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RE: Draft Public Health Study Remedial Design Work Plan for the Butte Priority Soils Operable Unit

Dear Ladies and Gentlemen:

Enclosed for your review is the draft Public Health Study Remedial Design Work Plan ("draft Work Plan") required by the U.S. Environmental Protection Agency (EPA) Unilateral Administrative Order (UAO) for "Partial Remedial Design/Remedial Action Implementation and Certain Operation and Maintenance at the Butte Priority Soils Operable Unit/Butte Site" (EPA Docket No. CERCLA-08-2011-0011). Butte-Silver Bow County (BSB) and Atlantic Richfield Company (AR), as Group 1 responsible parties under the UAO, have been working together and in consultation with EPA, the Montana Department of Environmental Quality, the Agency for Toxic Substances and Disease Registry, and members of a Health Studies Citizens' Advisory Committee to prepare the enclosed draft Work Plan.

The draft Work Plan satisfies the first public health studies deliverable specified in the UAO. In addition to the Work Plan for support of Superfund activities under the UAO, BSB submits with this letter BSB's Preliminary outline and schedule for conduct of a Summit Valley air quality

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study which is included as Appendix C to the Work Plan. The air quality study falls outside the purview of the Superfund program and is not provided to EPA as a deliverable under the UAO. The Summit Valley air quality study will be addressed in a separate process led by BSB.

If you have any questions, please do not hesitate to contact us.

Sincerely,

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DRAFT

Butte Priority Soils Operable Unit
Public Health Study
Remedial Design Work Plan
Phase 1 Studies

Prepared for:
Butte Silver Bow County and Atlantic Richfield Company
Butte, Montana

Prepared by:
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Date:
October 2012

Project Number:
3023914E

ENVIRON

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Acronyms and Abbreviations

AR	Atlantic Richfield Company
ATSDR	Agency for Toxic Substances and Disease Registry
BLL	Blood lead level
BPSOU	Butte Priority Soils Operable Unit
BSB	Butte Silver Bow
CAC	Citizens' Advisory Committee
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
DQO	Data Quality Objective
ENVIRON	ENVIRON International Corp
EPA	U.S. Environmental Protection Agency
HD	Health Department
MCSEP	Montana Cancer Surveillance and Epidemiology Program
MDEQ	Montana Department of Environmental Quality
mg/kg	milligram per kilogram
QNS	Quantity not sufficient
RMAP	Residential Metals Abatement Program
µg/dL	microgram per deciliter
WIC	Women, Infants and Children program
XRF	x-ray fluorescence

1 Introduction

As required by the U.S. Environmental Protection Agency (EPA) Unilateral Administrative Order (UAO) for "Partial Remedial Design/Remedial Action Implementation and Certain Operation and Maintenance at the Butte Priority Soils Operable Unit/Butte Site" (EPA Docket No. CERCLA-08-2011-0011; see Attachment 1), as well as the Final Multi-Pathway Residential Metals Abatement Program Plan (RMAP; April 2010; see Attachment 2), Butte-Silver Bow County (BSB) will perform public health studies every five years for a period of thirty years. This Public Health Study Remedial Design Work Plan ("Work Plan") satisfies the first public health studies deliverable specified in the UAO related to Superfund activities. The Work Plan also includes an outline to evaluate non-Superfund activities.

The activities to be conducted as part of the public health studies are described in the RMAP and include:

1. Identifying chemicals that the residents may have been exposed to, and compiling and interpreting toxicology information on those chemicals and routes of exposure.
2. Compiling and interpreting health studies as well as morbidity and mortality statistics as an epidemiology study, including influencing factors (environmental or cultural) for mortality rates.
3. Reviewing the latest epidemiological literature to determine if there are any newly established links between contaminants of concern and specific diseases.
4. Evaluating data gathered through the RMAP's routine activities and the results of previous public health studies to determine the content of future public health studies and potential improvements to RMAP routine activities.

Conduct of these activities is expected to address broad public health concerns encompassed under both Superfund and non-Superfund program activities within and near the Butte Priority Soils Operable Unit (BPSOU). All concerns will be addressed in the periodic public health studies using an iterative process that focuses initial study resources on evaluation of currently available information to inform the need for and direction of subsequent evaluations to be conducted in later study phases. Accordingly, a public health studies planning team comprised of representatives from EPA, the Montana State Department of Environmental Quality (MDEQ), BSB, the Agency for Toxic Substances and Disease Registry (ATSDR), and Atlantic Richfield Company (AR) began meeting in April 2012 to discuss the comprehensive goals of the public health studies and to develop and prioritize plans to address these goals in phases. Input to the planning process was provided by the community during two BSB public listening sessions and a BSB public meeting, during which BSB provided a summary of input received from the community at the two earlier listening sessions. Details of the public health study planning process were also provided at the public meeting.

1.1 Focus of Initial Public Health Studies Phase

As described above, implementation of the public health studies will occur in an iterative manner with subsequent phases of proposed study to be guided by the findings of prior phases. This Work Plan focuses on the initial study phase.

As part of planning for the initial study phase, the planning team identified the need for an update to and expansion of a 2001 ATSDR review of Silver Bow County cancer incidence rates compared to similar data for Montana and the U.S. (ATSDR 2002). The ATSDR analysis focused on cancer outcomes associated with exposure to heavy metals including arsenic, and, to a lesser extent, lead and mercury. Update of the ATSDR study aligns with public health studies activities specified in the RMAP and was prioritized to address heightened concerns about elevated cancer mortality rates in Butte expressed by community members during public listening sessions. In response to this need, in May 2012, the Montana Cancer Surveillance and Epidemiology Program (MCSEP) completed a cancer incidence and mortality study evaluating BSB data in the context of comparable state and national data (see Appendix A).

Both cancer incidence and mortality rates were studied, but cancer incidence is a better measure of the risk of getting a disease. Cancer incidence measures the number of newly diagnosed cancer cases in a population each year and provides the best way to assess the risk of getting this disease. The cancer mortality rate, on the other hand, is the number of deaths that occur each year from cancer. Mortality rates reflect both the risk of getting cancer and the ability to get effective diagnosis and medical treatment. Two communities can have similar incidence rates, but very different mortality rates. In fact, a community can have a relatively low incidence rate, but a relatively high mortality rate because of limited access to services. Therefore, incidence rates are the best way to compare the risk of getting a disease and mortality rates are a way to compare access to care and treatment after people become ill.

The MCSEP study showed that age-adjusted incidence rates for all cancers combined, and for each of the four most common cancers (i.e., cancers of prostate, female breast, colorectal, and lung and bronchus), were not elevated in BSB during three time periods from 1981 through 2010. Cancer mortality rates were elevated in one of the three time periods examined, but not in the other two. Colorectal cancer mortality rates were consistently elevated, while mortality rates for cancers of prostate, breast and lung and bronchus were not elevated. For rarer cancers, neither incidence nor mortality rates were elevated. Some of these findings were limited by small data sets. Cancer incidence data in the Montana registry are comprehensive. The disparity in cancer incidence and cancer mortality findings suggests possible issues in Butte with the ability to get effective diagnosis and medical treatment, which may be a factor in the elevated mortality from colorectal cancer. Exploration of these and other MCSEP study findings may be of interest for future public health study phases but are not addressed in the Work Plan.

During planning for the initial study phase, the planning team also identified the need for development of a series of fact sheets to help address comments and questions raised during the public listening sessions. To date, BSB, MDEQ, EPA, ATSDR, and AR have collaboratively prepared four fact sheets each of which is included in Appendix B. One of these fact sheets provides an introduction to members of a Citizens' Advisory Committee (CAC) appointed by BSB Board of Health to provide technical support and guidance to BSB in the Work Plan design and implementation of the public health studies. Formation of the CAC was one of the early study priorities identified by the planning team during initial meetings. Other fact sheets developed to date include a summary of: the MCSEP cancer incidence and mortality study; a review of local drinking water quality; and a summary of EPA's process for identification of lead, arsenic, and mercury as contaminants of concern within the Butte Priority Soils Operable Unit

(BPSOU). Preparation of additional fact sheets that address other topics of interest expressed by the community is also planned.

During initial planning team discussions and community outreach sessions, a number of health concerns (e.g., asthma prevalence and poor air quality) were identified by members of the Butte community. For phase 1, evaluation of long-standing concerns by BSB residents regarding air quality in the Summit Valley is planned. Because management of regional air quality issues and other environmental conditions related to many of these public health concerns rests with BSB and/or MDEQ outside of the Superfund program, portions of the periodic public health studies that address these concerns will be designed and implemented under BSB's leadership as part of a separate process from the public health studies conducted to address concerns under the Superfund program. Appendix C includes a draft outline of the study design elements prepared by BSB to address the Summit Valley air quality study to be conducted during the initial public health study phase. A preliminary schedule for study execution is also included in Appendix C.

Specific to the Superfund program and aligned with public health study activities specified in the RMAP, the planning team identified evaluation of available RMAP biological monitoring data collected through 2011 as a priority for inclusion in the first phase of the public health studies as required by the UAO issued by EPA in 2011. Accordingly, the remainder of the Work Plan specifies the approaches for review and evaluation of available RMAP biological monitoring data that have been collected to date in order to objectively document the efficacy of the RMAP and identify areas where improvement to activities conducted via the RMAP is needed. Environmental data collected as part of the RMAP is also considered in the RMAP evaluation to assess the extent to which it provides information on effectiveness in mitigating exposure pathways and additional insights for interpretation of the biological data.

2 Phase 1 Public Health Study Design: RMAP Evaluation

The Superfund-related public health study required under the UAO to evaluate the RMAP program will focus on review and evaluation of biological data and will include consideration of environmental data to identify changes to RMAP activities that may be needed to effectively identify and mitigate potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. As Group 1 responsible parties, AR and BSB are responsible for the design, implementation, and funding of the Work Plan that pertains to this Superfund-related public health study. ENVIRON International Corporation (ENVIRON) has prepared the Work Plan on behalf of AR and BSB, and in close coordination with the public health studies planning team representatives from EPA, MDEQ, ATSDR, and the CAC.

Sections of the Work Plan that follow are specific to the RMAP evaluation public health study proposed for Phase 1 of the periodic public health studies.

2.1 Background

Background information regarding the BPSOU study area and population characteristics of the Butte community is summarized below along with an overview of the RMAP including available environmental and biomonitoring data collected in conjunction with the RMAP. Prior health studies that may be relevant to informing the current public health study are also summarized.

2.1.1 BPSOU Study Area and Population

The BPSOU surface boundaries are defined under the Superfund Program. The BPSOU is approximately five square miles centered on "Butte Hill," the location of the historic Butte Mining District and includes residential, commercial, and industrial properties as well as schools and parks. The boundaries of the proposed public health study coincide with the areas addressed by the RMAP (Figure 1), which includes the BPSOU and an identified adjacent area as well as a separate attic abatement area which may have an exposure pathway associated with attic dust although this area was not historically associated with mining or smelting waste dumps.

The 2011 population estimate for Butte-Silver Bow is 33,704 (US Census Bureau 2012). Butte has a high percentage of individuals greater than 65 years of age (16.4 percent compared to 14.8 percent for Montana and 13.3 percent for the U.S.). EPA's 2012 Draft Community Engagement Plan identifies Butte as an area of potential environmental justice concern. The percentage of people living in poverty is higher in Butte (17.5 percent) than in Montana (14.5 percent) or the U.S. (13.8 percent). Additionally, 46.7 percent of families with children less than five years old within Butte have incomes below the poverty level (US Census Bureau 2010).

Starting in the late 1800s and continuing for 120 years, copper mining and related activities, including processing and smelting, occurred in Butte. Mining and ore-processing wastes (e.g., mill tailings, waste rock, slag, smelter fallout) in Butte related to mining represent primary sources for contaminants of concern, namely aluminum, arsenic, cadmium, copper, iron, lead, mercury, silver, and zinc (EPA 2011). While this complete list of contaminants may be of concern in surface water and/or groundwater, the list of contaminants of concern for soil is arsenic, lead, and mercury, as determined in the Superfund human health risk assessment for BPSOU. Appendix B includes a fact sheet regarding how EPA identified contaminants of concern in BPSOU soil. Remediation within the BPSOU is ongoing and has included, in addition to the RMAP, removal of mine waste dumps, cleanup along railroads, removal of sediment, and capture and treatment of ground and storm water.

Human health risk assessments conducted for the BPSOU concluded that arsenic and lead are the primary contaminants of concern for residential soil and dust. A subsequent risk assessment for the Walkerville neighborhood resulted in the addition of mercury to BPSOU contaminants of concern.

2.1.2 Overview of the RMAP

In accordance with EPA requirements under the Superfund remedy for the BPSOU, the BSB Health Department operates a multi-pathway RMAP "[t]o ensure public and environmental health of the residents of the [BPSOU] and the adjacent areas by effectively identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury" (BSB & AR 2010). Development of a predecessor to the RMAP began in 1991 in response to EPA's Superfund directive to begin cleanups of yards with elevated soil lead. The final RMAP was developed in response to EPA's Record of Decision for BPSOU in 2006, and was approved by EPA in 2010. The RMAP specifies the processes and protocols for identification and evaluation of residential properties with respect to risk-based action levels for lead, arsenic, and mercury in

indoor dust and outdoor soil. An additional risk-based action level applies to mercury vapor in air[1] within residences.

For properties within the BPSOU and the identified adjacent area where one or more action levels is exceeded, the program details specific criteria used to prioritize abatement project selection and details the processes and requirements for conducting abatement of soil, living-space areas, and/or attic dust. Within the attic abatement area, selection criteria for abatement are limited to attics. All properties within the BPSOU, identified adjacent area, or attic abatement area, attic dust sampling will be provided upon request by a resident or upon receipt of a development proposal which may result in development of an attic exposure pathway in a residential property. Cleaning of an attic in the attic abatement area will occur if the RMAP sampling result exceeds an action level and there is "either a pathway allowing dust from the attic to enter the living space or the property owner is planning a remodel that will disturb the attic (non-living space) dust." Properties with attic dust results above an action level, but without an established exposure pathway or planned remodel are tracked over the long-term for abatement if exposure pathways arise in the future.

As part of the evaluation process, BSB personnel complete an in-home assessment and assist the homeowner and/or occupant with completion of a questionnaire to evaluate the residence for potential exposure pathways. Due to the multi-pathway focus of the RMAP, possible sources of metals exposure sampled for the presence of arsenic and lead may include outdoor soil, and/or interior dust, tap water, and interior and exterior paint (for lead only). Based on information from the in-home assessment and resident questionnaire, BSB will determine whether or not a direct pathway for exposure to the attic or crawl space (non-living spaces) exists and, if so, a sample is collected and submitted for analysis for lead, arsenic and mercury. If sampling results indicate results above defined action levels, the property owner is afforded the opportunity for abatement.

Environmental data collected as part of the home evaluation process are compiled in an electronic database managed by BSB. In conjunction with development of the Work Plan, BSB provided with a copy of the RMAP environmental database (as a Microsoft Access file) in July 2012. Since that time BSB has undertaken additional database development and quality assurance work related to that database and advised AR to defer further database review until the updated version was provided. The updated version was provided on October 23, 2012 and review has been initiated, but not yet completed. Consequently, section 2.1.2.1 of this Work Plan currently summarizes information contained within the July 2012 environmental database. Section 2.1.2.1 will be updated in the final Work Plan, as needed, once review of the October 23, 2012 environmental database is completed.

