APPENDIX B
1994 OSWER Directive 9355.4-12

EPA
OSWER Directive #9355.4-12
August 1994

MEMORANDUM:
OSWER DIRECTIVE:
REVISED INTERIM SOIL LEAD GUIDANCE FOR CERCLA SITES AND RCRA CORRECTIVE ACTION FACILITIES

Office of Solid Waste and Emergency Response
U.S. Environmental Protection Agency
Washington, DC 20460

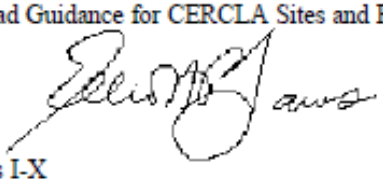
NOTICE

This document provides guidance to EPA staff. It also provides guidance to the public and to the regulated community on how EPA intends to exercise its discretion in implementing the National Contingency Plan. The guidance is designed to implement national policy on these issues. The document does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA may change this guidance in the future, as appropriate.

MEMORANDUM

SUBJECT: Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities

FROM: Elliott P. Laws
Assistant Administrator



TO: Regional Administrators I-X

PURPOSE

As part of the Superfund Administrative Improvements Initiative, this interim directive establishes a streamlined approach for determining protective levels for lead in soil at CERCLA sites and RCRA facilities that are subject to corrective action under RCRA section 3004 (u) or 3008 (h) as follows:

- It recommends screening levels for lead in soil for residential land use 400 (ppm);[1]
- It describes how to develop site-specific preliminary remediation goals (PRGs) at CERCLA sites and media cleanup standards (MCSs) at RCRA Corrective Action facilities for residential land use; and,
- It describes a plan for soil lead cleanup at CERCLA sites and RCRA Corrective Action Facilities that have multiple sources of lead.

This interim directive replaces all previous directives on soil lead cleanup for CERCLA and RCRA programs (see the Background section, 1989-1991).

KEY MESSAGES

Screening levels are not cleanup goals. Rather, these screening levels may be used as a tool to determine which sites or portions of sites do not require further study and to encourage voluntary cleanup. Screening levels are defined as a level of contamination above which there may be enough concern to warrant site-specific study of risks. Levels of contamination above the screening level would NOT automatically require a removal action, nor designate a site as "contaminated."

The residential screening level for lead described in this directive has been calculated with the Agency's new Integrated Exposure Uptake Biokinetic Model (IEUBK) model (Pub. # 9285.7-15-2, PB93-963511), using default parameters. As outlined in the Guidance Manual for the IEUBK Model for Lead in Children (Pub. # 9285.7-15-1, PB93-963510, February 1994), this model was developed to: recognize the multimedia nature of lead exposure; incorporate important absorption and pharmacokinetic information; and allow the risk manager to consider the potential distributions of exposure and risk likely to occur at a site (the model goes beyond providing a single point estimate output). For these reasons, this approach is judged to be superior to the more common method for assessing risks of non-cancer health effects which utilizes the reference dose (RfD) methodology. Both the Guidance Manual and the model are available to Superfund staff through the Superfund Document Center (703-603-8917) and to the public through the National Technical Information Service (703-487-4650).

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[1] The residential screening level is the same concept as the action level proposed in the RCRA Corrective Action Subpart S rule (July 27, 1990, 55 *Federal Register* 30798).

Residential preliminary remediation goals (PRGs) for CERCLA remediations and media cleanup standards (MCSs) for RCRA corrective actions can be developed using the IEUBK model on a site-specific basis, where site data support modification of model default parameters. At some Superfund sites, using the IEUBK model with site-specific soil and dust characteristics, PRGs of more than twice the screening level have been identified. However, it is important to note that the model alone does not determine the cleanup levels required at a site. After considering other factors such as costs of remedial options, reliability of institutional controls, technical feasibility, and/or community acceptance, still higher cleanup levels may be selected.

The implementation of this guidance is expected to provide for more consistent decisions across the country and improve the use of site-specific information for RCRA and CERCLA sites contaminated with lead. The implementation of this guidance will aid in determining when evaluation with the IEUBK model is appropriate in assessing the likelihood that environmental lead poses a threat to the public. Use of the IEUBK model in the context of this guidance will allow risk managers to assess the contribution of different environmental sources of lead to overall blood lead levels (e.g., consideration of the importance of soil lead levels relative to lead from drinking water, paint and household dust). It offers a flexible approach to considering risk reduction options (referred to as the "bubble" concept) that allows for remediation of lead sources that contribute significantly to elevated blood lead. This guidance encourages the risk manager to select, on a site-specific basis, the most appropriate combination of remedial measures needed to address site-specific lead exposure threats. These remedial measures may range widely from intervention to abatement. However, RCRA and CERCLA have very limited authority to address interior exposures from interior paint. For detailed discussion of the decision logic for addressing lead-contaminated sites, see the Implementation section and Appendix A.

