UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

TECHNICAL REVIEW WORKGROUP FOR LEAD

Technical Memorandum

Review of Human Health Risk Assessment for the Coeur d'Alene Basin

Prepared for

Sean Sheldrake
Marc Stifelman
U.S. EPA Region 10
Seattle WA

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U.S. Environmental Protection Agency

Technical Review Workgroup for Lead

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1.0 INTRODUCTION

1.1 Charge to the TRW

This report summarizes comments of the EPA Technical Review Workgroup for Lead (TRW) on the *Human Health Risk Assessment for the Coeur d'Alene Basin Extending from Harrison to Mullan on the Coeur d'Alene River and Tributaries Remedial Investigation Feasibility Study* (July 2000, Public Review Draft) (referred to in this report as the CDAB HHRA, or the HHRA). EPA Region 10 requested this review *to ensure that the HHRA is technically sound and consistent with EPA policies* (August 1 memorandum from Region 10 to TRW). The Region requested that the TRW give attention to the following priorities related to the assessment of lead risks:

- Is the Risk Characterization transparent, clear, consistent, and reasonable?
- Does the Uncertainty Discussion provide context for the risk results?
- Do the predicted house dust concentrations associated with various yard soil action levels support subsequent blood lead predictions and Preliminary Remediation Goals derivations?
- Does discussion of blood sampling methods, participation rates, and age distribution (which changed over time) help to interpret the blood lead screening results?
- Is the discussion of the results from the two modeling approaches sufficient to support risk management decisions protective for human health risks from lead?

The CDAB HHRA included an extensive assessment of exposures and risk associated with chemicals other than lead. These portions of the HHRA were not the subject of the TRW review.

1.2 Documentation and Data Reviewed

Documents provided to the TRW for this review included the CDAB HHRA report (July 2000 Public Review Draft) and various supporting memoranda and data tabulations provided by the Region at the request of the TRW, usually in response to requests for clarification of portions of the HHRA or to supplement knowledge of the historical background of the Basin assessment. Within the CDAB HHRA are contained the following types of information which the TRW reviewed:

- summaries of blood lead, soil, and dust lead measurements made during sampling events that occurred in the period 1996 - 1999;
- summaries of the results of correlation and regression analyses of PbB and environmental exposure levels of lead;

- summaries of results of simulations run with the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model), both community and residence batch runs;

- summaries of the results of applications of the EPA Adult Lead Methodology (ALM);

- results of a sensitivity analyses and risk reduction predictions;

- an uncertainty assessment.

Actual data inputs used in IEUBK model runs were not available to the TRW and, therefore, could not be reviewed, and predictions made using alternative inputs could not be compared with those in the HHRA.

2.0 MAJOR COMMENTS

2.1 Relative Merits of Using the IEUBK Model in Community-mode or Batch-mode

Section 6.6.1 of the CDAB HHRA presents child risk estimates that are based on community-mode and batch-mode IEUBK model runs. In the community mode, geometric mean exposure levels for house dust and yard soils for a given Conceptual Site Model Unit (CSMU) were used as input to the model to predict the geometric mean blood lead concentration and P_{10} for the CSMU. In the batch mode, house dust and yard soil lead levels for each residence were used as input and a geometric mean blood lead concentration and P_{10} were predicted for each residence. The corresponding CSMU values were calculated as the arithmetic means of the individual residence values.

The TRW supports the HHRA in not relying on the results of the community-mode runs to estimate community risk at CSUs or to estimate clean up levels. It also recognizes the utility of the uses of the community-mode runs in the HHRA as part of an exploration of the potential impacts of community yard soil and house dust exposure on risk, and in an analysis of the sensitivity of the model to variations in soil and dust lead levels, as a precursor to using the batch-mode runs to estimate soil clean-up levels (see Section 6.7.6, p 6-55 of the HHRA).

However, the TRW strongly agrees with Section 7.4.4 (p 7-39) of the CDAB HHRA which states the major limitations of the community-mode approach:

> *Use of the community mean input approach and subsequent estimation of community blood lead level means and blood lead level distributions is the least computationally and conceptually desirable of the various approaches that can be employed. The community approach subsumes too much uncertainty simply because it attenuates heterogeneity of lead exposures, and understates the most revealing depictions of blood lead distributions. For this reason, the IEUBK model's user manual (USEPA 1994a, b) discourages use of the model at this insensitive, gross level.*

EPA guidance stresses that, for the purpose of supporting remedial decisions for residential contamination, risk assessment approaches should focus on children who receive their principal lead exposures in the immediate vicinity of their homes (U.S. EPA, 1994). The batch-mode is the preferred approach to this end, because it ensures that risks at each residence are integrated into the site risk estimate.

While EPA guidance focuses on the need to evaluate risks for children at their homes, guidance also recognizes that other exposure scenarios can be important and should be considered where non-residential sources may make an important contribution to lead exposures in a community. In populations where young children spend a large amount of time at locations other than their homes (e.g., neighboring yards, homes of relatives, etc), risk estimates based only on exposure of individual children at their homes may not accurately capture risks associated with each child's actual exposure. At such sites, it may be desirable to include exposures from these community areas in the batch-mode runs. This could be accomplished, for example, by using the multiple source dust model in the batch mode (not in the community mode). Alternatively, activity of the child could be distributed between home yard and community areas having different mean soil lead concentrations, and a time-weighted average used as input in the batch mode. This approach is represented in the HHRA in the application of the IEUBK Box model, although there are other issues associated with this model (see Section 2.2 of this report for further discussion of the Box model).

The community-mode approach was explored in the HHRA as a method for capturing community-wide residential exposures in the risk estimates. However, as suggested in Section 7.4.4 of the HHRA, the results obtained from the community approach should be interpreted with caution, as there may not be any children in the community that are exposed to the actual calculated mean (geometric or arithmetic) soil and dust lead concentrations. Only if a children randomly accesses all yards within the community equally could we expect over time the average exposure concentration for any child to be represented by the community mean exposure level. Random accessing of all yards over a given year (the exposure time step of the IEUBK model) would represent an extreme scenario at many sites, but may reflect the activity patterns of children in the relatively small communities within the CDAB. If this is not the case, then risks at any individual residence may be underestimated or overestimated by community-mode predictions, depending on whether the exposure levels at that residence are lower or higher, respectively, than the community average. The estimates may also be affected by other variables. For example, the relative contributions of home or community exposures may depend on the age of the child in a given home, the presence of older siblings, the geography of the community, or local activity patterns and social customs of the community

2.2 Evaluation of Alternative Approaches to IEUBK Modeling

2.2.1 General Comments

Two approaches were used to estimate lead risks in the CDAB. One approach used the IEUBK model with site-specific exposure inputs and all other parameters kept at default values. In the HHRA and in this report, this model is referred to as the IEUBK default model. A second approach used the IEUBK model with site-specific exposure inputs, an adjusted bioavailability factor (18% total percent available), and a time-weighted soil lead contribution from the residential yard and neighborhood (dust: home yard soil: community yard soil ratio, 40:30:30). These adjustments were based on calibration exercises conducted as part of a Five-year Review of the of the Bunker Hill Superfund Site (BHSS, TerraGraphics, 2000). The adjusted IEUBK model is referred to in the HHRA and in this report as the IEUBK Box model, to distinguish it from the IEUBK default model. The HHRA presents risk estimates, as well as assessments of post-remediation risks assuming various clean-up action levels, based on both the IEUBK default and Box models.

The TRW supports HHRA in not relying exclusively on the IEUBK Box model to estimate pre-remediation risks in the CDAB (i.e., percentage of children exceeding 10 µg/dL, P_{10}). The Box model was calibrated to agree with the downward trend in post-remediation blood lead concentrations observed at the BHSS. Factors that may have affected this downward trend (e.g., decreased soil and dust intakes resulting from intervention and educational efforts) may not be operating or may not be as important in the CDAB. Ideally, if adjustments were to be made to the IEUBK model for its application to the CDAB, such adjustments should be based on the available information about exposures and blood lead concentrations in the CDAB and not at the BHSS. However, the extensive experience at the BHSS could be applied to the CDAB if there were a better understanding of the exposure factors that contributed to the downward trend in the blood lead concentrations at the BHSS, and whether or not these same factors affect blood lead concentrations to the same degree in the CDAB.

Aside from the extensive data base on the presence of lead contamination in the CDBA, the HHRA does not present site-specific data applicable to estimating specific parameters of the IEUBK model (see further discussion below). In the absence of data to estimate specific parameters, consideration of non-default choices can be useful for range-finding and sensitivity investigations. The blood lead concentrations and risk estimates based on the Box model represent an example of this, in that the Box model imposes certain assumptions that are thought to be valid at the BHSS, and the differences between the predictions made with the default and Box models show the impact of these assumptions. For example, if the fractional absorption of lead is lower than the default values, and there is a 50% contribution of community yard soil to soil lead intake in the CDAB, then the predicted blood lead concentrations will be lower than those based on the default model. The results of the Box model runs are interpreted from this perspective in the HHRA (see Section 7.4.4, p. 7-41, HHRA). At this time, there does not appear to be an adequate basis for determining which of the two models provide more accurate risk predictions in the CDAB. However, the differences in the predictions from the two models are not large, given uncertainties associated with both models, and it could be readily argued that actual risks fall within the range of predictions from the two models. Comparisons of the mode predictions with observed blood lead concentrations do not completely resolve this issue because of uncertainties regarding the representativeness of the blood lead data. These uncertainties are discussed at length in the HHRA (Section 7.4.1) and in this report (see Section 2.3 of this report). However, uncertainties not withstanding, the blood lead data do not exclude predictions from either model as being applicable to the CDAB.

It is also important to note that the soil and dust measurements used in the IEUBK model represent the 175 µm fraction, rather than the 250 µm fraction that is more commonly used in CERCLA site assessments. While, as is explained in the HHRA (Section 7.4.2, p. 7-29, HHRA), the smaller particle size fraction may better represent the fraction that adheres to the hands of children, it also is likely to have been enriched with lead, relative to the 250 µm fraction. The TRW has recently provided clarification and further guidance on this issue

(U.S. EPA, 2000). Therefore, risk estimates based on the 175 µm fraction would be expected to be higher than those based on the 250 µm fraction from the same samples. This introduces an additional conservative (health protective) bias into the risk estimates. Another way to view this, is that, had the 250 µm fraction been used as the basis for the soil and dust concentration terms, the risk estimates based on the IEUBK model would have been lower by some unknown degree. The use of the 175 µm soil and dust fractions also has relevance to the interpretation of the bioavailability adjustment used in the IEUBK Box model (see below).

