GUIDANCE DOCUMENT

DEVELOPMENT OF ALTERNATIVE REMEDIATION STANDARDS FOR THE INGESTION-DERMAL PATHWAY

INGESTION-DERMAL STANDARDS COMPLIANCE

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I. Alternative Remediation Standard

Introduction

The person responsible for conducting the remediation may request an alternative remediation standard (ARS) for the ingestion-dermal pathway at any time during the remediation process when there are sufficient data and/or site information to base a particular alternative standard. N.J.A.C. 7:26D-7 establishes the process and procedures for the person responsible for conducting the remediation to establish an ARS. The Department provides detailed direction in Appendices 2 & 4 that the person requesting an ingestion-dermal alternative standard must use to demonstrate that the proposed standard will meet the same human health goals set by the Legislature. The Department will review proposals for alternative remediation standards for the ingestion-dermal pathway on a site-by-site basis and will determine if the proposed alternative remediation standard is appropriate for the site. For those alternative standards that use site-specific conditions (lead model and different land use), the Department will not allow their use at other sites.

Alternative Remediation Options for the Ingestion-Dermal Pathway

An alternative remediation standard for the ingestion-dermal pathway may be requested based on: (1) advancements in risk-related methodology that support standards derivation such as new toxicity or exposure information, improved or advanced models and methods; (2) appropriate site-specific default parameters (for lead models); or (3) different land use determinations such as park and recreational scenarios.

Option 1- Advancements in Toxicity and Risk Assessment Methodology

The Department will accept an ARS request if new toxicity information becomes available for an existing dermal-ingestion standard that may require the Department to raise or lower that existing standard. The procedures for updating standards by notice of administrative change, as established at N.J.A.C. 7.26D-6.2, allows the Department to update soil remediation standards only under certain specified circumstances. A change in the carcinogenic slope factor or

reference dose data contained in the USEPA's Integrated Risk Information System (IRIS) could necessitate a change in an adopted remediation standard. USEPA's revisions to IRIS are subject to a comprehensive internal and external peer review process prior to their inclusion in the database and represent the Agency's official scientific position on the toxicity of chemicals based on the data available at the time of the review. If IRIS toxicity data are updated and result in a change, the Department will use the criteria development procedures set forth in Appendices 2 through 4 of the rules to update the soil remediation standards.

The IRIS database containing the status of updated toxicity reviews is available at www.epa.gov/iris/toxreviews. The public can access information regarding IRIS by telephone (202) 566-1676, or fax (202) 566-1749, email to the EPA IRIS hotline at hotline.iris@epa.gov, or by regular mail or visit to the IRIS reading room at IRIS Reading Room, EPA-West Building 1301 Constitution Avenue NW, Washington, DC 2005.

If the Department determines that it needs to use toxicity data from an alternate source than IRIS to update an existing residential or non-residential standard, the Department will conduct formal rulemaking with the required proposal and public comment period.

An ARS request may be made based on new risk assessment methodology such as changes in default assumptions or equations currently used to develop standards for the ingestion-dermal pathway. Such changes are likely to affect all the ingestion-dermal standards and, if not codified within these rules, will require formal rulemaking. However, if a dermal absorption fraction or gastrointestinal absorption factor becomes available or changes for a specific compound, an alternative standard request would be appropriate.

It is important for the Department to have the ability to update standards in a timely manner so that the standards remain protective of human health. The Department will monitor toxicity information on IRIS and will proactively update standards as new data become available. The provisions of N.J.A.C. 7:26D-5 and 6 will allow the Department to use the best available science to update these standards in a timely manner.

Option 2 – Site-Specific Default Values

The ingestion-dermal pathway uses EPA recommended default exposure parameters for residential and non-residential scenarios for all standards, except lead. These default exposure parameters are generic and reflect a reasonable maximum exposure (RME) that may not be adjusted. The default parameters for the residential and non-residential scenarios for the ingestion-dermal pathway include averaging time, exposure frequency, exposure duration, soil ingestion rate, skin-soil adherence factor and event frequency. The Department has determined that these variables represent reasonably conservative default values (but not the worst case) and are designed to be consistent with EPA's concept of the RME and are protective of the majority of the population. A modification of one or more of these default parameters may be argued as site specific at a particular time (e.g. 4-day work week), however, the Department can not ensure that property conditions will remain the same over time. The Department will continue to protect for the reasonably exposed resident or worker on site.

The Department will update default parameters if research becomes available that supports the use of a different default parameter (e.g. child ingestion rate) or new default parameters (e.g. additional dermal absorption fractions). Such changes are likely to affect all the ingestion-dermal standards and, if not codified within these rules, will require formal rulemaking.

For lead, other risk assessment tools have been developed that use models to predict appropriate blood lead levels. The Department may accept an application for an ARS for residential exposure based on input parameter identified in the *Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK)* guidance (USEPA, 1994) using site-specific data for soil and dust lead concentrations. Site data may be used to refine estimates for other exposure related model parameters, such as bioavailability.

The Department may accept an application for alternative remediation standard for lead for non-residential site use based on input parameters identified in the document, *Recommendations of the Technical Review Workgroup (TRW) for Lead for an Interim Approach to Assessing Risk Associated with Adult Exposures to Lead in Soil* (USEPA, 1996).

The Department may accept an application for an alternative remediation standard for a recreational land use at a lead site based on the assessment of non-continuous exposure for all ages identified in the EPA guidance, *Assessing Intermittent or Variable Exposures at Lead Sites* (EPA, 2003). This guidance addresses the assessment of non-continuous exposure that may be appropriate for all ages rather than young children (IEUBK model) or adults (ALM model). The application of this guidance will vary with the exposure intensity and complexity of the site; therefore, the DEP will review requests on a case-by-case basis.

