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May 26, 2009

**REMEDIAL INVESTIGATION
FOR OPERABLE UNIT 3
LIBBY ASBESTOS SUPERFUND SITE**

PHASE III SAMPLING AND ANALYSIS PLAN

**Prepared by
U.S. Environmental Protection Agency
Region 8
Denver, CO**



With Technical Assistance from:

**SRC, Inc.
Denver, CO**



and

**NewFields Boulder LLC
Boulder, CO**



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APPROVAL PAGE

This Phase III Sampling and Analysis Plan for Operable Unit 3 of the Libby Asbestos Superfund Site is approved for implementation.



Bonita Lavelle
Remedial Project Manager, Libby OU3

5/26/09
Date

FINAL

DOCUMENT REVISION LOG

Revision	Date	Primary Changes
0	05/26/09	--

TABLE OF CONTENTS

1.0 PROJECT OVERVIEW 1

1.1 Purpose of This Document 1

1.2 Project Management and Organization..... 1

2.0 BACKGROUND AND PROBLEM DEFINITION 5

2.1 Site Description 5

2.2 Basis for Concern..... 5

2.3 Scope and Strategy of the RI at OU3 6

2.4 Scope and Purpose of the Phase III SAP 6

3.0 DATA NEEDS FOR HUMAN HEALTH RISK ASSESSMENT..... 9

3.1 Human Exposure to Asbestos 9

 3.1.1 Conceptual Site Model..... 9

 3.1.2 Summary of Data Needs for Human Exposure to Asbestos 12

 3.1.3 Evaluation of Existing Asbestos Data..... 12

 3.1.4 Data Quality Objectives for ABS Data..... 14

 3.1.5 Detailed Sampling Design for ABS Air Samples..... 21

 3.1.6 Analytical Requirements for Asbestos..... 24

 3.1.7 Quality Control for Asbestos Data..... 25

3.2 Human Exposure to Other (Non-Asbestos) Contaminants..... 27

 3.2.1 Conceptual Site Model..... 27

 3.2.2 Summary of Data Needs for Human Exposure to Non-Asbestos Contaminants.. 28

 3.2.3 Data Quality Assessment of Existing Data..... 28

 3.2.4 Data Quality Objectives for New Non-Asbestos Data 30

4.0 DATA NEEDS FOR ECOLOGICAL RISK ASSESSMENT..... 31

4.1 Problem Formulation 31

4.2 Exposure of Ecological Receptors to Asbestos..... 34

 4.2.1 Conceptual Site Model..... 34

 4.2.2 Focus of Phase III Ecological Investigations for Asbestos..... 35

 4.2.3 Exposure of Fish to Asbestos..... 35

 4.2.4 Exposure of Benthic Invertebrates to Asbestos 46

 4.2.5 Exposure of Mammals to Asbestos..... 53

 4.2.6 Exposure of Amphibians to Asbestos 64

4.3 Exposure of Ecological Receptors to Non-Asbestos Chemicals..... 72

 4.3.1 Conceptual Site Model..... 72

 4.3.2 Focus of Phase III Ecological Investigations for Non-Asbestos Chemicals..... 73

 4.3.3 Exposure of Fish to Non-Asbestos Chemicals..... 74

 4.3.4 Exposure of Benthic Invertebrates to Non-Asbestos Chemicals 77

 4.3.5 Exposure of Amphibians to Non-Asbestos Chemicals..... 80

5.0 OTHER DATA NEEDS FOR RI/FS..... 83

6.0	SAMPLE HANDLING AND DOCUMENTATION	85
6.1	Field Procedures	85
6.1.1	Sample Documentation and Identification.....	85
6.1.2	Sample Containers and Preservation	85
6.1.3	Holding Times	86
6.1.4	Chain of Custody and Shipment	86
6.2	Laboratory Procedures	86
6.2.1	Chain of Custody	86
6.2.2	Documentation and Records	87
6.2.3	Data Deliverables.....	87
6.2.4	Archival and Final Disposition	88
7.0	DATA MANAGEMENT	89
7.1	Data Management Applications	89
7.2	Roles and Responsibilities for Data Flow	89
7.2.1	Field Personnel.....	89
7.2.2	Laboratory Personnel.....	90
7.2.3	Database Administrators.....	90
7.3	Data Storage	90
8.0	ASSESSMENT AND OVERSIGHT	91
8.1	Assessments	91
8.1.1	Field Oversight.....	91
8.1.2	Laboratory Oversight.....	91
8.2	Response Actions	91
8.3	Reports to Management	92
9.0	DATA VALIDATION AND USABILITY	93
9.1	Data Validation and Verification Requirements	93
9.2	Reconciliation with Data Quality Objectives	93
10.0	REFERENCES	95

FINAL

LIST OF APPENDICES

Appendix A Phase II Data (*provided electronically on the attached CD*)

LIST OF ATTACHMENTS

Attachment A Composite ABS Script

Attachment B Standard Operating Procedures

Attachment C Laboratory Modification Forms

Attachment D Summary of Pathological Findings in Laboratory Animals Following Ingestion and Inhalation of Asbestos

Attachment E Interim Approach for Evaluation of Uncertainty Around the Mean of a Set of Asbestos Concentration Values

Attachment F Estimation of RBF for PCME Fibers

FINAL

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LIST OF FIGURES

- Figure 2-1 Operable Unit 3 Study Area
- Figure 3-1 Conceptual Site Model for Human Exposure to Asbestos
- Figure 3-2 Effect of Sample Size and Variability on Uncertainty in the Mean
- Figure 3-3 Ambient Air Sampling Stations
- Figure 3-4 Tentative ABS Sampling Areas
- Figure 3-5 Conceptual Site Model for Human Exposure to Non-Asbestos Contaminants
- Figure 3-6 Comparison of On-Site Soil Samples to Montana Background
- Figure 3-7 Groundwater Well Locations
- Figure 4-1 Conceptual Site Model for Exposure of Ecological Receptors to Asbestos at OU3
- Figure 4-2 Sampling Locations in Rainy Creek Watershed
- Figure 4-3 Surface Water Flow and Asbestos Concentrations, Libby OU3
- Figure 4-4 Aquatic Reference Locations
- Figure 4-5 Power of Signed Rank Test to Detect A Difference (N=5)
- Figure 4-6 Results for LA in Sediment – Rainy Creek
- Figure 4-7 Results for LA in Sediment – Tailings Impoundment
- Figure 4-8 Effect of Sample Size on Power on WRS Test
- Figure 4-9 Gosner Stages of Amphibian Development
- Figure 4-10 Conceptual Site Model for Exposure of Ecological Receptors to Non-Asbestos Contaminants at OU3

FINAL

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LIST OF TABLES

Table 3-1	Screening Level Risk Calculations for Ambient Air
Table 3-2	Summary of Surface Water Samples Collected and Analyzed for Non-Asbestos Contaminants
Table 3-3	Summary of Sediment Samples Collected and Analyzed for Non-Asbestos Contaminants
Table 3-4	Screening Level Risk Calculations for Human Exposure to Surface Water
Table 3-5	Screening Level Risk Calculations for Human Exposure to Sediment
Table 3-6	Summary of Groundwater Samples Collected and Analyzed for Non-Asbestos Contaminants
Table 3-7	Screening Level Risk Calculations for Human Exposure to Groundwater
Table 4-1	LA Concentrations in Surface Water Toxicity Testing, Cycles 1 & 7
Table 4-2	LA Concentrations in Surface Water Toxicity Testing, Cycles 2 & 4
Table 4-3	LA Concentrations in Sediment
Table 4-4	Summary of Results of Sediment Toxicity Test with <i>Chironomus tentans</i>
Table 4-5	Summary of Results of Sediment Toxicity Test with <i>Hyallela azteca</i>
Table 4-6	Phase III Aquatic Sampling Program
Table 4-7	Surface Water Concentrations of LA in OU3 Ponds
Table 4-8	Sediment Concentrations of LA in OU3 Ponds
Table 4-9	Amphibian Long-Term Exposure Study Design
Table 4-10	Detection Frequencies of Non-Asbestos Contaminants in Surface Water, Sediment, and Soil
Table 4-11	Availability of Data for Metals in Surface Water and Sediment
Table 4-12	Surface Water Data for Metals in Mill Pond Samples
Table 4-13	Metal Concentrations in the Surface Water Samples Collected for Site-Specific Surface Water Toxicity Test
Table 4-14	Concentrations of Metals in Sediment Toxicity Tests
Table 4-15	Comparison of Chromium, Copper, Manganese, and Nickel Concentrations in Site Sediments vs. Sediment Toxicity Tests

FINAL

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LIST OF ACRONYMS

ABS	Activity-Based Sample
AOC	Administrative Order on Consent
ATV	All Terrain Vehicle
BCF	Bioconcentration Factor
CAR	Corrective Action Request
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COC	Chain-of-Custody
CSM	Conceptual Site Model
CV	Coefficient of Variation
DQO	Data Quality Objective
EDD	Electronic Data Deliverable
EDXA	Energy Dispersive X-Ray Analysis
EPA	U.S. Environmental Protection Agency
ERA	Ecological Risk Assessment
FOV	Field of View
FS	Feasibility Study
FSDS	Field Sample Data Sheets
FSP	Field Sampling Plan
FTP	File Transfer Protocol
GO	Grid Opening
GPS	Global Positioning System
GSD	Geometric Standard Deviation
HQ	Hazard Quotient
ID	Identification
IL	Inter-laboratory
ISO	International Organization for Standardization
KDC	Kootenai Development Corporation
LA	Libby Amphibole
MCE	Mixed Cellulose Ester
MDEQ	Montana Department of Environmental Quality
MFL	Million fibers per liter
MMI	Mountain Multimetric Index
NTP	National Toxicology Program
NVLAP	National Voluntary Laboratory Accreditation Program
OU	Operable Unit
PAH	Polycyclic Aromatic Hydrocarbon
PCB	Polychlorinated Biphenyl
PCM	Phase Contrast Microscopy
PEC	Probable Effect Concentration
PDF	Portable Document Format

FINAL

QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
RBC	Risk-Based Concentration
RBP	Rapid Bioassessment Protocol
RD	Recount Different
RI	Remedial Investigation
RPM	Remedial Project Manager
RS	Recount Same
SAED	Selective Area Electron Diffraction
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure
SRC	Syracuse Research Corporation
SVOC	Semi-volatile Organic Compound
TEM	Transmission Electron Microscopy
TRV	Toxicity Reference Value
TWF	Time-Weighting Factor
UCL	Upper Confidence Limit
UR	Unit Risk
VOC	Volatile Organic Compound
WRS	Wilcoxon Rank Sum

**REMEDIAL INVESTIGATION
FOR OPERABLE UNIT 3
LIBBY ASBESTOS SUPERFUND SITE**

PHASE III SAMPLING AND ANALYSIS PLAN

1.0 PROJECT OVERVIEW

1.1 Purpose of This Document

This document is the Sampling and Analysis Plan (SAP) for Phase III of the Remedial Investigation (RI) for Operable Unit 3 (OU3) of the Libby Asbestos Superfund Site (the site). This SAP contains the elements required for both a field sampling plan (FSP) and quality assurance project plan (QAPP), and has been developed in accordance with the U.S. Environmental Protection Agency (EPA) Requirements for Quality Assurance Project Plans (EPA 2001) and the Guidance on Systematic Planning Using the Data Quality Objectives Process – EPA QA/G4 (EPA 2006). The SAP is organized as follows:

- Section 1 – Project Overview
- Section 2 – Background and Problem Definition
- Section 3 – Data Needed For Human Health Risk Assessment
- Section 4 – Data Needed For Ecological Risk Assessment
- Section 5 – Other Data Needs for the RI/FS
- Section 6 – Sample Handling & Documentation
- Section 7 – Data Management
- Section 8 – Assessment and Oversight
- Section 9 – Data Validation and Usability
- Section 10 – References

1.2 Project Management and Organization

Project Management

EPA is the lead regulatory agency for Superfund activities within OU3. The EPA Remedial Project Manager (RPM) for OU3 is Bonita Lavelle, EPA Region 8. Ms. Lavelle is a principal data user and decision-maker for Superfund activities within OU3.

The Montana Department of Environmental Quality (MDEQ) is the support regulatory agency for Superfund activities within OU3. The MDEQ Project Manager for OU3 is Catherine LeCours. EPA will consult with MDEQ regarding all Superfund investigations and assessments

FINAL

within OU3, as provided for by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the National Contingency Plan, and other applicable guidance.

EPA has entered into an Administrative Order on Consent (AOC) with Respondents W.R. Grace & Co.-Conn. and Kootenai Development Corporation (KDC). Under the terms of the AOC, W.R. Grace & Co.-Conn. and KDC will implement this SAP. The designated Project Coordinator for Respondents W.R. Grace & Co.-Conn. and KDC is Robert Medler of Remedium Group, Inc.

Technical Support

EPA will be supported in this project by a number of contractors, including:

- SRC, Inc. will assist in the development of sampling and analysis plans, and in the evaluation and interpretation of the data.
- NewFields Boulder LLC, a contractor to SRC, will provide support in planning sampling and analysis activities, preparation of maps and other GIS applications needed to summarize and interpret data, maintenance of a web site with site data, and evaluation of geotechnical issues needed for the FS.

Oversight for all field sampling and data collection activities will be provided by a contractor selected by EPA.

Field Sampling Activities

All field sampling activities described in this SAP will be performed by W.R. Grace & Co.-Conn. and KDC, in strict accord with the sampling plans developed by EPA. W.R. Grace & Co.-Conn. and KDC will be supported in this field work by MWH Americas, Inc. (MWH) and by their subcontractors. Individuals responsible for implementation of field sampling activities are listed below:

- Program Director: Mike DeDen
- Project Manager: John Garr
- Field Team Leader: Toby Leeson
- Field Quality Control Officer: Stephanie Boehnke
- Quality Control Officer: Mike DeDen

On-Site Field Coordinator

Access to the mine is currently restricted and is controlled by EPA. The on-site point of contact for access to the mine is Courtney Zamora of the U.S. Department of Transportation, John A. Volpe National Transportation Systems Center (Volpe).

FINAL

Sample Preparation and Analysis

All samples collected as part of the Phase III investigation will be sent for preparation and/or analysis at laboratories selected and approved by EPA.

Data Management

Administration of the master database for OU3 will be performed by EPA contractors (SRC and NewFields). The primary database administrator will be Lynn Woodbury. She will be responsible for sample tracking, uploading new data, performing data verification and error checks to identify incorrect, inconsistent or missing data, and ensuring that all questionable data are checked and corrected as needed. When the OU3 database has been populated, checked and validated, relevant asbestos data will be transferred into the Libby2 database or other Libby Asbestos Site database as directed by EPA for final storage.

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2.0 BACKGROUND AND PROBLEM DEFINITION

2.1 Site Description

Libby is a community in northwestern Montana that is located near a large open-pit vermiculite mine. Vermiculite from the mine at Libby is known to be contaminated with amphibole asbestos that includes several different mineralogical classifications, including richterite, winchite, actinolite and tremolite. For the purposes of EPA investigations at the Libby Asbestos Superfund Site, this mixture is referred to as Libby Amphibole (LA).

Historic mining, milling, and processing of vermiculite at the site are known to have caused releases of vermiculite and LA to the environment. Inhalation of LA associated with the vermiculite is known to have caused a range of adverse health effects in exposed humans, including workers at the mine and processing facilities (Amandus and Wheeler 1987, McDonald et al. 1986, McDonald et al. 2004, Sullivan 2007, Rohs et al. 2007), as well as residents of Libby (Peipins et al. 2003). Based on these adverse effects, EPA listed the Libby Asbestos Site on the National Priorities List in October 2002.

Starting in 2000, EPA began taking a range of cleanup actions at the site to eliminate sources of LA exposure to area residents and workers using CERCLA (or Superfund) authority. Given the size and complexity of the Libby Asbestos Site, EPA designated a number of Operable Units (OUs). This document focuses on investigations at Operable Unit 3 (OU3). OU3 includes the property in and around the former vermiculite mine and the geographic area surrounding the mine that has been impacted by releases and subsequent migration of hazardous substances and/or pollutants or contaminants from the mine, including ponds, Rainy Creek, Carney Creek, Fleetwood Creek, and the Kootenai River. Rainy Creek Road is also included in OU3.

Figure 2-1 shows the location of the mine and a preliminary study area boundary for OU3. EPA established the preliminary study area boundary for the purpose of planning and developing the scope of the remedial investigation/feasibility study (RI/FS) for OU3. This study area boundary may be revised as data are obtained during the RI for OU3 on the nature and extent of environmental contamination associated with releases that may have occurred from the mine site. The final boundary of OU3 will be defined by the final EPA-approved RI/FS.

2.2 Basis for Concern

EPA is concerned with environmental contamination in OU3 because the area is used by humans for logging and a variety of recreational activities, and also because the area is habitat for a wide range of ecological receptors (both aquatic and terrestrial). Contaminants of potential concern to EPA in OU3 include not only LA, but any other mining-related contaminants that may have been released to the environment.

2.3 Scope and Strategy of the RI at OU3

As noted above, Respondents W.R. Grace & Co.- Conn. and KDC are performing an RI in OU3 under EPA oversight in order to characterize the nature and extent of environmental contamination and to collect data to allow EPA to evaluate risks to humans and ecological receptors from mining-related contaminants in the environment.

The RI is being performed in several phases. Phase I of the RI was performed in the fall of 2007 in accord with the *Phase I Sampling and Analysis Plan for Operable Unit 3* (EPA 2007). The primary goal of the Phase I investigation was to obtain preliminary data on the levels and spatial distribution of asbestos and also other non-asbestos contaminants that might have been released to the environment in the past as a consequence of the mining and milling activities at the site.

Phase II of the OU3 RI was performed in the spring, summer, and fall of 2008. Phase II was composed of three parts, as follows:

- Part A (EPA 2008a) focused on the collection of data on the levels of LA and other chemicals of concern in surface water and sediment, as well as site-specific toxicity testing of surface water using rainbow trout.
- Part B (EPA 2008b) focused on the collection of data on LA levels in ambient air samples collected near the mined area, and on the collection of data on LA and other chemicals of potential concern in groundwater.
- Part C (EPA 2008c) focused on the collection of other data needed to support the ecological risk assessment at the site.

2.4 Scope and Purpose of the Phase III SAP

This SAP describes the sampling and analysis that will be performed during Phase III of the RI. For convenience, the program has been divided according to objective into three main sections as follows:

- Section 3: data needed to support the human health risk assessment
- Section 4: data needed to support the ecological risk assessment
- Section 5: other data needed to support the RI and FS

Within each of these three sections, the text of the SAP is organized in the following way:

- Description of data that would be helpful to support EPA objectives
- Summary of data collected to date
- Evaluation of the adequacy of the data collected to date
- Identification of additional data needed

FINAL

- Data quality objectives (DQOs) for needed data
- Detailed sampling plan
- Detailed analysis plan
- Quality control plan

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3.0 DATA NEEDS FOR HUMAN HEALTH RISK ASSESSMENT

3.1 Human Exposure to Asbestos

3.1.1 Conceptual Site Model

Figure 3-1 presents a conceptual site model (CSM) for human exposure to asbestos that summarizes EPA's current understanding of the environmental media in OU3 that are likely to be contaminated by past and ongoing releases of LA from the mine, and the pathways by which humans might be exposed to LA, now or in the future. The CSM for LA focuses on pathways of inhalation exposures, because the inhalation pathway is generally considered to be of much greater risk than oral or dermal pathways.

A range of different human receptors may be exposed to LA in OU3, including:

- *Trespasser or "rockhound" in the mined area* – This population includes older children and adults who trespass on the area that has been disturbed by past mining activities. In this document, this is referred to as the "mined area". Exposures of potential concern for asbestos include inhalation of ambient air and inhalation of air in the vicinity of soil and solid waste (e.g., tailings, ore) disturbances.
- *Recreational visitors in the forested area* – This receptor population includes older children and adults who engage in activities such as camping, hiking, dirt bike riding, all terrain vehicle (ATV) riding, hunting, etc. Exposures of primary concern for asbestos include inhalation of ambient air, inhalation of air in the vicinity of contaminated soil, duff (organic debris), or roadways/trails disturbed by recreational activity, and inhalation of LA released from contaminated tree bark during sawing, stacking, or burning of contaminated trees.
- *Recreational visitors along streams and ponds* – This receptor population includes adults and older children who hike, fish, wade/swim or explore site drainages, including the streams and ponds along Fleetwood Creek, Carney Creek, and Rainy Creek, as well as reaches of the Kootenai River that may be impacted by site releases. Exposures of potential concern for asbestos include inhalation of ambient air and inhalation of air in the vicinity of dried soils or sediments that are disturbed by walking or playing. As noted above, exposure from ingestion of LA in fish is judged to be of minor concern compared to inhalation exposures that would occur during visits to OU3.
- *Wood cutters in the forested area* – This receptor population includes adult area residents who engage in sawing, hauling, and stacking wood for personal use, as well as adult workers who are employed in commercial logging operations. Exposures of potential

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concern for asbestos include inhalation of ambient air and inhalation of air that contains LA released from soil or duff as well as LA fibers released to air by cutting and stacking timber that has LA in the tree bark.

- *Fire fighters in the forested area* – This population includes adults who may respond to forest fires in the area of the site. Exposures of potential concern for asbestos include inhalation of ambient air and inhalation of air in the vicinity of soil disturbances such as digging a fire break, tree cutting/sawing activities, or the burning of potentially contaminated trees.

Note that the CSM for OU3 does not include residential exposure scenarios. This is because any properties geographically within OU3 that are currently residential will be evaluated as part of OU4, and, based on information currently available to EPA, future residential development is not reasonably anticipated in other areas of OU3. If any parcel in OU3 ever were developed for residential land use, exposure pathways of potential concern would include inhalation of asbestos and might also include ingestion of other (non-asbestos) contaminants in soil and water.

Pathways Selected for Quantitative Investigation in Phase III

Not all of the exposure scenarios to asbestos identified in Figure 3-1 are of equal concern or require equal levels of investigation. The following sections identify the pathways of chief concern to EPA and which are considered to warrant quantitative evaluation in the human health risk assessment.

Exposure to Ambient Air

All people who are present in OU3 may be exposed to LA in ambient air. Therefore, this pathway is selected for quantitative evaluation.