Relationship to lead paint guidance. In addition, this interim directive clarifies the relationship between guidance on Superfund and RCRA Corrective Action cleanups, and EPA's guidance on lead-based paint hazards (discussed further in Appendix C). The paint hazard guidance will be issued to provide information until the Agency issues regulations identifying lead-based paint hazards as directed by Section 403 of the Toxic Substances Control Act (TSCA).[2] Lead-based paint hazards are those lead levels and conditions of paint, and residential soil and dust that would result in adverse health effects.

The two guidance documents have different purposes and are intended to serve very different audiences. As a result the approaches taken differ to some degree. The lead-based paint hazard guidance is intended for use by any person who may be involved in addressing residential lead exposures (from paint, dust or soil). It thus relates to a potentially huge number of sites, and serves a very broad potential audience, including private property owners or residents in addition to federal or state regulators. Much residential lead abatement may take place outside any governmental program, and may not involve extensive site-specific study.

This OSWER guidance, on the other hand, deals with a much smaller number of sites, being addressed under close federal regulatory scrutiny, at which extensive site characterization will have been performed before cleanup decisions are made. Thus, the RCRA and CERCLA programs will often have the benefit of much site-specific exposure information. This guidance is intended for use by the relatively small number of agency officials who oversee and direct these cleanups.

Both the TSCA Section 403 and OSWER programs use a flexible, tiered approach. The OSWER guidance sets a residential screening level at 400 ppm. As noted above, this is not intended to be a "cleanup level" for CERCLA and RCRA facilities, but only to serve as an indicator that further study is appropriate. The Section 403 guidance indicates that physical exposure-reduction activities may be appropriate at 400 ppm, depending upon site-specific conditions such as use patterns, populations at risk and other factors. Although worded somewhat differently, the guidances are intended to be similar in effect. For neither guidance is 400 ppm to automatically be considered a "cleanup level"; instead, it indicates a need for considering further action, but not necessarily for taking action. Neither is meant to indicate that cleanup is necessarily appropriate at 400 ppm. The greater emphasis in this OSWER guidance on determining the scope of further study reflects the fact that both CERCLA and RCRA cleanups proceed in stages with detailed site characterization preceding response actions in every case.

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[2]Title IV of TSCA (including section 403) was added by the Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X of the Housing and Community Development Act of 1992).

Above the 400 ppm level, the Section 403 guidance identifies ranges over which various types of responses are appropriate, commensurate with the level of potential risk reduction, and cost incurred to achieve such risk reduction. For example, in the range of 400 to 5000 ppm, limited interim controls are recommended depending, as noted above, on conditions at the site, while above 5000 ppm, soil abatement is recommended. This OSWER guidance does not include comparable numbers above 400 ppm; instead, as discussed above, it recommends the site-specific use of the IEUBK model to set PRGs and MCSs, when necessary. The remedy selection process specified in the National Contingency Plan (NCP) should then be used to decide what type of action is appropriate to achieve those goals.

In general, because the Section 403 guidance was developed for a different purpose and audience, OSWER does not recommend that it be used as a reference in setting PRGs and MCSs or in determining whether action at a particular site is warranted. (To put it another way, it generally should not be treated as a "to be considered" document or "TBC" under CERCLA.) The section 403 guidance is meant to provide generic levels that can be used at thousands of widely varying sites across the nation. The detailed study that goes on at CERCLA or RCRA sites will allow levels to be developed that are more narrowly tailored to the individual site. Nothing in the section 403 guidance discourages setting more site-specific levels for certain situations; in fact, it specifically identifies factors such as bioavailability that may significantly affect the evaluation of risk at some sites.

The IEUBK model. The Agency is further studying both the IEUBK model and analyses of epidemiologic studies in order to better develop the technical basis for rulemaking under TSCA Section 403. The Agency intends to promulgate regulations under Section 403 setting health-based standards for lead in soil and dust. OSWER intends to issue a final soil lead directive once the TSCA Section 403 regulations are finalized. For additional information on TSCA Section 403 developments, call (202) 260-1866.

However, the Agency believes that risk managers (risk assessors, on-scene coordinators, remedial project managers, and other decision-makers at Superfund and RCRA sites) are currently in need of the best guidance available today. The Agency believes that the IEUBK model is the best available tool currently available for assessing blood lead levels in children. Furthermore, use of the IEUBK provides allows the risk manager to consider site-specific information that can be very important in evaluating remediation options. Therefore, using the latest developments in the IEUBK model and the collective experience of the Superfund, RCRA Corrective Action, and TSCA Section 403 programs, the Agency is offering this guidance and is recommending a residential screening level for Superfund and RCRA sites of 400 ppm.

