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

Prepared for:
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Acronyms and Abbreviations

AR	Atlantic Richfield Company
ATSDR	Agency for Toxic Substances and Disease Registry
BPSOU	Butte Priority Soils Operable Unit
BSB	Butte Silver Bow County
CAC	Citizens' Advisory Committee
CDC	U.S. Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CIP	Community Involvement Plan
CTEC	Citizens Technical Environmental Committee
DQO	Data Quality Objective
EJ	environmental justice
ENVIRON	ENVIRON International Corp
EPA	U.S. Environmental Protection Agency
MCTR	Montana Central Tumor Registry
MDEQ	Montana Department of Environmental Quality
MDPPHS	Montana Department of Public Health and Human Services
mg/kg	milligram per kilogram
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NHANES	National Health and Nutrition Examination Survey
QNS	Quantity not sufficient
RMAP	Residential Metals Abatement Program
UAO	EPA Unilateral Administrative Order
µg/dL	microgram per deciliter
WIC	Women, Infants and Children program
XRF	x-ray fluorescence

1 Introduction

This document presents the work plan for a public health study for the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County, Montana. The study will consist of analyses of blood lead and environmental data compiled over nearly ten years to determine if lead exposures differ across neighborhoods within the study area or between the study area and other comparable populations. These analyses are proposed to support an evaluation of the effectiveness of ongoing remediation and residential metals abatement efforts, and to yield recommendations regarding whether future changes are needed to these efforts.

The plan for this specific study was developed after consideration of a range of possible studies. Health studies for communities affected by environmental contaminants can start either with evaluation of exposures or of disease rates. If a study beginning with evaluation of exposures reported elevated exposures, the next step would be to recommend ways to reduce exposures and the results could also guide design of future studies of disease rates to focus on diseases possibly related to those specific chemical exposures. Other studies looking broadly at disease rates may be a useful supplement to exposure studies, but in most cases such studies are not as sensitive as focused exposure studies. As described below, both kinds of studies were considered prior to developing the study described in this work plan, and a study of cancer incidence and mortality was also requested and subsequently conducted by the Montana Department of Public Health and Human Services (MDPHHS).

The U.S. Environmental Protection Agency's (EPA's) goal in managing Superfund sites is to ensure that chemical exposures are kept low enough to prevent increases in disease rates. EPA conducts assessments that predict potential risks for people expected to be most highly exposed and most susceptible to adverse health effects. EPA then sets cleanup goals expected to protect the most sensitive members of the population. For BPSOU, EPA reviewed data for multiple chemicals in soil and dust and determined that the primary chemicals of concern were lead, arsenic and mercury, and set cleanup levels for all three chemicals.

BPSOU cleanup efforts based on these cleanup goals have now been underway for approximately 20 years. Atlantic Richfield (AR) has conducted much of the cleanup outside of residential areas and Butte Silver Bow (BSB) County has been leading residential yard and home metals abatement efforts. The current Residential Metals Abatement Program (RMAP) and its predecessor program led by BSB have also included a biomonitoring program in which blood lead samples have been collected from over 2,000 Butte[1] children over the past ten years. Arsenic and mercury biomonitoring have also been offered under this program since 2010, but only when environmental sample concentrations are high enough to warrant such testing. Because the environmental concentrations were seldom high enough to offer such testing, there is no comparable arsenic and mercury biomonitoring data.

[1] Pertaining to the study area and population addressed by this Work Plan, "Butte" is used throughout this document in lieu of Butte Silver Bow County. Walkerville and other communities within the county are included by reference to "Butte" unless otherwise noted.

Using the available blood lead data to assess exposures in Butte is desirable because blood lead levels provide a direct and relatively stable measure of all sources of lead exposures a child may have. Because lead is the most prevalent chemical of concern present in Butte, a study of lead should also provide a surrogate for other metal exposures. Furthermore, blood lead levels are measured each year in thousands of U.S. children, making it possible to compare Butte levels with other communities.

Once it was determined that blood lead data might be available to support an exposure study, an effort was launched to determine if the data would be sufficient to support a robust exposure study. A small team of scientists working under the supervision of the BSB Health Department, and bound by the Health Department's confidentiality requirements to access clinical records has compiled a database with nearly 7,000 blood lead records covering the period from 2002 through 2012. Most of these blood lead samples were collected by BSB's Woman, Infants and Children (WIC) program, and includes large numbers of children from Butte neighborhoods with the highest risk factors for lead exposures and effects. Thus, the blood lead data available to support this study represents a unique resource to assess lead exposures in Butte.

This work plan describes the relation of this study to Superfund activities and the study design process (including public outreach and input). Specific to this study, background information about the study area, prior exposure studies, data sources, study objectives/approach, data quality objectives, and tasks are also described. During the course of public outreach for this study, Butte citizens expressed concerns about trust, transparency, and the need for more public participation. In response, the study design has been modified to allow for more engagement in the process of doing the work. Butte citizens also expressed a number of issues that are not within the scope of the current and future Superfund health studies including, for example, current air quality and municipal drinking water quality concerns. Consequently this work plan also briefly describes the separate actions being taken for some of these non-Superfund issues that will be addressed outside of the Superfund process.

2 Study Basis and Design Process

The 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), describe public health studies to be performed 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. This work plan addresses only the first Superfund study, the Phase 1 Superfund health study. The scope of future studies, as well as opportunities for public involvement related to such studies is not the focus of this work plan. Similarly, the development of studies in response to community health concerns that relate to factors outside the scope of Superfund chemicals of concern or actions to help BSB Health Department focus on broader public health improvement efforts are also not the focus of this work plan.

Public health study activities 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 BPSOU. Public health concerns will be addressed in the periodic 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 (hereafter, the "Working Group"), which was initially comprised of representatives from EPA, the Montana State Department of Environmental Quality (MDEQ), BSB, the Agency for Toxic Substances and Disease Registry (ATSDR), and 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. The community provided input to the Working Group early in the planning process 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.

One of the early study priorities identified by the Working Group during initial study planning meetings was formation of a Citizens' Advisory Committee (CAC) comprised of technically

qualified community members to provide input to the study design and implementation process. Since appointment by the BSB Board of Health, the CAC members have been invited to participate in Working Group meetings, interim draft reviews, and community open houses relating to development of this work plan.

A draft work plan was submitted to EPA and released for public comment at the end of October 2012. Multiple presentations describing the draft work plan were given during a four hour community open house held at the Maroon Activity Center in Butte on December 3, 2012. Working Group representatives at the December open house were also available to address other topics of interest identified during the prior spring's listening sessions. Discussions were aided by topic-specific exhibits and printed materials relating to air and water quality, the RMAP, BPSOU risk assessments, and incidence/mortality studies, as well as preliminary data descriptions and potential neighborhood study areas being considered as part of the work plan study design.

A January 16, 2013 open house at the BSB archives provided a second opportunity for individual discussion with Working Group representatives. As with the December 2012 open house, similar exhibits and printed materials were available at topical booths for review and discussion with Working Group representatives. In addition, two presentations were given. The first provided an overview of comments received on the draft Superfund health study work plan and identified general approaches the Working Group was considering to address these. The second provided an overview of the air quality study design that is currently under development via a process that is separate and distinct from the initial health study design described in this work plan. Both presentations were highly participatory with much interaction from the community audience in attendance. Based on heightened community interest in the public health studies process and plans, EPA extended the draft work plan public comment period from December 31, 2012 to February 16, 2013. Subsequently, the deadline for submission of the final work plan to EPA was revised from February 28, 2013 to May 15, 2013.

In response to interim comments received on the draft Superfund health study work plan, a technical representative of the Butte Citizens Technical Environmental Committee (CTEC) was appointed to the Working Group on January 28, 2013. The CTEC representative has participated along with other Working Group representatives to address draft work plan comments received and develop corresponding revisions to the draft work plan culminating in this document.

2.1 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 (Figure 1). As part of planning for the initial study phase, the Working Group identified two primary goals to be considered in design of the public health study. The first goal relates to Superfund and is to evaluate whether the RMAP has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. The second broader goal is to review community health concerns or actions to help BSB focus on pathways to improve public health. This work plan focuses on the first study goal. Specifically, related to the Superfund program and aligned with public health study activities specified in the RMAP, the

Working Group team identified evaluation of available RMAP blood lead biomonitoring data collected through 2011 as a priority for inclusion in the first phase of the public health studies.

Aligned with this focus, this work plan specifies the approaches for review and evaluation of available RMAP blood lead biomonitoring 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 are 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 blood lead biomonitoring data.

With regard to the second goal (i.e., to review community health concerns or actions to help BSB focus on broader public health improvement efforts), the Working Group identified the following needs:

- An updated evaluation of cancer incidence and mortality rates in Silver Bow County compared to state and national levels, including cancers associated with environmental exposures to contaminants of concern in Butte. This evaluation supports the Superfund-related health studies described in the UAO.

- A series of fact sheets addressing topics of interest to the Butte community. Some of these fact sheets directly support the Superfund-related health studies efforts, while others support efforts being conducted outside of the Superfund health studies.

- A focused air quality study in response to specific community concerns that do not relate to Superfund.

Details of each of the activities related to the second goal are provided in sections 2.1.1 through 2.1.3 below.

Scoping for subsequent phases of the Superfund health studies (i.e., future studies) has not yet been initiated and is not included in this work plan. However, the findings of this first phase of the Superfund health study can be used to help inform future studies. In this way, conduct of the public health studies will occur in an iterative or sequential manner with each phase informing and augmenting the next.

2.1.1 Summary of Silver Bow County Cancer Incidence and Mortality Study (MDPHHS 2012)

As part of the first phase of the Superfund-related health studies and to address broader community concerns, the Working Group 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 2002 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 study 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.

The updated study was conducted by the MDPHHS and included consideration of the most common cancers, as well as cancers associated with exposure to metals present in Butte. The health study Working Group did not provide input to or comment on the state's report (MDPHHS 2012), which is included in Appendix A to this work plan along with the ATSDR (2002) study. A summary of the MDPHHS (2012) approach and findings is provided below.

In May 2012, MDPHHS, evaluated cancer incidence and mortality among BSB residents using data from Montana death records and the Montana Central Tumor Registry (MCTR). Cancer incidence and mortality rates among BSB residents were compared to state and national rates to assess whether or not cancer is elevated in BSB. Cancers which are diagnosed or treated among Montana residents are required, by state law, to be reported to the MCTR. Similarly, all deaths which occur among Montana residents are also to be reported to MDPHHS. It is estimated that MDPHHS has records of over 95% of all cancers and deaths which occur among Montana residents.

According to MDPHHS, the best way to assess the effects of environmental exposure on cancer risk in humans is to measure cancer incidence. Cancer incidence measures the number of newly diagnosed cancer cases in a population each year. Cancer mortality, on the other hand, is the number of deaths that occur each year from cancer. Mortality reflects 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 is not a single disease. Cancer is actually a general term which includes over 100 different kinds of cancer. Each type of cancer has its own risk factors. The four most common types of cancer are prostate, female breast, colorectal, and lung and bronchus. The cancers known to be associated with exposure to specific heavy metals of concern in BSB are lung and bronchus cancer, bladder cancer, kidney cancer, and liver cancer.

To establish a background rate of cancer, MDPHHS assessed the incidence rate of all cancers combined, and for each of the four most common cancers (i.e., cancers of prostate, female breast, colorectal, and lung and bronchus). MDPHHS found[2] that:

- The age-adjusted incidence rates among Silver Bow County residents for all cancers combined and for each of the four most common cancers were statistically the same or lower than for Montana and the U.S. during three time periods from 1981 through 2010.

- Cancer mortality rates for all cancers combined were not statistically elevated in Silver Bow County compared to Montana in two of the three time periods examined, but were

[2] Note, MDPHHS's findings are based on statistical comparisons using a 95 percent confidence interval (i.e., the range of values within which the true value falls with 95 percent certainty). In general, where confidence intervals for two populations compared (e.g., Silver Bow and Montana) do not overlap, the populations can be said to be statistically different. When the confidence intervals for two populations being compared do overlap, the populations can be said to be statistically the same (or not statistically different).

elevated during one time period. In contrast with the incidence rates, colorectal cancer mortality rates were statistically higher for all three time periods in Silver Bow County compared to Montana. Mortality rates for cancers of prostate, breast and lung and bronchus were not elevated in Silver Bow County.

- For cancers associated with exposure to specific heavy metals of concern in BSB, neither incidence nor mortality rates were elevated. MDPHHS noted that some of these findings were limited due to small numbers because these cancers are rare.

The disparity in cancer mortality findings suggests possible issues in Butte with the ability to access diagnoses and medical treatment, which may be a factor in the elevated mortality from colorectal cancer. Exploration of these and other findings by BSB or MDPHHS may be of interest for future public health study phases but are not addressed in this work plan.

2.1.2 Development of Health Studies Fact Sheets

During planning for the initial Superfund-related health study phase, the Working Group 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 six fact sheets each of which is included in Appendix B. The titles of all six fact sheets are listed below:

1. *Cancer Incidence and Mortality Rates Butte-Silver Bow County*
2. *Health Studies Citizens' Advisory Committee*
3. *Butte's Drinking Water is Safe!*
4. *Contaminants of Concern*
5. *Air Quality Monitoring at Greeley School*
6. *Air Quality and Fine Particulate Studies*

Some of the fact sheet topics identified relate to Superfund (e.g., Fact Sheet 1, 2, and 4), while others are related to concerns outside of Superfund (e.g., Fact Sheet 3, 5, and 6). Preparation of additional fact sheets that address other topics of interest expressed by the community is also planned.

2.1.3 Development of a Separate Butte Air Quality Study

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 Superfund health studies. 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 by BSB. A preliminary schedule for study execution is also included in Appendix C.

2.2 Environmental Justice Considerations

In response to the community's comments received in response to the draft work plan and relating to environmental justice, this section has been added to identify environmental justice considerations that have been a part of the design and execution of this work plan as well as additional measures that have been implemented in response to public comment.

In EPA's Community Involvement Plan (CIP) for Butte Priority Soils Operable Unit (February 2013), EPA identified Butte Silver Bow County as "an area of potential EJ [environmental justice] concern" based on comparison of the percentage of persons below the poverty level in the county as compared to the state. As defined within the CIP:

> *Environmental Justice (EJ) is focused attention on communities which are disproportionately impacted by environmental problems, with the goal of ensuring a quality environment for all citizens regardless of race, ethnicity or other socioeconomic factors, and promoting equal access to public information and participation in matters relating to human health and the environment. The EJ Program consists of technical and administrative support personnel tasked with facilitating the Region's implementation of this goal.*

The CIP describes several ongoing and recent activities conducted by EPA to incorporate environmental justice into public engagement at the BPSOU including:

- assigning a local Remedial Project Manager;
- making public meetings accessible;
- providing information on a regular basis and in an accessible format;
- helping to set up a Technical Advisory Group or "TAG"; and
- screening environmental justice matters in conjunction with EPA's actions in the Butte Silver Bow area.

In consideration of EPA's commitment to environmental justice, community outreach conducted in support of the public health study seeks to promote meaningful involvement of all people (regardless of race, color, nationality, or income) by providing public information about and opportunities to participate in the health study process. This includes scheduling public meetings associated with the health study at times and locations that promote accessibility by all members of the community. Notices of meetings are broadly distributed multiple times to the community. Meetings are advertised using multiple media sources. Periodic distribution of fact sheets and ads in free newspapers has also been employed, along with posting health study information on the BSB and Silver Bow Creek/Butte Area websites, to promote community access to health study information.

As described previously, in response to the community's input, a representative from CTEC, the EPA-supported TAG for the Butte Site, has also been invited to participate in the study design process along with other Working Group representatives from EPA, BSB, MDEQ, ATSDR, the CAC, and AR. As part of the Working Group, all of these representatives are invited to participate in study design planning meetings and in review and comment of interim work plan drafts leading up to this work plan that will be submitted to EPA for final approval. Moreover, this work plan has been modified in response to public comment to allow for more collaboration by Working Group representatives leading up to a draft report. These efforts help to ensure that the needs and interest of the Butte community, including its low-income population, are considered.

In addition to promoting meaningful involvement of all citizens in community outreach, the study design itself also aligns with environmental justice considerations. For instance, as shown in Figure 2, the study area of interest for the public health study is broad and encompasses the Butte area of potential environmental justice concern identified by EPA in the CIP. Additionally, as detailed in section 3.4 below, this initial health study is focused on multiple years of blood lead data collected from Butte area children primarily through the county's WIC program (a program which serves low income persons) and in conjunction with 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 WIC. WIC services are offered free of charge to households with income at or below current WIC income guidelines assuring that participation in the blood lead testing program is available to low income households.

Finally, lead has been identified as one of the primary contaminants of concern based on EPA's risk assessments to support actions taken at BPSOU, but may also be present within the environment due to a number of other sources (i.e., industrial sources, lead-based paint, plumbing, etc.). The RMAP program investigates and remediates all potential lead sources, and is not limited to mining-related sources. Blood lead data provide direct evidence of exposure to lead without regard to individual sources. Directly assessing lead exposure by means of blood lead data has much less potential for confounding than does use of indicators of health impacts from environmental stressors, such as the number of illnesses attributable to lead as a percent of the community population. The Centers for Disease Control (CDC) considers children living at or below the poverty line who live in older housing to be at greatest risk of lead poisoning. Thus, the RMAP's unique design attempts to address a significant health concern for children at or below the poverty line. The blood lead data addressed by this health study design represents a large proportion of children subject to both of these conditions, thus considering the most vulnerable portion of the population.

Citizens are encouraged to contact EPA, MDEQ and/or BSB Health Department in addition to CTEC if they have additional engagement interests or suggestions on how to further enhance environmental justice responsiveness.

3 Phase 1 Public Health Study Design: RMAP Evaluation

The remainder of this work plan focuses on the initial (i.e., Phase 1) Superfund-related public health study to evaluate the RMAP program. Specifically, this study will focus on review and evaluation of blood lead data collected via the RMAP from 2002 through 2011 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 this work plan on behalf of AR and BSB, and in close coordination with the public health studies Working Group representatives from EPA, MDEQ, ATSDR, the CAC, and CTEC.

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 described by the UAO. Background information about the study area and population are summarized in section 3.1 along with key results from prior exposure studies conducted in the Butte Silver Bow area in section 3.2. The RMAP is described in section 3.3 including available biomonitoring and environmental data collected as part of the RMAP. A description of the proposed study objectives and approaches is then provided in section 3.4 along with an overview of the study's data quality objectives (section 3.5), and study tasks with a preliminary schedule for implementation (section 3.6).

3.1 BPSOU Study Area and Population

This section summarizes background information regarding the BPSOU study area and population characteristics of the Butte community. Spatially, the BPSOU 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 2, both pink and blue shaded areas), 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 despite the fact that 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 2013 CIP 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). The area addressed by the RMAP, which is the subject of this initial health study, includes the areas within Butte that have the highest percentages of families with incomes below the poverty level.

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 Superfund human health risk assessment 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. Fact sheet No. 4 included in Appendix B to this work plan provides more information regarding how EPA identified contaminants of concern in BPSOU soil. BPSOU action levels[3] for lead, arsenic, and mercury were developed in accordance with EPA's Risk Assessment Guidance's for Superfund[4] and fully satisfy the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) requirements for the protection of human health.[5] Additionally, the RMAP provides biomonitoring of blood lead levels within Butte and investigation of elevated blood lead levels in conjunction with the Superfund program to further manage risks. Remediation within the BPSOU is ongoing and has included, in addition to the RMAP abatements, removal of mine waste dumps, cleanup along railroads, removal of sediment, and capture and treatment of ground and storm water. Conduct of this and other periodic health studies is also a part of the Superfund remedy selected for BPSOU. EPA reserves the right to make changes to the record of decision (ROD) for BPSOU based on new information, which includes the results of the public health studies, as part of the Five Year Review process for the ROD.

3.2 Summary of Prior Exposure Studies

This section summarizes key findings from prior exposure studies conducted in the Butte Silver Bow area. Information from these prior environmental exposure investigations is useful to informing the scope and direction of the public health study design described in this work plan. Two studies have been conducted and are described below.

In the earlier investigation, 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 micrograms per deciliter (µg/dL) (Table 1), similar to U.S. levels and lower than values from other mining communities tested at that time.

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 2 shows blood

[3] Further information regarding the human health protectiveness of these action levels is provided in Attachment 3, Table 1, response to comment 1.B.1.
[4] http://www.epa.gov/oswer/riskassessment/risk_superfund.htm
[5] http://www.epa.gov/osweroe1/content/lawsregs/ncpover.htm

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 1: 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

Table 2: 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 predecessor to the RMAP was implemented in response to these recommendations. 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 blood lead levels.

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 3). Thus, this study did not find elevated exposures to arsenic in Butte area children before residential remediation had commenced.

Table 3: 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[6] 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."

3.3 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 recommendations from the University of Cincinnati study (BSBDH/UC 1992) and 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[7]. 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[8] within residences.

For properties within the BPSOU and the identified adjacent area (please refer to pink and blue shaded areas of Figure 2) 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.

[6] Analyses were for speciated arsenic (i.e., inorganic arsenic and its metabolites, monomethylarsonic and dimethylarsinic acid).
[7] http://www2.epa.gov/region8/residential-metals-abatement-program-butte-priority-soils-operable-unit
[8] 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.

As part of the RMAP, a database is used to track all properties that have been sampled. The database then is utilized to determine properties that have not been sampled and in turn those properties receive sample requests from the RMAP in a systematic approach. Eventually, all residential areas within the RMAP defined boundary will be sampled, using this method[9]. Per the UAO, assessments of all residential properties within the BPSOU shall occur by December 31, 2019 and all contaminated residential properties within the BPSOU shall be remediated by December 31, 2029.

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 this 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 3.3.1 of this work plan currently summarizes information contained within the July 2012 environmental database.

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.

A voluntary blood lead biomonitoring 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 WIC program. WIC services are offered free of charge to households with income at or below current WIC income guidelines which assures that participation in the WIC blood lead testing program is available to low income households. While the WIC program conducts routine blood lead testing on children less than seven years old, individuals seven years old or older need to be referred to WIC by RMAP staff based on the results of RMAP environmental

[9] Currently, the RMAP does not have the ability to track changes of ownership for every property within the BPSOU. This can result in new owners not being included in mailers requesting the opportunity to conduct an environmental assessment if such mailers were sent to a prior owner of record who did not respond.

assessments. Blood lead data collected for the biomonitoring program is used to identify children who have blood lead levels greater than 10 µg/dL[10]. 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. In contrast to blood lead testing, currently, BSB does not provide in-house testing for urinary arsenic when offered to individuals via the RMAP. Instead, the RMAP will reimburse the individual for the cost of testing conducted through the individual's private physician. 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 blood lead biomonitoring records from all available[11] hardcopy records that are maintained by BSB. The initial blood lead 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. A summary of the data compilation process used, including data quality assurance measures, is provided in Appendix D.

The blood lead biomonitoring records and the electronic database compiled from them contain confidential information that is protected from public disclosure by federal and state privacy laws. Accordingly, the data may be accessed only by individuals working for BSB under a confidentiality agreement. That agreement requires the individual to adhere to the policies and procedures of the BSB Health Department which include federal and state laws strictly protecting client health information. To assure protection of confidential information (i.e., name, birth date, address) during conduct of the initial health study, individual records contained within the blood lead database were preliminarily assigned to one of eight subareas within the study area, corresponding to census tracts 1 through 8. Defining neighborhoods based on census tracts is useful because the census provides data for many risk factors that are known to affect

[10] In May 2012 CDC accepted a recommendation from the Advisory Committee on Childhood Lead Poisoning Prevention 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.

[11] Some of the hardcopy records for blood lead biomonitoring 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.

blood lead levels. Table 4 shows the breakdown of the number of blood lead results for children ages 12 to 60 months by census tract for years 2003 through 2011 based on 2010 census boundaries. To solicit feedback on use of the proposed census tracts for coding blood lead data, this table was also presented to the community in enlarged format as an exhibit during the December 2012 and January 2013 health study open houses in Butte. While tracts 1 through 7 represent discrete areas within the most populated areas of the county, tract 8 covers the more expansive outer area. For execution of the health study, it may be appropriate to combine some of the census tracts with smaller numbers of results and the distribute the close-in results for tract 8 to other nearby census tracts in order to facilitate neighborhood level analyses. Further discussion of information contained the blood lead biomonitoring database is provided below in section 3.3.2. Additional information on finalizing neighborhood selections for use in the study is discussed in section 3.4.2.

Table 4: Number of blood lead results by year in 2010 census tracts (children ages 12 to 60 months)

2010 Census Tract	By Year									Percent of Total
	2003	2004	2005	2006	2007	2008	2009	2010	2011	
1	110	86	87	80	85	96	94	123	134	26.6
2	37	49	27	33	46	49	44	45	56	11.5
3	32	41	27	37	34	21	26	37	42	8.8
4	54	46	41	30	50	32	56	64	58	12.8
5	34	22	18	30	26	24	30	38	32	7.6
6	68	64	73	80	72	67	72	92	95	20.3
7	4	7	12	14	17	16	11	14	15	3.3
8	39	39	32	33	17	27	28	48	43	9.1
Totals	378	354	317	337	347	332	361	461	475	100.0

3.3.1 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 (Figure 3). 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.

3.3.2 Description of the RMAP Blood Lead Biomonitoring Database

As described previously, electronic compilation of individual blood lead biomonitoring records from hardcopies maintained by BSB was initiated in June 2012 and continued through completion of this work plan to fill in missing information (i.e., addresses) for some records that were not available in the original hardcopy records. Collectively, these individual blood lead biomonitoring results provide an overview of exposure levels measured within the study population over time. As described previously, although the RMAP includes triggers for biomonitoring for arsenic and mercury, in addition to lead, to date only blood lead biomonitoring data were collected and these are the focus of the study design proposed by this work plan.

All blood lead biomonitoring 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. Paper records are physically located at the BSB Health Department in secured file cabinets. No copies of paper records were removed from the BSB Health Department office during compilation in June 2012. The electronic database storing compiled confidential records is currently maintained at ENVIRON, however, access to the data on ENVIRON's electronic server is limited only to four ENVIRON staff working for BSB under a confidentiality agreement that requires each individual to adhere to the policies and procedures of the BSB Health Department, including federal and state laws strictly protecting client health information.

Based on the records compiled from the June 2012 effort, The total BSB blood lead database presently includes 6,893 blood lead test results collected from January 2002 through June 2012. These blood lead records include more 3,800 records for children ≥ 1 and < 5 years old, over 1,100 infants less than 1 year old, and over 1,000 pregnant women. Not all records compiled were for Butte residents, and address, gender and/or birthdate were sometimes missing. Records of blood lead data from 1992 through 2001 were not located (with a few exceptions)[12]. For most records, 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. Records are complete for over 2,000 Butte children, with over 300 records per year from 2003 through 2011. Records are defined as complete if they include location data, a blood lead result, gender, and age at blood test.

Blood lead results are also 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

[12] 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.

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 and were, therefore, excluded from the coded database.

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 5 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 2012.

Table 5: 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	196	137	135	32	18
2003	621	384	381	105	98
2004	584	364	356	78	117
2005	599	334	322	98	143
2006	710	345	339	177	147
2007	1102	357	352	453	192
2008	689	341	335	159	163
2009	611	375	368	65	149
2010	700	486	475	13	1
2011	762	549	527	6	--
2012	319	218	206	6	'--

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.

3.4 Study Objective and Approach

The primary study objective to be addressed by this work plan is the review and evaluation of available RMAP data that have been collected to date in order to objectively document the 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 biomonitoring screening data are limited to blood lead results. As described in section 3.3.1, in addition to the blood lead data, other 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).

3.4.1 Focus on Blood Lead Biomonitoring Data for Butte Children

As described previously, lead is the primary constituent of concern identified by EPA for the site due to its prevalence in environmental media and its toxicity. Due to its relatively long half-life, lead exposures are likely to be detected by blood lead biomonitoring and would represent combined exposures due both to site and non-site related sources. Thus, blood lead data provide a conservative indicator of exposures to lead from all sources within an individual's environment that were occurring in the weeks to months prior to measurement and can be used to identify differences in exposures between such environments on a neighborhood scale.

Because blood lead concentrations provide a good measure of lead exposures from all sources and provide a more sensitive assessment of the potential for adverse effects due to lead exposure, focusing on these data is the most effective way to assess the potential for adverse effects of lead on health in Butte. This is particularly true given that the health effects of lead are diverse and many of these effects may have other causes. Low level lead exposures, such as those documented in 1990 in Butte, are not likely to result in effects that can be detected in a study of health endpoints. Given this limitation, focusing the initial health study on lead exposure data is preferred to focusing on specific health outcomes within the Butte population that may not be specifically related to lead exposure.

To address the study objective, this work plan focuses on analyses of the more than ten years of blood lead data compiled by BSB to assess blood lead levels in Butte children. Young children (ages 1 to 5 years) are most susceptible both to lead exposures and also to adverse effects of lead. Numerous studies across the U.S. have demonstrated that this population has the highest blood lead levels. Therefore, focusing on this population provides the most effective means of detecting any elevation of lead exposures in affected neighborhoods. This focus on young children is also protective of all persons including older children and adults. Little additional value would be gained by evaluating blood lead levels for adults, who generally have lower lead exposures.

While there is no recent urine arsenic data for Butte residents, as described in section 3.2, elevations in urinary arsenic concentrations were not found in the 1990 study by BSB and University of Cincinnati (BSBDH/UC 1992) which examined lead and arsenic exposures in Butte children and was conducted before residential area remediation began. The later study of Walkerville residents (ATSDR 2001) further supported the conclusion, based on available data, that elevated arsenic exposures are not evident in Butte. To the extent that arsenic and lead

exposures are both site-related, the initial study's focus on lead may help identify whether expansion of prior arsenic exposure studies is indicated.

3.4.2 Overview of Proposed Analyses

The proposed exposure study seeks to better understand whether exposures to lead in the community have decreased in relation to cleanup activities and RMAP response actions conducted over the last decade. To better understand whether lead exposures in Butte are elevated, the study also will examine how blood leads, as a measure of exposure from all lead sources, compare between Butte and other similar populations that do not have a similar Superfund history.

Specific neighborhood selections, comparison populations, and statistical approaches/measures proposed for use in the initial health study will be presented for consideration and input by the health study Working Group at interim points during implementation of the health study. It is anticipated that 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. EPA's goal for lead has been (and continues to be) to reduce overall lead exposures. The 10 µg/dL "blood lead level of concern" issued by CDC in 1991 was a risk management level. CDC did not consider that level to be a "safe", but rather a level at which it was feasible to identify and modify sources contributing to the elevated lead exposure. Over the last few decades, mitigation of lead sources to air and drinking water has successfully lowered blood lead levels nationwide, such that, today, elevated blood lead levels are typically found in a few individual children, not in entire populations. This has enabled CDC to again lower the risk management level for blood lead. The new CDC reference level of 5 µg/dL is also not a "safe" level, but a population-based reference level. The new value represents the 97.5th percentile of blood lead levels in the U.S. population of young children. This value is still a risk management tool that helps to identify children who may have elevated lead exposures that can be addressed by home interventions. The health study will be examining the distribution of blood lead levels in Butte children, using all of the data to determine if there are differences across Butte neighborhoods or between Butte and other comparison populations. There will be no cut off value for levels considered.

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)[13]. It is important that the comparison community be matched to the Butte community for a variety of risk factors that are known to affect blood lead levels. Examples of significant risk factors associated with higher blood lead levels include socioeconomic status,

[13] 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 2001) 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.

urbanization, house age, renter occupied housing, single or multiple residential housing units, maternal education and smoking. While it may not be possible to match all of these factors, prospective comparison populations will be profiled for as many risk factors as can be determined. Several approaches are being 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 seek 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. However, to date no suitable Montana community has been identified that has blood lead data. The search for a comparison community will be expanded to nearby states.