2.2.2 Bioavailability Adjustment

The bioavailability value of 18% was applied as an alternative to the model default of 30%. No data specific to the bioavailability of lead in soil and dust at CDAB are discussed in the HHRA and such data apparently have not been generated at the site. The TRW's short sheet, *IEUBK Model Bioavailability Variable* (U.S. EPA, 1999a), discusses methods that can be used to study bioavailability of lead and which have been used in practical applications for other Superfund sites. The TRW recommends that bioavailability studies of soil and dust, or other relevant data, should be used to support a site-specific bioavailability value for the CDAB. However, as a means to provide information regarding the sensitivity of model predictions to this parameter, consideration of alternate bioavailability values, such as that used in the Box model, can provide useful information.

The TRW understands the intent in the HHRA in interpreting the bioavailability adjustment as a surrogate for adjustments in one or more of several variables that relate soil and dust exposure levels to the amount of lead taken up into the blood (see Section 7.4.4., p. 7-41, HHRA). However, the TRW does not endorse use of the bioavailability term in this way. Segregating the various factors that may affect lead uptake would allow one to consider the potential effects of these factors that may influence uptake of lead by children in the CDAB. For example, the CDAB lead concentration data are based on samples screened to a 175 µm sieve size. This may provide relatively conservative estimates of the lead concentration compared to a more common practice of using a 250 µm sieve size. To the degree that concentration estimates tend to be conservative, so would estimates of lead uptake in the model runs (see below). There is also a potential for some decrease in the soil and dust ingestion rates for children in households where health concerns about lead may have caused parents to use increased care in cleaning and supervision of children's activities.

Another uncertainty in extrapolating a bioavailability factor for the CDAB from BHSS data is that it is possible that exposures in the CDAB may be a mix of lead from the smelter and lead from mine wastes, or other sources, which may have different absorption fractions. The relative contribution of these sources may change with location in the CDAB (e.g., with upwind or downwind from the smelter, or up or down gradient from the smelter), and may change with remediation. For example, at some locations in the CDAB, historic smelter emissions may contribute more to lead in house dust than in yard soils. If lead in smelter dust has a different fractional absorption than lead from other sources, removal of yard soil may change the absorption fraction of the lead to which children would be exposed at that location. There is some support for this possibility in the BHSS, where the calculated bioavailability factor which resulted in better agreement between the IEUBK model predictions and observed blood lead concentrations changed (increased) over time as the remediation proceeded (see Appendix Q, HHRA).

Since the bioavailability adjustment had a pronounced impact on predicted blood lead concentrations and risk estimates, it would be informative to more directly display in the assessment the effects of changes in bioavailability (either directly or as a surrogate modifying lead uptake) on lead risk predictions. This might take the form of graphs and tables that show a range of choices for the parameter value and resulting changes in risk. Given the lack of information specific to bioavailability, such presentations could show the effect of a potential site-specific modification to lead uptake through undetermined mechanisms. An example of this is provided in the attached Figure 1 which shows the impact of various assumptions about lead enrichment in the 175 µm fraction relative to the 250 µm fraction on lead risk. The TRW notes that the IEUBK modeling assumptions regarding bioavailability (or more generally lead uptake) need not be linked exclusively to the multi-source soil exposure scenario presented in the Box model.

2.2.3 Partitioning of Source Contributions to Soil Dust Ingestion

Exposures for children at sites other than their homes were incorporated into the Box model results (using the batch mode calculations) by assigning to each a child a fraction of total soil exposure at home and a fraction of total exposure to an *average* community yard soil concentration (i.e., house dust: yard soil: community soil ratio, 40:30:30). This scenario would have particular relevance for those (often older) children who would spend much of their time away from home playing at a variety of residences, parks, or other areas in the community.

The basis for the 40:30:30 ratio derives from structural equation modeling of the data from the BHSS, which indicated a significant effect of community yard soils on blood lead concentrations (Appendix Q, HHRA). The use of this ratio in modeling lead risks in the CDAB assumes a similar community yard soil contribution in the BHSS and CDAB. The HHRA concludes that this is the case from a stepwise regression analysis of the CDAB data (Section 6.4.2, p. 6-23), This, together with the experience at the BHSS and the expected similarities in the Basin communities, in terms of behavior patterns of children, were the empirical bases for retaining the 40:30:30 ratio in the application of the IEUBK Box model to the CDAB. Although this is a major conceptual change from the default model, the impact of use of the 40:30:30 ratio on risk estimates appears to be relatively minor; the difference between the predicted blood lead concentrations when the default ratio of 55:45 or the 40:30:30 (or a 75:18:7) ratio were assumed in the model was relatively small (Table 4-28, Appendix Q of the HHRA). Thus, from a risk assessment perspective, the modification is of minor consequence.

The concept of including a community contribution to soil lead intake deserves further comment because of its potential utility at other sites. EPA guidance has encouraged the consideration of alternate sources of dust lead intake, other than that occurring at the home. This is the rationale for including the alternate dust source option in the IEUBK model. In the HHRA, the community average of yard soils was used to represent the soil lead concentration of the fraction of the soil lead exposure occurring away from home. There are many sources of dust in a typical community, such as deposition from industrial activity and vehicular traffic, that are not derived from soil. Consequently, an aggregate of individual property soils cannot fully represent community dust exposure. Nevertheless, the use of soil data in the absence of data from these other sources has the effect of assuming that the concentration in the unmeasured sources is the same as the aggregate community soil, not that the unmeasured sources do not exist. The community average serves as a reasonable central estimate in the absence of any information on additional sources of community dust or the behavior patterns of specific children. As an example of the potential utility of this measure, highly mobile children who lived at residences with *clean* soil (e.g., after yard remediation) may still have elevated risks due to access to lead at other yards in the community. The TRW would caution, however, that a community *average* concentration term is a non-specific measure. Risk calculations in which a child's exposure is assumed to be represented by a time-weighted average of home and community average values, may serve to indicate the importance of community wide lead sources for a highly mobile child. However this approach is of limited value in supporting clean-up decisions for specific non-home properties, for example daycare centers, schools, roadsides, and other public areas. A more useful alternative for these types of exposures would be to model results specific to contamination levels at specific schools, daycare locations, local parks (see Section 2.5 of this report for further discussion).

A specific technical concern pertains to how community *average* concentration values were calculated for use in IEUBK modeling (as applied in the Box model and in *community* mode calculations with the default model). As noted above, a rationale for use of a community average concentration term is that an (idealized) highly mobile child would be exposed to contamination throughout a community and the summation of these many events of contacting different concentrations would be equivalent to exposure to a lead concentration equal to the community average values. Under the circumstances where this scenario is applicable, explicitly calculating the summation of exposures will lead to the use of an arithmetic mean and not a geometric mean exposure concentration term. This may be illustrated with an example. Suppose that on three days, a child is exposed at three different locations with lead concentrations of 30, 300, and 3000 ppm. Further, assume that on each day the child ingests 0.1 g of soil at the exposure location. Therefore on the three days, the child has a lead intake from soil of 3 µg, 30 µg, and 300 µg, respectively (30 µg/g x 0.1 g/d x 1 d = 3 µg, etc.) The daily average lead intake for this period is 111 µg/d. For comparison, the arithmetic mean soil concentration at these locations is 1110 ppm and the geometric mean concentration is 300 ppm. Daily intake rates calculated using the arithmetic mean soil concentration value reproduce the daily lead intake level for the child (1110 µg/g x 0.1 g/d = 111 µg/d). However, an intake calculation using the geometric mean understates daily lead intake by more than a factor of three (300 µg/g x 0.1 g/d = 30 µg/d).

2.3 Use of Blood Lead Survey Data

Substantial efforts have been made to collect data on blood lead levels on children and adults living in the CDAB. The HHRA reports that through a combination of efforts in 1996-1999, 524 blood samples representing 424 children under age 9 years of age living in 843 households were collected in the Basin.

The blood lead data in CDAB were collected as a public health service provided to Basin residents and have been utilized by local public health authorities (Idaho Department of Health and Welfare) to provide advice and assistance to children found to have elevated blood lead levels. The HHRA reports that 50 children received follow-up assistance due to the detection of blood lead levels above 10 µg/dL. The majority of children re-screened after public health intervention showed a reduction of blood lead levels from their prior elevated levels indicative of a benefit of this intervention program.

The effort to screen children for elevated blood lead levels in the CDAB comports with CDC recommendations. CDC guidance succinctly describes the value of blood lead screening programs:

> *Blood lead screening is an important element of a comprehensive program to eliminate childhood lead poisoning. The goal of such screening is to identify children who need individual interventions to reduce their BLLs [blood lead levels].*

Blood lead screening may or may not provide data that is representative of the population of concern.

The blood lead screening data in the CDAB also serves the important purpose of demonstrating the presence of continuing risks of lead exposures to the Basin children. Basin wide, 12.5% of tested children up to 7 years of age had blood lead levels above 10 µg/dL (see Table 6-4c, HHRA). In some communities in the Basin, the risks were higher: 22%, Burke/Nine Mile; 19%, Wallace; 14%, Kingston; and 25%, Lower Basin. Risks of elevated blood lead levels were also higher in the younger groups of screened children. Basin wide, 19-26% of tested children one to three years of age had blood lead levels above 10 µg/dL. In some communities, in the Basin the risks were higher in this age group: 50%, 2-3 years, Burke/Nine Mile; 22-40%, 83% 1 years; Wallace; 2-3 years; Kingston; 20-50%, 1-3 years, Lower Basin (the smaller numbers of children make these figures less accurate) (Table 6-5, HHRA). These results serve to demonstrate the need for further attention to reduce sources of lead exposure in the Basin and the need to continue screening and interventions to reduce lead exposures.

However, in interpreting these data it is important to recognize that blood lead screening efforts were not intended to constitute a research investigation of subjects living in the Basin. Individuals were not randomly or systematically chosen for screening as part of a statistical study. Therefore, the screening data must primarily be interpreted as information regarding the children and families who desired screening. It should not be assumed, in advance of careful examination, that the data on screened children is also representative of the majority of children who did not participate in the screening programs. This issue is discussed in some detail below.

Blood lead data collected in the CDAB were used in the HHRA in three ways: 1) to characterize age-related and geographic patterns of excessive blood lead concentrations; 2) blood lead concentrations predicted from the IEUBK model were compared to observed blood lead concentrations in order to assess the effectiveness of various assumptions made in the model for describing current blood lead concentrations; and 3) blood lead data were used in correlation and regression analyses to evaluate relationships between environmental levels and blood lead concentrations in the Basin.

