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The Administrative Record Staff

DOE F 1325.8

United States Government Department of Energy

memorandum

Rocky Flats Office

DATE: MAR 3 0 1994

REPLY TO ATTN OF: ER.SRG-03600

COPY

SUBJECT: Resumption of All Work on Operable Unit Baseline Risk Assessments

TO: Sue Stiger Associate General Manager
Environmental Restoration Management
EG&G Rocky Flats Inc

Memorandum ER.SRC 03599 provides instruction for you to resume all work associated with Environmental Restoration Operable Unit (OU) baseline risk assessments that were stopped by memorandum ERD SRG-08450 dated August 18 1993

We reference the following memorandums concerning resumption of work for contaminants of concern and statistical comparisons with background for the baseline risk assessments.

- ERD.SRG-11731 October 13 1993 resumption of Contaminant of Concern selection and statistical comparisons of data to background for OU2.
  ERD-EAD 13779 December 22 1993 resumption of statistical comparisons of data to background for all operable units
  EG&G memorandum 94-RF-02971 - SG 179 94 March 14 1994 methodology for statistical comparisons of data to background.

DOCUMENT CLASSIFICATION REVIEW WAIVER PER CLASSIFICATION OFFICE

We have just recently reached agreement with the Environmental Protection Agency (EPA) and the Colorado Department of Health on the methodology for data aggregation and the methodology is attached.

ADMIN RECORD

You are directed to revise the schedules for the Operable Units to incorporate the agreed-upon risk assessment methodology by April 25 1994 In particular the data aggregation methodology represents additional work or modifications to work as per Part 32 of the Interagency Agreement (IAG) As a result we must determine revised schedules and costs including the additional scope to incorporate the revised methodology and make a request to EPA and CDH as per Part 42 (Extensions) of the IAG

Your April 25 1994 deliverable to us will include schedule extensions for all Operable Units affected by the stoppage of work, and will specifically denote the time needed (with sufficient rationale) for the additional work This is an important distinction because the IAG allows a day for day schedule extension (Paragraph 164 of the IAG) for the time the work scope was in effect and a schedule extension should easily be granted However the time needed for additional work is not as straightforward, and as a result needs a substantial rationale to support the request for additional time needed.

S Suger
ER-SRG-03600

2

MAR 3 0 1994

If you have any questions please contact Frazer Lockhart at extension 7846.

Jessie Roberson
Acting Assistant Manager for
Environmental Restoration

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DATA AGGREGATION FOR HEALTH EXPOSURE ASSESSMENT

Specific Data Aggregation Methodology at 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.

STATE OF COLORADO

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March 30 1994

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RE Resolution of Data Aggregation/Baseline Risk Assessment Dispute at the Rocky Flats Plant

Dear Mr Duprey

The Colorado Department of Health Hazardous Materials and Waste Management Division (the Division) hereby concurs with EPA's proposed resolution to the above referenced dispute However we do so with the following conditions

1) The attached language explaining how the 'conservative risk screen' will be conducted will be added to your proposal This language has been reviewed by your staff and DOE staff and is as far as we know acceptable to both As this screen is the first step in the risk evaluation process we feel it is valuable to add explicit language to this proposal so that consistent correct application of the screen may be achieved

2) The following changes are made to the text of your proposal as agreed to in staff conference calls on March 24 and 25 1994
   a) first page first paragraph, second sentence changed to 'Example exposure areas for the Rocky Flats Plant site may be '
   b) second page, first paragraph sixth sentence replaced with 'This will be made on will be made on a case-by-case basis '
   c) second page third paragraph fourth and fifth sentences changed to 'The guidance states that fewer than 10 samples per exposure area provides a poor estimate of the mean concentration Data sets with 20 to 30 samples per

Conservative Risk Screen for Sources[1] at the Rocky Flats Plant

This risk screen will be the first step in the risk assessment process used at Rocky Flats and will be the basis and justification for the type of next steps taken at a given OU (please see attached flow-chart)

The steps in the conservative risk screen are as follows

1 An entire OU RFI/RI data base will be compared to background using the previously agreed upon Gilbert methodology (flowchart block 1)
- The product of the background comparison will be a list of potential contaminants in the OU This list will consist of all organic chemicals that exceed detection limit somewhere in the OU and all inorganic chemicals whose OU population exhibits a significant statistical increase in concentrations compared to the background population either over the whole OU or within some portion of the OU

2 This list of potential contaminants will be used as the basis for the 'nature and extent' evaluation for each OU Within this evaluation source areas will be delineated For organic chemicals on the list the delineation criteria will be the detection limit; for inorganic chemicals on the list the delineation criteria will be the arithmetic mean of th background data set plus two standard deviations from th arithmetic mean (flowchart block 2)
- It is recognized that each chemical in each medium may have a different spatial extent within a source These different spatial extents do not affect the implementation of this screen A source however will be all contamination that can reasonably be tied together based on existing knowledge of the site contaminant types concentrations rates of migration etc

3 For each potential contaminant in each medium a medium-specific risk based concentration or RBC must be calculated These RBCs should be calculated based on 1) direct 'residential' exposure and intake parameters 2) direct ingestion dermal contact and inhalation pathways only and 3) assuming a carcinogenic risk of 1×10^{-4} and a non-carcinogenic hazard quotient of 1 0 (These RBCs could be calculated once site-wide since they are chemical-specific and not location specific

