

Follow Up Biologic Testing for Exposure to Arsenic ASARCO Hayden Smelter Site, Hayden & Winkelman, Arizona Exposure Investigation

ATSDR Exposure Investigations (EI) Generic Information Collection Request
OMB No. 0923-0048
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Supporting Statement Part A

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Attachments:

1. Supporting Statement A
2. Supporting Statement B
3. Hayden, AZ EI Parental Permission/Assent/Consent Forms
 - 3A. Parental Permission Form for Urine Arsenic Testing and Questionnaire: Children 6 to less than 18 years of age
 - 3B. Assent Form for Urine Arsenic Testing and Questionnaire: Children and Youth aged 7 to less than 18 Years of age
 - 3C. Consent Form for Urine Arsenic Testing and Questionnaire: Adults aged 18 years and over
4. Hayden, AZ EI Questionnaire
5. Hayden, AZ EI Research Determination
6. Hayden AZ Sample Results Letters
 - 6A. Sample Results letter to the Parent of a Participant 6 to less than 18 - Total Arsenic below follow up level
 - 6B. Sample Results Letter for Participant 6 to less than 18 Years of Age – Total As Above, Organic As Not Elevated, Inorganic As Elevated
 - 6C. Sample Results Letter for Participant 6 to less than 18 Years of Age - Total As Above, Organic As Elevated, Inorganic As Not Elevated
 - 6D. Sample Results Letter for Participant 6 to less than 18 Years of Age - Total As Above, Organic As Elevated, Inorganic As Elevated
 - 6E. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age 15 to less than 45 years - Total Arsenic Below Follow-up Level
 - 6F. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age 15 to less than 45 years) – Total As Above, Organic As Not Elevated, Inorganic As Elevated
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 - 6H. Sample Results Letter to a Pregnant Woman or Woman of Child Bearing Age 15 to less than 45 years) - Total As Above, Organic As Elevated, Inorganic As Elevated
7. Example of Prior EI Final Report
8. Arsenic Retest Recruitment Letter
9. Urine Collection Instructions
10. Hayden & Winkelman Site Map and Demographics
11. Tips for Reducing Exposure to Arsenic

Goal of the study: This investigation will retest Urine Arsenic Levels (UALs) for residents who volunteered for testing in the initial ATSDR Exposure Investigation (EI) during the ASARCO smelter shut down to determine if they have been exposed to unusual levels of arsenic. In addition ATSDR will coordinate with EPA and the Arizona Department of Environmental Quality (ADEQ) to provide UAL results for use in the Superfund Alternative process with ASARCO.

Intended use of the resulting Data: UAL data will be used by ATSDR to inform participants if they have elevated urine arsenic levels that should be evaluated by their healthcare provider and if intervention is needed to minimize or eliminate exposure. UAL results will also be used to assist EPA in prioritizing locations for cleanup of non-residential soils as well as evaluation of air contamination.

Methods to be used to collect: Data collection for EI involves convenience sampling methods, environmental and biological specimen collection to identify and investigate the most highly exposed individuals. For this exposure investigation, data collection will involve interviews and collection of urine samples from residents to assess the arsenic levels in the exposed population.

Subpopulation to be studied: All participants in the previous 2015 exposure investigation will be offered testing. Additional participants may include siblings of participants that are older than 5 years of age, at the parent's request or any other resident of Hayden or Winkelman that was not previously tested if space is available.

How data will be analyzed: The urine samples will be analyzed by the CDC National Center for Environmental Health Division of Laboratory Science (CDC/NCEH/DLS).

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 and Disease Registry (ATSDR) Exposure Investigations (EIs) – OMB Control No.0923-0048, expiration date 3/31/2019. The data collection for the ASARCO LLC Smelter site 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 Hayden Smelter Site is located in rural Arizona, about 100 miles southeast of Phoenix and 50 miles northeast of Tucson. Copper ore has been processed at this site for 100 years. The ASARCO Ray Complex continues to operate – producing copper from copper sulfide ore (ASARCO 2014). 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 and still are being deposited in soil across the area. The U.S. Environmental Protection Agency (EPA), Arizona Department of Environmental Quality (ADEQ), and ASARCO are completing site cleanup through a Superfund alternative process.

ATSDR conducted an Exposure Investigation (EI) in April 2015 to evaluate blood lead and urine arsenic in eligible residents in the Hayden and Winkelman community. The final report of this EI identified two residents (2 of 54 participants between the ages of 1 and 11 years old) with blood lead levels above the Investigation follow up level of 5 micrograms per deciliter ($\mu\text{g}/\text{dL}$). In addition, children and adolescents who participated in the EI had median blood lead levels that were about two times higher than the US population comparison group from the 2011-2012 National Health and Nutrition Examination Survey (NHANES). Total urinary arsenic levels and the creatinine corrected inorganic arsenic median levels were found to be similar to US population median levels for all age groups tested.