The RMAP also specifies distribution of educational materials to owners/occupants by BSB personnel during in-home assessments. Advertisements and direct mailings to various target groups are also delivered periodically to promote community awareness and education regarding potential risks from exposure to lead, arsenic and mercury within the BPSOU.

[1] Monitoring for mercury vapor in air is conducted if the action level for mercury in dust is exceeded. Elevated mercury in exposed earthen basement soils will also trigger collection of a mercury vapor sample in basement air.

A voluntary blood lead monitoring program is also operated by BSB as part of the RMAP. Participation in the blood lead testing program by resident children age 6 and under as well as expectant or nursing mothers is encouraged through a variety of means, including community/education outreach efforts, in-home assessments, referrals from local physicians, and the Women, Infants and Children (WIC) program. Blood lead data collected for the monitoring program is used to identify children who have blood lead levels (BLLs) greater than 10 micrograms per deciliter[2] (µg/dL). Additionally, the final EPA-approved RMAP also states that blood mercury and urinary arsenic testing will be offered to the residents if elevated concentrations of mercury or arsenic are discovered during the environmental assessment process. Prior to approval of the RMAP in April 2010, only blood lead testing was offered. After the RMAP was approved, BSB began offering arsenic and mercury biomonitoring if and when the action levels for arsenic and mercury, respectively, are exceeded in an indoor dust vacuum sample collected under the RMAP. However, since April 2010, environmental assessments conducted under the RMAP have identified only a single property with arsenic above the action level in an indoor dust vacuum sample. BSB has confirmed that residents at this property declined the offer of urinary arsenic testing. None of the properties assessed since April 2010 have had elevated mercury in indoor dust vacuum samples. In the absence of RMAP-related blood mercury or urine arsenic data, this public health study is focused on the very large amount of blood lead data that has been collected.

Beginning in early June, a team of professionals contracted by BSB began electronic compilation of individual biological monitoring records from all available[3] hardcopy records that are maintained by BSB. These records and the electronic database under development contain confidential information that is protected from public disclosure by federal and state privacy laws. The data may be accessed only by individuals working for BSB under a confidentiality agreement. A summary of the data compilation process used, including quality assurance measures, is provided in Appendix D. The initial biomonitoring data compilation effort was followed by additional database development activities including researching missing information and compiling housing age data for the Butte community to support future data analyses. The process of participant and neighborhood coding to preserve confidentiality is continuing during October 2012, as are efforts to ensure compatibility of the biological monitoring database with the existing RMAP environmental database. Section 2.1.2.2 provides a summary of the information contained in the biomonitoring database.

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[2] In May 2012 Centers for Disease Control and Prevention (CDC) accepted a recommendation from the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) to use the 97.5th percentile of blood lead levels in children aged 1 to 5 years old, currently corresponding to a value of 5 µg/dL (CDC 2012). Guidance for use of this level by various government agencies has not yet been issued. Evaluating whether and how the new reference level should be implemented by BSB HD is beyond the scope of this study (although it is reasonable to assume the new reference level will be adopted). The proposed study will fully characterize the available data, including presenting numbers or percentages of the population exceeding both 10 and 5 µg/dL.

[3] Some of the hardcopy records for biological samples collected since the RMAP and its predecessor program began were not located in the files maintained by BSB. Some of the unavailable records correspond to individual sample results reported verbally by St. James Hospital or by private physicians to BSB or WIC representatives for program follow-up. Older hardcopy records may also have been discarded by BSB and/or WIC over time. Consequently, the total number of blood lead screening results and the total number of elevated blood lead results reported by BSB in annual Construction Completion Reports for the residential metals program is often different than the total number of available blood lead results for each year of data compiled from BSB hardcopy records.

2.1.2.1 Description of RMAP Environmental Database

As of December 31, 2011, a total of 1,869 properties have been visited under the RMAP or its predecessor program. Soil sampling has been conducted at 1,593 properties and attic dust has been assessed at 612 properties. Additionally, a total of 522 abatements for yard soil, attic dust, and/or interior living spaces were conducted through the end of 2011. Of these 522 abatements, 325 addressed yard soil, 160 addressed attic dust, and 37 addressed interior living space.

Most properties in the database are residential, but there are also a small number of commercial, playground, vacant lot, and other properties. Soil and dust sample data included in the database were collected from all of these property types. Available information on the soil samples includes: analytical results (for arsenic, lead, and mercury), the agency conducting the sampling, sampling criteria (i.e., reason for the sampling), and the general location on the property where sampling was conducted (e.g., attic, basement, driveway, garden, play area, north/south/east/west yard). Most samples are dated from July 1992 or later although there are a few earlier samples and some with no dates.

The database includes paint sample results collected mostly from residential properties. Paint sample results are reported in the database qualitatively, as either above or below the federal standard for lead in paint (1.0 milligram per square centimeter [mg/cm^2] or 0.5 percent by weight). Other information associated with paint sample results pertains to the agency conducting the sampling, whether x-ray fluorescence (XRF) was used for the sample, and the general location on the property where the sample was collected (e.g., interior and/or exterior, outbuilding, or other). Most paint samples are dated from February 1992 or later.

The environmental database includes abatement data for playground, residential, vacant lot, and other properties. Abatement-related information contained in the database includes the following:

- abatement criteria (e.g., an elevated blood lead);
- identification of the agency conducting the abatement; and
- general location on the property where abatement was conducted (e.g., basement, yard, exterior, interior).

Project summary fields include narrative descriptions of abatement activities such as:

> *Interior: Interior of home was thoroughly cleaned utilizing the HEPA vac. TSP cleaning solution was used on non-carpeted surfaces. Windows in master bedroom and mother's bedroom were wet scraped and repainted. Other windows were treated as necessary.*
>
> *Exterior: Front porch floor was removed and replaced with redwood decking. Portions of the garage were scraped and repainted. Portions of the playhouse were also wet scraped and repainted.*

Project recommendation fields within the database are similarly descriptive, for example:

> *Exterior painted surfaces on the house and garage should be kept in good repair. If allowed to deteriorate the surfaces may result in unnecessary exposure to lead.*

Abatement records included in the environmental database range from August 1995 to July 2012.

A quality assurance review of the recently received RMAP environmental database, building upon what has already been done by BSB, is advised to ensure accuracy and completeness of available environmental records needed to inform the public health study. In addition, because much of the information of potential value to the public health study may be included in comment fields in the database, extraction and reorganization of the database may be necessary prior to use in the public health study.

2.1.2.2 Description of the RMAP Biomonitoring Database

As described previously, electronic compilation of individual biological monitoring records from hardcopies maintained by BSB was initiated in June 2012. The initial compilation effort has been completed; however, extraction by BSB of missing identifying information (i.e., addresses) for some records was still in progress during October 2012. Collectively, these individual biomonitoring results provide an overview of exposure levels measured within the study population over time. Although the RMAP includes biomonitoring for lead, arsenic, and mercury, to date, only biomonitoring data for lead were included in the records maintained by BSB. Therefore, the remainder of the Work Plan focuses on blood lead biomonitoring data only.

Based on the records compiled from the June 2012 effort, BSB blood lead database presently includes 6,436 blood lead test results collected from July 2002 through December 2011. Data compiled includes the patient's first and last name, gender, birth date, full address, provider (e.g., WIC), blood lead result, blood collection date, and report date for the blood lead result. The blood lead results are further distinguished by test type as capillary whole blood, capillary filter paper, venous whole blood, or Lead Care II. Most of the results included in the database correspond to capillary blood lead samples collected from the year 2003 through early December 2011.

Blood lead results are available for December 2011 and the first half of 2012, but the collection and analytical method was changed at that time to the LeadCare II method. This method has the advantage of providing immediate results while the subject is still in the clinic; however, the detection limit (3.3 µg/dL) is substantially higher than the detection limit for the previous method (1 µg/dL). The higher LeadCare II detection limit may be adequate for screening individual blood leads to determine whether confirmation testing is recommended. However, due to the wide prevalence of blood lead levels below the LeadCare II detection limit, such data are not suitable for use in evaluating the distribution of blood leads within a given population in comparison to historical or comparison populations.

Records of blood lead data from 1992 through 2001 were not located (with a few exceptions)[4]. All blood lead monitoring records included in the database are maintained by BSB authorized staff and contractors to ensure confidentiality of personally identifying participant information including name and address.

The blood lead records include about 3,500 records for children ≥ 1 and < 5 years old, over 1,100 infants less than 1 year old, and about 1,000 pregnant women. Not all records are for Butte residents, and address, gender and/or birthdate are sometimes missing. Records are complete for over 2,500 Butte children, with over 300 records per year from 2003 through 2009. Hundreds of additional records from 2010 and 2011 may be complete once addresses are retrieved by BSB.

Blood lead data compiled from BSB includes results for Butte as well as outlying areas. For a number of participants, more than one blood lead result is available in the database. Most results are accompanied by a hemoglobin result collected within one day of the blood lead sample. Table 1 summarizes the total number of blood lead results by year as well as the total for all children ages 1 year to less than 5 years (including outlying areas and limited to Butte) and the totals for all Butte infants and pregnant women tested from 2002 to 2011. Numbers of results for each category shown in Table 1 may be revised as BSB continues to review records and provides missing addresses.

[4] As noted previously, some of the older hardcopy records may have been discarded by WIC over time consistent with laws governing document retention that applied to the WIC program at the time.

Table 1: Preliminary summary of electronically-compiled blood lead database with number of results by year

Year	Number of Blood Lead Results Compiled from BSB Records				
	All Locations		Butte Locations Only		
	Total[a]	Children Ages 1 to < 5 Years[b]	Children Ages 1 to < 5 Years[c]	Infants (<1 year old)[d]	Pregnant Women[e]
2002	183	126	123	32	17
2003	588	362	356	101	94
2004	533	331	318	69	106
2005	589	327	311	97	142
2006	693	335	324	170	145
2007	1079	348	343	444	186
2008	673	331	322	154	160
2009	606	371	363	64	149
2010[f]	691	479	478	--	--
2011[f]	703	485	485	--	--

Notes:

[a] Records compiled from Health Department records during June 2012 for all ages and all locations. Does not include the 38 samples classified as "QNS" or quantity not sufficient.

[b] Includes results from Butte and other towns and for children with missing gender and/or address information. Does not include the samples classified as "QNS" or quantity not sufficient.

[c] Includes capillary results with complete personal data (birthdate, address, and gender information) as well as results with unknown address information. Therefore, results for some children outside Butte may be included in these totals. Does not include the samples classified as "QNS" or quantity not sufficient.

[d] Includes complete data (birthdate, address, and gender information). Does not include the samples classified as "QNS" or quantity not sufficient. Blood lead analyses in infants, conducted at St. James Medical Center, were discontinued after 2009 due to finding consistently low levels.

[e] Includes results with complete data (birthdate, address, and gender information). Blood lead analyses in pregnant women, conducted at St. James Medical Center, were discontinued after 2009 due to finding consistently low levels. Additional data for women of childbearing age may be included once addresses are confirmed.

[f] May be revised as BSB continues to review records and provides missing addresses.

2.1.3 Summary of Prior Exposure Studies

Prior environmental exposure investigations conducted within the Butte Silver Bow area are useful to informing the scope and direction of the public health study design. Two studies have been conducted and are described below.

An extensive blood lead and urine arsenic exposure study was conducted by the University of Cincinnati for BSB and AR in 1990. Dr. Robert Bornschein was principal investigator. A final report of the study findings was issued in 1992 (BSBDH/UC 1992). The study included blood lead assessment of 294 children up to age six and found the geometric mean blood lead level was 3.5 µg/dL (Table 2), similar to U.S. levels and lower than values from other mining communities tested at that time.

Table 2: Blood lead results reported in 1990 Butte exposure study

Statistic	1990 Butte Blood Lead (µg/dL)					
	< 72 mo.	72 mo. to 18 yr.	Adults	Nursing Women	Pregnant Women	All
N	294	53	48	11	24	430
Geo. Mean	3.5	3.5	3.1	2.4	2.1	3.4
G. Std. Dev.	1.2	1.8	1.9	1.6	1.5	1.8
95%-tile	10.5	13.6	10.3	5.0	3.3	9.5
Maximum	25.0	18.0	12.0	5.0	3.5	25.0

This large study was designed to have high sensitivity to detect lead exposure sources in the community and included over-representation of children living in high risk areas. Over 230 children from older neighborhoods with more lead sources affecting the soil concentrations (including deteriorated lead paint) had higher geometric mean blood lead levels than the roughly 60 children from a mobile home park and newer neighborhoods. So, although the community blood lead levels were not elevated compared with national values, there was evidence of some influence of a combination of soil, dust and paint lead on blood lead levels. Table 3 shows blood lead statistics for children in the study by neighborhood and includes information about the relative significance of different lead exposure sources for each neighborhood.

Table 3: Blood lead results for children <72 months by neighborhood reported in 1990 Butte exposure study*

	1990 Butte Blood Lead (µg/dL)						
	Area A	**Area B**	**Area C**	**Area D**	**Area E**	**Area F**	**Area G**
Lead Exposure							
Exposure to Waste Rock or Mill Tailings	High	Medium	Medium	Medium	Low	Low	High
Presence of Lead Paint	High	Low	Medium	High	Medium	Medium	High
Presence of Lead Pipe	High	Low	Medium	Medium	Medium	Medium	High
Statistic							
N	183	15	12	11	27	17	13
Geo. Mean	3.7	2.3	4.6	4.6	2.7	3.0	3.8
G. Std. Dev.	1.8	1.7	1.9	1.8	1.5	1.5	1.7
95%-tile	10.9	4.0	14.5	22.5	5.6	6.5	8.0
Maximum	25.0	4.0	14.5	22.5	6.0	6.5	8.0

Notes:
* The study also reports on 15 children less than 72 months that were outside of the study areas.

Based on the findings of this study, Dr. Bornschein and his co-investigator, Dr. Clark, recommended to the Board of Health that a blood lead surveillance and abatement program be established in Butte (June 5, 1991 letter included in the 1992 report). The RMAP was based, in part, on this recommendation. The findings of this study also provided site-specific data used by EPA in their health risk assessment and cleanup goal development.

The 1990 study included environmental samples (i.e., yard soil, dust, tap water, lead paint), as well as blood lead samples. The blood lead data and the environmental data were used to develop a structural equation model of lead exposure pathways. This analysis showed that residence location (i.e., neighborhood) and house age were the strongest predictors of paint lead, soil lead, and dust lead concentrations. Lead-based paint was shown to be associated with lead contaminated soil, which was in turn associated with lead contaminated house dust. Only house dust lead was directly related to blood lead. The indirect effect of soil lead on blood lead was shown to be both small and weak. The investigators concluded that 39% percent of the variability in soil lead concentrations was attributable to lead-based paint, while the remainder (61%) was attributable to “the heterogeneous distribution of lead in soil, and lead from other sources such as native lead in soil, mine waste and contaminates from ore

processing". Gardening or eating home grown produce was shown not to contribute to elevated BLLs.