The HHRA takes great care in discussing the limitations of the blood lead data for the above three uses in the risk assessment (see Section 7.4.1, HHRA). The TRW supports the uncertainty assessment of the blood lead data that is presented in the HHRA. In reviewing the documentation for the blood lead data in the HHRA, the TRW arrived at a similar conclusion; that several issues limit interpretations of both the empirical comparisons and the regression analyses. These include: 1) representativeness of the data with respect to the Basin community; 2) sampling bias; and 3) the potential effect of intervention on blood lead concentrations in the community (see detailed discussion below). The TRW concluded that the information presented in the HHRA that relate to these issues suggests that the data do not provide an adequate basis for reliably estimating central tendency blood lead concentrations, percentiles or the percent above 10 µg/dL, or other population parameters. Therefore, the data should be used with great caution and with appropriate consideration of the uncertainties associated with the method of solicitation of participants in the survey, particularly if it is used to characterize blood lead levels in the community. This has particularly important implications for extrapolating any results of these analyses to areas of the CDAB not sampled, or to extrapolations over time, such as post-remediation blood lead concentrations. In view of the limitations of the blood lead data, the TRW supports the approach adopted in the HHRA of basing risk estimates on the results of the IEUBK model runs. This approach is consistent with EPA Office of Solid Waste and Emergency Response (OSWER) guidance (U.S. EPA, 1994). The observed blood lead concentrations support the general outcomes of model runs, that the risk of exceeding a blood lead of 10 µg/dL is greater than 5% is substantial for children who live on many of the properties in the CDAB. A more detailed discussion of the blood lead data are provided below.

2.3.1 Representativeness of the Data

General Issues Concerning Representativeness

The TRW supports the HHRA in its conclusion regarding the blood lead survey data (Section 7.4.1, p. 7-23, HHRA):

> *The nature of this turnout* (i.e. participation in the blood lead surveys) *raises*

questions about the reliability of using these data in the HHRA and subsequent remedial decisions.

Blood lead data can provide information on relationships between environmental exposures and blood lead concentrations of individuals in the sample group; however, if such analyses are to be extrapolated to the general population of interest, in this case, residents in the Basin, the blood lead data must represent the entire CDAB population. A sample is likely to be representative if non-biased sampling methods are employed, such as random sampling (equal probability of selection of any individual or home) or stratified random sampling (probability of selection of any individual or home depends upon which strata to which they are assigned. If the sample is not random, it may have a bias which may result in the sample mean not reflecting the CDAB mean (this also applies to other descriptive variables of the sample and corresponding CDAB population parameters). A biased sample may still be used to estimate CDAB parameters, however, to do this, an understanding of the nature and quantitative effect of the bias is needed so that sample estimates can be adjusted to account for bias.

From the outset, the collection of blood lead data in the CDAB was never intended to provide a random sample for an epidemiological study. Blood lead data were collected as part of a public health service provided to CDAB residents. Thus, it would only be fortuitous if the sample turned out to approximate a random sample. Furthermore, data were not collected to specifically evaluate biases in the sample, although some data were collected that may be useful for this purpose.

The lack of a random sampling design in the blood lead program presents challenges for use of the data in the risk assessment, however, it should not preclude all use *a priori*, as the data do provide valuable information on a substantial number of children. In evaluating the data, all factors that might contribute to bias in the estimates need to considered and potential biases need to be identified and quantitatively explored, if possible. An exploration of information available to evaluate and adjust for sample bias is provided in the HHRA (Section 7.4.1, HHRA) and potential approaches are described in Section 2.3.2 of this report.

CDAB Sampling and Sample Size

If the sample is random, it can adequately represent the population even if it contains a relatively small fraction of population. However, concern for the representativeness of the sample increases as the fraction sampled becomes small. One of the concerns about the CDAB sample is that it captured a relatively small fraction of the target population. Child blood lead data used in the HHRA derive from surveys conducted during four consecutive summers, 1996-1999. In 1996, a CDAB-wide survey was conducted which attempted to capture all potentially impacted homes within one mile of the Coeur d'Alene River (essentially the entire flood plain), excluding the BHSS. In 1996, there were approximately 6252 homes in the CDAB. Among these, 2700 homes were identified as potentially subject to lead or other metal exposures and residents at 843 homes agreed to participate in the survey; blood samples were obtained from 98 children (ages 9 m-9 yr), or approximately 9% of the estimated number of children in the CDAB in identified impacted areas (1025-1120, p 6-9 of HHRA). Approximately 200 additional homes were sampled in subsequent sampling years. In 1997, samples from 26 children were collected in the impacted areas, 11 of whom had been sampled in 1996. In 1998, samples from 128 children were collected and 272 children provided samples in 1999. Thus, the total number of samples available for the assessment was 524. Approximately 100 children were sampled twice, therefore, the total number of children represented in the sample was approximately 424. This represents an unknown fraction of the population of children that lived in the CDAB over the four-year sampling period, including children who may have entered (included births) or left the area since 1996. The fraction of the children sampled may have varied across communities in the Basin.

In addition to differences in sample size, there were other notable differences in the four surveys. The HHRA does not provide much information on the sampling approach used in 1997 or 1998, for example, the extent to which it may have been targeted to certain groups of people, or geographically distributed within the Basin. The 1999 survey offered a cash incentive for participation, and was more aggressively promoted within the community (p. 6-9, HHRA).

2.3.2 Sources of Bias and Approaches to Evaluating Bias

Given the sampling objectives and approach, and the relatively small fraction of the population sampled, bias is a concern in extrapolations made from the sample to the CDAB population for the following reasons. Among the sampling data, the 1996 study came closest to being a systematic effort to capture all residences in the CDAB. However, because blood samples were obtained from only 9% of the potentially impacted children CDAB in 1996, there is no assurance that this study was representative of the community.

In the 1997 -1999 screening efforts, community residents were asked to take the initiative to bring their children into clinics for blood sampling. While a higher participation (272 children) was achieved in the 1999, the entirely self-selected nature of the participants reduces confidence that this sample would be representative of the non-sampled members of the community. It should also be noted that the later screening efforts did not limit participation to children from areas likely to be impacted by metals contamination, as was the case in 1996. As a result, that the numerically greater number of participants in1999, relative to1996, may have included a larger fraction of children who lived in areas that had lower potential for contamination.

Other data may be available to help judge the likelihood that data for screened children would be likely to be representative of the community as a whole. Relevant information would include consideration of factors that may be associated with lead risks such as age, residence in more contaminated locations, residence in properties in poor repair, and socioeconomic status. Data to allow a comparison of demographic characteristics of screened children and the community as a whole are unfortunately very limited. Data on factors such as socioeconomic status were not collected for screened children (unless a high blood lead value triggered a home intervention) and, therefore, cannot be compared with the larger community. However, age is one significant risk factor for which there is comparative data, and unfortunately, the younger groups of children that are at highest risk are substantially under represented in the group of screened children. This indicates that, taken as a whole, the screened group may be at somewhat lesser risk of elevated blood lead levels than the community at large. The deficit of young children in the screened group also indicates that the factors that motivated parents to participate in screening were not reflective of lead risks as they would be evaluated by public health professionals.

The HHRA discusses different hypotheses that have been offered concerning the potential biases in the available blood lead data (Section 7.4.1, p. 7-22, HHRA). One set of arguments suggests that parents with a greater level of concern about lead risks elected to have their children participate in screening. Such parents would be likely to act on their health concerns so as to limit their children's exposures to lead (e.g., limiting places of play, more contentious cleaning of dust at home or attention to hand washing and other hygiene measures). The TRW believes that this proposal has plausibility and that it corresponds with concerns of TRW about potential biases in some blood lead investigations conducted at other sites.

Alternately it has been contended that in the 1999 screening event, where the participation rate was greatest, the payment of a 40 dollars compensation to participants would have resulted in a disproportionate participation by lower income families. It is then argued that children in lower income families would have greater risks of elevated blood lead levels. In this regard, the TRW observes that, while socioeconomic variables have been shown to have correlations with lead risks in some other studies, caution needs to be exercised to avoid over interpretation of this issue. First, it is not clear that the payment of compensation to participants was the predominant factor in securing the somewhat larger participation rate in 1999. Considerable additional effort was invested in 1999 to inform and encourage participation in the 1999 survey. Secondly, to the extent that children in lower income families may have increased risks of elevated blood lead, such a correlation would be expected to result from more fundamental underlying factors, not monetary income itself. Some (not all) families experiencing economic hardship may also lack time or resources to provide for as much supervision of children as they would desire. Therefore, it is not clear that parents in families under such stress would have the option of dropping other commitments to take children in for screening. The TRW does not believe that it is appropriate to make the assumption that parents with lower incomes would provide less attention to environmental risks to their children.

Potential sources of bias can be proposed, and then an evaluation made as to whether or not data are adequate for quantitatively assessing the direction and/or strength of the bias. Examples of potential sources of bias include:

- Neighborhood clustering could result in certain areas of the CDAB being under-represented in the sample (spatial bias).

- Parents with younger children might have been less inclined to provide blood samples from their children. This would result in an age bias in the sample.

- The inclination to allow samples may have been influenced by duration of residence which could have affected knowledge and perceptions of the extent or importance of the problem.

- Differences in socioeconomic status (SES) could affect the inclination to allow sampling; for example, lower SES residents may have placed a higher or lower priority to lead as an issue for their families than higher SES residents.

- Information about environmental lead levels or blood lead levels could have influenced participation in the survey. For example, parents who more strongly suspected that there was a lead problem in their community may have been more motivated to participate.

- Cash incentives for participation (discussed above).

The above examples can be translated into a series of specific queries directed at the existing data to determine if available data suggest or do not suggest bias in selection, or an unequal probability of response. Examples of these that could be explored include:

- Were the sample statistics stable over time?

- Were the responders equally distributed geographically in the CDAB and within the CSUs?

- Did the response rate vary across communities?

- Are SES scores similar in the sample and CDAB?

- Are other demographic variables similar in the sample and CDAB (e.g., age, age of housing, residence time)?

Despite a rather large variation in the level of participation in the blood lead monitoring study over the 4-year period (26-272 children per year), minimum, maximums, arithmetic and geometric means and standard deviations of the sample blood lead measurements remained remarkably constant from year to year (see Table 6-1, HHRA). This would suggest that, if there was a strong bias, it may have been relatively constant from year to year. This outcome would also be expected if the samples were indeed representative of a stable population. On the other hand, the percent participation in the blood lead survey varied with age (see HHRA Table 6-4a). This would suggest a possible age bias or under representation of younger children relative to older children.

2.3.3 Potential Effects of Intervention on Blood Lead Concentrations

Another time-related consideration is the impact of community awareness on the time course of blood lead concentrations within the CDAB. Community awareness can and does play a role in affecting short-term behaviors, through temporary decreases in contact with lead sources and consequent transient decreases in blood lead concentrations. Questioning about hygiene and home conditions at a time preceding blood sample collection may promote actions that would tend to reduce risks of elevated blood lead levels. Since there is evidence that individual level contact with parents is important to the success of intervention efforts (Kimbrough, 1994), such studies may implicitly include an important individual level intervention component. This was most likely the case in the CDAB where the blood lead and environmental surveys were specifically intended as part of public health service to the community residents.