After collecting participants’ blood and urine samples April 17-19, 2015, ATSDR learned that the ASARCO Hayden Smelter was shut down for maintenance 11 days prior to the time of specimen collection for the EI (from April 6 – May 21, 2015. ATSDR used EPA air monitoring data from 10 monitoring stations located across Hayden and Winkelman to assess whether the shutdown changed the level of lead and arsenic in the air before and during our testing event. Results indicate that average concentrations of lead and arsenic were about 7 and 8 times lower, respectively, during the shutdown as compared with the average for the rest of 2015, excluding the shutdown. Because the half-life of lead in blood is approximately 30 days it is unlikely that blood lead level test results were significantly impacted by the smelter shut down (although at least some reduction in blood lead levels present in the population could have occurred). However, the half-life for urinary arsenic is approximately 72 hours. Since the shutdown occurred 11 days prior to collection of blood and urine it likely had a significant impact on the levels of urinary arsenic in residents tested. As a result, ATSDR was unable to determine whether the participants’ urinary arsenic levels reflected typical exposures.

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 Hayden, AZ site, the responses to the four questions (provided below) indicated that an EI was warranted at the site. This follow up EI will help answer questions that could not be determined by the initial EI.

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)

Urinary Arsenic Levels in Hayden, AZ Exposure Investigation

The four questions used to establish whether it was appropriate to conduct the initial EI for the Hayden, AZ site were as follows: Responses to ATSDR's EI criteria are provided below:

1. *Can an exposed population be identified?* Yes. Environmental sampling data (soil and air) and limited biological testing data indicate that sensitive populations could be at risk for exposure to harmful levels of lead and arsenic in this community. Population statistics (Attachment 10) for Hayden and Winkelman indicate that ATSDR can offer the testing to the entire population of children 9 months to <12 years of age and pregnant women in Hayden and Winkelman in the investigation.
2. *Does a data gap affect our ability to decide whether a public health hazard exists?* Yes. Some past testing for blood lead and urinary arsenic has been conducted in this area but the testing has occurred over a period of more than 10 years and included only a portion of the population. While blood lead test reporting data are available for Hayden and Winkelman children age 1 to <17 years of age from 2003-2012, ADHS estimates that less than 50% of children have received blood lead testing. Blood lead data gaps are concerning for sensitive populations included in the EI: children 9 months to less than 72 months of age and pregnant women. Urine arsenic testing was last conducted in 1999. Community members have ongoing exposure concerns and have recently requested additional biological testing.

3. *Can an EI address the data gap?* Yes. The EI will provide blood lead levels and urine arsenic levels for the populations most sensitive to exposure (young children and pregnant women). Moreover, due to the size of study population, the EI has the potential to provide a relatively complete picture regarding current exposure to lead and arsenic among these community members. To ensure that the data gap is addressed, the EI team will develop a robust community outreach plan to encourage broad participation in the EI among eligible community members, especially those who have not had blood lead testing previously.

4. *How will the EI results impact public health decision making?* The EI results will impact public health decision making at the household level and the community level. At the household level, ATSDR and ADHS will provide health education based on each participant's results. This health education will build community capacity to (1) understand health risks related to environmental exposures in the area and (2) take specific actions, if necessary, to reduce exposures at the household level. At the community level, the EI will provide EPA with information for use in risk management decisions. As noted earlier, while residential soils have been remediated, an EPA Phase 2 Remedial Investigation is underway to characterize river water, storm water, groundwater, soil (non-residential), and air. EI findings could influence EPA's environmental sampling and remediation strategies for these pathways. The EI results also have the potential to inform ongoing and future risk management decisions EPA's air division is taking in the area.

Once the EI data collection and analysis from the follow up EI is complete, the ATSDR Team will 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 arsenic.

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. A copy of the initial 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 and ongoing smelting operations is resulting in community members being exposed to arsenic in the air and soil at levels of health concern. If this is the case, ATSDR will make recommendations people can take to reduce their exposures and will recommend prioritization of remediation to EPA. If exposures are found at levels that might cause health concerns (≥ 28.4 grams per gram of creatinine), ATSDR may recommend the following:

- a) Recommend follow-up with a Healthcare professional for evaluation and follow up as indicated.

- b) Recommend ways to lower exposure to contaminated soil.
- c) Provide information on nutrition that will help to decrease the absorption of arsenic into the body.