The 1990 study also included collection of urine arsenic samples in a subset of the study subjects (N = 140). Mean urine arsenic concentrations did not increase with increasing soil arsenic concentrations in Butte (Table 4).

Table 4: Urinary arsenic results reported in 1990 Butte exposure study

Statistic	1990 Butte Urine Arsenic (µg/L)		
	All soil < 50 ppm As	Soil As 50-100 ppm*	Soil As > 100 ppm*
N	31	83	26
Mean	13.0	14.1	13.1
Std. Dev.	6.5	8.9	7.1
Median	13.0	12.0	11.5
95%-tile	25.0	30.5	27.0
Maximum	26.5	43.5	28.0

Notes:
* One or more yard samples.

In another study, ATSDR, in collaboration with BSB, conducted a health consultation focused on Walkerville that included blood lead and urine arsenic (ASTDR 2001). This study targeted residents of 28 houses with the highest indoor lead and arsenic dust concentrations that had resident children or regularly visiting grandchildren. House dust lead concentrations ranged from 1,130 to 4,640 milligrams per kilogram (mg/kg), while dust arsenic concentrations ranged from 3 to 131 mg/kg. The study was conducted during April 2001. Seventy percent of the children who qualified for this study participated, although not all children provided both blood and urine samples. Some adults from these households also participated. The highest blood lead level among the 9 children and 14 adults providing blood samples was 5 µg/dL (in a 70 year old adult). Fourteen samples (61 percent) were below the detection limit of 1 µg/dL. All 25 urine arsenic concentrations[5] were below the detection limit of 10 µg/L. ATSDR (2001) concluded that this study had good community participation and that, despite the high levels of lead in dust in the selected homes, "all blood lead levels and urine arsenic levels were well below levels of health concern."

2.2 Study Objective and Approach

The primary study objective to be addressed by the Work Plan is the review and evaluation of available RMAP data that have been collected to date in order to objectively document the

[5] Analyses were for speciated arsenic (i.e., inorganic arsenic and its metabolites, monomethylarsonic and dimethylarsinic acid).

efficacy of the RMAP and identify any areas where improvement to activities conducted via the RMAP may be needed to effectively identify and mitigate potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. Available RMAP biological screening data are limited to blood lead results. RMAP data collected to date include environmental assessment, abatement data, including lead, arsenic, and mercury concentrations in outdoor soil, and/or interior dust, tap water, air vapor (for mercury only) and interior/exterior paint (for lead only).

With regard to available blood lead data, analyses of the more than ten years of blood lead data compiled by BSB to assess blood lead levels (BLLs) in Butte children and pregnant women will be used to address the study objective. Summary statistics will be presented by year, including geometric mean, geometric standard deviation, 95th percentile and numbers (or percent) exceeding 5 and 10 µg/dL. The analyses will include time-matched comparisons of the distribution of study area BLLs to the distribution of BLLs within a comparison population. Selection of an appropriate comparison population for use in this analysis will consider the representativeness of the population sampled (i.e., sample size, age and demographics) as well as variability within the population and in measurements (i.e., sample type, analytical methods, and detection limits)[6]. Several approaches will be considered for identifying comparison populations, and it is possible that several such populations, each with different advantages and disadvantages, will be used. One approach is to identify a comparable Montana community (e.g., Billings) with sufficient blood lead data from some or all of the years for which Butte data are available. A second approach might involve adjusting data from the National Health and Nutrition Examination Survey (NHANES) (e.g., based on altered detection limits and house age profile and other characteristics) to develop an NHANES-based comparison population.

The analyses of blood lead data will also include a comparison of the distributions of BLLs across different neighborhoods of the study area to determine whether statistically significant differences in BLLs among neighborhoods that were identified in the 1990 by the University of Cincinnati study investigators have diminished as the number of abatements under RMAP has increased. The neighborhoods are still to be defined, and will be much more inclusive of the entire BPSOU than was the 1990 study. That said, the neighborhood breakdown from the 1990 study needs to be included so that these findings can be compared with more recent data. Once maps are developed showing numbers of blood lead samples by proposed neighborhoods, input will be solicited from advisors and the community to refine the neighborhood boundaries.

Execution of the RMAP and its predecessor program since 1992 has resulted in environmental assessments at nearly 1,600 properties, with more than 500 abatements conducted through the end of 2011. These environmental and abatement data will be summarized and the impact of

[6] There are differences between the methodologies used for previous blood lead studies conducted in Butte and the blood lead measurements that are on-going. In the 1990 Butte study (BSBDH/UC 1992), blood lead was measured in venous whole blood and analyzed by anodic stripping voltammetry. The detection limit was not explicitly stated, but the lowest value reported was 1 µg/dL. The 2001 Walkerville study (ATSDR 2002) also measured lead in venous whole blood. The detection limit in this study was 1 µg/dL, and the analytical method was not reported. The majority of the data compiled from BSB is from the analysis of capillary blood using either whole blood or filter paper. The detection limit for both is 1 µg/dL with the exception of recent analysis conducted with LeadCare II where the detection limit is 3.3 µg/dL.

these abatements on arsenic, lead, and mercury exposure pathways will be described. These data have not yet been linked to the blood lead data. Environmental data are available for many properties for which blood lead data are not available, and conversely, environmental data are not available for many people for whom blood lead data are available. The number of properties with both blood lead and environmental data will be determined and presented as the number with blood lead data from before or after abatement or both. These properties will also be presented by neighborhoods. Once this summary is developed, approaches to assess the data will be developed. If numbers are insufficient to support a quantitative analysis, it may be necessary to evaluate the data qualitatively.

The findings of the blood lead data analyses in addition to the evaluation of environmental and abatement data will be interpreted with regard to the efficacy of the RMAP and whether changes to current RMAP activities are needed to effectively identify and mitigate potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. The findings of this initial phase of the periodic public health studies may also be used to inform the need for and direction of subsequent study phases. It is important to keep in mind that even if the RMAP is effective, some children will likely still have elevated blood lead levels for several reasons: 1) potential sources of lead exposure that are not addressed by the RMAP are likely to be present in study area homes; 2) blood lead data for children with elevated levels who have recently moved to Butte from other areas may be included in the study; and 3) blood lead data for children living in homes with soil/dust/paint sources that have not yet been tested or abated may be included in the study. It will also be necessary to take into account the long half-life of lead, and assess what magnitude of declines in blood lead levels might be expected since abatements were conducted.

2.3 Data Quality Objectives

This section of the Work Plan describes the data needs, intended uses, and data quality objectives (DQOs) for the blood lead data analysis portion of the proposed study. For Agency-funded or regulated environmental programs and projects, EPA requires that, before information or data are collected, a systematic planning process must occur to establish performance or acceptance criteria for the collection, evaluation, or use of these data (EPA 2006). EPA guidance (2006) for DQO development outlines a systematic planning process that is intended to ensure a clear linkage between the study research goals and objectives, and the final study product. Specifically, the process "uses a common-sense approach to ensure that the level of documentation and rigor of effort in planning is commensurate with the intended use of the information and the available resources." Although this study does not involve new data collection efforts, EPA's DQO planning process was determined to be a useful guide for the Work Plan.

The EPA DQO process consists of seven steps, listed below and detailed in the following section:

1. State the Problem
2. Identify the Goals of the Study
3. Identify Information Inputs

4. Define the Boundaries of the Study
5. Develop the Analytical Approach
6. Specify Performance and Acceptance Criteria
7. Develop the Plan for Collecting Data.

2.3.1 Step 1: State the Problem

In accordance with EPA requirements under the CERCLA removal and remedy actions for the BPSOU, BSB has been conducting activities under the multi-pathway RMAP (and its predecessor) to effectively identify and mitigate potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community since 1992. Evaluation of the biomonitoring data collected as part of the RMAP is needed to assess the efficacy of ongoing monitoring and abatement activities and to identify any necessary improvements to the program.

For this Superfund-related public health study, the planning process will be led by BSB and AR, as Group 1 responsible parties. In addition to a Health Studies Citizens' Advisory Committee (CAC) appointed by the BSB Board of Health, EPA, ATDSR and the State of Montana will provide ongoing technical support and input to the study development. The Work Plan and the resulting public health study will be subject to approval by EPA, in consultation with DEQ.

Funding for the Work Plan and public health study will be secured by BSB in partnership with AR. The draft public health study Work Plan is scheduled for completion by October 31, 2012, with completion of the final Work Plan by February 28, 2013 following a public review and comment period. Implementation of the first public health study under the Work Plan is expected to be completed in September 2013.

2.3.2 Step 2: Identify the Goal of the Study

As stated previously, biomonitoring data collected as part of the RMAP is needed to assess the efficacy of ongoing monitoring and abatement activities and to identify any necessary improvements to the program. Further, the final RMAP states: "Data gathered through the [RMAP's] routine activities and the results of previous public health studies will be utilized to determine the content of future public health studies and potential improvements to RMAP routine activities."

The principal study question to be addressed by this public health study is:

> **Do environmental and biomonitoring data collected for the RMAP support a finding that the program has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community and, if not, what actions can be taken to improve the efficacy of the RMAP?**

If RMAP (or predecessor program) data collected since 1992 indicate that the program has not effectively identified and mitigated potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community, then deeper investigation into the likely cause(s) of this

outcome will be conducted and appropriate response actions will be identified and evaluated to improve the effectiveness of the RMAP. Potential response actions may include, but are not limited to revisions to program implementation approaches and practices including, but not limited to: record-keeping; long-term tracking of properties; sequencing and timeliness of assessments and abatements; consideration of alternate sources of lead exposure or magnitude of exposures; additional testing and biomonitoring for residents in previously remediated and non-remediated residences; and limited door-to-door interviews and encouragement of additional participation in the overall residential monitoring and abatement program.

2.3.3 Step 3: Identify Information Inputs

Data and information needed to assess the efficacy of the RMAP may include some or all of the following:

- Reliable and representative distributions of recent and past BLLs within the Butte community prior to and since initiation of the RMAP activities
- Reliable and representative distributions of BLLs within a community that is comparable to Butte, except for Butte's mining history, for the same time periods evaluated for Butte community data
- Reliable and representative measures of arsenic, lead, and mercury concentrations in Butte residential soils and indoor dusts for both remediated and non-remediated residential properties
- Information concerning mining versus non-mining sources of lead documented during RMAP home assessments
- Information regarding the types, locations and number of abatements resulting from the RMAP for each constituent of concern
- Analytical methods, analytical results and an evaluation of the quality of the analytical data collected in conjunction with RMAP activities
- Other data, as appropriate, relevant to the operation and evaluation of the efficacy of the RMAP (e.g., house age information).

Many of the above information inputs are available in the environmental and biomonitoring databases developed for the RMAP. Additional sources of information may include environmental data collected as part of Superfund-related remedial investigation activities, prior exposure studies conducted within the Butte community, and readily available exposure data for other reference communities.

Lines of evidence to be evaluated to assess the efficacy of the RMAP include:

1. Whether or not statistically significant differences in BLLs identified across neighborhoods within the Butte community prior to implementation of RMAP activities have persisted following implementation of RMAP activities.

2. Whether or not time-matched blood lead distributions for the study population BLLs are comparable to those in an appropriate comparison population.

3. Whether or not residential abatements have reduced exposure pathways for arsenic, lead and mercury.

Site-specific blood lead data from the RMAP biomonitoring database will be used in the evaluation. Environmental lead data will also be considered. Quality assurance review of each dataset will be performed prior to use.

2.3.4 Step 4: Define the Boundaries of the Study

The BPSOU surface boundaries are defined under the Superfund Program. The BPSOU is approximately five square miles centered on "Butte Hill," the location of the historic Butte Mining District and includes residential, commercial, and industrial properties as well as schools and parks. The spatial boundaries of the proposed public health study coincide with the areas addressed by the RMAP (Figure 1), which includes the BPSOU and an identified adjacent area as well as a separate attic abatement area which may have an exposure pathway associated with attic dust although this area was not historically associated with mining or smelting waste dumps.

Due to potential for more intense exposures with potentially affected environmental media and increased sensitivity to adverse health effects that may be associated with exposures, the target populations of interest are young children (under the age of 6 years) who reside within or are regularly cared for within these spatial boundaries and pregnant mothers living within the study boundaries.

Data needed for conducting the study have previously been collected as part of Superfund-related remedial investigation activities and in conjunction with the RMAP. Additional site-specific data collection is not anticipated as part of the study. However, blood lead data for comparison populations (children and pregnant women) outside of Butte will be researched and compiled upon initiation of the public health study. Selection of an appropriate comparison population for use in this analysis will consider the representativeness of the population sampled (i.e., sample size, age and demographics) as well as variability within the population and in measurements (i.e., sample type, analytical methods, and detection limits).

Some of the data to be utilized in analyses and decision-making (e.g., blood lead testing data) are associated with personally identifying information for sample donors. In addition, delineation of subareas within the Butte community to be used in comparative neighborhood analyses will also require access to confidential street address information housed within the electronic databases. Coded data will be developed to protect individual confidentiality.

The appropriate scales of decision-making will be the timeframe within which the RMAP has been executed and locations where data have been collected.

2.3.5 Step 5: Develop a Decision Rule

Appropriate statistical measures of significance will be identified for data comparisons and trend analyses used to evaluate the RMAP efficacy lines of evidence and to determine what actions, if any, are advised by the study.

If the lines of evidence favor a finding that improvements to the RMAP are needed to effectively identify and mitigate potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community, then response actions appropriate to addressing identified RMAP deficiencies will be investigated and proposed.

2.3.6 Step 6: Specify Tolerable Limits on Decision Errors

Any decision on revisions to the RMAP and design of future study phases must be made with regard to a demonstration that the RMAP has effectively identified and mitigated potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. The environmental data will be examined directly for evidence of reductions in exposure pathways, while biomonitoring data will require more community-wide data. For lead two requirements will be necessary to affirmatively demonstrate this reduction:

1. Statistically significant differences in BLLs across neighborhoods within the Butte community, measured in conjunction with the RMAP, will be reduced relative to differences documented pre-RMAP differences in BLLs across these same neighborhoods.

2. Temporal trends in Butte community BLLs and in general population BLLs will be similar in recent years.

Prior to evaluating the hypotheses presented below for each of these requirements, it will be determined that: (1) the database sample size has sufficient power to detect statistically significant neighborhood differences for pre- and post-RMAP conditions; (2) the database sample size has sufficient power to detect statistically significant differences between distributions of blood lead within the study and comparison populations; and (3) the blood lead sample is representative of the study population both spatially and in terms of exposure to lead in soil.

To meet these requirements, the baseline condition has been selected as “the RMAP has not been effective,” while the alternative condition is “the RMAP has been effective.” Two sets of statistical hypotheses are then:

Requirement 1 –

$H1_0$: Statistically significant differences in BLLs between specific neighborhoods evaluated in 1990 are still evident based on more recent BLL data.

$H1_A$: Statistically significant differences in BLLs between specific neighborhoods evaluated in 1990 are no longer evident based on more recent BLL data.

Requirement 2 –

$H2_0$: BLL distributions within the study population are significantly higher than BLL distributions for the comparison population based on statistical comparisons of time-matched data.