An alternative approach may involve adjusting data from the National Health and Nutrition Examination Survey (NHANES) to develop an NHANES-based comparison population. The NHANES became a continuous program in 1999, with surveys occurring in two-year intervals. With approximately 10,000 nation-wide participants selected for each survey, NHANES can be used to generate population based statistics for specific age groups. In that event the NHANES database may be the best available source of data for comparison, information collected from these surveys will be useful in understanding how the Butte community blood lead status compares to that of the rest of the United States. A number of strengths and weaknesses associated with using the NHANES data have been identified and will be described separately upon completion of the search for data sources within Montana and other nearby states. Preliminarily, it can be assumed that the NHANES data will allow for quantitative comparisons with the Butte dataset, both by age and two-year increments. Also, the blood lead data selected from the NHANES dataset can be matched to Butte community housing and economic characteristics to the maximum extent possible, using available socioeconomic and housing information for NHANES participants. Ideally, the larger sample size of the NHANES dataset will allow for selection of a subset of data that approximates characteristics of the Butte community while preserving a sufficient sample size to conduct statistical comparisons.

Comparison of the distributions of blood lead levels across different neighborhoods of the study area will be conducted to determine whether statistically significant differences in blood lead levels 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. As discussed in section 3.3, final selection of neighborhood boundaries within Butte has not been completed, but is expected to generally align with the neighborhood breakdown from the 1990 study by BSBDH/UC to allow for neighborhood differences identified in the current study to be compared to those identified in the 1990 study. However, given the available data, the final neighborhoods are expected to be much more inclusive of Butte than was the 1990 study, while still being concentrated in areas with the greatest proportion of older housing, lower income households, and proximity to site-related contaminants. Figure 4 shows the breakdown of county neighborhoods by census tracts 1 through 8, as discussed in section 3.3. An enlarged format exhibit of this figure was previously presented for community input at the December 2012 and January 2013 open houses.

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

these abatements on arsenic, lead, and mercury exposure pathways will be described. 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. For those properties where both blood lead and environmental data are available, such data cannot be linked on a property-specific basis while still assuring protection of confidential information associated with the blood lead biomonitoring data. Instead, both datasets must be coded to neighborhoods and evaluated on that level.

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.

3.5 Data Quality Objectives

This section of the work plan describes the data needs to support and intended uses of the blood lead data analysis portion of the initial health study. Although this study does not involve new data collection efforts, this section generally follows EPA's data quality objectives (DQO) planning process (EPA 2006), which is intended to ensure a clear linkage between the study research goals and objectives, and the final study product. EPA's DQO 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."

The EPA DQO process consists of the following seven steps:

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.

Each of these steps was reviewed in the context of the proposed evaluation addressed by this work plan with details provided below.

3.5.1 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. The predecessor to the RMAP was implemented in response to recommendations arising from completion of a 1990 study that examined lead and arsenic exposures in Butte children (BSBDH/UC 1992). That study and EPA's risk assessments supported a focus on lead exposures. Multiple years of blood lead biomonitoring data have been collected via the RMAP and its predecessor program. Evaluation of these biomonitoring data represents the logical next step to assess the efficacy of ongoing monitoring and abatement activities and to identify any necessary improvements to the program.

BSB and AR, as Group 1 responsible parties, are responsible for conduct of this Superfund-related initial public health study. A health study Working Group consisting of EPA, MDEQ, ATSDR, BSB, AR, CAC, and CTEC representatives provide valuable input to the study direction, approaches, interim work products, and community engagement opportunities to support completion of the initial health study. The work plan and the resulting public health study will be subject to approval by EPA, in consultation with MDEQ. Upon completion of the study, opportunities for publication of the study in a peer-reviewed journal or conference proceedings will be sought.

Funding for this work plan and public health study will be secured by BSB in partnership with AR. The draft public health study work plan was submitted to EPA on October 31, 2012. Public comments on the draft work plan were accepted through February 16, 2013. Two community open houses, on December 3, 2012 and January 16, 2013, were also conducted to provide more information on the planned study and solicit input from the community. Submittal of the final work plan to EPA is scheduled for May 15, 2013. Implementation of the first public health study under this work plan is expected to be completed in 2014.

3.5.2 Step 2: Identify the Goal of the Study

As stated previously, a review of multiple years of blood lead 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. As described earlier, implementation of the periodic public health studies described by the UAO will occur in an iterative manner such that subsequent phases to this initial study phase may be guided by the findings of preceding phases. This aligns with the final RMAP, which 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.

3.5.3 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 blood lead levels within the Butte community prior to and since initiation of the RMAP activities
- Reliable and representative distributions of blood lead levels within a community or other comparison population that is comparable to Butte, either with or without 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).

The goal of using representative distributions is to assess whether children in some areas Butte have any increase in lead exposures. This is a more sensitive measure than looking at the numbers of children with elevated blood lead levels.

Many of the above information inputs are available in the environmental and blood lead 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 blood lead levels 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 blood lead levels 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.

3.5.4 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 (please refer to pink and blue shaded areas on Figure 2), 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 despite the fact that this area was not historically associated with mining or smelting waste dumps).

The target population of interest for this study is young children (under the age of 6 years) who reside within or are regularly cared for within these spatial boundaries. Young children (ages 1 to 5 years) are most susceptible both to lead exposures and also to adverse effects of lead and numerous studies across the U.S. have demonstrated that this population has the highest blood lead levels. Therefore, focusing on this population is protective of all persons including older children and adults, while little additional value would be gained by evaluating blood lead levels for adults, who generally have lower lead exposures.

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) 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). Proposed datasets will be presented to the Working Group for consideration and input prior to use in the study.

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. In both cases, data will be coded to a neighborhood level within Butte to protect confidential information prior to use in the study.

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

3.5.5 Step 5: Develop a Decision Rule

Proposed statistical measures 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. Proposed statistical approaches will be presented to the Working Group for consideration and input prior to use in 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.

3.5.6 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.

Environmental data will be examined directly for evidence of reductions in exposure pathways without linkage to blood lead results.

Examination of the blood lead data will also be conducted to assess whether changes in community-wide exposures are evident based on the following lines of evidence:

1. Statistically significant differences in blood lead levels across neighborhoods within the Butte community, measured in conjunction with the RMAP, are reduced relative to differences documented pre-RMAP differences in blood lead levels across these same neighborhoods.

and/or

2. The distribution of blood lead levels in the Butte community and in a comparison population are similar over the same period evaluated.

Prior to evaluating the hypotheses presented below for each of these lines of evidence, 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.

Evaluation of these lines of evidence may yield one of four possible outcomes related to the following hypotheses pairs:

The null and alternative hypotheses for first line of evidence (H1) are:

$H1_0$: Statistically significant differences in blood lead levels between specific neighborhoods evaluated in 1990 are still evident based on more recent blood lead level data.

$H1_A$: Statistically significant differences in blood lead levels between specific neighborhoods evaluated in 1990 are no longer evident based on more recent blood lead level data.

The null and alternative hypotheses for the second line of evidence (H2) are:

$H2_0$: Blood lead level distributions within the study population are significantly higher than blood lead level distributions for the comparison population based on statistical comparisons of data collected over the same time period.

$H2_A$: Blood lead level distributions within the study population are not significantly higher than blood lead level distributions for the comparison population based on statistical comparisons of data collected over the same time period.

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

Given these hypotheses, four possible outcomes may result:

1. Both $H1_0$ and $H2_0$ are accepted
2. Both $H1_0$ and $H2_0$ are rejected
3. $H1_0$ is accepted and $H2_0$ is rejected
4. $H1_0$ is rejected and $H2_0$ is accepted

The specific outcome determined for this study will be interpreted with respect to its implications to whether or not the RMAP has been effective. While outcomes 1 and 2 are definitive with regard to the question of whether or not the RMAP has been effective based on the study conducted, outcomes 3 and 4 are not. However, evaluation of the environmental data plus consideration of all blood lead data all outcomes will provide a basis for determining what, if any, actions are needed to improve the effectiveness of the RMAP.

A false acceptance decision error corresponds to deciding that a specific hypothesis should be accepted when it really should be rejected. A false rejection decision error corresponds to deciding that a specific hypothesis should be rejected when it really should be accepted. The potential 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 potential 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.

3.5.7 Step 7: Optimize the Design for Obtaining Data

A quality assurance review will be conducted of all RMAP environmental and blood lead biomonitoring data selected for inclusion in the public health study. No additional samples will be collected to address this DQO. Specific neighborhood selections, comparison populations, database development documentation, and statistical approaches/measures proposed for use in the initial health study will be presented for consideration and input by the health study Working Group at interim points during implementation of the health study.

3.6 Public Health Study Tasks

This section of the work plan summarizes the tasks that have been or will be undertaken to complete the initial 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. A schedule for completion of remaining activities associated with each task is provided in Table 6. Table 6 will be updated with specific dates upon approval of this work plan.

3.6.1 Task 1 – Project Planning

Task 1 of the public health study is completion of project planning activities needed to initiate the public health study design described in this work plan. Completion of Task 1 project planning activities coincides with completion of this work plan (see Task 3). Section 2 of this work plan provides a detailed description of project planning activities conducted since the study planning was initiated in April 2012 through preparation of this work plan.

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

3.6.2 Task 2 – Community Outreach

Task 2 of the study is conduct of community outreach activities. Consistent with EPA's 2013 CIP, community outreach conducted in support of the public health study seeks to promote equal access by all citizens to public information about and participation in the health study process, regardless of race, ethnicity, or other socioeconomic factors. This includes scheduling public meetings associated with the health study at times and locations that promote accessibility by all members of the community. Meetings are advertised using multiple media sources. Periodic distribution of fact sheets and ads in free newspapers has also been employed, along with posting health study information on BSB's website, to promote community access to health study information.

Interactive outreach activities began early in the project planning process as described previously in section 2 of this work plan and have included a series of public listening sessions held by BSB in May 2012 followed by an EPA public meeting later that month and two community open houses held in Butte in December 2012 and January 2013.

One or two additional community meetings will be conducted following completion of the public health study to share study findings and answer questions community members may have about the study conclusions.

Community engagement will also be supported by presentation of proposed data and approaches for use in study implementation to the Working Group for consideration and input at periodic intervals prior to completion of the study. Table 6 summarizes the schedule for execution of Task 2 activities following approval of this work plan.

3.6.3 Task 3 – Work Plan

Task 3 activities relate to preparation of a final approved work plan for the initial Superfund-related public health study. The work plan specifies the approaches for review and evaluation of available RMAP blood lead biomonitoring 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 blood lead biomonitoring data. Completion of Task 3 corresponds to approval of this work plan by EPA.

3.6.4 Task 4 – Data Compilation

Task 4 data compilation activities associated with the blood lead biomonitoring data and RMAP environmental data are described in section 3.3. Task 4 also includes research and compilation of publically-available blood lead data for comparison populations outside of Butte as discussed in section 3.4.2. Remaining Task 4 data compilation activities are as summarized in Table 6.

3.6.5 Task 5 – Quality Assurance Review

Task 5 quality assurance review activities began with the June 2012 compilation of available 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). Additional quality assurance review is conducted for any new data entries. Throughout the process, individual decisions made with regard to specific data treatments are documented for future reference.

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 most recent RMAP environmental database is advised 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 documentation requirements associated with completion of the final health study.

The proposed schedule for execution of the remaining Task 5 activities is presented in Table 6.

3.6.6 Task 6 – Data Analysis and Reporting

Task 6 includes conducting analyses of data compiled in Task 4 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?” As described previously, proposed data and approaches for use in study implementation will be presented to the Working Group for consideration and input at periodic intervals (see Table 6) prior to conducting final analyses for completion of the study. Documentation of quality assurance reviews of data analyses will be as determined per Task 5.

Reporting is also included in Task 6 and includes development of a technical memorandum summarizing selection of appropriate comparison 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 remaining Task 6 deliverables is presented in Table 6.

Table 6: Preliminary schedule for implementation of remaining work plan tasks

Activity or Deliverable	Status/Deadline
Conduct data compilation and QA activities, as needed (Tasks 4 & 5)	In progress. Completion required prior to commencing data analyses for approved study design.
Conduct research and review of available data options to support selection of comparison population (Task 4)	In progress. Completion required prior to submission of proposed comparison data selection memorandum to EPA
Submit Final Work Plan (Task 3) to EPA and MDEQ	**May 15, 2013**
Approval of Final Work Plan by EPA in consultation with MDEQ	***To be determined by EPA in consultation with MDEQ***
Working Group Meeting #1: review proposed comparison data selection(s) (Task 2) and database development documentation (Tasks 4 and 5)	30 days following approval of Final Work Plan by EPA in consultation with MDEQ
Prepare draft Technical Memorandum of proposed comparison data selections (Task 2) for Working Group review and comment	14 days following Working Group Meeting #1
Submit Technical Memorandum of proposed comparison data selection(s) (Task 6) to EPA and MDEQ and for public comment	**30 days following Working Group Meeting #1**
Approval of Technical Memorandum by EPA in consultation with MDEQ	***To be determined by EPA in consultation with MDEQ***
Compile approved comparison data set(s) for use in the study (Task 4) and conduct QA activities (Task 5)	30 days following approval of Technical Memorandum by EPA in consultation with MDEQ
Identify proposed statistical approaches for study data analyses (Task 6)	In progress. Completion required prior to commencing data analyses for approved study design.
Working Group Meeting #2: review Butte neighborhood boundaries and proposed statistical approaches for study data analyses (Task 2)	60 days following approval of Technical Memorandum by EPA in consultation with MDEQ
Conduct data analyses (Task 6) and QA activities (Task 5)	To commence following receipt of input on proposed statistical approaches at Working Group Meeting #2
Working Group Meeting #3: review results of data analyses (Task 2)	30 days following Working Group Meeting #2
Prepare draft report of health study findings (Task 6) for Working Group review and comment	20 days following Working Group Meeting #3
Working Group Meeting #4: review draft health study report (Task 2)	30 days following Working Group Meeting #3

Table 6: Preliminary schedule for implementation of remaining work plan tasks	
Activity or Deliverable	**Status/Deadline**
Submit Draft Health Study Report (Task 6) to EPA and MDEQ	**14 days following Working Group Meeting #4**
Public comment period on Draft Health Study Report	***To be determined by EPA in consultation with MDEQ***
Submit Final Health Study Report (Task 6) to EPA and MDEQ	**30 days following receipt of public comments on Draft Health Study Report**
Present Final Health Study findings at EPA public meeting (Task 2)	***To be determined by EPA in consultation with MDEQ***

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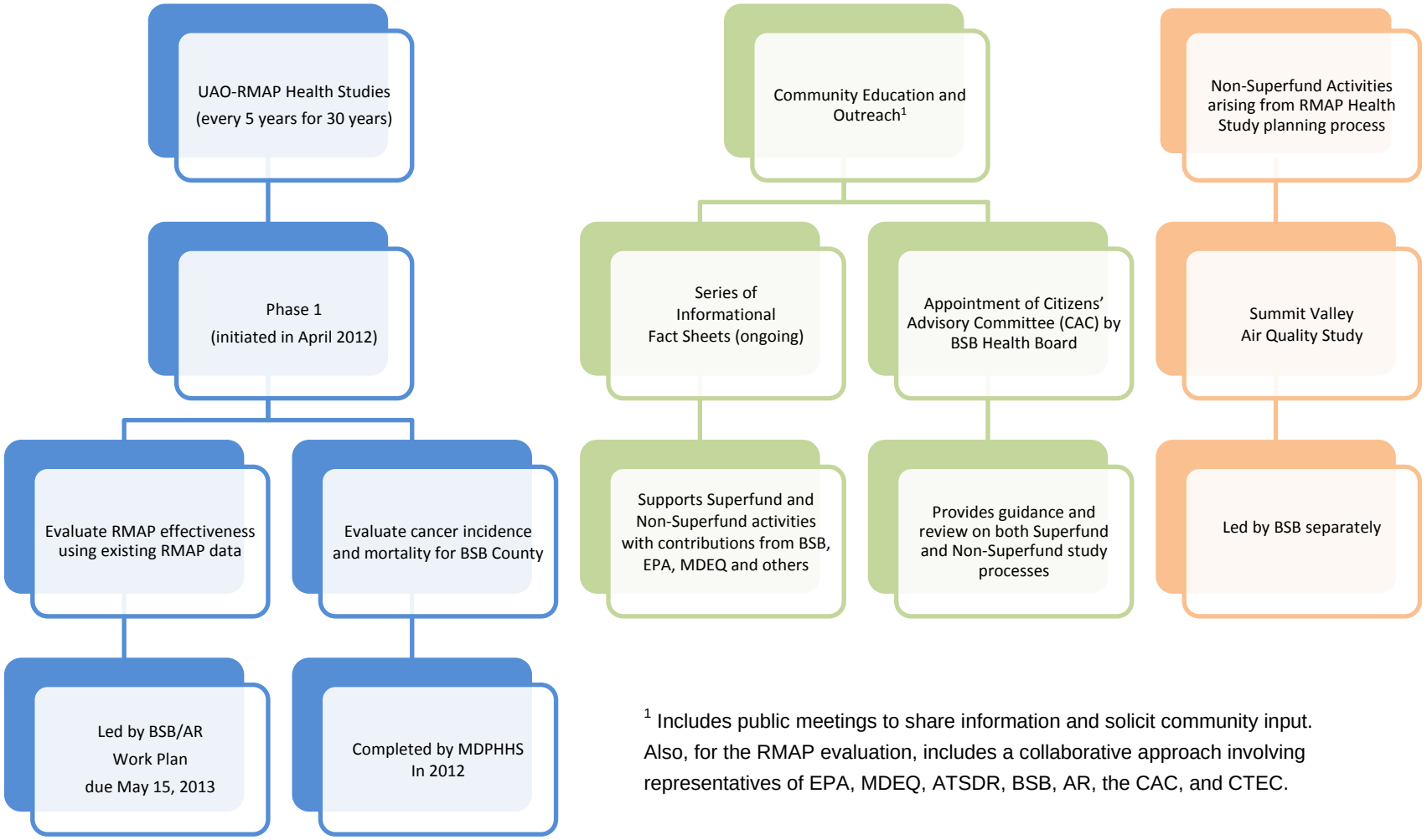
Figure 1. Summary of Health Studies Process



[1] Includes public meetings to share information and solicit community input. Also, for the RMAP evaluation, includes a collaborative approach involving representatives of EPA, MDEQ, ATSDR, BSB, AR, the CAC, and CTEC.

Figure 2. Public Health Study Area Boundaries

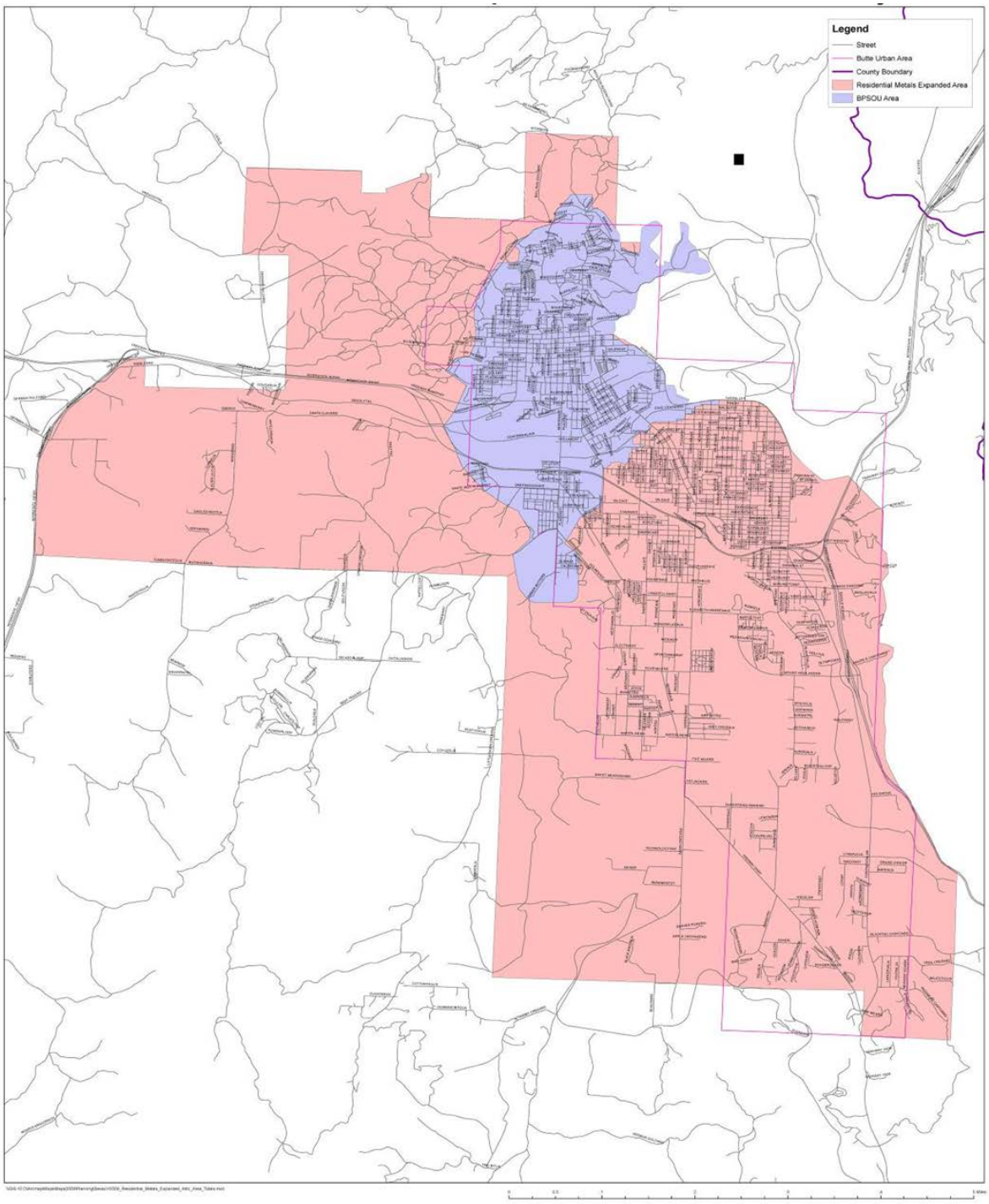


Figure 3. Summary of RMAP Environmental Program Property Evaluations and Abatements through 2011

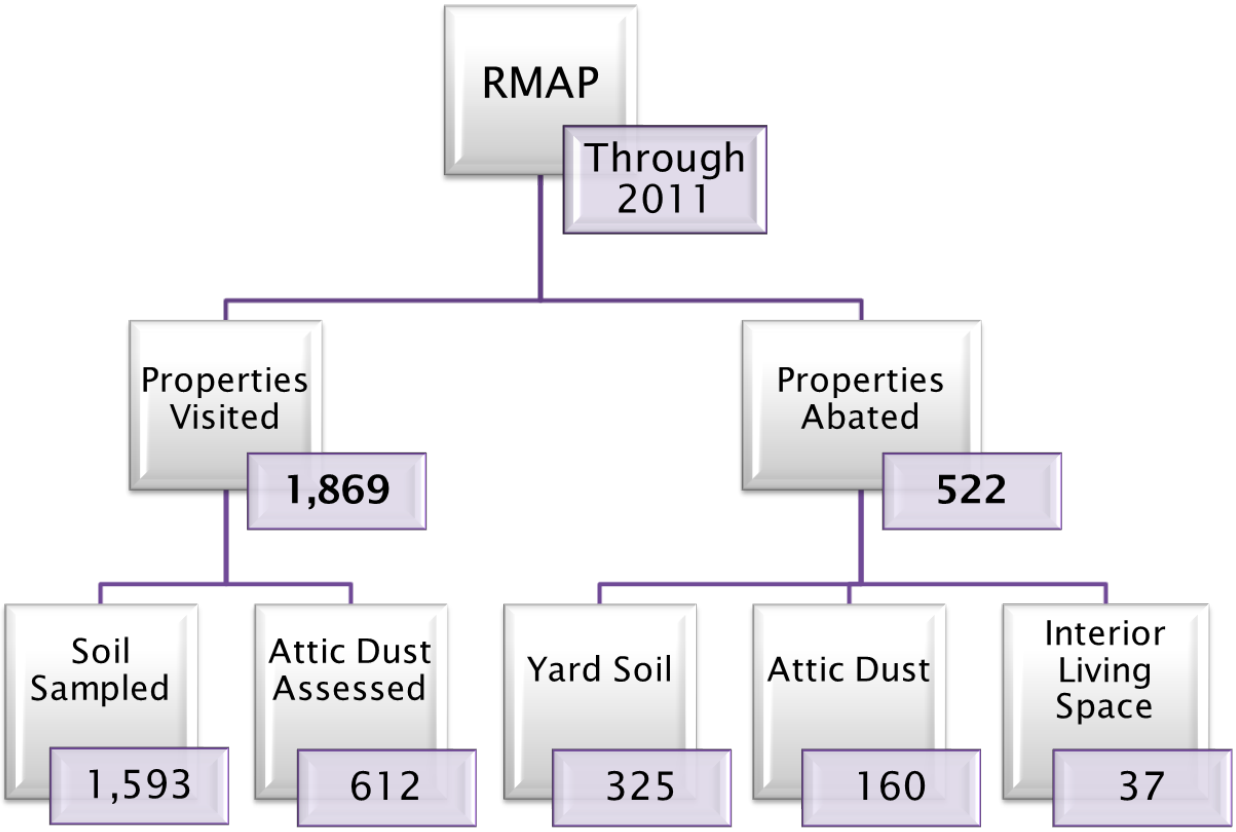
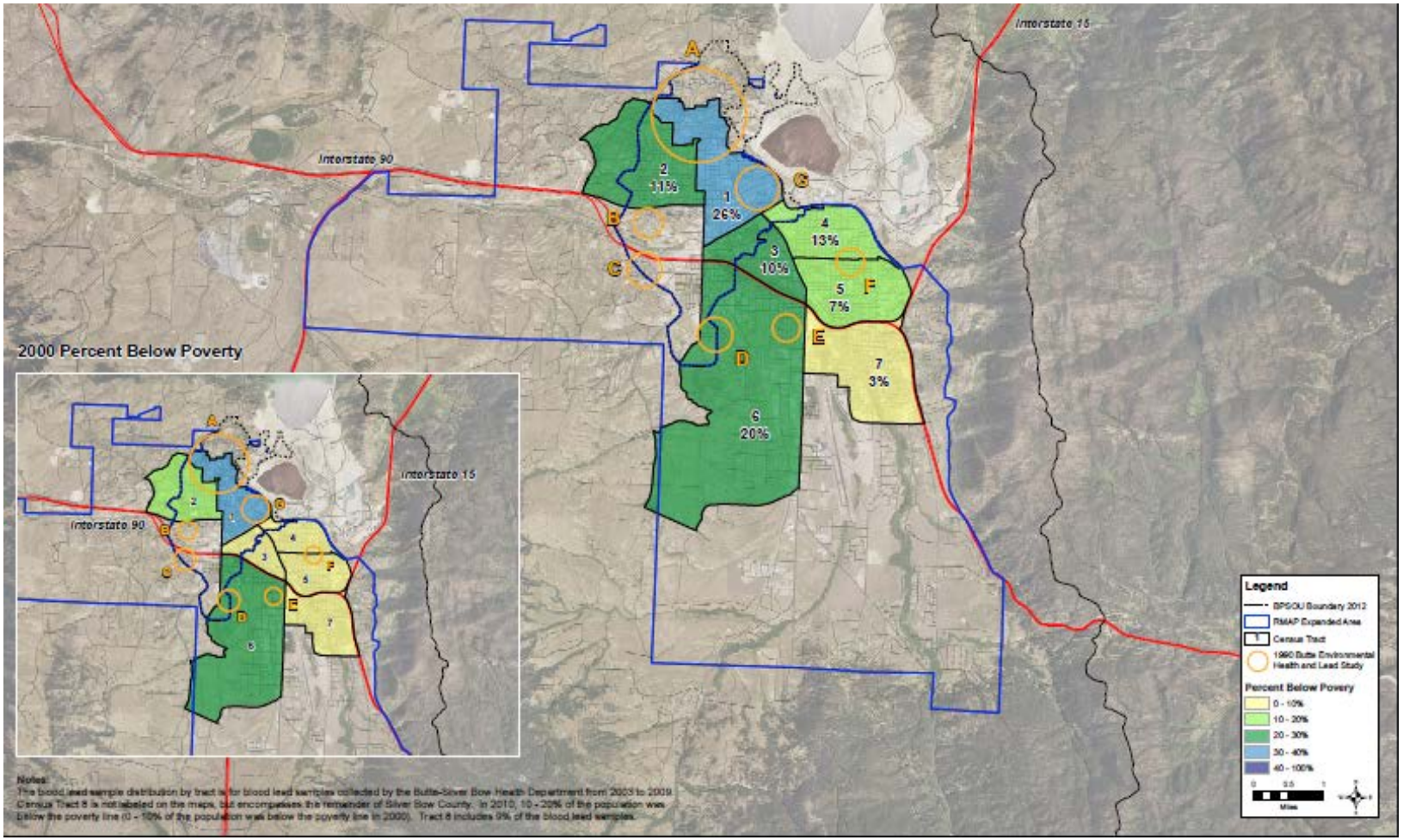


Figure 4. Butte Blood Lead Samples for Children - Percent of Samples in Each Census Tract (Tract Color Coded by Poverty Prevalence)



Appendix A

MDPHHS (2012) and ATSDR (2002) Studies

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.

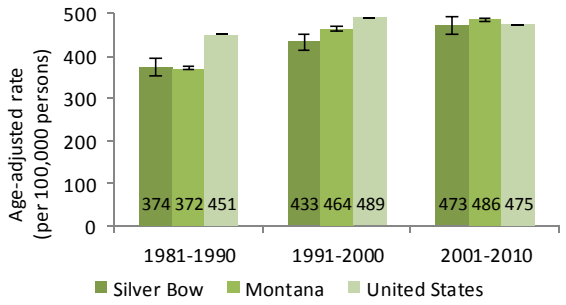
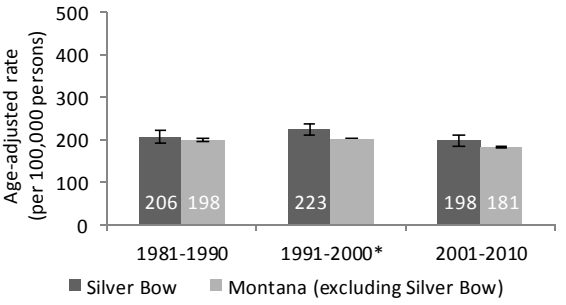


Figure 2. Age-adjusted mortality rate of all-site cancer, Silver Bow County and Montana



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.

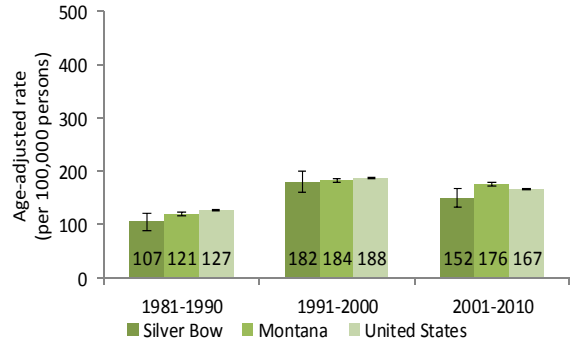


Figure 4. Incidence of breast cancer among female residents of Silver Bow County, Montana, and the U.S.

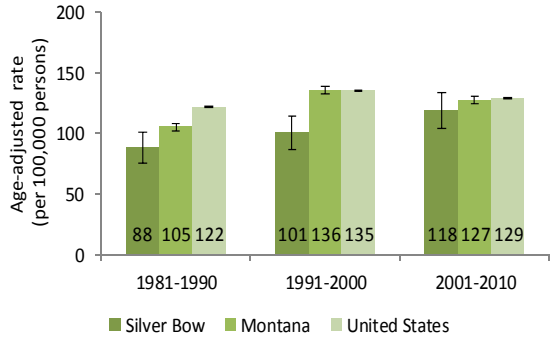


Figure 5. Incidence of colorectal cancer among residents of Silver Bow County, Montana, and the U.S.

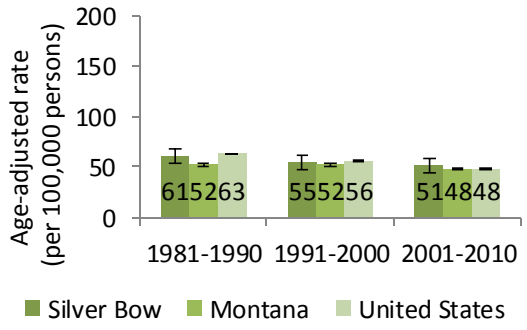
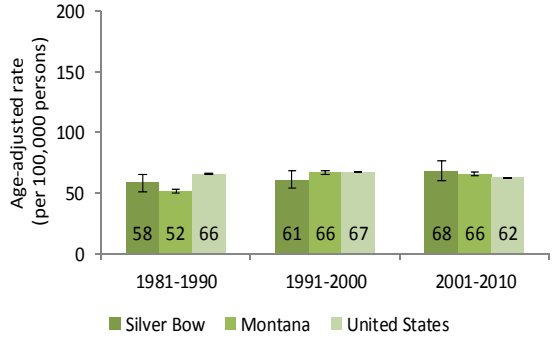


Figure 6. Incidence of lung & bronchus cancer among residents in Silver Bow County, Montana, and the U.S.



