The attached table (Table 1) summarizes comments received in response to the public comment period for the DRAFT Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan that was released by EPA on October 31, 2012. Comments received have been sorted into common comment categories or themes to facilitate response development. Comment themes fall within one of two comment groupings, "Group 1" (or "G1") or "Group 2" (or "G2). Group 1 comments pertain to topics that fall outside of the scope of the Superfund Health Study and draft work plan revisions. Group 2 comments pertain to topics that are more directly related to the Superfund Health Study and/or draft work plan revisions. Groups and themes represented in Table 1 are summarized as follows:

G1 Group 1 Comments
G1.A Comments Related to Fact Sheets
G1.B Comments Pertaining to Site-Specific Action Levels and Bioavailability
G1.C Comments Pertaining to Current Air Quality
G1.D Comments Pertaining to the RMAP Implementation and Ongoing Biomonitoring Program

G2 Group 2 Comments
G2.A Comments Pertaining to the Goals and Purpose of the Health Studies
G2.B Comments Pertaining to Public Involvement
G2.C Comments Pertaining to Environmental Justice
G2.D Comments Pertaining to Independence of Study/Investigators and Need for External Peer Review
G2.E Comments Pertaining to Specific Study Design Elements of the Draft Work Plan
G2.F Comments Pertaining to the Study Focus on Exposure vs. Health Outcomes
G2.G Comments Pertaining to Focus on Lead
G2.H Comments Pertaining to the Precautionary Principle
G2.I Comments Pertaining to Other Various Issues

It is important to note that assignment to these groups and themes was made based on ENVIRON's preliminary review of all comments received, but final groupings may be modified as suggested by comment response leads and contributors upon more detailed consideration of specific comments.

Specific comment excerpts are enumerated under the "Comment ID" column header with each assigned to a group and theme. A comment response lead is also identified for each theme based on discussion by the broader study planning team during the February 20, 2013 BPSOU Health Study conference call. The following planning team members attended this call:

- Steve Ackerlund (CTEC Representative)
- Merle Benedict (Citizens' Advisory Committee)
- Jay Cornish (Citizens' Advisory Committee)
- Lisa DeWitt (DEQ)
- Nikia Greene (EPA)
- Joe Griffin (DEQ)
- Susan Griffin (EPA)
- Cord Harris (AR)
- Eric Hassler (BSB)
- Dina Johnson (ENVIRON)
- Helen Joyce (Citizens' Advisory Committee)
- Dan Powers (BSB)
- Roz Schoof (ENVIRON)
- Dan Strausbaugh (ATSDR)
- Maria Viso (AR)
- Michelle Watters (ATSDR)

DRAFT

Draft responses have been provided by several entities/representatives. To facilitate review, the following shading has been applied to comments corresponding to different response drafters:

Responder
MDEQ
MT DPHHS
EPA (Nikia)
EPA (Susan)
BSB
Steve Ackerlund
ENVIRON

DRAFT

Table 1. Summary of Comments and Comment Response Leads, Sorted by Group and Theme		
Comment ID	Comment	Comment Response
G1.A	G1.A Comments Related to Fact Sheets - Comments are specific to information provided in Fact Sheets referenced in the initial health study work plan. - Lisa DeWitt (MDEQ) to coordinate comment response development within the State.	
G1.A.1 (note: comment is essentially identical to G1.A.2)	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.	Responses to each question are provided below: 1. The Montana Department of Environmental Quality (DEQ) is currently providing both PM10 and PM2.5 data from the Greeley School monitoring site to the Butte Silver Bow Health Department. 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 DEQ 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, DEQ regulation efforts, including monitoring, are focused on this problematic, health-impacting pollutant.