Data from ATSDR's EI follow up testing for exposure to arsenic in Hayden AZ 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, 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 biological 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) as well as complete a hard-copy questionnaire (Attachment 4) with the participants at the centralized urine collection location. The information will be recorded electronically on a laptop computer.

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

In 1999 the University of Arizona and ADHS completed a lead and arsenic exposure survey with funding from ASARCO (Burgess et al., 2000). All residents able to urinate in a cup were eligible for urine arsenic testing and 224 enrolled. The average urinary total arsenic concentration among study participants was 13.7 µg/L (range: non-detect – 114 µg/L). Arsenic samples were further analyzed to measure inorganic arsenic in 18 samples that had total arsenic concentrations over 30 µg/L. Five of these participants who came from three households had inorganic urinary arsenic concentrations over 30 µg/L (range 30 – 47 µg/L), the reference level investigators established for the study. This indicates the level of arsenic present is from an inorganic source (such as arsenic in the air or soil) and not associated with organic arsenic from dietary sources like seafood. In 2003-2004 NHANES data (the first survey data available for total urinary arsenic after 1999 when this survey was conducted) 47 µg/L was below the 95th percentile indicating it

was not significantly higher than the general US population. However it is important to note that urinary arsenic concentrations were not adjusted for creatinine in this study.

In ATSDR's initial 2015 EI, 58 Hayden and Winkelman residents age 6 – 40 years participated in urine arsenic testing. ATSDR performed several evaluations of urinary arsenic results to understand how participant arsenic exposure levels compare to the U.S. population. ATSDR used urine samples to evaluate participant exposures to total arsenic, inorganic arsenic, and individual types (i.e. species) of arsenic. ASARCO unexpectedly shut down the smelter for maintenance in the days before ATSDR collected urine samples. As a result, participants were exposed to about eight times less arsenic in the air than other times in 2015. Since arsenic is typically excreted from the body within several days of exposure, the lower level of arsenic in air in the days before testing could have led to a lower amount of arsenic in participants' urine. ATSDR needs more information to determine how much arsenic participants have in their bodies when air pollution levels are typical for the community.

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

There is no impact expected on small businesses as a result of conducting this EI.

A.6. Consequences of Collecting the Information Less Frequently

This request is for a follow up investigation for urinary arsenic because participants in the initial EI were exposed to about eight times less arsenic in the air than other times in 2015. 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.

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 Control No. 0923-0048 (expiration date: 03/31/2019). A 60-day Federal Register Notice was published in the *Federal Register*, Vol. 80, No. 189 on Wednesday, September 30, 2015. No comments were received.

ATSDR is conducting this EI in collaboration with EPA, ADHS and ADEQ.

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

ATSDR will not provide payments or gifts to participants.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by the NCEH Information Systems Security officer who determined that the Privacy Act does apply. The applicable Privacy Act System of Records Notice (SORN) for this EI is No. 09-19-0001, “Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances” (retrievable by name or SSN”).

The following Information in Identifiable Form (IIF) Categories apply to this information collection (**Attachment 4**):

- | | |
|--|---|
| <input type="checkbox"/> Name | <input type="checkbox"/> Phone Numbers |
| <input type="checkbox"/> Date of Birth | <input type="checkbox"/> Biological Specimens |
| <input type="checkbox"/> Mailing Address | <input type="checkbox"/> Email Address |

ATSDR will treat data obtained during the EI in a secure manner and will not disclose, unless otherwise compelled by law. Arizona Laws require openness in government, which may result in personal identification being accessible by the general public. The consent/assent parental permission forms (Attachments 3A–3C) will include a statement indicating that these laws may apply and the EI will comply with all appropriate requirements. 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.

The Hayden, AZ follow up EI will involve up to 60 participants, including 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 (Attachment 3A-C) to participate in the EI. Participation is completely voluntary; participants can stop participating in the EI at any time.

EI participants for the Hayden, AZ follow up EI are identified as all 58 participants who provided a urinary arsenic specimen in the initial ATSDR Hayden, AZ EI. The population in the initial EI were identified as the most highly exposed and/or susceptible populations and will be offered retesting for urinary arsenic. The 58 participants who provided a urinary arsenic specimen and will be offered a urinary arsenic retest and included the following categories:

- Children 6 to less than 18 years of age,
- Women who are pregnant or of childbearing age

If additional residents request testing, they will be accommodated if space and testing equipment is available up to a maximum of 60 participants.

The participants will be tested in fall of 2017. ATSDR will work with EPA and ASARCO to conduct testing at a time when the ASARCO Smelter operation is operating at normal capacity. In addition ATSDR will continue to evaluate air monitoring data provided by EPA before, during, and after the EI testing period to look for any evidence of a change in levels of arsenic in the air.