Exposures of Trespasser/Rockhound within the Mined Area

The mined area is characterized by the occurrence of naturally occurring vermiculite interspersed with veins of LA exposed by mining, as well as large piles of mine waste, waste rock, and a coarse tailings pile. Sampling results from the Phase I remedial investigation at OU3 indicate levels of LA greater than 1% occur at multiple locations in the mined area. The Phase I sampling results, along with observations of exposed veins of LA within the mined area, provide sufficient information to conclude that sources present are very likely to be of concern to human health. EPA guidance contained in OSWER Directive 9200.0-68 (“Framework for Investigating Asbestos-Contaminated Superfund Sites”, EPA 2008e), provides that “if data indicate high levels of asbestos are present in soil (e.g., >1% PLM), a risk manager may determine that a response action should be undertaken and that further efforts to characterize the source or potential airborne exposures before action is taken are not needed.” Therefore, EPA has concluded that

FINAL

response action is necessary to prevent human exposure to LA within the mined area of OU3. EPA anticipates that access restrictions to the mined area and adjacent lands surrounding the mined area that are owned by KDC (including the unpaved portion of Rainy Creek Road) will be part of any response action and that quantification of hypothetical future exposures of trespassers within this mined area and surrounding buffer zone is not needed to support risk management decision-making. EPA expects that alternatives to prevent human access to mined area will be evaluated in the feasibility study for OU3.

Exposures of Recreational Visitors in the Forest Area

Recreational visitors who enter the forested area around the mine site may be exposed to asbestos during a wide variety of activities that disturb contaminated source media, including soil, duff, and tree bark. The reasonable maximum exposure includes:

- Inhalation exposure while walking or hiking
- Inhalation exposure while riding an ATV
- Inhalation exposure while actively disturbing soil or duff when clearing a campsite or building a fire
- Inhalation exposure when sawing trees or stacking wood with LA contamination in bark
- Inhalation exposure to smoke from burning wood with contaminated bark

All of these activities are considered to be plausible and potentially important in evaluating human exposure in OU3, so all of these activities are selected for quantitative evaluation.

Exposures of Recreational Visitors Along Ponds and Creeks

Sediments in ponds and creeks that drain OU3 are known to be contaminated with LA, and recreational visitors who disturb the sediments while walking or fishing along the ponds or creeks might be exposed to LA released to air. In this regard, release of LA from sediments that are submerged is not of concern, and release from sediments that are exposed but still wet is likely to be relatively low. However, releases from contaminated sediments that become exposed and dry out during periods of low water could be of concern.

At present, the relative level of exposure of a recreational visitor from disturbance of soil and duff compared to that from disturbance of dried sediments is unknown. If exposures from disturbance of soil, tree bark and duff are above what EPA considers to be acceptable, then risk management options for soil, tree bark and duff will be developed and evaluated in the feasibility study for OU3. Risk management options will likely include restricting access to areas where exposure to soil, tree bark, and duff present unacceptable risks to humans. If the restricted area encompasses the ponds and creeks, assessment of these specific pathways may not be necessary. EPA will consider the need to investigate exposures of a recreational visitor from disturbance of

dried sediments in the future after considering the results for the other scenarios that will be evaluated.

Exposure of Commercial Loggers

The best approach for characterizing human exposure during this activity would be to monitor air levels during authentic commercial logging activities near the site. However, at present, commercial logging activities have been suspended in the area near the mine. EPA will consider the need to investigate this scenario in the future after consideration of the results for the other scenarios that will be evaluated.

Exposure of Forest Firefighters

This exposure scenario will not be investigated as part of the Phase III program. EPA will wait for the results of the Phase III program since these results may better define the area over which this scenario may be important.

3.1.2 Summary of Data Needs for Human Exposure to Asbestos

Based on the evaluation above, the Phase III investigation will focus on the collection of reliable and representative measures of LA in breathing zone air for people engaged in the following activities:

- Passive activities (inhalation of ambient air)
- Walking or hiking in the forest area around the mine site
- Riding an ATV in the forest area around the mine site
- Sawing trees or stacking wood with LA contamination in bark
- Actively disturbing soil and duff when clearing a camping area or building a fire
- Inhalation of smoke from burning wood with contaminated bark

3.1.3 Evaluation of Existing Asbestos Data

Basic Approach

An evaluation of the adequacy of an existing data set for asbestos is performed in two steps. The first step is to determine if the data are representative in space and time. This is usually a qualitative assessment. The second step is to determine if the data are statistically adequate. For data to be used for evaluation of risks to humans, statistical adequacy considers the magnitude of the uncertainty in the measured average exposure concentration, and whether the uncertainty is too large to support confident decision-making. Usually this is done by computing the 95% upper confidence limit (95% UCL) of the mean within an exposure unit using an appropriate

FINAL

statistical method, and determining if risk estimates based on the 95% UCL of the mean are adequate to allow reliable decision-making.

As discussed in Attachment E, statistical methods that have been developed by EPA for computing 95% UCL values are not well-suited for dealing with asbestos data sets. EPA is currently working to develop new tools that will be appropriate for application to asbestos data sets, but until these methods are developed and approved, an alternative interim approach must be used. The interim approach which has been developed for use at the Libby site is described in Attachment E. In brief, data adequacy may be assessed as follows:

1. Compute the mean and the geometric standard deviation (GSD) of the data set under consideration.
2. Using Figure 3-2, estimate the potential magnitude of the uncertainty in the mean based on the sample size and the observed GSD. For example, for a data set of size 20 and a GSD = 6, it may be estimated that the true mean is probably within a factor of about 3 of the observed mean.
3. Compute the risk estimate based on the mean, and estimate the range of uncertainty in the risk estimate based on the estimated uncertainty in the mean concentration value.
4. Determine if the estimated magnitude of the uncertainty in the risk estimate is too large to allow reliable risk management decision-making. For example, if risk is well above or well below a level of concern using both the best estimate and the high-end estimate of the mean, the data are likely to be adequate for risk management decision-making. However, if the risk estimate based on the best estimate of the mean is below a level of concern (e.g., $< \frac{1}{2}$ the level of concern) but is above the level of concern based on the high-end estimate of the mean, then the data adequacy is in a “grey” range where additional data may be needed to help improve confidence in the risk estimate. The cost of additional data collection (in term of both time and resources) may be weighed against the cost of implementing a response action based on the high end estimate of the mean.

As noted, this is an interim approach that will be replaced with a more rigorous method when it becomes available.

Evaluation of Existing Ambient Air Data

In Phase I, ambient air data were collected from 8 stations (A-1 to A-8) located around the mined area (yellow circles, Figure 3-3). Each sample spanned a collection interval of 5 days, and samples were collected continuously from October 2, 2007 to October 22, 2007. The total number of samples was 32. No LA structures were detected in any of these samples. These data suggest that airborne release of LA from the mined area is likely to be low under current site conditions. Although these data are considered to be spatially representative, the time period was relatively short (only 20 days) and the weather tended to be wet and rainy during this time interval, so the data may not be entirely representative of releases during drier weather.

FINAL

In Phase II, data were collected from 8 stations located close to the mined area. Four of the stations were the same as in Phase I (A4, A5, A6, A8), while four new stations were added (A9 to A12). These are shown by the yellow squares in Figure 3-3. Samples were collected beginning on July 7, 2008 and lasting until October 17, 2008. One 5-day sample was collected from each station every two weeks. The total number of samples was 96. These data are considered to be adequately representative in both space and time.

The raw data are provided electronically in Appendix A, and the average concentration at each station for Phase I and Phase II ambient air samples are summarized in Table 3-1, along with screening level excess cancer risk calculations for both the typical and high-end recreational visitor to OU3. As seen, screening level estimates of cancer risk are below EPA's acceptable risk range ($< 1E-06$) based on data from Phase I, Phase II, and the combined data set, both for typical and high-end visitors. The GSDs of the Phase I, Phase II, and combined data sets ranges from 2.9 to 3.5. The sample number is relatively large ($N = 32$ to 96). Using Figure 3-2, the uncertainty in the risk is estimated to be less than a factor of approximately 2. Based on this, the high end of the risk estimates for this data set is unlikely to exceed about $1E-06$ even for a high-end visitor. Because this risk is small compared to EPA's usual level of concern, it is concluded that the existing data are adequate for risk management decision-making purposes and that additional ambient air monitoring is not required during the Phase III investigation.

Evaluation of Existing ABS Air Data

Collection of personal air samples from individuals engaged in activities that actively disturb source materials is referred to as Activity-Based Sampling (ABS). EPA guidance contained in the "Framework for Investigating Asbestos-Contaminated Superfund Sites", OSWER Directive 9200.0-68 (EPA 2008e), recommends the use of ABS to evaluate releases of asbestos to air from disturbances of soil and other source materials. To date, no ABS data have been collected in OU3 for any exposure scenario during either Phase I or Phase II. Therefore, ABS data collection for each of the exposure scenarios identified above is required in Phase III. In Phase III, ABS data for recreational visitors in the forest area will be collected.

3.1.4 Data Quality Objectives for ABS Data

Step 1: State the Problem

Humans who are present in OU3 may be exposed to LA in breathing-zone air while engaged in activities that disturb LA from sources such as mine waste, contaminated soil, duff, or tree bark. At present, there are no data on the levels of LA in air for any of the scenarios of potential concern, and no methods currently exist for predicting what such air levels might be. Therefore, data are needed on the levels of LA in ABS air in OU3.

FINAL

Step 2: Identify the Goal of the Study

The goal of the study is to provide sufficient data to allow EPA to decide whether or not response actions are needed to protect humans from unacceptable risks from LA in air that is attributable to releases from human disturbances of contaminated environmental media in OU3.

Step 3: Identify Information Inputs

The information needed to characterize human exposures from recreational activities in OU3 consists of reliable and representative measurements of LA concentrations in air under exposure scenarios similar to those identified above. Such measurements are obtained by drawing a known volume of air through a filter that is located in the breathing zone of the individual performing the disturbance activity and measuring the number of LA fibers that become deposited on the filter surface.

Step 4: Define the Bounds of the Study

Spatial Bounds: The spatial bounds of the study include the preliminary study area around the former vermiculite mine (see Figure 2-1). Sampling locations should span a range of exposure and risk levels to allow risk managers to distinguish between areas where risks are acceptable and areas where risks are unacceptable at a scale that is practical and implementable. As noted above, the Phase III ABS investigation will not include the mined area itself or the surrounding lands owned by KDC, since human exposure data are not needed for risk management decision-making in these areas.

Temporal Bounds: The release of LA from source materials into air is expected to depend on several factors that may tend to vary over time, including, for example, the moisture content of the source, the amount of ground cover, and the wind speed and direction when sampling occurs. Therefore, ABS data should be, to the extent practicable, collected over a sufficient time frame to ensure the data are representative of the long-term mean concentration level. This time period should span the interval where access to the site is possible (usually from about April to October, depending on the weather). Because it is considered likely that human visits to OU3 are likely to be less frequent on days when the weather is poor than when the weather is good, ABS sampling should be restricted to days when it is not raining. To the extent that people do visit the site on rainy days, the ABS data may tend to overestimate exposures.

Step 5: Define the Analytical Approach

The results of the ABS program in OU3 will be used to calculate an exposure point concentration at each ABS location. The exposure point concentration will be combined with exposure parameters such as duration and frequency. These results will be used in a baseline risk assessment for OU3 that is expected to provide a basis for EPA to determine, in consultation

FINAL

with MDEQ, whether response action is needed within OU3 to protect human health. EPA guidance contained in OSWER Directive 9355.0-30, "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" (EPA 1991) indicates that where the cumulative carcinogenic risk to an individual based on reasonable maximum exposure for both current and future land use is less than 1E-04 and the non-carcinogenic hazard quotient is less than 1, remedial action is generally not warranted unless there are adverse environmental impacts. The guidance also states that a risk manager may decide that a risk level lower than 1E-04 is unacceptable and that remedial action is warranted where there are uncertainties in the risk assessment results.

Step 6 – Specify Performance or Acceptance Criteria

In making decisions about the risks to humans in OU3, two types of decision errors are possible:

1. A false negative decision error would occur if a risk manager decides that exposure to LA in OU3 is not of health concern, when in fact it is of concern.
2. A false positive decision error would occur if a risk manager decides that exposure to LA in OU3 is above a level of concern, when in fact it is not.

EPA is most concerned about guarding against the occurrence of false negative decision errors, since an error of this type may leave humans exposed to unacceptable levels of LA in OU3. For this reason, it is anticipated that decisions regarding this pathway will be based not only on the best estimate of the long-term average concentration, but will also consider an estimate of the upper end of the uncertainty range about the mean at each ABS sampling area (see Section 3.1.3 and Figure 3-2). Use of the upper end of the uncertainty range to estimate exposure and risk at each exposure area helps account for limitations in the data, and provides a margin of safety in the risk calculations, ensuring that risk estimates are more likely to overestimate than underestimate the true risk level.

EPA is also concerned with the probability of making false positive decision errors. Although this type of decision error does not result in unacceptable human exposure, it may result in unnecessary expenditure of resources. For the purposes of this planning effort, the strategy adopted for controlling false positive decision errors is to seek to ensure that, if the risk estimate based on the best estimate of the mean is $\leq \frac{1}{2}$ the level of concern but the estimate based on the high end of the estimated uncertainty range is above EPA's level of concern, then the ratio of the risk estimates (high end divided by best estimate) is less than a factor of 3. For example, if the risk estimate based on the mean were 10% of the level of concern and the risk estimate based on the high end of the uncertainty range were 50% of the level of concern (an uncertainty range of 5), the data would be considered to adequate for decision-making. However, if the risk estimate based on the mean were 40% of the level of concern and the risk estimate based on the high end of the uncertainty range were twice (200%) the level of concern (also a factor of 5), then it would be concluded that there is a substantial probability of a false positive error and that more data

FINAL

may be needed to strengthen decision-making. Conversely, if the risk estimate based on the mean were 80% of the level of concern and the risk estimate based on the high end of the uncertainty range were twice the level of concern (a factor of 2.5), then it would be concluded that there is only a small probability of a false positive error and that collection of additional data would be unlikely to improve the basis for decision-making.

Step 7: Develop the Plan for Obtaining Data

Activities to be Included in the ABS

As noted above, there are a wide variety of different activities that might result in exposure of humans in OU3. ABS results will be used to characterize exposure and risk to human health associated with current and reasonably anticipated future activities in OU3 in order to support risk management decisions. EPA anticipates that any access restrictions that may be necessary to manage human health risks within OU3 will be most practical if they are simple to understand and easily implementable. Therefore, EPA has selected a strategy of managing risks associated with exposure scenarios rather than individual activities within each scenario. For the purpose of supporting risk management decisions in OU3, EPA has developed a “composite” activity scenario for the Phase III program which characterizes human exposure during a combination of representative activities associated with recreational use. The “script” for this composite ABS scenario is presented in Attachment A, and is described in greater detail in Section 3.1.5, below.

Selection of Sampling Locations

EPA considered two basic strategies for the collection of ABS data in OU3, as follows:

- *Option A:* In this strategy, data would be collected at a series of locations selected to represent a range of different concentration levels in the source material (soil, duff, tree bark). At each location, data would be collected on the level of LA in each source medium, and on the level in air during ABS activities. Then, the data would be used to establish an empiric relationship between concentration in source material and mean concentration in ABS air. If successful, this relationship could then be used to predict ABS exposure levels at other locations, based on measures of LA in source material. Further characterization of the source material within exposure units would then be necessary to complete the human health risk assessment.
- *Option B:* In this strategy, no attempt would be made to establish a quantitative relation between LA levels in source media and the mean concentration in ABS air. Rather, ABS air data would be collected at a series of locations around the mined area, selected to provide data on the spatial pattern of exposure and risk.

FINAL

Because of the very complex nature of the source material (a mixture of duff, soil, and tree bark), the difficulty in thoroughly characterizing the LA concentrations in these source media, and the potential difficulty in establishing a reliable quantitative relation between source and ABS air, EPA has determined that Option B is the approach most likely to be successful for OU3.

Based on this decision, the strategy for selection of sampling locations is based mainly on a consideration of spatial representativeness, and is also informed by available data on LA levels in source media (soil, duff and tree bark) as a function of distance and direction from the mined area. These data, collected along seven transects radiating from the mined area during the Phase I investigation, are summarized in Figure 3-4.

Also shown in Figure 3-4 are 20 “ABS study areas” that are tentatively identified as appropriate locations for ABS. The locations of these tentative ABS study areas are based primarily on a consideration of the large-scale spatial variability of measured LA levels in soil, duff, and tree bark, as well as inspection of available maps on roads, trails, and terrain in OU3. Each tentative ABS study area includes roads and trails that may be used for access and for ATV riding, as well as a large amount of forest area that may be used for other ABS activities.

As shown in Figure 3-4, the 20 ABS areas are spaced around the KDC property to provide good spatial representation of the area. However, for Phase III, the primary focus is on ABS study areas that are located in the predominate downwind direction (north-northeast of the mine). These 11 ABS study areas are indicated in Figure 3-4 by yellow shading. The potential need for additional ABS in areas located predominantly cross-wind or up-wind of the mine will be considered after review of the ABS data from the downwind areas.

All of the ABS areas shown in Figure 3-4 are tentative. The exact locations or bounds of some ABS study areas may need to be revised because some of the roads or trails may not be accessible, and some portions of the study areas may not be appropriate or safe for implementation of ABS activities. Therefore, before ABS field sampling is initiated, a field reconnaissance will be performed to confirm or revise as needed the boundaries of the 11 ABS study areas selected for investigation in Phase III, such that each final study area will be accessible and appropriate for safe implementation of the ABS script. The findings of this reconnaissance trip will be documented and attached as an addendum to this SAP.

Optimizing Sample Number

As discussed in Step 6 of the DQO process for ABS air, the data quality objective for the ABS air study is to limit false positive decision errors such that, if the risk associated with the mean of a data set is $< \frac{1}{2}$ the level of concern, then the ratio of the upper bound to the mean should not exceed a factor of about 3. As discussed above in Section 3.1.3, EPA has not yet developed a rigorous mathematical approach for computing the upper confidence bound on the mean of an

FINAL

asbestos data set, but an interim method based on Monte Carlo simulation has been developed for use at the Libby Asbestos site. The results of the simulation are shown in Figure 3-2. Based on this figure, it may be seen that the width of the uncertainty interval depends strongly on the GSD of the data set. If the GSD is ≤ 3 , then the number of samples needed to ensure the upper bound of the risk estimate is within a factor about 3 of the mean is estimated to be 10 to 15. However, if the GSD is larger, then the number of samples needed is likely on the order of at least 25 to 50, depending on the size of the GSD.

At present, data are not available to estimate how close the mean concentration of LA in ABS air is to a level of human health concern, or on the magnitude of the underlying variability. In the absence of such data, the minimum number of samples to be collected and analyzed in this effort is 10 per ABS area. This should be sufficient to support decision making at each area if the GSD of the data set is ≤ 3 and if the observed mean concentration is not too close to decision thresholds (e.g., more than a factor of 2 apart). Additional sampling may be needed to support decision-making if the GSD is > 3 and/or observed means are close to decision thresholds (e.g., sample mean is within 2-fold of the decision threshold).

Selection of Target Analytical Sensitivity

The level of analytical sensitivity needed to ensure that analysis of ABS air samples from OU3 will be adequate is derived by finding the concentration of LA in ABS air that might be of potential concern, and then ensuring that if an ABS sample were encountered that had a true concentration equal to that level of concern, it would be quantified with reasonable accuracy.

At present, EPA has not developed a quantitative procedure for evaluating non-cancer risks associated with inhalation exposure to asbestos, but has developed a method for quantification of cancer risk (EPA 2008e). The basic equation is:

$$\text{Risk} = C \cdot \text{TWF} \cdot \text{UR}_{a,d}$$

where:

- C = Average concentration of asbestos fibers in inhaled air (f/cc)
- TWF = Time weighting factor to account for less than continuous exposure (unitless)
- UR_{a,d} = Unit risk (s/cc)⁻¹ based on continuous exposure beginning at age “a” and continuing for duration “d” years. EPA (2008e) provides a table of unit risk values for a range of start ages and exposure durations.

It is important to recognize that the value of C must be expressed in units of PCM f/cc. The concentration of PCM fibers in ABS air could be measured directly, but EPA believes it is better to measure the concentration of total LA fibers using TEM, and then to compute the number of

FINAL

PCM-equivalent (PCME) fibers based on the average ratio of PCME to total LA fibers. This is referred to as the “risk-based fraction” (RBF), and the calculation is performed as follows:

$$C(\text{PCME}) = C(\text{total LA}) \cdot \text{RBF}_{\text{PCME}}$$

Combining the equations above and re-arranging to solve for the concentration of LA that corresponds to a specified risk level yields the following:

$$C(\text{total LA}) = \text{Specified Risk} / [\text{RBF}_{\text{PCME}} \cdot \text{TWF} \cdot \text{UR}_{\text{a,d}}]$$

For convenience, the concentration of LA that corresponds to a specified risk level is referred to as a Risk-Based Concentration (RBC).

In order to compute the RBC, it is assumed that the maximally-exposed individual would be a present near the site no more than 8 hours per day for 50 days per year. This corresponds to a TWF of 0.046 ($8/24 \cdot 50/365 = 0.046$). Exposure is assumed to start at age 15 and to last for a duration of 30 years. Based on these values, the unit risk value is $0.093 \text{ PCM (f/cc)}^{-1}$ (EPA 2008e).

The value of RBF for ABS samples in OU3 is not known. However, the value of RBF for ambient air samples in OU3 is 0.16, and the RBF for ambient air samples in OU4 is 0.39 (see Attachment F). To be conservative, an RBF of 0.4 is assumed for the purposes of calculating the target analytical sensitivity. If the actual RBF for ABS in OU3 is lower, the only outcome will be that the data obtained are of higher than expected quality. Note that actual exposure and risk calculations in the baseline human health risk assessment for OU3 will use the observed, not an assumed, RBF.

Choosing a specified risk value of $1\text{E-}05$ (1/10 the level of concern), the RBC is then computed as follows:

$$\begin{aligned} \text{RBC} &= 1\text{E-}05 / (0.4 \cdot 0.046 \cdot 0.093) \\ &= 0.0059 \text{ Total LA f/cc} \end{aligned}$$

It is important to emphasize that choice of $1\text{E-}05$ as the “specified risk” is not a risk management decision. Rather, this choice is strictly for the purposes of deriving an analytical sensitivity that will be adequate for the OU3 Phase III ABS program. All actual evaluations of health risk will be performed by EPA in the risk assessment for OU3, and all risk management decisions will be documented in the Record of Decision.