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		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, the federal Environmental Protection Agency (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 is below. **Mass - $PM_{2.5}$** PM 2.5μ Gravimetric **Trace elements (33)** Aluminum, Antimony, Arsenic, Barium, Bromine, Cadmium, Calcium, Cerium, Cesium, Chlorine, Chromium, Cobalt, Copper, Indium, Iron, Lead, Manganese, Nickel, Phosphorus, Potassium, Rubidium, Selenium, Silicon, Silver, Sodium, Strontium, Sulfur, Tin, Titanium, Vanadium, Zinc, Zirconium

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		Magnesium **Cations - $PM_{2.5}$ (NH_4, K, Na)** Ammonium Potassium Sodium **Nitrate - $PM_{2.5}$** Nitrate (Total) **Sulfate - $PM_{2.5}$** Sulfate **Organic Carbon** **Elemental Carbon** 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. DEQ 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 Citizen Advisory Committee along with Montana Tech. That process may provide some insight to this question.

Table 1. Summary of Comments and Comment Response Leads, Sorted by Group and Theme		
Comment ID	Comment	Comment Response
G1.A.2 (note: comment is essentially identical to G1.A.1)	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.	The commenter is referred to the response to Comment G1.A.1 above.
G1.A.3	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 health study work plan was paraphrasing the Montana Cancer Surveillance and Epidemiology Program (MCSEP) report 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 tie 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) are being 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 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.

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		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.
G1.B	Comments Pertaining to Site-Specific Action Levels and Bioavailability - Comments relate to the validity of the site-specific action levels and bioavailability data. - Susan Griffin (EPA) to coordinate comment response development within EPA.	
G1.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 (approx 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.
G1.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. The US Environmental Protection Agency (USEPA) 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 to more accurately estimate exposure and develop remediation levels.

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		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 the USEPA, 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 the USEPA to estimate the bioavailability of lead and arsenic from contaminated soil at hazardous waste sites. The USEPA 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 (approx 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.
G1.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 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?	U.S. EPA's Office of Superfund Remediation and Technology Innovation (OSRTI) are in the process of evaluating the Center for Disease Control's (CDC) recommendations and implications for Superfund risk assessments. Part of OSRTI's evaluation includes close coordination and consultation with the CDC, including the Agency for Toxic Substances and Disease Registry (ATSDR), our health agency partner. It is important to note that the CDC recommendation of 5 ug/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 ug/dl with only 2.5% of the children in the U.S. exceeding 5 ug/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

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		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.
G1.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 G1.B.2 above.
G1.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 G1.B.1 above.
G1.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 G1.B.2 above.
G1.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 G1.B.2 above.
G1.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 G1.B.2 above.
G1.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 G1.B.3 above.
G1.C	Comments Pertaining to Current Air Quality - Comments relate to air quality concerns that need to be addressed. - Dan Powers (BSB) to coordinate comment response development within BSB.	
G1.C.1	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. The State DEQ may have some historical data that can be looked into to provide additional information from past sampling methods. DEQ will be contacted concerning this.

Commented [RS1]: Would it be appropriate to add a note that the Superfund program in Butte has a holistic program to monitor blood lead and investigate elevated levels that is not available in many communities?

Commented [RS2]: Should we add a sentence about how current sampling is focused on air particles that can be inhaled, and that older methods do not offer useful insights to assessing potential health impacts?

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G1.C.2	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 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.	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 DEQ 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.
G1.C.3	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

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		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 the Montana Department of Environmental Quality (DEQ) and the Butte-Silver Bow Health Department, does not extend to crystalline silica as an identified compound. Therefore, outside the broad regulation for ambient air particulate matter and fugitive dust precautions, DEQ and BSBHD cannot measure or respond to crystalline silica in a regulatory fashion. The selected remedy for the Butte Priority Soils Operable Unit (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. DEQ and BSBHD 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.
G1.D	Comments Pertaining to the RMAP Implementation and Ongoing Biomonitoring Program - Comments relate to how the RMAP program is being implemented, including biomonitoring elements. - BSB will lead comment response.	
G1.D.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 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	We thank the commenter for sharing his perceptions of the RMAP process based on his personal experience. The Health Department 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

Commented [RS3]: Would it be appropriate to add a note that community concerns about crystalline silica will be reviewed and considered during the non-Superfund health study process?

