

Colorado Smelter Exposure Investigation

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

Supporting Statement Part A

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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 ATSDR Exposure Investigations (EIs) – OMB No. 0923-0048. The data collection for the Colorado 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 ATSDR Division of Community Health and Investigation (DCHI) is conducting a public health assessment (PHA)¹ at the Colorado Smelter Site. The PHA process will inform the agency on whether people living near the Colorado Smelter Site have been, are being, or may be exposed to hazardous substances and, if so whether that exposure is harmful, or potentially harmful, and should therefore be stopped or reduced. The process also serves as a mechanism through which the agency responds to specific community health concerns related to hazardous waste sites.

ATSDR scientists have reviewed existing environmental data from the Colorado Smelter Site to see how much contamination exists, where it is, and how people might come into contact with it. The agency has determined that adequate environmental or exposure information does not exist to assess human exposures and possible related health effects. Therefore, ATSDR will use this EI to fill data gaps essential for evaluating whether the community is exposed to contaminants and whether a health hazard is present.

The Exposure Investigation Criteria and Recommendation Process

This EI will be conducted because four necessary criteria exist at this site:

1. An exposed population is identified.
2. A data gap exists that affects the ability to determine if a health hazard exists.
3. An EI could be designed that will address this data gap.
4. The EI results could impact the public health decision for the site.

The EI Team from the DCHI Science Support Branch (SSB) and the Region 8 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).

¹ 2005 ATSDR PHA Guidance Manual (<http://www.atsdr.cdc.gov/HAC/PHAManual/toc.html>)

Colorado Smelter Exposure Investigation

The Pueblo City County Health Department (PCCHD) has requested that ATSDR conduct an EI to address potential exposure by residents living near the Colorado Smelter.

The Colorado Smelter operated for 25 years (1883 to 1908) in south Pueblo, Colorado. Sources of contamination associated with the Colorado Smelter include particulates emitted from the smelter stacks and a residual slag material (slag pile) that covers 25 acres and is up 30 feet high. The stack emissions resulted in contamination of nearby residential soils with lead and arsenic.

Some of the slag generated by the smelter was removed and used as track ballast for the Denver and Rio Grande (D&RG) railroad track between Florence and Cannon City, though significant amounts of slag remain at the property. At present, there are remnants of buildings' foundations and large slag piles at the former Colorado Smelter property. They abut several active commercial properties to the east.

Current access to the slag area is unrestricted. Children reportedly access the area through several openings in the fence, one of which is located north of the public park. There are also indications that homeless people may have lived on the slag pile.

Two neighborhoods located near the smelter, the Eiler and Bessemer neighborhoods, have been identified as having high concentrations of lead and arsenic in the soil. Maximum levels of contamination in residential areas close to the remnants of the smelter include 962 mg lead/kg soil and from 343 mg arsenic/kg soil.

In addition to the lead and arsenic being present in neighborhood soils, an extensive slag pile (30 feet high and covering about 25 acres) is present in the area of the former smelter. The slag pile is not secured and is easily accessible to children and adolescents living in the neighborhoods. There are reports of children playing on and near the slag pile, which puts them at risk for exposure through accidental ingestion and inhalation. Maximum levels of contamination on the slag pile include 26,500 mg lead/kg slag and 3,400 mg arsenic/kg slag.

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

1. *Can an exposed population be identified?*

Yes. Historical smelting operations contaminated the soils of the Eiler and Bessemer neighborhoods of Pueblo, Colorado. Both the regional office Environment Protection Agency (EPA Region 8) and the Colorado Department of Health and Environment (CDPHE) have measured elevated levels of lead and arsenic in residential soils as well as in soil at a local park used by children. Moreover, an extensive slag pile (700,000 square feet, 30 feet high and covering 25 acres) is easily accessed. The high value for soils at the slag pile to date is 26,500 mg lead/kg slag and 3,400 mg arsenic/kg slag. There are

multiple reports of children playing on and near the slag pile, creating completed pathways through incidental ingestion and inhalation to highly contaminated lead soils and dust. One residence is 200 feet from the slag pile.

The 2008 EPA Preliminary Assessment (PA) identified 276 children under age 5 years within 0.5 mile-radius from the slag pile and 942 within a mile radius. The same PA stated that 30 residential soil sites were measured above the 400 ppm screening value for lead. According to the 2010 census, there are 382 children below 6 years of age and 703 women of childbearing age (15 to 44 years) within 0.5-mile radius of the site. The contaminated soils qualified the site for listing on the National Priorities List (NPL); however, resistance from the Pueblo City Council and some community members has caused EPA to pause the listing process in favor of community outreach for the time being.

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

While the Pueblo City County Health Department (PCCH) has participated in blood lead screenings in years past, a very small fraction of the sample population residing in the neighborhoods affected by historic smelter operations was tested. The total sample populations relative to the neighborhood populations are simply too small to make valid statistical conclusions. The definition of "elevated" has shifted from the previous 10 µg/dL "level of concern" to the new CDC reference value of 5 µg/dL (<http://www.cdc.gov/nceh/lead/publications/LeadandPregnancy2010.pdf>), which further complicates previous reports of elevated blood lead. The local population has only recently become aware of the dangers posed by the contamination, and it appears that they were not pro-active in ensuring blood lead testing for their children on the few occasions that it was available.

