects of postnatal exposure. This exposure investigation will be available to all women of child-bearing age.

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## A.5. Impact on Small Businesses or Other Small Entities

No small businesses are included in the ASARCO Smelter EI.

## A.6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection. There are no legal obstacles to reduce the burden.

## A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this data collection. The data collection will fully comply with the guidelines of 5 CFR 1320.5 and will be voluntary.

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

This data collection is being conducted using the Generic Information Collection mechanism for Exposure Investigations – OMB No. 0923-0048 (expiration date: 05/31/2016). A 60-day Federal Register Notice was published in the *Federal Register*, Vol. 77, No. 61 on Thursday, March 29, 2012. No comments were received.

## A.9. Explanation of Any Payment or Gift to Respondents

ATSDR will not provide payments or gifts to participants.

## A.10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by CIO who determined that the Privacy Act does apply. The relevant Privacy Act System of Records Notice (SORN) for this EI is the Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances (HHS/ATSDR). This SORN is intended to allow for the implementation of the legislated mandate of ATSDR to identify the public health threat caused by exposure to toxic and hazardous substances using exposure investigations.

Data obtained during the exposure investigation will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Arizona Sunshine Laws require openness in government, which may result in personal identification being accessible by the general public. The EI will comply with all appropriate requirements.

**Institutional Review Board**

Federal Regulations for Protection of Human Subjects (45 CFR 46) state that “*research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” In contrast, this EI is intended to be a systematic investigation but is not designed to develop or contribute to generalizable knowledge. The ASARCO Smelter EI is a nonresearch activity and human subjects review by an Institutional Review Board (IRB) is not required. The EI was reviewed by the NCEH/ATSDR Human Subjects Coordinator who is designated to make human subjects research-or-non-research determinations on a case-by-case basis (Attachment 5).

### A.10.1. Privacy Impact Assessment Information

The ASARCO Smelter EI will involve children, pregnant women, and women of child-bearing age. ATSDR provides participants with information on the EI process and what it can and cannot determine. After providing the participants this information, ATSDR will ask for parental permission and minor assent, or adult consent to participate in the EI. Participation is completely voluntary; participants can stop participating in the EI at any time.

**Overview of the Data Collection System**

The primary objective of the information collected for the ASARCO Smelter EI is to assess exposures to environmental lead and arsenic. Data obtained during this EI will include analytical measures of these metals in blood and urine. Information obtained from the participants assists the team in determining if exposure has occurred or is occurring. For this EI, a data collection system will include all of the measurements and procedures that are proposed to address data gaps in the blood and urine sampling.

The data collection system for this EI will be characterized by the following:

1. Who will use the EI Data Collection System?

The DCHI SSB EI Team and the ATSDR Region 9 staff will use the Data Collection System to perform the blood and urine specimen collection and laboratory analysis during the ASARCO Smelter EI.

1. Who can be included as part of the EI Generic Clearance?

EI participants for the ASARCO Smelter EI are identified as the most highly exposed and/or susceptible populations and will be offered testing. The participants will be targeted for inclusion by canvasing the two communities near the smelter site, Hayden and Winkelman:

* Children from 9 to <72 months (<6 years) of age (blood lead testing only),
* Children from 6 to <12 years of age (blood lead testing and urine arsenic testing), and
* Pregnant women (blood lead testing and urine arsenic testing).

ATSDR will recruit up to 200 people living in Hayden and Winkelman.

In addition, if the three participant categories above do not fill all 200 available appointments, children 12 to <18 years of age and women of child bearing age from 15 to <45 years will be included on a first come, first served basis.

Urine arsenic will not be tested in children aged 9 to <72 months given the lack of NHANES data available for evaluation and the difficulty in obtaining urine samples in young children.

1. What types of questions may be asked as part of the EI Generic Clearance?

For the ASARCO Smelter EI, the medium of concern is soil contaminated with lead and arsenic as well as lead contamination in the air. Attachment 4 provides the information collection form that will be used to evaluate chemical exposure of ASARCO Smelter EI participants.