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	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. I hope these comments are taken seriously and I hope I can be of further assistance if need be.	solely exposed to soil from one 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. (4) The Health Department 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 WIC 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. (5) Prior to 2011, WIC used a blood lead testing method with a detection limit of 1 ug/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

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		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 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.
G2.A	Comments Pertaining to the Goals and Purpose of the Health Studies - Comments relate to the need for clarity regarding why the studies are being done and how they will result in changes to the Superfund cleanup. - Dina Johnson (ENVIRON) will lead comment response in coordination with Nikia Greene (EPA).	
G2.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 work plan will be revised to clarify the goals of health studies required by the UAO. During an initial study planning meeting on April 16, 2012, participants from EPA, BSB, MDEQ, ATSDR and AR 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 program 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. (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 change the Record of Decision based on new information. Results of the health study will be examined and reviewed by EPA and DEQ upon completion.

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		(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 has 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 study design will evaluate whether the RMAP program 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.
G2.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.
G2.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 work plan will be revised to clarify the goals of health studies required by the UAO.
G2.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 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."*
G2.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.	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 USEPA "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*

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	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.	*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 program is needed to improve its effectiveness. The planning team 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 the State in response to a request by the health study planning team. 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.
G2.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 program. 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 Butte has significant lead sources greater than those found in most communities. However, such a comparison to the new reference level would need to be confirmed by venous samples (vs. the capillary samples used in the WIC testing) and the comparison would only be applicable for data collected from 2005 to 2008, the period corresponding to the national blood lead survey on which the new reference level is based.

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		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 program. 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 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.
G2.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 G2.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.
G2.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 regarding opportunities for the public to provide input to proposed response actions that may arise from the initial health study. [Dan, Need to add a response to the request for CTEC to have a more active role in encouraging participation in voluntary cleanup program?]
G2.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	In addition to the study presented in the work plan that is the subject of current comments, a number of additional activities have been undertaken

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	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.	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 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 planning team 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 the State in response to a request by the health study planning team. 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. [Note to reviewers: should each individual question in this comment be addressed separately?]
G2.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 G2.A.1 above.
G2.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 G2.A.1 above. [EPA/BSB – Need input for response regarding how the study will affect public policy]
G2.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	The purpose of the initial health study (i.e., the RMAP evaluation) is

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	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.	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 G2.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 G2.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 the Montana Cancer Surveillance and Epidemiology Program 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.
G2.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.	As noted in the response to comment G2.A.6 above, we will attempt to clarify the description of the analyses and study metrics for the blood lead study. Responses to comments G2.A.1 and G2.A.5 above describe ongoing and planned responses to issues beyond the scope of the current study.
G2.B	Comments Pertaining to Public Involvement - Comments relate to the need for more meaningful public input and participation in designing the study and perceptions of "secrecy" surrounding the study design. - ENVIRON, Nikia Greene (EPA) and Steve Ackerlund drafted.	
[Note: Summary suggested by Steve Ackerlund, with suggestion that other sections also have similar summaries.] **Summary of Individual Responses:** EPA's stated goal for public participation within the Superfund program is: "to advocate and strengthen early and meaningful community participation during Superfund cleanups."[1] The planning team recognized a high level of public interest in the health study planning process, and, consistent with EPA's stated public participation goal, implemented an extensive public outreach effort. Based on the comments received, we understand that opportunities remain, moving forward, to more fully achieve meaningful public participation. It is also clear that confusion remains regarding the two tracks of Superfund and non-Superfund studies. Individual comment responses below 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 Citizens' Advisory Committee (CAC) by BSB was a key step in ensuring active participation by technically qualified community residents the design and in overseeing the implementation of the health studies. In response to comments an additional technical representative of CTEC has been invited to join the study planning team. Continued 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 their needs. The Superfund health study work plan will be revised to clarify where public input will be sought within the current blood-lead focused plan. 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 health study design.		
G2.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

[1] See http://www.epa.gov/superfund/community/index.htm.