Given the RBC, the target sensitivity is set so that, on average, about 3 fibers would be counted in a sample whose true concentration was equal to the RBC:

FINAL

$$\text{Target Sensitivity} = (0.0059 \text{ LA f/cc}) / (3 \text{ LA fibers}) = 0.002 \text{ cc}^{-1}$$

This level of analytical sensitivity should be sufficient to allow reliable quantitation of ABS samples that approach or exceed a risk level of about 1E-05.

Optimizing the Sample Collection Strategy

Two key variables that may be adjusted during collection of air samples are sampling duration and pump flow rate. The product of these two variables determines the amount of air drawn through the filter, which in turn is an important factor in the cost and feasibility of achieving the target analytical sensitivity (see above). In general, longer sampling times are preferred over shorter sampling times because a) longer time intervals are more likely to yield representative measures of the average concentration (as opposed to short-term fluctuations), and b) longer collection times are associated with higher volumes, which makes it easier to achieve the target analytical sensitivity. Likewise, higher flow rates are generally preferred over lower flow rates because high flow is associated with high volumes. Note that, in cases where the air being sampled contains a significant level of dust, this strategy may lead to overloading of the filter with dust particles. In this event, the filter can not be examined directly, but must undergo an "indirect preparation" in which the material on the filter is suspended in water and only a fraction is re-deposited on a "secondary" filter, such that the secondary filter is not overloaded.

3.1.5 Detailed Sampling Design for ABS Air Samples

ABS Script

Two individuals will perform each ABS activity. The detailed script is presented in Attachment A, and is summarized below:

Time (min)		Person	
Start	Stop	No. 1	No. 2
0	20	ATV (lead)	ATV (follow)
20	40	ATV (follow)	ATV (lead)
40	60	Hike (lead)	Hike (follow)
60	80	Hike (follow)	Hike (lead)
80	100	Saw	Pile wood
100	120	Pile wood	Saw
120	140	Rake	Rake
140	150	Dig	Dig
150	180	Build and stand near campfire(a)	

(a) For safety reasons, this activity will not occur in the ABS study area in the forest, but will occur on W.R. Grace-owned property near Rainy Creek Road and Highway 37 (the area formerly known as the Flyway) that is specifically prepared so fires can be burned without concern.

FINAL

As indicated, each individual will engage in a timed series of different activities to generate a “composite” ABS sample that is representative of a range of realistic activities that may be performed by people visiting OU3.

Sampling Schedule

Access to the site is generally limited to the time period from about late April or early May until about mid to late October, depending on the amount of snowfall. Based on the assumption that human visits to the site are likely to be more common when the weather is good and the ground is relatively dry, the time interval of chief interest for ABS sampling is from the beginning of warm weather and snow melt (often June to July) until the end of September or early October. This also represents the time when environmental conditions tend to be most conducive to re-suspension of LA from soil and/or duff that contain elevated levels. Based on this, ABS sampling will be performed at each area once every 10 days, beginning as soon as final study area boundaries can be ground-truthed and confirmed by EPA. This is expected to occur no later than the first week in July. Once sampling begins, the sampling program should extend into the fall until weather prohibits safe and easy access to the ABS study areas. It is expected that this program will generate approximately 9-11 sample events at each of 11 ABS areas, with each event generating two ABS samples for a total of about 200-240 field ABS samples.

Because human visitation to OU3 is likely to occur mainly on days when it is not raining, ABS sampling activities should, to the extent possible, be restricted to days when rainfall is absent or minimal. Sampling events that were scheduled for days when rainfall does occur should be re-scheduled to occur after the rain has ceased and the ground has had a chance to dry. Limiting the ABS sampling to days when there is no rain will be more likely to overestimate than underestimate the long term average amount of LA released under actual conditions.

Activity Patterns within Each Area

In order to maximize the representativeness of the samples over space as well as time, it is important that the exact locations of the ABS activities within the ABS areas vary from visit to visit. For ATV riding (which is largely restricted to existing roads and trails), it may not be possible to incorporate much spatial variability unless the number of roads and trails in the study area are extensive. However, for the other components of the script (hiking, sawing/stacking wood, raking/digging), field crews should strive to select a different location within the ABS area during each event to perform these activities.

In order to create a record of the exact locations within each ABS area that were visited, each person will carry a GPS unit programmed to automatically record location (\pm about 5 meters) once every minute. Field crews will download this electronic record at the end of each ABS event. The Field Quality Control Officer and the Field Team Leader will be responsible for

FINAL

ensuring that ABS events are conducted at different locations within the ABS area. Any questions about the representativeness of sampling locations will be directed to the EPA Remedial Project Manager for resolution. At the completion of the Phase III ABS program (all ABS events completed at all areas), the tracks from all ABS events at each ABS areas will be superimposed to create maps of the locations that were visited at each area during the summer. These maps shall be submitted to EPA and MDEQ.

Personal Air Sampling Protocol

All ABS air samples will be collected in accord with SOP EPA-LIBBY-01 (Rev. 1, March 2001). A copy of this standard operating procedure (SOP) is presented in Attachment B. All air samples will be collected using cassettes that contain a 25 mm diameter mixed cellulose ester (MCE) filter with a pore size of 0.8 μm . The target pump flow rate is 8 L/min.

A battery-powered air sampling pump (F&J Model DF-40L-8 has successfully been used in other ABS programs at the site) will be carried in a backpack worn by the participant. The monitoring cassette will be attached to the pump via a plastic tube, and affixed to the shoulder of the participant such that the cassette is within the breathing zone. The breathing zone can be visualized as a hemisphere approximately 6 to 9 inches around an individual's face. The top cover from the cowl extension on the sampling cassette shall be removed ("open-face") and the cassette oriented face down.

Each air sampling pump will be calibrated at the start of each ABS sampling period using a rotameter that has been calibrated to a primary calibration source. For pre-sampling purposes, calibration will be considered complete when the measured flow is within $\pm 5\%$ of the target flow (8 L/min), as determined by the mean of three measurements.

As noted in the ABS script (see Attachment A), the pumps should be turned on at the beginning of each ABS event, and left to run for the duration of the script except for the interval when wood from the site is being transported from the forest down to the safe burning area.

Because flow may tend to change during the 3-hour ABS script, flow will be checked with a rotameter between each of the main phases of the ABS script (ATV riding, hiking, sawing/stacking, raking/digging, and fire building). If the flow is within the range of 7-9 L/min, the flow rate should simply be recorded. If the flow falls below 7 L/min or rises above 9 L/min, then the flow rate should be adjusted to bring the flow back to 8 L/min.

To prevent potential cross-contamination, each rotameter used for field calibration will be transported to and from each sampling location in a sealed zip-top plastic bag. The cap used at the end of the rotameter tubing will be replaced each morning after it is used.

FINAL

Field Documentation

All data associated with each ABS event shall be recorded on a field sample data sheet (FSDS) specifically designed for ABS activities in OU3. This FSDS is provided in OU3 SOP No. 9.

3.1.6 Analytical Requirements for Asbestos

Laboratory Qualifications

All laboratories that analyze samples of ABS air for asbestos as part of this project must participate in and have satisfied the certification requirements in the last two proficiency examinations from the National Institute of Standards and Technology/National Voluntary Laboratory Accreditation Program (NVLAP).

Phased Strategy for Sample Analysis

As described above, 10-11 ABS events will be performed at each area, with each event generating two ABS samples (filter cassettes). Initially, only the filter cassettes from Person No. 1 will be prepared and analyzed, and the filter cassettes generated by Person No. 2 will be held in archive as backup in case of any problems or loss of samples from Person No. 1. After analysis of the filter cassettes from Person No. 1, a determination will be made as to whether the resulting data are adequate for risk management decision making, or whether analysis of the filter cassettes from Person No. 2 may also be needed.

Analytical Method and Counting Rules

All samples of air collected during Phase III sampling will be submitted for asbestos analysis using transmission electron microscopy (TEM) in accord with the International Organization for Standardization (ISO) 10312 method (ISO 1995) counting protocols, with all applicable Libby site-specific laboratory modifications, including the most recent versions of modifications LB-000016, LB-000019, LB-000028, LB-000030, LB-000053, LB-000066, and LB-000085 (see Attachment C). All amphibole structures (including not only LA but all other asbestos types as well) that have appropriate Selective Area Electron Diffraction (SAED) patterns and Energy Dispersive X-Ray Analysis (EDXA) spectra, and having length greater than or equal to 0.5 μm and an aspect ratio (length:width) $\geq 3:1$, will be recorded on the Libby site-specific laboratory bench sheets and electronic data deliverable (EDD) spreadsheets. Data recording for chrysotile, if observed, is not required.

Stopping Rules

For field samples, evaluate each sample until one of the following is achieved:

FINAL

- A minimum of 2 grid openings (GOs) in each of 2 grids has been examined.
- The target sensitivity (0.002 cc^{-1}) is achieved. Assuming that the typical sample volume for an ABS sample will be about 1440 L (180 minutes x 8 L/minute), that the sample may be analyzed with using a direct preparation, and that the area of a GO is 0.01 mm^2 , it is expected that an analytical sensitivity of 0.002 cc^{-1} can be achieved by counting about 14 GOs.
- 50 LA structures are observed
- An area of 0.5 mm^2 has been examined (approximately 50 GOs)

When one of these goals is achieved, complete the final GO and stop.

For blanks (i.e., lot blanks, field blanks, and lab blanks), evaluate an area of 0.1 mm^2 (approximately 10 GOs) and stop.

3.1.7 Quality Control for Asbestos Data

Quality Control (QC) consists of the collection of data that allow a quantitative evaluation of the accuracy and precision of the field data collected during the project. QC samples that will be collected during ABS sampling include both field-based and laboratory-based QC samples.

3.1.7.1 *Field-Based Quality Control Samples*

Lot Blanks

Before any air cassettes may be used for asbestos sampling, the lot must be determined to be asbestos free. This will be accomplished by selecting 2 lot blanks at random from the group of cassettes to be used for collection of ABS air samples. Each lot blank will be submitted for TEM analysis as described above. Once the lot is confirmed to be asbestos free (i.e., both lot blanks are non-detect after evaluation of an area of 0.1 mm^2), that lot may be placed into use for sampling.

Field Blanks

A field blank for air shall be prepared by removing the sampling cassette from the box, opening the cassette to the air in the area where the investigative samples will be taken, then closing the cassette and packaging for shipment and analysis. Field blanks for ABS air will be collected at a rate of 1 per ABS sampling round. The ABS sampling location where the field blank is generated should be selected at random, choosing a new location (ABS area) for each field blank. This strategy will generate a total of 10 field blanks.

FINAL

3.1.7.2 Laboratory-Based Quality Control Samples for Asbestos Analysis by TEM

The QC requirements for TEM analyses of air samples at the Libby site are patterned after the requirements set forth by NVLAP. There are three types of laboratory-based QC analyses that are performed for TEM. Each of these is described below.

Lab Blank - This is an analysis of a TEM grid that is prepared from a new, unused filter in the laboratory and is analyzed using the same procedure as used for field blank samples.

Recounts - A recount is an analysis where TEM grid openings are re-examined after the initial examination. The type of recount depends upon who is performing the re-examination. A *Recount Same (RS)* describes a re-examination by the same microscopist who performed the initial examination. A *Recount Different (RD)* describes a re-examination by a different microscopist within the same laboratory than who performed the initial examination. An *Interlab (IL)* describes a re-examination by a different microscopist from a different laboratory.

Repreparation - A repreparation is an analysis of a TEM grid that is prepared from a new section of filter as was used to prepare the original grid(s). Typically, this is done within the same laboratory as did the original analysis, but a different laboratory may also prepare grids from a new piece of filter.

For this project, the frequency of these laboratory-based QC samples will be as follows:

QC Sample Type	QC Sample Rate	Approximate Number (a)
Lab Blank	1% (1 per 100)	1
Recount Different	2% (1 per 50)	2
Interlab	2% (1 per 50)	2
Repreparation	4% (1 per 25)	4

(a) Based on N = 110 (filters from Person No. 1 only)

The list of samples for Recount Different, Interlab, and Repreparation will be selected by SRC and provided to the laboratory by EPA after the results of the original sample analyses have become available.

The most recent version of laboratory modification LB-000029 (see Attachment C) summarizes the acceptance criteria and corrective actions for TEM laboratory QC analyses that will be used to assess data quality.

3.2 Human Exposure to Other (Non-Asbestos) Contaminants

3.2.1 Conceptual Site Model

Figure 3-5 presents a CSM for human exposure to non-asbestos contaminants at OU3. This might include a range of different types of contaminants, potentially including metals and metalloids released from ore and waste rock, as well as foaming agents, petroleum products, herbicides, pesticides, and polychlorinated biphenyls (PCBs) that may have been used or released during mining and milling operations within OU3. As seen, the receptor populations of interest are the same as identified above for asbestos. However, the exposure pathways requiring consideration include not only inhalation, but also ingestion and dermal contact with contaminated site media (soil, surface water, sediment, groundwater, etc.).

Pathways of Primary Concern for Non-Asbestos Contaminants

Not all of the exposure scenarios for non-asbestos contaminants identified in Figure 3-5 are of equal concern or require equal levels of investigation.

Based on experience at other mining sites, the highest concern for exposure to non-asbestos contaminants is due to ingestion of contaminated water, soil, or sediment. Therefore, data on the concentration of non-asbestos analytes in these media are needed to evaluate each of these exposure pathways. Inhalation exposure to particulates released from soil or sediment into air is typically much lower than from ingestion exposure, so quantitative data on non-asbestos contaminants in air are not needed.

Although incidental ingestion of non-asbestos contaminants in soil or mine wastes in the mined area of OU3 could be of potential concern for the rockhound/trespasser scenario, as discussed previously, EPA has concluded that response action is necessary to prevent human exposure to LA within the mined area of OU3. EPA anticipates that access restrictions to the mined area and adjacent lands surrounding the mined area that are owned by KDC (including the unpaved portion of Rainy Creek Road) will be part of any response action. EPA expects that alternatives to prevent human access to mined area will be evaluated in the feasibility study for OU3. Therefore, data to support quantitative evaluation of risk from oral exposure to non-asbestos contaminants at the mined area and the surrounding lands owned by KDC are not needed. This includes potential exposures along the un-paved upper portion of Rainy Creek Road located within KDC property.

Releases of particulate material from past mine operations into air may have led to the contamination of soil and duff in the forest area around the mine site with non-LA contaminants as well as LA. Of chief concern are metals and metalloids in the vermiculite ore and waste rock extracted at the mine. However, the mineral formation at the mine is composed primarily of vermiculite and is not rich in heavy metals or metalloids, so concentration values of most

FINAL

inorganic constituents in on-site samples are generally similar to background levels seen in the State of Montana (see Figure 3-6). Based on this, it is expected that any exposures and risks to humans in the forest area will be dominated by LA, and that any contributions from non-LA contaminants in the ore, tailings and waste rock will be minor. Therefore, data on the concentrations of non-LA contaminants in soil or duff the forest area are not needed for risk-management decision-making.

At present, there is no complete exposure pathway for groundwater, but it is conceivable that current or new wells might be used in the future to provide a source of drinking water to recreational visitors in OU3. Therefore, data on non-asbestos contaminants in groundwater are needed.

Evaluation of exposure from ingestion of fish caught in on-site ponds or streams may be evaluated using two alternative strategies. In one case, edible tissues from on-site fish are analyzed and the results are used to evaluate human exposure. In the alternative approach, mathematical uptake models are used to predict concentration levels in fish tissues based on measurements of contaminant levels in site waters. In this case, the latter approach will be used, so measures of non-asbestos contaminant levels in fish tissue are not required.

3.2.2 Summary of Data Needs for Human Exposure to Non-Asbestos Contaminants

Based on the evaluation above, the key data needed to evaluate human health risk from non-asbestos analytes in OU3 include the following:

- Surface water from site ponds and streams
- Groundwater
- Sediment from site ponds and streams

3.2.3 Data Quality Assessment of Existing Data

The basic approach for evaluating the adequacy of existing data for non-asbestos analytes in site media (surface water, groundwater, sediment) is generally similar in concept to that described previously for LA.

The process begins by considering whether the data are representative in time and space. If so, the next step is to perform an initial risk-based screen. In this approach, cancer and non-cancer risks are computed for a maximally exposed individual, based on the maximum detected concentration of each analyte in each medium anywhere on site. These screening level risk values are conservative estimates of the highest risk estimate that could be derived with the existing data, and actual risks, derived using more realist approaches, would generally be expected to be lower.

FINAL

If the screening-level risks, both individually and when summed across chemicals, are low (e.g., non-cancer hazard index [HI] < 1, cancer risk < 1E-05), it is concluded that the existing data are adequate to support risk-management decision-making, and that collection of additional data is not needed. If risks approach a level of concern (HI ≥ 1, cancer risk ≥ 1E-05), then additional data may be needed if uncertainty in the concentration values is high (95% UCL/mean > 3).

Application of this approach to available data for non-asbestos analytes in site media is presented below.

Surface Water and Sediment

Data on the concentration of non-asbestos analytes in surface water and sediment were collected in both Phase I and Phase II. Raw data are provided electronically in Appendix A. Table 3-2 summarizes the sampling locations and sampling times for surface water. As shown, data were collected from 20 different stations in the OU3 watershed. At most stations, three separate samples were collected, representing fall, spring, and summer time periods. Table 3-3 provides similar data for sediment samples. In general, a similar approach was used for sediment, except that multiple samples of sediment were collected in Carney Creek Pond, Fleetwood Creek Pond, the Tailings Impoundment, and the Mill Pond during the Phase II investigation.

The surface water and sediment data from OU3 are considered to provide good spatial representativeness, since multiple samples were collected from each major segment of the OU3 watershed. Temporal representativeness is considered to be adequate, since samples were collected from 3 different times of year.

All samples of surface water and sediment were analyzed for metals, petroleum hydrocarbons, nitrate/nitrite (surface water only), and anions. Several locations were also analyzed for a range of additional analytes, including pesticides, PCBs, volatile organic compounds (VOCs), semi-volatile organic compounds (SVOCs), polycyclic aromatic hydrocarbons (PAHs), and radionuclides (surface water only).

Results of the initial risk-based screening step for analytes detected in surface water are shown in Table 3-4. For the direct ingestion pathway, the screening level calculations indicate that both cancer and non-cancer risks to humans are low, both at the level of individual analytes and at the level of total risk. For the fish ingestion pathway, the concentration in fish tissue is estimated from the maximum concentration in surface water by assuming a bioconcentration factor (BCF) of 1.0:

$$C_{\text{fish}} (\text{mg/kg}) = C_{\text{water}} (\text{mg/L}) \cdot \text{BCF} (\text{L/kg})$$

FINAL

This assumption is conservative because none of the chemicals detected in surface water tend to bioaccumulate in fish tissue. As indicated, screening-level risk estimates for fish ingestion are low for both cancer and non-cancer effects.

Results of the initial risk-based screening step for sediment ingestion are shown in Table 3-5. As shown, the screening level calculations indicate that both cancer and non-cancer risks to humans are low, both at the level of individual analytes and at the level of total risk.

Based on these findings, it is concluded that the existing data for non-asbestos analytes in surface water and sediment are adequate to support risk management decision-making, and that additional data are not needed for the human health risk assessment.

Groundwater

In Phase II, the locations of 10 existing groundwater wells were identified (see Figure 3-7), and groundwater samples were successfully collected from 5 of these wells (A, C, D, E, and H). To date, two rounds of sampling have been completed at each well, occurring in the summer and fall of 2008. A third sampling round is scheduled for the spring of 2009. The analytes measured at each well are shown in Table 3-6.

At present, none of the existing wells are used for drinking water. However, Table 3-7 summarizes screening-level risk calculations that would apply if the water were used for drinking water by site visitors. As seen, screening-level risk estimates are low for both cancer and non-cancer effects, both for individual analytes and when summed across all chemicals. Based on this, it is concluded that, if the concentration of non-asbestos analytes in groundwater samples collected in the spring of 2009 (as the final part of the Phase II investigation) are not substantially higher than the data that are presently available, risks from hypothetical future exposure to groundwater can be adequately evaluated using the existing and scheduled data, and that collection of additional groundwater samples is not needed for evaluation of human health risk from non-asbestos analytes.

3.2.4 Data Quality Objectives for New Non-Asbestos Data

Based on the screening-level risk calculations presented above, it is concluded that current data on the concentrations of non-asbestos analytes in surface water, sediment, and groundwater are sufficient to support risk management decision-making, and that additional sampling for non-asbestos analytes in OU3 is not needed to support the human health risk assessment.

4.0 DATA NEEDS FOR ECOLOGICAL RISK ASSESSMENT

4.1 Problem Formulation

Problem Formulation is a systematic planning step that identifies the major concerns and issues to be considered in an ecological risk assessment (ERA), and describes the basic approaches that will be used to characterize ecological risks that may exist (EPA 1997). As discussed in EPA (1997), Problem Formulation is an iterative process, undergoing refinement as new information and findings become available. An initial ecological Problem Formulation for the Libby OU3 site was completed by EPA (EPA 2008d). This document identifies the major concerns and issues to be considered in the ERA for OU3, and describes the basic approaches that may be used to characterize ecological risks. Key elements of the problem formulation are summarized below.

Management Goals

The overall management goal identified for ecological health at the Libby OU3 site for non-asbestos contamination is:

Ensure adequate protection of ecological receptors within the Libby OU3 Site from the adverse effects of exposures to mining-related releases of asbestos and other chemical contaminants to the environment. "Adequate protection" is generally defined as the reduction of risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota (EPA, 1999).

In order to provide greater specificity regarding the general management goals and to identify specific measurable ecological values to be protected, the following list of sub-goals was derived:

- *Ensure adequate protection of the aquatic communities in Rainy Creek, Fleetwood Creek, the Tailings Impoundment, the Mill Pond, the Carney Creek Pond, and Carney Creek from the adverse effects of asbestos and other site-related contaminants in surface water and sediment.*
- *Ensure adequate protection of terrestrial plant and soil invertebrate communities within the mined area from the adverse effects of asbestos and other site-related contaminants in soils.*
- *Ensure adequate protection of the mammalian and avian assessment populations from adverse effects of non asbestos contaminants in the mined area and the site drainages, and from the adverse effects of asbestos in the mined area, the site-related drainages and the surrounding forest area.*

FINAL

- *Ensure adequate protection of the amphibian assessment population from adverse effects asbestos and non asbestos contaminants in the mined area and the site drainages, and the surrounding forest area.*

Definition of Population

For the Libby OU3 Site, the assessment populations are defined as the groups of organisms that reside in locations that have been impacted by mining-related releases. For exposure to non-asbestos contaminants, this is believed to be restricted to the mined area and the drainages associated with the mined area. For asbestos, the impacted area also includes surrounding forest lands that were impacted by airborne releases of asbestos.

