3.0 Analytical Approach and Methods

The requirements in this section address design and technical conduct of the assessment. The assessment also must meet or exceed all requirements of the Tri-Party Agreement. Management of the assessment is discussed in Section 4.0. The requirements in this section are provided in Appendix II-C and are categorized into seven groups: 1) ensuring that the factors contributing most to actual exposures/effects are always considered in any assessment task; 2) ensuring that assessment uncertainty is always known, quantified, consistent among all assessment tasks, and responsive to the needs of those who will use the results, especially Hanford decision makers; 3) ensuring that the assessment be designed as a single, integrated set of seamless tasks, which together form a logical, robust architecture for long-term use of the assessment tools; 4) developing and implementing meaningful data quality criteria that draw on the best features of the data quality objective process; 5) selecting and using assessment methods that capitalize on the progress made in the risk assessment field but are not subject to its limitations; 6) verifying assessment models and results; and 7) identifying new development efforts needed in assessment methods.

3.1 Identification and Management of Dominant Factors

Ensuring that the assessment effort is always focused on the most important contributors to contamination impact is the subject of this section. This is the first principle defined in the “Principles and General Requirements” section. Often, project efforts are prioritized in terms of a chronological sequence of tasks or favored alternative solutions; funding and staff skills are allocated accordingly. The requirements in Part II reject such approaches. Rather, it requires that methods developed to identify the dominant factors in this assessment be based on sensitivity study methods, parametric analysis methods, or related techniques. While smaller contributors to impact must be set aside, the methods must be adequate to preclude leaving out any major contributor. If useful, analysts are encouraged to visit advanced design organizations in other industries where such methods are more commonly found than in nuclear or environmental fields.

3.2 Identification and Management of Uncertainty

Section II-C.2 provides the requirements in this subject area. Uncertainties exist, for example, in how well the Hanford cleanup methods will contain the wastes; in our capability to forecast changes in climate, cultural, and economic scenarios; and in how well this assessment will be conceived, designed, funded, and technically executed. Uncertainty is addressed as a principle (see the “Principles and General Requirements”) because its management is pivotal to credible results and economy of resources required.

Allocating the maximum acceptable level of uncertainty in the assessment’s results is an approach often used; that is, each of the assessment’s models and calculation tasks would be allocated ceiling values of uncertainty based on the acceptable level of the results. Any task’s inability to meet its allocation would then suggest a reallocation of either allowable uncertainty or funding to the more difficult tasks. Other methods should be considered, such as those in the National Council on Radiation Protection and Measurements Commentary No. 14 (1996).

Uncertainty is highly dependent upon the dominant factors discussed above. For example, if offending levels of uncertainty reside among factors of little significance, then their uncertainty is also insignificant. Methods will be developed to identify and manage uncertainty consistently across all of the assessment tasks. The CRCIA Board will approve the methods planned to be used.

3.3 Analytical Architecture and Integration

A simple example of an architecture for this assessment is shown in Figures 3 and 4. That architecture was developed only to organize an approach for capturing and communicating the requirements in Part II of this document. That architecture may not be the approach preferred by the analysts. However, an approach must be conceived and understood by all those involved in this assessment. The CRCIA Board will review the recommended architecture for the assessment.

The fundamental concept preferred in developing this architecture is to identify all the assessment's necessary functions and arrange them in hierarchical form, partitioning upper level functions into subfunctions to the extent necessary to ensure clarity and completeness. Dependencies among functions must be defined to ensure the right information is generated for the right recipients. Such an architecture is not only useful in planning and sequencing assessment tasks, but it defines the necessary conditions for compatibly integrating all the assessment's tasks.

3.4 Data Quality

Developing data quality criteria for the assessment is essential. For example, managing uncertainty as discussed in Section 3.2 would not likely be successful without control of data quality. Data quality requirements are found in Section II-C.4. Like many areas in Part II of this document, Section II-C.4 provides little more than a conceptual framework for data quality requirements. It is left to the analysts to complete the definition of the assessment's data quality requirements for the CRCIA Board's approval. The best practices from the data quality objective process should form the basis for CRCIA data quality criteria. Criteria will include identifying data gaps, verifying and validating data, acquiring data, and managing data quality.

3.5 Assessment Methods

Some assume the CRCIA analysis is a risk assessment in the same sense as the practices that have emerged in response to EPA's environmental literature. The analyst is cautioned against this conclusion. This document has stressed many times that the CRCIA Team believes conventional risk assessments to be inadequate, especially with respect to cultural considerations (see "Problem Statement" in the "Introduction" section). If the analysts' intellectual perspective on this analysis is that of a conventional risk assessor, much of the needed innovation is unlikely to emerge. The experience accumulated in the risk assessment field should be drawn upon, and so should it be with radionuclide and chemical migration performance assessments methods, parametric and sensitivity analyses, mutagenic investigation methods, and many more. The requirements in this section reflect the concern expressed by several members of the CRCIA Team that the methods essential to this assessment's management of dominance, uncertainty, fidelity, and cultural impact would simply be ignored in favor of another conventional risk assessment. The analysts must design this assessment to take advantage of the best current practices but be limited by none of the popular approaches. The CRCIA Board will be kept informed and must approve the assessment approaches and design alternatives under consideration.

3.6 Verification and Validation

In discussing the required fidelity of the assessment to faithfully reflect reality without distortion (Section 2.0), the requirements for model validation were mentioned as one element of ensuring the assessment's quality. The requirements in this section address the need to verify and validate all the elements of the assessment. Among those matters to be addressed in this area are 1) use of peer reviews, 2) field data collected especially for verification purposes, 3) use of historical and ongoing monitoring data, 4) results of climatic trending studies, 5) medical research to verify toxicity correlations, 6) literature reviews, and 7) data traceability data bases.

3.7 Analysis Research and Development Needs

Research and development (R&D) efforts will be identified to extend existing analytical methods and develop new techniques as needed to meet the requirements of this assessment. Advancing the state-of-the-art is preferable, in most cases, to abandoning key objectives of this assessment. However, financial sponsorship of such development work will be sought from national grant programs and other sources. Using CRCIA funding for these purposes will be considered only as a last resort.

Developing the R&D needs will be done as an integral part of the assessment planning and design effort. To the extent that assessment funds are needed for R&D, the CRCIA Board will approve the R&D candidates along with the assessment design.

3.8 CRCIA Standards, Regulations, and Guidelines

See "Standards" in the section on Principles and General Requirements.

3.9 References

National Council on Radiation Protection and Measurements. 1996. *A Guide for Uncertainty Analysis in Dose and Risk Assessments Related to Environmental Contamination*. NCRP Commentary No. 14, Bethesda, Maryland.