In the CDAB, nurses visited homes where blood lead concentrations were considered to be elevated (greater than 10 µg/dL). Blood lead measurements taken in homes after a nurse visited that home may reflect the impact of the nurse-visit, and may not represent the blood lead that would be expected in that exposure scenario, had the nurse-visit not taken place (e.g. a new resident of the home). It is not clear from the HHRA whether blood lead measurements taken after a nurse-visit were excluded from or included in analyses reported in the HHRA. However, the TRW was advised by Region 10 that, if a second blood lead sample was collected as part of or as a follow-up to a nurse-visit, these data were excluded from the analyses. Therefore, nurse-visits are likely to be less of a factor in analyses of blood lead concentrations measured within a given sampling year. However, it is possible that blood samples may have been obtained from children who lived in homes that received a nurse-visit in previous years.

2.4 Use of the EPA Adult Lead Methodology (ALM)

The ALM was used in the HHRA to estimate Preliminary Remediation Goals (PRGs) for adult non-residential exposures, including occupational exposures and recreational exposures at upland parks and other Common Use Areas (CUAs). The EPA ALM includes algorithms that can be used to predict adult blood lead concentrations associated with site soil lead exposures or soil PRGs (U.S. EPA, 1996, 1999b).

PRGs were estimated based on central tendency and reasonable maximum exposure (RME) assumptions about exposure frequency and soil ingestion rate (see Section 6.5.2, pages 6-31 – 6-33, Tables 6-31 – 6-33 of HHRA). All other inputs to the ALM were default values from U.S. EPA (1996). The central tendency exposure frequency for the occupational scenario was 43 day per year which represented a 5 day per week construction project having a 2-month duration. The RME estimate was 195 days per year, representing a 5 day per week, 9-month (39 week) construction season. For CUAs, the corresponding central tendency and RME frequencies were 16 days per year and 32 days per year, respectively. For upland parks, the corresponding central tendency and RME frequencies were 15 days per year and 30 days per year, respectively. Soil ingestion rates for the three scenarios were as follows (central tendency, reasonable maximum): occupational, 0.1, 0.2; CUAs, 0.05, 0.1; upland parks, 0.05, 0.1.

The TRW supports the HHRA in the decision to calculate PRGs for non-residential soils based on the EPA ALM and supports the general approach used in applying the ALM at the site. However, several details in the application of the methodology were inconsistent with guidance developed by the TRW (U.S. EPA, 1996) and may have resulted in increased uncertainty in the risk estimates (Section 6.6.3, p. 6-46, Tables 6-57 – 6-60, HHRA) . These include the following:

- The EPA ALM should not be used to estimate PRGs for exposures that are less the three months in duration or less frequent than one exposure episode per week. Shorter exposure durations and lower exposure frequencies are not sufficient to achieve a quasi-steady state blood lead concentration, which is a required assumption for use of the ALM for predicting either PRGs for blood lead concentrations. The derivation of several of the parameters in the ALM (biokinetic slope factor and the absorption fraction) is based on steady-state observations. Furthermore, the relevance of the health criterion (10 µg/dL) to short-term exposures is less certain than it is for chronic exposures.

- The averaging time used in the EPA ALM should reflect the actual exposure duration. In the HHRA, the averaging time was the number of exposure days per year divided by the number of days in the year, even when the assumption made in the HHRA was that the exposure occurred over a shorter interval (e.g., 2 months in the occupational scenario). Time-averaging the exposure over a 365-day period, rather than over the exposure duration, results in higher calculated PRGs.

- In the HHRA, PRGs were calculated with the EPA ALM using the standard (integrated soil and dust pathway) and discrete soil and dust pathway approaches, however, in the later, a value of 1 was assumed for the soil weighting factor. This assumption effectively converts the discrete approach into the standard approach, since it represents a scenario in which there is no dust ingestion. Thus, the calculated PRGs will always be the same for the two approaches if the values of all other parameters the same.

- The PbB_0 parameter in the EPA ALM was assigned a value of 1.7 µg/dL, a value recommended by the TRW to represent non-Hispanic, white adult females, based on national survey data. The use of 1.7 µg/dL is consistent with TRW recommendations for sites where site data are not adequate to support site-specific estimates of PbB_0. However, the HHRA does not quantitatively explore alternative assumptions that could have been made, given the blood lead data collected at the site.

These topics are discussed in greater detail below.

2.4.1 Use of the EPA ALM for Short-term Exposures

The TRW has recommended a minimum exposure frequency of 1 day per week for a continuous duration of 3 months for applications of the ALM (U.S. EPA, 1996). This recommendation is based on the minimum exposures required to achieve a quasi-steady state blood lead concentration. A quasi-steady state is a required assumption in the methodology because the recommended values for the absorption factor and biokinetic slope factor were based on an analyses of data relating lead exposure to quasi-steady state blood lead concentrations. Furthermore, the relevance of the health criterion10 µg/dL) to short-term exposures is less certain than it is for chronic exposures. ALM-based predictions of adult or fetal blood lead concentrations associated with very short exposure durations or infrequent exposures would be highly uncertain and are discouraged for use in risk assessment. In the HHRA, exposure durations of two months for the occupational scenario do not meet these minimum criteria.

2.4.2 Averaging Time in Relation to Exposure Duration

The averaging time used in the ALM should reflect the exposure duration (U.S. EPA, 1996). This allows for a better assessment of a peak exposure period which may result in adverse health effects, and is more consistent with the biokinetics of lead (deposition and release) in the body. For example, if the assumed exposure season (e.g., warm weather construction season) is considered to be 39 weeks, and the exposure frequency is 5 days per week, or 195 days, a more appropriate averaging time would be 39 weeks x 7 days per week, or 273 days. Similarly, for a short term (3 month) construction project, the concern would be for the peak blood lead achieved during that time period. In this case, 64 day exposure period would be averaged over 90 days. In the HHRA, the averaging time was the number of exposure days per year divided by the number of days in the year. This effectively distributes the lead intake and uptake equally over a one-year period, even when the assumption made in the HHRA was that the exposure occurred over a shorter interval (e.g., 2 months in the occupational scenario). Time-averaging the exposure over a 365-day period, rather than over the exposure duration, results in higher calculated PRGs, which may not provide adequate protection to workers whose activities result in contact with soil.

2.4.3 Use of Soil/Dust Weighting Factor in ALM

The TRW has made recommendations regarding how to use the ALM to calculate PRGs when information is available to quantify discrete intake pathways from soil and dust (U.S. EPA, 1996). The methodology incorporates additional terms for the concentrations of lead in soil and dust (AF_S, AF_D), the mass fraction of soil in dust (K_{SD}), the absorption fraction for ingested dust (AF_D), and the fraction of the total soil plus dust ingestion rate contributed by soil (W_S, soil weighting factor).

In the HHRA, PRGs were calculated using the standard (integrated soil and dust pathway) and discrete soil and dust pathway approaches; however, in the latter, a value of 1 was assumed for the soil weighting factor. This assumption effectively converts the discrete approach into the standard approach, since it represents a scenario in which there is no dust ingestion. Thus, the calculated PRGs will be the same for the two approaches if the values of all other parameters are the same, and therefore, there is no justification for presenting the discrete pathway calculations.

2.4.4 Site-Specific Baseline Blood Lead (PbB_0) in an Uncertainty Analysis

The ALM includes a parameter that represents the blood lead concentration in adults expected at the site if the non-residential soil lead exposure of interest had not occurred. Ideally this should be estimated from blood lead measurements in women of child-bearing age who experience all exposures at the site with the exception of the non-residential exposures of interest, in this case, occupational, and recreational exposures. In reality, obtaining such a sample at a site, and in particular, identifying a representative subset of the population whose blood lead concentrations are not impacted by the non-residential exposures of interest is not always possible. As a result, the PbB_0 parameter is usually assigned a value based on data on other populations, such as national estimates.

In the HHRA, the PbB_0 parameter was assigned a value of 1.7 µg/dL, a value recommended by the TRW to represent non-Hispanic, white adult females, based on national survey data (U.S. EPA, 1996). The use of 1.7 µg/dL is consistent with TRW recommendations for sites where site data are not adequate to support site-specific estimates of PbB_0. However, the HHRA does not quantitatively explore alternative assumptions that could have been made, given the blood lead data collected at the site. As part of the HHRA, blood lead data were collected in 1996 on 667 adults in the CDBA. Based on the population data presented in Table 3-4 of the HHRA, this would appear to represent approximately 16% of the 4200 adults of ages 15-44 years. Table 6-8b indicates that blood lead samples were obtained from 151 women of child-bearing age, defined as 17-45 years of age. If the sex ratio of this age range in the CDAB was approximately 50:50 (see Table 3-4, HHRA), then the sample would represent approximately 7% of the of women of child bearing age in the CDAB (i.e., 151/2100). The HHRA presents the summary statistics of the blood lead concentrations in this group of adult women, and concluded that the geometric means were 2.0 or less in all areas except Burke/Nine Mile (2.4 µg/dL) and Wallace (2.6 µg/dL). Use of the national estimate of 1.7 µg/dL is reasonable in this case because it would be difficult to make a convincing argument that the blood lead sample was representative of women of child bearing age at the site who did not experience soil lead exposures at recreational sites or from occupational activities. Nevertheless, because the geometric mean blood lead concentration of the sample was higher than the national estimate, it would have been informative to explore the implications of a higher site-specific PbB_0 on the estimates of the PRGs as part of the uncertainty assessment. If a site-specific value for PbB_0 were to be used in ALM, it would have been within the range 1.6-2.6. Most of this range would have yielded lower calculated PRGs if used in the ALM in place of the national estimate of 1.7 µg/dL. This would suggest the possibility that the PRGs may need to be lower than those predicted when national estimates of PbB_0 are applied to the site. A similar type of uncertainty assessment could have been applied to the geometric standard deviation (GSD) parameter in the ALM, based on the observed GSD in the sample of women of child bearing age.

2.4.5 Use of Other Input Parameter Values

The construction scenario is usually considered to be a high-end exposure in a risk assessment; therefore, it is usually not necessary to evaluate both central tendency and RME scenarios. However, it is always useful to evaluate the impacts on both the risk and the PRG when the sensitive parameters are varied. These parameters are usually those relating to the intake and to the exposure frequency and duration. In the HHRA, both the ingestion rate and the exposure duration were varied. The TRW has recommended the use of a soil intake in the range of 100 mg/day for a worker with direct contact with soil and dust, however, a range of values could be explored in an uncertainty analysis. However, because the averaging time for a non-carcinogenic contaminant is usually the time over which the exposure occurs, not much change will be seen in risk estimates or the projected PRGs when this parameter is changed. A reasonable scenario that meets the pseudo-steady state criterion and allows evaluation of a range of soil ingestion rates, is probably the most useful, especially in developing a protective PRG for an outdoor worker in the CDAB.