Assessment Endpoints

Assessment endpoints are explicit statements of the characteristics of the ecological system that are to be protected. Because risk management goals are formulated in terms of the protection of populations and communities of ecological receptors, the assessment endpoints selected for use in the initial Problem Formulation focus on endpoints that are directly related to population stability. This includes:

- Mortality
- Growth
- Reproduction

Other assessment endpoints may be appropriate if it is believed that the endpoint can be related to population stability.

Measurement Endpoints

Measurement endpoints were initially defined by EPA guidance to represent quantifiable ecological characteristics that could be measured, interpreted, and related to the valued ecological components chosen as the assessment endpoints (EPA 1992, 1997). The term measurement endpoint was later replaced with the term measures of effect and was supplemented by two other categories of measures (EPA 1998). The problem formulation for OU3 uses the term “measurement endpoint” to describe both measures of exposure and effect.

Measurement endpoints that are often useful for evaluating the assessment endpoints identified above in populations of ecological receptors include the following:

- Hazard Quotient Approach. In this approach, the measurement endpoint is the concentration of contaminant in an environmental medium. This is interpreted by

FINAL

comparison to an appropriate toxicity reference value (TRV). If the ratio (referred to as a Hazard Quotient, or HQ) does not exceed 1, this indicates there is no significant concern, while an HQ value > 1 indicates that adverse effects may be occurring.

- Site-Specific Toxicity Tests. In this approach, receptors are exposed to an environmental medium from the site. This may be done either in the field or in the laboratory using media collected from the site. The measurement endpoints may include a variety of observations, including survival, growth, and reproduction of exposed organisms. The results are interpreted by determining if exposure to site media causes a meaningful decrease in any of the measurement endpoints, usually in comparison to a reference group.
- Population and Community Demographic Observations. In this approach, direct observations are made on ecological receptors in the field. Measurement endpoints usually include estimates of the density and/or diversity of a receptor population or community. The results are interpreted by comparison to similar measurement from a reference population.
- In-Situ Measures of Exposure and Effects. In this approach, direct observations are made on receptors collected from the field. Measurement endpoints may include measures of exposure (e.g., tissue burden), occurrence of visible abnormalities or deformities, and frequency or severity of histological lesions. Data are interpreted by comparison to similar measures from a reference population.

In the case of LA, TRVs have not been derived to date for any ecological receptor class. Consequently, it is not currently possible to use HQ-based methods as part of the assessment strategy for asbestos. However, if TRV values for LA can be estimated from appropriately designed laboratory-based toxicity studies, it may be possible establish TRV values and utilize these in an HQ-based approach.

Weight of Evidence Risk Evaluation

Each of these approaches for evaluating assessment endpoints have strengths and potential limitations. For this reason, whenever possible, risks to each receptor group will be evaluated using the results from two or more of the available strategies described above. The weight of evidence evaluation may take many factors into account, including the advantages and weaknesses of each line of evidence, and the degree of agreement between the different lines. For this reason, it is not possible to specify a quantitative rule for combining conclusions across the different lines of evidence. However, the following qualitative guidelines will be applied when interpreting the weight of evidence of risk to each ecological receptor of concern:

FINAL

- Case 1: All available lines of evidence agree there is not an unacceptable risk. In this case, the weight of evidence will be considered strong that effects are either absent or minimal.
- Case 2: All lines of evidence agree there is an unacceptable risk. In this case, the weight of evidence will be considered strong that effects are present and are likely to be significant.
- Case 3: The results from several different line of evidence are mixed. For example, calculated HQ values frequently and substantially exceed 1, but toxicity is not observed in site-specific toxicity tests and only marginal effects are observed in population demographic studies. In this situation, the results of each method will be weighed in proportion to confidence in the results of that method. In general, direct observations from site-specific toxicity tests, population and community demographic observations, and *in-situ* measures of exposures and effects are given greater weight than predictive methods (the HQ approach), although this varies from case to case and depends on the confidence in the exposure estimates and in the TRV used to derive the HQ values.
- Case 4: Only one line of evidence is available, and no weight of evidence assessment is possible. In this case, confidence in the risk characterization will be in proportion to the confidence in the available line of evidence. If confidence in the available line of evidence is good, then the results of this one line of evidence may be sufficient for decision-making. Conversely, if confidence in the available line of evidence is low, then the results may not be adequate to support reliable risk-management decision making, and the potential for collecting other lines of evidence may need to be evaluated.

Section 4.2 (below) reviews which of these assessment strategies are being pursued for ecological receptors exposed to asbestos, evaluates the adequacy of the data collected to date for each strategy, and identifies new data that will be collected in Phase III. Section 4.3 provides the same information for non-asbestos chemicals of potential concern.

4.2 Exposure of Ecological Receptors to Asbestos

4.2.1 Conceptual Site Model

Figure 4-1 presents a conceptual site model (CSM) for exposure of ecological receptors to asbestos at OU3. This CSM summarizes the current understanding of LA sources, fate and transport pathways, and exposure pathways that are possible for each group of ecological receptors in OU3.

4.2.2 Focus of Phase III Ecological Investigations for Asbestos

The primary focus of the ecological component of the Phase III investigation for asbestos is to collect data to support an evaluation of risks from LA to fish, benthic invertebrates, small mammals, and amphibians. The potential need for future investigations of risks from LA to other receptor groups will be determined after review and evaluation of all available data collected during the Phase I, II and III investigations.

4.2.3 Exposure of Fish to Asbestos

4.2.3.1 *Data That Are Valuable for Evaluating Effects of LA on Fish*

As discussed in the Problem Formulation document (EPA 2008d) and the Phase IIA SAP (EPA 2008a), data from several lines of evidence are valuable when seeking to evaluate risks to fish from exposure to LA in surface water. This includes:

- Asbestos concentrations in site surface waters as a function of time of year, coupled with a reliable TRV for LA in surface water by which to interpret the measurements.
- Site-specific surface water toxicity tests in fish
- Multiple years of fish population demographic observations

The following sections discuss the availability of each type of data at present and the plans for collection of additional data of these types during the Phase III effort.

4.2.3.2 *LA Concentration in Surface Waters*

As noted above, at present there is no TRV for exposure of fish to LA in water. In the absence of such a TRV or some other frame of reference, data on the concentration of LA in water are not directly useful in evaluating risks from LA. However, a study is planned that may support development of such a TRV (see Section 4.2.3.4, below). Consequently, data on asbestos in surface water may provide an important tool for evaluation of LA risks to fish, and a data quality assessment for LA in surface water (assuming implementation of an HQ approach) is presented below.

Surface Water Data Summary

In Phase I (October 11 to October 17, 2007), one sample of surface water was collected for analysis of LA at 17 stations. In Phase II, a much more extensive data set was collected, including multiple samples at 21 OU3 stations (Figure 4-2) and samples at 2 reference locations (Figure 4-4) during the time period from April 7 to October 8, 2008. The raw surface water data are provided electronically in Appendix A. Flow was also measured weekly at nine of the in-

FINAL

stream stations as a function of time. Figure 4-3 presents measured LA concentration and flow data collected during Phase II for these stations.

Streams

Data from Phase II indicate that LA levels in surface waters of flowing streams in OU3 are not constant, but tend to increase during the spring runoff, although the magnitude and timing of the increases seem to vary between locations. The clearest examples are at LRC-1 and LRC-6. Therefore, the conceptual model is that maximum exposure in streams will generally occur during this time interval (late April to late June, at least for the 2008 calendar year).

Ponds

Concentration values in ponds follow a less clear temporal pattern, but the data suggest that levels in ponds (including the Tailings Impoundment, the Mill Pond, and Fleetwood Creek Pond) may also tend to increase somewhat during the spring runoff. The data suggest that the highest concentration values tend to be observed in the ponds, although the data are somewhat erratic and not all of the high values occur during the runoff.

Surface Water Data Quality Assessment

Assuming that an appropriate TRV may become available, surface water data will be used to evaluate risk by characterizing the frequency and magnitude of HQ values above 1. In this regard, the TRV will be interpreted as being applicable to a 4-day average concentration. Thus, the ideal measure of LA in surface water would also be a series of 4-day average values. However, surface water collected to date are grab samples, which represent a concentration at only one point in time. In the absence of 4-day average concentration measurements, each grab sample will be evaluated as if it were an estimate of a 4-day average. This approach may either tend to overestimate or underestimate actual risk.

Data for surface water are considered adequate if three conditions are met:

- 1) the data provide a good representation of the spatial variability at different parts of the watershed within OU3
- 2) the data provide a good characterization of the variability as a function of time of year, with special attention of the time window that the most sensitive life stage is present
- 3) there are sufficient data to reliably characterize the magnitude and frequency of HQ values above 1 at a station or a reach

The existing surface data provide an good initial characterization of the temporal and spatial variability of LA concentrations in surface waters in OU3. Whether or not these data are sufficient for ecological risk assessment purposes can not yet be determined, because a TRV for

FINAL

LA in surface water is not yet available. For example, if the TRV is either much higher or much lower than the majority of measurements, it would be likely that an adequate risk characterization could be performed using the existing data set. However, if the TRV is found to be within the range of values seen in site water, then improved characterization of LA concentration levels and patterns over time and space might be needed to more accurately characterize the magnitude and frequency of any TRV exceedences.

Are Additional Surface Water Data Needed?

Based on the discussion above, the potential need for collection of additional data on LA levels in site surface waters to support ecological risk assessment can not be determined at present, and will be determined after the development of a reliable TRV for LA in surface water (see Section 4.2.2.4, below).

4.2.3.3 Site Specific Surface Water Toxicity Tests

Summary of Existing Data

As part of the Phase II Part A sampling effort (EPA 2008a), one site water was selected for use in site-specific toxicity testing. The water used was selected by monitoring the levels of LA as a function of space and time, and choosing a time and place that was believed to be near the high end of the range of concentrations observed in site waters.

The water sample selected for site-specific toxicity testing was collected from the tailings impoundment (TP) on May 8, 2008. Triplicate analysis of this sample for LA indicated the concentration was about 21 ± 6 million LA fibers per liter (MFL).

The toxicity test design is detailed in the Phase IIA SAP (EPA 2008a). The test was conducted with newly hatched larval (sac fry) rainbow trout (*Oncorhynchus mykiss*) under static renewal conditions for an exposure duration of 6 weeks. Survival, behavior and growth were observed during the exposure period. At the end of the test the histopathology of the fish were examined. During the larval stage water was changed once every 10 days and after swim up every three days for a total of seven “cycles”.

Results of the test are summarized in Parametrix (2009a). In brief, no significant effects on mortality, growth, or frequency of histological lesions were detected. However, measurement of LA levels in samples of water from the aquaria at the start and end of static renewal cycles 1 and 7 indicated that the concentrations of LA were not equal to the level expected (about 21 MFL), but were about 1 order of magnitude lower (1-2 MFL, see Table 4-1).

One possible explanation for the low levels of LA in the water samples is that there was a loss of fibers in the sample bottles after collection. In order to investigate this possibility, samples

FINAL

collected during the start (NEW) and end (OLD) of Cycles 2 and 4 were analyzed using a 3-step method.

Step 1: The sample bottle is gently swirled by hand to suspend any loose material and a 40 mL subsample is removed for TEM analyses. This sample is analogous to the samples evaluated for Cycles 1 and 7 (described above).

Step 2: A second 40 mL subsample is removed and placed in a clean beaker and sonicated for 15 minutes. The purpose is to disrupt and disperse any fibers that are in suspension but clumped together. The sample is then analyzed by TEM.

Step 3: A solution of 0.1 M NaCl + 0.1 M Graham's salt (sodium hexametaphosphate) is added to the sample bottle to restore the sample volume to the original level. The sample bottle is sonicated and treated with UV light and ozone in accord with EPA Method 100.1 Step 6.2. The intent of the treatment is to release and oxidize any microbial growth that may be present on the walls of the bottle that may have trapped fibers.

The results of the experiment are provided in Table 4-2. Inspection of these findings suggests the following:

- 1) There is a loss of fibers from the water in the sample bottles. However, this loss can be accounted for by calculating the total amount of LA in the bottles (in the water and on the bottle wall) and dividing by the volume of water in the bottle. The resulting value reflects the concentration in the aquarium at the time the sample bottle was prepared.
- 2) The concentration of LA in aquarium water at the start of Cycle 2 is similar to (actually, somewhat higher than) what was expected (32 MFL vs. 21 MFL). However, the concentration of LA in aquarium water at the start of Cycle 4 was decreased compared to what was seen for Cycle 2 (10 MFL vs. 32 MFL). These results suggest that there was a time-dependent loss of free fibers in the carboy used to hold the site water sample, with the loss beginning to be apparent sometime after the start of Cycle 2 (day 11 of the toxicity test).
- 3) Comparison of the NEW vs. OLD results within each Cycle shows there is a clear loss of fibers in the aquaria during each Cycle that can not be attributed to a loss in the sample bottle.

The reason for the time-dependent loss of fibers in the carboy, the aquaria, and the sample bottles is not certain. However, the release of fibers in the sample bottles by ozonation and sonication suggests that a microbial growth may be occurring that tends to clump fibers together and ultimately binds the fibers to the walls of the vessel.

Data Quality Assessment of Existing Data

Based on the observations described above, it is concluded that the concentrations of LA to which the test fish were exposed during the toxicity test were much lower than intended. Moreover, because of the complex and time-dependent pattern of loss (both in the carboy and in the aquaria), it is not possible to derive a reliable estimate of the actual exposures in the aquaria. Consequently, it is not possible to establish a no-effect concentration from the toxicity test, or to draw any reliable conclusions about the potential for LA to cause adverse effects on trout. Because of this, the existing site-specific fish toxicity test for LA is concluded to be inadequate.

Are Additional Site-Specific Surface Water Toxicity Tests Needed?

In general, site-specific toxicity tests are one of the best lines of evidence available for ecological risk assessment, especially for exposure of fish to water, and performance of a new site-specific study using site water (but preventing the loss of fibers) would potentially be valuable. However, it is suspected that the fiber loss observed during the first study may be a consequence of the fact that site waters are not sterile but contain a wide variety of microorganisms that flourish under laboratory test conditions. Consequently, it might be very difficult to develop a protocol that would allow successful toxicity tests using site waters. For this reason, additional toxicity testing using site water will not be performed during Phase III. Rather, tests using laboratory water spiked with LA will be used, as described below.

4.2.3.4 LA Spiking Study

A spiking study is different from a site-specific water toxicity test in a number of regards. First, laboratory water does not contain endogenous microorganisms, so growth of biofilm and any resultant problems may be diminished. Second, it is possible to control the concentration of LA in the spiking study more precisely than in a site water study. Third, the water in a spiking study contains only LA and not other potentially confounding contaminants that might be present in site waters. This makes it easier to interpret the results of a spiking study if adverse effects are observed. Finally, a spiking study can be performed using a flow-through design rather than a static renewal design, which helps minimize concern over the buildup of ammonia or other toxic byproducts, and may also help minimize microbial growth. Consequently, a spiking study has a number of potential advantages over a site-specific water toxicity study.

However, before implementation of a spiking study, it is necessary to determine if the study can be successfully performed without the loss of fibers that was experienced in the previous site-specific water test. For this reason, a pilot study will be conducted to measure the concentration of LA fibers in test chambers over time. This information will allow a determination of whether fiber loss occurs, and if so, when.

FINAL

A detailed protocol for the performance of the pilot study will be prepared by the testing laboratory and submitted to EPA for review and approval. The key features of the pilot study are listed below.

- Spiking material will be provided by the U.S Geological Survey (USGS). This material will utilize LA ore collected from the mine site, and will be ground and sieved to produce material with a particle size distribution (length and width distribution) that is generally similar to that seen in OU3 waters. Details of this spiking material including the source, the preparation methods, and the fiber size distribution, will be provided as a supplement to this SAP, when available.
- A series of 5 dilutions will be evaluated (100, 10, 1, 0.1 and 0.01 MFL), along with a laboratory control. The approach for preparation of a stock suspension to prepare these dilutions will be presented in the detailed protocol to be developed by the testing laboratory.
- A flow-through design will be used, with 4 replicate test chambers per dilution. The flow rate will be such that there are approximately 10 volumes of water exchanged per day in each test chamber. An air bubbler will be placed in each test chamber to help ensure LA fibers remain in suspension.
- One series of test chambers will contain water only (no fish). The second series will contain sac fry trout, and the third series will contain swim-up trout. Swim-up fry will be fed in accord with standard methods. The fourth series is not used in the pilot study.
- The pilot study duration will be 21 days. Starting on day 1 (the first day of the study), water samples will be withdrawn from near the center of a randomly selected test chamber for each dilution every 2 days, and promptly prepared for asbestos analysis by filtration through a 47 mm MCE filter with 0.2 μm pore size. Water volumes to be withdrawn for filtration are as follows:

Concentration (MFL)	100	10	1	0.1	0.01	0
Volume Filtered (mL)	5.0	50	200	200	200	200

- In order to obtain results in real time, all water samples will be analyzed by phase contrast microscopy (PCM) in basic accord with NIOSH Method 7400 using the PCM counting and stopping rules specified in NIOSH 7400 Method Modification 1, *Analysis of Water Samples for Asbestos by PCM* (see Attachment B). The approach for water sample preparation (e.g., sonication/ozone) will be presented in the detailed protocol to be developed by the testing laboratory. The expected structure counts for these PCM analyses are summarized below:

FINAL

Conc (MFL)	Vol (mL)	Loading		FOVs		Expected N
		s/mm2	s/FOV	Target	Actual	
100	5	386	3.03	33	33	100
10	50	386	3.03	33	33	100
1	200	154	1.21	83	83	101
0.1	200	15	0.12	825	200	24
0.01	200	1.5	0.01	8249	200	2

- Selected filters will also be analyzed by TEM to confirm the results. This will include one filter each from the 100, 10 and 1 MFL concentrations from days 1, 10 and 20 of the study (N = 9). Prepared TEM grids from each filter will be analyzed using the TEM counting and stopping rules specified TEM ISO 10312 Method Modification 1, *Analysis of Water Samples for Asbestos by TEM* (see Attachment B). The expected structure counts for these TEM analyses are summarized below:

Conc. (MFL)	Vol. (mL)	Loading		GOs		Expected N
		s/mm ²	s/GO	Target	Actual	
100	5	386	3.9	13	13	50
10	50	386	3.9	13	13	50
1	200	154	1.5	33	33	51

After the Pilot Study is completed, the results will be used to design the full-scale LA spiking study with fish. The purpose of this full-scale test will be to determine the no-effect and the low-effect concentration of LA in water, which will be used to develop a TRV for exposure of trout to LA in water. This TRV will in turn be compared to available measures of LA in site waters in order to characterize the frequency and magnitude of HQ exceedences. The detailed DQOs and detailed design of the full study will be specified in a supplement to this SAP.

4.2.3.5 Site-Specific Fish Population Studies

Summary of Existing Data

As part of the Phase IIC sampling effort (EPA 2008c), fish were collected by electroshock at 9 stream locations including two in upper Rainy Creek (URC-1A and URC-2), four in lower Rainy Creek (LRC-1, LRC-2, LRC-3, and LRC-5), one location downstream of the tailings impoundment (TP-TOE2) and at two reference locations (BTT-R1 and NSY-R1) (Figure 4-2 and 4-4). The results of this sampling event are provided in Parametrix (2009b).

Fish Populations

Fish were collected during Phase III using electroshock. The only type of fish captured at any station was trout. At stations located in OU3, this included rainbow trout (*Oncorhynchus mykiss*) and cutbow trout (a cross of Westslope Cutthroat Trout [*Oncorhynchus clarkii lewisi*] and

FINAL

rainbow trout). At one reference station, brook trout (*Salvelinus fontinalis*) were also captured. Cutthroat-Rainbow hybrids were the most numerous fish collected overall, followed by rainbow trout and brook trout. Population density estimates by species and location based show that the Lower Rainy Creek sites (LRC-1, LRC-2, LRC-3 and LRC-5) are estimated, in general, to have lower densities of fish species compared to either upstream sites or reference sites. There was a decrease in population density of fish > 65 mm and an apparent absence of young-of year fish (< 65 mm) in lower Rainy Creek compared to upper Rainy Creek and the reference streams.

Habitat Assessment

Variations in habitat can contribute to differences in fish populations between stations. Therefore a habitat assessment was completed as part of the Phase IIC SAP (EPA 2008c) using procedures from EPA's *Rapid Bioassessment Protocol* (RBP) (EPA 1989, 1999). Ten alternative measures of habitat quality were combined to yield a Habitat Assessment Score for each sampling location that reflects overall habitat quality. For each site sampling location a score as percent of reference was also calculated. This score indicates how closely habitat quality was matched to the reference station. The habitat assessment results are provided in Parametrix (2009b) and yielded the following conclusions:

- URC-1A and LRC-3 had higher habitat quality scores than either of the reference sites
- LRC-1 had the lowest habitat quality score, followed by LRC-5.
- All other OU3 sites (URC-2, TP-TOE2, and LRC-2) had similar total habitat assessment scores.
- For all OU3 stations, habitat was at least 84% of reference with most stations scoring above 92%, which indicates that habitat was similar across stations.

Data Quality Assessment of Existing Data

The fish population study performed to date provides a good initial estimate of fish population characteristics in OU3 and at two reference locations. However, because of the natural variability in fish populations over time and space, it is not appropriate to draw any strong conclusions from a single year's observations. Therefore, data from only this one study are not adequate to support this line of evaluation.

Are Additional Fish Population Studies Needed?

Based on the discussions above, additional fish population data for at least one additional year are required to help determine if the effects observed are reproducible and potentially significant.

In addition, because of the potential role of habitat variations between site and reference locations, a more detailed and quantitative habitat assessment is needed.