BACKGROUND

Early OSWER guidance (1989-1991). Four guidance documents on the soil lead cleanup were issued by OSWER during the period of 1989 to 1991:

1. September 1989, OSWER Directive #9355.4-02. This guidance recommended a soil lead cleanup level of 500 - 1000 ppm for protection of human health at residential CERCLA sites.

2. May 9, 1990. RCRA Corrective Action program guidance on soil lead cleanup. This guidance described three alternative methods for setting "cleanup levels" (not action levels) for lead in soil at RCRA facilities. One approach was to use levels derived from preliminary results of IEUBK model runs. The other two approaches were to use the range of 500 to 100 provided in the 1989 directive on CERCLA sites, or to use "background" levels at the facility in question.

3. June 1990, OSWER Directive #9355.4-02A. Supplement to Interim Guidance on Establishing Soil Land Cleanup Levels at Superfund Sites. This memorandum reiterated that the September 1989 directive was guidance and should not be interpreted as regulation.

4. August 29, 1991. This supplemental guidance discussed EPA's efforts to develop a new directive that would accomplish two objectives: (1) account for the contribution from multiple media to total lead exposure; and, (2) provide a stronger scientific basis for determining a soil lead cleanup level at a specific site.

Development of the IEUBK Model for OSWER use. During the 1989-91 time period, use of EPA IEUBK model was identified as the best available approach for accomplishing the objectives outlined in the August 1991 guidance. The model integrates exposure from lead in air, water, soil, dust, diet, and paint with pharmacokinetic modeling to predict blood lead levels in children (i.e., Children 6 to 84 months old), a particularly sensitive population.

In the spring of 1991, OSWER organized the Lead Technical Review Workgroup to assist Regional risk assessors and site managers in both using the model and making data collection decisions at CERCLA and RCRA sites. The workgroup was composed of scientists and risk assessors from the Regions and Headquarters, including the Office of Research and Development (ORD), and the Office of Pollution Prevention and Toxic Substances (OPPTS).

In November 1991, the EPA Science Advisory Board (SAB) reviewed the scientific merits of using the IEUBK model for assessing total lead exposure and developing soil lead cleanup levels at CERCLA and RCRA sites. In general, the SAB found the model to be an important advance in assessing potential health risks from environmental contaminants. However, the SAB also recommended additional guidance on the proper use of the model.

In response to SAB concern over the potential for incorrect use of the model and selection of inappropriate input values both for default and site-specific applications, OSWER developed a comprehensive "Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children" (referred to in this interim directive as the "Guidance Manual"). This Guidance Manual assists the user in providing inputs to the model to estimate risks from exposures to lead. It discusses the use of model default values or alternative values, and the application of the model to characterize site risks. Use of the Guidance Manual should facilitate consistent use of the IEUBK model and allow the risk assessor to obtain valid and reliable predictions of lead exposure. The Lead Technical Review Workgroup has been collecting data to further validate the model and to update the Guidance Manual as needed.

Relationship to RCRA Corrective Action "Action" Levels. The approach for calculating a screening level for lead (including exposure assumptions), set forth in this Revised Interim Soil Lead Directive, supersedes the guidance provided for calculating "action" levels set forth in Appendix D of the proposed Subpart S Corrective Action rule. In the July 27, 1990 RCRA proposal (55 *Federal Register* 30798), EPA introduced the concept of "action levels" as trigger levels for further study and subsequent remediation at RCRA facilities. In this respect, the current directive's "screening levels" are analogous to the proposed rule's "action levels." In the proposal, where data were available, action levels were developed for three pathways of human exposure to contaminants: soil ingestion, water ingestion and inhalation of contaminated air. Exposure assumptions used in the calculations were set out in Appendix D of the proposal. For the soil pathway, action levels were calculated two different ways depending on whether the contaminant in the soil was a carcinogen or systemic toxicant. Although lead was listed in Appendix A of the preamble to the rule as a class B2 carcinogen, no action level had been calculated because neither a carcinogenic slope factor (SF) nor a reference dose (RfD) had been developed by the Agency. Although the guidance in Appendix D of the proposed Corrective Action rule remains in effect with respect to other hazardous constituents, this directive now allows for the development of the lead screening ("action") level using the IEUBK model.

Recent developments (1992-Present). Following discussions among senior Regional and OSWER management, the OSWER Soil Lead Directive Workgroup (composed of Headquarters, Regional and other Federal agency representatives) recommended in the spring of 1992 that a "two step" decision framework be developed for establishing cleanup levels at sites with lead-contaminated soils. This framework would identify a single level of

lead in soils that could be used as either the PRG for CERCLA site cleanups or the action level for RCRA Corrective Action sites, but would allow site managers to establish site-specific cleanup levels (where appropriate) based on site-specific circumstances. The IEUBK model would be an integral part of this framework. OSWER then developed a draft of this directive which it circulated for review on June 4, 1992. The draft set 500 ppm as a PRG and an action level for RCRA facilities in residential settings.