$H2_A$: BLL distributions within the study population are not significantly higher than BLL distributions for the comparison population based on statistical comparisons of time-matched data

Unless the data analysis provides conclusive information to reject the null hypotheses (i.e., the baseline condition) for the alternative hypotheses (i.e., the alternative condition), we therefore assume that the baseline condition is true.

A false acceptance decision error corresponds to deciding that the RMAP has not been effective, when in reality it has been effective. In contrast, a false rejection decision error corresponds to deciding that the RMAP has been effective, when in reality it has not been effective. The following consequences have been identified for each type of error:

- The consequences of making a false acceptance decision error are: 1) the cost of making changes to the program that are unnecessary to ensure continued management of long-term potential exposures to lead within the Butte community; and 2) the negative perception by individuals within the Butte community that long-term potential exposures to lead are not being managed by the RMAP program as intended.
- The consequences of making a false rejection decision error are: 1) inadequate management long-term potential exposures to lead within the Butte community; and 2) continued expenditures toward ineffective risk management strategies.

Uncertainty in deciding whether to reject or accept the baseline condition exists when different decisions are made with regard to each set of hypotheses tested (i.e., $H1_0$ is rejected, while $H2_0$ is not rejected). However, because appropriate response actions will be determined for any needed improvements to the RMAP that are identified as part of the public health study, the consequences of such decision uncertainty are minimal.

2.3.7 Step 7: Optimize the Design for Obtaining Data

A quality assurance review will be conducted of all RMAP environmental and biomonitoring data selected for inclusion in the public health study. No additional samples will be collected to address this DQO. Proposed selection of a reference datasets to support BLL comparisons will be documented in a technical memorandum for EPA approval prior to completion of the public health study.

2.4 Public Health Study Tasks

This section of the Work Plan summarizes the tasks that have been or will be undertaken to complete the public health study. These tasks are:

Task 1 – Project Planning

Task 2 – Community Outreach

Task 3 – Public Health Study Remedial Design Work Plan

Task 4 – Data Compilation

Task 5 – Quality Assurance Review

Task 6 – Data Analysis and Reporting

Activities associated with each task are described in the subsections below and correspond to the tentative schedule presented in Table 5. A revised schedule that includes specific dates will be prepared upon approval of the Work Plan.

2.4.1 Task 1 – Project Planning

Task 1 of the public health study is completion of project planning activities needed to initiate the public health study. This task culminates in the completion of the Public Health Study Remedial Design Work Plan (see Task 3). As part of this task, EPA, MDEQ, ATSDR, BSB, AR and their technical experts participated in public health study remedial design planning meetings in April and May 2012 during which preliminary scoping and data needs were identified. Specific needs identified during these planning meetings included compilation of BSB's multi-year biomonitoring records into an electronic database and acquisition of BSB's RMAP environmental database with modification, as needed, to allow for integration of both databases to support data analyses conducted as part of the public health study. These activities are discussed further under Task 4 – Data Compilation.

Task 1 activities also included identification of community involvement opportunities and mechanisms to be employed during the study, which are discussed further under Task 2 – Community Outreach.

The proposed schedule for execution of Task 1 activities is presented in Table 5.

2.4.2 Task 2 – Community Outreach

Task 2 of the public health study is conduct of community outreach activities. Outreach activities began early in the project planning process. In May 2012, BSB held a series of public listening sessions where members of the public were given the opportunity to provide critical valuable input regarding community environmental health concerns. EPA also held a public meeting in May to provide additional information about the planning activities being conducted for the public health study.

Additionally, during the EPA public comment period for the draft Work Plan (November/December 2012 timeframe), community outreach will include a community information meeting to provide the public opportunities to ask questions about and provide input on the draft Work Plan. The draft Work Plan community meeting will be organized in an open-house format with representatives from the study planning team available for individual discussions of the proposed study as well as other topics of interest identified during the May 2012 public listening sessions. EPA will also hold a public meeting at the conclusion of the 60-

day public comment period. The date for the second meeting has not been set, but is anticipated to take place during the first half of January 2013.

An additional community meeting(s) will be conducted following completion of the public health study (September/October 2013 timeframe) to share study findings and answer questions community members may have about the study conclusions.

Periodic community updates will also be disseminated via the Citizens' Advisory Committee throughout the public health study process.

The proposed schedule for execution of Task 2 activities is presented in Table 5.

2.4.3 Task 3 – Work Plan

Task 3, the Public Health Study Remedial Design Work Plan, as it pertains to Superfund-related activities, is being prepared to specify approaches for review and evaluation of RMAP data that can objectively document the efficacy of the RMAP and identify any areas where improvement is needed. Relevant site background information including review of available data and prior studies is provided in the Work Plan. Although this study does not involve new data collection efforts, EPA's DQO planning process was followed to ensure existing, available data will be suitable for the uses intended.

The schedule for completion of Task 3 deliverables is presented in Table 5.

2.4.4 Task 4 – Data Compilation

Task 4 of the public health study, data compilation, began in June 2012 with electronic compilation of individual biological monitoring records from hardcopies maintained by BSB. The initial biomonitoring data compilation effort was followed by additional database development activities including researching missing information and compiling housing age data for the Butte community to support future data analyses. As noted in section 2.1.2, these records contain confidential information that can only be accessed by individuals working for BSB under a confidentiality agreement. Until confidential information is removed, access limitations also apply to the electronic database.

As described in section 2.1.2, BSB provided AR with a copy of the RMAP environmental database (as a Microsoft Access file) in July 2012. Preliminary review of the environmental database has begun to support data analyses to be conducted in the public health study. For both databases, the process of participant and neighborhood coding to preserve confidentiality is continuing during September 2012. Efforts to ensure compatibility of the biological monitoring database with the existing RMAP environmental database are also continuing under this task.

Environmental data collected within the BPSOU as part of other Superfund-related activities (i.e., not included in the RMAP) may also be compiled to supplement environmental data included in the RMAP database. The need for these supplemental data will be assessed upon completion of review of the RMAP environmental database.

Task 4 will also include research and compilation of publically-available blood lead data for comparison populations (children and pregnant women) outside of Butte. Task 4 data

compilation efforts will continue through the project planning stage and are anticipated to be completed soon after Work Plan approval is received.

The proposed schedule for execution of Task 4 activities is presented in Table 5.

2.4.5 Task 5 – Quality Assurance Review

Task 5 – Quality Assurance Review activities began with the June 2012 compilation of BSB biomonitoring data. As described in Appendix D, compilation of hardcopy medical records into the electronic data files was conducted with 100 percent review (i.e., all entries were double-checked by a second data entry team member). Records with incomplete information, particularly missing addresses, have been identified and forwarded to BSB for follow up research.

In July 2012, a preliminary review of the database suggests that some data entry errors may be included and that records may be missing. Full quality assurance review of the RMAP environmental database is necessary prior to conduct of the public health study and will be included under Task 5.

AR and BSB will work with EPA to determine study-specific quality assurance review procedures for the final Work Plan.

The proposed schedule for execution of Task 5 activities is presented in Table 5.

2.4.6 Task 6 – Data Analysis and Reporting

Task 6 includes conducting analyses to support decision-making regarding the principal study question to be addressed by the public health study. Specifically, “Do environmental and biomonitoring data collected for the RMAP support a finding that the program has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community and, if not, what actions can be taken to improve the efficacy of the RMAP?” During this task, appropriate statistical measures of significance will be identified for data comparisons and trend analyses used to evaluate the RMAP efficacy lines of evidence and to determine what actions, if any, are advised by the study. Per Task 5, all data analyses will be submitted for quality assurance review prior to being finalized.

Reporting is also included in Task 6 and includes development of a technical memorandum summarizing selection of appropriate reference data for blood lead analyses as well as completion of a draft and final data analysis and summary report for the public health study. Identified recommendations for future improvements to the RMAP will be presented, as will recommendations to address identified lead exposure sources that fall outside the RMAP.

The proposed schedule for execution of Task 6 data analysis and completion of each deliverable is presented in Table 5.

Table 5: Preliminary schedule for implementation of the public health study	
Timing	**Activity or Deliverable**
2012 Schedule	
April	• Technical team meeting (Task 1)
May	• Technical team meeting (Task 1) • Community Listening Sessions & BSB Public Meeting (Tasks 1 & 2)
June	• Electronic compilation of BSB biomonitoring data (Tasks 4 & 5)
July	• CAC appointed by BSB Board of Health (Task 2) • Review of BSB's RMAP environmental database initiated (Tasks 4 & 5) • Biomonitoring database development and quality assurance (QA) activities (Task 4)
August	• Work Plan development meetings, including meetings with CAC representative (Tasks 1, 2, & 3) • Biomonitoring database development and QA activities (Tasks 4 & 5) • Continued review of RMAP environmental database and follow up with BSB (Tasks 4 & 5)
September	• Work Plan development (Task 3), including technical team meetings (as scheduled) with involvement by CAC representative (Tasks 1 & 2) • Biomonitoring database development and QA activities (Tasks 4 & 5) • Continued review of RMAP environmental database and follow up with BSB (Tasks 4 & 5)
October	• Work Plan development (Task 3), including technical team meetings (as scheduled) with involvement by CAC representative (Tasks 1 & 2) • **Draft Work Plan Deliverable to EPA** (Task 3) – **Due October 31st** • Biomonitoring database development and QA activities (Tasks 4 & 5) • Continued review of RMAP environmental database and follow up with BSB (Tasks 4 & 5)
November	• 60-Day Public Comment Period begins • Initiate selection of blood lead reference data set for comparison to Butte community (Task 4) • Continued biomonitoring database development and QA activities, as needed (Tasks 4 & 5) • Continued review of RMAP environmental database and follow up with BSB, as needed (Tasks 4 & 5)
December	• Draft Work Plan community information meeting (tentatively scheduled for December 3rd) (Tasks 1 & 2) • Draft Work Plan comments received from EPA (Task 3)

Table 5: Preliminary schedule for implementation of the public health study	
Timing	**Activity or Deliverable**
2013 Schedule	
January	• EPA Public Meeting at end of 60-Day Public Comment Period for Draft Work Plan • Work Plan revisions to address comments (Task 3), including technical team meetings (as scheduled) with involvement by CAC representative (Tasks 1 & 2) • Ongoing data compilation and QA activities, as needed (Tasks 4 & 5)
February	• Work Plan revisions to address comments (Task 3), including technical team meetings (as scheduled) with involvement by CAC representative (Tasks 1 & 2) • **Final Work Plan Deliverable to EPA** (Task 3) – **Due February 28th** • Ongoing data compilation and QA activities, as needed (Tasks 4 & 5)
March	• Ongoing data compilation and QA activities, as needed (Tasks 4 & 5) • **Preparation of technical memorandum summarizing selection of blood lead reference data set for use in study** (Tasks 4 & 6) • **EPA approval of Work Plan** (Task 3)
April	• **EPA approval of reference data selection** (Task 4) • Compilation of reference data (Task 4) • Final QA of site-specific data compiled for data analyses (Task 5) • Initiating data analyses to support study (Task 6)
May	• Complete data analyses to support study and QA (Tasks 5 & 6) • Prepare draft data analysis and summary report (Task 6)
June	• **Draft Public Health Study Report to EPA** (Task 6) • Public comment period (Task 2)
July	• Revisions to Draft Public Health Study Report to address comments (Task 6)
August	• **Final Public Health Study Report to EPA** (Task 6) • EPA public meeting to present study findings and recommendations (Task 2)
Notes: [1] Schedule will be revised following approval of the public health study Work Plan.	

3 References

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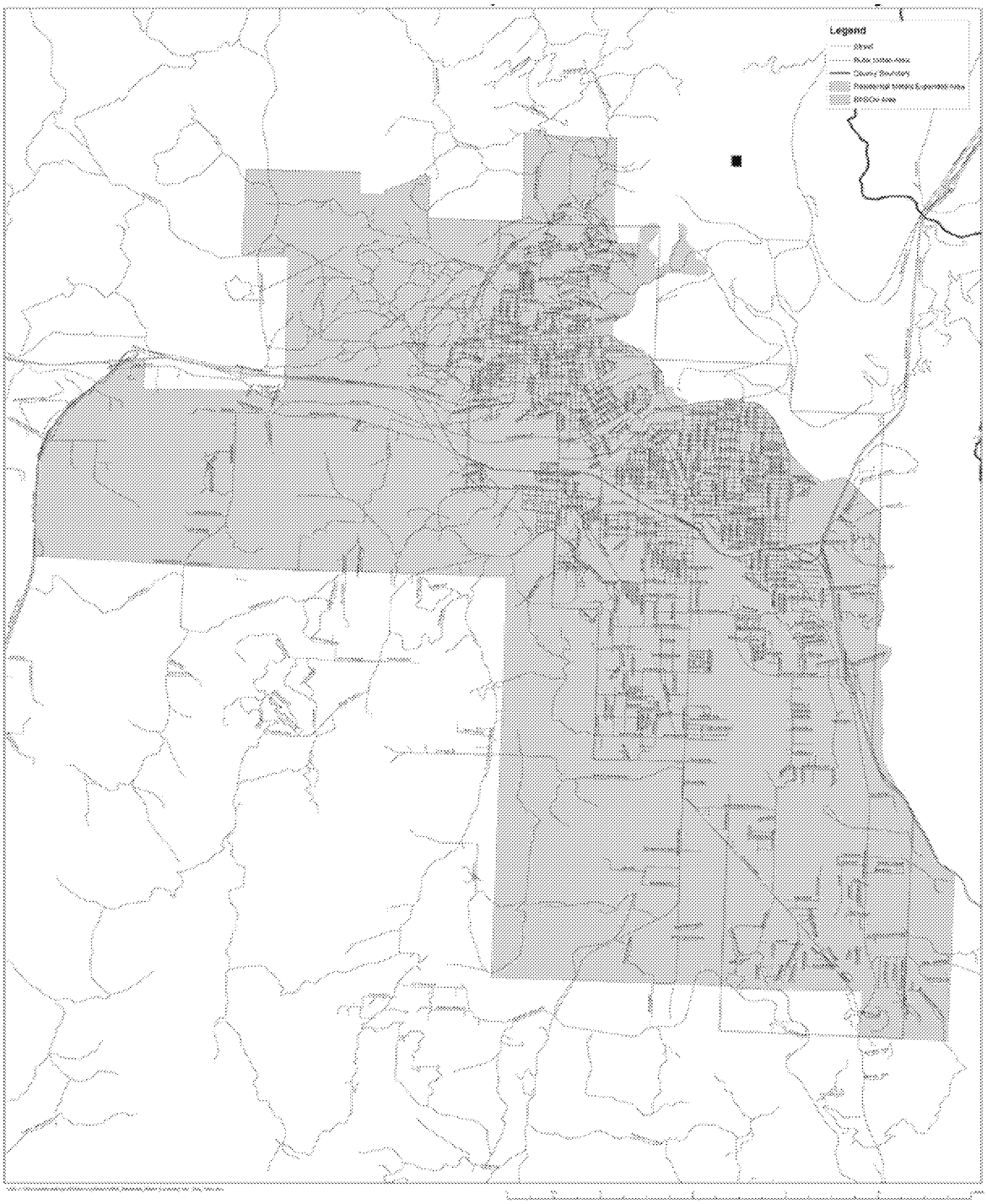
EPA. 2006. Guidance on Systematic Planning Using the Data Quality Objectives Process (EPA QA/G-4). EPA/240/B-06/001. February.