Data Quality Objectives for Fish Population Demographic Observations

Step 1: State the Problem

Comparison of fish population demographics at on-site locations with appropriate reference locations provides one valuable line of evidence for investigating if ecologically significant effects are occurring. Observations from fall of 2008 are presently available. However, fish populations are variable over time, so at least 2 years of data are needed to strengthen this line of evidence.

Step 2: Identify the Goal of the Study

The goal of the study is to collect additional data on fish populations at site and reference locations in order to improve the representativeness of the data so that comparisons between site and reference locations will have less uncertainty.

Step 3: Identify Information Inputs

Information needed to compare fish populations between two locations includes the following measures: density (number per unit area, mass per unit area), diversity (number of species present), condition (length and weight) and population age (or size) structure. In addition, because habitat is a key determinant of fish population status at any specified location, habitat data are also required at each station.

Step 4: Define the Bounds of the Study

Spatial Bounds: Fish population data are needed at the same sampling stations as specified in Phase IIA. This includes two stations in upper Rainy Creek (URC-1A and URC-2), four in lower Rainy Creek (LRC-1, LRC-2, LRC-3, and LRC-5), one location downstream of the tailings impoundment (TP-TOE2), and two at reference locations (BTT-R1 and NSY-R1).

Temporal Bounds: Fish populations may vary over time (season and year). In order to ensure that new (Phase III) observations are comparable to previous (Phase IIA) data, the Phase III sampling should occur at the same time of year (fall) as the Phase II study.

Step 5: Develop the Analytical Approach

The analytical approach is to compare various measure of fish population status at on-site locations with the corresponding measures at one or more reference locations. If statistically significant differences are found (site < reference), the next step is to seek to identify the most likely reason for the difference. The first factor to be considered is habitat. If differences in habitat are likely to account for observed differences in population parameters, then an influence

FINAL

of LA is likely to be minimal. However, if habitat differences are unlikely to account for observed population differences, then effects from LA or possibly other mining-related contaminants are considered to be the most likely cause.

Step 6: Specify Performance or Acceptance Criteria

In evaluating the results of fish population data, two types of decision errors are possible:

- A false negative decision error occurs when it is decided that there are no ecologically significant population level effects attributable to LA exposure, when in fact there are.
- A false positive decision error occurs when it is decided that there are ecologically significant population level effects attributable to LA exposure, when in fact there are not.

Because of the small size of the data sets that will be available after Phase III (N = 2 per station), the evaluation of the fish population data will depend in part on professional judgment rather than purely statistical techniques. That is, increased confidence will be placed in the data if variability within a station is low or if stations in the same reach tend to show similar results. Conversely, confidence will be decreased in results that are highly variable within a station, and if spatial patterns are not consistent between rounds.

Step 7: Develop the Plan for Obtaining the Data

Detailed Study Design

Sampling Locations

Fish will be collected in the same locations and in the same manner that they were collected as part of the Phase IIC SAP (EPA 2008c). Fish will be collected at 9 stream locations including two in upper Rainy Creek (URC-1A and URC-2), four in lower Rainy Creek (LRC-1, LRC-2, LRC-3, and LRC-5), one location downstream of the tailings impoundment (TP-TOE2), and at two reference locations (BTT-R1 and/or NSY-R1).

Fish Shocking Protocol and Field Data Recording

Fish will be collected using electroshock according to the procedures specified in SOP FISH-LIBBY-OU3. For each fish collected at each sampling station, the following information will be recorded by field personnel:

- The species. If the species can not be identified, the family should be recorded (e.g., “unknown trout”)
- The size (weight and length)

FINAL

- The gender (if possible)
- The occurrence of any observable external abnormalities.

In addition to the fish shocking procedures, small fish will be collected using small barrel or minnow traps as specified in an SOP (FISHTRAP-LIBBY-OU3) which will be prepared by Remedium and submitted to EPA for review and approval. The same information will be recorded (where possible) on these smaller fish.

Habitat Assessment

Habitat quality is not expected to vary substantially over time. However, habitat scoring may be variable, with scores largely dependant on the interpretation and observations of the personnel completing the scoring. For this reason, repeat collection of habitat parameters will be performed as part of Phase III. The habitat parameters will be collected using the same methods as those used in 2008, but by different individuals to identify agreement between independent observations and the degree of variability between sampling personnel.

In order to provide additional information on habitat quality and to better interpret differences in fish populations between site and reference, several additional measures of habitat quality will also be collected, including:

- The existence and location of any barriers to fish migration will be mapped and described so effects on fish populations may be assessed.
- Quantitative characterization of overhead cover estimated using a densitometer as specified in an SOP (SOP-COVER-OU3) which will be prepared by Remedium and submitted to EPA for review and approval.
- Stream substrate size distribution and embeddedness as quantified using a pebble count as specified in an SOP (SOP-PEBBLE-OU3) which will be prepared by Remedium and submitted to EPA for review and approval.
- Stream velocity measured from 10 points in each stream reach to better characterize velocity depth regimes. Stream velocity will be measured as specified in OU3 SOP No. 4.

For the later three measurements, the quantitative values will be used in the scoring of habitat quality as part of the habitat assessment score. The information on possible barriers will be used as one potentially relevant factor to be considered in the interpretation of any differences in fish population parameters between sampling sites.

Analytical Requirements

No chemical analyses are performed in a fish population study.

Quality Control

There are no quality control samples associated with fish population surveys.

4.2.4 Exposure of Benthic Invertebrates to Asbestos

4.2.4.1 Data That Are Valuable for Evaluating the Effects of Asbestos on Benthic Invertebrates

As discussed in the Problem Formulation document (EPA 2008d), three types of data are valuable when seeking to evaluate risks to benthic invertebrates from exposure to LA in sediment:

- Asbestos concentrations in sediment of site ponds and streams, coupled with a reliable TRV for sediment by which to evaluate the measurements
- Site-specific sediment toxicity tests with benthic invertebrates
- Multiple years of benthic invertebrate community demographic observations

The following sections discuss the availability of each type of data and the plans for collection of additional data during the Phase III effort.

4.2.4.2 LA Concentrations in Sediment

As noted above, at present there is no TRV for exposure of benthic organisms to LA in sediment. However, a site-specific sediment toxicity test has been completed (see Section 4.2.4.3, below), and this study may be adequate to derive a no-effect concentration for LA in sediment. Consequently, data on asbestos in sediment may provide an important tool for evaluation of LA risks to benthic organisms. A data quality assessment for LA in sediment is presented below.

Summary of Existing Data on LA in Sediment

In Phase I, sediment samples were collected from 17 locations in the Rainy Creek watershed and analyzed for LA. Phase II sampling was more extensive, with multiple samples collected from each of the ponds and multiple rounds of sampling at each station. In Phase II, samples were collected in both spring and summer (round 1 and 2) with some locations sampled an additional time in the fall (round 3).

Prior to analysis, sediment samples were divided into two fractions (coarse and fine) by sieving. Concentrations of LA in the coarse fraction were measured gravimetrically and expressed as a mass percent (grams of LA per 100 grams of coarse fraction). Concentrations in the fine fraction were measured using polarized light microscopy using a visual area estimation approach (PLM-VE). Results for PLM-VE are expressed as mass percent if the concentration is 1% or higher. If

FINAL

the estimated concentration is <1%, the results are expressed semi-quantitatively, according to the following scheme:

PLM-VE Result	Range of Mass Percent
Bin A (ND)	None detected (likely < 0.05%)
Bin B1 (Trace)	LA detected, > 0% but < 0.2%
Bin B2 (<1%)	LA detected, >0.2% but < 1%

Results that are >1% are categorized as Bin C. The raw sediment data are provided electronically in Appendix A. Table 4-3 summarizes the PLM-VE results for each sampling location. These results are also presented spatially in Figure 4-6 for the Rainy Creek watershed and Figure 4-7 for the tailings impoundment. Examination of the data reveals that asbestos contamination in sediments is widespread. The highest LA concentrations are observed in all ponds (Mill Pond, Carney Creek Pond, Tailings Impoundment and Fleetwood Creek Pond), the toe of the Tailings Pond (TP-TOE) and in the headwaters of Carney Creek (CC-1).

Data Quality Assessment for LA in Sediment

Available data on the concentration of LA in sediment provide good spatial and temporal representativeness. The numbers of samples available at each station are adequate to allow an evaluation of the likely magnitude and frequency of exceedences of the TRV (HQ>1) .

Are additional Data on LA in Sediment Needed?

Based on the evaluation above, no additional data on LA in sediment are needed.

4.2.4.3 Site-Specific Sediment Toxicity Data

Summary of Existing Data

As part of the Phase II Part C sampling effort (EPA 2008c), sediments were collected from two site sampling locations (CC-1 and TPTOE-2) for sediment toxicity testing. These locations had the highest measurements of LA in the Phase I or Phase IIA sampling efforts. Sediments were also collected for testing from two reference sites (BTT-R1 and NSY-R1). Sediment samples were tested for toxicity using the amphipod *Hyaella azteca* in a 42-day test for measuring the effects of sediment associated contaminants on survival, growth and reproduction (EPA Test Method 100.4; EPA 2000). Sediment samples were also tested for toxicity to the midge *Chironomus tentans* using the life-cycle test for measuring effects on survival, growth and reproduction (EPA Test Method 100.5; EPA 2000).

FINAL

Characterization of Test Sediments for Toxicity Testing

The test sediments submitted for testing were analyzed for asbestos using PLM-VE. Asbestos was not detected in the samples from the two reference sites BTT-R1 and NSY-R1. Asbestos concentration was estimated to be 5% in the sample from CC-1 and 3% in the sample from TP-TOE2.

*Test Results for the Midge (*Chironomus tentans*)*

The details of the test results are provided in Parametrix (2009c). The test was conducted according to the study protocol (EPA 2008c). The exposure was for 52 days from November 14, 2008 through January 5, 2009. Endpoints for the study included survival, growth, emergence, and reproduction. Following exposure to Libby OU3 sediments, CC-1 and TP-TOE2, *C. tentans* did not exhibit any statistically significant difference in survival, growth, or reproduction when compared to both laboratory control sediments and field-collected reference sediments. The results are summarized in Table 4-4.

*Test Results for the Amphipod (*Hyalalella azteca*)*

The details of the test results are provided in Parametrix (2009d). The test was conducted according to the study protocol (EPA 2008c). Effects on the survival (at 28, 35 and 42 days), growth (at 28 and 42 days) and reproduction (at 35 and 42 days) of *H. azteca* were assessed. Following exposure to site sediments with LA, the survival, growth or reproduction of the exposed organisms were not negatively affected when compared to control or reference sediments. The results are summarized in Table 4-5.

These results suggest that the effect level for LA in sediment on benthic organisms is likely to be higher than 3-5%.

Data Quality Assessment for Existing Data

The site-specific toxicity tests described above were well-performed, and no significant problems or deviations occurred during the studies. Therefore, these data are concluded to be of adequate quality for use in the risk assessment.

Are Additional Site-Specific Sediment Toxicity Tests Needed?

The results of the existing sediment toxicity test do not show any significant effects on either benthic test species in comparison to field and laboratory controls. Because the exposure concentrations were at the high end of concentrations of LA in sediments observed on site, further testing to identify a concentration-response relationship is not needed. The current tests

and results are sufficient to evaluate risks for benthic invertebrates using this line of evidence (site-specific toxicity).

4.2.4.4 Benthic Invertebrate Community Demographic Observations

Summary of Existing Data

As part of the Phase II Part C sampling effort (EPA 2008c), benthic invertebrates were collected at 9 stream locations including two in upper Rainy Creek (URC-1A and URC-2), four in lower Rainy Creek (LRC-1, LRC-2, LRC-3, and LRC-5), one location downstream of the tailings impoundment (TP-TOE2), and two at reference locations (BTT-R1 and NSY-R1). The benthic invertebrate data were collected and analyzed according to EPA's *Rapid Bioassessment Protocol* (RBP) (EPA 1989, 1999). In the RBP approach, a number of alternative metrics of benthic community status are combined to yield a Biological Condition Score. As described previously, ten alternative measures of habitat quality are combined to yield the Habitat Assessment Score. The biological condition score is evaluated compared to habitat assessment score based on information on reference areas (to understand what biological condition score is expected under habitat conditions). Variations in habitat can contribute to differences in benthic invertebrate community metrics between stations.

The details and results of the benthic invertebrate collections are provided in Parametrix (2009b). The following conclusions were made concerning the benthic invertebrate community:

- The lower Rainy Creek sites (LRC-1, LRC-2, LRC-3 and LRC-5) had lower taxa richness and Ephemeroptera, Plecoptera, Trichoptera (EPT) taxa richness than the reference sites (BTT-R1 or NSY-R1).
- The biological condition scores for benthic invertebrate communities in lower Rainy Creek (TP-TOE2, LRC-1, LRC-2, LRC-3 and LRC-5) were lower than both of the reference sites (BTT-R1 or NSY-R1) and upstream Rainy Creek (URC-1A or URC-2).
- Biological condition categories were assessed for each of the OU3 sites in relation to each reference site. The benthic communities in lower Rainy Creek were classified as either slightly or moderately impaired. The upper Rainy Creek sites were classified as not impaired.
- Habitat assessment scores (sum of ten individual scores for habitat quality) were highest at one upstream Rainy Creek site (URC-1A) and one Lower Rainy Creek site (LRC-3) compared to the reference sites (BTT-R1 and NSY-R1).
- Habitat assessment scores were lowest at LRC-1 and LRC-5. Scores for all other sites were similar to reference.
- Overall habitat conditions at all sample locations were only slightly different between locations based on habitat assessment scores.

FINAL

- Correlation analyses found correlations between sediment quality parameters (percent silt, clay and elevation) and some macroinvertebrate community metrics however there were not enough observations to be conclusive.

Data Quality Assessment of Existing Data

The benthic macroinvertebrate community study performed to date provides a good initial estimate of invertebrate community characteristics at multiple locations in OU3 and at two reference locations. However, because of the natural variability in benthic communities over time and space, it is not appropriate to draw any strong conclusions from a single year's observations. Therefore, data from only this one study are not adequate to support this line of evaluation.

Are Additional Benthic Population Data Needed?

Based on the evaluation above, additional benthic invertebrate community data of at least one additional year are required to help determine if any effects observed are reproducible and potentially significant. In addition, a re-characterization of habitat quality is needed, using the same method as used previously, supplemented with additional quantitative measures to strengthen the ability to interpret the population data.

Data Quality Objectives for Additional Benthic Invertebrate Population Study

Step 1: State the Problem

Comparison of benthic invertebrate community demographics at on-site locations with appropriate reference locations provides one valuable line of evidence for investigating if ecologically significant effects are occurring. Observations from fall of 2008 are presently available. However, population data tend to be variable over time, so at least 2 years of data needed to strengthen this line of evidence.

Step 2: Identify the Goals of the Study

The goal of the study is to collect additional data on the status of the benthic community on-site and at reference locations in order to judge whether the on-site communities are similar to or are impaired relative to reference communities.

Step 3: Identify the Information Inputs

The data needed to support the goal of the study include detailed information on the types (species or class) and the abundance of benthic organisms at site and reference areas. Because of the inherent variability of invertebrate populations and communities, observations are needed

FINAL

from multiple years in order to ensure the data are representative of the long-term average condition. In addition, data on habitat characteristics are needed at each station in order to assess the possible contribution of habitat to any observed difference in community status.

Step 4: Define the Bounds of the Study

Spatial Bounds: Benthic invertebrate data and habitat data are needed at the same sampling stations as were studied in Phase IIC (EPA 2008c). This includes two stations in upper Rainy Creek (URC-1A and URC-2), four in lower Rainy Creek (LRC-1, LRC-2, LRC-3, and LRC-5), one location downstream of the tailings impoundment (TP-TOE2), and at two reference locations (BTT-R1 and NSY-R1).

Temporal Bounds: Benthic invertebrate community parameters may vary over time (season and year). In order to ensure that new (Phase III) observations are comparable to previous (Phase IIA) data, the Phase III sampling should occur at the same time of year (fall) as the Phase II study.

Step 5: Develop the Analytic Approach

The analytic approach used to evaluate benthic invertebrate population data is described in Barbour et al. (1999). In brief, a number of different metrics of benthic community status at each station are calculated and expressed as a score. This score will be equal to the Mountain Multimetric Index (MMI) as recommended by MDEQ for the evaluation of mountain stream conditions in Montana using stream invertebrates (Jessup et al. 2006, MDEQ 2006). The sum of the scores across all metrics represents the overall biological condition score.

The MMI values will be evaluated both by comparison to the OU3 reference locations (BTT-R1 and NSY-R1) and also to MMI scores compiled by the State for a number of other reference mountains streams in Montana. In addition, the scores will be evaluated based on a consideration of habitat quality. Habitat quality scores will be available for both on-site and reference streams in Libby, and may also be available for the State reference streams, following the basic approach suggested by EPA (1999).

Step 6: Specify Performance or Acceptance Criteria

In evaluating the results of benthic invertebrate population data, two types of decision errors are possible:

- A false negative decision error occurs when it is decided that there are no ecologically significant population level effects attributable to LA exposure, when in fact there are.

FINAL

- A false positive decision error occurs when it is decided that there are ecologically significant population level effects attributable to LA exposure, when in fact there are not.

Limits on decision errors are usually controlled using statistical methods. However, because there will be only two rounds of data available, statistical analyses may have only limited potential to identify significant effects, so the evaluation of the benthic invertebrate community data will also depend in part on professional judgment as well as statistical techniques. That is, increased confidence will be placed in the data if variability within a station or a reach is low, if results tend to be similar between years, or if there are clear spatial trends in the data. Conversely, confidence will be decreased if results are highly variable within a station or reach, if results tend to differ between years, or if patterns are not consistent over space.

Step 7: Develop the Plan for Obtaining Data

Detailed Study Design

Sampling Locations

Benthic invertebrate samples will be collected from 9 stream locations (Table 4-6) including two in upper Rainy Creek (URC-1A and URC-2), four in lower Rainy Creek (LRC-1, LRC-2, LRC-3, and LRC-5), one location downstream of the tailings impoundment (TP-TOE2), and at two reference locations (BTT-R1 and NSY-R1).

Benthic Invertebrate Collection Method

Samples will be collected according to the procedures in SOP BMI-LIBBY-OU3 (Attachment B), which is the same method used in 2008. A number of metrics of benthic community status will be calculated for each sampling station and combined to yield a Biological Condition Score (equal to the MMI as described in MDEQ 2006).

Habitat Information

A number of measures of habitat quality will be obtained at each sampling location to yield a Habitat Quality Score using the same method as used previously in 2008. However, the visual scoring will be completed by a different individual(s) than the person(s) who completed the 2008 scoring. Habitat information will be collected as described in SOP BMI-LIBBY-OU3.

Additional habitat information (not collected previously) will include:

FINAL

- Quantitative characterization of overhead cover estimated using a densitometer as specified in an SOP (SOP-COVER-OU3) which will be prepared by Remedium and submitted to EPA for review and approval.
- Stream substrate size distribution and embeddedness as quantified using a pebble count as specified in an SOP (SOP-PEBBLE-OU3) which will be prepared by Remedium and submitted to EPA for review and approval.
- Stream velocity measured from 10 points in each stream reach to better characterize velocity depth regimes. Stream velocity will be measured as specified in OU3 SOP No. 4.

Analytical Requirements

No chemical analyses are to be performed in the benthic invertebrate community study.

Quality Control

Voucher specimens will be maintained as part of the benthic invertebrate identification effort for potential future confirmation of genus or species assignments, if needed.

4.2.5 Exposure of Mammals to Asbestos

4.2.5.1 Strategy of the Phase III Investigation

EPA considered several alternative strategies for an investigation of risks to mammals in OU3.

First, EPA considered whether it was necessary to characterize risk at multiple locations in OU3 (selected to include a range of measured LA concentration levels) to support risk management decisions, or whether collection of data from only two locations (area of highest measured LA concentrations vs. reference) would be sufficient. EPA determined that collection of data from only two locations (area of highest measured LA concentrations vs. reference) was the most appropriate first step. If no ecologically significant effects on mammals are observed in animals from the area of highest measured LA concentrations, then additional field investigations of mammals are unlikely to be needed. If ecologically significant effects are observed, then additional studies at multiple locations may be needed to establish either an exposure response relationship, or to derive an empiric map of the extent of the impact.

Next, EPA considered where the study area should be located. Three locations were considered: a) on the mined area, b) in the forest area surrounding the mine, and c) along streams and ponds. EPA determined that a study of risks to mammals from LA along streams and ponds was not a high priority because risk management decisions regarding ecological risks from LA in surface water and sediments along streams and ponds are likely to be determined mainly by risks to aquatic receptors, rather than to mammals. Similarly, a study in the mined area was not

FINAL

considered to be high priority because the mined area is heavily disturbed and the habitat for small mammals is substantially altered. Although a colony of Columbia ground squirrels (*Spermophilus columbianus*) have been observed in the disturbed mine area, the area occupied by these receptors represents only a small portion of the mined area, so a study of these receptors would have only limited utility in decision-making. In contrast, the forested area impacted by releases of LA is substantially larger than the mined area and habitat is not altered by mining. The habitat is suitable for a wide range of mammalian receptors. Based on these considerations, EPA determined that a study in the forested area would be most useful for risk-management decision making. Such a study will help answer the question of whether response actions need to be developed and evaluated to address unacceptable risks to mammals within the forested area. A final decision regarding the potential need for an evaluation of risks to mammals within the mined area will be deferred until the results for small mammals are available from the forested area.

4.2.5.2 Data That Are Valuable for Evaluating Effects of LA on Mammals

As discussed in the Problem Formulation (EPA 2008d), a weight of evidence approach will be used to evaluate ecological risks within OU3. One potential line of evidence used for mammals is the computational hazard quotient (HQ) approach. This approach requires a) accurate and representative measures of exposure (dose) of ecological receptors to site media, and b) a reliable dose-response relationship for an ecologically relevant response (a decrease in growth, reproduction and/or survival). However, in the case of LA, neither of these two types of data is presently available for mammals. Because of this, other lines of evidence will be considered to evaluate potential risks to mammals from LA in OU3. The other lines of investigation under consideration are laboratory-based oral and inhalation toxicity studies of LA in mammals, site-specific population studies, and measurements of *in-situ* exposure and effect.

The Phase III data collection program is focused on measurements of *in-situ* effects and possibly exposure. The goal is to determine if individual mammals from the LA-contaminated forested area have higher incidence and severity of histological lesions and/or gross deformities than mammals from a reference area. If needed to determine whether observed effects are related to exposure to LA, *in-situ* exposures (tissue burdens of LA) may be evaluated.