**Items of Information to be Collected**

Collecting identifying information is necessary to facilitate personal contact with participants, to obtain their parental permission/assent/consent to participate and to provide them with results. The information is also used by ATSDR to better interpret the results of the sampling. ATSDR uses the information only to contact respondents. Data is treated in a private manner, unless otherwise compelled by law.

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 biological investigations to assist with results interpretation.

ATSDR will ask participants questions about their recreational activities that could increase their potential exposure to lead and arsenic in the soil and air. Only questions needed to determine the extent of exposure in a particular situation will be asked. The questions are intended to estimate how long and how frequently participants may have contact with soil in the neighborhoods surrounding the ASARCO Smelter site and on the slag pile when applicable.

In addition, ATSDR will also collect information on other possible sources of arsenic and lead exposure such as age and construction characteristics of the home, foods eaten, hobbies, time spent outdoors, etc. That information represents their individual exposure history.

The blood and urine specimen collection will be overseen by ATSDR personnel, obtained by trained phlebotomists, and shipped directly to the CDC National Center for Environmental Health (NCEH) laboratory in Atlanta for analysis. Appropriate Quality Assurance Plans will be prepared and implemented by ATSDR. Blood lead samples will be collected at a central location within the community. Urine samples may be obtained in the home or at the blood collection location.

**Sharing and Purpose of Collected Information**

**The information collected for the Exposure Investigation (EI) will be used to evaluate whether participants may have been exposed to lead and arsenic in the environment in the area near the ASARCO Smelter. Participants will be notified of their individual results and an EI report will be prepared that will present the results of the investigation.**

**Securing of Collected Information**

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. 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 to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. All staff working on the project agree 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.

Data are treated in a private manner, unless otherwise compelled by law. Paper documents containing personal identifiers are kept in locked file cabinets at ATSDR. ATSDR computers comply with the HHS Standard 2008-0007.001S for encryption in accordance with information systems security requirements for safeguarding personally identifiable information. Access to computer files is password-protected and access is limited to authorized EI personnel. That information is stored in a secure database along with the laboratory and/or modeling results.

**Applicability of the Privacy Act**

A. The Privacy Act is applicable. The applicable System of Records Notice (SORN) is No. 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. 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, and to provide them their results.

All identifying information maintained by the agency will be managed by ATSDR and is subject to the ATSDR Comprehensive Record Control Schedule (CRCS), B-371, which contains authorized disposition instructions for ATSDR's administrative and program records.

C. Respondent Consent – Although this EI is not human subjects research, ATSDR will require that EI participants be fully informed of the potential risks and benefits of their participation and that the privacy of the participants’ information will be protected. The parental permission, minor assent, and adult consent forms for the ASARCO Smelter EI include all appropriate information from the Privacy Act including authority and purpose for collecting the data, with whom identifiable information will be shared, the voluntary nature of the information collection and the effect upon the respondent for not participating (Attachment 3). Arizona Sunshine Laws require openness in government, which may result in personal identification being accessible by the general public. The EI will comply with all appropriate requirements.

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

## A.11. Justification for Sensitive Questions

ATSDR will gather information about individual characteristics (e.g., gender, age, weight, ethnicity, and race) to assist with interpretation for biological samples. For example, the individual’s laboratory results are compared to similar ethnicity and race results in the *National Report on Human Exposure to Environmental Chemicals* (http://www.cdc.gov/exposurereport/). Beyond that, questions of a sensitive nature will not be not asked.

We will not ask questions on symptoms, medical outcomes, or drug and medication use. For the ASARCO Smelter EI, ATSDR will ask questions pertaining to recent or current pregnancy status because pregnancy makes a woman and her unborn child more vulnerable to the effects of lead and arsenic.

Social security numbers are not needed nor will they be requested.

