LANL/ER/Non-HSWA Regulatory

LANL Reference

interoffice
MEMORANDUM

To: John Kieling, LANL Facility Manager

From: Kim T. Hill and Barbara Toth

Subject: Finalized Position Papers

Date: June 17, 1999

The following position papers have been revised and are appropriate for final distribution:

- Application of Inorganic Background Values in the Risk Assessment Process
- Determination of Extent of Contamination
- Use of Tolerance Intervals for Determining Background Concentrations
- Risk-based Decision Process Strategy

If you have any questions regarding these position papers, please contact either myself or Barbara.

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HAZARDOUS AND RADIOACTIVE MATERIALS BUREAU

New Mexico Environment Department

Position Paper *Position Paper*

DETERMINATION OF EXTENT OF CONTAMINATION

The vertical and horizontal extent of contamination at a specific site (including off-site migration) is considered adequately determined once concentrations of (1) inorganic constituents (including radionuclides) have been spatially (in three dimensions) delineated relative to background concentrations and (2) organic constituents have been spatially (in three dimensions) delineated relative to practical quantitation limits.

The Facility may petition the Hazardous and Radioactive Materials Bureau for a variance from the above-stated requirements on a case-by-case basis by applying other criteria/considerations which demonstrate the protection of human health and the environment. Factors that may affect the determination of the extent (vertical and horizontal) of contamination include, but are not limited to, the following:

- contaminant concentration gradient,
- contaminant characteristics which influence environmental fate and transport,
- site environmental setting (e.g., geology, hydrogeology, erosion potential, etc.),
- operational history,
- number and location of samples,
- detection limits relative to background or other reference values[1],
- media,
- type of source (e.g., surface impoundment, outfall, etc.), and
- source integrity.

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[1]Other reference values may include environmental standards (e.g., New Mexico Water Quality Control Commission regulations, etc.) or criteria (e.g., Ambient Water Quality Criteria, etc.).

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Position Paper ***Position Paper***

RISK-BASED DECISION PROCESS STRATEGY

The traditional Corrective Action (CA) approach as implemented by the Environmental Protection Agency (EPA) was based on an interpretation of applicable statutory authorities, codified regulations and the detailed requirements set forth in the proposed subpart S regulations (55 FR 30798). Because this traditional approach emphasized the administrative process rather than results, it tended to be overly structured and costly to implement.

As a result, EPA, some states, and industry have undertaken initiatives to streamline the corrective action process and make cleanup decisions based on the level of risk posed to human health and the environment. A new risk-based management strategy was developed to expedite the CA process without relaxing protectiveness. Based on this new strategy, EPA Region 6 developed a draft guidance, *Risk Management Strategy* to promote and expedite the implementation of corrective action based on risk management. Once this document has been finalized, the Hazardous and Radioactive Materials Bureau intends to adopt it, all or in part (with or without modification), in the near future.

The *Strategy* establishes a non-traditional, tiered (and iterative) risk-based approach (RBA). The RBA allows for more flexibility as long as established performance standards are met. Therefore, a Facility may chose a CA path which best suits its needs. For example, a Facility may choose to perform a site-specific risk assessment, in lieu of or in addition to a screening-level risk assessment, to more closely examine risks from releases and refine the remedial objectives.

The RBA evaluates immediate threat, determines if a release has occurred, identifies the constituents of potential concern, and includes screening-level and site-specific risk assessments. The RBA emphasizes the importance of the site conceptual exposure model (SCEM). The SCEM is initially developed early in the corrective action process and is continually refined as more information is obtained.

HAZARDOUS AND RADIOACTIVE MATERIALS BUREAU
New Mexico Environment Department

Position Paper *Position Paper*

USE OF TOLERANCE INTERVALS FOR DETERMINING INORGANIC BACKGROUND CONCENTRATIONS

The Hazardous and Radioactive Materials Bureau (HRMB) does not endorse the use of tolerance intervals for estimating inorganic background concentrations; however, a Facility may propose the use of tolerance intervals for identifying background constituent concentrations[1]; however this proposal must be submitted to and approved by HRMB prior to implementation. The Facility must provide type of statistical analysis performed and a complete data set[2] used to perform the statistical analysis to HRMB. **The use of tolerance intervals is conditional upon the review of the data set and the approval of the use of this procedure by HRMB.**

The use of tolerance intervals is an alternate approach to the analysis of variance in determining the presence of statistically significant contamination if 50 percent or more of the observations for a given constituent are quantified (i.e., above the detection limits) AND the original data distribution has been determined to be normal. If the original data is not normally distributed, it should be logarithmically transformed (EPA 1989 and 1992). For some data sets which are not normally or log-normally distributed, non-parametric statistical analyses may be more appropriate. For those data sets which do not meet these requirements, HRMB will determine the applicability of this approach based on an extensive review of the data sets provided.