2.5 Assessment of Incremental Lead Intakes and Associated Health Risks to Children

The HHRA includes an assessment of incremental lead intakes and risks associated with recreational exposures of children to lead at neighborhood areas, upland parks and other CUAs (Section 6.6.2, p 6-43, HHRA). The TRW recognizes the importance of evaluating the *incremental* sources of lead exposure that may affect children and adults in the CDAB (e.g., waste piles and contaminated sediments) and supports the HHRA in including these assessments as an important component of the CDAB risk assessment. The HHRA, however, does not clearly indicate how the estimated increments were used in the IEUBK model. The HHRA should more clearly describe that the increments were input in addition to residential sources, and that the incremental blood lead concentration associated with a given recreational activity was (apparently) defined as the difference between the blood lead concentrations predicted when the incremental intakes were included or not included in the model. More importantly, however, the TRW believes that the reported incremental risks of elevated blood lead attributable to recreational exposures may have been underestimated, for several reasons discussed below.

First, exposure estimates for shorter-term exposures should not be averaged over the entire year, for use in the IEUBK Model. The IEUBK model is relevant for continuous exposure periods that are of sufficient duration to produce a quasi-steady state blood lead concentration. The TRW considers the minimum exposure duration to be three months. In order to predict the quasi-steady state that could occur during a shorter (less than a year) period, the soil exposure is not averaged across the year. The HHRA presented a number of assumptions regarding exposure frequencies for these recreational scenarios, which ranged over a period of 168 to 238 days per year. These periods should be long enough to attain a quasi-steady state concentrations if the incidents occur at least once per week.

An additional source of underestimation of risk is use of current environmental lead levels as the baseline for the incremental estimates. Once residences and other frequently used areas are remediated to lower lead concentrations, the incremental risk attributable to exposure at additional recreational areas, if not also remediated, will be greater than suggested in the HHRA, by a substantial amount in some cases.

Another factor qualifying the usefulness of the projected incremental exposures is the appropriate estimates of incremental soil ingestion. The HHRA reported increments estimated from total daily soil ingestion rates reduced by the proportion of waking hours spent at the site. The two components of these increments are the amount of soil ingestion associated with the recreational exposures, and any appropriate weighting. The TRW was not certain whether the intention was to assume that part of the total daily ingestion would occur at the recreational area, or whether the ingestion associated with recreational exposure was expected in addition to typical ingestion rates at more commonly frequented locations (home, school, daycare, etc.). The HHRA calculation resulted in a greater than default amount of daily soil ingestion, which may be quite reasonable. Even higher ingestion may result at a wet site, such as those involving sediments. However, the more representative weighting of soil ingestion is the proportion of outdoor time spent at the site, not the proportion of waking hours.

The approach taken in the HHRA is very similar to that recommended by the TRW, however, the HHRA does not calculate cumulative risks (e.g., P_{10}) associated with the various recreational exposures, but instead, calculates the incremental intakes and incremental central tendency blood lead concentrations. Calculation of the cumulative risks associated with each scenario, or a combination of scenarios would be informative in terms of showing the potential impacts of recreational exposures when combined with residential exposures. This type of analysis is also likely to show that, when recreational exposures are considered, the risk of exceeding a 10 µg/dL blood lead concentration will exceed 5% at all CSUs, when estimated with either the IEUBK default or Box models.

The TRW has made recommendations regarding approaches to utilizing the IEUBK model in assessing cumulative risks from residential and recreational exposures (see Attachment A of this report). This approach was implemented in the risk-based screening assessment of the CUAs in the Lower Basin and a detailed description of the approach is provided in Appendix B of the HHRA.

2.6 Environmental Data Sampling and Quality Assurance

2.6.1 Use of Floor Mats to Collect Residential Dust Samples

A novel feature of the CDAB HHRA was the use of floor mats to collect residential dust samples Section 2.2.1, p. 2-7, HHRA). The dust mat data were not used as input to the

IEUBK model runs; dust inputs were derived from vacuum bag samples. The TRW has recommended the use of floor dust samples for estimating house dust lead concentrations and input into the IEUBK model and recognizes that there is very little information available on vacuum cleaner bag samples and floor mat samples and the use of this data in risk estimation at lead sites. However, because the dust mat approach is currently being explored by other researches in the lead field, and because it is an approach that the EPA has no comparable experience, the following observations are offered in this report.

The 1996 sampling event was the first application of door mats for collecting residential indoor dust to assess exposure at a Superfund site. Dust mats were placed in approximately 500 homes in 1996, with no indication of whether vacuum bags and dust mats were collected from the same homes. Vacuum bag samples were collected from approximately 320 homes. Mats were placed inside the home in a *high traffic area* and as close to the main entry as possible. The mats were collected three weeks after placement. Instructions given to the residents of the homes were that the mats should be walked on, but were not to be used as a shoe cleaning mat. If mats were handled in a way that violates the protocol, the mat was excluded from the data set. The HHRA notes that two mats collected in 1999 were excluded from the data analysis. Although vacuum cleaner bag contents were collected, the HHRA does not specify how long the bags were in use, or how such information might have been obtained. It does indicate that efforts were made to verify with the homeowner that the vacuum had not been used outside of the home since previous bag change.

The CDAB HHRA provides comparisons of the dust lead concentrations estimated from the dust mat and vacuum bag samples. Arithmetic and geometric mean dust mat concentrations were higher than vacuum dust concentrations at all of the CSUs. A statistical comparison of the results from the two sampling approaches was not provided in the HHRA. It is unlikely that the unpaired group means presented in the summary tables (Table 6-11 of the HHRA) are significantly different (a paired comparison is not discussed in the HHRA).

2.6.2 Water Sampling

Water samples were collected from homes that were not on community water supplies. In the 1996 sampling event, samples were collected as close to the well head as possible. In subsequent years, flushed and first-draw samples were collected from the tap. The samples collected near the well head may not reflect drinking water exposures. Although this approach to sampling may be useful for detecting potential lead exposures from the water supply, it is not the most desired approach to developing inputs for the drinking water pathway in the IEUBK model because it may not provide a good estimate of actual exposures to children in home. Piping and solder in the home can contribute to lead in tap water. This contribution will vary during the day with use of the home water system, being higher after the water stands for a period and lower after flushing of the pipe system. It will also vary with the hardness or softness, and pH of the water. In order to ensure that this variability is represented in the estimates of drinking water lead concentrations, samples should be collected from the tap of each home, or a representative sample of homes, after the water has been allowed to stand in the pipes (e.g., first flush) and after the pipes have been flushed.

3.0 COMMENTS AND RECOMMENDATIONS IN RESPONSE TO REGION 10 PRIORITY ISSUES

3.1 *Is the risk characterization transparent, clear, consistent, and reasonable?*

The CDAB HHRA is a complex document that demands a careful and thorough reading if it is to be understood in its entirety. This is not surprising given the complexity and history of the site, and the wealth of data that was evaluated in the assessment, including analyses of data from the BHSS. Whether the risk characterization is clear and transparent will be determined only after it has had a wider readership. The sheer complexity of the assessment is likely to result in a wide range of opinions on this, determined, in part, by the background of individual readers and their willingness to give the entire report a complete and thoughtful reading.

From a technical perspective, the TRW found the risk characterization to be consistent and reasonable, in terms of the major outcomes of the assessment. That is, the individual parts of the assessment strongly support the dominant findings that: 1) lead risks to children in the CDAB are unacceptably high; 2) to achieve a reduction of risk to acceptable levels, the site will have to achieve soil lead levels of 400-800 ppm; and 3) the major uncertainties in the latter estimates are the magnitude of the impact of soil lead reductions on house dust lead levels, and the impact of education and intervention on soil and dust ingestion. That an assessment of this complexity can arrive at such a strongly supported set of conclusions, including strong support for a fairly narrow range in the soil clean up level, is remarkable, and a compliment to the architects of and contributors to the assessment.

The HHRA presents the results of three approaches that provide information about lead risk in the CDAB: 1) blood lead screening data gathered over a 4-year period, which may be biased to some unknown degree; 2) the IEUBK default model, which has worked well at other lead sites when data for children who were known to be exposed primarily at their homes were used in the model (Hogan et al. 1998; White et al. 1998), but for which only limited site-specific data to evaluate parameter estimates are available for the CDAB; and 3) IEUBK Box model, which was calibrated to agree with nine years of blood lead survey data, during which environmental and blood lead levels have been decreasing, and for which applicability to the CDAB has not been adequately assessed.

In general, blood lead surveys are the least desirable approach to estimating lead risks, unless the survey is convincingly representative of the population at the site, which does not appear to be the case at the CDAB from the perspective of the TRW. The blood lead screening data for the CDAB do, however, provide important data that show that there is a substantial problem with environmental lead exposures for children in the Basin. In view of the limitations of the blood lead data, many of which are discussed in the Uncertainty Discussion (Section 7.4.1, HHRA), the TRW supports the approach adopted in the HHRA of basing risk estimates on the results of the IEUBK model runs. This approach is consistent with OSWER guidance (U.S. EPA, 1994). Nevertheless, the blood lead measurements and the IEUBK default and Box models yield reasonably consistent information that support the same conclusion, that Basin-wide residential lead risks are above acceptable levels. The blood lead survey indicates that 13% of the screened children between the ages 9-84 months had a blood lead $10 µg/dL; the IEUBK default and Box models yield P_{10}s of 27% and 10.4%, respectively (for all parts of the Basin combined, 9-84 months). A reasonable estimate of Basin-wide residential risk is within this range and, risks may be higher by 5-10% if incremental risk from recreational exposures are considered. The risk estimates based on default assumptions may be somewhat conservative because of the use of the 175 µm fractions of soil and dust, which may have been enriched in lead relative to the 250 µm fractions that are more commonly measured at CERCLA sites.

This consistency in the outcome of various analyses could be emphasized to a greater extent in the HHRA. Indeed, some readers of the report may be left with a stronger impression of the differences in the outcomes of the three approaches rather than their similarities. The similarities of outcomes are a main strength in the Risk Characterization.

In addition to the above general comments related to consistency and reasonableness, the TRW offers several other suggestions that would strengthen both aspects of the Risk Characterization:

- More emphasis should be placed on estimates of residential lead risk that are based on the batch mode IEUBK model runs, in which risks are estimated at each individual residence, and not on community mode runs. The batch-mode approach is consistent with EPA policy that emphasizes that, for the purpose of supporting remedial decisions for residential contamination, risk assessment approaches should focus on children who receive their principal lead exposures at their homes (U.S. EPA, 1994). The analyses termed "community mode" in the HHRA utilize an inappropriate simplifying assumption that all children within a community are exposed to the same average lead concentrations. The batch-mode is the preferred approach for site assessment, because it ensures that risks at each residence are integrated into the site risk estimate.