EPA. 2011. Third Five-Year Review Report for Silver Bow Creek/Butte Area Superfund Site. Volume 6: Butte Priority Soils Operable Unit. June.

Figure 1. Public Health Study Area Boundaries



Attachment 1

Excerpt from U.S. Environmental Protection Agency (EPA) Unilateral Administrative Order (UAO) for "Partial Remedial Design/Remedial Action Implementation and Certain Operation and Maintenance at the Butte Priority Soils Operable Unit/Butte Site" (EPA Docket No. CERCLA-08-2011-0011)

Note: The full UAO is available at:
http://www.epa.gov/region8/superfund/mt/sbcbutte/ButtePSOU_UAOandWorkPlan07212011.pdf

Current 2011 Status: ICs have not been fully implemented. The ground water control area IC was enacted by the State of Montana Department of Natural Resources on October 13, 2009. Butte-Silver Bow County enacted a storm water control ordinance in early 2011. The Group 1 responsible parties prepared a draft IC plan to address certain other IC requirements, which was submitted for informal public review on April 23, 2010. Approval of this plan by EPA is discussed below. The Group 2 responsible parties prepared a draft IC plan which is undergoing agency review and is subject to EPA approval at a later date. Fencing and signing are implemented upon request by EPA.

2.9 Operation and Maintenance

General Remedy Description:

Many aspects of the Remedy require long term operation and maintenance. This work must be done under approved and detailed operation and maintenance plans.

Current 2011 Status: There are several short term operation and maintenance plans in existence. Long term plans for the various aspects are not yet complete.

3.0 Specific Work Requirements for 2011 and 2012 for Partial Remedy Implementation

This section describes briefly the major components of the remedial design, remedial action, and operation and maintenance work required for 2011 and 2012. As noted, the 2009 and 2010 Scopes of Work issued by EPA under other orders remain in effect and actions under those documents is required, in addition to the actions described below.

3.1 Residential Contamination

As noted above, the final Multi-Pathway Residential Metals Abatement Program Plan (RMAP) (Responsible Parties April 2010), which is the remedial action work plan for this component of the Remedy, was approved by EPA and DEQ. This work plan is incorporated by reference into the PRIWP and shall be implemented by the Group 1 Responsible Parties. Soils action levels are described in Attachment A, Table 1.

For years 2011 and 2012, the Group 1 responsible parties shall sample and remediate the number of residential areas described for such years in the RMAP. Other required actions under the RMAP, such as medical monitoring, community outreach and education efforts, and long term database upkeep and tracking, shall also be implemented as described in the RMAP. The Butte Site map, Attachment C to the UAO, describes the areas in which each of these elements will be applied.

In summary, the RMAP requires that all residential properties within the BPSOU and the attics in the adjacent area noted on the map, Attachment B, be sampled, assessed, and abated within 20 years as described in the RMAP. A complete indoor and outdoor assessment (i.e., residential yard soil, indoor and outdoor dust, attic dust, lead-based paint, drinking water, and mercury vapor) of all residential properties

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that are known to be occupied or expected to be occupied must be completed within the first 10 years of the initiation of the expanded program (initiation occurred in 2009). During this 10-year period, the clean-up of residential properties that exceed the action levels will occur in concert with the assessment program. In addition, the program uses community awareness and education, long term database upkeep and tracking, and medical monitoring to ensure its effectiveness.

The Group 1 responsible parties developed and submitted as part of the RMAP to EPA and DEQ for review and approval by EPA, in consultation with DEQ, a long-term tracking method and database to ensure that all data and residential activities are tracked. Properties that were not or are not occupied or the owner refused access during the assessment period will be tracked and abated in the future if necessary. In addition, the tracking program will follow changes in ownership and remodeling of homes that were found to have contaminated attic dust but no current pathway. The long-term BSB RMAP Data Base tracking program will be continued for at least 99 years.

The RMAP implementation shall include community awareness and education and medical monitoring conducted by the Group 1 Responsible Parties. Participation in the medical monitoring will be encouraged through community awareness and education. Medical monitoring shall use blood lead, blood mercury, and urinary arsenic data to identify individuals who have concentrations of those elements above risk-based thresholds. When individuals are found to have elevated blood lead, blood mercury, or urinary arsenic, the home where the affected person or persons live shall be scheduled for immediate sampling and evaluation. Residential remediation shall be performed if sampling determines that yard soil, interior living-space dust, or mercury vapor action levels are exceeded. The Group 1 Responsible Parties shall submit a draft Medical Monitoring Program Remedial Design Workplan deliverable as part of the RMAP. EPA and ATSDR, in consultation with DEQ will review and comment on the workplan deliverable. The final Medical Monitoring Program Remedial Design work plan deliverable shall be submitted for EPA review and approval, in consultation with DEQ, and completed by November 30, 2012 and, until then, medical monitoring shall continue under existing protocols and plans.

Annual reports describing all activities under the RMAP shall be prepared by the Group 1 Responsible Parties by December31, 2011 and December31, 2012, in conjunction with the reports required in Section 15 of the RMAP.

3.2 Non-Residential Solid Media and the Butte Reclamation Evaluation System (BRES)

Contaminated solid media located in non-residential areas within the BPSOU site include waste rock piles, smelter wastes, milling wastes, and contaminated soils. Solid media in non-residential areas including but not limited to commercial areas, open areas, and non-active mining areas may exceed action levels (see Attachment B). These areas may also pose a threat to the environment as a result of storm water runoff. For example, runoff from these areas is a source of copper and zinc loading to receiving waters.

Contaminated solid media shall be addressed through a combination of source removal, capping, and land reclamation. If a contaminated non-residential area is discovered, the PRPs will develop a draft site

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Attachment 2

Excerpt from Final Multi-Pathway Residential Metals Abatement Program Plan (April 2010)

Note: The full plan is available at:
http://www.epa.gov/region8/superfund/mt/sbcbutte/ResidentialMetalsAbatementPlanMar2010.pdf

4.0 MEDICAL MONITORING

When individuals are found to have elevated blood lead, urinary mercury, or urinary arsenic, the home where the affected person or persons live shall be scheduled for immediate sampling and evaluation. Blood lead levels of 10 ug/dL will be considered as an elevated blood lead levels for children six years of age or less. Urinary mercury levels above the normal range of 0-10 ug/L will be considered as elevated mercury levels for all participants. Urinary arsenic levels above the normal range of 0-52.7 ug/L will be considered as elevated arsenic levels for all participants. (See Appendix E

Influencing factors such as food consumption (i.e. seafood) and dental amalgams will be taken into consideration in conjunction with the data collected during an environmental assessment to determine the source of exposure. Bio-monitoring participants will be required to complete a consent form for participation and an ATSDR approved individual questionnaire for urinary collection. (See Attachment F 1-3) Blood lead screening will be conducted by the Women, infants and children program and analysis will be conducted by an accredited laboratory. Urinary arsenic and mercury screenings will be contracted to a local physician and analysis will be conducted by a certified laboratory. Residential remediation shall then be performed if sampling determines that yard soil, interior living-space dust, or mercury vapor action levels are exceeded.

Participation in the medical monitoring program will be voluntary. However, participation will be encouraged through a variety of means, such as the existing Women, Infants, and Children (WIC) program and referrals from local physicians. Residents will also be encouraged to participate when they are contacted for sampling access.

4.1 HEALTH STUDIES

Butte-Silver Bow will perform public health studies every five years for a period of thirty years. The reports will respect the privacy of the participants and will be available to the public, the EPA, Montana Department of Environmental Quality (DEQ), and potentially responsible parties for the BPSOU. The health studies will include: Identifying chemicals that the residents may have been exposed to; Compiling and interpreting toxicology information on those chemicals; Routes of exposure; Compiling and interpreting the morbidity and mortality statistics as an epidemiology study; Compiling and interpreting health studies; and Compiling and interpreting influencing factors (environmental or cultural) for mortality rates. The public health studies will also include review of the latest epidemiological literature to determine if there are any newly established links between the contaminants of concern and specific diseases.

Data gathered through the Residential Metals Abatement Program's (RMAP) routine activities and the results of previous health studies will be utilized to determine the content of future health studies and potential improvements to RMAP routine activities.

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Appendix A

MCSEP Study: Cancer Incidence in Silver Bow County, Montana, and the United States

Cancer Incidence in Silver Bow County, Montana, and the United States

MONTANA
CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION BUREAU

Figure 1. Age-adjusted incidence rate of all-site cancer, Silver Bow County, Montana and the U.S.

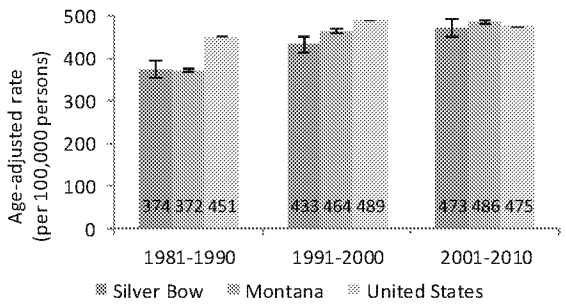
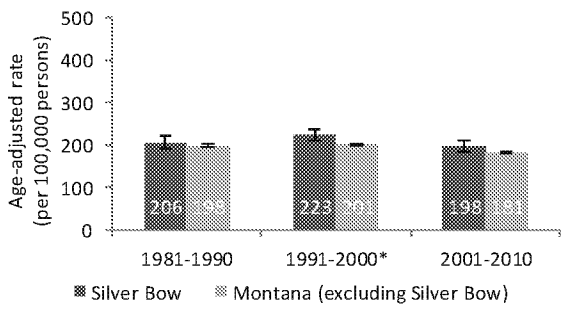


Figure 2. Age-adjusted mortality rate of all-site cancer, Silver Bow County and Montana



Cancer is a common disease in Montana and the United States. Approximately, 5,000 Montanans are diagnosed with cancer each year. A person can develop cancer for many reasons: genetics, environmental exposures, and life style behaviors (such as cigarette smoking, drinking alcohol, etc.). Unfortunately, however, it is often difficult to determine the exact cause for an individual's cancer.

The State of Montana has very complete data on cancer incidence. Cancer incidence is the number of newly diagnosed cancer cases each year. This data comes from the Montana Central Tumor Registry (MCTR). State law requires every case of cancer that is diagnosed or treated in Montana be reported to the MCTR (Montana Code Annotated 50.15.7). The MCTR has been collecting cancer data since 1979. The MCTR is very complete, over 95% of all cancer cases are in the registry.

Cancer incidence data for Montana and Silver Bow County was provided by the Montana Central Tumor Registry. Caner incidence data for the United States was provided by the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) program. Data on cancer mortality was provided by the Montana Office of Vital Statistics. All incidence and mortality rates in this report are age-adjusted to the U.S. Standard Million Population.

The incidence of cancer for all sites was the same among residents of Silver Bow County compared to the residents of the state of Montana (Figure 1). The U.S. all-site cancer incidence rate was higher than both Silver Bow County and Montana during the diagnosis period of 1981-1990 and 1991-2000 (Figure 1). The U.S. incidence rate was the same as Silver Bow County and Montana during the diagnosis period of 2001-2010 (Figure 1).

Mortality due to cancer (all-site) was the same in Silver Bow County as the rest of Montana for the periods 1981-1990 and 2001-2010 (Figure 2). The all-site cancer mortality rate for the period 1991-2000 was higher in Silver Bow County than the rest of Montana (Figure 2).

MT Cancer Surveillance & Epidemiology Program
1400 E Broadway
Helena, Montana 59260-2951
(406) 444-0064

http://www.dphhs.mt.gov/publichealth/cancer/datastatistics.shtml

MONTANA Department of Public Health & Human Services

May 2012

Figure 3. Incidence of prostate cancer among residents in Silver Bow County, Montana, and the U.S.

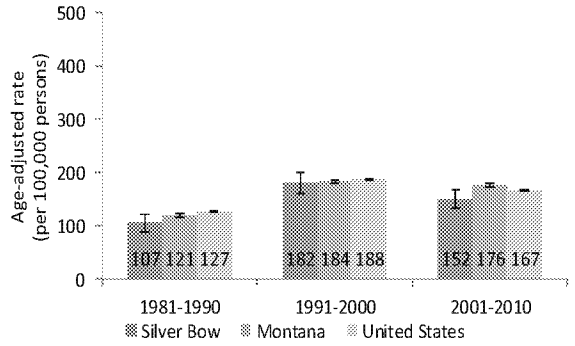


Figure 4. Incidence of breast cancer among female residents of Silver Bow County, Montana, and the U.S.

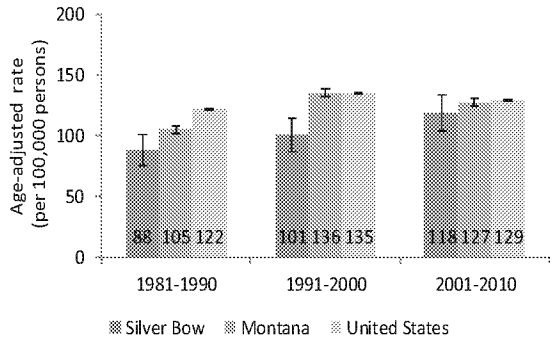


Figure 5. Incidence of colorectal cancer among residents of Silver Bow County, Montana, and the U.S.

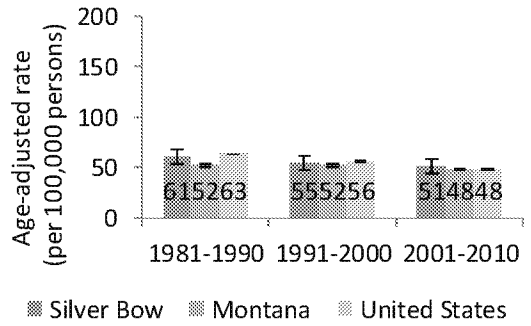
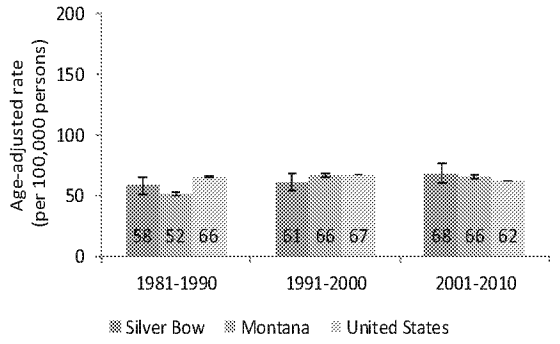


Figure 6. Incidence of lung & bronchus cancer among residents in Silver Bow County, Montana, and the U.S.



Incidence of the Most Common Cancers

The most common types of cancer in Silver Bow County are also the most common in Montana and in the United States. None of these cancers (except for lung cancer) are known to be affected by the heavy metals or chemicals of concern in Silver Bow County. Lung cancer is also associated with arsenic exposure. However the majority of lung cancer cases are caused by cigarette smoking (87% of cases among men and 74% of cases among women).