Following development of this draft, OSWER held a meeting on July 31, 1992 to solicit a broad range of views and expertise. A wide range of interests, including environmental groups, citizens and representatives from the lead industry attended. This meeting encouraged OSWER to think more broadly about how the directive would affect urban areas, how lead paint and dust contribute to overall risk, and blood lead data could be used to assess risk. In subsequent meetings with the Agency for Toxic Substances and Disease Registry (ATSDR) and Centers for Disease Control (CDC), options were discussed on how to use blood lead data and the need to evaluate the contribution of paint. In addition, during these meetings, a "decision tree" approach was suggested that proposed different threshold levels (primary and secondary) for screening decisions, action decisions and land use patterns.

Findings from the three cities (Baltimore, Boston, and Cincinnati) of the Urban Soil Lead Abatement Demonstration Project (peer review scheduled for completion in late 1994) indicate that dust and paint are major contributors to elevated blood lead levels in children. Furthermore, preliminary findings suggest that any strategy to reduce overall lead risk at a site needs to consider not only soil, but these other sources and their potential exposure pathways. (For further information on this demonstration project, contact Dr. Rob Elias, USEPA/ORD, Environmental Criteria And Assessment Office (ECAO), RTP, (919) 541-4167.)

Finally, in its efforts to develop this interim directive, the OSWER Soil Lead Workgroup has met with other EPA workgroups including the TSCA Section 403, Large Area Land Sites, and Urban Lead workgroups, as well as other Federal agencies including the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control, and Department of Housing and Urban Development.

Derivation of Lead Screening Levels. Development of the residential screening level in this interim directive required two important OSWER decisions. 1) OSWER determined that it would seek to achieve a specific level of protectiveness in site cleanups; generally, OSWER will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed children would have an estimated risk of no more than 5% exceeding the 10 µg lead/dl blood lead level. This 10 µg/dl blood lead level is based upon analyses conducted by the Centers for Disease Control and EPA that associate blood lead levels of 10 µg/dl and higher with health effects in children; however, this blood lead level is below a level that would trigger medical intervention. 2) In developing the residential screening level, OSWER has decided to apply the EPA's IEUBK model on a site-specific basis. This model has been designed specifically to evaluate exposures for children in a residential setting. Current research indicates that young children are particularly sensitive to the effects of lead and require specific attention in the development of a soil screening level for lead. A screening level that is protective for young children is expected to be protective for older population subgroups.

In general, the model generates a probability distribution of blood lead levels for a typical child, or group of children, exposed to a particular soil lead concentration and concurrent lead exposures from other sources. The spread of the distribution reflects the observed variability of blood lead levels in several communities. This variability arises from several sources including behavioral and cultural factors.

The identification of lead exposures from other sources (due to air, water, diet, paint, etc.) is an essential part of characterizing the appropriate blood lead distribution for a specific neighborhood or site. For the purpose of deriving a residential screening level, the background lead exposure inputs to the IEUBK model were determined using national averages, where suitable, or typical values. Thus, the estimated screening level of 400 ppm is associated with an expected "typical" response to these exposures, and should not be taken to indicate that a certain level of risk (e.g., exactly 5% of children exceeding 10 µg/dl blood) will be observed in specific community, e.g., in a blood lead survey.

Because a child's exposure to lead involves a complex array of variables, because there is population sampling variability, and because there is variability in environmental lead measurements and background levels of

lead in food and drinking water, results from the model may differ from results of blood lead screening of children in a community. Extensive field validation is in progress. The model will be evaluated further once these efforts are completed.

OBJECTIVE

With this interim directive, OSWER recommends using 400 ppm soil lead (based on application of the IEUBK model) as a screening level for lead in soil for residential scenarios at CERCLA sites and at RCRA Corrective Action sites. Residential areas with soil lead below 400 ppm generally require no further action. However, in some special situations, further study is warranted below the screening level. For example, agricultural areas, wetlands, areas with ecological risk, and areas of higher than expected human exposure are all situations that could require further study. For further guidance on ecological risks, Superfund risk managers are encouraged to consult their Regional Biological Technical Assistance Groups (BTAGs; see Appendix D).

Generally, the ground water pathway will not pose a significant risk since many lead compounds are generally not highly mobile. However, there are situations where, because of the form of lead, hydrogeology, or the presence of other contaminants at the site, lead may pose a threat to the ground water. In these situations, additional analysis is warranted, Superfund Regional Toxics Integration Coordinators (RTICs; seeAppendix B) or RCRA hydrogeologists should be consulted.

