Chapter 2
The Risk Assessment Process

This chapter discusses the data collection and evaluation issues that affect the quality and useability of radioanalytical data for baseline human health risk assessments. Part A, Exhibit 3 lists the four components of the risk assessment process and the information sought in each of the components.

2.1 DATA COLLECTION AND EVALUATION

Part A, Section 2.1.1 contains an overview of methods for data collection and evaluation that can be applied to sites contaminated with radioactivity as well as with chemical hazards. The development of data quality objectives as part of a carefully designed sampling and analysis program will minimize the subsequent need to qualify the analytical data during the data analysis phase. Specific radioanalytical methods are described in Section 3.0 of this guidance, along with a discussion of chemicals of concern in Section 3.2. Strategies for selecting analytical methods and designing sampling plans can be found in Section 4.0.

2.2 EXPOSURE ASSESSMENT

The approach to risk assessment for radionuclides shares the objectives stated in Part A, Section 2.1.2:

- Identify or define the source of exposure.
- Define exposure pathways (receptors) including external exposure.
- Identify potentially exposed populations.
- Measure or estimate the magnitude, duration, and frequency of exposure to site contaminants for each receptor (or receptor group).

Exposure pathways should be designated before the design of sampling procedures.

2.2.1 Identifying Exposure Pathways

This section describes a methodology for estimating the radiation dose equivalent to humans from exposure to radionuclides through all pertinent exposure pathways. These estimates of dose equivalent can be compared with radiation protection standards and criteria, with an important cautionary note. These standards have been developed for regulating occupational exposure for adults and are not completely applicable to assessing risk for the population at large. Section 2.4 describes a methodology for estimating health risk.

Part A, Section 2.1.2 describes the procedures for exposure assessment for chemical contaminants, and many aspects of this section apply directly to radionuclides. However, the term "exposure" has a specific meaning for radionuclides which is distinct from its use with chemical contamination (see Appendix I). For chemicals, exposure usually refers to the intake of the toxin (e.g., inhalation, ingestion, dermal exposure) expressed in units of mg/kg-day, the same units used for toxicity values. Unlike chemical toxins, an exposure assessment for radionuclides can include an explicit estimate of the radiation dose equivalent.

Inhalation and ingestion remain as important exposure pathways for radionuclides, although the units to express intake are in activity (i.e., Bq or Ci) rather than mass. Radionuclides entering through these pathways may become incorporated within the body where they emit alpha, beta or gamma radiation providing internal exposure to tissues or organs. Absorption is not an important exposure pathway for radionuclides. Dose equivalent is a quantity that incorporates both the energy deposited internally from ionizing radiation and the effectiveness of that radiation to cause biological damage to the organism. The dose equivalent was developed to normalize the unequal biological effects produced from equal absorbed doses of different types of radiation (i.e., alpha, beta, or gamma).

Radionuclides need not be taken into or brought in contact with the body to produce biological damage. High energy emissions of beta particles and photons from radionuclides can travel long distances with minimal attenuation, penetrate the body, and deposit their energy in human tissues. External radiation exposures can result from either exposure to radionuclides at the site area or to radionuclides that have been transported from the site to other locations in the environment. Potential external exposure pathways to be considered include immersion in contaminated air or water and direct exposure from ground surfaces contaminated with beta- and photon-emitting radionuclides. Gamma and x-rays are the most penetrating of the emitted radiations and comprise the primary contribution to the radiation dose from external

Acronyms

DCF	dose conversion factor
EPA	U.S. Environmental Protection Agency
HEAST	Health Effects Assessment Summary Tables
IRIS	Integrated Risk Information System
RPM	remedial project manager

exposures. External exposure to beta particles primarily imparts a dose to the outer layer skin cells, although high-energy beta radiation can penetrate into the human body. Alpha particles are not sufficiently energetic to penetrate the outer layer of skin and do not contribute significantly to the external dose.

The amount of energy deposited in living tissue is of concern because the potential adverse health effects of radiation are proportional to the energy deposited. The energy deposited is a function of a radionuclide's decay rate, not its mass. Therefore, as mentioned earlier, radionuclide quantities and concentrations are expressed in units of activity.

Environmentally dispersed chemicals, stable and radioactive, are subject to the same processes that affect their transfer rates and therefore their bioaccumulation potential. Radionuclides undergo radioactive decay. In some respects, this decay can be viewed as similar to the chemical or biological degradation of organic compounds. Both processes change the quantity of the hazard present in the environment and produce other substances. The products of radioactive decay may also be radioactive and can contribute significantly to the radiation exposure. These radioactive decay products must be considered for risk assessment purposes.

2.2.2 Exposure Quantification

One of the objectives stated for exposure assessment was to make a reasonable estimate of the maximum exposure to receptors or receptor groups. The equation presented in Part A, Exhibit 7 to calculate intake for chemicals can be applied to exposure assessment for radionuclides, except that the body weight and averaging time terms should be omitted from the denominator. However, exposures to radionuclides include both internal and external exposure pathways, and radiation exposure assessments take the calculation an additional step in order to estimate radiation effective dose equivalent which is directly translatable to risk.