Prostate Cancer Incidence

Prostate is the most diagnosed cancer in Montana and in the US. The incidence of prostate cancer among residents of Silver Bow County was the same as Montana and the United States for the time intervals 1981-1990 and 1991-2000 (Figure 3). From 2001-2010, the incidence rate in Silver Bow County was lower than Montana (Figure 3).

Female Breast Cancer Incidence

The incidence of female breast cancer among residents of Silver Bow County was lower than Montana and the United States for the time periods 1981-1990 and 1991-2000 (Figure 4). From 2001-2010, the incidence rate in Silver Bow County was the same as Montana and the United States (Figure 4).

Colorectal Cancer Incidence

The incidence of colorectal cancer among residents of Silver Bow County was the same as Montana and the United States for all three time intervals (Figure 5).

Lung & Bronchus Cancer Incidence

The incidence of lung & bronchus cancer was the same among residents of Silver Bow County and Montana for all three time intervals (Figure 6).

Mortality of the Most Common Cancers

Prostate Cancer Mortality
Mortality due to prostate cancer among residents of Silver Bow County was the same as Montana for all three time intervals (Figure 7).

Female Breast Cancer Mortality
Mortality due to female breast cancer among residents of Silver Bow County was the same as the rest of Montana for all three time intervals (Figure 8).

Colorectal Cancer Mortality
Mortality due to colorectal cancer among residents of Silver Bow County was higher than the rest of Montana for all three time intervals (35% higher in 1981-90, 50% higher in 1991-00, and 50% higher in 2001-10) (Figure 9).

Lung & Bronchus Cancer Mortality
Mortality due to lung & bronchus cancer was the same among residents of Silver Bow County as the rest of Montana for all three time intervals (Figure 10).

Figure 7. Mortality of prostate cancer among residents in Silver Bow County and Montana

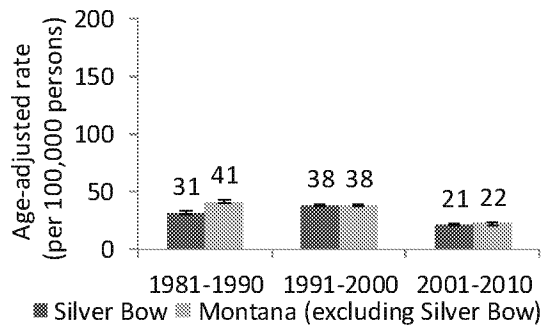


Figure 8. Mortality of female breast cancer among residents of Silver Bow County and Montana

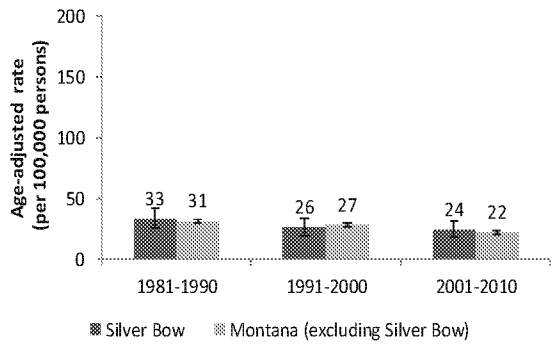


Figure 9. Mortality of colorectal cancer among residents of Silver Bow County and

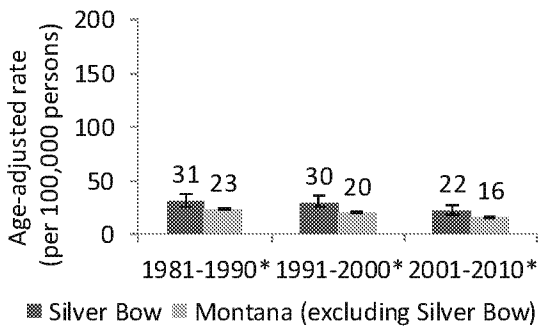


Figure 10. Mortality of lung & bronchus cancer among residents in Silver Bow County

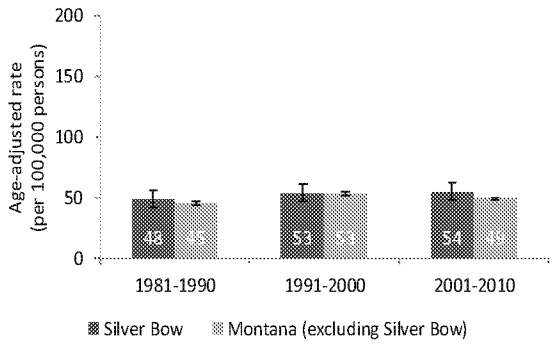


Figure 11. Incidence of bladder cancer among residents of Silver Bow County, Montana, and the U.S.

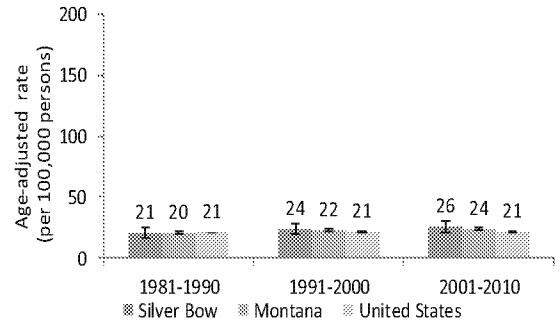


Figure 12. Mortality of bladder cancer among residents of Silver Bow County and Montana

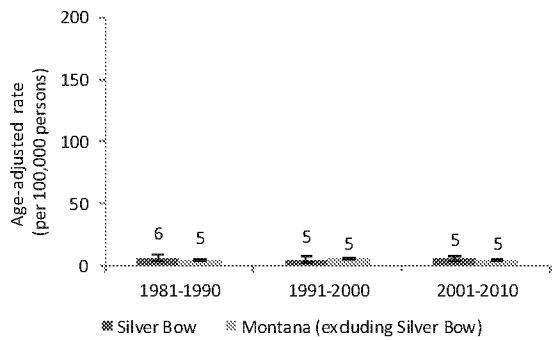
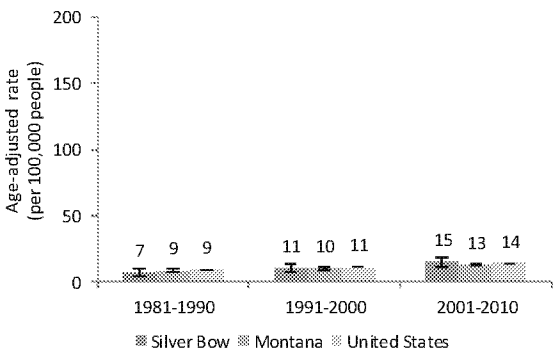


Figure 13. Incidence of kidney cancer among residents of Silver Bow County, Montana, and the U.S.



Cancers associated with Environmental exposures

Assessing cancer risk of humans due to exposure to environmental compounds requires the review of multiple scientific studies. These studies assess cancer risk in humans, animals, and in the laboratory. National and international agencies use the results of these studies to classify environmental compounds as to their cancer-causing potential. The International Agency for Research on Cancer (IARC) and the Agency for Toxic Substances and Disease Registry (ATSDR) have classified the carcinogenicity of the following heavy metals and chemical of concern in Silver Bow County:

Arsenic: *Carcinogenic to humans (Group 1)*
Inorganic Lead: *Probably carcinogenic to humans (Group 2A)*
Organic Lead: *Not classifiable as to its carcinogenicity to humans (Group 3)*
Metallic Mercury & Inorganic Mercury: *Not classifiable as to its carcinogenicity to humans (Group 3)*
Methylmercury compounds: *Possibly carcinogenic to humans (Group 2B)*
Pentachlorophenol (PCP): *Possibly carcinogenic to humans (Group 2B)*

Arsenic Exposure

Cancers known to be associated with arsenic exposure (via food or water contamination) include lung & bronchus, bladder, kidney, and skin cancer (squamous cell carcinoma). Squamous cell carcinoma of the skin is not a reportable cancer by Montana State Law. The MCTR does not have complete data on the incidence of this type of skin cancer, therefore it is not reported here.

Lung & Bronchus cancer

The incidence of lung & bronchus cancer was the same among residents of Silver Bow County and Montana for all three time periods (Figure 6). Mortality due to lung & bronchus cancer was the same among residents of Silver Bow County and as the rest of Montana for all three time intervals (Figure 10).

Bladder Cancer

The incidence of bladder cancer among residents of Silver Bow County is the same as Montana and the United States during each of the three time periods (Figure 11). Mortality due to bladder cancer was the same in Silver Bow County as the rest of Montana for three time intervals (Figure 12).

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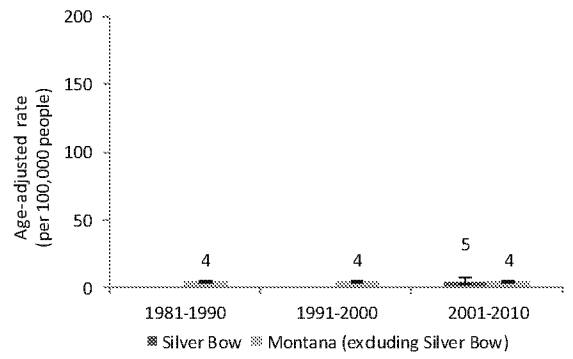
Kidney Cancer
The incidence of kidney cancer among residents of Silver Bow County is the same as Montana and the United States during each of the three time periods (Figure 13). There were too few deaths due to kidney cancer in Silver Bow County during the time intervals 1981-90 and 1991-00 to compute a rate (14 and 16 deaths, respectively). From 2001-2010 mortality due to kidney cancer in Silver Bow County was the same as the rest of Montana (Figure 14).

Figure 14. Mortality of kidney cancer among residents of Silver Bow County and Montana



Pentachlorophenol (PCP) Exposure

Pentachlorophenol is possibly carcinogenic to humans (Group 2B). There is inconclusive evidence of cancer in humans. However, increases in liver, adrenal gland, and nasal tumors have been found in lab animals. Cancers of the adrenal gland and the nasal cavity had too few cases in Silver Bow County to report.

Liver Cancer
The incidence of liver cancer was the same among residents of Silver Bow County, Montana and the United States during the time intervals of 1991-00 and 2001-10 (Figure 15). There were too few cases of liver cancer during the1981-90 time interval to calculate a rate. There were too few deaths due to liver cancer in Silver Bow County to calculate a rate during all three time intervals. The mortality rate of liver cancer in Montana remained the same during all three time intervals (Figure 16).

Figure 15. Incidence of liver cancer among residents of Silver Bow County, Montana, and the U.S.

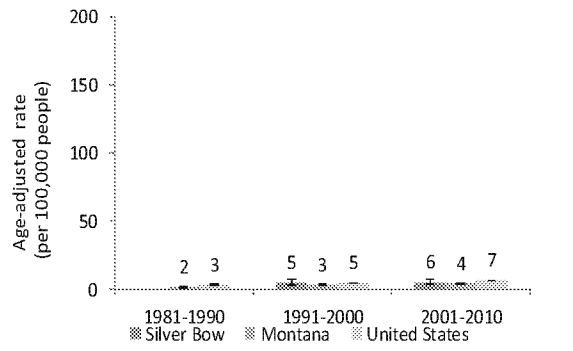
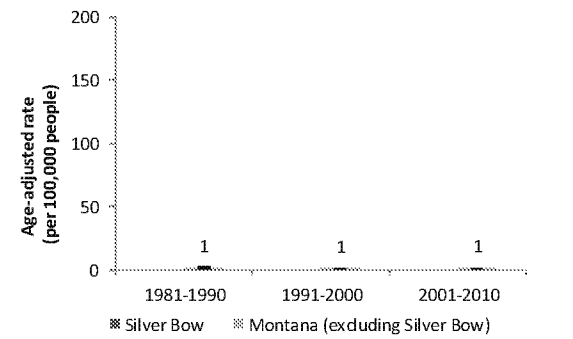


Figure 16. Mortality of liver cancer among residents of Silver Bow County and Montana



Appendix B

Butte Silver Bow Health Department Environmental Fact Sheets

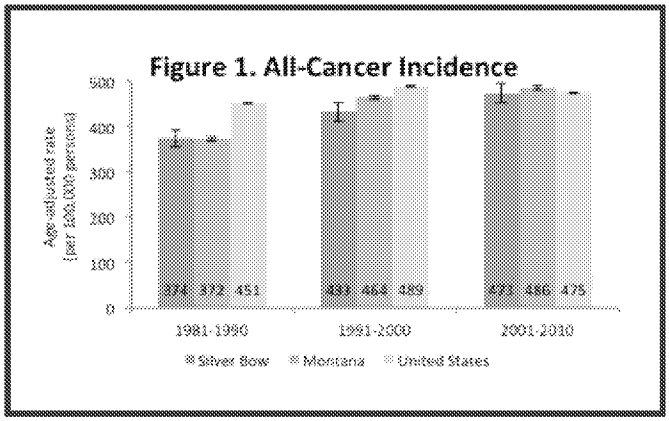
Butte-Silver Bow Health Department – 2012 Environmental Health Studies
Fact Sheet No. 1

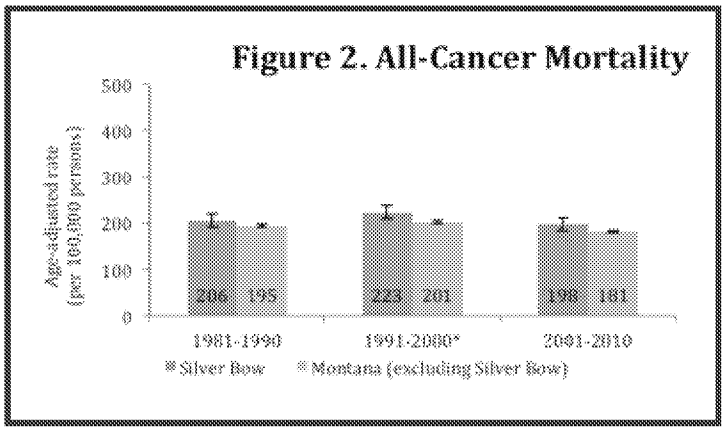
Cancer Incidence and Mortality Rates Butte-Silver Bow County

Cancer Incidence vs. Mortality Rates – Understanding the Difference
Cancer incidence measures the number of newly diagnosed cancer cases in a population each year and provides the best way to assess the risk of getting this disease. The cancer mortality rate, on the other hand, is the number of deaths that occur each year from cancer. Mortality rates reflect both the risk of getting cancer and the ability to get effective diagnosis and medical treatment.

Two communities can have similar incidence rates, but very different mortality rates. In fact, a community can have a relatively low incidence rate, but a relatively high mortality rate because of limited access to services. Therefore, **incidence rates are the best way to compare the risk of getting a disease and mortality rates are a way to compare access to care and treatment after people become ill.**

Cancer incidence is not elevated in Silver Bow County. A new study by the Montana Cancer Surveillance and Epidemiology Program (MCSEP) within the Montana Department of Health and Human Services (DPHHS) (http://www.dphhs.mt.gov/publichealth/cancer/datastatistics.shtml) has shown that incidence rates for all cancers and for each of the four most common cancers were not elevated in Butte-Silver Bow County from 1981 through 2010 (Figure 1). The four most common cancers include those of the prostate, female breast, colorectal and lung/bronchus. Figure 2 shows cancer mortality rates for the same period.