Recently some children at a local Head Start clinic were tested as part of an academic research project; however, the addresses, by and large, did not coincide with the area of concern, and the researchers used LeadCare II kits, which have some limitations. In a recent conversation with the PCCHD Acting Environmental Health Director, PCCHD expressed support for targeted blood lead testing in Eiler and Bessemer neighborhood children; however, PCCHD lacks the resources and expertise to undertake such an exposure investigation on their own. The EPA and the local health department agree that there is a completed exposure pathway. The data gap in bio-monitoring prevents determination of a public health risks to children for lead and the entire population to arsenic.

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

- Lead and arsenic exposures are measurable through blood and urine respectively.
- The boundaries of site impacts are clearly defined through EPA testing and physical barriers (e.g., the highway). The addresses of residents in this area are already available through PCCHD GIS data bases and maps.

- Lead and arsenic are the primary contaminants of concern identified to date, permitting clear conclusions about the current effects of site contamination on the population.
- The local health department, PCCHD, has voiced support for ATSDR to take on an EI and has offered their partnership, increasing the likelihood of a successful turn out and appropriate health education follow up.

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

Yes. First and foremost, if the EI indicates that exposures are significant, the PCCHD and ATSDR Regional Office can design a suitable health education and outreach effort. The EPA Regional Office would be able to make more informed decisions about clean up priorities. The community is currently formulating a consensus opinion on the value of an NPL listing, and, for them, evidence of exposure to the contaminants of concern are paramount. PCCHD is prepared to follow up with families and local physicians, consistent with regulations that protect health information privacy.

A.1.1. Privacy Impact Assessment

The Colorado 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 minor assent and parental or adult consent to participate in the EI. Participation is completely voluntary; participants can stop participating in the EI at any time.

A.1.2. Overview of the Data Collection System

The primary objective of the information collected for the Colorado 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 8 staff will use the Data Collection System to perform the blood and urine specimen collection and laboratory analysis during the Colorado Smelter EI.
2. Who can be included as part of the EI Generic Clearance?

EI participants for the Colorado 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 canvassing the two neighborhoods located within one half mile of the former smelter and slag pile:

- Children aged 9 to 72 months (blood lead only)
- Children aged 6 to 17 years (blood lead and urine arsenic)
- Pregnant women (blood lead and urine arsenic)
- Women of child-bearing age (15 to 44 years) (blood lead and urine arsenic)

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.

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

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

A.1.3. Items of Information to be Collected

Collecting identifying information is necessary to facilitate personal contact with participants, to obtain their assent/consent/parental permission 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 in nearby neighborhoods questions about their recreational activities on the slag pile that could increase their potential exposure to lead and 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 and on the slag pile.

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 Centers for Disease Control and Prevention (CDC) National Center for Environmental Health (NCEH) laboratory in Atlanta for analysis. Appropriate Quality Assurance Plans will be prepared and implemented by ATSDR.

A.1.4. Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

There are no web sites related to the Colorado Smelter EI for children under 13 years of age.

A.2. Purpose and Use of Information Collection

Section A.1.2, Overview of the Data Collection System, provides information on the data collection procedures. 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 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., the U.S. Environmental Protection Agency (EPA) and their 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 Colorado 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 sampled participants.

A.2.1. Privacy Impact Assessment

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

Children: No large-scale testing in children in the surrounding neighborhoods has been completed. Only a small fraction of children from one of the neighborhoods nearby the former smelter and slag pile were tested for blood lead and no urine arsenic testing was done.

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.

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

No small businesses are included in the Colorado 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.

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. 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. Groups outside the agency were consulted to obtain their views on whether the four criteria for an EI were fulfilled, as discussed in Section A.1:

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

ATSDR will not provide payments or gifts to participants.

A.10. Assurance of Privacy Provided to Respondents

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 Colorado 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

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 survey, 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.

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 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.

All staff working on the project agree to safeguard the data and not to make unauthorized disclosures. 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 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 be protected. The consent forms for the Colorado 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. Colorado 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. The Colorado Smelter EI assent, consent, and parental permission forms are provided in Attachment 3.

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 Colorado 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 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 Colorado 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 survey 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 100.

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)	Form
EI participants	300	1	20/60	100	Yes

A.12.2. 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 \$2,135. 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	100	1	\$21.35	\$2,135

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 – GS14-8)	1000	\$59.71	\$59,710
Medical Officer (Medical Officer – O-6)	200	\$50	\$10,000
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			\$95,930

Non-Personnel EI Costs	
Travel costs	

Attachment 1. Colorado Smelter Exposure Investigation: Supporting Statement A

Atlanta Personnel		\$9,017.00
Regional Personnel		\$4,268.00
Laboratory costs		
Includes phlebotomist, shipping and sample analysis		\$63,400.00
TOTAL NON-PERSONNEL COSTS		\$76,685.00
TOTAL EI COST	Personnel + Non-Personnel costs	\$172,615.00

The travel costs include the following:

- Travel to the site from Atlanta (2 people) and Denver (2 people) for two weeks to recruit participants and perform the blood and urine collection
- Travel to the site from Atlanta (1 person) and Denver (1 person) to complete followup urine collection
- Travel to the site from Atlanta (1 person) and Denver (1 person) for a followup 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.14-1 Project Time Schedule

The project Time Schedule for the Colorado 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

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.