## A.12. Estimates of Annualized Burden Hours and Costs

### A.12.1. Estimates of Annualized Burden Hours

The estimate for burden hours for the ASARCO Smelter EI is based on similar EIs that the EI team has conducted in the past. The time burden per respondent is estimated at 20 minutes. A typical questionnaire may include up to 20 general questions taking less than 30 seconds each to respond and 10 more in-depth exposure specific questions requiring less than one minute each. The total estimated burden hours are 67.

Estimated Annualized Burden Hours

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of Respondents | Name of Form | No. of Respondents | No. of Responses per Respondent | Average Burden per Response  (in hours) | Total Burden (In Hours) |
| EI Participants | Participant Questionnaire | 200 | 1 | 20/60 | 67 |

## 

### A.12.2. Annualized Cost to Respondents

Using a rate of $22.33/hr., the annualized cost to respondents for the hour burdens for the collection of information is $1,496. The hourly wage rate is based on the U.S. Department of Labor, Bureau of Labor Statistics’ most current statistics [May 2013 National Occupational Employment and Wage Estimates United States, released April 1, 2014].

Estimated Annualized Burden Costs

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Respondent | Total Burden Hours | No. Responses per Respondent | Hourly Wage Rate | Total Respondent Costs |
| EI participants | 67 | 1 | $22.33 | $1,496 |

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

There will be no direct costs to the participants other than their time to participate in the EI.

## A.14. Annualized Cost to the Government

Costs for ATSDR personnel are estimated based on experience with previous EI activities.

|  |  |  |  |
| --- | --- | --- | --- |
| Staff (FTE) | Average Hours per Collection | Average Hourly Rate | Average Cost |
| Medical Officer (Lead Investigator – O-6) | 1,000 | $50 | $50,000 |
| Regional Representative (Health Scientist – GS-13) | 400 | $43.70 | $17,480 |
| Regional Representative (Health Scientist – GS-13) | 200 | $43.70 | $8,740 |
| Estimated Total Personnel Cost of Exposure Investigation | | | $76,220 |

|  |  |  |  |
| --- | --- | --- | --- |
| Non-Personnel | | | Cost |
| Travel costs | | |  |
|  | Atlanta Personnel | | $9,017.00 |
|  | Regional Personnel | | $4,268.00 |
| Laboratory costs | |  |  |
| Includes phlebotomist, shipping and sample analysis | |  | $63,400.00 |
| Estimated Total Non-personnel Cost of Exposure Investigation | | | $76,685.00 |
| Total EI Cost (Personnel + Non-personnel costs) | | | $152,905.00 |

The travel costs include the following:

* Travel to the site from Atlanta (1 person) and San Francisco (1 person) for 3-4 days for a site visit and to meet with local partners and community leaders
* Travel to the site from Atlanta (1 person) and San Francisco (1 person) for two weeks to recruit participants and perform the blood and urine collection
* Travel to the site from Atlanta (1 person ) and San Francisco (1 person ) for a follow-up meeting

## A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

## A.16. Plans for Tabulation and Publication and Project Time Schedule

**A.16.1 Project Time Schedule**

The project Time Schedule for the ASARCO Smelter EI is as follows:

**Activity Time Schedule**

Start of data collection and field work …………………….....………1 week after OMB approval

Data and laboratory analysis………………………………......... 2-3 months after OMB approval

Respond to participants …………………………….…................3-6 months after OMB approval

Written report…………………………………….….................TBD - based on clearance process

Response letters to the participants will be sent for those with elevated and normal results (Samples are provided in Attachment 6). An example of a prior Exposure Investigation report is provided as Attachment 7.

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

We are not requesting an exemption.

## A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for Paperwork Reduction Act.

1. 2005 ATSDR PHA Guidance Manual (<http://www.atsdr.cdc.gov/HAC/PHAManual/toc.html>) [↑](#footnote-ref-1)