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Department of Energy

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94-DOE-02478

MAR 28 1994

Robert L. Duprey, Director
Hazardous Waste Management Division
Environmental Protection Agency, Region VIII
999 18th Street
Suite 500
Denver, Colorado 80202-2466

ADMIN RECORD

Dear Mr. Duprey:

The Rocky Flats Office (RFO) has received your March 22, 1994 letter and attachment which details your proposed resolution of the dispute between our agencies on data aggregation for exposure assessment. The RFO agrees with your letter and the attachment as modified per a conference call among RFO, Environmental Protection Agency, and Colorado Department of Health staff on March 25, 1994.

If you agree, please provide a copy of the modified text as enclosed for our concurrence. A separate letter from the Assistant Manager for Environmental Restoration will address the impacts of the work stoppage and the implementation of the proposed data aggregation methodology on the affected operable unit schedules.

I would like to thank you for the amount of time you have dedicated to resolving this issue. If you have any remaining questions or concerns, don't hesitate to call me at 966-2273.

Sincerely,


Shirley J. Olinger
Acting Assistant Manager
Environment, Safety and Health

Enclosure

DOCUMENT CLASSIFICATION
REVIEW WAIVER PER
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8704

Robert L. Duprey

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DATA AGGREGATION FOR HEALTH EXPOSURE ASSESSMENT

Specific Data Aggregation Methodology for Rocky Flats

The first consideration of data aggregation is the exposure scenario (land use). **Example** exposure areas for the Rocky Flats Plant site may be (1) for the industrial/commercial land use scenario, the area of a typical industrial park (2) for the ecological preserve scenario, the area of a preserve, and (3) for the residential land use scenario, the area of a residential neighborhood unless the consideration of a receptor's activity patterns and the mechanisms of toxicity of a particular contaminant indicate that a residential lot size is appropriate.

Following the application of the attached conservative screen (which identifies areas of elevated contaminant concentration which will be the focus of the baseline risk assessment), data must be aggregated for each environmental medium to arrive at the exposure point concentration estimate which will be used in the exposure assessment. Aggregation of all contaminant data, including data below background or detection limits, will be accomplished over the scenario-specific exposure areas within the area of concern identified by the screening process. The recommended data aggregation procedure is as follows:

- 1) Identify the exposure scenario(s) which will be assessed.
- 2) Agree on the size of the exposure area for each scenario by considering the receptors, the toxicity of the contaminants of concern (COCs), the exposure pathways, and contaminant variability. Determination of the appropriate exposure area requires an understanding of the mechanisms of toxicity as well as the concepts of exposure. For this reason, experienced risk assessors, toxicologists, and health physicists from all three agencies (EPA, CDH, and DOE) must be consulted.
- 3) Plot the COC data, including data points below background or detection limit, on a map of the operable unit, delineating the area of concern*.
- 4) Consult with toxicologists and health physicists from all three agencies (EPA, CDH, and DOE) to place a grid of exposure areas over the area of concern. The grid placement must be approved by the three agency toxicologists and health physicists due to considerations of mechanisms of toxicity. Of course, involvement of other scientific disciplines will also be required.

* Area of Concern = One or several sources** grouped spatially in close proximity.

** Source = Area defined by (1) contaminant levels exceeding background mean plus 2 standard deviations for inorganics and/or (2) detection limits for organics.

- 5) Risk assessment requires characterization of each exposure area for the site (OSWER Directive 9285.7-09A, April, 1992, p. 55). Generally this requires aggregation of data and a subsequent calculation of risk within each exposure area. This is especially important for heterogeneous data sets. However, at the Rocky Flats site, all parties agree that it is sufficient to calculate risks for only one exposure area per source: the exposure area associated with the highest risk, identified by considering the concentrations of COCs, the affected environmental media, and the number of exposure pathways. If the exposure area associated with the highest risk is not readily identifiable, several exposure areas may be analyzed. **This decision will be made on a case-by-case basis.** In general, not more than one exposure area per source will need to be evaluated unless the exposure pathways differ between exposure areas within the source. Data within the exposure area(s) will be aggregated using the following procedure:
- a. Using the complete operable unit data set, determine the statistical distribution for each COC in each environmental media. Present the statistical distribution graphically, along with the data plotted in a histogram which presents the frequency of detection and the magnitude.
 - b. Use EPA's "Supplemental Guidance to RAGS: Calculating the Concentration Term" to calculate the 95th percent upper confidence limit (95% UCL) of the arithmetic mean over each exposure area for each COC. If the COC data is log-normally distributed, highlight 5 of this guidance document should be used. If the COC data is normally distributed or is determined to be non-parametric, highlight 6 should be used. The guidance states that calculation of the 95% UCL using data sets with fewer than 10 samples per exposure area provides a poor estimate of the mean concentration. Data sets with 20 to 30 samples per exposure area provide fairly consistent estimate of the mean. **All parties agree that uncertainties in the estimates of the mean concentrations will be addressed in the uncertainty analysis. For OUs 2-7, additional field sampling in support of baseline risk assessment must be mutually agreed to by EPA, CDH, and DOE. On a case-by-case basis, with the approval of the regulators, geostatistics may be utilized to incorporate spatial continuity of data.**
- 6) Use the results of step 5(b) as the exposure point concentration term in the exposure assessment. Consider all COCs in calculating cumulative risks for each exposure area analyzed.

Summary

The above procedure provides the arithmetic average of the exposure concentration that is expected to be contacted over the exposure period within the exposure area associated with the maximum risk within the source.

Although this concentration does not reflect the maximum concentration that could be contacted at any one time, it is explicitly stated in OSWER Publication 9285.7-081, "Supplemental Guidance to RAGS: Calculating the Concentration Term", the average is used for two reasons:

1. carcinogenic and chronic noncarcinogenic toxicity criteria are based on lifetime average exposures; and
2. average concentration is most representative of the concentration that would be contacted over time if it is assumed that an exposed individual moves randomly across an exposure area.

Considerations of risk due to exposure to a source of contamination will be addressed because all COC data will be considered with respect to how a potential receptor may be exposed, not simply how the contamination is distributed in the environment.