Lead model software, users' manuals, guidance documents, frequent questions and support information are available on EPA's web site: www.epa.gov/superfund/health/contaminants/lead/index.htm

Option 3 – Recreational Land Use Scenario

The residential ingestion-dermal standards are levels of contaminants in soil that will not result in harm to the health of children and adults exposed to these contaminants through incidental ingestion or absorption through the skin of contaminated soils that they may be exposed to living at their residence. By policy, these standards are also applicable to individuals exposed to soil contamination at schools and day care centers. The non-residential standards are levels of contaminants that are protective of the health of an adult who may incidentally ingest or absorb through the skin contaminants in soil through exposure at the work place.

An alternative remediation standard may be based on use of the site for recreational purposes. Recreational purposes are site-specific uses that do not reflect either a residential or non-residential land use scenario. Alternative standards may be based on site-specific land use scenarios that effect the amount of time that people are likely to spend at a site that is designated for recreational use. There are two basic types of recreational land use scenarios, active and passive, that may be considered. Examples of active recreational land use are sports playing fields and playgrounds. Examples of passive recreational land use are walking or bike trails. No specific default values are given for park/recreational scenarios due to their site specific nature and variability. These pathways will be developed on a case-by-case basis, following careful

consideration of the appropriate land use and applicable exposure variables. As sites are being remediated, the Department anticipates the submittal of requests for alternative remediation standards based on other land use scenarios. For example, the Department will consider granting alternative soil remediation standards for hospitals, community centers, and other common land use scenarios in urban settings where there is little to no bare soil. In these cases, the Department may determine that an indoor worker scenario may be more appropriate. Due to the site specificity of these determinations, generalizations can not be made, and each submittal will be reviewed on its own merit. The approval of an alternative remediation standard for alternate land use determinations will be contingent on the use of proper institutional controls to ensure the continued use of the site for the proposed use.

II. Compliance for Ingestion-Dermal Pathway

Based on the anticipated land use for the site, concentrations of contaminants found in the soil are compared to their corresponding ingestion/dermal absorption standards. The standard for the residential pathway is considered protective for unrestricted land use, while the outdoor worker scenario is used for non-residential for sites that will have a restricted land use. When a standard for the ingestion-dermal pathway is not exceeded, that contaminant may be eliminated from concern. However, all sampled contaminants that exceed their relevant ingestion-dermal absorption standard must be addressed during remediation.

A. Site Wide Averaging

The Department does not routinely accept USEPA's methodology that allows site wide averaging of contaminant soil samples for comparison to ingestion/dermal absorption standards for the following reasons:

- Site wide averaging is only appropriate where contact with soil over all areas of the site is equally probable. When using site wide averaging, contamination may be allowed to remain

in areas that are frequented more readily (e.g. playground), resulting in exposure to unacceptable levels of contaminants.

- The ingestion/dermal standards are based on protection from chronic health effects. Site wide averaging increases the probability of leaving concentrations of contaminants on site that may exceed acute toxicity levels. Currently, there is limited consensus as to the appropriate data for evaluating acute toxicity concerns.

- Data needed to support a site wide averaging approach is inconsistent with the Department's current sampling philosophy that biases sampling to areas of greatest contamination.

The Department's not-to-exceed compliance policy entails remediating all soil with contaminant concentrations greater than a specified remediation standard. USEPA's area average approach involves treating or removing soils to a level that represents the average concentration in an exposure area, thereby leaving on site some soils with concentration levels that exceed the applicable standard. The Department believes that the uncertainty surrounding the type and adequacy of site sampling, the exposure assumptions, and the limited examination of only chronic toxicity does not support the use of an average exposure concentration or an area average approach for the ingestion-dermal exposure pathway. In addition, the Department does not believe that exposure should be considered to occur as a random event over the entire site or exposure area. The Department is concerned with exposure to contamination that is non-random. In residential land use, people can be repeatedly exposed to residual contamination at specific location during routine use of play areas and gardens. Similarly, in non-residential land use, workers frequent areas that are likely to be contaminated such as loading docks and product transfer areas. Instead, the Department believes that remediation of a site should start with a not-to-exceed approach.

The Department may accept an alternative remediation standard, if the uncertainty of exposure can be reduced significantly through a site-specific determination that non-random exposure will not occur, sampling is adequate to determine site wide representative conditions, the levels of contaminants left on site are not acutely toxic, and an appropriate exposure area is defined.

B. Area of Concern (AOC) Compliance Averaging

While currently allowed under the Technical Regulations at N.J.A.C. 7:26E-4.8(c)3i(5), compliance averaging over an area of concern is limiting and used infrequently by the Site Remediation and Waste Management programs. The Department allows averaging of sporadic low levels of contaminants with no discernable source area and minimal exceedances of a standard during post excavation sampling.

III. References

U.S. Environmental Protection Agency (USEPA). 1994. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children. Office of Solid Waste and Emergency Response, Washington, DC. OSWER 9285.7-15-1.

U.S. Environmental Protection Agency (USEPA). 1996. Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil, USEPA Technical Workgroup for Lead. December, 1996.

U.S. Environmental Protection Agency (USEPA). 2003. Assessing Intermittent or Variable Exposures at Lead Sites, Office of Solid Waste and Emergency Response, OSWER 9285.7-76.