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		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 and additional efforts have been initiated. BSB invited a technical representative from CTEC to participate in the Superfund health study planning team. 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 further improve public participation. Nikia Greene, Remedial Project Manager for this project (406-457-5019), is 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.
G2.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, EPA has invited a representative from CTEC to participate in the Superfund study planning team. Additional responsiveness addressing the desire for "a more deliberative and collaborative working relationship" is provided in response to the more detailed comments below.
G2.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 health study. It also commits to additional community meetings following completion of the study, and periodic updates through the Citizens' Advisory Committee and the planning team. This section refers only to the Superfund health study evaluating blood lead levels. There are also opportunities for public involvement in the currently ongoing non-Superfund health study planning effort and in any future Superfund health studies. The current work plan does not address those efforts and it would be inappropriate to specify public involvement plans here for those other efforts. The Residential Metals Abatement Plan (RMAP) contemplates that BSB, with participation of AR and the Federal and State oversight agencies will "perform health studies every five years for a period of thirty years."
G2.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	This comment raises two issues. Future epidemiology studies are addressed in responses G2.F3 and G2.F4. The last sentence addressing community involvement is addressed in the responses to comments 1,2 and 3 above.

Table 1. Summary of Comments and Comment Response Leads, Sorted by Group and Theme		
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	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.	
G2.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 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 planning team.
G2.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.
G2.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.
G2.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 comments 1, 2 and 3, technically qualified community representatives 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. 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.
G2.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.	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. Regarding the community advisory committee, that group was only formed after the study planning process was under way, and a fact sheet was issued by BSB describing the committee's role and identifying the members shortly after the committee was formed.
G2.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.	Please see responses to comments 1, 2 and 3 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 G2.C.

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	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.	
G2.B.11	All test results need to be made publicly available.	The original commitment to conduct a health study made in the Residential Metals Abatement Program (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.
G2.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.	[Nikia – please suggest response to this.]
G2.C	Comments Pertaining to Environmental Justice - Comments relate to failure of the study design and development process to address environmental justice concerns, meaningful involvement of the public, and low-income citizens within Butte, specifically. - Dina Johnson (ENVIRON) will work with Nikia Greene (EPA) to prepare comment response.	
G2.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, the following changes have been made to the work plan: Section 1.2 Environmental Justice Considerations has been added. This section identifies recent EJ screening and explains the unique design of the RMAP program, with a focus on low income persons. Additionally the section describes the efforts made in outreach to the community of Butte including low income citizens.
G2.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 team 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 EJ measures can be seen in section 1.2.
G2.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?	For example: A low income person might be more stressed to pay the bills than a wealthy person would be, therefore, exposure could be more significant to a lowered immune system caused by stress.

Commented [RS4]: Is there a better example?

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G2.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.
G2.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 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.	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 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 susceptible populations, and conservatively assumed that risks are additive. EJ considerations have been added within the design of the health studies required under the UAO. Additionally, please refer to the Multi-pathway Residential Metals Abatement Program Plan that will address all residential properties which exceed action levels within the BPSOU site and the adjacent area.
G2.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.	See section 1.2 Environmental Justice Considerations
G2.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 are receiving Temporary Assistance for Needy Families compared to the state average of 1.89%. Over 10% of the Butte population was receiving	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 Residential Metals Abatement Program Plan, a disproportionate impact upon the low-income residents will not result and therefore, it addresses EPA's EJ 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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	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.	
G2.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 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.	1. and 4. Please refer to the focus of the work plan explained in section 1.1. and section 2. 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 in 10 years and all contaminated residential properties within the BPSOU shall be remediated in 20 years. To accomplish these requirements, yearly goals for sampling and remediation contained in the Final Multi-Pathway Residential Metals Abatement Program Plan (RMAP) (April 2010 by Butte Silver Bow County and Atlantic Richfield Company) page II must be confirmed through yearly reporting, as provided in RMAP section 15, or revised appropriately (2011 ESD). 2. See section 1.1 and section 2 for the focus of the current phase 3. See G2.C.10 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

Commented [RS5]: This sounds as though EPA will compel access. Is that what is meant?