Radionuclide intake by inhalation and ingestion is calculated in the same manner as chemical intake except that it is not divided by body weight or averaging time. For radionuclides, a reference body weight and averaging time are already included in the dose conversion factors (DCFs), and the calculated dose is an expression of energy deposited per gram of tissue.

External exposures may be determined by monitoring and sampling of the radionuclide concentrations in environmental media, by direct measurement of radiation fields using portable instrumentation, or by mathematical modeling. Portable survey instruments that have been properly calibrated can display dose rates (e.g., Sv/hr or mrem/hr), and dose equivalents can be estimated by multiplying the dose rate by the duration of exposure to the radiation field. Alternatively, measured or predicted concentrations in environmental media may be multiplied by DCFs, which relate inhaled or ingested radionuclide quantities to effective dose equivalent. Federal Guidance Report No. 11 (EPA 1988) provides DCFs for each of over 700 radionuclides for both inhalation and ingestion exposures, as well as immersion exposures to tritium and the principle radioactive noble gases. It is important to note that these DCFs were developed for regulation of occupational exposures to radiation and may not be appropriate for the general population. The Integrated Risk Information System (IRIS) (EPA 1989) and the Health Effects Assessment Summary Tables (HEAST) (EPA 1990) provide slope factors for radionuclides of concern for each of the three major exposure pathways (inhalation, ingestion, and external exposure) that may be applied to determining the risk to the general population.

The dose equivalents associated with external and internal exposures are expressed in identical terms (i.e., Sv), so that contributions from all pathways can be summed to estimate the total effective dose equivalent value and prioritize risks from different sources. A more extensive discussion of quantifying exposure from radioactivity can be found in *Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual, Part A, "Baseline Risk Assessments"* (EPA 1991).

The radiation exposure assessment should include a discussion of uncertainty. This should include, at a minimum, a tabular summary of all values used to estimate exposures and doses, and a summary of the major assumptions used in the assessment process. Special attention should be paid to the three sources of uncertainty listed below:

- Correlation of monitoring data and the actual conditions on site.
- Exposure models, assumptions, and input variables used for the exposure estimate.
- Values of variables used to estimate intakes and external exposures.

2.3 TOXICITY ASSESSMENT

The objectives of toxicity assessment are to evaluate the inherent toxicity of the compounds under investigation, and to identify and select toxicological measures for use in evaluating the significance of the exposure. Certain

fundamental differences between chemicals and radionuclides somewhat simplify toxicity assessment for radionuclides.

Theoretically, any dose of radiation, no matter how small, has the potential to produce adverse effects, and therefore, exposure to any radioactive substance is hazardous. A large body of data derived from human and experimental animal studies establishes the principal adverse biological effects of exposure to ionizing radiation to be carcinogenicity, mutagenicity, and teratogenicity. EPA's current estimates of adverse effects associated with human exposure to ionizing radiation indicate that the risk of cancer is limiting and may be used as the sole basis for assessing the radiation-related human health risks of a site contaminated with radionuclides.

The dose-response assessment for radionuclides is also more straightforward, and this relationship is relatively well characterized at high doses. Accordingly, a detailed toxicity assessment for individual radionuclides at each site is not required. In general, radiation exposure assessments need not consider acute toxicity effects because the quantities of radionuclides required to cause adverse effects from acute exposure are extremely large and such levels are not normally encountered at Superfund sites.

2.4 RISK CHARACTERIZATION

The final step in the risk assessment process is risk characterization. This is an integration step in which the risks from individual radionuclides and pathways are summed to determine the likelihood of adverse effects in potentially exposed populations. Since the concern is for radiation dose equivalent, and since all pathway doses are calculated in comparable units, the total effective dose equivalent from all pathways is easily computed and can be translated directly to risk.

All supporting documentation provided for the exposure assessment should be compiled to ensure that it is sufficient to support the analysis, to allow an independent duplication of the results, and to ensure that all exposure pathways have been addressed. Additionally, all assumptions regarding site conditions, environmental transfer factors, etc., must be carefully reviewed to ensure that they are applicable.

Once all data are in order, the next step is to calculate the risk based on the estimated committed effective dose equivalents. As stated earlier, risk assessment for radionuclides needs to be considered only for the end point of radiation carcinogenesis.

2.5 ROLES AND RESPONSIBILITIES OF KEY RISK ASSESSMENT PERSONNEL

The key risk assessment personnel and their responsibilities are discussed in Part A, Section 2.2. It is recommended that a health physicist or radiochemist be involved in the risk assessment process to provide technical assistance to the remedial project manager (RPM) and the risk assessor. For a listing of EPA health physics and radiochemical support staff, see Appendix III.