- Information that would allow a more complete assessment of the degree to which the blood lead samples reflect the CDAB population would facilitate the interpretation of the blood lead data, particularly the interpretations of comparisons between observed and predicted blood lead concentrations and regression analysis of relationships between exposures and blood lead concentrations. Such information might include the geographic distribution of the sampling within the CDAB and within CSUs, the distribution of response rates across communities, SES scores within the sample compared to those of the CADB and various comparisons of various demographic variables in the sample and CDAB (e.g., age, age of housing, residence time).

- Comparisons between the blood lead concentrations predicted with the IEUBK model and those observed in the CDAB (p. 6-29, HHRA) should not be relied on as the sole basis for evaluating the accuracy of model to represent exposures and blood lead concentrations in the CDAB. In order for this type of comparison to be correctly interpreted, the HHRA would have to provide more evidence that the observed blood lead concentrations adequately represent the CDAB population and that the exposure assumptions adequately represent the individual children sampled. The blood lead comparisons (Appendix Q, Tables Q4.26, HHRA) using alternative assumptions about the dust:soil ratio are useful only as a sensitivity analysis, but not as a basis for adjusting the model, because there is no real basis for attributing a *better fit* between predicted and observed blood lead concentrations to any given variable or set of variables. Also, there is uncertainty regarding factors that may have biased the blood lead observations.

- The IEUBK Box model should not be used as the basis for estimating pre-remediation risks in the CDAB (p. 6-39, HHRA). The Box model was calibrated to agree with the downward trend in post-remediation blood lead concentrations observed at the BHSS. Factors that may have affected this downward trend (e.g., decreased soil and dust intakes resulting from intervention and educational efforts) may not be operating or may not be as important in the CDAB. If adjustments were to be made to the IEUBK model for its application to the CDAB, such adjustments should be based on the available information about exposures and blood lead concentrations in the CDAB. The experience at the BHSS could be applied to the CDAB by gaining a better understanding of the exposure factors that contributed to the downward trend in the blood lead concentrations at the BHSS, and whether or not these same factors can be expected to affect blood lead concentrations in the CDAB to the same degree.

- The concept of separating yard and neighborhood soil contributions to lead intake is a potentially useful one, in particular when applied to predicting the soil lead cleanup levels (p. 6-29, HHRA). If supporting data were available, a similar approach could be extended various potential sources of dust lead exposure. However, Appendix Q of the HHRA does not provide support for use of the 40:30:30 ratio of dust: yard soil: community soil. Appendix Q suggests that there was little difference in predicted blood lead concentrations when either of three dust:soil ratios (55:45, 40:30:30, 75:18:7) were assumed in the model (see Appendix Q, Table 4-26 4-27, HHRA), which leads to an inconsistency in the HHRA.

- In representing the community soil lead levels, the arithmetic mean, rather than the geometric mean is generally preferred (p. 6-39, HHRA).

- The discussion of the bioavailability adjustment in Appendix Q (p. Q-10/2, HHRA) seems to lump the absorption and intake terms in the IEUBK model into a single bioavailability term. These are actually separate parameters in the model that can be affected independently by site factors. Segregating these factors would allow one to consider the potential effects of changes in lead intake or absorption on risk estimates. The assumption that the bioavailability of lead in soil and dust is less than the IEUBK model default model (approximately 30% at low lead intakes) is not adequately justified to support adjustment of the IEUBK model for application to the CDAB (p. 6-39, HHRA). This assumption would be more strongly supported with evidence in animals or humans that the bioavailability of ingested lead in CDAB soil and/or dust is actually lower than the default values or lower than lead in soils from other mining/smelting sites.

- Inclusion of more detailed documentation on the IEUBK model runs would allow the reader to understand exactly how the model was implemented (p. 6-38, HHRA). Ideally, a file containing the inputs to the batch model runs would be important documentation that would enable a third party to reproduce the model runs described in the HHRA.

- The EPA ALM should not be used to estimate PRGs for exposures that are less the three months in duration or less frequent than one exposure episode per week (6-46, Tables 6-57 – 6-60, HHRA). The averaging time used in the EPA ALM should reflect the actual exposure duration.

3.2 *Does the Uncertainty Discussion provide context for the risk results?*

The uncertainty discussion is very comprehensive and does provide excellent context to the risk assessment. However, in some cases, the discussion may be interpreted as being in conflict with the Risk Characterization. For example, the Uncertainty Discussion states that the community-mode IEUBK model runs are of limited value for estimating risks (7.4.4, p 7-39, HHRA) A conclusion with which the TRW concurs. However, risk estimates based on community-mode runs are nevertheless included in the Risk Characterization. The Uncertainty Assessment discusses the limitations in the blood lead data collected in the CDAB and the implications these limitations place on interpreting comparisons with model predictions and in making remedial decisions (Section 7.4.1, p. 7-23, HHRA). However, these data are used in the Risk Characterization, and the outcomes of comparisons with model predictions are described in terms of *over predictions* or *under predictions*, suggesting a greater confidence in the blood lead data than is actually reflected in the Uncertainty Discussion. These inconsistencies are not major problems if the HHRA is thoroughly read and understood, but may lead to misunderstandings or misperceptions for a more casual reader.

The Uncertainty Discussion is largely qualitative and certain conclusions could be more strongly supported by more quantitative sensitivity analyses. For example, certain assumptions for which there is great uncertainty could have been varied in model runs, similar to the approach that was taken in the sensitivity analysis of soil and dist lead levels in the estimate of clean up goals (Section 6.7.6, p. 6-55, HHRA). An example of this is also included in this report as it pertains to the sieving fraction (see attached Figure 1). Assumptions about bioavailability and soil and dust ingestion rates could also have been quantitatively explored. A more quantitative uncertainty analysis, in which the more sensitive model parameters were allowed to vary according to their respective uncertainty ranges, may also have been of added benefit. Such an analysis would have shown, most likely, that the apparent differences in the predictions of the IEUBK default and Box models are actually well within an overlapping range of model predictions, when uncertainty is considered. This would have supported a convergence, rather than a divergence, of the model outcomes. The above suggestions, if feasible, would have complimented the HHRA, but are not needed to support the conclusions of the HHRA or remedial decisions that might follow.

3.3 *Do the predicted house dust concentrations associated with various yard soil action levels support subsequent blood lead predictions and Preliminary Remediation Goals derivations?*

The goal of the approach taken in the HHRA of estimating post-remediation house dust lead concentration from the regression relationship between pre-remediation soil lead and house dust lead is reasonable, given the options available. However, the applicability of the outcome of such an analysis to the post-remediation conditions is uncertain. It should be recognized that when there is substantial noise in the data (e. g., in the lead contamination estimates for specific residences), regression models have a tendency to under-predict the strength of the true relationship between the variables. In this context, it is plausible that cleanup of yard soil will have a larger impact in the reduction of indoor dust levels in residences than is predicted by the regression equations developed in the HHRA. At this point there is insufficient data to determine the magnitude or kinetics of the impact of soil remediation on house dusts at the CDAB site. Numerous factors could result in the post-remediation dust lead levels having a very different relationship to soil lead levels than in the pre-remediation condition.

The dust lead projection will remain an important variable in any projection of post-remediation risks or estimation of clean up levels. This is demonstrated clearly in the sensitivity analysis presented in the HHRA (Section 6.7.6, p. 6-55, HHRA). The effectiveness of soil remediation in lowering blood lead concentrations will depend on the degree to which house dust lead levels decrease in response to changes in soil lead levels. A program in which dust lead levels in the homes were monitored before and after remediation would provide data to develop additional analyses at the site that may allow a more certain quantitation of the impacts of remediation on house dust lead levels.

3.4 *Does discussion of blood sampling methods, participation rates, and age distribution (which changed over time) help to interpret the blood lead screening results?*

The discussion of the blood lead data, in particular, that which appears in the Uncertainty Discussion (Section 7.4.1, HHRA), is very helpful. However, the TRW noted certain details that would have helped if emphasized, but which were absent or difficult to glean from the

HHRA. (Ultimately, this information was made available to the TRW via conversations with Region 10).
These include:

- Additional information on the sampling approaches used in 1997 or 1998, for example, the extent to which the sampling was targeted or geographically distributed, would be useful for assessing the representativeness of the data, and whether or not the data should be combined with data collected in other sampling events.

- Additional information on the timing of the blood samples with respect to the timing of environmental samples, noting that all blood lead samples were collected in August and within one or two months of the collection of environmental samples. This is an important positive aspect of the sample design in that it alleviates variables that might otherwise affect interpretations of relationships between the blood lead concentrations and environmental lead levels at individual residences

- Because of the potential effects of health intervention activities in soil and dust ingestion and blood lead concentrations, it would be useful to indicate whether or not blood lead data collected after intervention (e.g,. nurses visits) were used in the various blood lead analyses. As it turns out these data were not used in the risk estimates.

In addition to the above, certain other information and analyses would be helpful, if feasible to provide. These would include the geographic distribution of the sampling within the CDAB and within CSUs, the distribution of response rates across communities, SES scores within the sample compared to those of the CDAB and various comparisons of various demographic variables in the sample and CDAB (e.g., age, age of housing, residence time). Such information might be useful, if available, for exploring further the existence and quantitative significance of biases in the blood lead measurements.

3.5 *Is the discussion of the results from the two modeling approaches sufficient to support risk management decisions protective for human health risks from lead?*

The discussion of the results from the IEUBK default and Box modeling approaches in the batch mode will support risk management decisions. The TRW considers the use of the IEUBK default model to be the preferred approach for decision-making, based on the results of previously reported empirical comparisons (Hogan et al., 1998). These empirical comparisons showed satisfactory agreement between observed blood lead concentrations and IEUBK model predictions for children with environmental lead exposure measurements that characterized the majority of their exposure (approximately 90%-100%), and was relatively stable (that is, not decreasing over time), as the model was designed to be used. This review has discussed a number of reasons why the blood lead data collected in the CDAB, while very helpful for the children surveyed, may not be suitable for calibrating IEUBK predictions for decision-making:

- incomplete information about children's exposures (admittedly, this information is difficult to obtain; typically, about 50% have exposures away from their residences);
- possible enrichment of the residential soil and dust lead concentrations in the 175 µm soil and dust fractions relative to the measurements the IEUBK model was formally calibrated with;
- the non-steady-state nature of the lead contamination, due to on-going clean-up efforts; and
- the on-going community awareness of the lead problem, possibly lowering (temporarily) dust and soil ingestion rates.

The first factor has a unknown impact on the correspondence of observed and predicted blood lead levels, while the last three logically tend toward higher IEUBK predictions relative to observed blood lead levels, due to the design of the IEUBK model. For decision-making, the primary intended use of the IEUBK model, the TRW recommends considering the default dust/soil ingestion rate to estimate risk for future children populations, when environmental lead levels will have finally equilibrated after the last clean-up and behavioral interventions may let up under the presumption that there is no remaining *hazard*.

