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SUBJECT: Evaluation of IEUBK version 2.0 model performance

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The purpose of the memorandum is to address the suitability of the Integrated Exposure Uptake Biokinetics Model for Lead in Children model (IEUBK) version 2.0 for informing human health risk assessments at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) hazardous waste sites. The Technical Review Workgroup (TRW) for Lead (Pb) recommended a number of changes to IEUBK version 1.1 input parameter default values to reflect recent scientific information. The IEUBK version 2.0 reflects these TRW recommended changes in default parameters and other software modifications to improve model functionality. The changes to the IEUBK (especially the TRW recommended changes to highly influential soil/dust ingestion rates) mandated an evaluation of model performance as indicated by White et al. (p. 1524 of EHP, 106(S6):1513-1530, 1998) and as suggested in the Technical Support Document for the IEUBK Model (pp. 32-33 of OSWER #9285.7.22). Accordingly, my staff in collaboration with SRC, Inc., under contract (EP-C-17-015), have conducted an evaluation of the IEUBK version 2.0 model performance as it would be typically applied at CERCLA sites. This evaluation relied on data collected from 1995 to 2018 at the Bunker Hill Superfund Site (BHSS) located in the Coeur d'Alene River basin in northern Idaho. The full results and additional details related to this evaluation of model performance will become available soon in a technical report and journal publication. Collectively, the evaluation results, which are only partially presented here, provide strong support for applications of the IEUBK version 2.0 model in related human health risk assessment.

Data available from the BHSS provided several important features that contributed to the strengths of this model evaluation. First, a relatively large number of individual children's blood Pb levels (n=1,144 above detection or reporting limits) were available that could be geographically matched to measured soil Pb and house dust Pb concentrations and, for approximately 5% of children, measured Pb in drinking water. Importantly, the children's blood Pb levels (BLLs) were measured in the fall, when BLLs are typically at their greatest annual value, as recommended in Section 4.4.4 of the Guidance Manual for the IEUBK Model (OSWER#9285.7-15-1, February 1994). Second, with temporal trends showing ever decreasing BLLs in U.S. children, there was a need to evaluate the IEUBK model at BLLs below the range in geometric mean BLLs of 5 to 7 µg/dL for children included in the prior evaluation of the

model by Hogan et al. (EHP, S6:1557-1567, 1998). The children's BLLs from the BHSS showed a geometric mean of 3.6 µg/dL with a substantial number of BLLs (approximately 70%) that were ≤5 µg/dL. Additionally, measurements of Pb bioavailability in BHSS soils and dusts improved prediction of Pb absorption and, thereby, confidence in the model predicted BLLs.

The IEUBK model performance was evaluated by comparing BHSS observations and model predictions using three comparison metrics: (1) prediction of population geometric mean BLLs; (2) prediction of probability of the BLL exceeding 5 µg/dL; and (3) prediction of distribution of observed individual child BLLs. These performance metrics were selected for the following reasons. Although the U.S. EPA has recommended application of the model in the CERCLA program for predicting the probability of the BLL exceeding 10 µg/dL at residential sites (OSWER 1994 Directive #9355.12 and 1998 Directive #9200.4.27), more recent data suggest the need to consider lower decision levels, including 5 µg/dL. Although, predicting BLLs of individual children is not a recommended application of the IEUBK, in this evaluation and in previous studies, evaluation of geometric mean and upper percentile BLLs predictions has relied on the observed BLL data of individual children. Therefore, it was also of interest to understand how well the model predicts the distribution of individual child BLLs that comprised the performance evaluation dataset.

In general, this evaluation showed that the IEUBK version 2.0 model performed well at predicting population geomean BLLs of the evaluation dataset when used with available site data (concentrations and bioavailability of Pb in soil and dust; water Pb concentrations were included for the small subset of children for whom values were available) and model defaults where site data were not available. The model predicted a geomean BLL for the population that was within 0.3 µg/dL of the observed geomean. As illustrated in Figure 1A, a strong correlation (r^2=0.90) was found between the predicted and observed geomean BLL by age group (i.e., by year). The model predicted probability of exceeding 5 µg/dL for the population was within 5% (absolute) of the observed mean and showed relatively low negative and positive biases ranging from -12 to 14% with a mean absolute difference of 2.6%. The model also performed well at predicting the overall empirical distribution of individual child BLLs, the distributions of observed individual BLLs and predicted geomean BLLs were not significantly different. Furthermore, only 14% of the observed individual child BLLs were located outside the 95% prediction limits of the model as compared to 20% outside the 95% prediction limits in the prior IEUBK evaluation by Hogan et al. (EHP, S6:1557-1567, 1998). These results provide strong support for using version 2.0 of the IEUBK model as part of CERCLA-related site human health risk assessments.

