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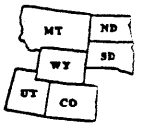

Region VIII

REGION 8 SUPERFUND TECHNICAL GUIDANCE

No. RA-01: RI/FS Statement of Work for BRA

September 1994

Risk Assessment (Short Title / Key Words)

TITLE: *Model Statement of Work for RI/FS Baseline Risk Assessments of Human Health*

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SUMMARY

This regional guidance is intended to provide EPA Remedial Project Managers and EPA contractors with summary directions on how to conduct a baseline risk assessment (BRA), including general applications to both human and ecological health evaluations. A step-wise process is outlined that includes expected deliverables for the RI / FS. Pertinent guidance is cited to direct the reader to more in-depth material as needed. This model statement of work for a BRA serves as a general framework for all RI / FS documents in Region VIII.

Methodology to be applied for development of risk assessments for the USEPA is described in the interim Risk Assessment Guidance for Superfund: Human Health Evaluation Manual Part A, (July 1989 (EPA/540/1-89/002) as supplemented by interim Part B (9285.7-01B) and interim Part C (9285.7-01C). Development of the sampling and analysis plan for the collection of RI data which may be used to support the risk assessment must follow the interim Guidance for Data Useability In Risk Assessment (Parts A and/or B), October 1990 (EPA 9285.7-09A and B) to the extent possible and should be developed with complete consideration of Data Quality Objectives for Remedial Response Activities (EPA 540/G-87/003A). A complete and contemporary list of background and guidance documentation for the practice of risk assessment in the USEPA is presented in appendix A of this workplan. Regional toxicologists may be contacted for literature and guidance which may be applicable to specific sites, characteristics, or particular contaminants of concern. Region 8 Guidance presented in this statement of work supplements that provided in the above documents. Interim deliverables which must be submitted during the development of the RI/FS baseline risk assessment are included.

I. RI/FS Workplan

SCOPING INTERIM DELIVERABLES:

The following deliverables are to be submitted to the Region VIII Remedial Project Manager for review prior to the RI/FS scoping meeting. The finalized versions of the following deliverables will be included in the workplan for the baseline risk assessment.

1. A conceptual site model which includes both current and potential future land use. The conceptual site model should be presented in the form of an iterative flow chart which depicts specific site characteristics to include: (1) contaminant sources; (2) release mechanisms; (3) transport routes; (4) exposure routes; and (5) receptors. The model should clearly provide for conceptual understanding of pathway interrelations and should include aspects pertaining to both human health and ecological risk at the site. It should be presented in schematic format. The conceptual site model will serve as the iterative foundation for the

growth and development of the final baseline risk assessment.

2. Exposure scenarios for both current and potential future site use. Scenario development should include a description of receptors and pathways of exposure for both human and ecological components of the baseline risk assessment. This section should also include a table detailing all exposure algorithms and specific parameters to be used in the risk assessment report. Parameters employed should be consistent with those found in the Exposure Factors Handbook (EPA/600/8-89/043) or the OSWER Directive 9285.6-03 Standard Default Exposure Factors and should be clearly justified. Exposure parameters which deviate from those provided in the above documents should be completely referenced with accompanying explanations for the deviation which must be fully substantiated and plausible to be used in lieu of default exposure factors. Identification of the need for collection of site specific exposure information should be presented here. Indicator species to be sampled or proposed bioassays to support the ecological on human health portions of the risk assessment should be identified and rationale for the proposed choices clearly presented and substantiated. Criteria to be used in selection of reference areas to be used in the ecological risk assessment should be identified and critically evaluated for validity of use.

3. A determination of the applicability of analytical detection limits and methodology for use in the baseline risk assessment. A presentation in tabled format should include a comparison between preliminary health-based limits such as inhalation unit risks, drinking water unit risks, RfDs, or RfCs for compounds identified in the site investigation and available detection and quantitation limits. A discussion of potential matrix effects and available alternative analytical techniques should be provided where necessary.

4. Proposals for the application of computer-based pharmacokinetic models or models to predict contaminant migration for the purpose of developing exposure point concentrations must be presented at this stage. Contaminant migration models may include air dispersion models, soil leaching models, ground water flow and transport models, etc.

For a given purpose, one or more models should be presented and described in detail. The contractor's experience with each model must be clearly indicated. Model strengths,

weaknesses, and complete references should be presented. The applicability of each model to the site should be discussed. Objectives of model employment and predictive ability must be described in detail.

All model inputs and methods of obtaining model inputs should be listed in tabled format. Required accuracy of each input and expected accuracy of the model should be also be presented.

5. The contractor must submit a list of the contaminants identified in the preliminary site assessment for which there are no available numerical estimates of toxicity. The submission of this list must consider both temporal aspects of potential exposure (acute, subchronic, and chronic) and route specific aspects of the exposure (oral, inhalation, dermal).

II. BASELINE RISK ASSESSMENT REPORT

The baseline risk assessment report is completed as a part of the Remedial Investigation report. The risk assessment document should be presented as a self contained, stand alone document in the Remedial Investigation report. The overall format of the report should closely follow the outline presented as exhibit 9-1 in the Risk Assessment Guidance for Superfund; Human Health Evaluation Manual (RAGS, Part A, 1989). In accordance with the National Contingency Plan and the RAGS, need for action at Superfund sites should be based upon an assessment of the reasonable maximum estimate of exposure (RME). Guidance for determination of the RME is presented in chapter 6 of the RAGS. Risk assessments conducted in Region VIII must also include average estimates of exposure (95% UCL, see 8RA-01) alongside RME estimates of exposure.