4.2.5.3 Summary of Existing Data

There are no existing data on *in-situ* measures of either effects (histological lesions) or exposure (tissue burden of asbestos) in mammals at OU3.

4.2.5.4 Data Quality Objectives for Small Mammals

Step 1: State the Problem

Mining operations at OU3 have resulted in the release of LA to the forested area surrounding the mine site, impacting soils, tree bark, and duff. Mammals in the forest area may be exposed to asbestos from contact with these media (mainly soil and duff) both via inhalation and ingestion. However, it is not known if exposures to LA in these media cause unacceptable asbestos related lesions in small mammals when compared to a reference location. The problem to be resolved is: Do the concentrations of LA at the Libby OU3 site cause unacceptable asbestos-related effects in small mammals when compared to a reference location?

Step 2: Identify the Goals of the Study

The Phase III investigation is a focused investigation of effects in one area of the surrounding forested area that, based on measured concentrations of LA in duff, is maximally contaminated, and to compare the results from this area to an appropriate reference area. Because the area selected would capture maximal exposure levels, if no adverse effects (related to assessment endpoints) are observed in comparison to reference, then further investigations would not be needed (i.e., exposures within areas with lower levels of LA would be less than those in the highest impacted area). If adverse effects (related to assessment endpoints) are observed, then a follow-up study to determine an LA concentration protective of small mammals and an area of concern (spatial) might be required to support risk management decisions.

A secondary goal (conditional on the finding that potentially significant effects are occurring in animals from the contaminated area) is to confirm LA exposure in the animals from the contaminated area (by measuring LA in tissues) compared to the reference area. This information will be collected if needed to help determine if the observed effects are attributable to LA exposure.

Step 3: Identify the Types of Data Needed

The data needed to support the primary study goal are quantitative measures of the frequency and/or severity of histological lesions in mammals collected from an area of OU3 that is contaminated with highest levels of LA in duff in the forested area surrounding the mined area and from a reference location where LA contamination is either zero or negligible.

The data needed to support the secondary goal are reliable measures of the LA in tissues in which the effects are observed.

Step 4: Define the Boundaries of the Study

Spatial Bounds

In order to maximize the probability of detecting *in-situ* effects if they are present (and minimize the chance of a false negative), it is necessary to collect mammals at a location where exposures to asbestos are expected to be highest. If *in-situ* effects are not observed in the area of highest LA contamination then it is unlikely that effects will be measured in areas of lower LA contamination. Figure 3-4 summarizes the available data on the levels of LA in forest duff, soil and tree bark at OU3. As shown, the highest levels of LA are observed in the area just north (downwind) of the mined area). Based on the duff data, the collection of mammals will occur within a polygon bounded by four sampling locations where the highest LA concentrations have been measured in duff. The four sampling locations and their corresponding LA concentrations in duff are:

Station	Duff (% LA)
SL-15-02	3.65%
SL-45-02	1.74%
SL-45-03	4.27%
SL-75-03	3.52%

This set of 4 stations bounds a polygon that is roughly triangular in shape and covers an area of about 716,000 m² (72 Ha).

The reference area should be matched as closely as possible to the habitat of the forested area north of the mined area, but must be located cross-wind or upwind of the mined area, and far enough from the mined area (e.g., > 5 miles) that contamination with LA is zero or negligible. This distance will also ensure that mammals collected at the reference will represent a separate local population from that sampled north of the mine. The reference trapping area should be similar in size as the trapping area north of the site (about 72 Ha). The exact location will be selected during an initial field reconnaissance and will be subject to approval by EPA.

Temporal Bounds

The asbestos contamination of forest soils and duff is not expected to vary with time. However, the level of exposure of mammalian receptors to environmental media is expected to vary over time. For example, weather may influence the releaseability of LA from duff into the breathing zone of mammals, and activity patterns may vary over seasons. Based on these considerations, the Phase III sampling of mammals should occur in late summer (August or September, no later than September 15) when releaseability is likely to be high (due to dry weather) and when small mammals populations are at peak levels.

Target Species

There are many different species of mammalian receptors that may be exposed to LA in OU3, but it is neither feasible nor necessary to attempt to collect organisms from each species. Rather, attention will be focused on species most likely to be maximally exposed to asbestos in soils and forest duff. As part of the Problem Formulation (EPA 2008d) selection criteria were specified and used to identify the species most likely to be maximally exposed to asbestos in forest duff. It is expected that the most exposed species are non-transitory, have a small home range, forage on the ground, burrow into the ground or create shallow runs under forest litter, and have a small body weight. Taking these criteria into account, ground foraging mammals were identified as the mammalian receptor group most likely to be exposed to asbestos. Of the ground foraging mammals identified within Lincoln County, Montana, the most common species reported are the deer mouse (*Peromyscus maniculatus*) and the southern red-backed vole (*Clethrionomys gapperi*). These two species are identified as the target species.

Results for these two target species will be utilized to evaluate the potential risks to all ground-dwelling mammals, and may also be used to estimate potential effects on other mammalian species that may be exposed in OU3 (taking differences in exposure patterns and feeding behaviors into account).

Target Tissues for Histopathology Examination

Attachment D provides a summary of studies that have been performed in laboratory rodents to identify the effects of inhalation and oral exposure to various types of asbestos (but not LA). The following provides a summary of the data reviewed in Attachment D:

- For inhalation exposures to asbestos (amosite, chrysotile, crocidolite, or anthophyllite) eighteen chronic studies were reviewed. There are no studies available for exposures to LA. With one exception, the only tissues examined in these studies were the lung and mesothelium. One study examined the gastrointestinal tract.
- Following inhalation exposure (at doses where effects were observed) the histological lesions include a) pleural and interstitial lung fibrosis, b) lung cancer (adenomas, adenocarcinomas, or squamous cell carcinomas), and c) pleural and peritoneal mesothelioma.
- For oral exposures to asbestos (amosite, chrysotile, tremolite, or crocidolite) eleven chronic studies were reviewed. Of these, five are National Toxicology Program (NTP) studies that examined several tissues including gastrointestinal tract, nervous system, endocrine system, reproductive organs, respiration system, heart, liver and kidneys.

FINAL

- Following oral exposure, there is generally little or no evidence of histological or clinical injury to any systemic tissues, with the possible exception of effects on the gastrointestinal tract. For example, a series of lifetime feeding studies in rats and hamsters did not observe any systemic lesions except for benign adenomatous intestinal polyps in the large intestines of male rats. Studies by other researchers have reported signs of injury to the colon including inflammation, benign productive peritonitis, increases in aberrant crypt foci (putative precursors of colon cancer), and colon cancer (carcinomas, adenomas and adenocarcinomas).

Based on these findings in laboratory animals, it is expected that the primary target tissues of inhalation and oral exposure of rodents to asbestos are the pulmonary tract and the gastrointestinal tract. Other possible target tissues are those where pathologic changes were noted but were determined not to be of biological importance in the lab study because 1) a similar incidence of pathology was observed in temporal and/or pooled controls or 2) lesions were not observed in target organs. In the studies reviewed, these types of observations were made for effects on the thyroid and adrenals. EPA believes it is appropriate to include these tissues as well as the primary target tissues (pulmonary tract and gastrointestinal tract) in the tissues examined for potential effects in the field collected small mammals. The list of target tissues for collection from the field collected mammals (deer mouse and red-backed vole) includes the following:

- Complete pulmonary tract
- Complete gastrointestinal tract
- Thyroid, and
- Adrenals.

After collection of the target tissues, the remaining individual organism will be preserved in the event that the histologic findings or other future concerns suggest the need to examine other tissues in the future.

Step 5: Develop the Analytical Approach

The analytical approach is to compare the nature, frequency, and/or severity of histopathological lesions in animals collected from the LA-contaminated study area with that for animals from the reference area. Possible outcomes of this analysis are listed below.

- Outcome 1: There are no statistically significant differences in histopathological effects, and there are no effects that are definitively LA-related (even if not statistically significant). In this case, it will be concluded that adverse effects of LA on mammals are either absent or minimal in OU3, and that no further investigation is needed.
- Outcome 2: Statistically significant differences are observed, and/or effects are observed that are definitively caused by LA (even if not statistically significant). In this event, the

FINAL

nature and severity of the effects will be evaluated to determine if the effects are likely to result in an impact on growth, reproduction or survival of the individual. If so, then further investigation may be needed to determine: a) if LA is the cause of the lesions (e.g., by measuring LA tissue burdens in the exposed animals), b) whether the effects result in an ecologically significant effect on the population, and if so, c) to characterize the spatial extent of ecologically significant impacts as may be necessary to support risk management decisions.

Step 6: Specify Performance or Acceptance Criteria

When comparing two data sets (site *vs.* reference), two types of decision errors are possible:

- A false negative decision error occurs when it is decided that there are no important differences between site and reference, when significant differences actually do exist
- A false positive decision error occurs when it is decided that important differences do exist between site and reference, when no significant differences actually exist

As discussed in EPA (2002), the probability of decision errors when comparing two data sets (site *vs.* reference) is controlled by the selection of the null hypothesis, and by selection of an appropriate statistical method to test the null hypothesis. Two alternative forms of null hypothesis are possible:

- Form 1: The null hypothesis is that no difference exists between site and reference. A confidence level of $100(1-\alpha)\%$ is required before the null hypothesis is rejected and it can be declared that the site data are higher than the reference data.
- Form 2: The null hypothesis is that the site is higher than reference by some amount (S) that is considered to be biologically significant. A confidence level of $100(1-\alpha)\%$ is required before the null hypothesis is rejected and it is declared that that the difference between site and reference, if any, is smaller than S.

For the purpose of this effort, the Form 1 null hypothesis is selected for use because it is the most familiar, is the easiest to interpret, and does not require specification of an effect that is presumed to be significant. In accord with EPA (2002), when the Form 1 null hypothesis is used, it is appropriate to select a value of α that is somewhat higher than the usual value of 0.05, such that marginal differences between site and reference are more easily identified as being significant. In accord with this, α is set to 0.20.

FINAL

Step 7: Develop the Plan for Obtaining Data

Statistical Test

The statistical test that is most appropriate for comparing histological lesions and tissue burdens (if needed) in animals from the site with animals from the reference area can not be determined with certainty until the data are obtained. However, for the purpose of designing the sample collection program, it is assumed that the most appropriate method for dichotomous endpoints (e.g., each animal is classified either having or not having a particular lesion) will be the Fisher Exact Test. For continuous endpoints (e.g., histopathological scores are assigned to each animal evaluated), it is assumed that most appropriate test will be the Wilcoxon Rank Sum (WRS) test (EPA 2002). This is a non-parametric test that is well-suited for comparison of data sets from a site and a reference area. This test would also be well-suited to a comparison of tissue burden data, if needed.

Because it is expected that a histopathological score will be generated for each animal that will reflect the lesions observed, stratified by tissue type, the severity of each lesion, the pathogenesis of the lesion, and significance, it is expected that the WRS test will be the primary test used in data analysis.

Number of Individuals to be Collected

The power of the WRS test to identify a difference between the site and the reference area depends on the number of observations (i.e., number of animals) in each data set and the variability between the observations. Figure 4-8 shows Test Performance Plots (EPA 2002) that indicate the probability that a statistically significant difference ($p < 0.20$) will be detected between the site and the reference area as a function of the number of animals collected in each data set, the degree of variability between animals within each data set (as reflected in the coefficient of variation, or CV), and the magnitude of the difference between site and reference. As shown, if between-animal variability is low (CV = 0.1, Panel A), then a difference of 20% between site and reference can easily be recognized by collection of as few as 5 animals per area. However, if variability is higher (e.g., CV = 0.6, Panel C), then it would be necessary to collect about 30 animals per area in order to have a high probability (> 90%) of detecting even a 50% difference. Increasing animal number to 50 would offer only a small increase in power to detect a 50% difference, but would not be enough to allow reliable detection of a 20% difference.

At present, no data are available on the degree of variability in histopathological score between animals within an area, or on the potential magnitude of difference between animals from site and reference areas. In the absence of data, it's assumed that the variability in histopathological score between animals within an area is high since exposures are likely to be quite variable. Given this assumption, the target number of animals per area is selected to be 30. Unless the CV is substantially greater than 0.6, this should provide sufficient power to detect a difference of

FINAL

50% or less with a probability of about 90% or more using the WRS test. Based on this, the goal is to collect 30 individuals for each of the two target species (deer mouse, red-backed vole) in each area. The total number of individual mammals to be collected is 120.

At present, it is not known whether gender is an important factor that influences the level of exposure or effect. In the absence of information, it is assumed that between-gender variation is not likely to be substantial, and that the data from males and females can be combined into one data set. Therefore, to ensure representativeness, the goal is to collect 15 males and 15 females of each species in each area. If important differences are detected between gender and it is appropriate to stratify the data on this basis, the power of the test to detect differences may be decreased, and additional study might be needed.

To the extent possible, individuals selected for histopathological evaluation should include only adults, with a preference for the largest (heaviest) individuals. This will help ensure that the individuals studied have been exposed for a maximal period of time.

4.2.5.5 Detailed Sampling Design

Initial Field Reconnaissance

Prior to the small mammal trapping effort, an initial field reconnaissance will be completed to map the bounds of the on-site sampling location, to select and map the bounds of the reference area, and to establish trap locations in each area. Key features of the small mammal trapping are discussed in the following sections. The results of the field reconnaissance will be detailed in a report that will be submitted to EPA and MDEQ for review and will be subject to EPA approval. The field reconnaissance report will provide additional details concerning the small mammal trapping program to be performed including trap type, the number, arrangement and spacing of traps, measurements on mammals collected, and gross necropsy and the collection of tissues for histopathological examination.

Trap Type

Small mammal collection at Libby OU3 will use a mixture of Sherman Live traps and Havahart traps. Both trap types are effective for capturing small terrestrial mammals unharmed (Jones et al. 1996). Live trapping is selected for the Phase III investigation to ensure that captured animals are suitable for gross and histological examination, since animals collected from kill traps begin to decompose quickly, making tissue examination impossible.

Number, Arrangement, and Spacing of Traps

Although the exact number and arrangement of traps will be detailed in the final field reconnaissance report, as a guide each sampling area (site, reference) should be trapped using at

FINAL

least 100 traps. Traps should be arranged to provide good spatial coverage across the entire trapping area, using trap lines. Assuming a total of 100 traps, the average inter-trap distance should be about 100 m. However, exact trap locations may be adjusted based on a consideration of the habitat in the vicinity of each target location, as well as the accessibility and safety for the field crews.

Trapping Effort

Traps will be set in the evening at dusk and collected in the early morning. The trapping will continue until the target number of organisms is obtained. If the target number of organisms cannot be obtained after sampling over a period of 5 days, then EPA should be contacted to discuss potential changes in the sampling design.

Measurements on Mammals Collected in Traps

For all traps that are found to contain a small mammal of any type, the species will be recorded. All individuals that are not target species (deer mouse or red-backed vole) shall be promptly released.

All traps that are found to contain an individual of either target species (deer mouse or red-backed vole) will be promptly transported in the trap to a pre-established necropsy and tissue preparation station. In order to ensure examination of older individuals, only adults will be sampled and those with the highest weights (without fetuses) will be selected for gross necropsy and the collection of target tissues. Each of the selected animals will be sacrificed and subjected to prompt necropsy and collection of target tissues for histopathology and potential tissue burden analysis. Animals not selected for analysis will be sacrificed and properly disposed of.

Gross Necropsy and Collection of Target Tissues

Selected animals will be sacrificed for the examination of gross pathology and the collection of target tissues (described previously) for histopathology examination. The details of the examination and collection of tissues is described in SOP MAMMAL-LIBBY-OU3.

Each of the target species collected will be sacrificed by carbon dioxide asphyxiation followed by cervical dislocation. A gross necropsy will be performed on those selected for further analysis. The animal will then be weighed and photographed. The body surface of each animal will be examined and denoted as normal or abnormal with any abnormalities recorded. This includes the location and type of any visible lesions.

Once gross necropsy is completed, the animal will be wetted with a slightly soapy solution to control release of fur into the open body cavity as well as to control airborne release of any particles/fibers from the animal's fur. Dissection will then be performed to examine internal

FINAL

organs and to obtain tissue samples. The internal organs will be examined for color, size (swelling), and other gross abnormalities including the presence of macroscopic lesions, nodules or plaques. The uterus of pregnant females will be weighed (to obtain a total body weight irrespective of pregnancy state). Photographs will be made to document each examination and each identified abnormality.

From each mammal, a sample of tissue from each target organ will be collected and preserved by placement into formalin fixative. The eye ball from both eyes of each mammal will be removed and preserved for possible analyses of eye lens weight for aging. Carcasses will be retained and preserved in case future analyses of the remaining tissues are needed. The details of the necropsy and collection of target tissues is detailed in SOP MAMMAL-LIBBY-OU3.

4.2.5.6 Analytical Requirements

Measurement of Histopathological Effects

The collection of tissues for histopathological effects is detailed in SOP MAMMAL-LIBBY-OU3. The tissue samples will be examined by a qualified pathologist. The general procedures for the examination will be detailed in an SOP (SOP HISTOPATH-LIBBY-OU3) which will be prepared by the qualified pathologist and submitted to EPA for approval.

Measurements of Asbestos Tissue Burden

If the frequency and/or severity of a particular type of lesion is increased in animals from the study area compared to the reference area, but the cause of the increase (LA vs. other factors) is uncertain, then it may be necessary to measure the level of LA in the tissue of interest to help determine if exposure to LA plays a causal role. The exact design of such a study can not be specified *a priori*, but might involve the measurement LA in the tissue of animals a) from the study area with the lesion, b) from the study area without the lesions, and/or c) from the reference area.

If such analyses of LA tissue burden are deemed to be necessary, they will be performed TEM ISO 10312 Method Modification 2, *Analysis of Tissue Samples for Asbestos by TEM* (see Attachment B). In brief, a portion of the tissue sample collected and preserved for histopathological examination will be removed and weighted (wet weight), and then dried (lyophilized) and ashed at low temperature (plasma ashing). The ashed residue will be resuspended in acid and water and an aliquot deposited on a filter for analysis by TEM. Results will be expressed as fibers of LA per gram (wet weight) of tissue. The target analytical sensitivity will be $1E+05 \text{ g}^{-1}$. Counting rules and stopping rules are specified in the method modification.

4.2.5.7 *Quality Control for Tissue Burden Analysis*

If tissue burden analyses are performed, the following QC requirements will apply.

Field-Based QC Samples

For LA tissue burden analyses, *tissue blanks* will be prepared at a rate of 2 blanks per day on days that tissues are processed. The tissue blank will contain a tissue sample that does not have LA (liver or beef from the supermarket) and is collected and preserved in the same manner as the other tissue samples. These blanks will identify if LA is introduced in the tissue sample collection and transportation processes.

Laboratory-Based QC Samples

Laboratory-based QC samples will be analyzed in accord with TEM ISO 10312 Method Modification 2, *Analysis of Tissue Samples for Asbestos by TEM* (see Attachment B). This method modification summarizes the acceptance criteria and corrective actions for TEM laboratory QC analyses that will be used to assess data quality.

4.2.6 Exposure of Amphibians to Asbestos

4.2.6.1 Data That Are Valuable for Evaluating Effects of LA on Amphibians

Amphibians may be exposed to LA in the aquatic environment (including exposure to both water and sediment), and also to LA in soil in terrestrial environment. Of these two environments, it is suspected that the highest exposure and the greatest susceptibility is likely to occur during the early (aquatic) life stages of this receptor group, so attention is focused on aquatic media (i.e., surface water and sediment). The following lines of evidence are all potentially useful in evaluating risks to amphibians from LA in surface water and/or sediment:

- The computational HQ approach: measurement of LA concentrations in site waters and sediments, interpreted by comparison to appropriate TRV values
- *In-situ* measurements of effects: measurement of malformation frequency in metamorphs in the field
- Site-specific population studies: measurement of amphibian population density and diversity in the field
- Site-specific toxicity tests: Measurement of toxicity to selected life stages in laboratory-based toxicity tests using site water and/or sediments
- LA toxicity tests: Measurement of toxicity to selected life stages in laboratory-based spiking studies using LA added to laboratory water and/or sediment

4.2.6.2 Summary of Existing Data

At present, there are no data from OU3 to support any of the lines of evidence potentially useful for evaluating the risks to amphibians from LA in surface water or sediment. Measures of LA concentration in water and sediment from OU3 are available, but there is no suitable TRV for LA toxicity in either medium for amphibians.

4.2.6.3 Data Quality Objectives for Amphibians

Step 1: State the Problem

Historic mining and milling operations at OU3 have resulted in the release of LA to the environment, including surface water and sediment in ponds within OU3. Amphibians may be exposed to LA in these environmental media during their aquatic life stage via direct contact and ingestion. The problem being investigated is : Do exposures to concentrations of LA in site sediment and water result in significant reductions in survival, growth or reproduction in site specific amphibian toxicity tests?.

Step 2: Identify the Goal of the Study

The goal of the Phase III amphibian investigation is to determine if exposure of amphibians to LA in surface water and sediment in ponds in OU3 will result in ecologically significant adverse effects on growth, reproduction, or mortality.

Step 3: Identify the Information Inputs

The information inputs that are needed to address the study goal include reliable measures of growth, survival, metamorphosis, and reproductive status in developing amphibians exposed to LA in water and sediment. Exposure levels should include LA values that are at the high end of the range of concentrations observed in OU3 ponds. Analogous data from amphibians exposed to uncontaminated water and sediment are also needed to allow for comparisons between contaminated and uncontaminated locations.

Step 4: Define the Bounds of the Study

Spatial Bounds

Amphibians breed primarily in ponds rather than flowing streams. Based on this, the areas of OU3 that are most likely to provide suitable habitat for amphibians include the Tailings Impoundment, the Mill Pond, Fleetwood Creek Pond and Carney Creek Pond. Testing will be conducted in the laboratory with concentrations of LA consistent with conservative measures of LA found within these OU3 site ponds (spatial bounds).

Concentration Bounds

The concentrations of LA in surface water and sediment to be tested were selected to be near the high end of the concentrations that have been observed in water and sediment in on-site ponds. Although there is variability in the environmental cues that influence the timing of breeding and metamorphosis for amphibian species that are likely to occupy OU3, the time interval of chief interest is from about early May to mid July, since this is the time period in which most amphibians will have emerged from their protective egg cases and will be undergoing development and metamorphosis in the aquatic environment.