Nevertheless, the uncertainties discussed in the HHRA and this review argue against completely dismissing risk estimates based on the Box model. Parameter assumptions in the box model are within a range that can reasonably be considered in a sensitivity analysis of IEUBK risk estimates for this site. For the most recent years of data, there are indications that the calibrated (Box) model tends to underestimate some of the risks and that the default model tends to overestimate some risks. In the absence of any strong scientific basis for excluding either model from consideration, the residential clean up levels can be bracketed by using the two models and accounting for 1) recreational exposure-related increments in blood lead, 2) additional uncertainty introduced by the relatively high blood lead concentrations observed in the Lower Basin, given the relatively low soil and dust lead concentrations there; and 3) consideration of the possible effects of lead enrichment in the 175 µm fraction on the risk estimates. These considerations would support a relatively narrow clean up range, for example, 400–800 ppm. The difference between the extremes of the range, although highly significant in terms of potential clean up costs, would be well within the range of uncertainty bounds for each model if uncertainty were to be quantitatively introduced into the modeling results.

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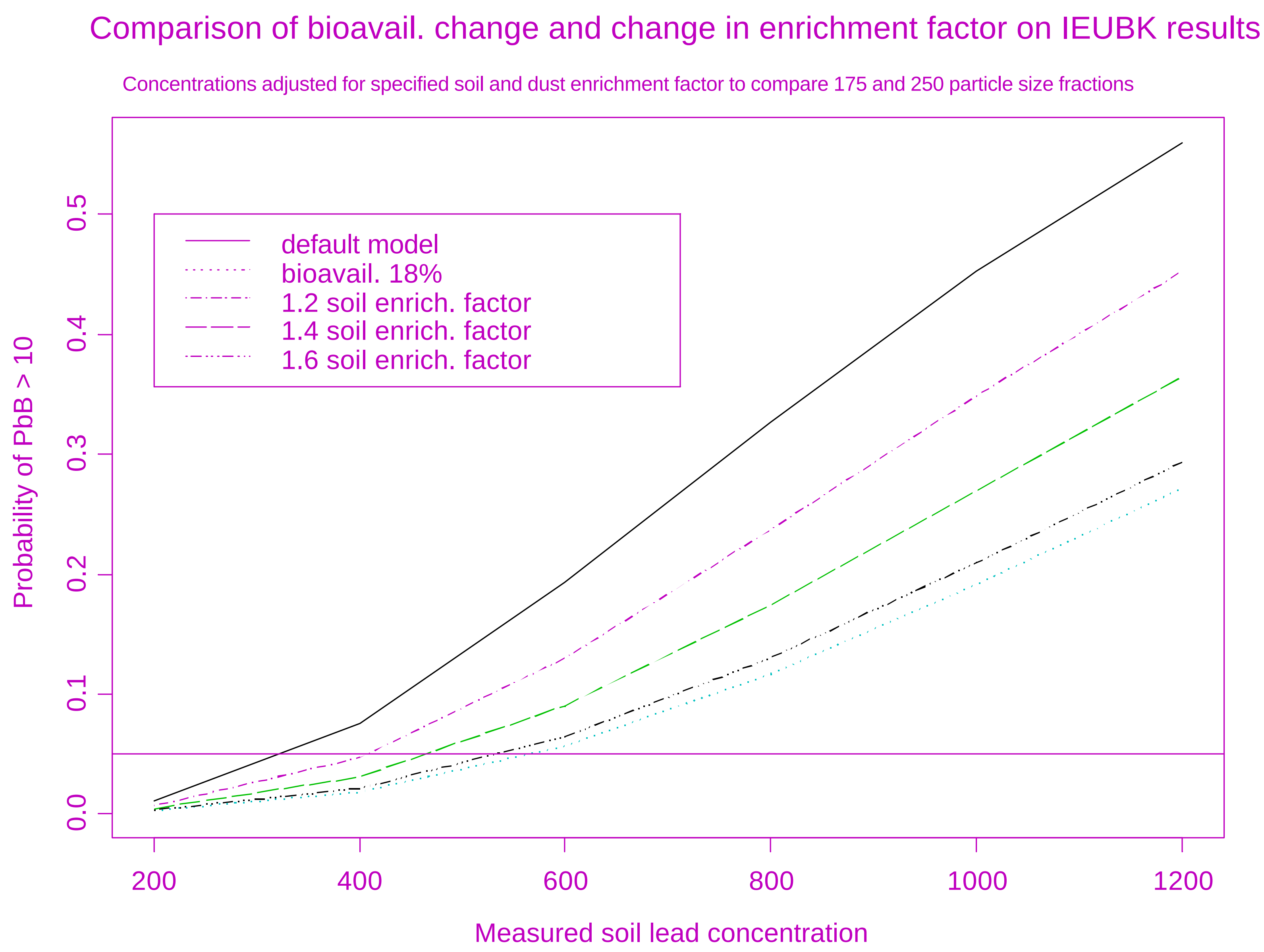

Comparison of bioavail. change and change in enrichment factor on IEUBK results
Concentrations adjusted for specified soil and dust enrichment factor to compare 175 and 250 particle size fractions
default model
bioavail. 18%
1.2 soil enrich. factor
1.4 soil enrich. factor
1.6 soil enrich. factor
Probability of PbB > 10
0.0
0.1
0.2
0.3
0.4
0.5
200
400
600
800
1000
1200
Measured soil lead concentration

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U.S. EPA Technical Review Workgroup for Lead
Review of Human Health Risk Assessment for the Coeur d' Alene Basin

Appendix A

Risk-based Soil Lead Clean-up Goals for a Recreational Area or Trespassing Scenario - Draft Recommendations

SUBJECT: Risk-based Soil Lead Clean-up Goals for a Recreational Area or Trespassing Scenario - Draft Recommendations

TRW members Karen Hogan and Paul White, and Gary Diamond (Syracuse Research Corporation, OERR Contract #68-W6-0038) organized this response, which was discussed by the TRW on May 28, 1998.

1.0 MODELING OF MULTIPLE SOIL LEAD EXPOSURES

The term "park soil" will be used to distinguish soil exposure for a recreational area or trespassing situation from that a child's residence.

1.1. Issues Related to the Temporal Pattern of Exposure

The temporal pattern of exposure to "park" soil can be expected to affect PbB concentrations in the children and, therefore, should be considered in developing the modeling approach. Exposure to "park" soil will result in an increase in PbB concentration above the "background" PbB concentration attributed to the residential sources of lead. For the purpose of this discussion, the TRW will refer to this increase as the park soil-related increment. The magnitude and duration of the PbB increment will vary depending on the temporal pattern of exposure to "park" soil. The PbB increment would be greatest if exposure to "park" soil occurs for 52 days in succession (*e.g.*, over the summer). Exposures to park soil that are evenly spaced over the year (*e.g.,* once every seven days) would give rise to a smaller PbB increment. Exposure patterns within these two extremes would result in increment magnitudes and durations that are within these extremes. The IEUBK model was designed to simulate PbB concentrations associated with exposures of sufficient duration to result in a quasi-steady-state PbB concentration. The TRW has recommended 3 months as the minimum duration of exposure that is appropriate for modeling exposures that occur no less often than once every seven days (U.S. EPA, 1994a, 1994b). The reliability of the model for predicting PbB concentrations in children exposed to Pb for durations shorter than three months (*e.g.,* 52 days) has not been assessed due to insufficient data. To assist risk assessors and managers in interpreting the impact of exposure frequency assumptions on risk-based cleanup goals, this report presents three alternate scenarios for different frequency and duration assumptions that are compatible with the specified exposure of assumption of 52 days/year.

1.2. Use of Weighted Average Exposure Concentrations

Scenarios in which there are exposures to both residential and park soils with different soil lead (PbS) concentrations can be simulated in the IEUBK model using a weighted exposure approach. In this approach, a weighted value is assigned to PbS that reflects the fraction of outdoor hours exposed to residential or "park" soil. The TRW recommends that these weighted exposure calculations apply to the period (*e.g.,* seasons of the year) during which active exposure is occurring. The goal of this calculation is to provide reasonably accurate predictions of quasi-steady-state PbB levels that will result from such sustained exposure. Other exposure variables may be similarly weighted (*e.g.,* dust lead (PbD) concentration). The soil concentrations are weighted based on the estimated fraction of total soil ingestion that occurs at the residence and at the park. Adjustments of other variables in the model also may need to be considered (*e.g.,* water, air).

Various factors could contribute to either an overestimate or an underestimate of the estimated PbB concentration when weighted exposures to park and residential soil are used as inputs to the IEUBK model. Such factors need to be considered in interpreting IEUBK model predictions that are based on the weighting approach described in this report. For example, if exposures to park soil were to occur over a number of days in succession, the cumulative effect would be a temporary elevation of the PbB concentration during and after this period of exposure. This elevation may be greater that estimated using a time weighted average approach. Additionally, estimates for soil and dust ingestion rates used in the model are intended as average daily rates for typical children. Depending on specific eating habits, play, or sports activities, soil ingestion while at the park may exceed typical average values. The TRW recommends that assessors consider the potential for alternative, higher ingestion rates that may occur during soil contact activities and include risk calculations using these rates in the assessment. Also, the IEUBK model predicts that absorption fractions will decrease when higher quantities of Pb are ingested. The daily quantity of Pb ingested will be greater under a sporadic exposure scenario than under a daily exposure scenario that results in the same total amount of Pb intake. Consequently, there is a potential that Pb uptake may be slightly overestimated through the use of time weighted average calculations. Finally, the IEUBK model can provide only a quasi-steady-state approximation to PbB levels during non-continuous exposure scenarios because the model's computer implementation currently allows for changing exposure variables on only an annual basis. These examples indicate the importance of evaluating the available information about exposure patterns at the site in order to assess how well the assessment assumptions are likely to approximate the actual exposure patterns that may be occurring at the site.

2.0. IEUBK-BASED PBB DISTRIBUTIONS FOR A SITE-SPECIFIC PBS LEVEL, USING WEIGHTED SOIL EXPOSURES

The weighting calculations presented in the Appendix were used to develop inputs to the IEUBK model. The following assumptions were made in calculating the weighted concentrations:

1. Children have exposure to "park" soil each day the park is visited, for a total of 52 days spread over 1 year, 6 months, or 3 months (*i.e.,* 1, 2, or 4 days per week, respectively); exposure during the remaining waking hours of the day is indoors at the residence.
2. The lead concentrations of park and residential soil concentrations are 3159 ppm and 10 ppm, respectively. These values were specified in the request to the TRW.