Commented [RS6]: Can we provide the calendar year instead for these two timeframes?

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	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.	the public health study. Questions and concerns that came from the public meetings are being addressed through a suite of fact sheets designed by the health study team and distributed in the local newspaper. See section 1.2 for additional activities.
G2.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 level is exceeded and a pathway exists. For more information see section 12 (2006 ROD). Based on consideration of CERCLA requirements, the detailed analysis of remedial alternatives, State 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 remedy for the BPSOU.
G2.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.	Representatives of the Butte community are a part of the Health Study Team. It is not known if any member is of low or non-low income status. However, due to community input a representative of the local TAG group (CTEC) has been invited to be a member of the team and encourages the process to find new avenues and be more transparent.
G2.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 work study team encourages input to promote public involvement and EJ. Numerous efforts have been made throughout this process to promote both. Additionally, The Health Study Team had a vision to include experts at the public meetings held. These experts where able to address public comment and concerns at listening sessions and open house meetings throughout the process.
G2.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.	See section 1.2 Environmental Justice Considerations. At this time, Region 8 does not have a specific EJ action plan, however, the following are several sources of information that help describe the Region's EJ 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 EJ website: http://www.epa.gov/region8/ej/

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		-- 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
G2.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: - How the housing stock (quality, design, size, etc.) might influence exposure in ways that differ from common risk assessment assumptions? - How potentially lower health status among low income people increases susceptibility? - Potential synergistic effects of exposure to multiple contaminants. - How this and future health studies will avoid inadvertent discrimination against low-income residents? - In what ways are those most affected, i.e. low income people, directly involved in the health studies?	- Superfund does not have the authority to address the design of a home, however, Superfund does have the authority to enforce cleanup of all residential properties which exceed action levels within the BPSOU and the adjacent areas. - See example in response G2.C.3 - See section 1.1 and section 2 for the focus of the current phase - All residential properties within the BPSOU and adjacent areas will be assessed and remediated if necessary and continued efforts to promote public involvement and EJ will be built upon. Public meetings, information in the local Newspapers, websites, CTEC, News media, point of contact, advisory board, location of meetings, notices (paper, water-bill, website). Generally speaking the most direct way that anyone is involved is through the cooperation with the RMAP program.
G2.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 Multi-pathway Residential Metals Abatement Program Plan 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. EJ will continue to be a priority of the health studies in Butte.
G2.D	Comments Pertaining to Independence of Study/Investigators and Need for External Peer Review - Comments question the independence of the study and its investigators, and cite the need for external peer review of the study. - Dina Johnson (ENVIRON) will coordinate comment response.	
G2.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, BSB, MDEQ, ATSDR 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:

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		"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 Butte Silver Bow County (BSB) and University of Cincinnati that examined lead and arsenic exposures in Butte children. 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 the Montana Cancer Surveillance and Epidemiology Program 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. Contrary to the comment, the outcome of the study is not yet known.
G2.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 the Health Department apologizes if that impression was given by any Health Department spokesperson. [Dan – please review and edit as appropriate.]
G2.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, BSB, MDEQ, ATSDR and AR have collaborated in designing the current study. In addition, a citizens' advisory committee has been established to review and provide input regarding study plans and analyses. In addition, comments on the work plan have been solicited from the public, and additional opportunities will be provided to review the study findings. The study participants will also be exploring the possibility of submitting the study results for peer review and publication.
G2.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 G2.D.3 above.
G2.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 G2.D.3 above. Both the citizens' advisory committee and an expert epidemiologist from ATSDR are participating in review of the design and conduct of the study. An independent peer review is a good suggestion and is being considered.
G2.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 G2.D.3 above.