Data on surface water concentrations of LA in OU3 ponds during the period early May to mid July are summarized in Table 4-7. As seen, concentrations of LA in pond water over the time frame of interest range from non-detect (<0.05 MFL) to a maximum of 83 MFL (Fleetwood Creek Pond). Based on this, the water concentration to be tested will be 100 MFL.

The concentration levels of LA in sediment in the ponds are summarized in Table 4-8. As seen, the maximum LA level measured in all OU3 ponds analyzed by PLM-VE was 2%. Based on this maximum, the concentration of LA in sediment to be tested is 2%.

Step 5: Develop the Analytic Approach

The analytic approach is to measure ecologically relevant endpoints in amphibians exposed LA in water and sediment at concentrations that represent the high end of on-site conditions, and to determine if these endpoints are statistically different from those measured in organisms exposed to control sediment and water. The following table summarizes the endpoints and their relation to the assessment endpoints:

Assessment Endpoint	Measurement Endpoints
Survival	- % mortality - Incidence of malformations that could affect survival
Growth	- Individual metamorph weights - Incidence of malformations that could affect growth - Time to metamorphosis
Reproduction	- Gonad development - Incidence of malformations that could affect reproduction - Incidence and severity of histological lesions in gonad tissue

The precise statistical tests that will be used to compare exposed and control organisms will vary between the measurement endpoints. For discrete endpoints (survival, malformation frequency), it is expected that comparisons will be made using the Fisher Exact test. For continuous endpoints (body weight, histopathological score), it is expected that the comparisons between

FINAL

control and treated groups will be performed using the Wilcoxon Rank Sum (WRS) Test (unless the data are distributed approximately normally in which case comparisons may be performed using t-statistics). Other statistical tests that may be appropriate include one-way ANOVA or an ANOVA on ranks. *Post hoc* tests may also be used such as Dunnett's test or Bonferroni t-test for parametric sets, or Dunn's test for non-parametric tests.

If no statistically significant differences in any of the endpoints are detected between the exposed and the control organisms, it will be concluded that exposures to LA in surface water or sediment at concentrations equal to or less than the levels tested are not likely to cause effects that are ecologically significant. If statistically significant changes in one or more measurement endpoints are observed, additional investigation may be needed to determine if those effects result in ecologically significant effects at the population level, to determine if the effect is caused by the water or the sediment, and to identify a no-effect level that may be used to evaluate remedial alternatives.

Step 6: Specify Performance or Acceptance Criteria

In evaluating the results of amphibian toxicity testing, two types of decision errors are possible:

- A false negative decision error occurs when it is decided that there are no significant effects on amphibians, when in fact there are
- A false positive decision error occurs when it is decided that there are significant effects on amphibians, when in fact there are not

As discussed in EPA (2002), the probability of decision errors when comparing two data sets (site *vs.* reference) is controlled by the selection of the null hypothesis, and by selection of an appropriate statistical method to test the null hypothesis. Two alternative forms of null hypothesis are possible:

- Form 1: The null hypothesis is that no difference exists between site and reference. A confidence level of $100(1-\alpha)\%$ is required before the null hypothesis is rejected and it can be declared that the site data are higher than the reference data.
- Form 2: The null hypothesis is that the site is higher than reference by some amount (S) that is considered to be biologically significant. A confidence level of $100(1-\alpha)\%$ is required before the null hypothesis is rejected and it is declared that that the difference between site and reference, if any, is smaller than S.

For the purpose of this effort, the Form 1 null hypothesis is selected for use because it is the most familiar, is the easiest to interpret, and does not require specification of an effect that is presumed to be significant. In accord with EPA (2002), when the Form 1 null hypothesis is used, it is appropriate to select a value of α that is somewhat higher than the usual value of 0.05, such that

FINAL

marginal differences between site and reference are more easily identified as being significant. In accord with this, α is set to 0.20.

Step 7: Develop the Plan for Obtaining Data

A detailed protocol for the amphibian toxicity study will be developed by the toxicity testing laboratory and submitted to EPA for review and approval. Table 4-9 summarizes important features of the amphibian toxicity test that will be performed. Key features are discussed below.

Study Design

The target exposure concentrations of LA in surface water (100 MFL) and in sediment (2%) might be achieved either by collecting on-site media of the appropriate concentration levels, or by adding (“spiking”) LA to control media. Based on a consideration of the potential complexities of collecting sufficient quantities of on-site media with the appropriate concentration levels, as well as the potential for problems caused by microbial growth in on-site media, the spiking approach is judged to be the most appropriate for use in this investigation.

Based on this strategy, the study design will include three groups:

Group	Sediment	Water
1	Synthetic sediment	Laboratory water
2	Reference (uncontaminated) field sediment	Laboratory water
3	Reference (uncontaminated) field sediment spiked with LA	Laboratory water spiked with LA

Each exposure group will consist of four replicate exposure chambers each containing 20 organisms. Embryos will be assigned to exposure chambers at random. The study protocol will specify how embryos will be assigned to control/treatment groups.

Exposure chambers will be 10-L aquaria fitted with standpipes to provide a tank volume of 6 L. Aquaria temperature will be maintained at $23^{\circ}\pm 1^{\circ}\text{C}$. A flow-through design will be used, with a water flow rate into each tank of 10 mL/min. This will provide a 6 L volume renewal approximately every 10 hours.

The test sediments will be added to each tank and will cover the bottom to a depth of 2 cm. The expected volume of sediment required for each exposure tank is approximately one liter. The study protocol will specify how water and sediment will be added to the aquaria and how system will be allowed to equilibrate before organisms are introduced.

FINAL

Feeding of organisms and cleaning of tanks will occur daily. The details of how the tanks will be cleaned (particularly any measures to mitigate fiber loss) will be addressed in the study protocol.

Test Materials

Spiking material will be provided by the U.S Geological Survey (USGS). This material will utilize LA ore collected from the mine site, and will be ground and sieved to produce material with a particle size distribution that is generally similar to that seen in environmental media at the Libby site. Details of this spiking material including the source, the preparation methods, and the fiber size distribution, will be provided as a supplement to this SAP, when available.

The water used for the amphibian study will be dechlorinated laboratory water. This will be used for both the control water and as the diluent for preparing all aqueous chemical solutions used in this study. Dechlorination will be performed by the testing laboratory by passing laboratory water through three filters: 1) a 10 inch Big Blue™ pre-treatment filter (5.0 µm) to remove solids; 2) a 3.6 cubic foot activated virgin carbon treatment filter to remove chlorine, ammonia, and higher molecular weight organics; and 3) a 5.0 µm post-treatment filter to remove any carbon particles from the carbon treatment phase.

In this study, a single water dilution will be evaluated (100 MFL), along with a laboratory control. The approach for preparation of a stock suspension to prepare this dilution will be described in the detailed protocol prepared by the toxicity testing laboratory.

The field-collected reference sediment, from an area outside of Libby OU3, will be spiked by adding sufficient mass of LA (provided by USGS) to yield a final concentration of 2% (dry weight) in the sediment. Mixing will occur as a wetted slurry. Full details will be provided in the laboratory protocol for the study. No confirmation of the concentration of LA in sediment by PLM-VE is needed, since the accuracy of gravimetric spiking is much higher than the accuracy of PLM-VE.

Test Species and Life Stage

Based on on-site observations and data available for Lincoln County, Montana, there are four frog and toad species identified as potentially occurring at OU3 including the western toad (*Bufo boreas*), the Columbia spotted frog (*Rana luteiventris*), the Rocky Mountain tailed frog (*Ascaphus montanus*) and the Pacific treefrog (*Pseudacris regilla*). However, none of these species are available from commercial sources for use in toxicity testing, and the collection of egg masses on-site is not considered feasible. Several ranid species are available commercially for use in toxicity testing, including the Southern leopard frog (*Rana sphenoccephala*), the Northern leopard frog (*Rana pipiens*) and the green frog (*Rana clamitans*). The test species will be one of these Ranid species, because they are good surrogates for the Columbia spotted frog

FINAL

(*R. luteiventris*) present on the site and are also surrogates for the other North American species present on-site. *Rana pipiens* will be the preferred test species. If *Rana pipiens* eggs are not available then the following will be used in order of preference: *Rana sphenocephala* and *Rana clamitans*. Bullfrogs (*Rana catesbeiana*) will not be used because they are considered to be more tolerant in comparison to the other ranid species. The source of the test species will be identified in the study protocol.

Egg masses will be cultured without LA exposure until the embryos reach Gosner stage 20 (see Figure 4-9). Earlier life stages will not be exposed because eggs in protective jelly are expected to have no physical contact with LA in either water or sediment. Exposure will continue until at least 80% of the control animals complete metamorphosis (Gosner stage 46). This is expected to require approximately 45 days.

Following exposure, juvenile frogs will be maintained in large tubs for an additional 10 days. This additional period of growth allows for examination of potential delayed effects of exposure on growth and survival, as well as for examination of the reproductive organs for potential adverse effects of exposure.

Measurements Performed During the Study

Water Quality Measurements

Aliquots of water will be removed from each of the four LA-spiked replicate chambers and from one of the four un-spiked reference sediment replicate chambers (selected at random) twice a week (Monday and Thursday) (N = 10 samples per week). Each aliquot will consist of 5-10 mL withdrawn from the middle of the water column, being careful not to disturb the sediment. All water samples will be analyzed by PCM to provide fast turn-around results to ensure that fiber loss is not occurring. Water samples collected on the first, third and final Monday of the test (N = 15 samples) will be submitted for LA quantification by TEM.

Temperature, pH, and DO (dissolved oxygen) will be measured 3 times per week. Ammonia-nitrogen will be measured once per week.

Biological Measurements Obtained During the Study

All animals will be observed daily. Data that will be recorded daily shall include:

- survival counts
- developmental stage and metamorph counts
- other observations on occurrence of malformations or other abnormalities

FINAL

All animals will be weighed at metamorphosis. Study log sheets will be provided in the study protocol.

Biological Measurements at Study Termination

All animals will be necropsied at study termination. Metamorphosed specimens that die prior to the final stage will also be necropsied.

At necropsy, each animal will be anesthetized, digitally photographed, weighed, and examined for external abnormalities. The body cavity will then be opened and all major internal organs will be inspected for developmental stage and appearance. Necropsy observations will be recorded and a second set of digital photos taken. Special attention will be paid to the gonads, which will be removed, weighed, and inspected for any abnormalities. Gonad tissues will be removed and fixed for histological examination to identify any lesions and/or abnormalities. The tissue samples will be examined by a qualified pathologist. The general procedures for the examination will be detailed in an SOP which will be prepared by the qualified pathologist and submitted to EPA for approval.

Analytical Requirements

The approach for water sample preparation (e.g., sonication/ozonation) will be described in the detailed protocol prepared by the toxicity testing laboratory.

All water samples will be analyzed by PCM utilizing the PCM counting and stopping rules specified in NIOSH 7400 Method Modification 1, *Analysis of Water Samples for Asbestos by PCM* (see Attachment B). Selected filters (from the first, third, and final Monday of the test) will also be analyzed by TEM to confirm the results. Prepared TEM grids from each filter will be analyzed using the TEM counting and stopping rules specified in TEM ISO 10312 Method Modification 1, *Analysis of Water Samples for Asbestos by TEM* (see Attachment B) using the standard analysis procedure for data recording.

Quality Control for PCM

Two types of laboratory-based QC analyses will be prepared for the PCM water samples, as follows:

Lab Blank - This is a filter through which is filtered 2.0 mL of dechlorinated laboratory water. The purpose is to evaluate whether the laboratory water used in the study contains any fibers. One laboratory blank will be prepared and analyzed each day that PCM analyses are performed. The acceptance criterion for this type of QC sample is that the number of PCM fibers in an examination of 100 fields-of-view (FOVs) does not exceed

FINAL

7. If a lab blank with more than 7 fibers per 100 FOVs occurs, the laboratory should cease analytical activities until the source of contamination is identified and corrected.

Blind Recounts - A total of 5% of all PCM slides will be submitted for blind recounts. In this procedure, a slide that has been analyzed is re-labeled by a person other than the original analyst and re-submitted for a second analysis. The acceptance criterion for this type of QC sample is that no more than 5% of the re-analysis pairs are statistically different from each other.

Quality Control for TEM

Two types of laboratory-based QC analyses will be prepared for the TEM water samples, as follows:

Lab Blank - This is an analysis of a TEM grid that is prepared from a new, unused filter in the laboratory and is analyzed using the same procedure as used for field blank samples. One lab blank should be prepared and analyzed along with the water samples selected for TEM analysis. The acceptance criterion for this type of QC sample is that no asbestos structures should be observed in an examination of 10 GOs. If one or more asbestos structures are observed, the laboratory should cease analytical activities until the source of contamination is identified and corrected.

Recounts - A recount is an analysis where TEM grid openings are re-examined after the initial examination. A *Recount Different* (RD) describes a re-examination by a different microscopist within the same laboratory than who performed the initial examination. A total of two samples will be selected by SRC for Recount Different (RD) analysis after the results of the original sample analyses have become available. The most recent version of laboratory modification LB-000029 (see Attachment C) summarizes the acceptance criteria for these Recount Different analyses.

4.3 Exposure of Ecological Receptors to Non-Asbestos Chemicals

4.3.1 Conceptual Site Model

Figure 4-10 presents a CSM for exposure of ecological receptors to non-asbestos chemicals at OU3. This CSM summarizes the current understanding of non-asbestos chemical sources, fate and transport pathways, and exposure pathways that are possible for each group of ecological receptors in OU3. However, not all of these exposure scenarios are of equal concern or require equal levels of investigation. The following sections discuss the analytes and the pathways of primary concern.

4.3.2 Focus of Phase III Ecological Investigations for Non-Asbestos Chemicals

Contaminants of Primary Concern

Data have been collected on a wide range of non-asbestos contaminants of potential concern in environmental media in OU3, including metals and metalloids, petroleum hydrocarbons, nitrate/nitrite, anions, pesticides, PCBs, volatile organic compounds (VOCs), semi-volatile organic compounds (SVOCs), polycyclic aromatic hydrocarbons (PAHs), and radionuclides. The raw data are provided electronically in Appendix A. Table 4-10 provides detection frequencies by analyte for surface water, sediment, and soil. Inspection of these data reveals that the only analytes regularly detected in site media are inorganic chemicals (metals, metalloids, and anions), and that organic chemicals are either never detected or are only rarely detected. Based on this, the non-asbestos analyte class of chief concern for evaluation in OU3 is metals and metalloids.

Exposure Scenarios of Primary Concern

The primary focus of the ecological component of the Phase III investigation for non-asbestos chemicals is to collect data to support an evaluation of risks to aquatic receptors (fish, benthic invertebrates, and amphibians) in the creeks and ponds within the OU3 watershed. This is because the streams and ponds of OU3 are known to be contaminated with mine waste, both from direct historic discharges into these waterways and from ongoing releases from residual mine wastes. Therefore, this component of the ecosystem is considered to be the most likely to be impacted by non-asbestos contaminants.

Another portion of the site where exposure to mine-related non-asbestos contaminants is likely to be high is the area of the former mine. However, this area of OU3 is heavily disturbed by the historic mining activity, and habitat for terrestrial receptors (including both plants and animals) is generally impaired. Further, the site continues to be disturbed by heavy machinery, and may undergo remedial actions due to potential concerns over LA releases. Therefore, EPA is not presently planning to perform a quantitative evaluation of ecological risks from non-asbestos contaminants at the mined area. If an evaluation of the toxicity of non-asbestos chemicals is needed for plants, soil invertebrates or wildlife in the mined area, this will be undertaken at the level of the FS.

The final area of potential concern is the forested area around the mine site. This area may have been impacted by airborne releases on non-LA contaminants in airborne particulates. Of chief concern are metals and metalloids in the ore used at the mine. However, concentration values of most metals and metalloids in on-site samples are generally similar to background levels seen in the State of Montana (see Figure 3-6). Based on this, it is expected that impacts to soil in the forest area from non-LA contaminants are likely to be minimal, and data on non-asbestos chemicals in the forest area are not needed for risk management decision-making.

4.3.3 Exposure of Fish to Non-Asbestos Chemicals

4.3.3.1 *Data That Are Valuable for Evaluating Effects on Fish*

As discussed in the Problem Formulation document (EPA 2008d), data from several lines of evidence are valuable when seeking to evaluate risks to fish from exposure to chemicals in surface water. This includes:

- Comparisons of chemical concentrations in site surface waters to a reliable chemical-specific surface water TRV (evaluated as an HQ)
- Site-specific surface water toxicity tests in fish
- Multiple years of fish population demographic observations

The following sections discuss the availability of each type of data at present, reviews the adequacy of the existing data, and identifies additional data collection that may be needed during Phase III.

4.3.3.2 *Surface Water Data*

Summary of Existing Surface Water Data

Data on the concentration of non-asbestos chemicals in surface water were collected in both Phase I and Phase II. Table 3-2 summarizes the sampling locations and sampling times for surface water. As shown, data were collected from 20 different stations in the OU3 watershed. At most stations, three separate samples were collected, representing fall, spring, and summer time periods.

All surface water samples were analyzed for metals, petroleum hydrocarbons, nitrate/nitrite, and anions. Samples from several stations were also analyzed for a range of additional analytes, including pesticides, PCBs, VOCs, SVOCs, PAHs, and radionuclides. Raw data are provided electronically in Appendix A.

Surface Water Data Quality Assessment

Spatial and Temporal Representativeness

Surface water data from OU3 are considered to provide good spatial representativeness, since multiple samples were collected from each major segment of the OU3 watershed. Although the number of samples is limited (3 samples per station), the samples are representative of three different seasons within the year (fall, spring, summer), and at least one sample was collected

FINAL

during the spring run-off period, when concentrations are likely to be highest. Therefore, temporal representativeness is considered to be adequate.

Sample Number

In the HQ approach, potential risks to fish from surface water are assessed based on an evaluation of the frequency and magnitude of exceedence of the surface water TRVs within each exposure reach. In order to provide a reliable characterization of the frequency and magnitude of HQ exceedences, multiple samples are needed for each reach. The actual number of samples needed is a matter of judgment and depends upon the underlying variability across samples (more samples are needed when variability is high than when variability is low). For the purposes of this data adequacy evaluation, data adequacy was evaluated using the following procedure:

- Determine the number of samples that are presently available for each reach. If the sample number is 8 or more, assume that the data will be sufficient for risk characterization.
- If the number of samples is less than 8, evaluate the variability between the samples. If the variability is low ($CV < 0.5$), then assume that the data will be adequate for risk characterization.
- If data are sparse ($N < 8$) and variability is high ($CV \geq 0.5$), determine the HQ values for the samples. If the HQ values are either all well above or all well below 1.0, then assume the data are adequate for risk characterization. If the HQ values are near 1.0, then assume that additional data collection may be needed.

Table 4-11 summarizes the number of surface water samples with data for metals for each reach in OU3. As seen, all reaches have at least 8 samples except for the Mill Pond ($N = 3$) and the reference stations ($N = 1$ per reference stream).

Table 4-12 summarizes the data for metals in the Mill Pond. As seen, most of the analytes were never detected, and those that were (barium, calcium, magnesium, potassium, and sodium) have relatively small CV values (< 0.2). Based on this, it is concluded that even though only three samples are available from this station, the data are of adequate quality to support the risk assessment.

As noted, only one surface water sample has been analyzed for non-asbestos analytes from each of the two reference streams (Bobtail Creek [BTT-R1] and Noisy Creek [NSY-R1]). Obviously, one sample per stream is not sufficient to evaluate the mean or the variation of chemical concentration values. Even if the two data sets were combined, two samples would still too limited to draw any strong conclusions or to perform any meaningful statistical analyses. However, available data suggest that Upper Rainy Creek may be a suitable reference location for

on-site streams. If so, the number of samples from Upper Rainy Creek (N = 8) is sufficient to allow reliable comparisons with potentially impacted reaches.

Are Additional Surface Water Data Needed?

Based on the discussion above, it is concluded that the existing surface water data for non-asbestos chemicals are adequate to support decisions based on this line of evidence (surface water HQs), and that additional surface water data are not needed to support an assessment of risks to fish.

4.3.3.3 Site-Specific Surface Water Toxicity Tests

Data Quality Assessment of Existing Data

As part of the Phase II Part A sampling effort (EPA 2008a), one site water was selected for use in site-specific toxicity testing. The toxicity test design is detailed in the Phase IIA SAP (EPA 2008a). In brief, the test was conducted with newly hatched larval (sac fry) rainbow trout (*Oncorhynchus mykiss*) under static renewal conditions for an exposure duration of 6 weeks. Survival, behavior and growth were observed during the exposure period, and the histopathology of the fish was examined at the end of the study.

Because the primary focus of this test was on evaluating the potential toxicity of LA in surface water, the water used in the test was selected by monitoring the levels of LA in OU3 waters, and choosing a time and place that was believed to be near the high end of the range of LA concentrations observed in site waters. The water sample selected for site-specific toxicity testing was collected from the tailings impoundment (TP) on May 8, 2008. However, the sample also contains other chemicals that could be of potential concern to aquatic receptors. Table 4-13 summarizes the measured concentrations of metals in this surface water sample.

Results of the test are summarized in Parametrix (2009a). In brief, no significant effects on mortality, growth, or frequency of histological lesions were detected. These results suggest that exposure to non-asbestos contaminants in site surface water at the concentration values indicated in Table 4-13 is unlikely adversely impact fish in the tailings impoundment.

However, conclusions from this study are limited because it is known that concentration levels of LA in the test water tended to decrease over time (see discussion in Section 4.2.3.3). Because the concentrations of metals were measured only at the study initiation, and not at subsequent times, it is unknown whether or not the concentrations of non-asbestos contaminants remained constant or also changed (decreased) over time. Based on this, the results of this study are not considered to provide reliable data on the toxicity of non-asbestos contaminants in site water.

Are Additional Toxicity Tests Needed?

In general, site-specific toxicity tests are one of the best lines of evidence available for ecological risk assessment, especially for exposure of fish to water, and performance of a new site-specific study using site water (but ensuring that exposure concentrations remained constant) would potentially be valuable. However, because of the problems encountered in the first test, design and implementation of a repeat test is likely to be difficult. For this reason, additional toxicity testing using site water will not be performed during Phase III, and assessment of risks from non-asbestos contaminants will be based on other lines of evidence.