Over 95% of all cancer cases in Montana are reported. The State of Montana maintains extensive data on cancer incidence, based on information from the Montana Central Tumor Registry (MCTR). Cancer mortality rates for Silver Bow County and Montana come from the Montana Office of Vital Statistics. The MCSEP study looked at incidence data for Silver Bow County compared to the State of Montana and to the United States. Mortality data for the county was compared to the state of Montana (excluding Silver Bow County). All incidence and mortality rates in the study were age-adjusted to a standard reference population, correcting for the older population in the county.

Cancers associated with exposure to environmental carcinogens - Cancer is a common disease in Montana and the United States. Approximately 5,000 Montanans are diagnosed with cancer each year. A person can develop cancer for many reasons including genetics, environmental exposures, and life style behaviors (such as cigarette smoking, drinking alcohol, etc.). Although the lifetime risk of cancer incidence can approach one in three individuals, only a small fraction of those arise from exposure to chemicals in the environment.

Among the four most common types of cancer in Butte-Silver Bow County, only lung cancer rates might be suspected of being affected by arsenic or other hazardous substances associated with historical mining practices. Neither lung cancer incidence nor mortality is elevated in Butte-Silver Bow County; however, because more than 90% of all lung cancer is directly attributable to smoking it would be impossible to detect an increase in lung cancer attributable to arsenic or another environmental exposure over the high background rate caused by smoking. The MCSEP study also examined rates of rarer cancers (bladder, kidney and liver cancer) that might be associated with chemicals present in Butte, and neither incidence nor mortality rates were elevated for any of these cancers. These results cannot be viewed as conclusive because of the small number of cases reported (it should be noted that during a few time periods, there were too few cancers or deaths reported to calculate county rates).

The Butte-Silver Bow Health Department requested the MCSEP Study in response to community concerns associated with cancer and exposures to chemicals in the environment. The fact sheet was prepared using excerpts from the DPHHS report. A copy of the full report is available at the following site:

http://www.dphhs.mt.gov/publichealth/cancer/documents/CancerIncidenceSilverBowCounty.pdf
http://www.dphhs.mt.gov/publichealth/cancer/documents/MortalityinSilverBowCountyandMontana.pdf

Please contact the Butte Silver-Bow City/County Health Department for further information at 406-497-5020.

Health Studies Citizens' Advisory Committee

Introducing the Citizens' Advisory Committee
The Committee will work closely with the Butte-Silver Bow (BSB) Health Department in designing and overseeing the implementation of the environmental health studies (see Figure 2). Members include:

- Dr. John Pullman, M.D. (Mercury Street Medical)
- Jay Cornish, Senior Environmental Biologist, (MSE)
- Dr. Richard Rossi, Department Head, Mathematical Sciences and Statistics at Montana Tech
- Shannon Holland, R.N. (St. James Hospital)
- Helen Joyce, Program Manager, MSE
- Dr. Merle Benedict, Assistant Professor of Safety, Health and Industrial Hygiene at Montana Tech

The Butte Silver Bow Board of Health has appointed a six-member Citizens' Advisory Committee, to provide support and guidance to the Public Health Department on the work plan design and plan for implementation of a series of community health studies. The goal of the Health Department and the Advisory Committee is to assure the design of meaningful health studies, which are called for both in the Residential Metals Abatement Program Unilateral Administrative Order issued by the Environmental Protection Agency (EPA) in September 2011, and in the 2011 Community Health Improvement Plan. In launching this effort, the Health Department held a series of listening sessions in May of 2012, where members of the public provided valuable input regarding community environmental health concerns.

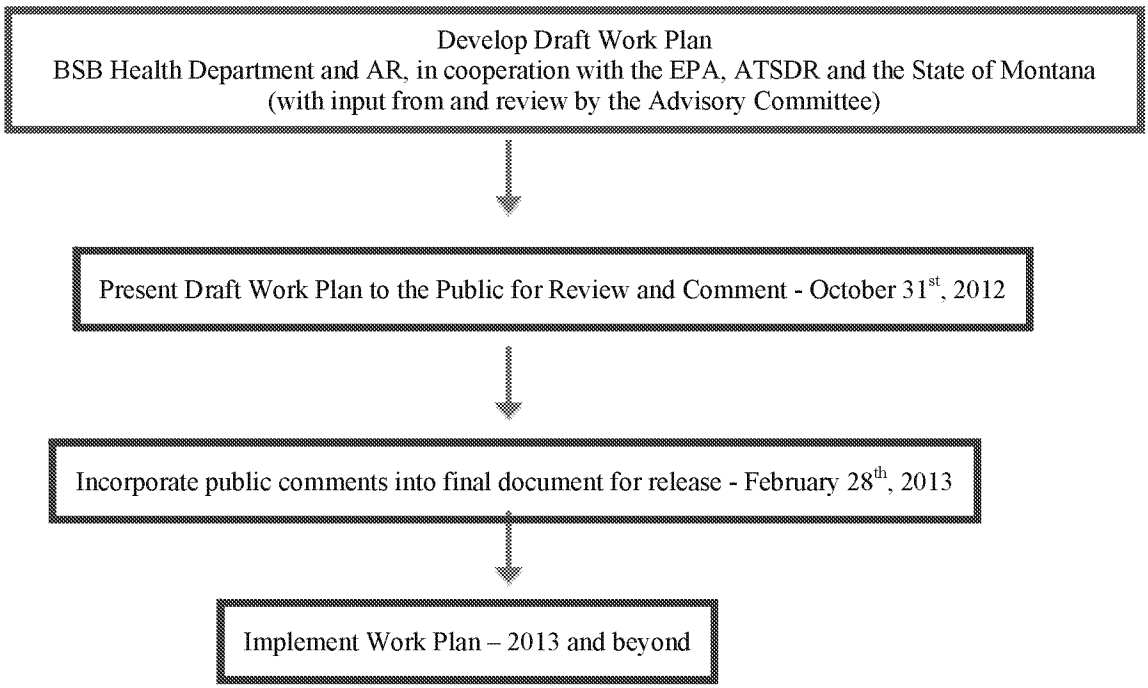
Committee Responsibilities. Members of the Committee will have responsibilities that include the following:

- Providing overall guidance to the Butte-Silver Bow Health Department and working with Atlantic Richfield in designing and implementing the work plans for the environmental health studies related to Superfund activities
- Providing overall guidance to the Butte-Silver Bow Health Department in designing and implementing the work plans for environmental health studies not related to Superfund activities
- Reviewing information including
  - Montana Department of Health and Human Services report on cancer incidence data
  - Workplan and report on analyses of historical blood lead data (currently being compiled in a database)
  - Public Listening Session Comments
- Reviewing Health Studies fact sheets for public distribution
- Providing representatives to meet with agency representatives and Atlantic Richfield (AR)
- Reporting to the Board of Health

The Butte Silver Bow Health Department shares with Atlantic Richfield responsibility for developing work plans and implementing the environmental health studies related to Superfund activities, while

EPA, the Agency for Toxic Substances and Disease Registry (ATSDR) and the State of Montana will provide ongoing technical support and input. The figure below shows the overall work plan design time line.

Butte-Silver Bow Environmental Health Studies Development Process Chart



For further information, please contact the Butte-Silver Bow County Health Department for further information at 406-497-5020.

Butte-Silver Bow Health Department – 2012 Environmental Health Studies
Fact Sheet No. 3

Butte's Drinking Water is Safe !

Is our drinking water safe? The present and future of our community depends on the availability of clean water. Reliable and adequate sources of potable water are critical to public health and to the ability of Butte to sustain itself over time.

In 1991, the City and County of Butte-Silver Bow (BSB) acquired a water system plagued by crumbling infrastructure and poor water quality, the result of decades of deferred maintenance and a failure to invest in capital improvements. BSB made immediate improvements to get the system back on line by 1994, providing safe drinking water for the community's residents. Today, while tens of millions of dollars of improvements are needed to provide a safe and reliable source of water into the future, **our drinking water remains safe.**

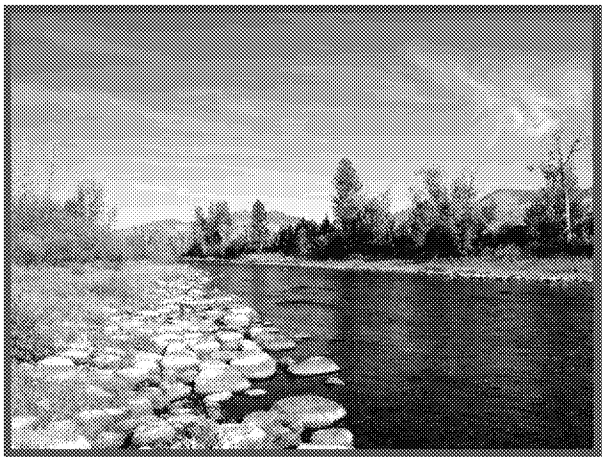


Figure 1 Big Hole River

Where does our water come from?
BSB is responsible for providing safe drinking water to its residents. Our water comes from three watersheds, the Big Hole River (Figure 1), the Moulton Reservoir and the Basin Creek Reservoirs. The Big Hole water supply is filtered and disinfected at the Big Hole Water Treatment Plant located at the Feeley Interchange south of Butte on I-15. The Moulton Watershed supply is filtered and disinfected at the Moulton Water Treatment Plant above Walkerville and the Basin Creek Watershed supply is disinfected/treated at the point of the source at the lower Basin Creek Reservoir south of Butte.

Water Sampling – The BSB Water Utilities Division samples drinking water supplies at multiple sites throughout the community on a routine basis. In addition, BSB is required to sample Basin Creek, which is presently an unfiltered water source. Division personnel sample for fecal coliform bacteria five times per week. Fecal coliform bacteria are commonly found in the intestines of animals and humans. Fecal coliform present in water comes from human and animal waste. During rainfalls, snow melts, or other types of precipitation, coliforms may be washed into creeks, rivers, streams, lakes, or groundwater due to animals in the watershed. **Sample results have never exceeded the allowable levels for fecal coliform in any of Butte's water supplies.**

The Federal Safe Drinking Water Act was established in 1974 to protect the quality of drinking water in the United States. The Act authorizes the United States Environmental Protection Agency (US EPA) to establish standards to protect public water supplies and requires all owners or operators of public water systems to comply with health-related standards. In Montana, the Department of Environmental Quality (MDEQ) has been approved to implement these rules for EPA. As an owner and operator of a public water system, BSB takes every possible action to comply with the Safe Drinking Water Act and continuously and systematically samples, analyzes and evaluates the drinking water supplies throughout all of the service area in accordance with the Standards set by EPA and enforced by MDEQ.

BSB routinely samples for Secondary Disinfection By-Products (DBPs). DBPs result from the interaction between the chlorine that is used to "disinfect" water and the dissolved organic carbon that is present in the water. The Water Utilities Division samples 12 sites throughout the community for DBPs on a quarterly basis in accordance with EPA's Stage 1 Disinfectants and DBP Rule. Although Basin Creek water is not presently in compliance with the DBP Rule, plans are being made to address this issue.

BSB Water Utilities completed monthly sampling for the period of 2008 through 2010 on the Basin Creek Watershed supply in accordance with EPA's Long Term 2 Enhanced Surface Water Treatment Rule (LT2 rule) to evaluate if there was any potential of disease-causing microorganisms (*Cryptosporidium* and *Giardia lamblia*) present in the Basin Creek Watershed supply. The purpose of the LT2 rule is to identify cryptosporidium in the source water for systems that use surface water as their main source of drinking water. *Cryptosporidium* is a significant concern in drinking water sources because it may be present in surface waters used as drinking water with inadequate or no treatment and can cause gastrointestinal illness if consumed. **The Basin Creek Watershed supply tested low in numbers of *Cryptosporidium* cysts and was classified in Bin 1. Bin 1 is considered the "safest" or having the least potential for *Cryptosporidium* contamination.** Following this two year sampling and analysis program, BSB is not required to further monitor for *Cryptosporidium* until the second round of sampling in 2017.

Through its management of the Basin Creek Watershed, disinfection of the source water with chlorine and continued sampling of the water supplies, **BSB provides safe drinking water to the people of our community.**

Contact Information

For further information, please contact the Butte Silver-Bow Water Division at (406) 723-9429 or the Butte-Silver Bow City/County Health Department at 406-497-5020.

Butte-Silver Bow Health Department – 2012 Environmental Health Studies
Fact Sheet No. 4

Contaminants of Concern

Selecting contaminants to be quantitatively evaluated in a human health baseline risk assessment

At hazardous waste sites, data are often available on the concentration of a wide variety of hazardous substances. Carrying a large number of contaminants through a quantitative risk assessment may be unnecessary and complex, and may consume significant amounts of time and resources. In these cases, a selection process is used to eliminate contaminants of interest which clearly present a minimal risk, and focus on those contaminants which should be investigated further in a quantitative risk assessment. Those analytes selected for further evaluation are identified as contaminants of concern. This process can include a comparison of onsite contaminant levels to background levels, an analysis of detection frequency, and an assessment of relative risk. This selection process is described in detail in EPA's Risk Assessment Guidance for Superfund, Part A (http://www.epa.gov/oswer/riskassessment/ragsa/index.htm) and EPA Region 8's Risk Assessment Website (http://www.epa.gov/region8/r8risk/hh_exposure.html).

In 1988, the Butte Soils Screening Study was conducted to provide analytical data for the purpose of prioritizing future Remedial Investigation/ Feasibility Studies and removal activities in Butte, Montana. The study was conducted under a cooperative agreement with EPA, Montana Department of Health, the Montana Bureau of Mines and Geology and Montana Tech. A total of 701 soil samples were collected from the Butte study area (Figure 1, approximately 8.5 square miles) and analyzed for a complete suite of inorganics. The analysis was focused on inorganics because these are the contaminants typically associated with mining, milling and smelting processes.

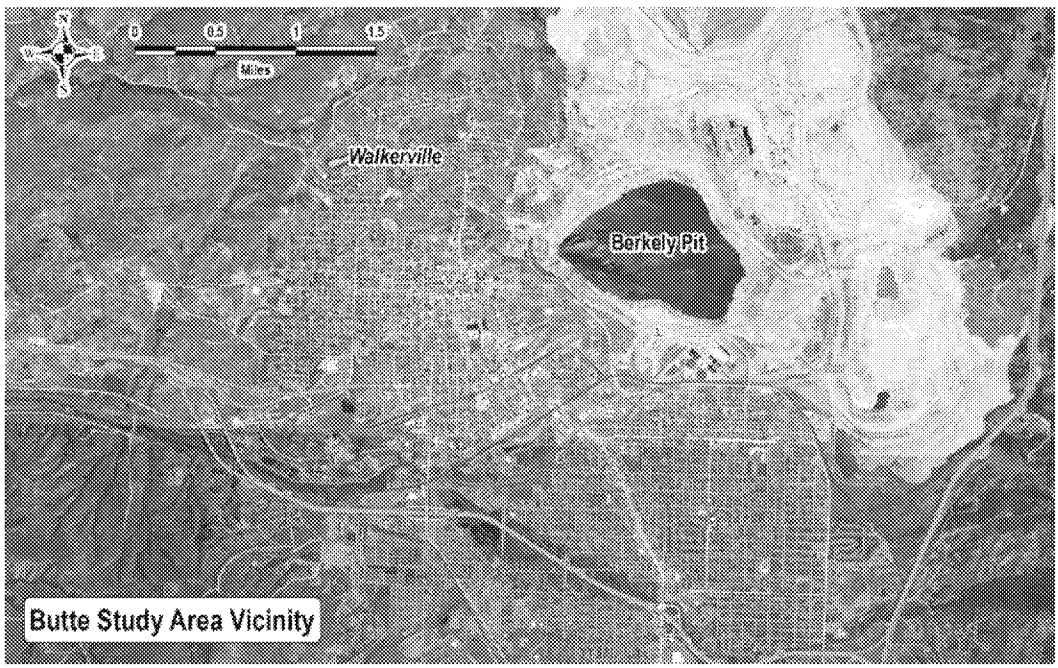


Figure 1

These inorganics which were analyzed for are shown in Table 1. For the Butte Priority Soils Operable Unit (BPSOU) risk assessments, lead and arsenic were identified as contaminants of concern in soil for the BPSOU. Mercury was added as a contaminant of concern in soil for the Walkerville area. These three contaminants of concern in soil were then further investigated in quantitative human health risk assessments for the BPSOU and Walkerville sites. The other inorganics analyzed in soil were eliminated as contaminants of concern because residential areas were below conservative risk-based screening levels and considered to present a minimal health risk.