While recognizing that urban lead is a significant problem, this interim directive is not designed to be applied in addressing the potential threat of lead in urban areas other than at CERCLA or RCRA Corrective Action sites. Guidance and regulations to be developed under TSCA Section 403 will provide an appropriate tool for addressing urban sites of potential concern.

Generally, where the screening level is exceeded, OSWER recommends using the IEUBK model during the Remedial Investigation or the RCRA Facility Investigation for evaluating potential risks to humans from environmental exposures to lead under residential scenarios. Site-specific data need to be collected to determine PRGs or MCSs. At a minimum, this may involve collecting soil and dust samples in appropriate areas of the site. Further guidance on data collection or modification of the non-residential equation can be obtained by contacting the RTICs or RCRA Regional risk assesors, who in turn may consult the Lead Technical Review Workgroup.

The type of site-specific data that should be collected will obviously depend on a number of factors, including the proximity of residences to the contaminated soil, the presence of site access controls, and other factors that would influence the probability of actual human exposure to the soils. At a minimum, when residences are at or near the site, it is expected that using the model will generally involve taking soil and dust samples from appropriate areas of the site. In many cases, it may not be necessary to gather certain types of data for input into the model. For example, when there are no residences nearby, or where there is otherwise no exposure or very limited exposure to lead contamination, it may not be necessary to collect site-specific data (e.g., dust, water, paint, blood-lead, etc.)

In developing a PRG for CERCLA sites or a MCS for RCRA facilities, EPA recommends that a soil lead concentration be determined so that a typical child or group of children exposed to lead at this level would have an estimated risk of no more than 5% of exceeding a blood lead of 10 µg/dl. In applying the IEUBK model for this purpose, appropriate site-specific data on model input parameters, including background exposures to lead, would be identified.

When the PRG or MCS is exceeded, remedial action is generally recommended. Such action does not, however, necessarily involve excavating soil. A range of possible actions may be considered, as discussed in greater detail under the Implementation section of this directive: Issues for Both Programs.

IMPLEMENTATION
Superfund

This interim directive applies to all future CERCLA Remedial Investigation/Feasibility Study (RI/FS) work; this interim directive should generally not be applied at sites for which risk assessments have been completed. For

removal sites, this interim directive recommends that decisions regarding removal actions be considered first by the Regional Decision Team (RDT). The RDT will then refer sites to the removal program for early action, as appropriate.

The approach in this interim directive helps meet the goals set by the Superfund Accelerated Cleanup Model (SACM) for streamlining remedial decision-making. (This streamlined approach is described in Appendix A, Suggested Decision Logic for CERCLA and RCRA Corrective Action.) This interim directive also recognizes that other methods (e.g., slope studies and others) for evaluating risks at lead sites may also be appropriate and may be used in lieu of, or in conjunction with, the IEUBK model. If an alternate approach to lead risk assessment is to be applied, an EPA scientific review should be obtained. For example, expert statisticians would need to review slope factor calculations for statistical biases before their use could be supported. Recognizing that all assessment methods involve some uncertainties, the Agency, at this time, believes the IEUBK model is the most appropriate and widely applicable tool for Superfund and RCRA sites. Alternatively, EPA may require setting cleanup levels below the screening level if site-specific circumstances warrant (e.g., ecological risk). For further information on the use of the IEUBK model at CERCLA sites, contact the Regional Toxics Integration Coordinators identified in Appendix B.

RCRA Corrective Action

It is expected that the RCRA corrective action program will generally follow an approach similar to CERCLA's (as described above) in using the IEUBK model. In the case of RCRA facilities at which lead contaminated soils are of concern, collection and evaluation of data for the purpose of using the model will be primarily the responsibility of the owner/operator.

Issues for Both Programs

Cleanup of soils vs. other lead sources: OSWER's approach to assessing and managing risks from lead is intended to address the multi-media/multi-source nature of environmental lead exposures because it is expected that people at or near CERCLA and RCRA Corrective Action sites will experience lead exposures from sources in addition to contaminated soil. In some instances, these other exposures may be large (e.g., where there are children living in houses with high levels of lead dust form deteriorated paint). The presence of various sources of lead exposure may be very important in both the development of site-specific risk assessments and in the consideration of alternative risk management options.

From an assessment perspective, estimating blood lead levels, that might result from exposures at a site, depends on appropriately integrating exposures from all relevant media. Specifically, it is important to consider direct soil exposures and indoor dust exposures (which can include contributions from both soil and lead-based paint) on a site-specific basis, as well as any contributions from drinking water or other local sources of lead exposure. In using the IEUBK model to estimate blood lead levels, it is important to note that the risk attributable to soil lead exposures is dependent upon the existing level of exposures from other sources. That is, the amount by which the total risk would be lowered if all exposures to lead in soil were removed is not a constant, but varies with the level of existing non-soil exposures. This is because the model derives "distribution" (rather than a simple point estimate) as an output whose shape and size is quite dependent on the predicted variability of exposures from each lead source. As a result, other factors being equal, the risks attributable to soil will generally be higher in the presence of elevated lead exposures from other sources. Therefore, in applying the IEUBK model, the risk attributable to soil lead can be predicted as the difference between the risk estimated when all sources of lead exposure are assessed, and the risk estimated considering only non-soil related exposures. This concept is especially important when evaluating different options for risk reduction at a given site.