The above assumptions yielded weighted PbS and PbD concentrations for 1, 2, or 3 visits/week to the park. These were used as inputs to the IEUBK model, with default values for all other model variables. In particular, residential dust concentrations were calculated using the weighted mean soil level to which the child was assumed to be exposed and the model default assumptions for the mass transfer of soil into house dust. See the discussion in the Appendix concerning the potential for transport of soils into the home.

The predicted geometric mean PbB concentrations and estimates of the probability (%) of exceeding 10 µg/dL (P_{10}) for children 0-84 months old are shown in Table 1. For scenarios having exposures that occur 1, 2, or 4 times per week, the estimated P_{10} values are, respectively, 10%, 38%, and 75%.

Table 1 also provides geometric mean PbB and P_{10} estimates by age group. This is provided to give the reader information on the age-related pattern of PbB levels that the model predicts for children having these exposure scenarios. However, it is important to note that while the IEUBK is expected to be adequately predictive for children up to 84 months old as a group, IEUBK model predictions are somewhat less certain for specific age subgroups, even when exposure can be assumed to be constant from birth until the age being considered. Specifically, in confirmation exercises, model predictions for children older than 3 years have tended to be similar to or *lower* than observed PbB levels, on average, when considering exposures assumed to be constant from birth (Hogan et al, 1999). The TRW expects that these geometric means and P_{10} for the older groups of modeled children may be slight underestimates, and recommends focusing on the full age range 0–84 months for guiding clean-up decisions.

Note that geometric mean PbB levels corresponding to 2 visits/week are approximately 60 percent higher than those for 1 visit/week, and all P_{10} estimates are substantially higher than 5 percent for all age groups. Two visits/week leads to a substantial increase in PbB levels over 1 visit/week, off-setting some of the uncertainty in the estimated amount of park soil transferred to house dust discussed in the Appendix. Under the assumption of default soil ingestion, with 2 visits/week, <u>any</u> transfer (>0%) of park soil to house dust would be associated with a greater than 5 percent risk of elevated blood lead.

3.0. IEUBK MODEL-BASED CLEAN-UP GOALS

The IEUBK model was run in reverse–mode to identify the weighted PbS concentrations corresponding to P_{10} = 5% for children 0–84 months of age, assuming the other model defaults apply, including the default mass transfer of soil to dust. Then Equation A–2 was used to calculate clean-up goals corresponding to the three use patterns. These clean-up goals are summarized in Table 2. For exposure scenarios in which site visits occurred on 1, 2, or 4 days per week the risk-based soil goals were 2446 ppm, 1228 ppm, and 619 ppm, respectively. Note that the baseline weighted soil concentration of 358 ppm is the basis of the OSWER soil screening level of 400 ppm, by rounding to the nearest 100 ppm. In general, while estimated soil concentrations were reported to the nearest 1 ppm, clean-up goals are more realistic if rounded to the nearest 50 or 100 ppm, depending on site-specific considerations.

Note, however, that through exposures in house dust, children who do not visit the park can have exposure to soil brought home from the park by older children and adults who do visit the park. Also, most regional TRW members have had experiences with sites where older children brought younger children along to visit areas where adult supervision would generally be desired. It is probably useful to consider both the exposed population and the maximally exposed individual in developing a set of use patterns before choosing a clean-up goal. The OSWER soil lead guidance, however, focuses on a slightly different criterion, limiting the individual risk of elevated PbB for a typical child to less than 5 percent, which is not the same as limiting the population risk to less than 5 percent.

4.0. APPLICABILITY OF IEUBK MODEL-BASED CLEAN-UP GOALS TO ADOLESCENTS

In general, the TRW expects that clean-up goals designed to be protective for children less than 84 months old, the most sensitive subpopulation, will be at least as protective for older children. Table 1 indicates that within the age range that it addresses, the IEUBK model generally predicts lower risks of elevated PbB levels for older children. Although less is known about lead exposure and biokinetics for children between 7 and 18 years of age, available data suggest that environmental Pb levels that are protective of younger children will be as or more protective for older children. As children progress towards adult physiology, body weights will increase and Pb absorption is likely to decrease. Additionally, EPA assessments generally assume less soil ingestion for older children and adults than for young children. The Adult Lead Model provides guidance for individuals at least 18 years old. While the IEUBK and Adult models provide bounds for the risk of elevated PbB and for clean-up goals for adolescents with direct exposure to park soil, the processes involved are well understood that any scaling, such as linear interpolation, between the predictions of the two models cannot be supported.

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TABLE 1. Estimated Geometric Mean (GM) PbB and Probability of PbB >10µg/dL (P_{10}), Based on IEUBK Model Simulations of Weighted Average Exposures to Park and Residential Soils[1]

Age Range (months)	1 park visit/week PbS_w = 460 ppm PbD_w = 322 ppm		2 park visits/week PbS_w = 910 ppm PbD_w = 637 ppm		4 park visits/week PbS_w = 1809 ppm PbD_w = 1267 ppm	
	GM PbB (µg/dL)	P_{10} (%)	GM PbB (µg/dL)	P_{10} (%)	GM PbB (µg/dL)	P_{10} (%)
0 – 84	5.5	10.0	8.8	38.2	14.1	75.5
0 – 12	5.7	10.6	8.6	36.1	13.3	69.7
12 – 24	6.9	19.8	11.0	55.5	17.5	86.1
24 – 36	6.5	16.5	10.4	50.0	16.5	83.6
36 – 48	6.2	14.5	10.0	48.0	16.1	81.0
48 – 60	5.1	7.3	8.3	32.1	13.7	72.6
60 – 72	4.4	3.7	7.1	21.1	11.7	61.0
72 – 84	3.9	2.3	6.3	15.5	10.4	50.0

[1]PbS_{park} = 3159 ppm, $PbS_{residential}$ = 10 ppm. Estimates apply to quasi-steady state elevations in blood lead (PbB) levels during the period of exposure. See the Appendix for other abbreviations.

TABLE 2. Soil Lead Levels Associated with a 5% Risk of PbB >10µg/dl (P_{10} = 5%), Based on IEUBK Model Simulations of Weighted Average Exposures to Park and Residential Soils[1]

Age Range (months)	Weighted Soil Concentration at P_{10} = 5%[1]	Clean-up Goals corresponding to P_{10} = 5% and frequency of park usage[2]		
		1 park visit/week	2 park visits/week	4 park visits/week
0 – 84	358	2446	1228	619

[1] PbD = 0.7 x PbS_w, $PbS_{residential}$ = 10 ppm. Estimates apply to quasi-steady state elevations in blood lead (PbB) levels during the period of exposure. See the Appendix for other abbreviations.

[2] See Equation A-2.

APPENDIX

The following set of assumptions is provided to illustrate how Technical Review Workgroup for Lead (TRW) recommendations can be applied to estimate appropriate input values for the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children when soil exposures occur at more than one location.

1. Estimate the weighted soil exposure. For simplicity, it is assumed here that on days that the park is visited, there is no direct (outdoor) exposure to residential soil. See item 4 for more general equations.

$$PbS_w = EF_{site} \times PbS_{site} + EF_{yard} \times PbS_{yard} \qquad \text{Equation A–1}$$

where

PbS_w = Weighted soil concentration
EF_i = Exposure frequency at location *I* (days/week); dimensionless.
PbS_i = Soil concentration at location *I* (ppm), *I* = site (park), residential yard

Example for park exposure, 1 day/week:

$$PbS_w = \frac{1\ day}{7\ days} \times 3159\ ppm + \frac{6\ days}{7\ days} \times 10\ ppm = 460\ ppm$$

2. Estimate dust concentrations. The IEUBK default assumption for the transfer of (residential) soil lead (PbS) to dust lead (PbD) was not developed for a situation where a significant source of lead in soil is distant from the house. Some track-in from the site/park is likely, but all other things being equal, track-in may be less than if the soil source were in the residential yard. There would likely be fewer incidents of track-in per day per person visiting the park in comparison with a residential yard. On the other hand, more intense or sustained play and sporting activities in the park setting could result in larger "loading" of soil on the children (or adult) that could be tracked into the home. Activities at the park, such as organized sports, could contribute to a greater than usual accumulation of soil to bring back to the residence. The extent to which this soil is actually transferred into the residence would depend on a variety of site and person specific factors. For example, soil adhering to outerwear has more time to drop off the more distant the park is from the residence. On the other hand, if weather conditions are damp, the maximum mass of soil picked up is more likely to get to the residence. Without some actual measurements of house PbD levels under these conditions, estimates of PbD concentrations are uncertain. Additionally, while it might be inferred from the very low residential soil level of 10 ppm that the scenario of interest involves new housing, it is important for the assessment to explicitly consider whether other indoor PbD sources, particularly lead based paint, are likely to be present.

An estimate of the residential PbD concentration may be derived using the default soil to dust mass transfer parameter if it is reasonable to assume that the conditions permitting using the default mass transfer rate of 0.70 apply to this situation:

(1) Soil lead is the major source of indoor PbD, and
(2) There is no enrichment or reduction of Pb in the soil fractions transported to indoor dust.

In the absence of further information upon which to evaluate the site specific mass transfer of soil into dust, the TRW recommends using the default of 0.70 to estimate PbD levels for this application. Thus, the dust input value (PbD) for the IEUBK model for this example would be PbD = 0.70 x 460 ppm = 320 ppm..

3. **Back-calculation of clean-up goals from a weighted soil concentration**. This equation is a rearrangement of Equation A-1.

$$PbS_{site} = \frac{PbS_w - EF_{yard} \times PbS_{yard}}{EF_{site}} \qquad \text{Equation A–2}$$

4. **More general equations allowing for soil exposure at both locations (site & residence) on the same day**:

$$PbS_w = EF_{site} \times [(F_{site} \times PbS_{site}) + (F_{yard} \times PbS_{yard})] + (EF_{yard} \times PbS_{yard}) \qquad \textbf{(4)}$$

where:

EF_{site} = Exposure frequency at site, or fraction of the days/week site is visited during the exposure period (dimensionless).
F_{site} = Fraction of daily outdoor time spent at the site on days when the site is visited (dimensionless). If, two hours out of four total hours of outdoor activity are spent at the site, then F_{site} would be (2 hours)/(4 hours) = 0.5.
PbS_{site} = Average soil lead concentration at an exposure unit on the site (µg/g).
F_{yard} = Fraction of daily outdoor time at local background soil lead level (usually near home) = 1 - F_{site}.
PbS_{yard}= Average soil lead concentration near home (µg/g).
EF_{yard}= Fraction of the days/week child does not visit the site during the exposure period = 1- EF_{site}.

For back-calculating a clean-up level:

$$PbS_{site} = \frac{PbS_w - PbS_{yard} \times [(F_{yard} \times EF_{site}) + EF_{yard}]}{EF_{site} \times F_{site}} \qquad \textbf{(5)}$$