

Date: January 21, 1991

To: Tom Ottensman,  
From: Dennis Smith,

Subject: Operable Unit 5, Woman Creek Priority Drainage, Phase I  
RFI/RI Work Plan Review,

Section 8.1 Overview

Second paragraph, insert "of potential for adverse human health effects to occur"

Page 8-2, Add: Guidance For Data Useability in Risk Assessment.  
EPA/540/G-90/08

Page 8-2, Paragraph after 5 bullets expand to five general steps and add Uncertainty Analysis after Risk Characterization.

Section 8.2.1 Data Collection

First paragraph, add that the sampling and analysis plan for the RFI/RI will detail the data collection program.

Section 8.2.2 Data Evaluation

This section seems to lack focus. The goal of Contaminant Identification is to derive (1) list of "contaminants of concern" and (2) a set of analytical results to support the exposure and risk assessment steps. Please revise to emphasize this.

Please add a discussion of how the observed analytical results will be compared to background data. The goal of this exercise will be to make sure that we are not giving site related contamination status to background chemicals/nuclides. Inorganic, some radionuclides, and certain organics such as phthalate esters are common in the environment. This should be done on a medium-by-medium basis.

Add discussion that reflects the concept of (1) starting with an exhaustive list of candidate analytes which will be reduced to a (2) a finite data set (chemicals of concern) for the exposure and risk assessment. See Sections 5.8 and 5.9 of RAGS and Section 3 of the old Superfund Public Health Evaluation Manual (SPHEM) for information to support development of this important concept in our approach.

Page 8-4, Delete first paragraph after first sentence. This is not normally done (re-analysis, assignment of "proxy" concentrations, etc.,) Add quantitation limits will be ... to the sentence beginning "Qualified and coded..."

ADMIN RECORD

A-DU05-000004

### Section 8.3 Exposure Assessment

The objective of exposure assessment is to identify likely receptors and to quantify their dose.

Revise last sentence of 1st paragraph to reflect the following concept. Exposure scenarios will be developed that reflect the potential current and future land-use of the O.U. These can include: residential, recreational and agricultural exposure scenarios. Within each of these scenarios, a range of exposure conditions will be evaluated. One of those evaluated will be an approximate 95% upper confidence limit estimate of the central tendency exposure. The upper 95% UCL is analogous to the Reasonable Maximum Exposure (RME). (Note: WCFS See attached Figure A for an example of how exposure & risk will be presented.)

Page 8-5, Revise the exposure pathway to include a fifth component; contaminant release. Thus the components are: source > release > transport and processes occurring during transport > contact with a receptor > receptor route of exposure. See the attached Figure 1. Build your discussion around this model and emphasize that exposure assessment is largely devoted to quantifying the blocks in this model.

Add that fate and transport modeling may be necessary to evaluate the future-use exposure scenarios. Fate and transport modeling will involve the following:

Scenario specification

Formulation of the conceptual model (i.e., flushing-out the components illustrated in Figure 1)

Formulation of the computational model (i.e., selecting appropriate candidate source-codes)

Estimation of input parameter values (i.e., determining inputs, sensitivity analysis etc.,)

Calculation and documentation of results (including calibration and confidence interval estimation)

NOTE: The above 5 points describe a conceptual approach to transport and fate modeling. WCFS will be expected to demonstrate modeling accuracy and reliability against a performance criteria based on simulating the current-case condition. For general guidance, please consult Evaluating the Reliability of Predictions Made Using Environmental Transfer Models International Atomic Energy Agency (IAEC), Safety Series Publication No. 100. It is likely that fate and transport modeling of the Future Use Scenario will drive the baseline risk

assessment and the establishment of medium-specific cleanup levels. As such, the ultimate cost of remediation could hang significantly in the balance. As a consequence, applying conservative assumptions in the absence of hard quantitation of the conceptual and computational model must be avoided.

Page 8-6, Please expand the discussion of exposure pathways in this Section by tying-in the conceptual models identified in Section 2.6. Develop the discussion around a conceptual exposure assessment model similar to the Example Exposure Pathways attached. EPA will be expecting to see models such as this that relate the source > release > transport > receptor concept for each discernable source. Attached also is Example Conceptual Model that has been transferred to a Site cross-section. See also what is being done for the O.U. 2 WP's. Note: the pathways and conceptual model examples are not from the same Site.

Page 8-6, Last sentence: Revise, Based on an analysis of the likelihood of occurrence and considerations of physiology, multimedia exposure will be evaluated and intakes across pathways will be combined.