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

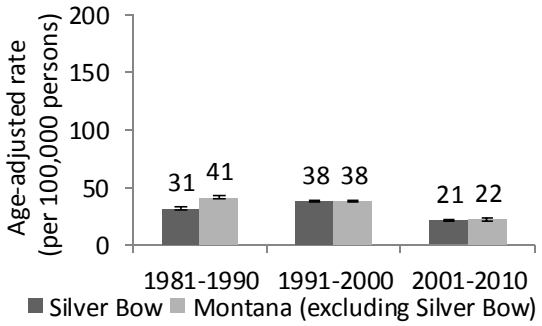


Figure 8. Mortality of female breast cancer among residents of Silver Bow County and Montana

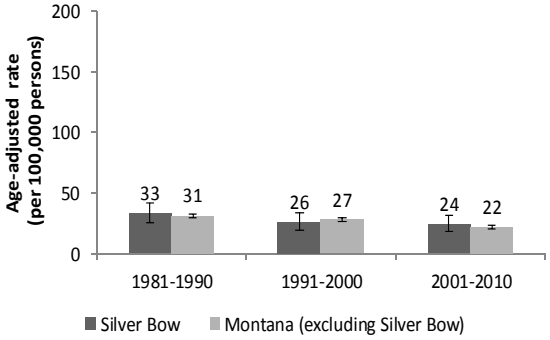


Figure 9. Mortality of colorectal cancer among residents of Silver Bow County and

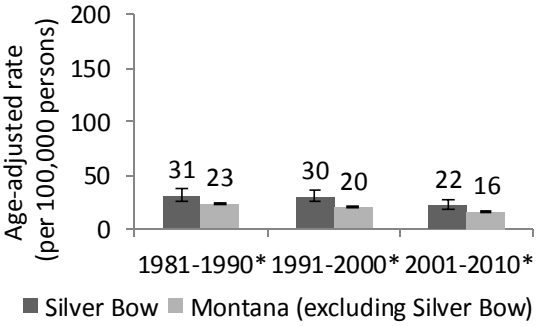


Figure 10. Mortality of lung & bronchus cancer among residents in Silver Bow County

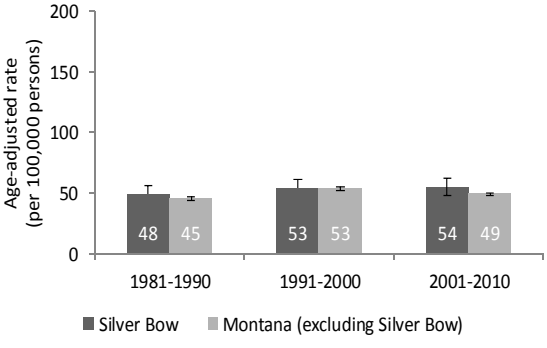


Figure 11. Incidence of bladder cancer among residents of Silver Bow County, Montana, and the U.S.

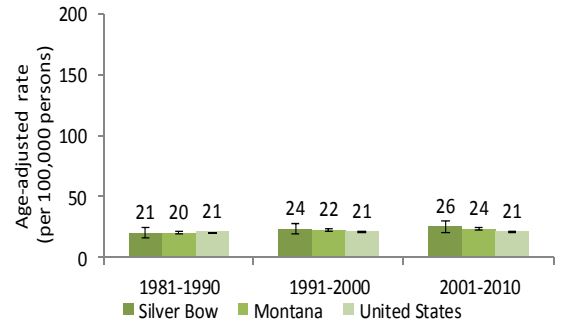


Figure 12. Mortality of bladder cancer among residents of Silver Bow County and Montana

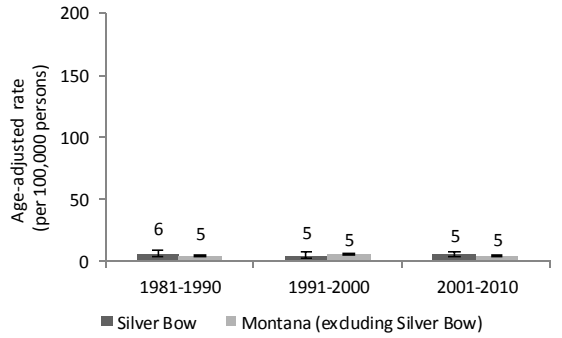
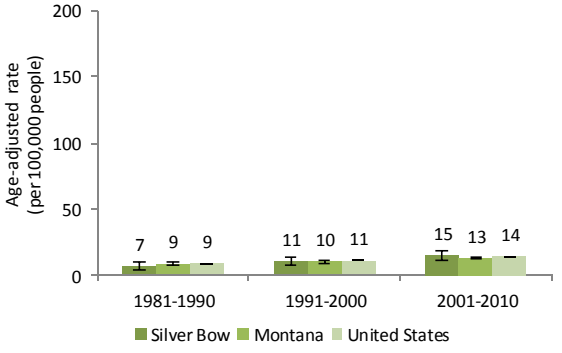


Figure 13. Incidence of kidney cancer among residents of Silver Bow County, Montana, and the U.S.



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).

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).

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

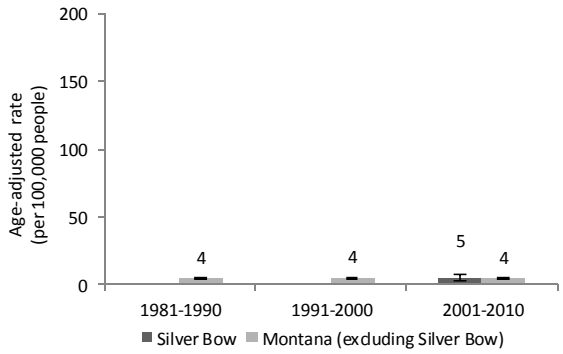


Figure 15. Incidence of liver cancer among residents of Silver Bow County, Montana, and the U.S.

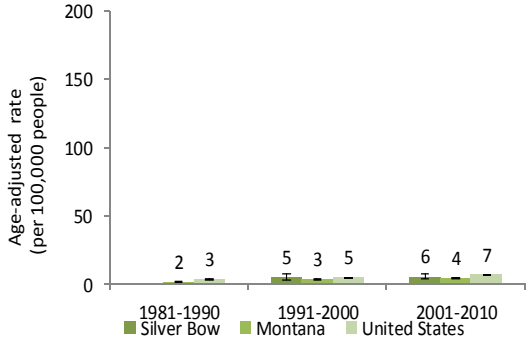
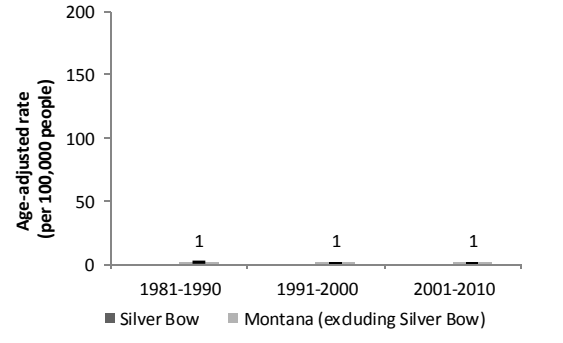


Figure 16. Mortality of liver cancer among residents of Silver Bow County and Montana



ATSDR Agency for Toxic Substances & Disease Registry

Public Health Assessments & Health Consultations

HEALTH CONSULTATION

SILVER BOW CREEK/BUTTE AREA
BUTTE, SILVER BOW AND DEER LODGE COUNTIES, MONTANA

INTRODUCTION

In June 2001, the Montana Department of Public Health and Human Services (MDPHHS) requested that the Agency for Toxic Substances and Disease Registry (ATSDR) evaluate cancer incidence data for Silver Bow County. The MDPHHS and Silver Bow County Health Department have had reports of possible cancer excesses from residents and physicians in the area for many years. This analysis focused on cancer outcomes associated with exposure to heavy metals including arsenic, and, to a lesser extent, lead and mercury.

Historically, elevated environmental levels of numerous heavy metals have been found in Silver Bow County soils as a result of mining and milling practices in the area. The Silver Bow Creek/Butte Area National Priorities List (NPL) site is an extensively contaminated site located in Silver Bow and Deer Lodge Counties. ATSDR has issued numerous documents related to this NPL site including health assessments, site review and updates, and health consultations. The agency has also conducted various health studies and exposure investigations in the Silver Bow area.

The purpose of this data review is to compare cancer incidence rates from Silver Bow County with similar data at the State and national levels. This ecologic analysis does not include any exposure information. Instead, it relies solely on cancer incidence data from state and national cancer registries and population demographic data from the U.S. Census Bureau.

MATERIALS/METHODS

The Montana Central Tumor Registry provided cancer incidence data to ATSDR in the summer of 2001. This data described all newly diagnosed cases occurring in Silver Bow County and the entire state of Montana during the twenty-one year period from 1979 to 1999. Specific cancer sites analyzed included the urinary bladder, kidney, liver, lung, prostate, and skin. Skin cancers used in this analysis included malignant melanomas as well as nonmelanomas. These outcomes were chosen because of their reported associations with arsenic exposure [1]. Mercury is not considered a human carcinogen and therefore did not influence the choice of cancers being analyzed [2]. There is limited information on the potential for lead to cause cancer so this contaminant also had little influence on the cancer sites analyzed [3].

Standardized incidence ratios (SIRs) were calculated using two comparison groups. The comparison groups included the entire state of Montana and a representative portion of the United States population. The Montana Central Tumor Registry provided cancer incidence data for the state of Montana for the years 1979 to 1999. Cancer incidence data for the United States were obtained from the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) program. The SEER program collects and publishes cancer incidence and survival data from 11 population-based cancer registries and three supplemental registries covering approximately 14 percent of the U.S. population. The SEER data used for comparison in this analysis included cancer incidence from 1989 to 1998.

Cancer incidence data for Silver Bow County and the two comparison populations were standardized using four age groupings; 20-54, 55-64, 65-74, and 75 and over. These predefined age groupings are used in publicly available SEER datasets. Age standardization eliminated the effects of age differences among residents of Silver Bow County, the state of Montana, and the United States as a whole. Cancer incidence rates for the state of Montana were adjusted using 1990 Census Bureau data. United States (SEER) incidence data were adjusted using the standard 1970 U.S. population.

RESULTS

Skin cancer was the only outcome that demonstrated elevated rates when compared to both Montana and U.S. reference populations (Table 1, Table 2). The SIR for all persons age 20 and over when compared to the state of Montana was 1.23 (95% CI, 1.04-1.44) and compared to the U.S. population was 1.24 (95% CI, 1.05-1.45). There were also elevated SIRs within multiple age-specific categories for skin cancer when compared with both reference populations.

Other cancer outcomes including urinary bladder, kidney, and lung demonstrated elevated rates in some age-specific categories but these elevations were not consistent when compared with both reference populations. Liver and prostate cancer rates were not elevated when compared with either reference population.

DISCUSSION

A previous ecologic analysis of skin cancer rates in Silver Bow County and neighboring Deer Lodge County by Wong et al. failed to show any significant increases in cancer morbidity [4]. However, their analysis used only six and one-half years of cancer incidence data (1980 to mid-1986) and this analysis looked at cancer incidence over a much longer time frame (1979-1999). Wong et al. identified all skin cancer cases through area pathologists and dermatologists, a less effective method compared with the use of data obtained from the state's central tumor registry. Case ascertainment in this analysis should be significantly increased through the use of registry data.

There are numerous limitations to this ecologic analysis including the potential for in- and out-migration of cases, a lack of exposure data, and no assessment of temporal variables (i.e. were subjects exposed before the occurrence of disease and were these exposures early enough to account for cancer latency). This analysis measured skin cancer incidence in aggregate instead of distinguishing between the two distinct forms of this disease,

malignant melanoma and nonmelanoma. Nonmelanoma is the only type of skin cancer that has been associated with arsenic exposure [5]. However, none of these limitations should consistently bias SIRs towards positive or negative associations.

Another limitation in interpreting the apparent elevation in skin cancer incidence is the demographic difference between Silver Bow County and the U.S. comparison population. Both malignant melanoma and nonmelanoma skin cancers are much more common in white populations. There is a higher percentage of Caucasians in Montana in contrast to the U.S. Therefore, some increase in skin cancer in the Montana population can be expected when compared to the total U.S. population. However, the demographics of Silver Bow County and Montana are fairly similar so this does not explain the elevated SIRs generated through comparisons with state cancer incidence data.

The process for age-adjusting cancer rates in Silver Bow County and Montana were similar as was the time frame for comparison (1979-1999). In comparing Silver Bow County with U.S. rates, there were some discrepancies. The analysis used different time frames of cancer incidence data for Silver Bow County (1979-1999) and the U.S. reference population (1989-1998). Also, there was a difference in the age-adjustment process with the U.S. reference group standardized using the 1970 U.S. population. These discrepancies in age standardization were unavoidable since NCI does not provide the raw data collected through the SEER program.

Even with these limitations and the minor differences in age standardization methods, there appears to be a slight increase in skin cancer incidence in this area of widespread arsenic contamination. Historically, skin and lung cancer have been the most prevalent cancer outcomes associated with arsenic exposure in the public health literature. Unfortunately no dose estimates were available for this analysis so the slight increase in skin cancer incidence cannot be evaluated against potential arsenic exposure in the area.

CONCLUSION

The data indicate a slightly elevated incidence of skin cancer in Silver Bow County when compared with age-standardized rates at the State and national level. No other cancer outcomes were consistently elevated when compared with these two reference groups. The slight increase in skin cancer incidence cannot be directly attributed to soil arsenic contamination in the area since no exposure assessments were included in this analysis.

RECOMMENDATIONS

1. Evaluate melanoma and nonmelanoma skin cancer incidence separately since only nonmelanoma skin cancers are associated with arsenic exposure.
2. Educate local citizens on ways to reduce or eliminate exposure to ambient arsenic contamination.
3. Educate local physicians on the symptoms, effects, and treatment regimes for arsenic exposure.
4. Consider reviewing pre-1979 cancer statistics to determine if cancer incidence was elevated prior to the time frame used in this analysis.

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2. Agency for Toxic Substances and Disease Registry. Toxicological Profile for Mercury. 1998.
3. Agency for Toxic Substances and Disease Registry. Toxicological Profile for Lead. 1998.

4. Wong O, Whorton MD, Foliart DE, Lowengart R. 1992. An ecologic study of skin cancer and environmental arsenic exposure. Int Arch Occup Environ Health 64:235-241

5. Schottenfeld, Fraumeni. 1996. Cancer epidemiology and prevention. New York: Oxford University Press. p. 1282-1330.

TABLES

Urinary Bladder Table 1.

Standardized Incidence Ratios using the Montana Population as a Reference, 1979-1999

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	1	11.2	0.09	0.00	0.50
55-64	18	23.6	0.76	0.45	1.21
65-74	90	50.5	**1.78¶**	1.43	2.19
75+	68	61.7	1.10	0.86	1.40
20+ (all ages combined)	177	147.0	**1.20¶**	1.03	1.40

Kidney

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	9	12.5	0.72	0.33	1.23
55-64	15	14.9	1.00	0.56	1.56
65-74	30	22.9	1.31	0.88	1.81
75+	34	18.6	**1.83¶**	1.27	2.48
20+ (all ages combined)	88	68.9	**1.28¶**	1.02	1.56

Liver

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	2	1.8	1.11	0.12	4.01
55-64	5	2.0	2.50	0.81	5.83
65-74	6	4.9	1.22	0.45	2.67
75+	10	5.9	1.69	0.81	3.12
20+ (all ages combined)	23	14.6	1.58	1.00	2.36

Lung

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	57	40.2	**1.42¶**	1.07	1.84

55-64	127	110.6	1.15	0.96	1.37
65-74	210	194.2	1.08	0.94	1.24
75+	159	148.5	1.07	0.91	1.24
20+ (all ages combined)	553	493.5	**1.12¶**	1.03	1.22

Prostate

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	11	14.5	0.76	0.38	1.24
55-64	87	91.5	0.95	0.76	1.03
65-74	212	232.3	0.91	0.79	1.04
75+	209	213.5	0.98	0.85	1.12
20+ (all ages combined)	519	551.8	0.94	0.86	1.02

Skin

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	43	28.4	**1.51¶**	1.10	1.99
55-64	25	19.8	1.26	0.82	1.79
65-74	39	30.3	1.29	0.92	1.72
75+	39	39.8	0.98	0.70	1.31
20+ (all ages combined)	146	118.3	**1.23¶**	1.04	1.44

Table 2.

Standardized Incidence Ratios using the U.S. population (SEER) as a Reference, 1979-1999

Urinary Bladder

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	1	15.2	0.07	0.00	0.37
55-64	18	28.5	0.60	0.37	1.00
65-74	90	62.8	**1.40¶**	1.15	1.76
75+	68	76.3	0.89	0.69	1.13
20+ (all ages combined)	177	182.8	0.97	0.83	1.12

Kidney

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	9	14.9	0.60	0.28	1.03
55-64	15	18.8	0.80	0.45	1.23
65-74	30	29.0	1.04	0.70	1.43
75+	34	27.0	1.26	0.87	1.71
20+ (all ages combined)	88	89.7	0.98	0.79	1.20

Liver

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI

20-54	2	5.2	0.39	0.04	1.39
55-64	5	7.0	0.71	0.23	1.66
65-74	6	12.3	0.49	0.18	1.06
75+	10	13.6	0.74	0.35	1.35
20+ (all ages combined)	23	38.2	0.60	0.38	0.90

Lung

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	57	53.2	1.07	0.81	1.39
55-64	127	118.4	1.07	0.89	1.28
65-74	210	226.7	0.93	0.81	1.06
75+	159	195.0	0.82	0.69	0.95
20+ (all ages combined)	553	593.3	0.93	0.86	1.01

Prostate

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	11	51.5	0.21	0.11	0.35
55-64	87	251.5	0.35	0.28	0.42
65-74	212	668.9	0.32	0.28	0.36
75+	209	666.2	0.31	0.27	0.36
20+ (all ages combined)	519	1638.25	0.32	0.29	0.34

Skin

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	43	44.1	0.98	0.71	1.28
55-64	25	21.4	1.17	0.75	1.65
65-74	39	26.7	**1.46¶**	1.04	1.95
75+	39	25.4	**1.54¶**	1.09	2.05
20+ (all ages combined)	146	117.6	**1.24¶**	1.05	1.45

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Appendix B

Butte Silver Bow Health Department Environmental Fact Sheets

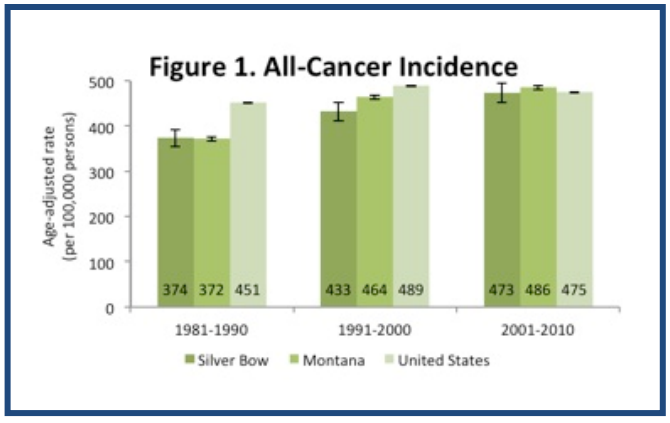
Butte-Silver Bow Health Department – 2012 Environmental Health Studies
Fact Sheet No. 1

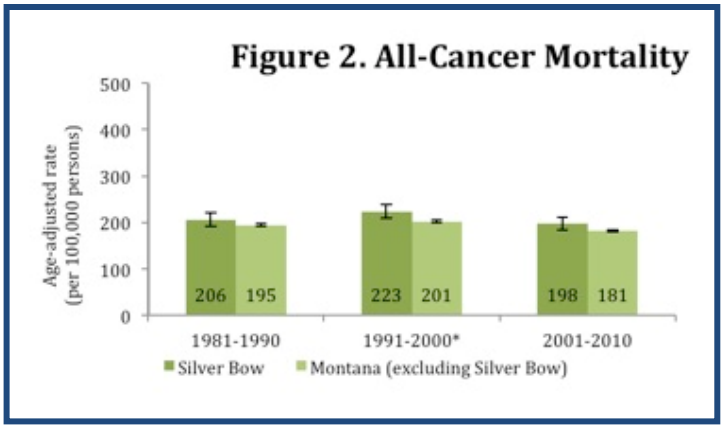
Cancer Incidence and Mortality Rates Butte-Silver Bow County

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.

Butte-Silver Bow Health Department – 2012 Environmental Health Studies
Fact Sheet No. 2

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.

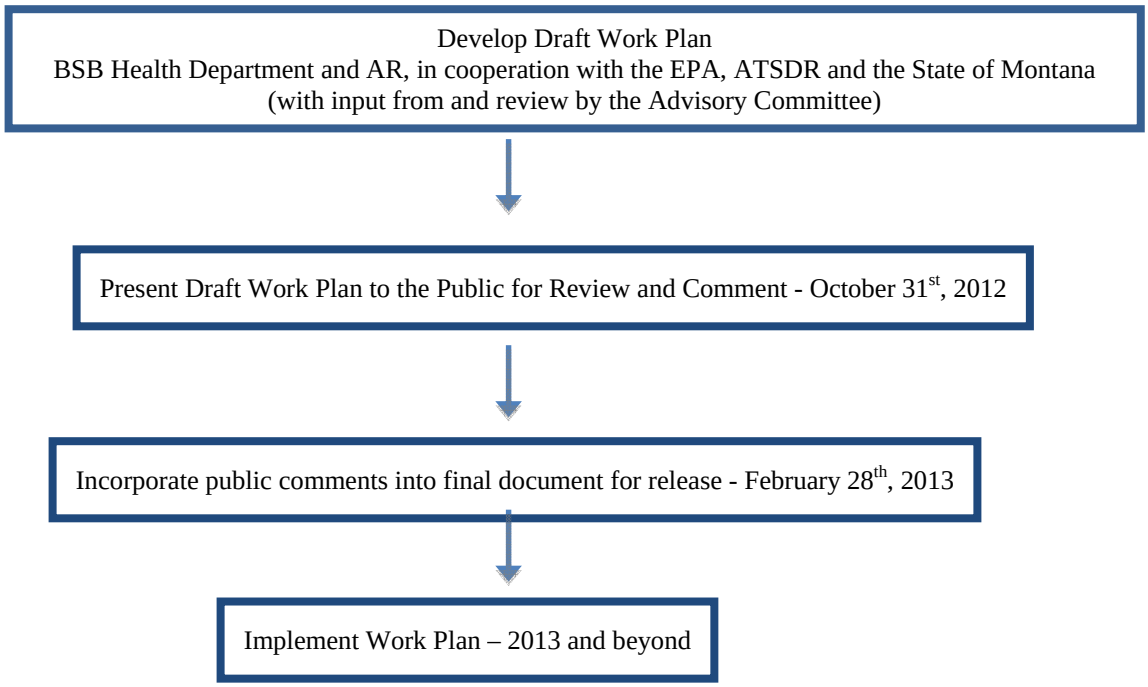
Committee Responsibilities. Members of the Committee will have responsibilities that include the following:

- 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.

Butte-Silver Bow Health Department

2012 Environmental Health Studies
Fact Sheet No. 5

Subject: Air Quality Monitoring at Greeley School

Discussion: Butte-Silver Bow County (BSB) has had air pollution challenges for many years. The first administrative requirements for BSB were prompted by the Environmental Protection Agency (EPA) and state public health agencies in the late 1970s. Over time, as EPA's National Ambient Air Quality Standards (NAAQS) have become increasingly protective, BSB has continued to struggle with keeping air pollution below the standards for public health protection. This is particularly true in regard to the standard for fine airborne particulate matter ($PM_{2.5}$).

Over the years, the DEQ air pollution monitor located at the Greeley School site has measured many days when the concentration of fine particulate matter in the air was worse than the standard. The following graph shows average $PM_{2.5}$ values measured at Greeley School from 2008 through 2011 and compares those averages to the EPA standard. The measured values exceeded the standard in 2002, 2005, 2010, and 2011(See Figure 1).

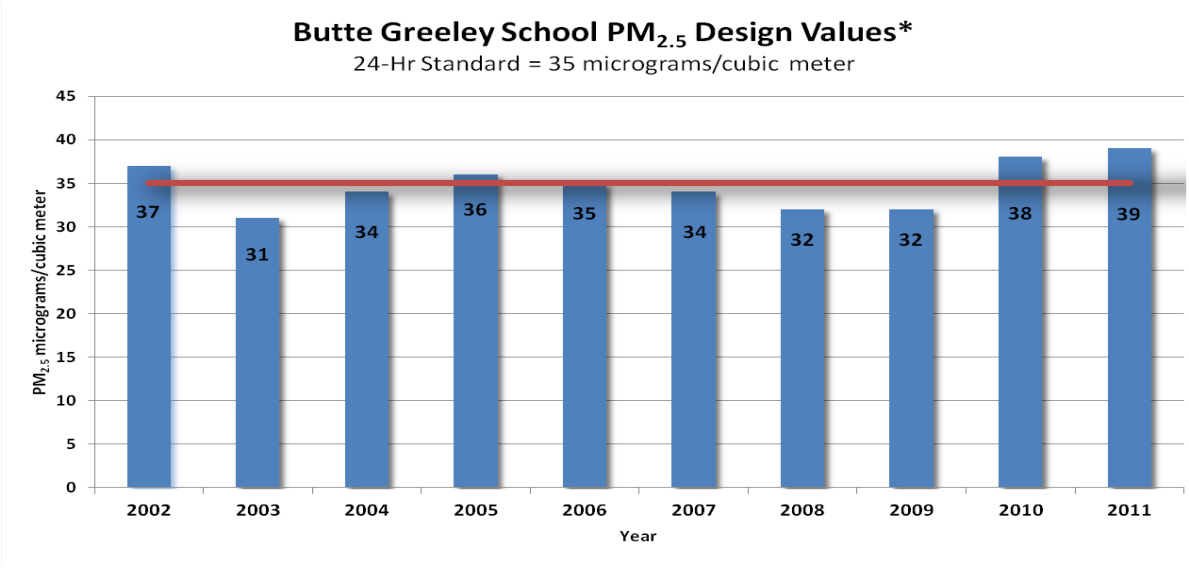


Figure 1. Greeley School $PM_{2.5}$ Average Measurements.

*Design Values are the three year average of the 98th Percentile values for each year. Compliance with the 24-Hr Standard is determined by comparing the design values with the Federal Standard, which is currently 35µg/m³ in a 24-hour day.

What is $PM_{2.5}$? $PM_{2.5}$ is microscopic-sized particulate matter that can stay suspended in the air. Its name indicates that the particles have a relative diameter of 2.5 microns or less - approximately 30 times smaller than the diameter of a human hair. $PM_{2.5}$ is important because it may lodge deeply within the lungs when inhaled and harm people's health as a result. $PM_{2.5}$ can be made up of a variety of chemical compounds, most of which are by-products from the combustion of various fuels such as wood, diesel fuel, and gasoline. It is important to

understand what those compounds are in the air around Butte so that their local sources may be addressed.

To help understand what these different compounds are, the Montana Department of Environmental Quality (DEQ) contracted with the University of Montana (UM) to conduct studies to identify the chemical makeup of $PM_{2.5}$ in several western Montana communities during the winter months. This study was conducted in Butte from November 8, 2007 through March 1, 2008. The results of the study showed that wood smoke (likely from residential wood burning) was the major chemical component of the fine particulate throughout the winter months, contributing an average of 77.0% of the total measured $PM_{2.5}$. Figure 2 below shows a summary of the study results.

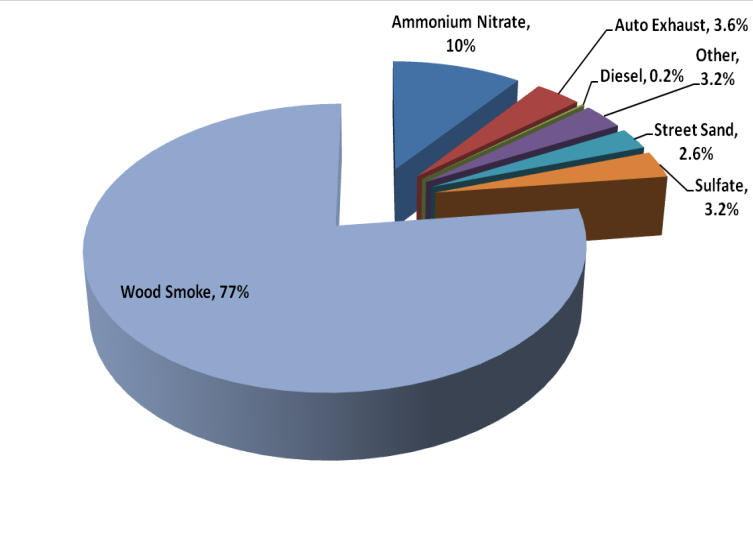


Figure 2. Chemical Makeup of $PM_{2.5}$ in Butte

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Butte-Silver Bow Health Department

2012 Environmental Health Studies
Fact Sheet No. 6

Subject: Air Quality and Fine Particulate Studies

Discussion: In November 2008, the Montana Department of Environmental Quality (DEQ) began operating a unique set of air monitors at the Butte Greeley School site. These monitors are used to collect samples of fine particulate ($PM_{2.5}$) that are analyzed for many possible chemical components including organic carbon, elemental carbon, thirty-three (33) different trace elements, nitrate, sulfate, ammonium, sodium, potassium, and total $PM_{2.5}$ mass. Although the analysis of the samples from these monitors does not look at exactly the same components as the University of Montana's 2008 study (see Fact Sheet No. 5), the results from the 2011 data show that organic carbon continues to be the largest portion of the chemical makeup of the fine particles being measured. In total, the organic components, or smoke, are 62% of measured particulate matter. Figure 1 shows these results:

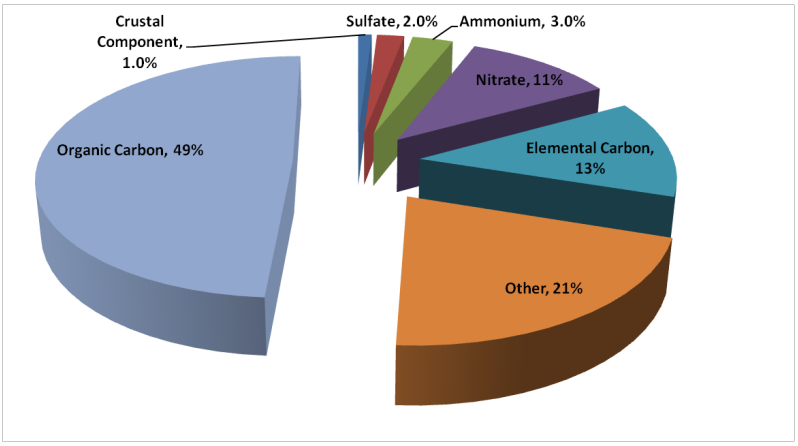

Figure 1. Makeup of Fine Particulate in Butte, 2011.

Together, the DEQ 2011 data and the results of the 2008 University of Montana study show that most of the higher concentrations of fine airborne particulate in the Butte area are due to wood burning during cold, stagnant days in winter.