The evaluation team identified and assessed a potential vulnerability in the IEUBK version 2.0 model. This vulnerability lies in the reliance on soil/dust ingestion rates from von Lindern et al. (EHP, 124:1462-1470, 2016) as recommended by the TRW committee rather than those recommended by the EPA in the 2017 update for Exposures Factors Handbook (EFH; available at: https://www.epa.gov/expobox/exposure-factors-handbook-chapter-5). The use of von Lindern results was perceived to be a potential vulnerability because: (1) the results depended on old default parameters (e.g., dietary Pb intake, water Pb concentration, and water intake) in version 1.1 that have been subsequently revised in version 2.0; (2) the TRW selected ingestion rates from the von Lindern study that are inconsistent with the 55/45% partitioning of dust/soil ingestion in the IEUBK model; and (3) the von Lindern study is a single scientific publication, whereas the EFH considered a larger body of evidence that included the von Lindern study. Figure 1 shows that the IEUBK version 2.0 performs well and similarly for predicting observed geomean BLLs

whether using its default soil/dust ingestion rates or those recommended in the EFH. The predicted site-wide probabilities of the BLL exceeding 5 µg/dL were also similar when the TRW recommended and EFH ingestion rates were used in the model, with an absolute difference of less than 2%. These findings are unremarkable given the similarity in the ingestion rates selected by the TRW versus those in the EFH. Of note, the IEUBK version 2.0 model estimates a slightly higher geomean BLL when the default ingestion rates are used compared to when the EFH rates are used. On this basis, the model is slightly more conservative (i.e., health protective) when the TRW recommended soil/dust ingestion rates are used in the model. Overall, the differences in these ingestion rates have minimal influence on the predictive ability of the model.

In summary, the model evaluation results presented here along with additional details presented in the full report, provide strong support for applications of the IEUBK version 2.0 model in CERCLA-related human health risk assessments.

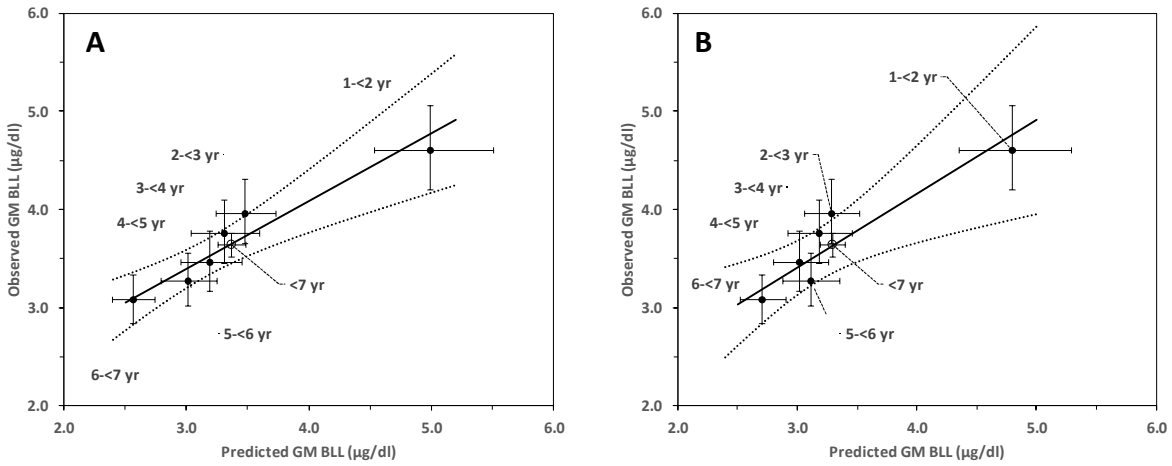

Figure 1: Weighted linear regression model for BHSS site-wide observed and IEUBK predicted geomean BLLs by age group. An aggregate of the other age strata, the open circle is the geomean for all children <7 years and was not included in the regression models. Panels A and B use TRW recommended and Exposure Factors Handbook soil/dust ingestion rates, respectively. Strong relationships (Panel A, r^2=0.90; Panel B, r^2=0.81) were found between the predicted and observed geomean BLL by age group (i.e., by year). Points are age group geomean blood lead levels and flags are 95% confidence limits. Dotted lines show the 95% confidence limits for the weighted regression models.

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