#### Section 8.4 Toxicity Assessment

1st paragraph, insert "evaluate the" for estimate. Point out to the reader that this is an evaluation of:

Evidence of a dose/response relationship

Magnitude of the dose/response relationship

Uncertainty in the dose/response relationship

Applicability of the toxicologic data to the exposure scenarios identified in Section 8.3

2nd paragraph, add that the data considered will be limited to that of the public domain and the assessment will not include development of new toxicological data.

3rd paragraph, Suggested verbiage: The toxicity assessment will identify suitable toxicologic reference criteria that will support the risk assessment. In the case of compounds exhibiting non-carcinogenic effects, the reference toxicity criteria will be a reference dose (RfD). For compounds suspected as being capable of producing carcinogenic effects, the assessment will identify and evaluate a cancer potency dose/response slope-factor. The toxicity assessment will consider appropriate sources of public domain literature including, but not limited to: EPA's Integrated Risk Information System (IRIS) and the Health Effects Assessment Summary Tables (HEAST), and the National Research Council's, Biological Effects of Ionizing Radiation (BEIR) reports.

Appropriately trained specialists including toxicologists, health physicists and biostatisticians will be utilized as appropriate.

Add a paragraph that one of the outcomes of this exercise will be an assessment of the primary target organ for each non-carcinogen. This will facilitate a correct application of the Hazard Index (HI) versus indiscrete summing as is customarily done in EPA style risk assessment.

4th paragraph, Suggested verbiage: Uncertainties relating to the toxicity assessment will be evaluated and their implications for the risk assessment identified. Included in this discussion will be an analysis of the "weight of evidence" determinations given in IRIS as well as similar assessments from the International Agency for Research on Cancer (IARC). Uncertainties associated with applying biased, upper 95th percentile cancer potency slope factors versus maximum likelihood estimate (MLE) slope factors will be evaluated. Additionally, the "uncertainty factors" applied to obtain RfD's will also be assessed and discussed.

#### Section 8.5 Risk Characterization

1st bullet: please clarify the "made consistent" portion of this segment.

Delete 5th bullet. I don't think that we intend to do this.

Delete 4th bullet.

6th bullet. The results of the risk assessment will be summarized and presented as a range of possible risks potentially resulting from exposure to the compounds present at the site and the under various exposure conditions. The range presented will represent an unbiased characterization of uncertainty in the central tendency risk estimate and will include an upper 95% confidence limit RME.

#### Section 8.6 Uncertainty Analysis

An uncertainty analysis will be performed to identify factors that produce uncertainty in the risk assessment. Sources of uncertainty will be identified and quantified to the extent practicable. The uncertainty analysis will investigate the impact of factors such as assumptions inherent in the development of toxicological assessment criteria (potency slope factors and reference doses) and assumptions considered in the exposure assessment (model input variability and population dynamics). Techniques employed to assess uncertainty in the risk assessment may include propagation of errors analysis (i.e., first order analysis), sensitivity analysis, statistical sampling methods (Monte-Carlo) or other methods that are appropriate to the assessment. The goal of this task will be to quantify, to the extent practicable, the magnitude and extent of uncertainty

propagated through the risk assessment process. The uncertainty analysis will present the spectrum of potential risks under the specified scenarios so that the risk management decision maker can acquire an understanding of the level of confidence associated with all estimates of human health risk.

### Section 3.0 Development of Remedial Action Alternatives

Clarify: Is this the Work Plan for the Full FS? The detailed analysis of alternatives reads like it! Will there be more? Where do Treatability Studies fit in?

Add a bullet (2nd) " Develop preliminary risk-based remedial action goals for affected media. Preliminary remedial action goals will be applied as performance objectives (along with chemical specific ARARs) for evaluating the effectiveness of specific technology processes identified as candidate components of viable remedial action alternatives. Consistent with the NCP, preliminary remediation goals will be established at a 1 E-6 excess cancer risk point of departure and at other intervals within the 1 E-4 to 1 E-6 decision range. As the Feasibility Study evolves, preliminary remediation goals may be revised to a different risk level based on consideration of appropriate factors including, but not limited to: exposure, uncertainty, and technical issues."

3rd bullet; change biosphere to environment, change should to will in last sentence.

4th bullet; change technology options to process options

5th bullet; add some language to limit the number of alternatives for detailed evaluation. 7-8 including no action, is a very sizable work scope.

If this is the full FS Work Plan, this Section need to be expanded and placed in another (later) portion of the document.