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G2.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 G2.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.
G2.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 G2.D.3 above. Experts from EPA, BSB, MDEQ , ATSDR and the citizens' advisory committee will be participating in oversight of the consulting firm in addition to ARCO.
G2.D.9	The needs to be independent, peer review of the whole development and execution of the Butte Health Study.	Please see response to comment G2.D.3 above. An independent peer review is a good suggestion and is being considered.
G2.D.10 *(note: comment is incomplete but reproduced as received by BSB via email)*	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	Please see response to comment G2.D.3 above. An independent peer review is a good suggestion and is being considered. The suggestion that "*the Montana Department of Health and ARCO have an agreement to underreport the incidence of malignant diseases in Butte*" is completely false. Reporting rules for malignant diseases statewide are well established and not subject to tampering. [May need additional input from MT Health]
G2.E	Comments Pertaining to Specific Study Design Elements of the Draft Work Plan - Comments relate to various specific study design elements included in the draft work plan. - Dina Johnson (ENVIRON) will lead comment response.	
G2.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

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		considered in identifying a comparison population.
G2.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 team 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 revised work plan will show that census tracks have been defined as the most appropriate way to define neighborhoods. The primary reason for relying on census tracks 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 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 revised 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.
G2.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.
G2.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 work plan will be revised to better define the target population of interest and its relevance to spatial boundaries specified for the study.
G2.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	The initial study is focused on lead exposures and the target population

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	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.	specified in the 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.
G2.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. The type, quality, and quantity of data available for use in the study need to be considered in determining appropriate statistical measures of significance.
G2.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.
G2.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.
G2.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.
G2.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.	The 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 be support the health study analyses and results reporting. De-coded data will not be subject to the same protections as the confidential source data.
G2.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 work plan will be reviewed in consideration of

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		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.
G2.E.12	Dust needs to be a focus of the study.	House dust is a potentially significant source of lead exposure andHpouseHousre 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. [Need Dan and Susan to review]
G2.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. No further investigation of attics is planned for the health study. [Need Dan and Susan to review]
G2.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 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 G2.F.8. (2) Please see responses to comments G2.G.1 and G2.G2. (3) Please see the response to comment G2.F.9. (4) Please see responses to comments G2.F.3 and G2.F.4.
G2.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	The study planning team 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 should provide opportunities for input regarding remaining community health needs. It may indeed be useful to identify a way to have those discussions facilitated. [Need Dan and Nikia to review]

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	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 (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.	
G2.F	Comments Pertaining to the Study Focus on Exposure vs. Health Outcomes - Comments relate to limitations of the initial study design on exposure to lead and assert the need to evaluate health outcomes instead. - Roz Schoof (ENVIRON) will lead comment response.	
G2.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.	As described in EPA's Butte risk assessments, lead is the primary contaminant of concern. A 1990 study by Butte Silver Bow County (BSB) and University of Cincinnati 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). The BSB health department's RMAP program 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 the available biomonitoring data. 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

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		epidemiologists view incidence data as a much more reliable indicator of cancer burden than mortality data. Mortality rates may be affected by access to health care providers or services, but incidence reports will be unaffected by how quickly the patient seeks treatment.
G2.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 the Montana Cancer Surveillance and Epidemiology Program, not ATSDR. This study was performed at the request of the health study planning team, but we did not provide input to or comment on the state's report. We agree examining the outcome of this 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, 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 may be a helpful resource for obtaining information on what data are available or may be feasible to obtain.
G2.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 5 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.
G2.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 the Montana Cancer Surveillance and Epidemiology Program 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

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		from 1981 through 2010. As noted on page 2 of the 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.
G2.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.
G2.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 Women Infants and Children (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.
G2.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.
G2.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 program, i.e., to identify individual children with elevated blood lead concentrations.
G2.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.