Wind Direction and $PM_{2.5}$: When comparing the 2011 data from the air samplers at Greeley School with wind direction, the highest concentrations of fine particulate are most often measured when the air comes from the southeast. Figure 2 below shows that relationship. The center of the graph is on the Greeley School site located just southeast of the Berkeley Pit. The colored bars that extend from the center show how much PM2.5 is measured from each of the wind directions around Greeley School, where the darker red color represents the highest particulate contributions:

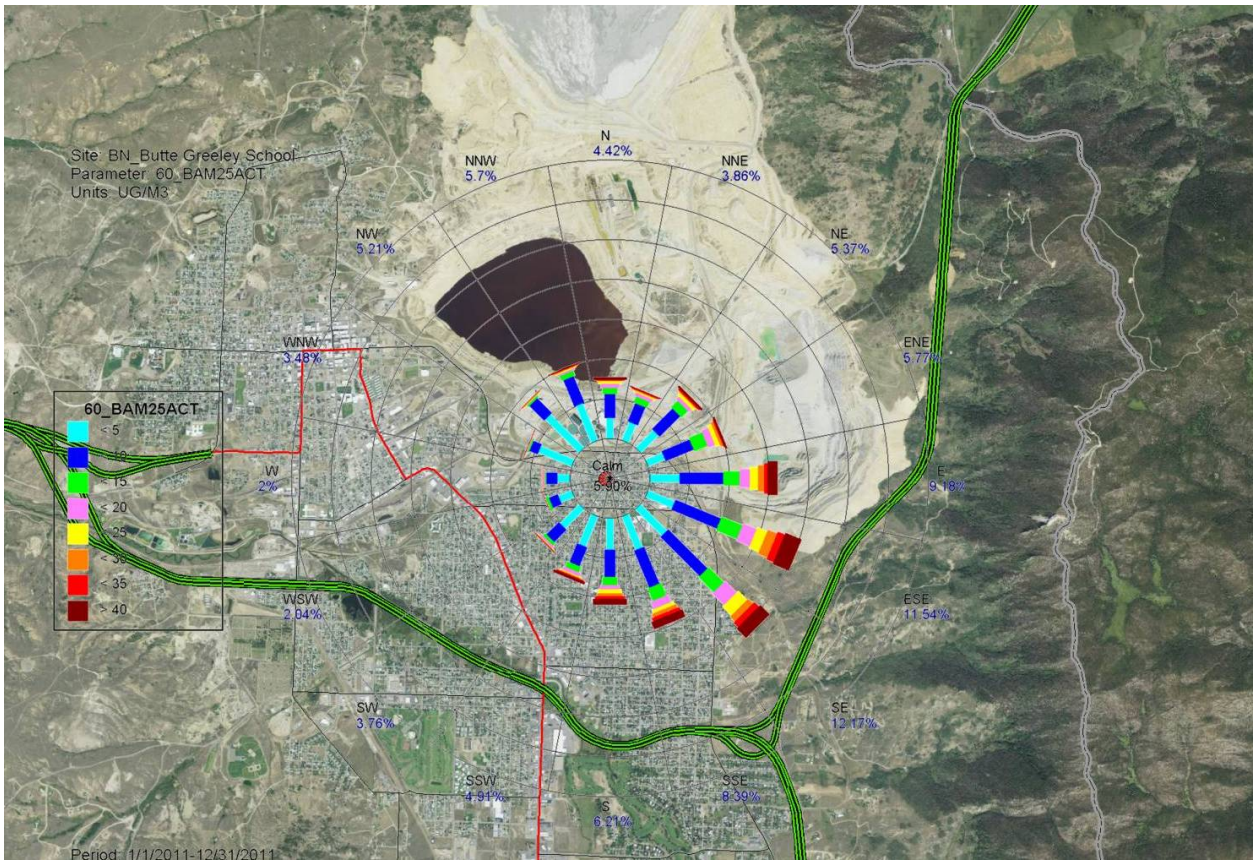

Figure 2. Wind Direction and $PM_{2.5}$ in Butte, 2011.

$PM_{2.5}$ and Wood Burning

To reduce winter-time fine particulate impacts that come from using residential wood stoves, the BSB Health Department has a solid fuel burning regulatory program, which includes a woodstove control program. In short, the program limits or shuts-down woodstove use during times of poor air quality, which usually occurs on cold stagnant winter days. Typically, the number of days that woodstove use will be limited is less than 10 during a given winter. BSB is also regulating new or remodeled installations of wood burning devices by requiring that any installations be EPA-certified devices.

Also, BSB has a new electronic sign located at the health department building, 301 Front Street, to let the public know when residential wood burning is restricted. BSB provides education and outreach opportunities to teach wood stove users of best burning practices and the importance of using cleaner, state-of-the-art, wood stove technologies to reduce health impacts in the community.

The DEQ plans to perform additional monitoring during the winter of 2012-2013 to help better understand the $PM_{2.5}$ in the Butte area.

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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.

The initial, Phase One study will not include crystalline silica. This may be addressed at a later time.

The working group consensus was to concentrate on PM-10 and PM-2.5 issues, which are regulated by Butte-Silver Bow. Additional concerns, such as the current mining operation and other industrial sources, will be addressed, specifically, by the Montana Department of Environmental Quality. This entity is charged with the regulatory authority and all associated permitting for these sources.

These air quality 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. Figure 1 represents the Phase One segment for the work plan of the non-Superfund Public Health Study. Table 1 represents the Timeline associated with the air quality studies that will be done in 2013..

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.***

Figure 1
Work Plan

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.); identify current rules and regulations associated with existing National Ambient Air Quality Standards for heavy metals; review of Montana Department of Environmental Quality/Clean Air Act rules and regulations for heavy metals; 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.

Two studies will occur during the timeframe of May through August of 2013 with final reports due in October and December.

Table 1
Timeline

1. Assessment of particulate concentration in Butte relative to PM-10 and PM-2.5. This will include metals analysis associated with the Greeley School's speciation monitor.

The project will start in May 15, 2013 and end in October 15, 2013.

Task	Description	Time Schedule
1	PM_{10} data analysis and graphical display	May 15- July 15, 2013
2	$PM_{2.5}$ data analysis and graphical display	June 15- Aug 15, 2013
3	Analysis of wind data for Butte and wind rose display	June 15- Augt.15, 2013
4	eBAM data analysis and graphical data display	July 15- Aug 15, 2013
5	Performing the speciation data analysis for $PM_{2.5}$ particulates from Greely school site.	June 1-Aug 15, 2013
6	Report writing, review and submitting the final report	**Aug 15-Oct 15, 2013**

2. A summer months PM-2.5 Source Apportionment Project (Chemical Mass Balance). This will identify the sources of PM-2.5 in Butte during the months of June, July, and August, 2013.

Final Reporting

Involves writing the final report, and submitting it to the Butte-Silver Bow Health Department. The report will include a full discussion of the experimental procedures used (sampling, analytical, and modeling methodologies), as well as results and discussion sections. A comparison between the results of the summer 2013 and the winter 2012/2013 CMB program will also be included in the final report. A draft of the report will be submitted to the Butte-Silver Bow Health Department by November 30, 2013, with the final report submitted by December 31, 2013.

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[14] 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

[14] 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.

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://www2.epa.gov/region8/administrative-order-partial-remedial-designremedial-action-implementation-and-certain

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

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

Attachment 2

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

Note: The full plan is available at:
http://www2.epa.gov/region8/residential-metals-abatement-program-butte-priority-soils-operable-unit

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.

Attachment 3

Response to Comment Summary for October 31, 2012 draft "Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan"

Executive Summary

This document provides responses to public comments received on the October 31, 2012 draft "Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan", hereafter "the Draft Work Plan".

Study Responsibility: BSB and AR are required to conduct this study as part of the Butte Priority Soils Operable Unit (BPSOU) Unilateral Administrative Order (UAO). Oversight of the Draft Work Plan development and study conduct are being provided by a Working Group composed of representatives of EPA[1], MDEQ[2], ATSDR[3], BSB[4], AR[5], and a representative of CTEC[6]. The Working Group also includes a Citizens' Advisory Committee (CAC), which was formed to support the health studies process. ENVIRON is the consultant executing the work plan and study. This health study has also been referred to as the Superfund health study, reflecting the requirement for this study in the BPSOU UAO and to differentiate it from "non-Superfund" health studies that are under development separately.

Study Planning Process: The Draft Work Plan is the result of a collaborative planning process by the Working Group begun in April 2012. During initial study scoping meetings, available exposure and health data for Butte were reviewed and the feasibility of conducting various kinds of studies was evaluated. Feasibility issues included availability of suitable data, as well as the ability to complete a study in a timely manner. Two possible studies were identified. One was an update of a 2001 health consultation by ATSDR which evaluated cancer incidence data for Silver Bow County (ATSDR 2002). An update and expansion of the ATSDR cancer incidence study (ATSDR 2002) was completed by epidemiologists with the Montana Cancer Surveillance and Epidemiology Program (MCSEP)[7] in 2012 following the Working Group request. The second possible study was an evaluation of lead exposures using blood lead data collected by BSB as part of the RMAP[8]. The proposed lead exposure study is the subject of the Draft Work Plan.

The initial study scoping process also determined that studies of other health outcomes (other than cancer) were not feasible due to lack of reliable data and/or sufficient numbers of cases across Butte neighborhoods and/or county-wide. It was also determined that biomonitoring data was not available for other chemicals, that a focus on lead as the principal Superfund chemical of concern in BPSOU was appropriate, and that lead provides a good surrogate for exposures to other site-related contaminants that may be present along with lead. Additional discussion of these points is provided in the section on key issues below.

[1] U.S. Environmental Protection Agency
[2] Montana Department of Environmental Quality
[3] Agency for Toxic Substances and Disease Registry
[4] Butte Silver Bow County
[5] Atlantic Richfield Company
[6] Citizens Technical Environmental Committee
[7] MCSEP is a part of the Montana Department of Public Health and Human Services (MDPHHS).
[8] Residential Metals Abatement Program

Sources of Comments: Comments were received in the form of emails and as verbal comments during the two public meetings that were held after the Draft Work Plan was issued. The Working Group would like to express its thanks to all of the Butte citizens who took the time to review the Draft Work Plan, attend the public meetings and to submit comments. The insights and perspectives provided have improved the Work Plan, and will inform ongoing planning for other health studies (both the non-Superfund studies and future health studies that may be conducted under the Superfund order). The Working Group is committed to facilitating continued outreach to the community as this study progresses. A similar commitment has been expressed by the group planning additional non-Superfund health studies.

Method of Developing Responses to Comments: To facilitate consideration of comments, individual comments were grouped into several common themes. While all of the comments received are listed, along with a response, multiple comments from the same individual are not presented together as submitted[9]. Responses to various comments were drafted by different members of the Working Group. In addition, MDPHHS contributed some responses to comments related to the MCSEP 2012 epidemiology study of cancer incidence and mortality. ENVIRON compiled the comments and responses as presented.

Comment themes fall within one of two comment groupings. Group 1 comments pertain to topics that fall outside of the scope of the Superfund Health Study and draft work plan revisions and are summarized in Table 1. Group 2 comments (Table 2) pertain to topics that are more directly related to the Superfund Health Study and/or draft work plan revisions. Groups and themes represented in the following tables are summarized as follows:

Table 1 Comments

1.A Comments Related to Current Air Quality
1.B Comments Pertaining to Site-Specific Action Levels and Bioavailability
1.C Comments Pertaining to the RMAP Implementation and Ongoing Biomonitoring Program

Table 2 Comments

2.A Comments Pertaining to the Goals and Purpose of the Health Studies
2.B Comments Pertaining to Public Involvement
2.C Comments Pertaining to Environmental Justice
2.D Comments Pertaining to Independence of Study/Investigators and Need for External Peer Review
2.E Comments Pertaining to Specific Study Design Elements of the Draft Work Plan
2.F Comments Pertaining to the Study Focus on Exposure vs. Health Outcomes
2.G Comments Pertaining to Focus on Lead
2.H Comments Pertaining to the Precautionary Principle
2.I Comments Pertaining to Other Various Issues

[9] Comments reproduced in the table were not corrected for typographical errors. In some cases, comments including several parts related to the same theme were assigned numbers or bullets and corresponding responses were developed using the same numbering/bulleted structure to facilitate clarity of response.

Summary of Key Issues and Responses

Due to the length of the comment/response table, we provide below a summary of key issues of concern to citizens, along with our responses.

Table 1 Comments – Comments that Fall Outside the Scope of the Superfund Study

Some of the comments received address Butte health concerns or issues that are not pertinent to the Draft Work Plan or to future Superfund studies. As described above, the Draft Work Plan describes the Superfund health study, as provided by the BPSOU UAO. The Draft Work Plan is not intended to describe additional "non-Superfund" health studies under development separately. Some of the comments expressed confusion regarding the scope presented in the Draft Work Plan versus other health study discussions and issues. In response to these comments, the language in the Draft Work Plan describing its role versus other studies will be augmented.

1.A. Air Quality: Some comments were about current air quality in Butte and the recently issued Fact Sheet on that topic. Current air quality issues are being addressed by MDEQ and BSB. The responses to these comments amplify the information on this topic provided in Fact Sheet 5 (see Appendix B to the final work plan), and explain in some detail the ongoing air quality monitoring program in Butte and plans for future actions to address citizens' concerns about air quality.

1.B. EPA Risk Assessments, Action Levels and Bioavailability: Other comments pertained to EPA health risk assessments, action levels, and bioavailability. In the responses, EPA explains why the action levels developed for Butte are health-protective, describes in detail the development of the methods used to assess soil lead and arsenic bioavailability, and EPA's current view regarding the new CDC blood lead reference level and why the soil lead action level is not being changed at this time.

1.C. RMAP and Biomonitoring: Details of the RMAP and associated biomonitoring program are described in response to one long comment from an individual resident. Further information on the RMAP is provided at http://www.epa.gov/region8/superfund/mt/sbcbutte/.

Table 2 Comments – Comments Related to Superfund Health Studies

2.A. Goals and Purpose of the Health Studies (Current and Future): As noted above, some commenters expressed confusion and/or frustration in trying to understand the various discussions of health studies reported in the news, in fact sheets or discussed at public meetings. Concern was also expressed regarding the clarity of the goals for the study as described in the Draft Work Plan. Based on these comments, the Draft Work Plan will be revised to clarify the goals of health studies described in the UAO. During an initial study planning meeting on April 16, 2012, representatives from EPA, MDEQ, ATSDR, BSB, and AR (hereafter, the "Working Group") reviewed scoping elements for health studies described in the UAO and identified two primary goals to be considered in design of the studies. The first goal is to evaluate whether the RMAP has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. The second goal is to review community health concerns that relate to factors outside the scope of Superfund chemicals of concern or actions to help BSB focus on broader public health improvement efforts. The study design described in the October 31, 2012 Draft Work Plan is focused on BSB/AR approaches to address the first goal; however, design elements that BSB is considering separately to address the second goal are

included in Appendix C to the Draft Work Plan. As described in the UAO and Draft Work Plan, public health studies will be performed every five years for a period of thirty years. The scope of the first of these studies was described in the October 2012 Draft Work Plan and will be clarified in the final work plan. The scope of subsequent future studies will be determined at a later date.

Responses to individual comments provide additional detail regarding the basis for the current study design, the metrics by which the efficacy of the RMAP will be evaluated, possible impacts of the study findings on the RMAP and cleanup activities in Butte, and ways in which the current study might inform the design of future studies.

2.B. Public Participation: EPA's goal for public participation within the Superfund program is: "to advocate and strengthen early and meaningful community participation during Superfund cleanups." The Working Group recognized a high level of public interest in the health study planning process, and, consistent with EPA's public participation goal, implemented an extensive public outreach effort. Based on the comments received, we understand that opportunities remain, moving forward, to more fully engage meaningful public participation. Individual comment responses identify what was originally done in the public participation process, actions that were taken to improve public participation during the comment and response period, and additional commitments that will be made moving forward.

The appointment of a CAC by BSB was a key step in ensuring opportunities for active participation by technically qualified community residents in the study design and in overseeing the implementation of the health studies. In response to comments, a technical representative of CTEC has also joined the Working Group[10]. Opportunities for public participation will continue to be provided throughout the process of planning and executing both Superfund and non-Superfund studies. Moreover, EPA, BSB and AR remain open to further recommendations from members of the public on how public participation can be improved to meet community needs.

The Superfund health study work plan will be revised to expand and clarify where public input will be sought within the current blood-lead focused study design. For the non-Superfund studies, BSB is leading the planning effort, which is still in the early stages. BSB should be contacted directly to seek opportunities to participate in the non-Superfund health study design process.

2.C. Environmental Justice: In response to comments asking how environmental justice concerns will be addressed in the study, a new section will be added to the revised work plan that identifies environmental justice considerations that are incorporated in the health study design and community outreach process. The goals of the proposed study are intended to evaluate those aspects of the RMAP that deserve additional assessment, including but not limited to environmental justice considerations. The responses to comments also provide information on EPA's environmental justice programs and specific efforts in Butte, and describe in more detail how EPA's risks assessments and remediation goals have sought to protect the most sensitive members of the population.

2.D. Independence of Study: Comments also addressed concerns that the study be conducted in an unbiased manner and that the findings be subject to independent peer review. The responses describe the participation of experts from EPA, MDEQ, ATSDR, BSB and AR in designing the current study, and

[10] The CTEC representative was appointed to the Working Group January 28, 2013.

note that the CAC has been established to enable technically qualified Butte residents to review and provide input regarding study plans and analyses. In addition, comments on the Draft Work Plan have been solicited from the public, and additional opportunities will be provided to review the study findings. Based on the comments received, the Working Group will also be exploring the possibility of submitting the study results for independent peer review and publication.

2.E. Specific Study Design Elements: In response to comments on specific study design elements, the work plan will be revised to clarify the study boundaries and target population of interest (and the basis for focusing on that population). Some of the detail requested by commenters regarding documentation of the development and quality evaluation of the study database, selection of Butte neighborhoods and comparison populations from outside Butte, and statistical tests that will be used in the study are still, under development and will be provided in subsequent memoranda or briefings. The work plan will be revised to provide greater detail regarding the development of the database and handling of the confidential information from which the database is being derived.

2.F. Focus on Exposures vs. Health Outcomes: Several comments raised concerns regarding the study reliance on analysis of exposures to lead as opposed to a focus on occurrence of diseases. The responses describe the limited ability of studies of health outcomes to detect effects of chemical exposures such as those occurring in Butte. As described in the Draft Work Plan at the request of the study Working Group, MCSEP did conduct a cancer incidence and mortality study. That study did not identify any cancers with elevated incidence. Many of the diseases that may be associated with toxics found in Butte may also be associated with other causes. In the case of lead and arsenic, and there are many different sources of potential exposures (e.g., environment, diet, paint). Given these facts, the ability of health endpoint studies to detect effects in small populations is very limited for all but the most common diseases. Where effects may be detected, it may still not be possible to determine the contribution from a specific source when multiple sources of exposure are present.

In contrast, the proposed exposure study seeks to better understand whether exposures to lead in the community have decreased in relation to cleanup activities and RMAP response actions conducted over the last decade. Lead is the primary contaminant of concern in Butte and thus, is a useful surrogate of other environmental exposures. The study also will examine how blood leads, as a measure of exposure from all lead sources, compare between Butte and other similar populations that do not have a similar Superfund history. Understanding the nature and sources of exposure is necessary if steps are to be taken to improve conditions in the community. Determination of exposures is also a fundamental step in determining the potential for adverse effects from chemical exposures. Therefore, we believe an exposure study is the most effective way to identify potential impacts to the community.

2.G. Focus on Lead vs. Other Chemicals: Comments were also received saying that all metals need to be considered, that additive and synergistic effects of metals should be considered, and that arsenic biomonitoring is needed. In the responses it is noted that EPA's risk assessments identified lead, arsenic and mercury as the chemicals of concern after considering multiple metals present in Butte. EPA's risk assessments do consider additive effects of metals, and synergistic effects are not expected at the concentrations of metals present in Butte. Regarding arsenic biomonitoring, previous studies in Butte have not demonstrated elevated urine arsenic levels, and to date the RMAP has not identified a broad need for arsenic or mercury biomonitoring in Butte.

2.H. Precautionary Principle: Several comments asked that the precautionary principle guide the health studies. The precautionary principle or precautionary approach states if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is not harmful falls on those taking an action. An example of the precautionary principle would be banning genetically modified foods even though there is no evidence at this time to suggest that they pose a harm. This principle doesn't pertain to the remedial activities or health study at the Butte site. There is no question that exposures to lead and arsenic can be harmful to people. This is well documented. However, simply removing all lead and arsenic from the environment is not possible, since these inorganics are naturally occurring in the soil, water, and air. We know that adverse effects from exposure to these inorganics are associated with the dose or amount of exposure that people receive. At the Butte site, risk assessments fully evaluated potential exposures, and those estimates formed the basis for development of the RMAP and cleanup plans. In addition, the RMAP and health study ensure that individual children who may be at risk from other sources of lead exposure (e.g., lead-based paint, ceramics, etc.) are identified and addressed.

2.I. Other Comments: Responses are provided in this section for additional comments that didn't fit in any other categories.

Table 1. Comments and Responses Pertaining to Topics that are Outside the Scope of the Superfund Health Study and Draft Work Plan		
Comment ID	**Comment**	**Comment Response**
1.A Comments Pertaining to Current Air Quality Concerns		
1.A.1	As a resident of the Greeley Neighborhood Community I am most concerned about what Fact Sheet No. 5 does not say. It does not say: 1. What is the measurement of fine airborne particulate matter (PM2.5) by month? (Our greatest repertory problems are during the months of July, August and September, the high dust months not the high smoke months. 2. What are the contaminants of concern that are not even being monitored? (Our greatest concerns are air-born heavy metals and crystalline silica.) 3. What period "Figure 2, Chemical Makeup of PM2.5 in Butte" covers? (Was this from the 2007-2008 period when the study was made, when Average Measurements, were below the 24-Hr Standard +35 micrograms/cubic meter, or from a later period?) 4. Why Figure 2, does not show any metals analysis? (When a sample of dust collected from the roof of a residence near the monitoring site contained significant concentrations of metals.) 5. Why the only disease of concern seems to be cancer? (Our school nurses indicate that other air quality related diseases seem to be on the rise. We were recently told that Butte has more Ghost Signs than most any other city in the country. But I have noticed that we also seem to have more people sucking oxygen out of little portable containers than in any other of the ten communities of the world I have lived in, in my life time So if the Team is going to give us a fact sheet, please include all of the facts, and cover all of the major concerns. *(note: comment is essentially identical to 1.A.2)*	Responses to each question are provided below: 1. MDEQ is currently providing both PM10 and PM2.5 data from the Greeley School monitoring site to BSB. That data will be segregated into monthly reports so that it may be reviewed and analyzed by whatever combination of seasonal periods is desired. 2. The ambient air monitoring at the Greeley School site has been conducted according to the authorities, prescriptions, and directions of the Clean Air Act of Montana and the Federal Clean Air Act. Those laws direct the regulation of specific air pollutants that are believed to pose the greatest risk to public health, known as "criteria pollutants." The criteria pollutants currently include the gases sulfur dioxide, carbon monoxide, nitrogen dioxide, and ozone; particulate matter in the aerodynamic size forms of PM10 and PM2.5; and airborne lead. Montana law adds hydrogen sulfide and fluoride-in-forage. Therefore, ambient air monitoring conducted according to the Clean Air Acts is limited to those pollutants, and MDEQ has no authority to monitor other materials in the atmosphere. Most of the criteria pollutants are not currently present in the air in most of the communities of Montana, or are present in such low quantities as to not pose any risk to public health. Historically, however, airborne particulate matter has posed a greater challenge to many Montana communities, particularly those in the mountain valleys of western Montana such as Butte. Currently, monitoring across the State of Montana shows that concentrations of PM10 in the atmosphere do not normally exceed levels that are deemed to pose a risk to public health. However, smaller particulate matter that exists in the aerodynamic size of 2.5 microns in diameter or less can accumulate in the breathable atmosphere in mountain valleys to the point where it does exceed prescribed thresholds that pose a health risk. This dynamic is true in Butte in the winter time when smoke, primarily from wood combustion, accumulates in the valley. As a result, MDEQ regulation efforts, including monitoring, are focused on this problematic, health-impacting pollutant. When federal and state laws established health-protecting limits for concentrations of PM2.5 in the breathable atmosphere health professionals knew that this pollutant adversely impacted human health, but they did not know if it did so simply because of its small size or because of the chemical makeup of the small particles. It was also not known whether or not there were regional differences in the chemical makeup of PM2.5. In an attempt to answer these questions, EPA established the Chemical Speciation Network (CSN). This network includes PM2.5 samplers located across the United States that are designed and deployed specifically and exclusively to define the general chemical makeup of regional PM2.5. In Montana, the CSN monitors have been operated in Libby, Missoula, and now in Butte. A separate speciation monitor was started last year near a wilderness area north of Helena to provide background comparisons. The samples obtained from the CSN equipment are analyzed for a specific and nation-wide standard list of chemical components that are known to comprise PM2.5. It is important to recognize that the CSN samplers are not intended to provide a comprehensive analysis of all the chemicals that may be present in an area's breathable air, and they are not capable of doing so. Rather, the CSN process is intended and able only to discern the chemical makeup of PM2.5 in an area according to recognized chemical categories. A list of the chemicals analyzed by the CSN program follows:

Table 1. Comments and Responses Pertaining to Topics that are Outside the Scope of the Superfund Health Study and Draft Work Plan		
Comment ID	**Comment**	**Comment Response**
		Mass - $PM_{2.5}$ PM 2.5μ Gravimetric **Nitrate - $PM_{2.5}$** Nitrate (Total) **Sulfate - $PM_{2.5}$** Sulfate **Cations - $PM_{2.5}$ (NH_4, K, Na)** Ammonium Potassium Sodium **Organic Carbon** **Elemental Carbon** **Trace elements (33)** Aluminum Antimony Arsenic Barium Bromine Cadmium Calcium Cerium Cesium Chlorine Chromium Cobalt Copper Indium Iron Lead Magnesium Manganese Nickel Phosphorus Potassium Rubidium Selenium Silicon Silver Sodium Strontium Sulfur Tin Titanium Vanadium Zinc Zirconium 3. The results of the chemical mass balance (CMB) study as depicted in Figure 2 of the Fact Sheet No. 5 were from ambient air samples collected from November 8, 2007 to March 1, 2008 collected at Greeley School. Although Figure 1 indicates 2007 and 2008 had average measurements of fine particulate (PM2.5) just below the federal standard, the relative percentages of components are considered to be representative of the sources of fine particulate matter in the area. A new CMB study conducted during the winter of 2012-2013 is just now being completed and seeks to identify any changes in sources and concentrations of PM2.5 as measured at Greeley School. Results from that study will be available for public review around the summer of 2013. 4. Please see the response to the questions above. In addition, the CMB study uses a methodology that incorporates the use of chemical 'fingerprints' for a variety of PM2.5 sources. The PM2.5 captured on the sample filter is analyzed per the CSN categories, and the proportions of chemicals in the results are compared to a library of fingerprints via a computer model. The fingerprints are based on the known proportions of the CSN components that result from various distinct industrial and residential processes ranging from industrial work to meat cooking. The computer model attempts to assign the measured CSN PM2.5 results to the best-fit fingerprint of originating sources. The model identifies the most abundant and distinct classes of PM2.5-generating processes, but where it does not find exact fingerprint matches the generic category called 'other' is reported. 5. MDEQ conducts ambient air sampling studies limited to the pollutants that it has regulatory authority to control. The consideration for a larger community health study is being led by the Butte Citizens' Advisory Committee (CAC) along with Montana Tech. That process may provide some insight to this question.

Table 1. Comments and Responses Pertaining to Topics that are Outside the Scope of the Superfund Health Study and Draft Work Plan		
Comment ID	**Comment**	**Comment Response**
1.A.2	As a resident of the Greeley Neighborhood Community I am most concerned about what Fact Sheet No. 5, Fact Sheet No. 6 do not say, and what the Remedial Design Work Plan does not cover. It does not say/cover: 1. What is the measurement of fine airborne particulate matter (PM2.5) by month? (Our greatest repertory problems are during the months of July, August, September and October, the high PM10 dust months not the high smoke months. 2. What are the contaminants of concern that are not even being monitored? (Our greatest concerns are air-born heavy metals and crystalline silica.) 3. What period "Figure 2, Chemical Makeup of PM2.5 in Butte" covers? (Was this from the 2007-2008 period when the study was made, when Average Measurements, were below the 24-Hr Standard +35 micrograms/cubic meter, or from a later period?) 4. Why Figure 2, does not show any metals analysis? (When a sample of dust collected from the roof of a residence near the monitoring site contained significant concentrations of metals.) 5. Why the only disease of concern seems to be cancer? (Our school nurses indicate that other air quality related diseases seem to be on the rise. We were recently told that Butte has more Ghost Signs than most any other city in the country. But I have noticed that we also seem to have more people sucking oxygen out of little portable containers than in any other of the ten communities of the world I have lived in, in my life time So if the Team is going to give us a fact sheet, please include all of the facts, and cover all of the major concerns. *(note: comment is essentially identical to 1.A.1)*	The commenter is referred to the response to Comment 1.A.1 above.
1.A.3	Nuisance Dust and General Air Quality is a problem in dry, windy, and disturbed areas, like Butte, but we are not assessing all these problems since the changes from Dust Jars/Teflon Plates to Total Suspended Particulates (TSP) and to PM10 and PM2.5 combustion product assessment methods. We should reconsider some of the older air quality methods that measure larger particulates (nuisance dust?), and analyze for contaminants such as lead and arsenic.	Current air quality sampling methods are the only ones recognized by the EPA and ensure that Quality Assurance/Quality Control (QA/QC) associated with equipment, sampling parameters, laboratory analysis, data interpretation, etc. reflects the most current air quality standards. MDEQ may have some historical data that can be looked into to provide additional information from past sampling methods. MDEQ will be contacted concerning this.
1.A.4	As a resident of the 1900 block of Locust Street in Butte, Montana, I would like to express my appreciation for extending the scope of the BPSOU Health Study to include a preliminary evaluation of the health effects of the ongoing mining operation. You have been very responsive in listening to the concerns of residents whose homes have been receiving fine particulate dust from the crushing operation at the mine and chemical odors from the concentrator. While a thorough evaluation of the impacts may be beyond the possible scope of the current study, your efforts will identify whether particular aspects of these problems represent health concerns. Some residents on my block have lived there since before the Anaconda Company was sold to ARCO. While they suffered some impacts from dust, they report that current levels they are experiencing are unprecedented. Further, there was formerly no odor associated with the operation until the current owners first occupied the site. I have lived there for over ten years and, until recently, almost never experienced the sulfide odor. Now, it is a regular feature of the outdoor air. It is my understanding that the study you are undertaking will focus on PM2.5 sized particles, since current regulations are based on that fraction. While I agree that investigating respiratory exposures in that size range is important, limiting data collection to that size range ignores the possibility that children could be exposed to heavy metals through ingestion of dust particles by other routes, similar to lead exposures. I would suggest that the PM10 monitor at the Greeley School site be used to collect data in	The ambient monitoring at the Greeley School site has been conducted according to the authorities, prescriptions, and directions of the Clean Air Act of Montana and the Federal Clean Air Act. Those laws direct the regulation of specific air pollutants that are believed to pose the greatest risk to public health, known as "criteria pollutants." These currently include the gases sulfur dioxide, carbon monoxide, nitrogen dioxide, and ozone; particulate matter in the aerodynamic size forms of PM10 and PM2.5; and airborne lead. Montana law adds hydrogen sulfide and fluoride in forage. Therefore, ambient air monitoring conducted according the Clean Air Acts is limited to those pollutants, and MDEQ has no authority to monitor other materials in the atmosphere. With this being said, the non-Superfund health study will concentrate its efforts toward PM2.5; updating the Chemical Mass Balance Study (winter time 2012/2013); and initiating an additional Chemical Mass Balance Study for the summer time months (June through September). The two seasonal CMB's will be compared to see what differences there may be and will also be compared to other cities to determine if Butte falls within those acceptable ranges. Additional studies may be warranted based on results of the non-Superfund air quality study. A phased approach to these multiple issues is suggested since resources are limited.