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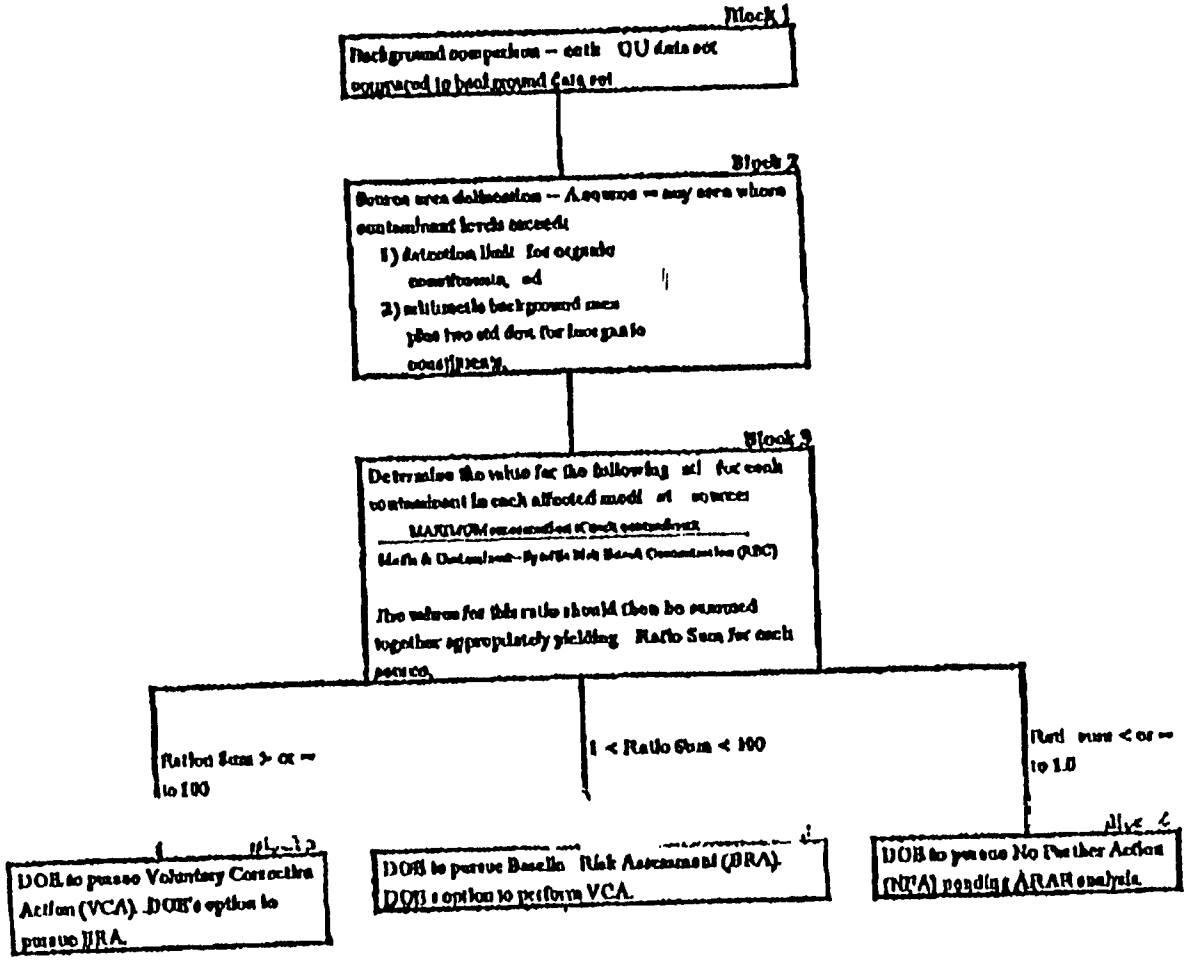
[1] Source Area defined by 1) contaminant levels exceeding background mean plus 2 standard deviations for inorganics and/or 2) detection limits for organics

4 For each source delineated in #2 above it is necessary to determine the maximum contaminant levels for each potential contaminant in each affected medium

5 On the maximum contaminant levels have been determined each media/contaminant-specific maximum should be divided by its respective RBC These maximum/RBC ratios for each contaminant should then be summed for each medium and then across all affected media in a source Those sources where the ratio sum is less than 1 0 have a risk less than $1X10^{-4}$ and/or a hazard quotient less than 1 0 Those sources where the ratio sum is greater than 1 0 have a risk greater than $1X10^{-4}$ and/or a hazard quotient greater than 1 0 (flowchart block 3)

6 For sources where the ratio sum was less than 1 0 DOE would pursue a no further action decision pending an ARAR analysis (flowchart block 4) For sources that have a ratio sum greater than 100, DOE would pursue a voluntary corrective action but could proceed with a Baseline Risk Assessment (BRA) at their discretion (flowchart block 5) For sources where the ratio sum was between 1 0 and 100 DOE would pursue a BRA but could perform a voluntary corrective action at their discretion (flowchart block 6)

CONSERVATIVE RISK SCREEN



For QA/QC methodology previously agreed upon.

For nature and extent evaluation.

RBCs based on:
1) direct "residential" exposure parameters, 2) direct ingestion inhalation, and dermal contact, 9) $10E-6$ carcinogenic risk and 1.0 hazard quotient.