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Comment ID	Comment	Comment Response
		Consequently, it has been appropriate to focus remediation efforts on reduction of potential exposures to lead. A 1990 study by Butte Silver Bow County (BSB) and University of Cincinnati 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). 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 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. While urine arsenic could be tested in a future study, it is important to recognize that a large population will need to participate in order for such a study to be useful. Urine arsenic levels primarily reflect exposure to arsenic naturally present in food, and the arsenic levels are highly variable based on what each person ate in the prior 2-3 days. Consequently, only the trends across a large population will be helpful in interpreting potential exposures in Butte.
G2.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. 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.
G2.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,	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 Butte Silver Bow County (BSB) and University of Cincinnati 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

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	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.	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.
G2.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.	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 and 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.
G2.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.	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.

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G2.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 exposures as much as practicable. The 10 µg/dL "blood lead level of concern" issued by the Centers for Disease Control (CDC) in 1991 was a risk management level. The 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. 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.
G2.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 is very limited for all but the most common diseases. The State did conduct a cancer incidence and mortality study during 2012 in response to a request from the planning team for the health study. Even at the County level, the state study could not evaluate some rarer 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.
G2.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

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		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.
G2.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.
G2.F.18	A monitoring system for disease and mortality rates needs to be implemented.	While such a system could be developed, the ability of health endpoint studies to detect effects in small populations is very limited for all but the most common diseases. The State did conduct a cancer incidence and mortality study during 2012 in response to a request from the planning team for the health study. Even at the County level, the state study could not evaluate some rarer cancers. If disease incidence data was compiled across neighborhoods in Butte, it is unlikely to yield statistically reliable data. We agree that the community may benefit from engaging in discussions of what kinds of new epidemiology data is maybe feasible and useful to collect. We suggest that the state epidemiologists may be a helpful resource for such discussion. [BSB/MDEQ – Please review and revise this response as appropriate.]
G2.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 G2.F.18 above.
G2.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 work plan will be revised to clarify the role of the blood lead study in the context of the broader health study objectives.
G2.G	Comments Pertaining to focus on Lead - Comments relate to the focus on lead vs. other constituents in the initial health study work plan. - Roz Schoof (ENVIRON) will lead comment response.	
G2.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 G1.B.1, 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. [Susan – should we add reference to other COCs and how determined?]. Exposures to other metals were determined by EPA to not pose health risks for Butte residents.

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G2.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.
G2.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 Butte Silver Bow County (BSB) and University of Cincinnati 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.
G2.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 G2.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.
G2.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 G2.G.1 above.
G2.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 Butte Silver Bow County (BSB) and University of Cincinnati 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.
G2.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 G2.G.2 above.]
G2.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

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		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.
G2.H	Comments Pertaining to the Precautionary Principle - Comments request that the Precautionary Principle inform and guide the health study. - Susan Griffin (EPA) will lead comment response.	
G2.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 program ~~m~~ 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.
G2.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	The commenter is referred to the response to Comment G2.H.2 above.

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	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 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.	
G2.I	Comments Pertaining to Other Various Issues - Comments relate to various issues not otherwise captured under themes detailed above. - Dina Johnson (ENVIRON) will coordinate comment response.	
G2.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	EPA is overseeing and working closely with, the BSB Health Department and other stakeholders on the work plan and resulting documents.

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	not meeting the requirement and terms of the unilateral order.	
G2.I.2	Need to incorporate hair and fingernail sampling.	The commenter is referred to the response to Comment G2.G.8 above.
G2.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.
G2.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.
G2.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.
G2.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. [Dan to provide more detail on what water testing is done and compliance with the EPA rule?]
G2.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 Health Study. Please refer to the protectiveness statements in the recent Five Year Reviews for BMFOU and BPSOU. Groundwater contamination from the Parrott Tailings area and other sources are intercepted and treated under BPSOU remedy.
G2.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.	We respectfully disagree with this comment. EPA and the AR made every attempt to provide comments only on the technical merits of the work.
G2.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.	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 NCP.

Commented [RS7]: Could we change this word? Seems like jargon that may not be clear to all.

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	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!	
G2.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, and certainly has not done anything resembling a "hatchet job" towards the study.

DRAFT