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	that size range and that a chemical and mineralogical analysis be conducted on a composite sample of that material. Basically, the PM10 study should answer the questions, "What is it?" and "How much of it is entering the neighborhood?" In addition to the elements being analyzed for the BPSOU purposes, the following elements should be quantitated: Co - cobalt CAS NO. 74440-48-4 Ni - nickel CAS NO. 7440-02-0 Mo - molybdenum CAS NO. 7439-98-7 U – uranium CAS NO. 7440-61-1 Th – thorium CAS NO. 7440-29-1 Further, the alpha, beta and gamma radiation activity of the sample should be determined. Again, thank you for extending the range of the current study to include the Greeley neighborhood.	
1.A.5	In research I conducted in 1998-99 at Montana Tech on dust left on the streets from sanding, I found it contained seven times the amount of <3 micron size crystalline silica as the maximum allowed in the State of Vermont. That small size goes deep in the lung and is not able to be expelled. Nor can this glass be absorbed, thus causing scarring of lung tissue and lung disease.) Please request the US EPA to finally name crystalline silica a contaminant of concern in their Butte Superfund work and to, finally, include air quality issues – something they have ignored to date. Named a 1A carcinogen in ambient air by the International Agency for Research on Cancer in 1996, it resides alongside the contaminants EPA did choose to name as "of concern." It blows through Butte air along with those named contaminants. It is a known cause of a wide variety of diseases besides cancer, some of which are or may be in excess in Butte (COPD, immune deficiency, scleraderma, kidney disease, e.g.,). It does not seem reasonable that it is not included as a "contaminant of concern" given the large number of diseases associated with crystalline silica in scientific literature and its prevalence in Butte soils and air. Please expand your study workplan to include a request to ATSDR for comprehensive data on ambient crystalline silica in combination with the other metals it resides alongside in Butte's street sanding material and from the "historic mining landscape" dust that blows across the Butte Hill in windy weather. ATSDR should be required to complete the work it began in determining synergistic action of each of the named contaminants of concern not just with crystalline silica, but in combination with each other, as well. One wonders if the excess deaths (per CDC data) in Butte attributed to Multiple Sclerosis and Lou Gehrig's Disease has a cause that can be determined by looking for what happens when, perhaps, arsenic, lead, and crystalline silica are inhaled or ingested together in the same human organism.	Crystalline silica is a compound not currently regulated under the National Ambient Air Quality Standards (NAAQS) or listed as a Hazardous Air Pollutant (HAP) in the Federal Clean Air Act. To the extent crystalline silica is regulated, it is confined to the federal workplace safety standards as administered through the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), and is strictly limited to the workplace. However, ambient particulate matter is regulated through the coarse (PM10) and fine (PM2.5) particulate matter NAAQS. PM10 is defined as particulate matter with an aerodynamic diameter of 10 microns and less and PM2.5 is defined as particulate matter with an aerodynamic diameter of 2.5 microns or less. It is recognized that ambient concentrations of crystalline silica may be sampled by PM10 and PM2.5 samplers, but the concentration and type of silica (crystalline vs. non-crystalline) is unknown. Maintaining compliance with the PM10 and PM2.5 NAAQS serves, in part, to limit the amount of blowing dust, which may include particles of silica in its various forms. Street sweeping and flushing requirements are examples of road dust control measures currently implemented by the Butte-Silver Bow Public Works Department. Dust generated from permitted sources is regulated in state-issued permits that contain regulatory requirements limiting PM10 and PM2.5 emissions. This response is consistent for all Montana communities. The regulatory authority of MDEQ and BSB, does not extend to crystalline silica as an identified compound. Therefore, outside the broad regulation for ambient air particulate matter and fugitive dust precautions, MDEQ and BSB cannot measure or respond to crystalline silica in a regulatory fashion. The selected remedy for BPSOU, as described in the 2006 Record of Decision (ROD), addresses those contaminants resulting from prior mining operations. The remedy includes components to address contaminated solid media (mine waste, soil, and residential soils and dust), specific land use areas such as the Granite Mountain Memorial Interpretive Area; the Syndicate Pit, surface water (base flow and stormwater) and both the bedrock and alluvial groundwater. The contaminants of concern are defined to be lead, arsenic, and mercury. MDEQ and BSB concur with the ROD, and will not request that crystalline silica be included as a contaminant of concern under the ROD. Additionally, both parties agree that any request to ATSDR is also outside the scope of the 2006 BPSOU ROD due, in part, to the global nature of the request and long-term study requirements.

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1.B Comments Pertaining to Site-Specific Action Levels and Bioavailability		
1.B.1	Are the Superfund action levels in Butte protective of human health and the environment? What data warrants the conclusion that the action levels set by EPA are in fact, protective of human health?	The action levels developed for the Butte Priority Soils Operable Unit were developed in accordance with EPA's Risk Assessment Guidance's for Superfund (http://www.epa.gov/oswer/riskassessment/risk_superfund.htm) and fully satisfy the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) requirements for the protection of human health (http://www.epa.gov/osweroe1/content/lawsregs/ncpover.htm). Soil, housedust, tap water, and paint were collected from the residential homes in Butte. The soil was analyzed for a complete suite of inorganics. The soil was also tested in animal models for the bioavailability of lead and arsenic. This site-specific information was input to EPA's recommended risk equations to estimate exposure and risk to residents in Butte and develop site-specific cleanup levels. One of the major considerations in the development of a soil cleanup level is the bioavailability of the lead in the soil. This is the amount of lead that is absorbed from the stomach into the bloodstream when people inadvertently ingest soil. At the Butte site a number of bioavailability studies were done and it was found that only a very small amount (approximately 10%) of the lead in soil is actually absorbed. Because only a small amount of lead is absorbed from soil, the 1200 ppm cleanup level is protective of young children and adults who inadvertently ingest the soil.
1.B.2	Need to thoroughly assess, in an effective, reliable and valid manner, issues related to the bioavailability of heavy metals in Butte.	One of the major considerations in the development of a soil cleanup level is the bioavailability of the lead or arsenic in the soil. This is the amount of lead or arsenic that is absorbed from the stomach into the bloodstream when children or adults inadvertently ingest soil. EPA has developed and conducted studies in juvenile swine to assess the bioavailability of lead and arsenic contaminated soils for over 20 years now. The results of the bioavailability studies have been used at numerous Superfund sites, including the Butte Priority Soils Operable Unit (BPSOU) site, to more accurately estimate exposure and develop remediation levels. The bioavailability study design and protocols were developed by a team of interdisciplinary scientists which included veterinarians, pharmacologists, toxicologists, chemists, quality assurance specialists, geologists and statisticians from EPA, University of Missouri College of Veterinary Medicine, Michigan State University Department of Pharmacology and Toxicology, Michigan State University Department of Large Animal Clinical Sciences, the Centers for Disease Control and Prevention, and the University of Colorado at Boulder. Nineteen different test soils were evaluated for lead bioavailability in the juvenile swine model and 26 different test soils were evaluated for arsenic bioavailability. These test materials came from mining and smelting sites, woodtreating sites, lead-based paint and pesticide application sites. The study design and specific results have been published in a number of peer-reviewed journal articles and books. More importantly the juvenile swine animal model, study design and protocols have been accepted nationally by EPA to estimate the bioavailability of lead and arsenic from contaminated soil at hazardous waste sites. EPA considers the juvenile swine bioavailability work to be the gold standard against which alternate animal models, such as the mouse model, or in vitro (bench top) bioaccessibility assays are compared and validated to gain scientific credibility and national acceptance. At the Butte Priority Soils Operable Unit site a number of animal bioavailability studies were conducted on soils from residential yards and source areas. It was found that only a very small amount (approximately 10%) of the lead in soil is actually absorbed. This site-specific estimate of bioavailability was used to more accurately estimate risk and develop soil cleanup levels for Butte.
1.B.3	I still don't see why EPA has not adopted the new 5 microgram standard vis a vis the action levels in Butte. EPA's failure to do so continues the disparate toxic burden that low-income citizens must endure in Butte. In Butte, low-income citizens endure a disparate exposure level to lead compared to the non-poor and	EPA's Office of Superfund Remediation and Technology Innovation (OSRTI) is in the process of evaluating the U.S. Centers for Disease Control and Prevention's (CDC's) recommendations and implications for Superfund risk assessments. Part of OSRTI's evaluation includes close coordination and consultation with CDC, including

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	low-income citizens are less able to withstand the health effects of lead expsure than the non-poor. Why is EPA dragging its feet? EPA, when it suits them, has always waxed eloquent in supporting the findings of the CDC? Why not now? Why haven't the action levels changed to conform to the CDC reccommendatons? Why is this public health issue and this environmental justice issue being ignored? Is it because the EPA doesn't want to go to the trouble of reopening or modifying Records of Decision at sits such as Butte?	ATSDR, EPA's health agency partner. It is important to note that the CDC recommendation of 5 µg/dL is a "reference level", not an action level or level of concern. It was intended for clinicians to reevaluate at what lead blood level medical intervention may be warranted, considering all sources of lead, including lead paint. That target was to be reassessed every five years based on existing blood lead levels. The average blood lead level for young children in the U.S. is approximately 2 µg/dL with only 2.5% of the children in the U.S. exceeding 5 µg/dL. In the 20th century elevated blood lead levels could be associated with a common source such as lead in air or drinking water. Mitigation of that source successfully lowered blood lead levels in the population. Today, elevated blood lead levels are typically found in a few individual children, not in entire populations. From a public health perspective it is more effective to identify those individual children through blood lead testing and work one-on-one with the families to identify and mitigate the source of the lead. The Superfund program in Butte includes a holistic program (i.e., the RMAP) to monitor blood lead levels and investigate elevated levels, which is not typically available in many communities. In Butte, EPA will work with the local public health authorities to use the CDC reference value in the manner described above. At this time, and in accordance with EPA national direction, EPA will not change its Superfund human health risk assessments for lead or its selection of lead action levels based solely on the CDC reference value. EPA is confident its lead action level is protective and that its prior risk assessments for lead were done appropriately.
1.B.4	The question: Is the reduction of bioavailability rates for arsenic valid? needs to be answered by the Health Study.	The commenter is referred to the response to Comment 1.B.1 and 1.B.2 above.
1.B.5	The protectiveness of the site specific action levels in Butte needs to be part of the Health Study. If the action levels are not protective, continuing to use them is unjustifiable.	The commenter is referred to the response to Comment 1.B.1 and 1.B.2 above.
1.B.6	The bioavailability of the toxics on the Butte Hill needs full and complete study.	The commenter is referred to the response to Comment 1.B.1 and 1.B.2 above.
1.B.7	The action levels were established from one study that used only a handful of pigs as subjects to determine bioavailability. The pigs were gavage fed contaminated soil in a method that does not mimic any kind of natural process. The direct leap from force feeding pigs dirt to my kid's uptake seems like a stretch. There is also another study conducted at the same time that shows a much higher bioavailability that was apparently ignored by the EPA (R. Poppeng et al.1990).	The commenter is referred to the response to Comment 1.B.1 and 1.B.2 above.
1.B.8	Based in part on the often sited bioavailability study, an action level of 1200 ppm was established for Pb concentrations in soil. This is dramatically higher than the EPA's standard of 400 ppm for play areas.	The commenter is referred to the response to Comment 1.B.1 and 1.B.2 above. EPA is not aware of a 400 ppm lead level for play areas, or any national standard of 400 ppm.
1.B.9	As stated in the draft, The CDC and EPA are moving toward a BLL action level of 5 (ug/dL) for Lead. The soil concentration action levels are based on the old value of 10 (ug/dL). When will these levels be revised?	The commenter is referred to the response to Comment 1.B.1 and 1.B.2 above.
1.C Comments Pertaining to the RMAP Implementation and Ongoing Biomonitoring Program		
1.C.1	It is difficult to know where to start or end my comments regarding the health study. Many of my concerns lie in the original action plan, and are not a direct comment on the study. I am relatively new to Butte, but I have done my best to educate myself on the issues. I am very interested in the outcome for many reasons, not least of which is I am a father of two boys living in uptown. Our home was one of the properties remediated by RMAP. The folks who did the sampling and the abatement were very helpful, efficient and informative and I have no complaints with how they did their jobs. I do, however, have concerns with the process. The following is a sample of my concerns, but for a more complete discussion, I would be happy to participate in an interview. Our home was tested for Lead, Arsenic, and Mercury. Action levels were exceeded for Pb in one portion of our yard and action levels were exceeded for Pb and As in our attic dust. I have a number of concerns	We thank the commenter for sharing his perceptions of the RMAP process based on his personal experience. BSB will take these concerns into consideration going forward with the program and follow up with the commenter to clarify specific concerns regarding his property separately. Additionally, we would also like to take this opportunity to clarify a few of the commenter's more general concerns below which have been numbered to correspond to numbers in the comment. (1) The RMAP is required to sample properties according protocols that are approved by the EPA and which were developed with consideration of potential "hot spots" within a given yard. An average yard soil concentration is based on a composite sample collected from multiple areas of the yard where residents are likely to contact soil. The cleanup levels are also based on average yard concentrations, given the assumption that a person will not be solely exposed to soil from one

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	with this process: (1) The yard samples were averaged over a number of samples. This opens the possibility of seriously contaminated soils averaged with non-contaminated. For instance: in the portion of my yard that was not flagged, a Pb level of 498 ppm was found. This could easily be skewed by several samples from areas of soil imported for gardening. (2) Only areas of our attic with access were remediated. This left many areas with dangerously high Pb and As levels. In a drafty house as old as ours (built in 1890) dust certainly migrates within the house. (3) I had to make the call to start the process with RMAP. I was only aware of it because of my own research. How will the study attempt to quantify all of the residents who, for one reason or another, have not had their homes or their blood tested? Beyond simple ignorance of the issue, there is a social stigma associated with heavy metal exposure. (4) Soon after the remediation I attempted to establish a baseline for our blood lead and urinary Arsenic levels. I called the health department and was referred to WIC. At first, WIC claimed only my 9 year old would be eligible for testing. After some arguing they agreed to test my older son and myself. WIC did not offer Arsenic testing. I called the Health Department again to request As testing. At first they claimed they knew nothing about it. After two more calls with two different people I was told they did not offer it and I should request it from my personal Physician. This testing process, which seems to be the basis of the health study, is seriously flawed. • The lower detection limit of the BLL test at WIC is 4 (ug/dL). My sons and I all fell below this limit so we were unable to establish a baseline. • It is true that high BLLs are of greatest concern for young children, but Lead can affect anyone. The stated principal study question asks if the program has been effective in mitigating harmful exposure in the Butte community. I feel this should include everyone in the community, with particular attention paid to the most vulnerable. (5) The CDC is moving toward an action level of 5 (ug/dL) and has recognized negative effects with levels as low as 2(ug/dL). Shouldn't the Health Department be testing for lower levels than 4? (6) I did not find the process to be easy or inviting. If I had not taken the initiative, I would not have known about it. As a single father I have no reason to visit WIC, and they seemed to think it was strange that I would. The person who tested me said she had never tested an adult. • Without the data from kids with levels from 0-4 ug/dL, the study is seriously flawed. • The claim that As testing is offered to residents with high levels in their residence is false. Even after repeated requests I was not offered urinary testing. This leads to my primary concern with the study. It does not take into account people like me. I naively believed that the RMAP would actually clean up my property. When it became obvious they had not, I resorted to other methods. I discourage my children from playing in the soil, I do not garden, I don't allow my children in portions of our home and so on. I do not believe this is fair. The responsible parties should have cleaned up the contamination to level that is safe for normal activity. Now because my children are not inflicted with high BLLs the study will call RMAP a success? What a joke. The only way to determine the effectiveness of the program is to actually and thoroughly remove the contaminants. I would like to see my own and my neighbor's properties remediated to a level where we would feel comfortable gardening and allowing children to play outdoors. Then a secondary measure of success could be to monitor the health of the community as a whole. The health study should be conducted by a third party, and should have a wider focus than just those who volunteer for BLL testing.	location within a yard. (2) The RMAP is only able to remediate attic spaces that are large enough for an abatement technician and the equipment to safely access. The RMAP does not remove building components (i.e. wall board) to gain access to un-accessible areas. The potential for migration of dust within a house is the primary reason for the indoor dust vacuum sample. The indoor dust vacuum determines if any contaminated soils and/or attic dust has entered the living space of the residence. If indoor dust vacuum sample results are below the action levels for lead, arsenic and mercury, it indicates that the contaminated dust and soil have not affected the living space. Such a finding often occurs and is not surprising because studies have demonstrated that dust in inaccessible areas of attics have little impact on metal concentrations in dust in living areas. (3) As part of the RMAP, a database is used to track all properties that have been sampled. The database then is utilized to determine properties that have not been sampled and in turn those properties receive sample requests from the RMAP in a systematic approach. The health study design proposed is not dependent on having data from every Butte resident. Instead the study will be based on a large enough sample of the population to be representative of conditions in all Butte neighborhoods. Eventually, all residential areas within the RMAP defined boundary will be sampled, using this method. (4) BSB will work on establishing more effective lines of communication amongst the various programs within the department. We acknowledge the commenter's frustration and confusion about the testing offered under the RMAP. To clarify, blood lead and urinary arsenic testing offered via the RMAP is not intended to establish an individual's baseline blood lead or urinary arsenic level. Test results obtained under the RMAP are used to determine if an individual is nearing or exceeding specific levels of concern. While the Women, Infants and Children (WIC) program conducts routine blood lead test on children less than seven years old, individuals seven years old or older need to be referred to WIC by RMAP staff. During environmental assessments, residents are informed of the opportunities for biomonitoring. However, the RMAP is required to offer urinary arsenic testing, per the Action Plan, only when there is a direct source of exposure to arsenic such as in residential soils or indoor dust and the levels of arsenic in the soils or indoor dust exceed the arsenic action level. Attic dust is not considered a direct exposure. In contrast to blood lead testing, currently, BSB does not provide in-house testing for urinary arsenic when offered to individuals via the RMAP. Instead, the RMAP will reimburse the individual for the cost of testing conducted through the individual's private physician. In the commenter's specific case, the environmental assessment results did not meet the conditions necessary to offer the residents urinary arsenic testing. (5) Prior to 2011, WIC used a blood lead testing method with a detection limit of 1 µg/dL. The health study will only rely on the pre-2011 data with lower detection limits. More recently a method with a higher detection limit was adopted because it offered an immediate measurement before the patient left the clinic. Due to the recent reduction in the blood lead level used by CDC to manage lead exposure risk, a method with a lower detection limit is being considered. (6) Unfortunately, the RMAP does not have the ability to track changes of ownership for every property within the BPSOU. This can result in new owners not being included in mailers requesting the opportunity to conduct an environmental assessment if such mailers were sent to a prior owner of record who did not respond. This appears to be the case for the commenter's property for which a mailer was sent to the owner of record in 2010 without response. However, in addition to direct mailers, the RMAP also utilizes PSA's, local health fairs, realtors, pediatricians, CTEC, construction

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	I hope these comments are taken seriously and I hope I can be of further assistance if need be.	professionals, flyers posted at various locations and the WIC program to inform the public about the program to encourage individuals such as the commenter to initiate the process even if the direct mailer request has not been successful.

Table 2. Comments and Responses Pertaining to the Superfund Health Study and/or Draft Work Plan		
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2.A Comments Pertaining to the Goals and Purpose of the Health Studies		
2.A.1	(1) The goal of future health studies needs clear articulation. So far, other than complying with the terms of the EPA's unilateral order, the goal and purpose of these future health studies is unclear. Why are these health studies being performed, other than to satisfy the terms of the EPA's unilateral order? (2) How will these health studies impact Superfund cleanup in Butte? (3) If diseases related to heavy metals exposure have not decreased but in some cases increased since the inception of Superfund in Butte, will the ROD(s) for Butte, particularly Butte Priority Soils be reopened to be more protective?	(1) The Draft Work Plan will be revised to clarify the goals of health studies described in the UAO. During an initial study planning meeting on April 16, 2012, representatives from EPA, MDEQ, ATSDR, BSB, and AR (hereafter, the "Working Group") reviewed scoping elements for health studies described in the UAO and identified two primary goals to be considered in design of the studies. The first goal is to evaluate whether the RMAP has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. The second goal is to review community health concerns that relate to factors outside the scope of Superfund chemicals of concern or actions to help BSB focus on broader public health improvement efforts. The study design described in the October 31, 2012 Draft Work Plan is focused on BSB/AR approaches to address the first goal; however, design elements that BSB is considering separately to address the second goal are included in Appendix C to the Draft Work Plan. The UAO and the Draft Work Plan provide that public health studies will be performed every five years for a period of thirty years. The scope of the first of these studies was described in the October 2012 Draft Work Plan and will be clarified in the final work plan. The scope of subsequent future studies will be determined at a later date. (2) Without knowing the results of the health study, at this time it is impossible to determine any impacts on Superfund cleanup in Butte related to the health studies. However, EPA reserves the right to make changes to the ROD based on new information as part of the Five Year Review process for the ROD. Results of the health study will be examined and reviewed by EPA and MDEQ upon completion. (3) Characterization of disease outcomes and whether such diseases have increased or decreased in Butte since inception of the Superfund program will not be addressed by the initial health study design. Because most diseases have multiple risk factors, a change in disease incidence alone would not provide sufficient causal evidence to assess the RMAP effectiveness or trigger a change in the ROD. Instead, as noted above, the proposed initial study design will evaluate whether the RMAP has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. Reducing exposures is the most direct way to ensure there will not be increases in disease incidence. Thus, a study of how exposures might be changing is a much more direct way to determine if the cleanup program is being health-protective.
2.A.2	In all of the discussion about the direction of future health studies, it is important to remember that: 1. Butte does have a heavy metals exposure problem due to past mining activity. 2. The heavy metals present in Butte do pose a threat to human health and the environment. 3. Study after study has established that the toxics of concern in Butte are harmful to human health, i.e. they adversely affect human health. If they did not, why have Superfund in the first place? 4. Superfund was created to lessen, mitigate, remediate or remove these threats.	Comment acknowledged. A site-specific risk assessment was conducted at Butte to evaluate exposures to the residents from inorganics. Based on the assessment, cleanup levels were derived to mitigate those risks and protect human health. A Superfund remedy was selected to address the risks in a protective manner, and that remedy is now being implemented. The Health Study is part of that remedy. Additionally, the RMAP provides monitoring of blood lead levels within Butte and investigation of elevated blood lead levels in conjunction with the Superfund program in Butte to further manage risks. Specific to the Superfund program and aligned with public health study activities specified in the RMAP, the health study Working Group identified evaluation of available RMAP biological monitoring data as a priority for inclusion in the first phase of the public health studies described in the UAO. Scoping for subsequent phases of the public health studies (i.e., future studies) has not yet been initiated and is not included in the Draft Work Plan. However, the findings of this first phase of the public health study can be used to help inform future studies. In this way, conduct of the public health studies described in the UAO will occur in an iterative or sequential manner with each phase informing and augmenting the next.

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2.A.3	Overall, CTEC supports the near-term focus on evaluating biomonitoring data, and we are encouraged to see that the blood lead and other relevant data are being incorporated into a useable database. This is relatively easy to do and is perhaps most directly applicable to established EPA procedures for assessing exposure and risk. However, we find that the draft health plan does not fully live up to the mandated expectations.	Comment acknowledged. The Draft Work Plan will be revised to clarify the goals of health studies described in the UAO.
2.A.4	No longer-term studies or conceptual strategy proposed: Section 4.1 of the Final Multi-Pathway Residential Metals Abatement Program Plan (RMAP) states, "Butte-Silver Bow will perform public health studies every five years for a period of 30 years" , p. 7. No studies beyond a report next year evaluating existing biomonitoring data are proposed. Only vague reference is given on page 1 of the Draft Plan to focusing "initial study resources" on evaluation of currently available information.	The scope of future studies has not been determined and is not intended to be addressed by the initial study phase Draft Work Plan. As stated in the October 31, 2012 Draft Work Plan: *"…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."*
2.A.5	Narrowly defined and poorly articulated study question: The study question is not clearly presented until page 16 of the Draft Plan (though shades of it are mentioned on pages 3 and 13). This presentation of the proposed study objective comes too late in the document and is too poorly constructed relative to typical scientific norms to effectively guide the document. Structurally, it seems inappropriate to have the study question dependent upon available data. Technically, the focus on exposure rather than health and the focus on lead, arsenic and mercury, seem too narrow. The types of questions that Terri Hocking related in his guest opinion to the Montana Standard are more meaningful to CTEC and more consistent with the proper structure of research questions (though we do not intend these to be CTEC's proposed list of study questions): • "Do we have higher cancer rates than other communities, and are they caused by environmental contaminants? • Why are the contaminants of concern as defined by EPA limited to lead, arsenic, and mercury? • Are there cumulative effects of environmental contamination of one or more chemicals of concern? • Is our drinking water safe?" The drinking water concern is particularly relevant to those residents using well water. Some of these types of questions are addressed, in part, in the Draft Plan, but is difficult to discern because of the structure of the document. Some of the needed information is provided in Section 2.1 while other information related to the same point is provided in Section 2.3. Regardless, we do not ask that the document must be re-written (other than as needed to address our specific comments below). We reiterate our shared understanding of the central importance of evaluating the biomonitoring data. However, the narrowly defined study question in combination with the structure of the document seems to distract from a compelling and coherent assessment of the above listed questions which are more central to the concerns of CTEC and the broader Butte community. Overall, the work reflects the efforts of applied environmental scientists and policy makers rather than public health research scientists.	The Draft Work Plan structure and organization will be reviewed and clarified as appropriate to more clearly articulate the study question early in the document. The principal study question presented in the Draft Work Plan was identified in accordance with EPA "Guidance on Systematic Planning Using the Data Quality Objectives Process (EPA QA/G-4)" which states: *"The principal study question will help focus the search for information that will address the study problem, and therefore, should be stated as specifically as possible. It will also help identify key unknown conditions or unresolved issues that will lead to finding a solution to the problem. The answer to the principal study question will provide the basis for deciding on a proper course of action to solve a decision problem or provide the missing information needed to make an accurate estimate on an estimation problem."* In this case, the principal study question is intended to provide the basis for deciding on a proper course of action to solve a decision-making problem, that is, whether modification of the RMAP is needed to improve its effectiveness. The Working Group identified multiple years of blood lead data for Butte community members and environmental data collected as part of the RMAP as information needed to address the principal study question. The types of questions noted by the commenter in bullets are being addressed outside of the Draft Work Plan by several approaches. A cancer incidence and mortality study was already conducted by MCSEP in response to a request by the health study Working Group. Air and drinking water quality issues are being addressed in a separate work plan being developed by BSB. Additionally, fact sheets on some of these topics are being developed and distributed to the community. The Draft Work Plan and the proposed study are not intended to address these questions.

Table 2. Comments and Responses Pertaining to the Superfund Health Study and/or Draft Work Plan		
Comment ID	**Comment**	**Comment Response**
2.A.6	p. 14-15, Section 2.2, Study Objectives and Approach: Three different metrics are proposed to assess the "efficacy of the RMAP": summary statistics by year, time matched comparisons with other population(s), and comparisons across neighborhoods. However, the reasons for these metrics are not stated. Moreover, it's unclear how the "efficacy of the RMAP" is to be assessed. Some restatement of the quantitative metrics for "mitigating harmful exposure" need to identified, such as those listed on page 7 of the RMAP with due consideration to recent reconsideration of what constitutes safe blood lead levels. It can then be shown how the three proposed metrics relate to this broader goal. While the first metric makes some sense for reasons that extend beyond the explanation provided in the text, the need for the next two metrics are not clear. The bottom line is that blood lead levels need to remain below acceptable levels, on a community wide basis, consistent with the expressed professional judgments of the CDC and EPA. We appreciate that lead exposures can remain elevated for the reasons stated at the close of this section on page 15; however, the section should end with criteria that would define unacceptable levels and the kinds of actions that would be considered to remedy such a finding. [Note: we recognize that some of this requested information may be covered in other sections, such as Section 2.3.2, page 17, but the repetitive structure of the document makes it hard to put it all together in a way that is clear, concise and not open to contradiction.]	Our intent was to have two different metrics, not three. We do not anticipate that the summary statistics by year will be a useful tool to assess the efficacy of the RMAP. The summary statistics by year will provide some indication of the fraction of children in Butte with elevated blood lead levels, but are unlikely to provide a reliable indication of overall changes in lead exposures in the population. In the past EPA and BSB have found very few children with blood lead levels that exceeded the prior CDC blood lead of concern of 10 µg/dL. The new CDC reference level of 5 µg/dL represents the 97.5th percentile of blood lead levels in U.S. children from 2005—2008. Nationally, 450,000 children are estimated to have BLLs above 5 µg/dL. The Butte summary statistics may provide us with some indication of the percentage of Butte children with blood lead levels above the new reference level. If Butte has a much higher fraction of children with values exceeding 5 µg/dL than the national average (i.e., 2.5%), such a finding might suggest that further evaluation is needed. Due to differences in analytical methods, the influence of multiple risk factors on blood lead levels, and the changes in blood lead levels over time, the exceedance of the national average in a population could be a function of many factors. That is why we propose to rely more on the full distribution of blood lead levels and comparisons across neighborhoods and/or with a matched comparison population. We already know that Butte has elevated lead in soils and also a high proportion of older housing with deteriorated lead paint, which represent both a Superfund-related source and a non-Superfund-related source. RMAP is aimed at identifying and reducing exposures from these and other potential sources, which is a holistic approach and goes beyond the standard Superfund requirements. It is our expectation that evaluation of the entire distribution of blood lead values will provide us with a more sensitive measure of the effectiveness of the Superfund cleanup and RMAP. In other words, we aim to assess whether these efforts are contributing to a decline in blood lead levels regardless of whether or not the reference level is exceeded. The metrics that we plan to use to make that determination include: • comparing blood lead levels across Butte neighborhoods to see if children from the neighborhoods with the highest levels of mine waste and also the highest concentration of older homes with lead-based paint have higher blood lead levels compared with children from neighborhoods with less mine waste and fewer older homes, and • comparing the distribution of blood lead levels in Butte with the distributions from other comparable communities or datasets that are not affected by mine waste. We will attempt to provide some of the clarification the commenter requests in the final work plan, especially with regard to the selection of and goals for the neighborhood comparison. For the comparison population selection and goals, more detail will be provided in the technical memorandum that is being prepared to describe possible populations and how they might be used.
2.A.7	p. 16, 2nd paragraph (not including bullets), Section 2.3.1, State the Problem: Verb tenses throughout this paragraph seem amiss with past and future work in confusing ways. Moreover, the text's flow seems to be from past to future to present actions. Key here is the need to clarify what the agencies really propose to do regarding support and input to the study development. Is this referring only to this work plan and the proposed 2013 report, or is it to the future 5-year health studies. We suggest it should include the latter, and in either case, what kind of support is needed?	Yes, section 2.3.1 is referring only to the Draft Work Plan and the RMAP evaluation public health study proposed for Phase 1 of the periodic public health studies. As noted in response to Comment 2.A.4, the scope of future studies has not been determined and is not intended to be addressed by the initial study phase work plan. However, the verb tenses for section 2.3.1 will be reviewed and revised as appropriate.

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2.A.8	p. 17, 1st paragraph, Section 2.3.2, Step 2: Identify the Goal of the Study: Public participation should be integrated into this description for how any RMAP deficiencies are identified and responded to. In particular, CTEC seeks an active role in encouraging participation in the voluntary cleanup program. Also, the roles and responsibilities of various agencies in supporting/approving of response actions should be stated.	Community outreach activities (Task 2 of the public health study) are described in section 2.4.2 of the Draft Work Plan. The description of these activities will be clarified in the final work plan regarding opportunities for the public to provide input to proposed response actions that may arise from the initial health study. CTEC will be engaged to provide additional community outreach activities.
2.A.9	As currently articulated, it is not clear what will be the focus of the Health Study. The focus of the Health Study has been all over the place since it was announced a number of months ago. Is it focusing on just evaluating the RMAP program? Is it focusing on investigating the health effects and remediation efforts concerning all toxics of concern in Butte—lead, mercury and arsenic? Will it evaluate the health protectiveness of institutional controls and the waste left in place solution including caps? Will it investigate the health effects of the contaminants at the Poll Plant? Will it investigate the protectiveness of the remediation efforts at the Poll Plant? Will it investigate the general public health of Butte, including life style, diet, smoking, alcohol consumption, etc.? Depending on which official is speaking, the focus of the study wanders. There needs to be a clear, unambiguous statement of the focus of the Health Study.	In addition to the study presented in the Draft Work Plan that is the subject of current comments, a number of additional activities have been undertaken to respond to concerns raised by the public. We recognize that these multiple activities may have led to confusion regarding the study presented in the Draft Work Plan. The focus of the health study presented in the Draft Work Plan is articulated at the beginning of section 2 (Phase 1 Public Health Study Design: RMAP Evaluation), which states: *"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."* Aside from this focus, as described in section 1 of the Draft Work Plan, as part of the planning for this initial study phase, the Working Group also identified the need for other activities to help address concerns and questions expressed by community members during BSB-led listening sessions. Such activities included a 2012 cancer incidence and mortality study conducted by MCSEP in response to a request by the health study Working Group. Air quality issues raised by the community are being addressed in a separate work plan being developed by BSB. Additionally, fact sheets on some of these topics (e.g., drinking water safety) are being developed and distributed to the community. BSB and EPA are committed to responding to the broader range of health concerns identified by the public and, as described in the UAO, public health studies will be performed every five years for a period of thirty years.
2.A.10	It is unclear what is the purpose of the study. Why are we doing the study, other than it is mandated under the UAO? Is it to evaluate the effectiveness of the Butte Superfund cleanup? Is it to reach general conclusions regarding the public health of Butte? How does it relate to the recently completed Five-Year Review? There needs to be a clear, unambiguous statement of the purpose of the study.	The commenter is referred to the response to Comment 2.A.1 above.
2.A.11	There needs to be a clear statement regarding how this study will be used and how it will affect public health policy. What is to prevent it from becoming just another study that sits on a shelf?	As stated in the introduction to section 2 of the Draft Work Plan, the proposed RMAP evaluation will be used 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."* Additional discussion of how the study results might be used is provided in the response to comment 2.A.1 above.Following the health study results, EPA in consultation with MDEQ will determine what will need to be changed or not changed concerning the RMAP. Additionally, Five Year Reviews are designed to determine whether the remedy at a site is or upon completion will be protective of human health and the environment.