From a risk management perspective, achieving a safe environment for populations at CERCLA and RCRA Corrective Action sites may require attention to multiple sources of lead, not all of which may be related to contamination from the source that was the initial concern at the site. Generally, the goal of the Agency, while acting within the constraints of CERCLA and RCRA legal authorities, is to reduce, to the maximum extent feasible, the risk of having significantly elevated blood lead levels. On a site-specific basis this can include remediation approaches that would lead to reduction of exposure from other sources, such as lead-based paint, in conjunction with appropriate soil remediation. Following from the risk assessment discussion in the previous

paragraphs, exposures from lead in soils may have a lesser impact in producing high blood lead level if existing exposures from lead in soils may have a lesser impact in producing high blood lead levels if existing exposures from lead-based paint are reduced.

Abatement vs. Intervention: Remedial measures can be divided into those that remove the source of contamination (abatement) and those that leave the contamination in place but block the exposure pathway (intervention). These combinations of measures might include but not be limited to:

Abatement - Soil removal or interior and exterior lead paint abatement.

Intervention - Institutional controls, education/public outreach, gardening restrictions, indoor cleaning and dust removal, or additional cover.

Generally, the most appropriate CERCLA or RCRA response action or combination of actions will be based, in part, on the estimated level of threat posed at a given site. However, as mentioned earlier, key decision criteria also include the overall protectiveness of response options, attainment of Applicable or Relevant and Appropriate Requirements (for CERCLA), a preference for permanent remedies, implementability, cost-effectiveness, and public acceptance. Intervention measures may be more appropriate than abatement (e.g., soil excavation) at many sites, especially in areas where soil lead levels fall at or near the site-specific PRG or MCS.

Addressing exposure from other sources of lead may reduce risk to a greater extent and yet be less expensive than directly remediating soil. In some cases, cleaning up the soil to low levels may, by itself, provide limited risk reduction because other significant lead sources are present (e.g., contaminated drinking water or lead-based paint in residential housing). If it is possible to address the other sources, the most cost-effective approach may be to remediate the other sources as well as, or (if exposures to lead in soil are relatively low) instead of full soil lead abatement.

Lead-based paint can be a significant source of lead exposure and needs to be considered when determining the most appropriate response action. Interior paint can contribute to elevated indoor dust lead levels. In addition, exterior paint can be a significant source of recontamination of soil. Appendix A-3 of this document contains more information on how to evaluate and address the contribution of paint.

Certain legal considerations arise in considering remediation of sources other than soil. In particular, interior exposures from interior paint generally are not within the jurisdiction of RCRA or CERCLA. In addition, where other sources are addressed, issues may arise regarding the recoverability of costs expended by the Agency, or the possibility of claims being asserted against the Fund where other parties are ordered to do the work.

As discussed above, in considering whether to address sources other than soil, it is necessary to consider the risk that would remain from the lead in the soil. In some cases, after risks from other sources have been addressed, unrestricted exposure to soil could be allowed while still being protective (e.g., where the IEUBK model result was heavily affected by the other sources). In other cases, soil risks may still be high enough to require abatement, containment or institutional controls to prevent high levels of exposure. In such cases, before a conclusion is made that the overall remedy will be protective, institutional controls should be carefully studied to make sure that they will be implementable, effective in both the long-term and short-term, and likely to achieve community acceptance.

A potentially useful approach that can be considered in conjunction with other, more active measures in reducing blood lead levels is to develop and promote public education and awareness programs that focus on the causes and prevention of lead poisoning in children. EPA's Office of Pollution Prevention and Toxics (OPPT) provides information on abatement of lead-based paint by the homeowner as well as inexpensive preventive measures the public can take to reduce their exposure to lead. Additional research to evaluate the effectiveness of educational efforts in reducing lead exposures are needed to allow better evaluation of the usefulness of this option. Further, OPPT is assessing the effectiveness of various lead paint abatement options emphasizing low-cost methods. For additional information, contact the National Lead Information Center at 1-800-424-LEAD.

Mining-related sites: Both risk assessors and site managers should be aware that there are a number of factors that affect the relationship between soil lead concentrations and blood lead levels. These factors include the

variability in soil lead contribution to house dust levels, or differences in the bioavailability of lead. See discussion in next section, Use of blood lead data, for assessing differences between measured and predicted blood lead levels.