A tolerance interval for a given constituent is constructed from the analytical results obtained from background sampling locations. The site constituent concentrations are

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[1] *Inorganic background concentrations* mean naturally-occurring concentrations of inorganic constituents in an environmental medium (sediment, soil, air and water) **not** affected by Facility operations.

[2] The complete data set includes both detectable and non-detectable constituent concentrations and all data points (sampling locations) shown on a map.

then compared with the tolerance interval. If the site constituent concentrations exceed the upper bound of the tolerance interval (UTL), contamination may be present.

UTLs may be used for determining statistically significant contaminant concentrations if the following criteria are met and documented:

1. UTLs are appropriate for sites with homogeneous soil or rock types. The presence of homogeneous soil or rock types must be verified. For instance, the tolerance interval approach is appropriate for sites that overlie extensive homogeneous geologic deposits (e.g., thick homogeneous lacustrine clays) that do not naturally display geochemical variations.

2. The data set must be evaluated for outliers (i.e., unusually high or low concentrations) which should not be used for calculating UTLs for a given constituent. The identity and source (such as analytical laboratory transcription errors) of the outliers must be documented.

3. A normality test must be applied to the data set prior to the selection of the tolerance interval approach.

4. Based on the degree of homogeneity, the UTL must be calculated using an adequate data set (i.e., greater than 20). The size of the data set can vary and should be based on such factors as the size of the contaminated area, etc.

5. HRMB requires a coverage[3] of 95 percent. HRMB also requires a tolerance coefficient[4] of 95 percent. This means that at least 95 percent of the background population is expected to be at or below the UTL at a confidence level of 95 percent.

6. Statistical descriptors for each data set must be determined (i.e., minimum and maximum constituent concentrations; mean, median standard deviation; and 25th, 75th and 95th percentiles). The detection limit and frequency of detection must also be provided for each constituent.

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[3]Coverage is defined as a specified proportion (percent) of a population of background observations (i.e., constituent concentrations) that is contained within a tolerance interval.

[4]The tolerance coefficient is defined as the probability that the tolerance interval includes the specified proportion of the background population.

REFERENCES

US EPA, 1989. *Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities - Interim Final Guidance*. Office of Solid Waste, Permits and State Programs Division, Washington, D.C. NTIS PB89-151047.

US EPA, 1992. *Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities - Addendum to Interim Final Guidance*, Draft. Office of Solid Waste, Permits and State Programs Division, Washington, D.C.

HAZARDOUS AND RADIOACTIVE MATERIALS BUREAU
New Mexico Environment Department

Position Paper

Position Paper

APPLICATION OF INORGANIC BACKGROUND VALUES[1] IN THE RISK ASSESSMENT PROCESS[2]

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1. *Introduction*

The application of representative inorganic background values in the risk assessment process eliminates the need to include chemicals which occur at naturally high concentrations in the environment. Background values are relied upon by project managers (and risk assessors) to expedite the corrective action process by identifying areas of release and defining the nature and extent of contamination.

This paper does not address the decision regarding when and how to establish background values and assumes that background values have been adequately established for a specific site.

2. *Procedure*

The selection of contaminants of potential concern (COPCs) occurs primarily by comparing chemical concentrations with representative inorganic background values[3]. Chemicals with measured concentrations above background values are considered

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[1]*Background value* means an inorganic chemical concentration representative of background concentrations that has been approved by the Hazardous and Radioactive Materials Bureau. *Inorganic chemical concentration* means a naturally-occurring concentration of an inorganic chemical in an environmental medium (sediment, soil, air and water) **not** affected by Facility operations.

[2]This position paper was developed jointly with the Environmental Protection Agency Region 6 and adapted from the EPA-NMED concept paper of the same title dated October 9, 1997.

[3]The detection status, relative concentrations of the chemical and presence/absence of the chemicals in other media matrices should also be considered in the selection of COPCs.

COPCs and should be retained for inclusion in the risk assessment process. Conversely, chemicals with concentrations at or below established background values are not considered COPCs and are eliminated from the risk assessment process.

The potential risk posed by COPCs should be estimated based on the actual detected values[4] or on representative concentrations (e.g., 95% upper confidence limits, upper tolerance limits or maximum concentrations). Background values of COPCs should not be subtracted from actual detected or representative COPC concentrations in assessing risk for a site[5]. Risk due solely to background values may be estimated independently for comparison to the risk posed by the actual detected or representative COPC concentrations.

3. Conclusion

Chemicals present at a site in concentrations at or below Facility-specific (or site-specific, if applicable) or regional background values are eliminated from the risk assessment process. The Facility should submit values representative of background concentrations to the Hazardous and Radioactive Materials Bureau (HRMB) for approval prior to their use in risk assessments.

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[4]Data should be obtained using established EPA-recommended analytical methods.

[5]The goal of the risk assessment is to establish the risk from exposure to chemical concentrations present at the site regardless of their origin (i.e., natural, anthropogenic background/fallout, or site-derived).