Table 2. Comments and Responses Pertaining to the Superfund Health Study and/or Draft Work Plan		
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2.A.12	I do not see the recent health study as being much different. The residents of Butte deserve and want the facts and the truth. The purpose of the health Study should be to determine the facts as they exist and then to take the necessary steps to address the facts. It appears the purpose of this study is designed to justify the irresponsible Superfund cleanup in Butte and not to address the health issues facing Butte that the residents of Butte deal with on a daily basis. I hope I am wrong.	The purpose of the initial health study (i.e., the RMAP evaluation) is detailed in the Draft Work Plan, as are the methods and data to be used to address that purpose. As noted in response to comment 2.A.1, BSB will conduct separately, a review of health concerns that relate to factors outside the scope of Superfund chemicals of concern or actions to help BSB focus on broader public health improvement efforts. Also as discussed in the response to comment 2.A.1, evaluation of existing blood lead data collected as part of the RMAP is a necessary and appropriate first step to determining whether widespread exposure to lead has been occurring in Butte. Consideration of the results of the proposed evaluation can then be used by EPA, along with findings by MCSEP from a 2012 study of cancer incidence in Silver Bow County, Montana, and the U.S. (included in Appendix A of the Draft Work Plan), to help inform the direction of future studies.
2.A.13	Openness, Objectivity and Validity: Drawing in part from potential inadvertent biases related to EJ, we have expressed a number of concerns pertaining to scientific objectivity and validity. These concerns draw from an overall lack of open inclusion in the study design that is needed to ensure that multiple perspectives on the problem are addressed. Prior comments along these lines include: - Clarifying commitments on study scope beyond the current blood lead study. - Improved contextualization and expression of the study question(s) for the current proposed blood-lead study.	Comment acknowledged. Opportunities to promote greater collaboration between representatives of the community and the Working Group are being considered as the study development process moves forward. As noted in the response to comment 2.A.6 above, we will attempt to clarify the description of the analyses and study metrics for the blood lead study. Responses to comments 2.A.1 and 2.A.5 above describe ongoing and planned responses to issues beyond the scope of the current study.
2.B Comments Pertaining to Public Involvement		
2.B.1	We were promised full, meaningful and efficacious public involvement. This whole process has been characterized by secrecy on the part of EPA, MDEQ and the Health Department. The so called “listening sessions” are designed, not to solicit meaningful public input, but to “sell” the public on the Health Study. Using the technique of “listening sessions” is a well tried and used technique to stifle public comment and place the public in the role of passive received of “information” from the EPA and PRPs. Such as approach is bad public policy decision making and is contrary to the EPA’s own mandates regarding public involvement.	EPA, BSB and AR seek to achieve EPA’s expressed goal of achieving meaningful public involvement. EPA, BSB and AR recognized that the health study is an important concern of residents. Accordingly, they sought to achieve meaningful public participation through several outreach efforts and public meetings. The listening sessions did yield comments that have been incorporated into either the Superfund or non-Superfund study efforts. As the public comment period progressed it became apparent that despite these efforts, community members had additional needs. Accordingly, EPA extended the comment period on the Draft Work Plan and additional efforts have been initiated. The Working Group invited a technical representative from CTEC to participate in the Superfund health study Working Group. Dr. Steve Ackerlund, a CTEC technical consultant under EPA’s Technical Assistance Grant (TAG) program, is serving in that role. Dr. Ackerlund has assisted in drafting comment responses pertaining to public participation and has been provided the opportunity to review and comment on all response to comments on the Superfund health study. Moving forward, Section 2.4.2 of the draft Work Plan, titled Project Planning, will be revised to describe additional efforts directed toward improving public participation in the health study process. Nikia Greene and Sara Sparks, Remedial Project Managers for this project are available at any time to receive other specific recommendations on how to improve our work such that we do achieve meaningful public involvement. All recommendations will be considered within the goal of achieving meaningful public involvement.
2.B.2	CTEC appreciates the opportunity to comment on the Draft Public Health Study Remedial Design Work Plan for the Butte Priority Soils Operable Unit (Draft Plan). We believe that a scientifically rigorous health study can do much to develop an objective and commonly recognized understanding as to whether the Superfund Program is providing for a safe and healthful environment. Given Draft Plan’s overall importance to the Superfund project, we are, as you know, quite disappointed that you decided to take a more limited approach to public participation thus far. Moving forward, we wish to establish a more deliberative and collaborative working relationship. Accordingly, we submit these comments recognizing there are some things we may not yet understand and in a sincere effort to be constructive.	In response to comments of this nature, the Working Group has invited a representative from CTEC to participate in the Superfund study Working Group. Additional responsiveness addressing the desire for “a more deliberative and collaborative working relationship” is provided in response to the more detailed comments below.

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2.B.3	Minimal opportunities for future public involvement: Section 2.4.2 of the Draft Plan provides minimal opportunities for public involvement. While this minimal approach is perhaps adequate for the evaluation of biomonitoring data, with modest expansion as indicated in our Specific Comments, it is not sufficient to address the longer-term study needs as reflected by the kinds of questions mentioned in comment 3 above *[Note: "comment 3 above" references the November 30, 2012 CTEC comment letter]*	Section 2.4.2 of the draft Work Plan identifies the community information meeting and the public meeting that were held to seek public involvement in the initial health study. With regard to the initial health study, Section 2.4.2 also commits to additional community meetings following completion of the study, and periodic updates through the Working Group. This section refers only to the Superfund health study evaluating blood lead levels. The work plan for the initial health study is not intended to address public involvement opportunities related to future studies to be performed as described in the UAO every five years for a period of thirty years. The initial work plan also is not intended to address public involvement opportunities related to the currently ongoing non-Superfund health study planning effort. The scope of subsequent future studies and details of public involvement related to such scope will be determined at a later date.
2.B.4	General Comment Summary and Proposed Actions: The core issue underlying our General Comments is the desire to constructively identify what kinds of epidemiological studies might be done in the future that would improve our understanding of the health protectiveness of the remedy. CTEC is concerned that thus far there has been inadequate involvement by qualified epidemiological researchers. A highly polarized, dueling science kind of debate has been going on this past year, often through the media, that has undermined public understanding of and trust in the science. While we support moving forward with the biomonitoring assessment, CTEC proposes a separate track to assess possible options for future 5-year health studies. We believe this process needs to start by more thoughtfully considering the kinds of questions the studies need to ask, better understanding the limitations of what existing epidemiology can do to answer the study questions, what kinds of new epidemiology data is maybe needed, and what other kinds of studies such as ongoing biomonitoring should be conducted into the future. Moreover, we strongly believe that a well designed, deliberative process of engagement between the agencies and affected, interested community members will do much to achieve a well-informed, common understanding of the healthful nature of the Butte community and any additional remediation needs for the Superfund Program moving forward.	This comment raises two issues. Future epidemiology studies are addressed in responses 2.F3 and 2.F4. The last sentence addressing community involvement is addressed in the responses to comments 2.B.1, 2.B.2 and 2.B.3 above.
2.B.5	p. 21, last paragraph, Section 2.4.2 Task 2 – Community Outreach: Given CTEC's strong interest in this Draft Plan, the nature of our questions, and the redundant structure of the Draft Plan that makes it hard to follow (see the next comment for example), we request that the proposed open house also include a presentation and group discussion on the proposed approach. We think that will be the best way to resolve many of our comments.	The open houses did include presentations and opportunities for group and individual discussions. The Draft Work Plan is being revised to attempt to increase clarity. Additional discussion of the details of the planned technical analyses, and specifically the selection of comparison populations, will be provided in a technical memorandum that will be reviewed by the Working Group.
2.B.6	p. 23, paragraph 5, Section 2.4.5 Task 5 – Quality Assurance Review: CTEC requests that public review be added to any and all parts of this Draft Plan that involve decision-making and agency approval.	Public comment is already being provided at points that require agency approval. Going forward, there will be additional opportunities for the Working Group to provide input to key decision points regarding study details and data analysis.
2.B.7	My First comment is a question: How is the Public suppose to comment when they have not been informed when, where, why, and way they are to comment? I would have expected that the same procedure as was used by the BNRC to inform The Public and invite The Public to their meetings would have been used by this committee.	Various forms of public outreach have been used and we welcome additional suggestions on how to solicit broader community involvement. Unlike the BNRC, Montana's Open Meeting laws do not apply to the working group for the reasons identified below.

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2.B.8	The process of developing and conducting the Health Study needs to be open and transparent. There needs to be full compliance with Montana Open Meetings law as well as federal law on the subject. Meetings pertaining to the design and conduct of the Health Study need to be open to the public with due notice of these meetings posted in the media. The public needs to be afforded the opportunity to comment and participate in these meetings. So far the process of developing the Health Study has been marked with excessive secrecy.	As described in responses to comments 2.B.1, 2.B.2, and 2.B.3, technically qualified community representatives from the Working Group are participating in the study planning process and public input has been sought through public meetings and the opportunity to provide written comments on the Draft Work Plan and other study documents. Going forward, there will be additional opportunities for the Working Group to provide input to key decision points in data analysis. Montana's Open Meeting laws do not apply to the meetings of the working group. Montana's Open Meeting laws apply only to meetings of a public agency. The working group is not a public agency because it is not a governmental body, board, bureau, commission, department or authority authorized to make rules, determine contested cases or enter into contracts.
2.B.9	The process has been marked by secrecy. The public has had to constantly demand information about what was going on. Grudgingly, the EPA has released tidbits of information. How can the public participate in Superfund decision-making if it does not know what is happening? It took me countless emails just to find out, for example, who was on the Health Study advisory board and when it was meeting and what were the results of those meetings.	For clarity, the health study Working Group is comprised of representatives from EPA, MDEQ, ATSDR, BSB, AR, the CAC, and more recently, CTEC. The CAC was formed after the study planning process was underway. A fact sheet was issued by BSB in Summer 2012 describing the CAC's role and identifying the CAC members. All CAC members are invited to participate in health study Working Group planning meetings. The Draft Work Plan has been made available for public comment and public meetings have been held with the goal of achieving meaningful public input and participation. EPA, BSB and AR are receptive to improving the public participation process, as indicated throughout these comment responses. Going forward, there will be additional opportunities for the Working Group to provide input to key decision points in data analysis.
2.B.10	Butte citizens question the independence and validity of the study. It is the old story of the EPA evaluating itself and finding that it has done a good job. This Health Study has no credibility in the community. The EPA publicly laments a lack of citizen participation. Why should citizens participate when their comments have no efficacy? Why should citizens participate when they are criticized for participating? Time and again I have been told by members of the public that participation in Superfund is a total waste of time and effort. Perhaps it is time for Region 8 to become more involved. The above was not always the case. Years back the EPA in Montana was much more open to public input. Today, it is a defensive, hunker down agency. At a minimum, the Montana Office should have a public meeting and respond publicly to the comments it has received in addition to putting out a responsiveness summary. The whole Health Study design and execution should be subject to independent peer review. Will things change? We will see. We will see how seriously EPA takes the comments it receives. We will see if the EPA responds in a substantive manner to the comments it receives. We will see if the EPA makes changes in the Health Study Work Plan to respond to citizen input. We will see if EPA takes seriously its commitment to meaningful public involvement and environmental justice. I am not optimistic. It is hard to hold an agency publicly accountable. We can't vote agency personnel out of office. I suspect all we will get is some perfunctory response to citizen input. Hopefully, I will be proved wrong.	Please see responses to comments 2.B.1, 2.B.2, 2.B.3, and 2.B.8 addressing community involvement and public input. BSB and AR have committed to seeking an independent peer review of the completed study. Environmental justice concerns are addressed in responses to comments section 2.C.
2.B.11	All test results need to be made publicly available.	The original commitment to conduct a health study made in the RMAP indicated that, "The reports will respect the privacy of the participants and will be available to the public…" Under state law, certain information must be withheld from public reports, such as the identity of individual blood-lead results. Otherwise, greater participation in the scoping and analysis parts of the study, as outlined in prior comments, is expected to achieve public expectations for full transparency and disclosure of information to the extent permissible under law.

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2.B.12	Please use the transparent model of the Butte Natural Resources Committee in future by allowing citizens like myself to be present at health study meetings and by calling for public input at each meeting, as well as actually listening to the concerns of citizens and scientists like Dr. Stacie Barry.	The public involvement process is described in responses to comments above. The process is not identical to the Butte Natural Resource Damage Restoration Council processes. Nevertheless, public involvement is important to the Working Group and the agencies involved in the Working Group, and the substantial public involvement efforts described above reflect this. The Working Group is open to different ideas moving forward with the analysis.
2.C Comments Pertaining to Environmental Justice		
2.C.1	On October 31, 2012, the Butte Silver Bow Health Department released a draft "work plan" for their study of the health effects of contaminants of concern at Butte area Superfund sites. This work plan was mandated pursuant to an EPA unilateral order regarding Butte, Montana area Superfund sites. While I will have substantive comments regarding the Butte/Silver Bow Health Study "work-plan" in due course, I wish to complain with utmost vigor about the neglect of the "work plan" to address or consider, in any substantive manner, issues related to environmental justice in the design of the Health Study "work plan". Even though Butte has a disparate number of low-income citizens located within the Superfund site, Environmental justice is mentioned only twice in the "work plan" and neither time in a substantive way, i.e. nothing regarding the design and execution of the "work plan" specifically addresses environmental justice issues. The poor are never mentioned in the "work plan" nor are low-income citizens. The poor and low-income citizens are ignored, contrary to the EPA's environmental justice mandate and promises made by that Montana Office of EPA that environmental justice issues would be a major focus of the health studies.	In response to comment, a new section, "Environmental Justice Considerations," will be added in the final work plan. This section will identify recent environmental justice screening and explain the unique design of the RMAP, with a focus on low income persons. Additionally the section will describe the efforts made in outreach to the community of Butte including low income citizens. The goals of the proposed study are intended to evaluate those aspects of the RMAP that deserve additional assessment, including but not limited to environmental justice considerations.
2.C.2	Citizens were promised that environmental justice concerns would be at the forefront of the design, methodology and conduct of the health study. Environmental justice is ignored.	From the beginning an emphasis was placed on actively seeking public participation including low income persons. The Working Group discussed and presented several public meetings held at accessible, central locations and encouraged different avenues of notification, such as sending out 10,000 notices in the water bill (response to the community also). From the beginning a series of fact sheets have been developed and continue to be developed to address public concern. The fact sheets are distributed in the local newspaper. More environmental justice considerations will be summarized in the final work plan.
2.C.3	How does exposure to the toxics of concern affect low-income citizens that tend to be concentrated in the Butte Priority Soils Superfund site?	We do not know how low-income citizens near the Butte Priority Soils Superfund site may be differentially affected by exposures to toxics of concern. Such populations, for example, may be less likely to have access to health insurance or affordable care to prevent or treat health concerns that arise, including ones that may be related to exposure to toxics in the environment. At the same time, cleanup standards at Superfund sites are intended to be protective of sensitive individuals within the bounds of available scientific knowledge and including uncertainty factors that reasonably account for variability within the affected population.
2.C.4	Need to consider the effect of heavy metals exposure on low-income citizens.	The baseline risk assessment examined all of the potentially complete and significant exposure pathways present.
2.C.5	So far EPA has failed to assess the risks to low-income citizens posed by the toxics of concern in Butte. The differential effects on low-income citizens of exposure to the toxics of concern have been ignored. "In epidemiological studies, the term confounding is used to describe the situation where an association between the factor of interest and the disease outcome is explained by the association of both these factors with another variable, the confounder, which itself is either a cause or closely related to the cause of the disease. Age and social class, for example, are commonly regarded as confounders as they are strongly related to disease occurrence and are also related to a wide range of environmental exposures." [Lesley Rushton and Paul Elliott, Institute for Environment and Health, "Evaluating evidence on environmental health risks," British Medical Bulletin [2003]68 (1)] Any health study that fails to consider the health effects of toxic metals exposure on low-income	There is disagreement in the comment made that EPA has failed to assess the risks to low-income citizens posed by the toxics of concern in Butte. Please refer to EPA's response letter to this same concern dated Jan 23, 2007, where Dr. Susan Griffin concludes that the risk assessment conducted by EPA looked at exposure pathways specific to the community, estimated exposure to the reasonably maximum exposed individual in that community, compared that exposure to a toxicity benchmark which is protective of sensitive populations, and conservatively assumed that risks are additive. The final work plan will summarize environmental justice considerations incorporated within the design of the health studies described under the UAO. Additionally, please refer to the multipathway RMAP that will address all residential properties which exceed action levels within the BPSOU site and the adjacent area.

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	citizens will be seriously incomplete as well as violating the requirements of environmental justice. Butte's low income citizens are at special risk in terms of the effects of exposure to heavy metals and that risk must be fully assessed and mitigated. "Assessment of the impact of a potential adverse health effect from an environmental pollutant is dependent on an understanding of several issues, including: the variability and susceptibility of the potentially exposed population, for example, regarding sub-groups of the population that might be at especial risk due either to the pattern and distribution of exposures in the population, or to non-environmental factors that might influence the risk of disease." (Ibid.) Different areas in Butte have different levels of toxics exposure. Butte's areas of greatest toxic concentration correspond to areas that are home, disproportionately to the rest of Butte and Montana as a whole, to low-income citizens. Therefore, environmental justice concerns must be at the forefront of any future health studies in Butte.	
2.C.6	So far environmental justice issues and concerns seem to be missing from the work plan for conducting the Health Study. The current work plan is silent on environmental justice. It is not clear how or whether environmental justice concerns/issues are going to be specifically addressed by the proposed Health Study. I would ask that the final version of the Health Study work plan specifically address environmental justice issues. I would ask that the final version of the Health Study work plan specifically state how the Health Study will address environmental justice concerns. I would ask that there be a specific, discrete and identified section of the Health Study devoted to addressing environmental justice issues.	The commenter is referred to response to comment 2.C.1.
2.C.7	The EPA has a mandate to consider and to promote environmental justice in all of its activities which would, of course, include Superfund. A central focus of the Butte Health Study mandated by the Montana Office (Region 8) of EPA's unilateral order is central Butte—an area encompassed under the designation of Butte Priority Soils OU. Central Butte has a disproportionate number of low-income citizens. Low-income citizens within the Butte Priority Soils site endure a disparate toxics burden which is not considered or addressed by the Health Study work plan. **Environmental Justice and Uptown/Central Butte** The EPA has a mandate to promote environmental justice in all of its activities. The EPA defines environmental justice as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin or income with respect to environmental laws, regulations and policies." No minority or low-income population should bear a disproportionate toxics exposure burden. EPA Administrator Lisa Jackson has made promoting environmental justice a top EPA priority. Low-income citizens are a particular target for environmental justice activities. Given that low income citizens are concentrated in Uptown/Central Butte, the toxic substances in Uptown/Central Butte disproportionately impact Butte's low-income citizens, who are concentrated within uptown/central Butte **Extent of Poverty in in Uptown/Central Butte** In Butte-Silver Bow, the poverty rate is at 15.8%, which is higher than both the national and state rates, and has risen almost a full percentage point since 2000. (U.S. Census Bureau) According to the U.S. Census Bureau, over 25% of Butte families with children under the age of five years have incomes below the official poverty line. 21% of Butte children live below the poverty line. (Butte Silver Bow Health Department, Community Needs Assessment.) According to the Montana Department of Public Health and Human Services, about 2.4% of Butte citizens	It has been recognized that low-income status may make this population more vulnerable to harm from environmental stressors at a rate higher than the rate for a non-low-income community. However, EPA has concluded that through the RMAP, a disproportionate impact upon the low-income residents will not result and therefore, the RMAP addresses EPA's environmental justice mandate as established in Executive Order 12898. Please refer to the response letter dated January 12, 2010 on "Environmental Justice Issues: Multi-Pathway Residential Metals Abatement Program Plan".

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	are receiving Temporary Assistance for Needy Families compared to the state average of 1.89%. Over 10% of the Butte population was receiving food-stamps compared to 7.56% statewide. Thirty-seven percent (37%) of the county population is at or below 200% of the federal poverty line, qualifying them for low-income assistance programs like Low Income Energy Assistance (LIEAP) and a sliding fee at the Community Health Center. (2011 Community Health Improvement Plan—Butte Silver Bow Health Department) Most of Butte's poor live in uptown Butte, the area encompassed by the Superfund site—Butte Priority Soils. Within Butte/Silver Bow, there are pockets of deep poverty which tend to occur in uptown Butte. Forty percent of Butte-Silver Bow's Census Block Groups (17 out of 43) had poverty rates higher than the overall county rate in 2000 that ranged from 15% to 61%. Of the 17 high poverty Block Groups, ten (or 59%) were located in Census Tracts 1 and 2, inside the older town site, which is the area encompassed by the Butte Priority Soils Superfund Site. These two tracts contain 52% (2,550 people) of the county's poor while containing only 29% of the total population (Butte-Silver Bow Growth Policy). The poor in Butte's central district do have to endure a disproportionate toxics exposure and risk burden. Much of the housing stock in uptown/central Butte is in a state of decay and often has contaminated attic and indoor dust, contaminated yards and lead based paint in the home. Consider the fact that of the 1200 houses in Butte that have a high risk of lead exposure, the vast majority are in the Butte Priority Soils site. Given EPA's mandate to consider and promote environmental justice, it is a glaring weakness in the Health Study work plan that there is no mention of environmental justice nor is there any special consideration given in the work plan to the issue of environmental justice in the Butte Priority Soils OU. As designed, the current work plan will actually have a discriminatory effect against low income citizens. For example, the use of rolling averages whereby low-income and non-low-income citizens are conflated together for purposes of the study has a discriminatory effect against low-income citizens. The failure of the Health Study to consider mortality rates or incidences of disease related to the toxics found at the Butte Priority Soils site has a discriminatory effect against low-income citizens residing within the Butte Priority Soils site. The failure of the study to consider the bio-accumulative, synergistic and cumulative effects on human health of the toxics found at the Butte Priority Soils site has a discriminatory effect against low-income citizens residing within the Butte Priority Soils site. This lack of attention needs to be corrected. There needs to be specific consideration of the health effects of the toxics found within the Butte Priority Soil OU on low-income citizens residing with the Butte Priority Soils site.	
2.C.8	As described in the work plan, the Butte Health Study mandated under an EPA unilateral order is not a health study. At best, it is another exposure study. <u>Yet, it does not look at toxics exposure specifically as such exposure pertains to low-income residents of the Butte Priority Soils OU.</u> Therefore, the Health Study work plan is at variance with EPA's mandate to consider and promote environmental justice. The work plan needs to be changed to remedy this defect. **Environmental Justice Failures**: 1. The work plan does not examine the health effects of multiple individual exposures to multiple toxics within the Butte Priority Soils OU, which is the focus of much of the	1 and 4. Responses addressing the focus on lead and multiple chemical exposures are addressed in responses to comments 2.G.1 and 2.G.2. Please refer to the focus of the initial study designexplained in sections 1.1 and 2 of the Draft Work Plan. The Final Work Plan will include more detail regarding the rationale behind focusing the initial study on lead. The results of this initial phase will be used to assess the efficacy of the RMAP, as well as inform the need for and objectives of subsequent study phases. Assessments of all residential properties within the BPSOU shall occur by December 31, 2019 and all contaminated residential properties within the BPSOU shall be remediated by December 31, 2029. To accomplish these requirements, yearly goals for sampling and remediation contained in the Final RMAP (April 2010 by BSB and AR) page II must be confirmed through yearly reporting, as provided in RMAP section 15, or revised appropriately (2011 ESD).

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	Superfund part of the Health Study. The Health Study seems to concentrate exclusively on lead exposure. Low-income residents residing with the Butte Priority Soils OU are exposed to numerous Superfund related toxics—lead, arsenic, mercury, cadmium, zinc, copper, etc. The study ignores the other toxic threats by concentering exclusively on lead. Given that the immune systems of low-income citizens tend to be more compromised and more susceptible to the adverse health effects of exposure to the toxics listed above, the failure to consider the health effects of exposure to multiple toxic threats regarding low-income citizens is a serious environmental justice lapse. It could well be that an exposure level that is deemed "safe" for a non-low-income person would be harmful to a low-income citizen. By filing to consider the disparate impact on low-income citizens of the toxics found within the Butte Priority Soils OU, the Health Study, as currently designed, continues to perpetuate a disparate toxics burden on low-income citizens and is, therefore, contrary to EPA's environmental justice mandate. 2. Another serious environmental justice failure is that the proposed Health Study fails to look at the synergistic, bio-accumulative and cumulative effects of multiple exposures to all of the toxics of concern on low-income residents of the Butte Priority Soils OU. Low-income residents are not exposed to lead, arsenic, mercury, cadmium etc. as isolated toxics. Low-income citizens are exposed to these toxics at the same time. To look just at lead, for example, is a misrepresentation of the toxics' picture that low-income citizens face. 3. Low-income residents have been excluded from the planning of the Health Study. The Health Study advisory board has no representative from any low-income group. No attempt has been made to specifically address the health issues related to Superfund that are of particular concern to low-income citizens. No specific outreach to low-income citizens is planned or has been conducted. 4. By mixing exposure data from low-income areas with exposure data from non-low-income areas, the study will misrepresent the specific toxic effects on low-income citizens. The Health Study needs a specific focus on the health effects of the toxics found at the Butte Priority Soils OU on low-income residents, specifically. 5. The Health Study work plan needs to document what specific outreach programs will be pursued relative to low-income citizens. What specific endeavors will there be to include and meaningfully involve low-income citizens in the planning and execution of the Health Study? So far, no such outreach activity is discussed. Low-income citizens are on the outside looking in, which is contrary to EPA policy. The Butte Priority Souls OU, because of its disproportionate number of low-income citizens, should be a focus of environmental justice activities by EPA. It is time for EPA to get serious about addressing environmental justice concerns and the current Health Study would be a good place to start.	2. See section 1.1 and section 2 of the Draft Work Plan for the focus of the initial health study 3. See response to comment 2.C.10 below. 5. Outreach activities began early in the project planning process. A major goal of the Health Study Team was to find ways to increase public participation. In May 2012, BSB HD held a series of public listening sessions where members of the public including low income citizens were given the opportunity to provide critical 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. Questions and concerns that came from the public meetings are being addressed through a suite of fact sheets designed by health study Working Group members and distributed in the local newspaper. Section 1.2 of the Draft Work Plan summarized additional activities conducted.

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2.C.9	The EPA also needs to adopt action levels for the toxics of concern in Butte that specifically apply to low-income citizens who are more susceptible to the effects of lead poisoning than the non-poor. The failure to do so perpetuates environmental injustice.	The Selected Remedy requires residential areas, including low income areas, to be remediated if the action levels are exceeded and a pathway exists. For more information see section 12 (2006 ROD). Based on consideration of requirements pertaining to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the detailed analysis of remedial alternatives, MDEQ comments, and all public comments, EPA has determined that the preferred remedial alternative presented in the Proposed Plan, site-wide Alternative 4 in combination with Alternative 2 from the Focused Feasibility Study for Metro Storm Drain, as modified in the 2006 ROD, is the appropriate and protective remedy for the BPSOU. When investigating exposures to lead EPA focuses on the most susceptible members of the population (children < 7 years of age) to the adverse neurological effects of lead. Young children are more sensitive because their neurological system is rapidly developing, their stomach absorbs more lead than adults, and they have higher contact rates with soil and housedust. At each Superfund site EPA looks at how the children at that site can be exposed to lead, since these exposure pathways may differ from location to location. EPA looks at oral and inhalation exposure to lead in outdoor soil, indoor housedust, tap water, ambient air, and paint. The bioavailability of lead in soil is also assessed because it may differ from site to site. Finally, if blood lead data is collected it allows us to see if other sources of lead exposure may be present in the community such as parental occupations, hobbies, cooking ware from outside of the U.S., etc. When EPA looks at those exposures, they don't just consider average exposures. They base their assessment on the individual who receives the highest amount of exposure considered to be reasonable. In summary, the assessment that the EPA conducts, and the resulting cleanup levels, are focused on the most susceptible members living in that community who receive the highest amount of exposure considered to be reasonable.
2.C.10	The composition of the Health Study Advisory Board needs to be changes and a representative of Butte's low-income community appointed to this board. Environmental justice demands that this takes place. At present, low-income citizens are meaningfully excluded from the process of developing and executing the Butte Health Study.	The commenter is referred to response to comment 2.B.9 regarding the composition and interaction of the health study Working Group and CAC. It is not known if any representative from these groups is of low-income status. Going forward, there will be additional opportunities for the Working Group, which includes the CAC representatives, to provide input to key decision points in data analysis.
2.C.11	I don't need to repeat the details of EPA's written commitment, in terms of policy and procedure, to "meaningful public involvement" and to promoting environmental justice. We will see if the EPA's reaction to the comments received is congruent with the agency's written commitment to promote efficacious public involvement and to promote environmental justice. If the public comments simply get "blown-off" and become only the subject of a perfunctory responsiveness summary, Butte citizens will see once again that the EPA only pays "lip-service" to meaningful public involvement in Superfund decision-making and to environmental justice.	The health study Working Group encourages input to promote public involvement and environmental justice. Numerous efforts have been made throughout this process to promote both. Going forward, there will be additional opportunities for the Working Group to provide input to key decision points in data analysis.