Thus, for mining-related sites without significant past smelting/mill activity, this interim directive encourages further research for characterizing the potential impact of particle size and speciation on soil bioavailability.

Site managers and risk assessors are cautioned that most areas impacted by mining activities are also associated with present or historical smelting or milling operations. Generalizations regarding distinct differences between mining and smelting or milling sites should be avoided until adequate site history and characterization are complete.

Use of blood lead data: In conducting Remedial Investigations (RIs) for CERCLA or RCRA Facility Investigations (RFIs) for RCRA Corrective Action, the interim directive recommends evaluating available blood lead data. In some cases, it may be appropriate to collect new or additional blood lead samples. In general, data from well-conducted blood lead studies of children on or near a site can provide useful information to both the risk assessor and site manager. However, the design and conduct of such studies, as well as the interpretation of results, are often difficult because of confounding factors such as a small population sample size. Therefore, any available blood lead data should be carefully evaluated by EPA Regional risk assessors to determine their usefulness. The Guidance Manual discusses how to evaluate observed blood lead survey data and blood lead data predicted by the IEUBK model.

The Guidance Manual recommends that blood lead data not be used alone either to assess risk from lead exposure or to develop soil lead cleanup levels. During its review of the IEUBK model, the SAB supported this position by asserting that site residents may temporarily modify their behavior (e.g., wash their children's hands more frequently) whenever public attention is drawn to a site. In such cases, this behavior could mask the true magnitude of potential risk at a site and lead to only temporary reductions in the blood lead levels of children. Thus, blood lead levels below 10 µg/dl are not necessarily evidence that a potential for significant lead exposure does not exist, or that such potential could not occur in the future.

Non-residential (adult) screening level. EPA also believes there is a strong need to develop a non-residential (adult) screening level. The IEUBK model is, however, not appropriate for calculating this screening level since it is designed specifically for evaluating lead exposures in children. At this time, EPA is considering a few options for developing this screening level. Several adult models have recently become available. Developing a screening level by using any of them is likely to require significant additional work by the Agency. This work might include testing, validation, and selection of one of the existing models or development of its own model, both of which would require a considerable amount of time. Consequently this would probably be a long-term option. A short-term option would be to develop a screening level based on a simple approach that approximates the more complicated biokinetics in humans. This can serve in the interim while more sophisticated adult lead exposure assessment tools can be identified or developed.

NOTICE: Users of this directive should bear in mind that the recommendations in this document are intended solely as guidance, and that EPA risk managers may act at variance with any of these recommendations where site-specific conditions warrant, as has been noted above. These recommendations are not intended, and cannot be relied upon, to create any rights, substantive or procedural, enforceable by any party in litigation with the United States, and may change at any time without public notice.

Because this document and the related Guidance Manual are not legally binding either upon EPA or other parties, Agency personnel should keep in mind if they are questioned or challenged in comments on a proposed remedial plan, such comments must be considered and a substantive explanation must be provided for whatever approach is ultimately selected. For example, while the IEUBK model is recommended here, its use is not a regulatory requirement and comments on the model or its use should be fully considered.

APPENDICES

A Suggested Decision Logic for CERCLA and RCRA Corrective Action

A-1 Suggested Decision Logic for Residential Scenarios for CERCLA and RCRA Corrective Action

A-2 Suggested Decision Logic for Lead-based Paint for CERCLA and RCRA Corrective Action

B Regional Toxics Integration Coordinators (RTICS)

C Relationship between the OSWER Soil Lead Directive and TSCA Section 403 Guidance

D Biological Technical Assistance Group Coordinators (BTAGS)

Appendix A-1

Suggested Decision Logic for Residential Scenarios for CERCLA and RCRA Corrective Action

Step 1: Determine soil lead concentration at the site.

If soil lead is less than 400 ppm:
STOP, no further action is required, UNLESS special circumstances (such as the presence of wetlands, other areas of ecological risk, agricultural areas, shallow aquifers, or other areas of potentially high exposure) warrant further study.

If soil lead is greater than 400 ppm:
PROCEED to Step 2, UNLESS 400 ppm is selected as a cleanup goal based on consideration of all relevant risk management factors.

Step 2: Evaluate probable land use and develop exposure scenarios.

Step 3: Collect appropriate site-specific data based on selected scenarios.

For example, sampling data may include:

- Soil and dust (at a minimum), paint, water, and air,
- For unique site situations, data on speciation and particle size, and behavioral activities may be required.

Available blood lead data:

- If blood lead data are available, consult the Guidance Manual and Regional Risk Assessor.
- If blood lead data are not available, Regional Risk Assessors and site managers should consider the appropriateness of consulting a blood lead study to supplement available data.

Step 4: Run the IEUBK model with site-specific data to estimate risk and evaluate key exposure pathways at the site.