4.3.3.4 Site-Specific Fish Population Studies

As noted above, one line of evidence that can be useful in evaluating potential risks to fish from exposure to chemicals in surface water is to make direct observations of fish in the field, seeking to determine whether the population has unusual numbers of individuals (either lower or higher than expected), or whether the diversity (number of different species) is different than expected.

Although abundance and diversity of the fish population may depend on chemical contamination, data adequacy conclusions regarding this line of evidence is not chemical-specific. Therefore, conclusions regarding fish population data adequacy presented in the LA-specific section above (Section 4.2.3.5) are also applicable to the non-asbestos chemicals.

In brief, it was determined that, while the fish population study performed as part of the Phase IIC investigation provides a good initial estimate of fish population characteristics in OU3, because of the natural variability in fish populations over time and space, strong conclusions cannot be drawn based on observations from a single year. Therefore, additional fish population data for at least one additional year are required to help determine if the effects observed are reproducible and potentially significant. DQOs specific to the collection of additional fish population data were provided in Section 4.2.3.5.

4.3.4 Exposure of Benthic Invertebrates to Non-Asbestos Chemicals

4.3.4.1 Lines of Evidence Useful for Evaluating Effects on Benthic Invertebrates

As discussed in the Problem Formulation document (EPA 2008d), three types of data are valuable when seeking to evaluate risks to benthic invertebrates from exposure to non-asbestos chemicals in sediment:

- Chemical concentrations in sediment of site ponds and streams, coupled with a reliable chemical-specific sediment TRV by which to evaluate the measurements (evaluated as an HQ)
- Site-specific sediment toxicity tests with benthic invertebrates

FINAL

- Multiple years of benthic invertebrate community demographic observations

The following sections discuss the availability of each type of data and the plans for collection of additional data during the Phase III effort.

4.3.4.2 *Sediment HQs*

Summary of Existing Sediment Data

Data on the concentration of non-asbestos chemicals in sediment were collected in both Phase I and Phase II. Table 3-3 summarizes the sampling locations and sampling times for sediment. As shown, data were collected from 19 different stations in the OU3 watershed. At most stream stations, three separate samples were collected, representing fall, spring, and summer time periods. During the Phase II investigation, multiple sediment samples were collected in the ponds (Carney Creek Pond, Fleetwood Creek Pond, the Tailings Impoundment, and the Mill Pond).

All samples of sediment were analyzed for metals, petroleum hydrocarbons, nitrate/nitrite, and anions. Samples from several stations were also analyzed for a range of additional analytes, including pesticides, PCBs, VOCs, SVOCs, PAHs, and radionuclides. The raw data are provided electronically in Appendix A.

Sediment Data Quality Assessment

Representativeness

The sediment data from OU3 are considered to provide good spatial representativeness, since multiple samples were collected from each stream and pond in the OU3 watershed. Although concentrations of chemicals in sediment are usually not as time-variable as concentrations in surface water, concentrations may fluctuate as contaminated material is added or removed by surface water flow. Since sediment samples were collected from 3 different times of year (fall, spring, summer) at most stations, temporal representativeness is considered to be adequate.

Sample Number

The number of sediment samples available for each exposure reach is summarized in Table 4-11. As seen, there are a minimum of 10 and a maximum of 43 samples available for on-site locations, which is considered to be sufficient to allow a reliable evaluation of the frequency and magnitude of HQ exceedences.

As was the case for surface water, the number of samples from the reference streams is not sufficient to support meaningful comparisons of site to reference (N = 1 at each reference

location). However, available data suggest that Upper Rainy Creek may be a suitable reference location for on-site streams. If so, the number of samples from Upper Rainy Creek (N = 10) is sufficient to allow reliable comparisons with potentially impacted reaches.

Are Additional Sediment Data Needed?

Based on this, it is concluded that the existing sediment data for non-asbestos chemicals are adequate to support decisions based on this line of evidence (sediment HQs), and additional sediment data are not needed to support an evaluation of risks to benthic invertebrates.

4.3.4.3 *Site-Specific Sediment Toxicity Tests*

Data Quality Assessment of Existing Data

As part of the Phase II Part C sampling effort (EPA 2008c), sediments were collected from two site sampling locations (CC-1 and TP-TOE2) for sediment toxicity testing. These locations were selected because they had the highest measurements of LA in the Phase I or Phase IIA sampling efforts (but not necessarily high non-asbestos chemical concentrations). Sediments were also collected for testing from the two reference sites (BTT-R1 and NSY-R1). Table 4-14 summarizes the measured concentrations of metals in these sediment samples.

Sediment samples were tested for toxicity using the amphipod *Hyaletta azteca* in a 42-day test for measuring the effects of sediment associated contaminants on survival, growth and reproduction (EPA Test Method 100.4; EPA 2000). Sediment samples were also tested for toxicity to the midge *Chironomus tentans* using the life-cycle test for measuring effects on survival, growth and reproduction (EPA Test Method 100.5; EPA 2000).

Results of the sediment toxicity tests are summarized in Parametrix (2009c). In brief, test organisms (*Hyaletta* and *Chironomid* species) did not exhibit any statistically significant difference in survival, growth, or reproduction when compared to both laboratory control sediments and field-collected reference sediments.

These results suggest that exposure to non-asbestos contaminants, at the levels present in the test materials, is unlikely adversely impact benthic invertebrates. However, the concentrations of contaminants in the samples tested may not be representative of the range of values observed in other site sediments. Based on comparison of measured sediment concentrations to sediment probable effect concentrations (PECs) for benthic invertebrates (EPA 2008d), the only contaminants that exceed PEC values are chromium, copper, manganese, and nickel, indicating that these chemicals are the primary metals of potential concern in sediment.

Table 4-15 compares the concentrations of these metals in the tested sediments with concentrations measured in other sediment samples. As seen, metal concentrations of chromium,

FINAL

copper, manganese, and nickel in the TP-TOE2 sediment test material tended to be similar to or higher than the maximum concentrations observed in most creeks, but there are some pond samples that had concentrations higher than those tested. In most cases, the difference between concentrations in the TP-TOE2 sediment and concentrations in the creeks is usually less than a factor of 2, which means that it is possible to bound calculated HQ values in the creeks to ≤ 2 . In the ponds, differences were generally within a factor of 2 for chromium, manganese, and nickel, and within a factor of 3-5 for copper.

Are Additional Sediment Toxicity Tests Needed?

Based on the data quality evaluation described above, it is concluded that the results of the existing site-specific sediment toxicity study will be adequate to draw conclusions regarding HQ distributions of risks from chromium, manganese, and nickel in OU3 creeks and ponds. For copper, the data are likely to be adequate for creeks, although the data may be difficult to interpret with confidence for ponds. Based on this, additional site-specific sediment toxicity tests are not required as part of the Phase III study, although some additional studies to clarify the potential risk from copper might be needed if the combined weight of evidence evaluation is not sufficient to support risk management decision-making.

4.3.4.4 Site-Specific BMI Population Studies

As noted above, one line of evidence that can be useful in evaluating potential risks to benthic invertebrates from exposure to chemicals in sediment is to make direct observations of organisms in the field, seeking to determine whether the population has unusual numbers of individuals (either lower or higher than expected), or whether the diversity (number of different species) is different than expected. However, data adequacy conclusions regarding the benthic invertebrate population metrics are not chemical-specific (i.e., conclusions regarding benthic invertebrate population data adequacy presented in the LA-specific Section 4.2.4.4 above are also applicable to the non-asbestos chemicals).

In brief, it was determined that, while the benthic invertebrate population study performed as part of the Phase IIC investigation provides a good initial estimate of population characteristics in OU3, because of the natural variability in these populations over time and space, strong conclusions cannot be drawn based on observations from a single year. Therefore, additional benthic invertebrate population data for at least one additional year are required to help determine if the effects observed are reproducible and potentially significant. DQOs specific to the collection of additional benthic invertebrate population data were provided in Section 4.2.4.4.

4.3.5 Exposure of Amphibians to Non-Asbestos Chemicals

As noted previously, amphibians may be exposed to site-related contaminants in the aquatic environment (including exposure to both water and sediment), and also to LA in soil in terrestrial

FINAL

environment. Of these two environments, it is suspected that the highest exposure and the greatest susceptibility is likely to occur during the early (aquatic) life stages of this receptor group, so attention is focused on these media.

The principal line of evidence that will be utilized in the risk assessment for evaluating risks to amphibians from non-asbestos contaminants in surface water and sediment is the HQ approach. Other lines of evidence (e.g., field surveys) would also be valuable if performed, since these are not chemical-specific.

The adequacy of the existing surface water and sediment data to support an HQ-based evaluation for non-asbestos contaminants has been reviewed above (see Sections 4.3.2.2 and 4.3.3.2). Based on this review, it is concluded that existing surface water and sediment data are adequate to support the HQ approach (assuming that appropriate and reliable TRV values for amphibians are available), and that no additional data collection is needed to support this portion of the risk assessment.

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5.0 OTHER DATA NEEDS FOR RI/FS

This section will be provided at a later date.

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6.0 SAMPLE HANDLING AND DOCUMENTATION

6.1 Field Procedures

6.1.1 Sample Documentation and Identification

Data regarding each sample collected as part of Phase III sampling activities will be documented in accord with OU3 SOP No. 9 using Libby OU3-specific field sample data sheets (FSDS). At the time of collection, each sample will be labeled with a unique 5-digit sequential identification (ID) number. The sample IDs for all samples collected as part of Phase III sampling activities will have a prefix of “P3” (e.g., P3-12345), unless specified otherwise. Information on whether the sample is representative of a field sample or a field-based QC sample (e.g., field blank, field duplicate/split) will be documented on the FSDS.

Each field sampling team will maintain a field log book. The log book shall record all potentially relevant information on sampling activities and conditions that are not otherwise captured on the FSDS forms. Examples of the type of information to be captured in the field log include:

- Names of team members
- Current and previous weather conditions
- Field sketches
- Physical description of the location relative to permanent landmarks
- Number and type of samples collected
- Any special circumstances that influenced sample collection
- Any deviations from sampling SOPs
- For ABS samples, the location description (what trails and areas) the ABS activities were performed in

As necessary for sample collection and location documentation, photographs will be taken using a digital camera. GPS coordinates will be recorded for all sampling locations on the FSDS form. A flag, stake or pole identifying the sampling station will be placed at or near the location for future identification.

6.1.2 Sample Containers and Preservation

All sample containers used for sample collection and analysis for this project will be prepared according to the procedures contained in the EPA document, *Specifications and Guidance for Obtaining Contaminant-Free Sample Containers*, dated December 1992. This document specifies the acceptable types of containers, the specific cleaning procedures to be used before samples are collected, and requirements relevant to the containers and cleaning procedures. The

FINAL

analytical laboratories will supply all sample containers utilized for this investigation. If field personnel observe any cracked or dirty containers, or if the appropriate preservative is missing in the sample bottles, those containers will be discarded and the laboratory will be notified of the problem to prevent its re-occurrence.

6.1.3 Holding Times

There are no holding time requirements for the analysis of asbestos.

6.1.4 Chain of Custody and Shipment

Field sample custody and documentation will follow the requirements described in OU3 SOP No. 9. Sample packaging and shipping will follow the requirements described in OU3 SOP No. 8.

A chain-of-custody (COC) form specific to the Libby OU3 sampling shall accompany every shipment of samples to the analytical laboratory. The purposes of the COC form are: a) to establish the documentation necessary to trace possession from the time of collection to final disposal, and b) to identify the type of analysis requested. All corrections to the COC record will be initialed and dated by the person making the corrections. Each COC form will include signatures of the appropriate individuals indicated on the form. The originals will accompany the samples to the laboratory and copies documenting each custody change will be recorded and kept on file. One copy of the COC form will be kept by field personnel.

All required paper work, including sample container labels, COC forms, custody seals and shipping forms will be fully completed in indelible ink (or printed from a computer) prior to shipping of the samples to the laboratory. Shipping to the appropriate laboratory from the field or sample storage will occur through overnight delivery.

All samples that may require special handling by laboratory personnel to prevent potential exposure to LA or other hazardous substances will be clearly labeled.

6.2 Laboratory Procedures

6.2.1 Chain of Custody

Upon sample receipt, the laboratories will implement the following procedures:

- A sample custodian will be designated.
- Each sample shipment will be inspected by the sample custodian to assess the condition of the shipping container and the individual samples. The enclosed COC form will be reviewed and cross-referenced with all the samples in the shipment. Any discrepancies

FINAL

or abnormalities in samples will be noted and the EPA Project Manager or the appropriate delegate will be promptly notified. The EPA Project Manager shall be notified by telephone at (303) 312-6579 or email at lavelle.bonita@epa.gov.

- The COC form will be signed by the sample custodian and placed in the project file.
- Sample storage will be secured in the appropriate environment (i.e., refrigerated, dry, etc.), sample storage records and intra-laboratory sample custody records will be maintained, and sample disposal and disposal date will be properly documented.
- Internal COC procedures will be followed by logging and assigning a unique laboratory sample number to each sample upon receipt (this number identifies the sample through all further handling at the laboratory).
- Internal logbooks and records will maintain the COC throughout sample preparation, analysis, and data reporting. These records will be kept in the project files.
- The original COC form will be returned to the Project QA Officer with the resulting data report from the laboratory.

Chain-of-custody will be maintained until final disposition of the samples by the laboratory and acceptance of analytical results.

6.2.2 Documentation and Records

Data reports will be submitted to EPA in accordance with the procedures described in Section 6.2.3 below. Data reports shall include a case narrative that briefly describes the number of samples, the analyses, and any analytical difficulties or QA/QC issues associated with the submitted samples. The data report will also include signed COC forms, analytical data summary report pages, and a summary of laboratory QC sample results and raw data, where applicable. Raw data are to consist of instrument preparation and calibration logs, instrument printouts of field sample results, laboratory QC sample results, calibration and maintenance records, COC check in and tracking, raw data count sheets, spectra, micrographic photos, and diffraction patterns.

6.2.3 Data Deliverables

Asbestos data generated during this project will be entered into Libby-specific EDD spreadsheets by appropriately trained data entry staff. The data will include all relevant field information regarding each environmental sample collected, as well as the analytical results provided by the laboratory. Analytical results will include the structure-specific data for all TEM analyses. All data entry will be reviewed and validated for accuracy by the laboratory data entry manager or appointed delegate.

All asbestos EDDs will be submitted to EPA technical contractors (SRC) electronically. Whenever possible, data files should be transmitted by e-mail to the following address:

FINAL

LibbyOU3@srcinc.com

When files are too large to transmit by e-mail, they should be provided on compact disk to the following address:

Lynn Woodbury
SRC, Inc.
999 18th Street, Suite 1975
Denver CO 80202
(303) 357-3127

All original data records (both hard copy and electronic) will be cataloged and stored in their original form until otherwise directed by the Project Manager. At the termination of Phase III, all original data records will be provided to the EPA Project Manager in a format specified by EPA for incorporation into the OU3 project files.

6.2.4 Archival and Final Disposition

All sample materials, including filters, grids, and cassettes will be maintained in storage at the laboratory unless otherwise directed by EPA. When authorized by EPA, the laboratory will be responsible for proper disposal of any remaining samples, sample containers, shipping containers, and packing materials in accordance with sound environmental practice, based on the sample analytical results. The laboratory will maintain proper records of waste disposal methods, and will have disposal company contracts on file for inspection.

7.0 DATA MANAGEMENT

7.1 Data Management Applications

All data generated as part of the Phase III sampling will be maintained in an OU3-specific Microsoft® Access database. This will be a relational database with tables designed to store information on station location, sample collection details, preparation and analysis details, and analytical results. Results will include all asbestos data, including detailed structure attributes for TEM analyses.

As needed, EPA staff and designated contractors will develop tabular and graphical data summaries, perform statistical analyses, and generate maps using commercially-available applications such as Microsoft® Access and Excel and ArcGIS®.

7.2 Roles and Responsibilities for Data Flow

7.2.1 Field Personnel

W.R. Grace Contractors will perform all Phase III sample collection in accordance with the project-specific sampling plan and SOPs presented above. In the field, sample details will be documented on hard copy media-specific FSDS forms and in field log books (see Section 6.1.1). COC information will be documented on hard copy forms (see Section 6.1.4). FSDS and COC information will be manually entered into a field-specific¹ OU3 database using electronic data entry forms. Use of electronic data entry forms ensures the accuracy of data entry and helps maintain data integrity. For example, data entry forms utilize drop-down menus and check boxes whenever possible. These features allow the data entry personnel to select from a set of standard inputs, thereby preventing duplication and transcription errors and limiting the number of available selections (e.g., media types). In addition, entry into a database allows for the incorporation of data entry checks. For example, the database will allow a unique sample ID to only be entered once, thus ensuring that duplicate records cannot be created.

Entry of FSDS forms and COC information will be completed weekly, or more frequently as conditions permit. Copies of all FSDS forms, COC forms, and field log books will be scanned and posted in portable document format (PDF) to a project-specific file transfer protocol (FTP) site weekly. This FTP site will have controlled access (i.e., user name and password are required) to ensure data access is limited to appropriate project-related personnel. File names for scanned FSDS forms, COC forms, and field log books will include the sample date in the format YYYYMMDD to facilitate document organization (e.g., FSDS_20090831.pdf).

¹ The field-specific OU3 database is a simplified version of the master OU3 database. This simplified database includes only the station and sample recording and tracking tables, as well as the FSDS and COC data entry forms.

After FSDS data entry is completed, a copy of the field-specific OU3 database will be posted to the project-specific FTP weekly, or more frequently as conditions permit. The field-specific OU3 database posted to the FTP site will include the post date in the file name (e.g., FieldOU3DB_20090831.mdb).

7.2.2 Laboratory Personnel

Each of the laboratories performing analyses for the Phase III sampling are required to utilize all applicable Libby-specific Microsoft[®] Excel spreadsheets for data recording and electronic submittals (see Section 6.2.3). Upon completion of the appropriate analyses, EDDs will be transmitted via email to a designated email distribution list within the appropriate turn around time. Hard copies of all analytical laboratory data packages will be scanned to a PDF and either posted to the project-specific FTP site or emailed to a designated email distribution list. File names for scanned analytical laboratory data packages will include the laboratory name and the job number to facilitate document organization (e.g., LabX_12365-A.pdf).

7.2.3 Database Administrators

Day-to-day operations of the master OU3 database will be under the control of EPA contractors. The primary database administrator will be responsible for sample tracking, uploading new data, performing error checks, and making any necessary data corrections. New records will be added to the master OU3 database within an appropriate time period of FSDS and/or EDD receipt.

Incremental backups of the master OU3 database will be performed daily Monday through Thursday, and a full backup will be performed each Friday. The full backup tapes will be stored off-site for 30 days. After 30 days, the tape will be placed back into the tape library to be overwritten by another full backup.

Each Friday, a copy of the master OU3 database will be posted to a project-specific FTP site to allow timely access to results by data users. The master OU3 database posted to the FTP site will include the post date in the file name (e.g., MasterOU3DB_20090831.mdb).

7.3 **Data Storage**

All original data records (both hard copy and electronic) will be cataloged and stored in their original form until otherwise directed by the EPA Project Manager. At the termination of this project, all original data records will be provided to the EPA Project Manager in a format specified by EPA for incorporation into the site project files.

8.0 ASSESSMENT AND OVERSIGHT

Assessments and oversight reports to management are necessary to ensure that procedures are followed as required and that deviations from procedures are documented. These reports also serve to keep management current on field activities. Assessment, oversight reports, and response actions are discussed below.

8.1 Assessments

8.1.1 Field Oversight

All individuals who collect samples during field activities will be provided a copy of this SAP and will be required to participate in a pre-sampling readiness review meeting to ensure that methods and procedures called for in this SAP and associated SOPs are understood and that all necessary equipment is on hand. EPA may perform random and unannounced field audits of field sampling collection activities, as may be deemed necessary.

8.1.2 Laboratory Oversight

All laboratories selected for analysis of samples for asbestos will be part of the Libby analytical team. These laboratories have all demonstrated experience and expertise in analysis of LA in environmental media, and all are part of an on-going site-specific quality assurance program designed to ensure accuracy and consistency between laboratories. These laboratories are audited by EPA and NVLAP on a regular basis. Additional laboratory audits may be conducted upon request from the EPA, as may be needed.

8.2 Response Actions

If any inconsistencies or errors in field or laboratory methods and procedures are identified, response actions will be implemented on a case-by-case basis to correct quality problems. All response actions will be documented in a memo to the EPA RPM for OU3 at the following address:

Bonita Lavelle
U.S. EPA, Region 8
1595 Wynkoop Street
Denver, CO 80202-1129
E-mail: lavelle.bonita@epa.gov

Any problems that cannot be corrected quickly through routine procedures may require implementation of a corrective action request (CAR) form.

8.3 Reports to Management

Field and analytical staff will promptly communicate any difficulties or problems in implementation of the SAP to EPA, and may recommend changes as needed. If any revisions to this SAP are needed, the EPA RPM will approve these revisions before implementation by field or analytical staff.

9.0 DATA VALIDATION AND USABILITY

9.1 Data Validation and Verification Requirements

Data validation consists of examining the sample data package(s) against pre-determined standardized requirements. The validator may examine, as appropriate, the reported results, QC summaries, case narratives, COC information, raw data, initial and continuing instrument calibration, and other reported information to determine the accuracy and completeness of the data package. During this process, the validator will verify that the analytical methodologies were followed and QC requirements were met. The validator may recalculate selected analytical results to verify the accuracy of the reported information. Analytical results will then be qualified as necessary.

Data verification includes checking that results have been transferred correctly from laboratory data printouts to the laboratory report and to the EDD. Some of the data verification checks are performed as a function of built-in quality control checks in the Libby-specific data entry spreadsheets. Additional verifications of field and analytical results will be performed at a frequency of 10%. This initial rate may be revised as samples are analyzed and results evaluated. Data validation, review, and verifications must be performed on sample results before distribution to the public for review.

9.2 Reconciliation with Data Quality Objectives

Once all samples have been collected and analytical data has been generated, data will be evaluated to determine if DQOs were achieved. Evaluation of the Phase III data will include a qualitative and quantitative review of all QC samples and all deviations from sampling and analysis plans described in this report, along with conclusions regarding the reliability of the data for their intended use. Results of the data quality evaluation will in general be reported in the Baseline Human Health Risk Assessment, the Baseline Ecological Risk Assessment, and the final RI Report for OU3.

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