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2.C.12	Although central Butte has a disproportionate number of low income citizens, environmental justice concerns have been ignored. Look to the work plan and you will see environmental justice is ignored. In this area I fault not only the Montana Office of EPA but Region 8's office in Denver which has an environmental justice staff. I was shocked to find that Region 8, unlike most EPA regions, does not even have an environmental justice action plan.	The commenter is referred to the new section, "Environmental Justice Considerations," of the final work plan. At this time, Region 8 does not have a specific environmental justice action plan, however, the following are several sources of information that help describe the Region's environmental justice focus which are useful: -- , EPA's Environmental Justice website that includes a link to EPA's "Plan EJ 2014." http://www.epa.gov/environmentaljustice/ -- EPA Region 8's environmental justice website: http://www.epa.gov/region8/ej/ -- EPA's Strategic Plan (and associated Annual Action Plans) for FY11-15: http://www.epa.gov/planandbudget/strategicplan.html -- EPA's Annual National Program Managers (NPM) Guidance: http://www.epa.gov/planandbudget/annualplan/fy2013.html
2.C.13	Environmental Justice (EJ): The Butte community has clear EJ concerns given its elevated poverty rate in areas most impacted. Specific concerns adequately expressed in prior comments are: 1. How the housing stock (quality, design, size, etc.) might influence exposure in ways that differ from common risk assessment assumptions? 2. How potentially lower health status among low income people increases susceptibility? 3. Potential synergistic effects of exposure to multiple contaminants. 4. How this and future health studies will avoid inadvertent discrimination against low-income residents? 5. In what ways are those most affected, i.e. low income people, directly involved in the health studies?	1. Superfund does not have the authority to address the design of a home. However, Superfund does have the authority to enforce cleanup of residential properties which exceed action levels within the BPSOU and the adjacent areas. 2. See example in response 2.C.3 3. See section 1.1 and section 2 of the Draft Work Plan for the focus of the initial study 4. All residential properties within the BPSOU and adjacent areas will be assessed and remediated if necessary and continued efforts to promote public involvement and environmental justice will be built upon. 5. Generally speaking the most direct way that anyone is involved is through the cooperation with the RMAP. Participation is sought via public meetings in accessible locations, information in the local newspapers and other news media, EPA, BSB, and CTEC points of contact and websites, and other notices (e.g., via water-bills).
2.C.14	Please make Environmental Justice a priority of both the Superfund and the non-Superfund health studies. EJ is a key issue regarding pollution and health in Butte because the county poverty rate is 15.8% and over 37% of citizens live below 200% of the national poverty rate. These are people who necessarily live in lower-rent, older housing, apartments and mobile homes, much of which is located in areas impacted by pollutants – the Greeley neighborhood inversion area adjacent to mine operations, the dusty area near the gravel and sand operation at Maryland and Second Streets, heavy wood smoke inversion areas like Nevada Street in central Butte, and notably, the entire Butte Hill (full of older housing stock) that becomes invisible on windy days when contaminated dust from the historic mining area blows across town. As everyone in Montana has the right to a clean and healthful environment per the State Constitution, it would seem the Health Study should identify all the areas of discrete inversion, the areas where street sanding kicks up <3 micron particles of crystalline silica, and it should call for testing the ambient air around gravel and sand operations in residential areas, and then address these poorer neighborhoods as a first priority. If funds are not available for replacement of more than 15 wood stoves for homes that cannot afford the changeover in areas like this, could the Health Department please look into finding grants to effect a broader replacement project.	The Final RMAP shows that the plan will address all residential properties which exceed action levels within the BPSOU site and the adjacent areas. The plan also uses a prioritized approach that addresses the affected populations which include young children and pregnant or nursing mothers. environmental justice will continue to be a priority of the health studies in Butte.

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2.D Comments Pertaining to Independence of Study/Investigators and Need for External Peer Review		
2.D.1	Simply put, after reading the draft work plan, I am convinced that it is inadequate in design, scope, methodology, reliability and validity. It is designed simply to prove, as has already been articulated by the Butte Health Department even before the study has been conducted, that Superfund is working to protect human health.	Experts from EPA, MDEQ, ATSDR, BSB and AR have collaborated in designing the current study. As stated in the introduction to section 2 of the Draft Work Plan, the proposed study will be used 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."* The predecessor to the RMAP was implemented in response to recommendations arising from completion of a 1990 study by BSB and University of Cincinnati that examined lead and arsenic exposures in Butte children (BSBDH/UC 1992). That study and EPA's risk assessments supported a focus on lead exposures. Thus, the proposed initial study design is a logical next step following collection of multiple years of lead biomonitoring data via the RMAP. Evaluation of existing blood lead data collected as part of the RMAP is a necessary and appropriate first step to determining whether widespread exposure to lead has been occurring in Butte. Consideration of the results of the proposed evaluation can then be used by EPA, along with findings by MCSEP from a 2012 study of cancer incidence in Silver Bow County, Montana, and the U.S. (MCSEP 2012; included in Appendix A of the Draft Work Plan), to help inform the direction of future studies. Contrary to the comment, the outcome of the study is not yet known.
2.D.2	The Health Study announces the results of the study before the study is even done. This is an egregious example of poor and sloppy, as well as biased, investigation on the Health Department's part.	The results of the study are not known, and BSB apologizes if that impression was given by any BSB spokesperson.
2.D.3	Citizens were promised an independent health study. We are not getting an independent health study. Because the Health Department lacks the expertise to do such a study, we are getting the same old story of the EPA and the PRPs evaluating their own work. How can the public have any confidence in such an approach? Isn't there a potential for bias here? The Health Department is simply going along and will rubber stamp whatever EPA and the PRPs come up with as their conclusions.	Experts from EPA, MDEQ, ATSDR, BSB and AR have collaborated in designing the current study. In addition, the CAC has been established to review and provide input regarding study plans and analyses as part of the Working Group. In addition, comments on the Draft Work Plan have been solicited from the public, and additional opportunities will be provided to review the study findings. The Working Group will also be exploring the possibility of submitting the study results for peer review and publication.
2.D.4	Any future health studies need to be conducted by an independent and highly qualified investigator (s). The public needs assurance that future health studies will be totally unbiased.	The commenter is referred to the response to Comment 2.D.3 above.
2.D.5	Issues regarding the independence and validity of the study need to be addressed. This Health Study, so far, is just another case of the agencies who have done the work so far in Butte evaluating the effectiveness of their own work. How can the public, at present, have any degree of confidence that this will be an independent, valid and unbiased study? At a minimum, the design and conduct of the Health Study needs to be subjected to outside, independent peer review from an entity not connected to or part of the EPA, MDEQ, ARCO or Butte/Silver Bow.	The commenter is referred to the response to Comment 2.D.3 above. Both the CAC and experts from ATSDR are participating in review of the design and conduct of the study. Independent peer review is a good suggestion and is being considered, most likely in the form of submission of a report of the study in a peer-reviewed journal.
2.D.6	The Atlantic Richfield Company/British Petroleum Company is funding the study and they hired and chose the contractor conducting the study. I have absolutely no doubt that the local people currently involved with the Health Study of this committee are good folks and are trying to do what is right. The problem they face is that as long as they receive their research and information from the Federal and State agencies, and the Atlantic Richfield/British Petroleum Company their research is always going to be suspect.	The commenter is referred to the response to Comment 2.D.3 above.

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2.D.7	I have said for years that Butte needs an unbiased analysis by some independent environmental research firm or University outlining what truly is necessary to have a responsible cleanup and restoration of the Community. The same holds true for this health study---Butte needs a totally independent analysis of the health situation of the community. Until this happens, folks from Butte will always be suspect.	Please see response to comment 2.D.3 above with regard to the current proposed study. With regard to the broader question of assessing the health situation in Butte, BSB made a substantial effort to provide such an analysis in the 2011 Silver Bow County Public Health Needs Assessment report. That report provides a broad overview of health issues and challenges facing the community. The needs assessment and the non-Superfund study planning effort should provide a means to address community-wide health concerns separate from the Superfund focused studies.
2.D.8	The consulting firm chosen to perform the study has been intimately involved with ARCO for many years. These people are not independent, third-party experts.	Please see response to comment 2.D.3 above. Representatives from EPA, MDEQ , ATSDR, BSB, AR, the CAC, and CTEC who participate in Working Group meetings weigh in on the health study process including scoping, technical direction, approaches and interpretation proposed by the consulting firm conducting the study under contract to AR.
2.D.9	The needs to be independent, peer review of the whole development and execution of the Butte Health Study.	Please see response to comments 2.D.3 and 2.D.8 above. An independent peer review is a good suggestion and is being considered.
2.D.10	The followup health study of the effectiveness of the remediation efforts for Butte seems to have an appropriate design. Previous studies have shown that urine arsenic levels and fingerstick levels of mercury were not elevated. The present design to use whole blood lead level testing seems to be more accurate. However, the hiring of the toxicologist by ARCO and the review of the study design by an in house panel of the EPA are problematic to me. I am not a conspiracy kind of person. I believe that both agencies are interested in obtaining the most appropriate dara possible. However, this community has a three to for generation culture of not always receiving accurate information from industry officials regarding health issues. Within my time in Butte we have received at least two sets of misinformation about water quality in our drinking water. The first information about the relationship of water to the increased incidence of Giardia stated that there was no relationship and the water was being tested regularly. That was patently untrue. They were not testing various sites regularly. I personally feel that if you do not get an independent of the project by an independent review agency you will have to contend with conspiracy theory for years to come. f the whole process is transparent from the beginning the Butte people will much more likely accept the findings. I am surprised by the number and frequency of outrageous ideas expressed, e.g. the Montana Department of Health and ARCO have an agreement to underreport the incidence of malignant diseases in Butte. I think that periodic testing for heavy mental in storm run off would provide value as would periodic chemical a *(note: comment is incomplete but reproduced as received by BSB via email)*	Please see response to comments 2.D.3 and 2.D.8 above. An independent peer review is a good suggestion and is being considered. We agree that a suggestion that "*the Montana Department of Health and ARCO have an agreement to underreport the incidence of malignant diseases in Butte*" is outrageous. Reporting rules for malignant diseases in Montana are well established and are in adherence with Tumor Registry Law (Montana Code Annotated 50-15-701).
2.E Comments Pertaining to Specific Study Design Elements of the Draft Work Plan		
2.E.1	Need to compare Butte to: (a) a same size city, with similar rates of alcohol consumption, obesity and smoking, that does not have a heavy metals problem, (b) to a same size city, with similar rates of alcohol consumption, obesity and smoking, that has a heavy metals problem similar to Butte and (c) to a city similar to Butte in terms of size and contamination that has undergone extensive Superfund remediation. This city would have similar rates of alcohol consumption, obesity and smoking.	The comparison community needs to be matched for a variety of risk factors known to affect blood lead levels. Examples of significant risk factors associated with higher blood lead levels include socioeconomic status, urbanization, house age, renter occupied housing, single or multiple residential housing units, maternal education and smoking. We may not be able to match all of these factors, but will profile the prospective comparison populations for as many risk factors as can be determined. Alcohol consumption and obesity are not primary risk factors for blood lead levels, consequently these are not the primary factors that will be considered in identifying a comparison population.

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2.E.2	p. 17, 1st and 2nd bullets, Section 2.3.3, Step 3: Identify the Information Inputs: (1) Please explain why "representative distributions" are needed as it relates to the planned assessment criteria. A community level response seems inconsistent with the individual level response identified on page 7 of the RMAP. (2) Also, it seems you need representative data within neighborhoods rather than "within the Butte community" to meet the first line of evidence listed as bullet 1 at the bottom of the page. Please clarify what those neighborhoods are and why a neighborhood approach is important. (3) Also, what about arsenic and mercury biomonitoring data needs? (4) Also, enough is known to state at this point in the Draft Plan at some level of professional judgment if the available data meets your input needs, and if not, what needs to be done.	(1) The intent of the RMAP is to encourage broad participation of Butte children in the biomonitoring program. As described in page 7 of the RMAP, the individual response (i.e., a home assessment) is made when an individual is identified as having a verified blood lead value of 10 µg/dL or greater (or elevated urine mercury or arsenic). The goal of the health study is to determine if the cumulative effect of the home assessments and other remediation activities in Butte have had the overall effect of reducing community exposures. One possible approach to assess exposures would be to track the number of children with blood lead levels greater than 10 µg/dL; however, the health study Working Group does not believe that is a sufficiently sensitive approach considering very low numbers of Butte children with blood lead levels greater than 10 µg/dL. The goal of using representative distributions is to assess whether children in some areas Butte have **any** increase in lead exposures. This is a more sensitive measure than looking at the numbers of children with elevated blood lead levels. (2) The commenter is correct that we need representative data for neighborhoods, as well as for Butte as a whole. At the time the work plan was issued the blood lead data were still being compiled and the neighborhoods had not yet been defined. The final work plan will show that census tracts have been defined as the most appropriate way to define neighborhoods. The primary reason for relying on census tracts is that the census provides data for many risk factors that are known to affect blood lead levels. (3) BSB's observations from the RMAP are that elevated mercury concentrations are seldom detected in residential samples, and that arsenic concentrations are seldom high enough to warrant requests for urine arsenic samples. The health study will include a review of the compiled mercury and arsenic environmental data to determine if any additional follow up might be needed. (4) Yes, we are now more confident that the available data will support a neighborhood analysis. The final work plan will include a table and figure similar to those presented at the public meetings showing the numbers of samples available for each neighborhood, as well as additional discussion of why we judge these data to meet the input needs.
2.E.3	p. 17, possible new bullet, Section 2.3.3, Step 3: Identify the Information Inputs: Please address the potential for exposure via groundwater as another route of exposure.	The proposed study relies upon blood lead data, which reflects exposures to lead from all sources, including lead in drinking water.
2.E.4	p. 18, 2rd paragraph (not including bullets), Section 2.3.4 Step 4: Define the Boundaries of the Study: The area is restricted to BPSOU's RMAP, but most of the data has been collected from the Butte-Silver Bow County; how are they to be compared? It seems the study boundary needs to match the areas for which there are data? Also, as we consider alternative studies beyond evaluation of available blood-lead data, the study boundary may need to be modified. Perhaps the study boundary needs to be stated in more general terms, the greater Butte community, with individual studies focusing on sub-parts consistent with the available data?	The Draft Work Plan will be revised to better define the target population of interest and its relevance to spatial boundaries specified for the study.
2.E.5	p. 18, 3rd paragraph (not including bullets), Section 2.3.4 Step 4: Define the Boundaries of the Study: Please clarify what is meant by "the target populations of interest are young children…and pregnant mothers." Does this apply to all metals? Are others therefore excluded? CTEC believes that protections should be extended to all persons.	The initial study is focused on lead exposures and the target population specified in the Draft Work Plan is the most appropriate group to study in relation to such exposures. The target population of interest is well defined in the section noted by the commenter. Because young children are most susceptible both to lead exposures and also to adverse effects of lead, focusing on this population is protective of all persons. Numerous studies across the U.S. have demonstrated that this population has the highest blood lead levels. Little additional value would be gained by testing adults, who generally have lower lead exposures. Further, due to its relatively long half-life, lead exposures are likely to be detected by blood lead monitoring of children, which provides a good surrogate for exposures to other site-related contaminants that may be present along with lead.

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2.E.6	p. 19, 1st paragraph, Section 2.3.5. Step 5: Develop a Decision Rule: Why should statistical measures of significance be decided later? What factors might lead to higher or lower limits? At a minimum, the role of oversight agencies and the public in this important decision-making process should be detailed at this point in the document.	The Draft Work Plan specifies that "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." Data to be evaluated in the study are currently being compiled from existing data sources. Statistical analyses and measures of significance will be proposed for input from the Working Group prior to deciding a specific approach.
2.E.7	p. 19, Section 2.3.6 Step 6: Specify Tolerable Limits on Decision Errors: There are no limits specified in this section. Rather, what is given are more in line with Decision Rules. Also, it's not clear why statistical differences across neighborhoods or comparative temporal trends across communities are needed. The central point seems rather to get blood lead levels down to acceptable levels for all people who chose to participate in the voluntary cleanup program.	Tolerable limits described in section 2.3.6 are qualitative and relate to the consequences of making a false acceptance decision error versus a false rejection decision error. The rationale for statistical comparisons proposed in section 2.3.6 is discussed in section 2.2.2, Study Objective and Approach. Section 2.2.2 will be reviewed and revised, as appropriate, to provide greater clarity with regard to the rationale for the comparisons proposed.
2.E.8	p. 19, paragraph 4, Section 2.3.6 Step 6: Specify Tolerable Limits on Decision Errors: The three data needs seem to belong in a prior section. Again, more planning thought and assessment should go into this plan regarding the ability of existing data to meet the proposed decision rule needs. Otherwise, we risk a major change to the plan outside of the existing agency review and public participation process.	The three data needs directly relate to the hypothesis testing included at this step in the data quality objectives process and are appropriate for inclusion in this section. Existing data are being compiled and prior to initiating the study, a technical memorandum will be prepared for EPA approval that provides more detail regarding the use of these data in the proposed study.
2.E.9	p. 20, Section 2.3.7, Optimize the Design for Obtaining Data: Reiterating the last comment, this plan should not be approved until these optimization tasks are complete. Details for how the quality assurance review of RMAP data is to be done should be provided. Reference communities (if really needed) should also be selected prior to approval of the plan. The public should have the chance to review and comment on these procedures.	Existing data are being compiled and prior to initiating the study, a technical memorandum will be prepared for EPA approval that provides more detail regarding the use of these data in the proposed study.
2.E.10	p. 22, paragraph 7, Section 2.4.4 Task 4 – Data Compilation: More detail is needed on how confidential information is to be handled throughout this study. Appendix D only describes the transcription process, not the storage, analysis and reporting of data put into electronic files. Bits and pieces of good information are provided in pages 7 to 9, 21, 23 and Appendix D in ways that are hard to integrated and understand. Page 6 mentions "participant and neighborhood coding", yet page 8 mentions names and addresses, among other fields of information in the data file. Questions on details remain, such as: how is coding done, how many people have access to confidential information, how is access controlled, how is biomonitoring data connected with yard and house data, and how is quality control in transcription being done? A discussion on these points may be more helpful than a written response.	Confidential data are accessible only by BSB and a limited number of individuals from ENVIRON, under contract to BSB. All such individuals were required to sign a confidentiality agreement with BSB prior to gaining access to the confidential data. That agreement requires the individual to adhere to the policies and procedures of the BSB Health Department which include federal and state laws strictly protecting client health information. The Draft Work Plan will be revised to include more detail regarding the handling and protection of confidential information compiled for the blood lead database. Only de-coded data (i.e., data that has been stripped of any personally identifying information) will support the health study analyses and results reporting. De-coded data will not be subject to the same protections as the confidential source data.
2.E.11	p. 23, Section 2.4.5 Task 6 – Data Analysis and Reporting: Detail, perhaps alluded to elsewhere, is needed regarding agency and public participation review procedures associated with a draft and final report. Also, some reconnecting of the "recommendations for future improvements" to the five-year reassessment process may be appropriate.	The Draft Work Plan identified public comment periods for the study work plan and reporting deliverables in Table 5, the preliminary schedule for implementation of the public health study. Opportunities for community review and input are also summarized in section 2.4.2, Task 2 – Community Outreach. However, the Draft Work Plan will be reviewed in consideration of these suggestions and revised as appropriate to ensure clarity. Recommendations for future improvements to the RMAP will, as specified in Task 6, be included in the final reporting for this study. These recommendations and any resulting follow up will be available to EPA for consideration in the Five-Year Review process. However, it is beyond the scope of this study to prescribe how EPA will consider the findings of this study.
2.E.12	Dust needs to be a focus of the study.	House dust is a potentially significant source of lead exposure and was studied as part of the EPA risk assessments. The RMAP includes dust sampling, and the RMAP dust data will be reviewed as part of the health study. If the blood lead data shows evidence of increased exposures in some areas of Butte or in Butte compared to other communities, the house dust data is likely to become a focus in identifying potential sources of exposure.

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2.E.13	A complete and thorough investigation of attic dust needs to be part of the study.	Potential exposures to attic dust were evaluated in the EPA risk assessments. Unlike house dust, attic dust was shown to have little influence on either house dust metal concentrations or on potential exposures in cases where the attic was not used as part of the living space of a house. The RMAP includes sampling of dust in attics in the attic abatement area with action being taken when a remodel includes accessing the attic. Beyond the existing RMAP, no further investigation of attics is planned as part of the initial health study.
2.E.14	Methodology: Many concerns have been expressed about the methodology for the current blood lead study and future studies: (1) Clarifying the limitations associated with current blood lead data, including elevated detection limit concerns, other data quality limitations, representation (particularly for low income neighborhoods), and statistical power to evaluate significant differences on a neighborhood and/or community wide basis. (2) Addressing risk from exposure to chemicals other than lead, and considering possible affects of combined exposure. (3) Release and use of existing urinary arsenic data. (4) Methods for addressing disease incidence and mortality in ways that are more constructive than has been achieved through the kind of "dueling expert" approach that has been thus far fostered though the health study process.	(1) Several of these concerns are addressed in responses to other comments. Briefly, only data with low detection limits (i.e., 1 µg/dL) are being used in the study, the data are of sufficient quality to support the study objectives, the Draft Work Plan will be revised to document the neighborhoods and representation is best for the neighborhoods with the highest proportion of residents below the poverty threshold based on income, and a separate technical memorandum is being drafted to address statistical analyses. See also the response to comment 2.F.8. (2) Please see responses to comments 2.G.1 and 2.2. (3) Please see the response to comment 2.F.9. (4) Please see responses to comments 2.F.3 and 2.F.4.
2.E.15	While a written response to all prior comments submitted is expected, CTEC does not believe that this kind of back-and-forth will be adequate to resolve all our concerns. Moving forward, CTECs direct involvement with the Citizens' Advisory Committee provides the possibility of achieving a huge step forward in addressing our concerns. However, as achieving more common understanding will take time, we request the following short-term changes to planned work: - Re-assess the schedule and process for conducting the blood lead study. There are too many concerns about the objectives, validity and methodology for the current blood lead study to expect quick and easy resolution. Any attempt at a response to comments with a final study plan, followed within a few short months by a draft study is likely to lead to an ongoing "dueling experts" approach and lack of agreement on study conclusions. This will not achieve the objective of enabling Butte citizens to achieve understanding of any remaining community health needs, as it applies to lead exposure in this case. CTEC recommends that we move to a phased approach that begins by framing up the broader objectives of the health study (over the long term) versus short-term objectives (of the blood lead study), clarifying relevant EJ questions and response methods, and then proceed in step-wise fashion to evaluate the blood lead data. For example, we might first address data quality and representation concerns before addressing other study questions. While perhaps slower, we believe this approach will result in less written comment and response, less redoing of work, and more community involvement leading to improved common understanding. So while slower, it need not be any more costly than the current approach and stands a much better chance of achieving overall goals. - Apply state-of-the-art process expertise for conducting the remainder of the health study. This health study involves technical complexity, disparate stakeholder interests, and social controversy that is at least partially rooted in risk perception influences. EPA has established programs that provide state-of-the-art expertise and procedures to meet exactly these kinds of challenges. EPA's Alternative Dispute Resolution program	The study Working Group believes that sufficient time is being provided to fully vet the objectives, validity and methodology for the current blood lead study. The ongoing non-Superfund health study planning process will provide opportunities for input regarding remaining community health needs. Additionally, the CTEC representative participating in the Working Group provides both technical and public involvement expertise to the process.

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	(http://www.epa.gov/adr/cprc_adratepa.html) is a prime example. We recommend that the study team give full consideration to the use of these resources to meet the longer-term aspirations of the health study.	
2.F Comments Pertaining to the Study Focus on Exposure vs. Health Outcomes		
2.F.1	Future health studies in Butte need to look answer the following questions: - How do the contaminants of concern impact the health of Butte residents? - What is the relationship in Butte between exposure to the toxics of concern and diseases such as cancer, diabetes, ALS, multiple sclerosis, etc.? "In the realm of environmental health, epidemiologic research generally aims to portray the frequency of disease occurrence in the population or to link disease outcomes to specific exposures."(Environmental Epidemiology, Jones and Bartlett Learning, p. 29) - What are the health effects Butte residents experience from exposure to the toxics of concern? - What proportion of disease in the population of Butte/Silver Bow would be prevented if exposure to heavy metals were significantly reduced? - Is Butte safer today than before Superfund commenced its cleanup activities? - What are the chronic as compared to the acute effects of exposure to the toxics of concern? "In environmental epidemiology, concern usually centres on chronic effects from low-level exposures." [Lesley Rushton and Paul Elliott, Institute for Environment and Health, "Evaluating evidence on environmental health risks," British Medical Bulletin [2003]68 (1)] - Need to focus on incidences of disease. - Need to rely much less on incidence studies. For example, many low-income residents don't have ready access to health care providers or services. Low-income citizens would therefore, contrary to EPA's environmental justice mandate, be underreported and underrepresented if future health studies rely extensively on incidence studies.	The nature of future health studies has not yet been determined; however, for many reasons the study described in the Draft Work Plan should provide insights that will be helpful in planning future studies. As described in EPA's Butte risk assessments, lead is the primary contaminant of concern. A 1990 study by BSB and University of Cincinnati (BSBDH/UC 1992) examined lead and arsenic exposures in Butte children and found that blood lead levels were slightly higher in neighborhoods with more mine waste impacts and with older housing. The 1990 study did not find elevated arsenic exposures in Butte (as indicated by urine arsenic concentrations). BSB's RMAP has also confirmed that lead is the predominant contaminant of concern. The health effects of lead are diverse and many of these effects may have other causes. Low level lead exposures, such as those documented in 1990 in Butte, are not likely to result in effects that can be detected in a study of health endpoints. Blood lead concentrations provide a good measure of lead exposures from all sources and provide a more sensitive assessment of the potential for adverse effects; consequently, such studies are the most effective way to assess the potential for adverse effects of lead on health in Butte. The commenter asks "*What proportion of disease in the population of Butte/Silver Bow would be prevented if exposure to heavy metals were significantly reduced?"* This question includes an assumption that there have been (and are currently) substantial exposures in Butte; however, this assumption is not supported by older biomonitoring data. If the proposed study finds evidence of elevated exposures, that information can be considered in designing future studies. The commenter also suggests the need to rely less on incidence studies. The only incidence studies conducted to date are cancer incidence studies. Contrary to the commenter's suggestion, the Montana state epidemiologists view cancer incidence data as a much more reliable indicator of cancer burden than mortality data. Cancer mortality rates may be affected by access to health care providers or services, but cancer incidence reports will be unaffected by how quickly the patient seeks treatment.
2.F.2	Inadequate assessment of epidemiology information: Section 4.1 of the RMAP (p. 7) provides several different requirements for the health studies, including, "compiling and interpreting the morbidity and mortality statistics as an epidemiology study, and compiling and interpreting influencing factors (environmental or cultural) for mortality rates". Only three paragraphs of the Draft Plan are focused on meeting these objectives (see page 2) with reference to brief summary of prior work done by ATSDR (provided in Appendix A). However, there is no critical examination of the thoroughness of ATSDR's work. We note for example that one of the more common types of cancers caused by arsenic, squamous cell carcinoma, is not reportable and not assessed. What might be done to overcome this limitation? Also, non-cancer endpoints are not addressed. Lastly, the three paragraphs of Draft Plan text conclude with a reference to epidemiological studies that might be of interest to future public health studies, but no details are given as to if, when or how this interest might be addressed.	Appendix A of the Draft Work Plan includes a copy of a study performed by MCSEP, not ATSDR. The MCSEP study was performed at the request of the health study Working Group to update and expand upon an ATSDR review of Silver Bow County cancer incidence rates compared to similar data for Montana and the U.S. (ATSDR 2002). The ATSDR study focused on cancer outcomes associated with exposure to heavy metals including arsenic, and to a lesser extent, lead and mercury. A summary of the ATSDR (2002) study will be included in the Final Work Plan. The MCSEP study (2012) was conducted independently by state epidemiologists. The health study Working Group did not provide input to or comment on the state's report. We agree examining the outcome of the 2012 MCSEP study is a useful starting point for identifying potential issues in Butte (e.g., higher mortality from colorectal cancer when incidence is not increased may point to a need for better diagnosis and treatment of that disease). In general, we believe that future studies should be focused on endpoints that are related to identified exposures. Arsenic has not been identified as having elevated exposures in Butte in the study by BSB and the University of Cincinnati (BSBDH/UC 1992) or the ATSDR study of Walkerville (ATSDR 2001), consequently, the value of pursuing a study of squamous cell carcinoma may be limited. Available data for non-cancer endpoints may be limited. The state epidemiologists from MCSEP may be a helpful resource for obtaining information on what data are available or may be feasible to obtain. These are questions that could be

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		considered in scoping additional health studies described by the UAO to be conducted every five years for a period of 30 years.
2.F.3	General Comment Summary and Proposed Actions: The core issue underlying our General Comments is the desire to constructively identify what kinds of epidemiological studies might be done in the future that would improve our understanding of the health protectiveness of the remedy. CTEC is concerned that thus far there has been inadequate involvement by qualified epidemiological researchers. A highly polarized, dueling science kind of debate has been going on this past year, often through the media, that has undermined public understanding of and trust in the science. While we support moving forward with the biomonitoring assessment, CTEC proposes a separate track to assess possible options for future 5-year health studies. We believe this process needs to start by more thoughtfully considering the kinds of questions the studies need to ask, better understanding the limitations of what existing epidemiology can do to answer the study questions, what kinds of new epidemiology data is maybe needed, and what other kinds of studies such as ongoing biomonitoring should be conducted into the future.	As CTEC suggests, there can be separate tracks for health endpoint focused studies vs. biomonitoring studies. As noted on page two of the Draft Work Plan, health endpoint focused studies were considered in the initial study planning phase, and a need for an updated cancer incidence and mortality study was identified. This study was conducted last year by the State of Montana. We agree that the community may benefit from engaging in discussions of the outcome of this study, considering the kinds of questions future studies need to ask, better understanding the limitations of what existing epidemiology can do to answer the study questions, what kinds of new epidemiology data is maybe needed. We suggest that the state epidemiologists may be a helpful resource for such discussion. Future biomonitoring studies will be most effective if the data and conclusions generated by the current studies are used to help inform the design of subsequent studies. Recommendations from this study can be used to guide data collection during the next five years to improve future studies. For example, if current detection limits for blood lead levels are found to be too high, different analytical methods might be recommended, or if blood lead data for children are being missed, a new method of tracking the data might be needed.
2.F.4	Anyone who lives in this community and does not believe that the cancer rates and other diseases like MS, emphysema in adults, asthma in our children, and other lung related diseases are not higher in Butte than in other communities in Montana is naive!	A study performed by MCSEP during 2012 (and included in Appendix A of the Draft Work Plan) indicates that age-adjusted incidence rates for all cancers combined, and for each of the four most common cancers (i.e., cancers of the prostate, female breast, colorectal, and lung and bronchus), were statistically similar or lower in BSB compared to Montana during three time periods examined from 1981 through 2010. As noted on page 2 of the Draft Work Plan, colorectal cancer mortality rates were statistically elevated, suggesting possible limitations in screening or treatment. Rarer cancer rates were also not statistically elevated, but sometimes the number of cases was very small, so the results were not conclusive. The ability to study health endpoints other than cancer is limited for health endpoints that physicians are not required to report to the state, but as noted in responses below, these may be useful issues to pursue with the state epidemiologists.
2.F.5	The study proposes to analyze some blood lead data. Blood lead is not "health." Thus, you should not call the proposed project a "health study."	The health effects of lead are diverse and many of these effects may have other causes. Low level lead exposures, such as those documented in 1990 in Butte, are not likely to result in effects that can be detected in a study of health endpoints. Blood lead concentrations provide a good measure of lead exposures from all sources and provide a more sensitive assessment of the potential for adverse effects due to lead exposure; consequently, such studies are the most effective way to assess the potential for adverse effects of lead on health in Butte.
2.F.6	The blood lead program in Butte has many deficiencies, but ARCO/EPA did not design the program to be a comprehensive or conservative marker of exposure in Butte. They chose a small subset of the population to test, some of whom (i.e., pregnant women) happened to show the lowest blood lead levels in the 1990 University of Cincinnati study (also funded by ARCO). Thus, the data will be biased towards lower concentrations.	BSB designed the blood lead program to focus on the population expected to be most susceptible both to lead exposures and also to adverse effects of lead (i.e., young children). Numerous studies across the U.S. have demonstrated that this population has the highest blood lead levels. Blood lead testing was offered to children via the WIC program, and large numbers of Butte children were tested each year. While there are also data for infants and pregnant women, these data will not be mixed with the data for young children, and no specific plans for analysis of those data have been made at present.
2.F.7	The blood lead program has been very limited to whom is/was eligible for testing.	As described above, the blood lead program has been focused on the population expected to be most susceptible both to lead exposures and also to adverse effects of lead. The large numbers of children tested each year indicates a high level of participation among families with young children. It is important to focus the study on those members of the population most likely to have increased exposures.