- If blood lead data are available, compare the data to the model results.

Step 5: Where risks are significant, evaluate remedial options.

If lead-based exterior or interior paint is the only major contributor to exposure, no Superfund action or RCRA corrective action is warranted.

If soil is the only major contributor to elevated blood lead, a response to soil contamination is warranted, but paint abatement is not.

If both exterior lead-based paint and soil are major contributors to exposure, consider remediating both sources, using alternative options as described in Appendix A-2.

If indoor dust levels are greater than soil levels, consider evaluating the contribution of interior lead-based paint to the dust levels. If interior lead-based paint is a major contributor, consider remediating indoor paint to achieve a greater overall risk reduction at a lower cost. (See Appendix A-2.)

NOTE: Available authority to remediate lead-based paint under CERCLA and RCRA is extremely limited.)

Step 6: If the IEUBK model predicts elevated blood leads, rerun the model using the site-specific parameters selected to reflect remedial options in Step 5 to determine site-specific PRGs or MCSs for soil.

Appendix A-2

Suggested Decision Logic for Lead-based Paint for CERCLA and RCRA Corrective Action

(If soil lead levels are below screening levels, lead-based paint could be addressed by authorities other than RCRA or CERCLA.)

If soil lead levels are above screening levels:

Step 1: Examine condition of exterior paint and determine its lead content, if any.

- If the paint is deteriorated, assess contribution or potential contribution of paint to elevated soil lead levels through speciation studies, structural equation modeling, or other statistical methods.

Step 2: Evaluate potential for recontamination of soil by exterior paint.

Step 3: Remediate exterior paint only in conjunction with soil.

- Determine appropriate remediation based on risk management factors (e.g., applying the nine criteria), remediating the major contributor first.

Step 4: Examine condition of indoor paint and determine its lead content, if any.

- If indoor dust lead concentration is greater than outdoor soil lead concentration (because of contamination from both interior paint and outdoor soil), remediate indoor dust (e.g., through a removal action, or making HEPA-VACS available to community).

Step 5: Once the risk from indoor paint has been assessed, examine options to abate indoor paint (e.g., PRP, State, local, HUD) and consult TSCA Section 403 program for additional information and/or guidance.

Step 6: While RCRA and CERCLA have very limited authority regarding the cleanup of interior paint, the remedy may take into account the reduction of total risk that may occur if interior paint is addressed by other means. Thus, for example, a Record of Decision (ROD) or Statement of Basis (SB) may recognize that interior lead-based paint is being addressed by other means, and narrow the response accordingly (possibly making this contingent on completion of the interior lead-based paint abatement effort).

Appendix B

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Appendix C

Relationship between the OSWER Soil Lead Directive and TSCA Section 403 Guidance

Since lead exposures occur through all media, a variety of Agency programs address lead under a number of statutes. Lead in soil is addressed under TSCA Section 403, the RCRA Corrective Action program, and CERCLA, each of which differs somewhat in the types of sites that apply and the types of standards that are used. These differences are primarily due to differences in the purposes of the programs and the authority granted by the statutes under which they are developed. Section 403 soil standards will apply only to residential soil and the current TSCA guidance is generic in nature, with the same standards applying on a nationwide basis. Given the wide applicability of Section 403, generic standards are used in the current guidance in order to reduce resource requirements, as compared to site-specific decisions which can involve expensive and time-consuming analyses. Required RCRA and CERCLA activities are determined on a site-specific basis. The agency's recommendations for evaluating RCRA Corrective Action and CERCLA sites are contained in the OSWER Interim Soil Lead Directive.

In all three of these programs, the Agency's approach is to consider soil lead in the context of other lead sources that may be present and contribute to the total risk. For example, TSCA Section 403 specifically requires the Agency to consider the hazards posed by lead-based paint and lead-contaminated interior dust, as well as lead-contaminated soil. Likewise, the OSWER Soil Directive includes evaluation of other lead sources at a site as part of site assessment / investigation procedures. In addition, the primary focus of the three programs is primary prevention -- the prevention of future exposures from the source(s) being remediated.

The fundamental difference between the relatively new TSCA Section 403 program and the RCRA Corrective Action and CERCLA cleanup programs is that, under current guidance the Section 403 program seeks to establish national standards to prioritize responses to lead hazards whereas the other two programs usually develop site-specific cleanup requirements. This is because TSCA Section 403 deals with a potentially huge number of sites, and resources for the investigation needed to accurately identify their risks are typically very limited. Therefore most decisions under Section 403 will be made with little or no regulatory oversight and clear generic guidelines will be more effective. The more established RCRA and CERCLA programs, on the other hand, deal with a much smaller number of sites, at which extensive site characterization will have been performed before cleanup decisions are made. In addition, these programs have well-established funding mechanisms.

Appendix D

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