Table 1
Inorganics Analyzed for the BPSOU

Aluminum	Calcium	Magnesium	Silver
Antimony	Chromium	Manganese	Sodium
Arsenic	Cobalt	Mercury	Thallium
Barium	Copper	Nickel	Tin
Beryllium	Iron	Potassium	Vanadium
Cadmium	Lead	Selenium	Zinc

A different set of screening processes were used to identify contaminants of concern for ground water and surface water, based largely on existing regulatory standards for these analytes and sampling showing exceedances of these standards. Table 2 shows all of the contaminants of concern identified for soil, groundwater, and surface water for the BPSOU.

Table 2
Summary of Human Health Chemicals of Concern for the BPSOU, Silver Bow Creek/Butte Area NPL

Chemical	Solid Media	Groundwater	Surface Water
Aluminum			X
Arsenic	X	X	X
Cadmium		X	X
Copper		X	X
Iron		X	X
Lead	X	X	X
Manganese		X	
Mercury	X	X	X
Silver			X
Zinc		X	X

Contact Information
Please contact the Butte Silver-Bow City/County Health Department for further information at 406-497-5020.

Appendix C

Non-Superfund Public Health Study
Work Plan Design; Phase One
Summit Valley Air Quality Butte, Montana

DRAFT

Non-Superfund Public Health Study

Work Plan Design; Phase One
Summit Valley Air Quality
Butte, Montana

1 Introduction

Air quality in the Summit Valley has been a long standing concern for the residents of Butte-Silver Bow. Historically, air quality in the Butte area was greatly impacted by mining operations including smelters, heap roasting techniques, wood and coal burning, dust, and other additional sources. More recently, the air quality has been impacted by wood burning, automobile and diesel exhaust, street sand (re-entrained road dust), sulfates, and ammonium nitrate. For further details, see Fact Sheets #'s 5 and 6.

2 Health Studies Listening Sessions

During the public listening sessions conducted in May of 2012, many of the concerns voiced by the general public were directed toward dust issues associated with the current mining operation and road sanding materials used for traction control on Butte's streets and roadways. More specifically, residents were concerned with the potential for heavy metals exposure associated with the current mining operation and other industrial sources that become airborne, as well as the use of road sanding materials containing crystalline silica (quartz monzonite) which is indigenous to the geology throughout the area.

These concerns are not related to EPA's Superfund requirements associated with the Unilateral Administrative Order (UAO) put forth to the Settling Defendants by the EPA in September 2011 for the Butte Priority Soils Operable Unit; therefore, they are being addressed as "non-Superfund" issues. This study will be completed during the same general time-frame as the Superfund Health Study, which is required as part of the UAO. Table 1 and Figure 1 represent the Phase One segment of the non-Superfund Public Health Study.

NOTE: ***These issues can quickly become resource intensive projects. With limited available resources, a phased approach to addressing these issues is the most practical way to ensure the public's concerns are being addressed in a prudent, scientific-based study, with the goal of***

protecting public health. Issues identified in the public listening sessions will be the focus of Phase One.

1. Summit Valley Air Quality Work Plan (Phase One)

1.1 Goals and Objectives

1.1.1 Goal: Review studies, current and past, to assess multi-source/multi contaminant information for the Summit Valley.

1.1.2 Objectives: Identify and confirm major air pollution sources and their respective pollutants; determine what gaps in data or other information exist in relation to the current mining operation (sulfide vs. oxide ore body; heavy metals; PM-10 and PM-2.5, etc.) and crystalline silica; identify current rules and regulations associated with the existing National Ambient Air Quality Standards for lead and particulate matter; review of Montana Department of Environmental Quality/Clean Air Act rules and regulations for heavy metals and crystalline silica; review of existing control measures adopted by Butte-Silver Bow in relation to PM-10 and PM-2.5 standards; review current and past air quality studies being done by Butte-Silver Bow/MDEQ (e.g. Chemical Mass Balance, Emissions Inventory, Dispersion Modeling, etc.); work closely with MDEQ to develop future studies based on valid, scientific based, methodologies determined to be necessary for the protection of public health based on public concerns and other available resources. Other scope of work to be considered in future studies (Phase II) is presented in Figure 1.

Timeline
Non-Superfund Public Health Study

Table 1

ITEM	Working Group dates	Public Release Date	Public Comment	Final Document	Phase One Completion
Phase One Non-Superfund Work plan Draft	10/11/12				
Phase One Non-Superfund Work plan Draft Comments	10/18/12				
Phase One Non-Superfund Work plan Final Draft		10/31/12	30-60 days		
Phase One Non-Superfund Work plan Final w/public comments		1/31/13		2/28/13	
Phase One Non-Superfund Draft Report	5/31/13				
Phase One Non-Superfund Final Report		6/30/13			6/30/13

NOTE: Timeline is not specific to the UAO's Superfund requirements. With this in mind, there will be some flexibility associated with the Non-Superfund, Phase One segment if necessary.

FIGURE 1

Community Non-Superfund Health Studies Work Plan
Working Draft Table of Contents

1.0 SUMMIT VALLEY AIR QUALITY STUDY

- 1.1 GOALS AND OBJECTIVES
  - 1.1.1 Goal: Assess multi-source/multi-contaminant impacts on residents of valley
  - 1.1.2 Objectives: identify major air pollution sources and their respective air pollutants; perform air dispersion modeling for each source– contaminant pair (e.g., PM from MR Concentrator) under defined meteorological conditions (e.g., inversions vs. well–ventilated); perform screening–level, air pathway–based risk assessments for "key" COCs (i.e., those that exceed regulatory limits or EPA/ATSDR guidance values); prepare impact mitigation plans for those source contaminant "pairs" that exceed regulatory or risk–based thresholds.
- 1.2 BACKGROUND
  - 1.2.1 Current Air Quality Conditions (monitoring station sites, pollutants monitored per station, years of record per site, COC–specific exceedances of NAAQS or health–based comparison values for acute or chronic inhalation exposure)
  - 1.2.2 Current Demographics (by age and gender per census tract within Valley)
  - 1.2.3 Current Data Gaps (e.g., PM 2.5 speciation of metals, polycrystalline silica, carbon constituents…diesel/wood smoke particulates)
- 1.3 METHODS
  - 1.3.1 Emissions Inventory (amount/types of pollutants emitted per stationary source, by gasoline and diesel motor vehicles, and wood stove/fireplace sources)
  - 1.3.2 Dispersion Modeling (e.g., ISCST3 or CALPUFF): establish ground level pollutant concentrations throughout valley under defined meteorological conditions (e.g., one hour max for acute vs. annual average levels for chronic exposure)
  - 1.3.3 Air Pathway (only?) Risk Assessment
    - 1.3.3.1 Calculation of non-carcinogenic, target organ-specific health quotients (per COC), using acceptable RfCs or other comparison values (EPA/ATSDR)
    - 1.3.3.2 Calculation of LEIC (theoretical cancer risk) using EPA's COC-specific slope factors.

    Note: Some details will probably be appended.

  - 1.3.4 Anticipated Limitations and Uncertainties (e.g., accuracy and completeness of emission inventories, toxicology data available for each COC, and potential discrepancies between monitoring data and model output)
- 1.4 REPORTING (annual vs. five-year trends?)
  - 1.4.1 Point Source Category: Tabular and graphical summaries of source-and target organ-specific LEIC and non-cancer hazard indices…e.g., for Pole Plant?

1.4.2 On-road Category: Same as above, for gasoline and diesel sources of particulate, select PAHs, VOCs, and metals

1.4.3 Wood Stove/Fireplace Category: Same as above

1.4.4 MR's pit/concentrator/tailings pond (total area source)...separate from above categories?

1.4.5 Cumulative Impact (from all sources and COCs)

1.4.5.1 Cancer Impacts by target organ

1.4.5.2 Non-Cancer Impacts by target organ

Note: Will include discussions on sensitive sub-populations (e.g., young children and those with prior respiratory problems...elderly with COPD) and census tracts (environmental justice issues)

1.4.6 Inputs to Community Health Improvement Plan (e.g. recommendations for emissions mitigation, follow-up health assessments/biomonitoring, and public education)

Other potential scope of work to be considered in future studies (Phase II)

1.5 REFERENCES CITED

Appendix A: Toxicological Data for Contaminants of Concern

Appendix B: Risk Assessment Details (algorithms)

Appendix C: Dispersion Model (s) Input/Output

Appendix D

Butte-Silver Bow Health Department Biomonitoring Records Description and Compilation Procedures

Butte-Silver Bow Health Department Biomonitoring Records Description and Compilation Procedures

Available biomonitoring data stored at the Butte-Silver Bow Health Department (BSB) consisted almost entirely of blood lead[7] testing data located in seven 5-drawer filing cabinets, one filing box, and a few loose file folders of blood lead summary sheets. Medical record files were housed in the filing cabinets and the additional filing box, roughly in alphabetical order. Individual files varied in the number of documents contained and the date range encompassed. Within folders, files were arranged in stapled bundles or loose-leaf on both sides of the folder. The left-hand side typically contained identifying documents such as proof(s) of address, driver's license(s), proof of income(s), and signed authorization and registration forms, while the right-hand side of a medical file contained healthcare information including medical history, lifestyle/diet questionnaires, laboratory test results, growth/weight forms, and medications prescribed. A single file sometimes contained records for multiple children and/or parents. These materials were largely produced through the Butte-Silver Bow Women, Infants and Children Program (WIC). Given that nearly all of the biomonitoring records reviewed pertained to blood lead biomonitoring, the remainder of this summary focuses on procedures specific to blood lead testing information that was compiled. Analogous procedures were used to compile non-lead biomonitoring data (to the extent such data were identified).

In addition to the medical record files, there were a few files containing blood lead data on summary sheets. These sheets presented information in a table layout providing the patient's name, date of test, and blood lead result. Most of the blood lead results were of the capillary test type as indicated by the column header, but some were identified as venous. A sheet contained either Lead Care II or whole blood lead results. On each single-sided page were 12 to 13 blood lead records, one per row. Occasionally, hemoglobin results were also provided. All of the information filled out on the summary sheets was hand-written, which increased the potential for misinterpretation of recorded information as discussed further below.

The process for transcribing hardcopy blood lead data and patient information into the electronic database was undertaken in a systematic and thorough manner. All records were handled in a manner to ensure files were returned to their original location in the same condition in which they were found when data compilation activities were initiated. When the data source was a file of summary sheets, the process was straightforward as only blood lead records were listed on each page. However, a more comprehensive strategy was used when a medical record file was investigated due to the variety and volume of information contained in each file. Every page within the file was examined for evidence of laboratory tests with particular attention paid to quarter-page lab slips, full-page lab results, and blood lead authorization forms. When a blood lead record was found, it was tagged for visibility with a strip of colored paper. Data from a record was then transcribed onto the Excel spreadsheet including the patient's first and last name, gender, full address, provider (e.g., WIC), blood lead result, blood draw date, and report

[7] All records were reviewed for arsenic and mercury biomonitoring records as well, but only one case was identified with results for arsenic and mercury measured in biological samples (both blood).

date for the blood lead result. The blood lead results were further distinguished by test type as capillary whole blood, capillary filter paper, venous whole blood, or Lead Care II.

Within the medical files, some information required interpretation or further research for verification prior to entry into the electronic file; this was accomplished using other documents in the medical file. For example, if a name or birthdate was hard to read or written differently on two separate records, attempts were made to find a birth certificate or other government-issued identification so that the data could be validated or corrected. For each blood lead result, an effort was also made to locate a complementary hemoglobin result recorded within one day of the blood lead draw date. Additional information or comments were typed into the spreadsheet as needed. For example, notes were made if the patient was pregnant at the time of the blood draw or if a patient's name changed over the date range of the records. Researchers also provided comments to assist in the Quality Assurance/Quality Control (QA/QC) procedure, e.g., if a driver's license was used to validate a name or birthdate.

Most of the blood lead results transcribed from the medical record files were collected and analyzed between 2002 and 2009. There were relatively few records found from 1992 to 2001 and none from 1990 or1991.

A 100% QA/QC procedure was used for all material transcribed into the database. This procedure was completed by a researcher other than the one who originally entered the data. The QA/QC researcher was supplied with the original Excel spreadsheet and directed to the source(s) of the transcribed data. One file at a time, each page in both sides of a file was reviewed to ensure all blood lead records were entered. The tagging of records within medical files performed by the original researcher facilitated this process. If a non-transcribed record was discovered, it was added to the spreadsheet. All data entered into the spreadsheet from a record was compared with the original material in the file, and any necessary corrections or additions were made within the spreadsheet. If anything in a cell was edited or added, the cell was highlighted. Copies of both the original, pre-QA/QC spreadsheet and the post-QA/QC spreadsheet containing highlights were retained. Once QA/QC was completed for a blood lead record, all flagging tags were removed, taking care to ensure the filed documents were kept as they were found. Once all blood lead records in a file had been reviewed, the file was placed back in the filing cabinet in its original position. The QA/QC procedure for summary sheets was the same as described above in that it was a 100 percent review of every piece of data transcribed. Every blood lead record on each summary sheet was compared with the information on the spreadsheet. Any edits or additions to a cell were highlighted and both pre- and post-QA/QC spreadsheets were retained.

As noted above, the summary sheets contained only hand-written data. The only information given to identify a patient was a first and last name; no birthdates, genders, or addresses were provided. When a name was unclear or illegible, no other documents were available in the summary sheet files to use in a validation process. Original researchers used best judgment in these cases, and the QA/QC researcher provided interpretation as well. Both the original and QA/QC researchers utilized the comments section in the spreadsheet to provide alternative name spellings when necessary. Almost all of the blood lead results in the database from 2010 up to June 2012 came exclusively from summary sheets and do not have patients' birthdates,

addresses, etc. However, results transcribed from summary sheets sometimes duplicated results found in a medical file. This occurred with some results from 2007 to 2009 resulting in a mix of patient information is available for data from this time period.