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2.F.8	The blood lead data will not be sufficient to understand risks because the instrumentation used to analyze the samples had a detection level that was too high. (For example, recent medical research has shown behavioral and learning problems in children and young adults at much lower blood lead levels than the detection limit used in the Butte program.)	The detection limit for the blood lead data that will be used in the health study was 1 µg/dL. This detection limit is sufficiently low to support the study objectives, i.e., comparison of average blood lead levels across Butte neighborhoods and also to compare Butte with other communities. Furthermore, this detection limit is also low enough to support the objectives of the RMAP, i.e., to identify individual children with elevated blood lead concentrations.
2.F.9	Lead is only one of the contaminants of concern in Butte. Arsenic exposure should also be a primary focus. While the EPA has publicly claimed to have years of urinary arsenic data, it is not true.	The commenter is correct that multiple metals have been considered as contaminants of concern in Butte. EPA's Superfund risk assessments evaluated a range of metals and concluded that lead is the primary chemical with a potential to cause adverse health effects in Butte. Consequently, it has been appropriate to focus remediation efforts on reduction of potential exposures to lead. Arsenic and mercury action levels were also established, in accordance with EPA's risk assessment policies. A 1990 study by BSB and University of Cincinnati (BSBDH/UC 1992) examined lead and arsenic exposures in Butte children and found that blood lead levels were slightly higher in neighborhoods with more mine waste impacts and with older housing. The 1990 study did not find elevated arsenic exposures in Butte (as indicated by total arsenic concentrations in urine). The commenter is correct in noting that there is not much more recent urine arsenic data for Butte residents. The most recent data we are aware of are from a 2001 ATSDR study in which all 25 Walkerville residents tested had total inorganic urine arsenic concentrations below the detection limit of 10 µg/L. Based on the available data, there is no evidence that arsenic exposures are a problem in Butte. To the extent that arsenic and lead are both site-related, the initial study's focus on lead may help identify whether expansion of prior arsenic exposure studies is indicated.
2.F.10	Samples of soil and dust in Butte have indicated that the contamination is not evenly-spread throughout Butte and Silver Bow County; thus, a comprehensive health study of disease rates, mortality rates, and other health-related problems on neighborhood scales is needed.	The commenter identifies an important and legitimate concern regarding variation in the level of contamination across Butte neighborhoods. The current study of blood lead data is designed to address the commenter's concern using lead biomonitoring data as an indicator for exposures to contamination in soil and dust, and incorporating comparisons across Butte neighborhoods into the proposed study design. Blood lead data provides a good surrogate for exposures to site-related contaminants. Lead is the primary constituent of concern identified by EPA for the site due to its prevalence in environmental media and its toxicity. Due to its relatively long half-life, lead exposures are likely to be detected by blood lead monitoring and would represent combined exposures due both to site and non-site related sources, thus blood lead data provides a conservative indicator of exposures to lead from all sources within an individual's environment that were occurring in the weeks to months prior to measurement and can be used to identify differences in exposures between such environments on a neighborhood scale. In contrast, it is unlikely that disease rates can be effectively studied on a neighborhood scale due to low incidence rates for most diseases. As shown in the state's 2012 study of cancer incidence, even on the county level, many rarer cancers did not have sufficiently high incidence to reliably detect differences between BSB and the rest of Montana or the U.S. The lead biomonitoring study provides a much more sensitive method to address the commenter's concern.

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2.F.11	I completely agree with each of Dr. Peterson's points. I can only hope the members on this routing list and on the study committee take the time to investigate each of her points. She is a highly educated expert in this matter and can back up each of these statements with a plethora of references. Lead is not the chief or only contaminant in the BPSOU or surrounding areas and it is both misleading to the public and unscientific to present a study of blood lead levels as a comprehensive health study or an indication of risk or toxic effects stemming from exposure to other contaminants. There has been absolutely no attempt to understand the chemicals as a mixture, either. This study is being done this way because EPA, ARCO, and their researcher believe that they already know the outcome of the study based on the results of blood lead studies done in recent years. This is the same reason they are willing to look at incidence rates. In my dissertation, I reported the lower incidence rates for Butte-Silver Bow versus the rest of the State. I found it amusing that they put this forward as new information after my study. I think there are several compounding reasons for the lower incidence rates, but that is another topic for another day. I have tried my best to stay out of this as well, because my previous involvement was a truly atrocious experience, but obviously care very deeply about the issue and am having a hard time remaining silent. I think it is truly incorrect and deceptive to present this current study to the public as anything other than a blood lead study and I think the public deserves to know if there are health issues in the community and if so, what can be done about them. There are several things, such as calcium supplementation, that could be promoted to prevent lead and other metal absorption, but instead of looking into this type of practical solution the powers that be are instead spending time and energy defending themselves and their previous actions. I, for one, am truly disappointed.	The commenter is correct that multiple metals have been considered as contaminants of concern in Butte; however, EPA's Superfund risk assessments concluded that lead is the primary chemical with a potential to cause adverse health effects in Butte. This finding was supported by the 1990 study by BSB and University of Cincinnati (BSBDH/UC 1992) that examined lead and arsenic exposures in Butte children and found that blood lead levels were slightly higher in neighborhoods with more mine waste impacts and with older housing, but that urine arsenic concentrations were not elevated. Consequently, it is appropriate to focus the health study on potential exposures to lead. The commenter's suggestion that calcium supplementation can be used to reduce lead absorption is not supported by the literature for low level exposures such as those documented in Butte. Even for individuals with very high lead exposures, calcium supplementation has not always had clear cut beneficial effects, particularly in individuals without calcium deficiencies. Interventions like this should only be undertaken for people with significant exposures who are under a doctor's care for treatment.
2.F.12	The Health Study has been unjustifiably limited to, not a health study, but an exposure study. Doing so is a disservice to the Butte community and is an unjustified and unwarranted limitation of the Health Study. The argument that there are many potential causes of diseases that are related to the toxics found in Butte is not persuasive. It repeats the old and tired argument that industry constantly uses that we can never know whether or not a particular toxic directly causes a specific disease.	As described in the Draft Work Plan and in prior comment responses 1.A.1 and 2.F.3, at the request of the study Working Group, MCSEP did conduct a cancer incidence and mortality study. That study did not identify any cancers with elevated incidence. It is a scientific fact that many of the diseases that may be associated with toxics found in Butte may also be associated with other causes. In the case of lead and arsenic, it is also fact that there are many different sources of potential exposures (e.g., environment, diet, paint). Given these facts, the ability of health endpoint studies to detect effects in small populations is very limited for all but the most common diseases. Where effects may be detected, it may still not be possible to determine the contribution from a specific source when multiple sources of exposure are present. In contrast, the proposed exposure study seeks to better understand whether exposures to lead in the community have decreased in relation to cleanup activities and RMAP response actions conducted over the last decade. As described in response 2.F.10, lead is the primary contaminant of concern in Butte and thus, is a useful surrogate of other environmental exposures. The study also will examine how blood leads, as a measure of exposure from all lead sources, compare between Butte and other similar populations that do not have a similar Superfund history. Understanding the nature and sources of exposure is necessary if steps are to be taken to improve conditions in the community. Determination of exposures is also a fundamental step in determining the potential for adverse effects from chemical exposures. Therefore, we disagree that a disservice will be done to the Butte community by the proposed exposure study and instead we believe an exposure study is the most effective way to identify potential impacts to the community.

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2.F.13	We know that the toxics found in Butte such as lead, arsenic, mercury, zinc, cadmium, etc. cause disease. As a member of the public, I want to know whether or not the incidences of diseases and mortality rates related to the toxics found in Butte are decreasing.	We recognize that some members of the community may have concerns about the cleanup process. While it is true that high doses of lead, arsenic, mercury, zinc and cadmium cause a variety of diseases, many of these adverse health effects will not be caused by lower doses of these metals. All people everywhere are exposed to low levels of these metals, most commonly in foods they eat. Zinc is a required nutrient and is present in vitamin supplements as well as meat and all other foods. Mercury is present at the highest levels in fish. Arsenic and cadmium are found in plants as well as other foods. Consequently, it is not until exposures from a contaminated area begin to substantially exceed these normal background exposures that an increased disease burden is expected. A large study in 1990 indicated that urine arsenic and blood lead levels of Butte residents were not substantially greater than levels in similar populations. Additionally, cadmium and mercury have not been found to be consistently elevated in Butte soils. For these reasons, it is unlikely that there is an elevated disease rate that can be detected, let alone shown to be reduced. The difficulty in detecting such effects is one reason why EPA bases remediation decisions on risk assessments that are highly health-protective. EPA's goal is to remediate based on theoretical risk estimates even if no adverse effects can be detected in the population.
2.F.14	The "safe" levels of exposure to toxics found in Butte are constantly being tightened. What was considered a "safe" level a few years ago is no longer considered "safe". For example, consider how so called "safe" levels of exposure to lead are constantly being reduced. What was a safe level of lead exposure five years ago is no longer considered "safe" today.	EPA's goal for lead has been (and continues to be) to reduce overall lead exposures. The 10 µg/dL "blood lead level of concern" issued by CDC in 1991 was a risk management level. CDC did not consider that level to be a "safe", but rather a level at which it was feasible to identify and modify sources contributing to the elevated lead exposure. Over the last few decades, mitigation of lead sources to air and drinking water has successfully lowered blood lead levels nationwide, such that, today, elevated blood lead levels are typically found in a few individual children, not in entire populations. This has enabled CDC to again lower the risk management level for blood lead. The new CDC reference level of 5 µg/dL is also not a "safe" level, but a population-based reference level. The new value represents the 97.5th percentile of blood lead levels in the U.S. population of young children. This value is still a risk management tool that helps to identify children who may have elevated lead exposures that can be addressed by home interventions. The health study will be examining the distribution of blood lead levels in Butte children, using all of the data to determine if there are differences across Butte neighborhoods. There will be no cut off value for levels considered.
2.F.15	By concentrating only on exposure to toxics, the non-Health Study the EPA has mandated by unilateral order misses the point. Superfund is supposed to protect the public health. The central question is whether or not Superfund is protecting the public health. This can only be determined by looking at incidences of mortality and disease related to the toxics found in Butte. By examining only levels of exposure and then saying, based on exposure levels, that Superfund is working to protect the public health is a fallacious, non-protective process. What might be a "safe" level of exposure today may not be safe tomorrow. However, we can tell whether or not the public's health is being protected by looking at mortality and disease rates related to toxics found at Butte Superfund sites.	The basic premise of this comment, i.e., that protection of public health can be only be determined by examining mortality and disease rates, is not correct. The ability of health endpoint studies to detect effects in small populations (such as a neighborhood scale) is very limited for all but the most common diseases, or in the case of very rare diseases that are only linked with a specific chemical exposure (such as mesothelioma and asbestos). MCSEP did conduct a cancer incidence and mortality study during 2012 in response to a request from the Working Group for the health study. Even at the county level, the MCSEP study could not evaluate some less common cancers. As another commenter noted, there are variations in the levels of contamination across neighborhoods in Butte. Disease incidence data is not readily available by Butte neighborhood and even if it could be compiled, it is unlikely to yield statistically reliable data. Recognizing this limitation of epidemiologic studies, EPA's risk assessment process is designed to be much more health-protective than would be the case if remediation did not occur until increased disease burden could be detected. By focusing on exposure estimates, the goal is to remediate based on *potential* for adverse health effects, even if none are detectable in the population. Determination of exposures is also a fundamental step in determining the potential for adverse effects from chemical exposures. Understanding the nature and sources of exposure is necessary if steps are to be taken to improve conditions in the community. In the case of lead, we are fortunate in that blood lead concentrations provide a good measure of lead exposures from all sources and provide a sensitive assessment of the potential for adverse effects; consequently, such studies are the most effective way to assess the potential for adverse effects of lead on health in Butte.

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2.F.16	Mortality rates and disease rates need to be studied on a neighborhood and not just a Silver-Bow County basis.	The commenter identifies an important and legitimate concern regarding potential variation of health risks across Butte neighborhoods. However, it is unlikely that mortality and disease rates can be effectively studied on a neighborhood scale due to low incidence rates for most diseases. As shown in the State's 2012 study of cancer incidence, even on the county level, many rarer cancers did not have sufficiently high incidence to reliably detect differences between BSB and the rest of Montana or the U.S. The current study of blood lead data offers a more effective way to examine potential differences across neighborhoods.
2.F.17	The health effects of lead on adults needs to be considered as well as the health effects on children. While critical, focusing on children is not enough. Again, to get a true picture of Butte's health we need to look at exposure levels, disease rates and mortality rates for those diseases linked to exposure to the toxics on the Butte Hill for ALL age levels. Failure to do so contaminates the results of the study.	Young children are most susceptible both to lead exposures and also to adverse effects of lead. Numerous studies across the U.S. have demonstrated that this population has the highest blood lead levels. Little additional value would be gained by testing adults, who generally have lower lead exposures. The database does include data for infants and women of child bearing age; and summaries of those values will be provided in the health study report.
2.F.18	A monitoring system for disease and mortality rates needs to be implemented.	Presently, surveillance of mortality among Montana residents (including Silver Bow County) exists through an extensive database of death records which are maintained by the Office of Vital Statistics at MDPHHS. MDPHHS also conducts statewide surveillance on newly diagnosed cancers among Montana residents. Unfortunately, there are no other systematic, state-wide surveillance systems for other diseases that may be related to heavy metal exposure in Montana. The ability of disease monitoring to detect effects in small populations is very limited for all but the most common diseases and requires a suitable comparison population for meaningful interpretation. MCSEP did conduct a cancer incidence and mortality study during 2012 in response to a request from the Working Group for the health study. Even at the county level , there were too few occurrences of some cancer types to evaluate these cancers in Silver Bow County. If disease occurrence data was compiled across neighborhoods in Butte, it is unlikely to yield statistically reliable results. We agree that the community may benefit from engaging in discussions of what kinds of data may be feasible and useful to collect in order to monitor exposure to heavy metals.
2.F.19	Mortality rates and disease rates for those diseases linked to exposure to the toxics on the Butte Hill need to be tracked in the future.	The commenter is referred to the response to Comment 2.F.18 above.
2.F.20	Clarifying the difference between the blood lead exposure study and broader health study objectives that are expected to be more epidemiological in nature.	The Draft Work Plan will be revised to clarify the role of the blood lead study in the context of the broader health study objectives.
2.F.21	I would offer a comment on the Health Study Remedial Design Work Plan Work Plan presented by the Butte Silver Bow Health Department and prepared by Environ International with respect to the assessment that "lung and bronchus cancers were not elevated in BSB during the three time periods from 1981 through 2010". If you examine Figure 6, you can clearly see that the incidence of lung cancer is elevated for BSB above the state and national incidence for the period 2001 – 2010. During that same period, Figure 10 shows the mortality due to lung cancer is significantly elevated over the state average. We must remember that the state average also includes figures from Libby, Montana, where the incidence of lung cancer is extreme due to asbestos exposure. It is incumbent that the question be asked as to the cause of this increased incidence of respiratory disease in the county during the period from 2001 – 2010. The cause may or may not be related to BPSOU factors, but to understate or ignore the increased incidence of lung disease in BSB is a disservice to the citizens of BSB who are living with whatever conditions are causing them to suffer this problem.	The Draft Work Plan was paraphrasing the Montana Cancer Surveillance and Epidemiology Program report (MCSEP 2012) which says that lung and bronchus cancer incidence and mortality are the same among residents of Silver Bow County and Montana for all three time periods tested. This statement is based on the outcome of statistical tests. The commenter is correct that the written statements about the incidence and mortality of lung cancer could be misunderstood without an explanation of their basis. Within the MCSEP report, the statement referring to Figure 6 should read "The incidence of lung & bronchus cancer was statistically the same among residents of Silver Bow County and Montana for all three time intervals". The statement referring to Figure 10 should also read "Mortality due to lung & bronchus cancer was statistically the same among residents of Silver Bow County as the rest of Montana for all three time intervals". Please note the symbols which look like an "I" in Figures 6 and 10. This symbol represents the 95% Confidence Interval (CI). The 95% CI is the range of values within which the true value falls with 95% certainty. In general, where confidence intervals for two populations (Silver Bow and Montana in this case) compared do not overlap, the populations can be said to be statistically different. When the confidence intervals for two populations being compared do overlap, the populations can be said to be statistically the same (or

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		not statistically different). In this case, the confidence intervals for both lung cancer incidence and mortality in Silver Bow County overlap with Montana; therefore we can conclude that the two populations are statistically the same. The summary of the MCSEP study presented in the final work plan will be revised to clarify the statistical comparisons referenced. The lung cancer incidence and mortality estimates for the State of Montana are influenced very little by Lincoln County (Libby). This is because Lincoln County has a relatively small population (2% of the Montana population) and, therefore, does not contribute enough to the change the statewide estimate. The age-adjusted lung cancer estimate for Montana, excluding Lincoln County, during the period 2001-2010 was 64.3 (95% CI: 62.8-65.9) compared to an incidence rate of 65.8 (95% CI: 64.3-67.4) when all 56 counties in Montana are included. These two estimates are statistically the same because the 95% CI overlap.
2.G Comments Pertaining to Focus on Lead		
2.G.1	Need to consider exposure to all heavy metals, not just arsenic, lead and mercury.	Lead, arsenic, and mercury are the focus because these are the metals selected by EPA for development of action levels for the Butte Priority Soils Operable Unit. As noted in response to comment 1.B.1 and in Fact Sheet No. 4 included in Appendix B to the Draft Work Plan, the focus on these chemicals resulted from a process in accordance with EPA's Risk Assessment Guidance for Superfund. Multiple metals were considered as possible contaminants of concern in Butte. EPA's Superfund risk assessments identify contaminants of concern at a site by considering the sources and processes that led to contamination, and the potential for various identified chemicals to cause adverse effects. EPA evaluated a range of metals and concluded that lead is the primary chemical with a potential to cause adverse health effects in Butte. Exposures to other metals were determined by EPA to not pose health risks for Butte residents.
2.G.2	Need to consider the additive bio-accumulative, synergistic and antagonistic effects of exposure to heavy metals.	Additive effects of chemicals are considered in EPA risk assessments. Synergistic effects and antagonistic effects of metals have also been studied. A synergistic effect is the enhanced effect of one chemical due to the presence of another chemical, while an antagonistic effect refers to reduced effects of one chemical due to the presence of another chemical. Such effects are typically dose dependent, i.e., at low doses there is little risk of enhanced or reduced effects. Consequently, EPA risk assessments assume that evaluation of additive effects (I.e., no synergistic or antagonistic effects) of multiple chemicals at typical environmental exposure levels is adequately health-protective.
2.G.3	Need to be actually monitoring of urinary arsenic in Butte.	The commenter is correct in noting that there is no recent urine arsenic data for Butte residents; however, an older study conducted before residential area remediation began did not find any elevation in urinary arsenic concentrations. The 1990 study by BSB and University of Cincinnati (BSBDH/UC 1992) examined lead and arsenic exposures in Butte children. This study did not find elevated arsenic exposures in Butte (as indicated by urine arsenic concentrations). Similarly, a 2001 ATSDR study in which all 25 Walkerville residents tested has urine arsenic concentrations below the detection limit of 10 µg/L. Based on the available data, there is no evidence that arsenic exposures are a problem in Butte.
2.G.4	p. 6, 1st paragraph, Section 2.1.2, Overview of the RMAP: The current plan for collection of arsenic and mercury biomonitoring data has not resulted in the collection of adequate data to evaluate the effectiveness of Superfund remediation. There should be a commitment to reconsider the current approach as part of a broader commitment to consider additional studies in future years, beyond the currently proposed blood-lead data evaluation.	Regarding arsenic biomonitoring, the commenter is referred to the response to Comment 2.G.3 above. For mercury, RMAP residential samples have not identified mercury as a continuing concern in Butte, i.e., mercury concentrations in environmental samples have not been high enough to trigger a need for biomonitoring.
2.G.5	More than just the so called toxics of concern need to be evaluated. The Health Study should not just focus on lead, mercury and arsenic.	The commenter is referred to the response to Comment 2.G.1 above.

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2.G.6	Testing for urinary arsenic needs to be done whether or not dust samples in the home show elevated levels of arsenic.	The only reason to test urine for arsenic would be if there was an expected source of exposure or if a broad study of a large population was being conducted. An older study conducted before residential area remediation began did not find any elevation in urinary arsenic concentrations. The 1990 study by BSB and University of Cincinnati (BSBDH/UC 1992) examined lead and arsenic exposures in Butte children. This study did not find elevated arsenic exposures in Butte (as indicated by urine arsenic concentrations). Similarly, a 2001 ATSDR study in which all 25 Walkerville residents tested has urine arsenic concentrations below the detection limit of 10 µg/L. Based on the available data, there is no evidence that arsenic exposures are a problem in Butte.
2.G.7	In addition to the additive, synergistic and bio-accumulative effects of exposure to the toxics on the Butte Hill, consideration must be given to the antagonistic effects of exposure to the various toxics on the Butte Hill.	The commenter is referred to the response to comment 2.G.2 above.
2.G.8	Hair and fingernail sampling for arsenic exposure should be part of the Study as this gives a better picture of chronic exposure in Butte to toxics.	Urine arsenic is regarded by the Centers for Disease Control as the most reliable way to test for recent arsenic exposure. While hair and nail samples can provide an indication of exposure over the last few weeks or months (as opposed to the last few days for urine arsenic), hair and nail samples are susceptible to external contamination that can confound results. Also, chronic exposure is defined as occurring over a period of years. Samples representative of the past few weeks or months do not represent chronic exposure. The goal of biomonitoring studies is typically to test a large enough population that a variety of behaviors and exposure settings will be included among the study population, and thus give a picture of the range of exposures that have been occurring. A 1990 study that included urine arsenic samples from Butte children did not find elevated exposures even before residential remediation began.
2.H Comments Pertaining to the Precautionary Principle		
2.H.1	Future health studies need to fully incorporate the precautionary principle. “The precautionary principle is, in fact characterized precisely because it states that the lack of a full scientific certainty should not be a reason for postponing the adoption of appropriate preventive measures in relation to a specific risk factor, when there is a reasonable but not certain reason to consider it so. According to the precautionary principle, the uncertainty of data loses a big part of its paralyzing power because the principle reverses the burden of proof. Indeed this principle does not ask to show that there is a certain risk in some exposures to those who wish to intervene with preventive action, but instead it asks to those who don’t want to intervene to show that there is no risk. In environmental epidemiology, moreover, uncertain risks are still risks which are individuated by scientific procedures, and the degree of uncertainty of the results does not always undermine the risk of the occurrence of adverse effect on human health (uncertainty may regard the ability of a study to measure the risk, not the existence of the risk itself).” (Gordana Pagliarani and Caterina Botti, “Prevention, communication and equity in environmental epidemiology: ethical issues,” Ann Ist Super Sanita 2011, Vol. 47, No 3) The precautionary principle fits nicely into the retroactive, strict, joint and several liability scheme of Superfund.	The precautionary principle or precautionary approach states if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is not harmful falls on those taking an action. An example of the precautionary principle would be banning genetically modified foods even though there is no evidence at this time to suggest that they pose a harm. This principle doesn’t pertain to the remedial activities or health study at the Butte site. There is no question that exposures to lead and arsenic can be harmful to people. This is well documented. However, simply removing all lead and arsenic from the environment is not possible, since these inorganics are naturally occurring in the soil, water, and air. We know that adverse effects from exposure to these inorganics are associated with the dose or amount of exposure that people receive. At the Butte site soil, housedust, tap water, and paint were collected from the residential homes in Butte. The soil was analyzed for a complete suite of inorganics. The soil was also tested in animal models for the bioavailability of lead and arsenic. This information was input to EPA’s recommended risk equations to estimate site-specific exposure and risk to residents in Butte and develop cleanup levels protective of human health. In addition, the RMAP and health study ensure that individual children who may be at risk from other sources of lead exposure (e.g., lead-based paint, ceramics, etc.) are identified and addressed.

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2.H.2	I ask that the Precautionary Principle inform and guide the Butte Health study. This principle is part of both federal as well as Montana law. The essence of the precautionary principle is that government should act before harm to human health and the environment occurs from the releases of toxic substances. The precautionary principle "dictates that indication of harm, rather than proof of harm, should be the trigger for action." (Sandra Steingraber, Living Down Stream: An Ecologist Looks at Cancer and the Environment, p. 270.) If there is a reasonable suspicion that harm to human health and the environment could occur from the release or presence of a toxic substance, government should step in and fix the problem before its hurts people and the environment. The 1998 Wingspread Statement on the Precautionary Principle states: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." Former EPA director Christine Todd Whitman stated: "policymakers need to take a precautionary approach to environmental protection. . . . We must acknowledge that uncertainty is inherent in managing natural resources, recognize it is usually easier to prevent environmental damage than to repair it later, and shift the burden of proof away from those advocating protection toward those proposing an action that may be harmful." If there is a strong suspicion that something bad is going to happen, government has an obligation to stop it prior to its occurring. The precautionary principle is really grounded in old common sense sayings: "An ounce of prevention is worth a pound of cure." "Better safe than sorry." "A stitch in time saves nine." "Look before you leap." The President's Council on Sustainable Development supports the precautionary principle. The Council declared: "Even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health or the environment is thought to be serious or irreparable." The American Public Health Association has passed a similar resolution concerning chemical exposure. (Resolution 9606) The U.S. Court of Appeals for the District of Columbia Circuit upheld the EPA's use of the precautionary principle in Ethyl Corp. v. U.S. Environmental Protection Agency (541 F. 2d 1, 6 ELR 20267 (D.C. Cir.), cert denied, 426 U.S. 941 (1967) This was the case which supported the banning of leaded gasoline by the EPA. The banning of lead additives to gasoline was an example of the precautionary principle in action. "The U. S. Court of Appeals for the D.C. Circuit upheld the U.S. Environmental Protection Agency's decision to take a precautionary approach and ban lead anyway, even in the absence of scientific evidence adequate to demonstrate exactly what the risks from the lead were or what the benefits of removing it would be. As it turned out, banning leaded gasoline was the single most important contributor to the virtual elimination of lead from air and from most children's blood." (Charnley and Elliott, Risk Versus Precaution: Environmental Law and Public Health Protection, Environmental Law Institute, March 2002) There is ample support for the precautionary principle from international organizations and treaties, to many of which the United States is a signatory. For example, the Rio Declaration from the 1992 United Nations Conference on Environment and Development, also known as Agenda 21, stated: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The United States signed and ratified the Rio Declaration.	The commenter is referred to the response to Comment 2.H.1 above.

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	The precautionary principle is also part of the following: Ozone Layer Protocol, Second North Sea Declaration, United Nations Environment Programme, Nordic Council's Conference Declaration of October 18, 1989, PARCOM Recommendation 89/1, Third North Sea Conference, Bergen Declaration on Sustainable Development, Second World Climate Conference, Bamako Convention on Transboundary Hazardous Waste into Africa, OECD Council Recommendation of January 1991, Maastricht Treaty on the European Union, Climate Change Conference, UNCED Text on Ocean Protection, and the Energy Charter Treaty. The precautionary principles would encompass far more than just looking at exposure data. My point is that it is a specious argument that we cannot look at incidences of disease because the specific cause of a disease cannot be traced to a specific toxic. If the incidence of diseases associated with toxics found in Butte is not decreasing or actually increasing, something is wrong. If disease rates for diseases associated with the toxics found in Butte are steady or increasing, as the Barry report found, the ROD for Priority Soils should be reopened to deal with the diseases associated with the toxics found in Butte. We can of course only ascertain the above if we expand the scope of the Health Study to look at mortality rates and disease rates, not just exposure data. To confine the study to exposure data is unwarranted and inimical to the public interest.	
2.I Comments Pertaining to Other Various Issues		
2.I.1	The Butte Silver Bow Health Department and EPA need to coordinate what they are doing. It appears, at present, that the BSB Health Department and the EPA are on parallel, independent tracks regarding future health studies. Such a situation could lead to the same problems experienced earlier, i.e. the Health Department develops a health study proposal that does not fit EPA's requirements and is rejected by EPA for not meeting the requirement and terms of the unilateral order.	EPA is overseeing and working closely with, BSB and other stakeholders on the work plan and resulting documents.
2.I.2	Need to incorporate hair and fingernail sampling.	The commenter is referred to the response to Comment 2.G.8 above.
2.I.3	Need to have adequate funding provided for future health studies.	Respondents are required to conduct and design health studies in Butte on a periodic basis, as required by RMAP and EPA. Adequate funding for the efforts will be the responsibility of the respondents.
2.I.4	The practice of averaging across age groups needs to be ended. Such averaging distorts the true picture of Butte health and is poor statistical practice.	It is not clear to us if the commenter is referring to the planned Superfund health study or to other studies that have been done in Butte. We agree that for blood lead studies, it is crucial to evaluate different age groups separately. The planned Superfund health study is focusing on blood lead data from young children in the age range expected to have the highest blood lead levels.
2.I.5	Local health impacts to Butte children associated with lead exposure have been reduced by the Multi-Pathway Residential Metals Abatement Program, but all body burden sources of lead should be considered including not only lead based paint dust and chips, but also nuisance dust, drinking water and air.	The advantage of evaluating blood lead levels is that these levels will reflect contributions to exposure from all of the sources mentioned by the commenter. The RMAP does provide for testing drinking water in a home if a child has an elevated blood lead level. Inhalation of airborne dust is unlikely to be a significant source of exposure. If airborne dust is a significant exposure pathway, it should be reflected in house dust concentrations.
2.I.6	Potable Drinking Water is a necessary resource, and our Community system has been greatly improved and provides good water. But, it is possible to have near home contaminants associated with old lead taps, old lead pipes and older solder with higher than acceptable lead levels. We should be aggressive with the EPA Lead and Copper Rule and check for lead in all the old systems, not just the required sample sites. Private Water Wells should be evaluated, when possible, for lead, arsenic and other issues.	The RMAP does provide for testing drinking water in a home if a child has an elevated blood lead level. The Butte-Silver Bow Municipal Water System meets all standards associated with EPA's Lead and Copper Rule.

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2.I.7	As a lifelong Butte resident and a former seven-term member of the Montana House of Representatives, I have been directly involved with the Superfund cleanup issue in Butte for over thirty years. I served in the Legislature when the Atlantic Richfield Company closed the Smelter in Anaconda and closed the Berkeley Pit and Butte Mines. I have a good historical perspective on this issue and the positives and negatives of mining and the cleanup and restoration of this community. I believe the Environmental Protection Agency, the State of Montana, the Atlantic Richfield/British Petroleum Company and the Local Government have failed this community in protecting the health and the environment of the Community and to providing a responsible cleanup and restoration of our community, as required by law and the Constitution. A couple examples of the type of cleanup we have received; the Berkeley Pit currently contains over 42 billion gallons of toxic water and continues to rise---Georgetown Lake contains 10.1 billion. We have learned since the Record of Decision was issued on Butte Priority Soils that the groundwater in the Parrott Tailings area around the Civic Center is more toxic than Berkeley Pit Water and many experts believe a plume of toxic groundwater is spreading out over the town from that area and further contaminating the community.	The issues raised in this comment are outside of the scope of the initial Health Study. Please refer to the protectiveness statements in the recent Five Year Reviews for the Butte Mine Flooding Operable Unit and BPSOU. Groundwater contamination from the Parrott Tailings area and other sources are intercepted and treated under BPSOU remedy.
2.I.8	Several months back a very reputable Butte resident, Stacy Barry, prepared a Doctorate Dissertation on the cancer rates in Butte. She prepared this information under the advice and assistance of professors from Montana Tech and the University of Montana outlining the facts. The way the Environmental Protection Agency, the State of Montana, the Atlantic Richfield/British Petroleum Company have dealt with this research was to “kill the messenger” rather than dealing with the message.	EPA and the AR made a sincere effort to provide technical comments on the work. Several efforts are being made to improve the public participation process and make this process more constructive.
2.I.9	I am currently involved along with Sister Mary Jo McDonald and Ron Davis as members of the Silver Bow Creek Headwaters Coalition in a lawsuit concerning the name of Silver Bow Creek flowing through Butte. The agencies and ARCO continue to call Silver Bow Creek flowing through Butte Metro Storm Drain, even though they know it is not Metro Storm Drain and its proper legal name is Silver Bow Creek. We believe the State’s repeated references to Silver Bow Creek flowing through Butte, as the “Metro Storm Drain” in public documents and other references are illegal, and degrade the Creek’s status as the headwaters of the Clark Fork and Columbia Rivers. We also believe the reason they chose and continue to call it Metro Storm Drain is so they will not have to provide the responsible cleanup and restoration of this section of Silver Bow Creek that is now taking place on the Creek from Interstate 15 to the Warm Springs Ponds. Unbelievable!	The area in question has been called Metro Storm Drain since at least the 1960’s. Regardless of the name of the area, the remedy for BPSOU is in compliance with CERCLA and the regulations governing Superfund cleanups known as the NCP.
2.I.10	Butte citizens are not happy with the whole Health Study process. From its inception the Health Study process has been problematic. It appears that the Health Study process that we are going through at the present was necessitated because the EPA did not like the results of Stacie Barry’s study which showed that Superfund had serious problems in Butte. In all my years of involvement in Superfund, I have never seen such a “hatchet job” done on a study and the author of that study.	The Health Study obligations were required under the RMAP prior to the release of the Stacie Barry dissertation. EPA has made limited scientifically based comments on the dissertation, which was done outside of the EPA Superfund process.