INTERIM DELIVERABLES FOR THE BASELINE RISK ASSESSMENT

The following should be submitted to the Region VIII RPM for review prior to calculation of baseline risks for the site:

A. Data Evaluation:

1. A list of all chemicals which are determined to be site related. Completed exhibits 45 (parts 1-3) of the ***Guidance for Data Usability in Risk Assessment*** and a qualitative assessment of the COC list must accompany the submittal. Generation of the list of COCs must comply with both National and Regional guidance.

2. A completed table which compares commonly available quantitation limits (MQLs, MDLs, and IDLs) with health-based numerical criteria for chemicals which are site related.

3. Rationale for the selection of chemicals of concern for the site referring to HHEA-RAGS part A and Region 8 Technical Guidance RA-03.

B. Exposure Assessment:

1. A final list of exposure parameters (average and RME) to be used in the risk assessment must be submitted to the RPM for review prior to calculation of risk estimates. Any parameters which are specific to the site must be adequately supported by appropriate references and data.

2. Calculation of the exposure point concentration(s) which will be employed in the risk assessment which meets the requirements of pertinent EPA guidance ***(Supplemental Guidance to RAGS: Calculating the Concentration Term*** OWSER Publication # 9285.7-081) and Region 8 EPA Technical guidance #RA-02.

3. Region 8 will accept proposals for the conduct of quantitative uncertainty analysis on exposure parameters only. Proposals for quantitative exposure analysis must be submitted to the RPM within 30 days of the scoping meeting. Proposals must identify any modeling software to be used in the analysis and a discussion of the data sources to be used to establish distributions. Rationale for assuming distribution shapes for those parameters lacking sufficient data must be included. The decision to proceed with quantitative uncertainty analysis will be made by the RPM in consultation with the regional toxicologist assigned to the site.

C. Toxicity Assessment:

The toxicity assessment portion of the risk assessment should be both brief (preferably <1 page per COC) and concise. The toxicity assessment should include a description of the chemical toxicity written for the lay public. The Toxicity assessment for a given chemical should not be a reproduction of material which is commonly available in ATSDR toxicological profiles but should reference these profiles if available.

1. The toxicity assessment portion of the risk assessment should be submitted to the RPM for review prior to incorporation into the risk assessment document should not exceed one page. Included in the

toxicity assessment for each chemical of concern should be a short description of the critical study(s) used to derive the numerical estimate of toxicity presented on IRIS or HEAST. The date of the IRIS or HEAST reference must be included. The description should include: (1) the quantitative toxicity estimate from the source used; (2) species employed; (3) critical toxicity endpoint or target organ (both human health and ecological receptors) as well as all endpoints evaluated; (4) duration of the study and all doses or exposures examined; (5) overall weight of evidence or uncertainty factors applied, confounders and rationale.

3. The toxicity assessment must include sound rationale for the additivity of any hazard quotients in the development of the hazard index. Deviations from additivity of carcinogenic effects must be solidly justified.

4. Route to route extrapolations must be presented to the RPM for review prior to inclusion in the baseline risk assessment.

D. <u>Risk Characterization</u>:

1. Summary tables of risk calculations should be submitted for review prior to incorporation into the risk assessment. Summary tables and figures should comply with the format presented in RAGS (Part A) Chapter 8.

2. If a quantitative uncertainty analysis (Monte Carlo, Latin Hypercube, etc.) is being considered for the site, parameter distributions, summary statistics on these distributions (arithmetic means, geometric means, 50th and 95%iles), associated references for the development of distributions, and proposed methodology, must be submitted to the RPM prior to the conduct of the uncertainty analysis. This information should be clearly and completely presented in the baseline risk assessment.

3. An accurate and complete qualitative (as well as semi-quantitative) description of uncertainty surrounding the risk estimates should be clearly summarized.

III. ROLE OF THE BASELINE RISK ASSESSMENT IN THE FEASIBILITY STUDY:

A. Prior to completion of the Baseline risk assessment the contractor will develop a set of preliminary remediation goals (PRGs). PRGs are based upon readily available information such as generic health-based media levels or chemical specific

ARARS and provide remedial design staff with targets to use for identification of potential remedial alternatives which are refined during the development of the baseline risk assessment.

PRGs are to be developed according to procedures outlined in the Risk Assessment Guidance for Superfund: Volume 1 --Human Health Evaluation Manual (Part B).

B. After completion of the Baseline Risk Assessment, the contractor will develop remediation goals which establish health-based exposure levels for each media and contaminant of concern. Ranges of exposure levels, and corresponding iso-concentration lines on site maps, maybe presented to describe areas of exceedance with various attributed risk levels (10^{-6}-10^{-4} cancer risks, or HI = 0.5, 1.0, 2.0, 5.0, etc.). This can help define the extent and relative magnitude of excessive health risks at a site.

C. A risk evaluation of remedial alternatives may be necessary prior to completion of the feasibility study. The alternatives requiring evaluation and the level of effort employed are to be defined by the Remedial Project Manager. Risk evaluation of remedial alternatives should be conducted according to procedure presented in Risk Assessment Guidance for Superfund: Volume 1 -- Human Health Evaluation Manual (Part C).

D. The baseline risk assessment will serve as a guide by which to develop or compare media specific action levels with health based goals or Federal or State standards. Cumulative risk resulting from multiple contaminants and/or multiple pathway exposure should be clearly presented so that a comparison of remedial alternatives is possible.

E. The level of confidence and/or corresponding uncertainty in the risk estimates should be clearly defined and placed into credible technical perspective based on weight of scientific evidence and current biomedical knowledge.