For the Hayden, AZ follow up EI, the mediums of concern include soil and particularly air contaminated with arsenic. Attachment 4 provides the information collection form that will be used to evaluate arsenic exposure of EI participants.

ATSDR collects contact information (e.g., name, address, phone number, email address) to provide the participant with their individual results. General information, which includes age/date of birth, race, gender, etc., will be collected since we are recruiting specific age groups in the EI. Data is treated in a private manner, unless otherwise compelled by law.

ATSDR will ask participants questions about their recreational activities that could increase their potential exposure to arsenic in the soil. 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 site. In addition, ATSDR will also collect information on other possible sources of arsenic exposure such as foods eaten, hobbies, time spent outdoors, etc. That information represents their individual exposure history.

The urine collection will be overseen by ATSDR personnel and shipped directly to the CDC National Center for Environmental Health laboratory in Atlanta for analysis. Urinary arsenic samples will be collected at a central location within the community using Attachment 9. Identifiable information for each participant is delinked by assigning a personal laboratory ID to each sample that is maintained by the lead investigator of the EI. The laboratory will not have access to IIF for each sample. Appropriate Quality Assurance Plans will be prepared and implemented by ATSDR.

The information collected for the EI will be used to evaluate whether participants may have been exposed to arsenic in the air and soil in the area near the smelter site. Participants will be notified of their individual results and an EI report will be prepared that will present the results of the investigation. Personal identifiable information will not be included in the published report. Sample results letters are in Attachments 6A–6H.

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 in a private manner, unless otherwise compelled by law. The paper document containing IIF are kept in locked file cabinets at 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.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

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 Hayden, AZ follow up EI is a non-research 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 (Attachment 5).

ATSDR will gather information about individual characteristics (e.g., gender, age, 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 Hayden, AZ follow up 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 arsenic.

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

A.12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours for the Hayden, AZ follow up EI is based on similar EIs that the EI team has conducted in the past. The time burden per respondent is estimated to be a maximum of 30 minutes. The questionnaire (Attachment 4) includes up to 29 general questions to respond and 16 exposure specific questions. Urine specimen collection is estimated to take less than 5 minutes for a total of 30 minutes per respondent. The total estimated burden hours are 30.

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	EI Questionnaire	60	1	30/60	30

Using a rate of \$23.23/hr., the annualized cost to respondents for the hour burden for the collection of information is \$696.90. The hourly wage rate is based on the U.S. Department of Labor, Bureau of Labor Statistics' most current statistics [May 2015 National Occupational Employment and Wage Estimates United States http://www.bls.gov/oes/current/oes_nat.htm#00-0000].

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	No. Responses per Respondent	Hourly Wage Rate	Total Respondent Costs
EI participants	30	1	\$23.23	\$696.90

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	Average Hourly	Average Cost

Attachment 1. Follow Up Biologic Testing for Exposure to Arsenic ASARCO Hayden, AZ Exposure Investigation:
Supporting Statement A

	Collection	Rate	
Medical Officer (Lead Investigator – GS-15)	500	\$57.95	\$28,975
Medical Officer	100	\$57.95	\$5795
Regional Representative (Health Scientist – GS-13)	300	\$41.69	\$12,507
Regional Representative (Health Scientist – GS-13)	300	\$41.69	\$12,507
Estimated Total Personnel Cost of Exposure Investigation			\$59,784

Non-Personnel	Cost
Travel costs	
Atlanta Personnel	\$3500.00
Regional Personnel	\$3000.00
Laboratory costs	\$15,000.00
Shipping, venue and supplies	\$1500.00
Estimated Total Non-personnel Cost of Exposure Investigation	\$21,000.00
Total EI Cost (Personnel + Non-personnel costs)	\$82,784.00

The travel costs include the following:

- Travel to the site from Atlanta (2 people) for 1 week (sampling event: one week for recruiting and urine collection)
- Travel to the site from San Francisco (2 people) for one week (sampling event: one week for recruiting and urine collection)
- Travel to the site from Atlanta (1 person) and San Francisco (2 persons) to provide the results to the community

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

The project Time Schedule for the Hayden, AZ follow up EI is as follows:

Activity

Time Schedule

Winter Sampling

Start of data collection and field work2-4 weeks after OMB approval
 Data and laboratory analysis..... 1-2 months after OMB approval
 Respond to participants4-6 months after OMB approval

Attachment 1. Follow Up Biologic Testing for Exposure to Arsenic ASARCO Hayden, AZ Exposure Investigation:
Supporting Statement A

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.