CHAPTER 5

Risk Assessment

5-1. Introduction. Risk assessments are a required element of CERCLA and RCRA site investigations. They are used on both non-radiological and radiological chemical environmental restoration projects to determine whether a site poses a potential threat to human health and the environment. Information from a risk assessment is used to demonstrate whether a site warrants further investigation, whether a removal or remedial action is warranted, or if a site may be closed with no further action. Dose is frequently assessed for radionuclides because many standards that regulate radionuclides, such as those issued by the Nuclear Regulatory Commission (NRC), which are based on radiological dose. However, CERCLA guidance requires that risk be assessed as part of site investigations. Differences between dose assessment and risk assessment are discussed below.

5-2. Risk Assessment and Dose Assessment Comparison.

a. In many ways, risk assessments and dose assessments are synonymous with one another. In both risk assessments and dose assessments, measurements of constituents of potential concern are used together with exposure assumptions to develop the “dose” that a receptor may receive. The meaning of the word “dose” is part of what distinguishes radionuclide from non-radiological chemical risk assessment. In chemical risk assessment “dose,” or intake, means the mass of a substance taken into an organism through all pathways (such as inhalation, ingestion, absorption, etc.) per unit body weight per unit time and is usually expressed as mg/kg per day. This is combined with toxicity information to develop estimates of excess cancer risk, or a hazard index for non-carcinogenic risk. In terms of radiological risk, dose means energy imparted by ionizing radiation to matter per unit mass. This may be expressed in units of rad. Radiological dose assessments generally express dose in units of mrem/year; for example 1 rad of gamma radiation will produce 1 rem dose equivalent. Dose assessments estimate dose imparted to an organism by combining exposure information with radionuclide-specific characteristics. Dose will be a function of the type of radiation emitted by particular radionuclides and the frequency and duration of exposure of organisms to that radiation. Another difference between chemical and radionuclide risks is that radionuclide exposure estimates must consider an additional pathway, exposure to radiation that has sufficient energy to penetrate the skin. This is called the external pathway.

b. As stated above, information from a risk assessment or dose assessment is used to determine whether a site is safe, or whether it requires further action. The site risk assessment is used to develop remediation goals under CERCLA when there are no ARARs available, or when ARARs are not protective owing to multiple contaminants or pathways of exposure to contaminants. Remediation goals based on a dose assessment are used as components of many regulations, specifically, the NRC’s Final Rule for Radiological Criteria

for License Termination (10 CFR 20, Subpart E) and to develop supplemental standards under the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (40 CFR 192, UMTRCA). The following paragraphs further discuss the roles and procedures for dose and risk assessments in regulatory programs that commonly cover USACE projects where radionuclides contamination occurs.

5-3. Role of Risk Assessment in Regulatory Programs. There are certain instances, such as Work for Others on nuclear decommissioning projects, where USACE work may be carried out under direct regulation by the NRC. Most USACE environmental restoration projects with radionuclide contamination, however, will follow CERCLA with NRC regulations as a potential ARAR. The paragraphs below discuss the CERLCA process and how risk assessment is used in the various stages. Some projects may be regulated by the Resource Conservation Restoration Act (RCRA); the role of risk assessment or dose assessments in projects regulated by RCRA is functionally equivalent to that of CERCLA. The processes followed by RCRA are similar to those of CERCLA, except that different terminology is used.

a. At sites regulated by CERCLA, the first step after discovery of a site is preparation of a Preliminary Assessment/Site Inspection (PA/SI). The objectives of an SI are to eliminate from further consideration any releases that do not pose a threat to human health or the environment, to collect data to initially characterize any releases, and to identify any immediate threats to public health or the environment. A screening level risk assessment is used during the PA/SI stage to meet these objectives.

b. At the end of the PA/SI, EPA applies a scoring system known as the Hazard Ranking System (HRS) to determine if a site should be listed on the National Priorities List (NPL).

c. Performance of the HRS is EPA's responsibility and is generally not done by USACE or by DOD. However, site investigations should be designed to ensure that adequate data are available for EPA to conduct the scoring. Though DOD does not use the HRS, it does use a system for ranking sites for resource allocation and prioritization called the Relative Risk Ranking System. It is not a risk assessment, but does consider factors common to risk assessment, such as migration pathways, contaminant hazard, and receptors.

d. The purpose of the Remedial Investigation (RI) phase of the CERLCA process is to collect data to characterize the nature and extent of contamination and to quantify risks to human health and the environment in a baseline risk assessment. Results of the risk assessment are used to determine the contaminants, the media, and the areas of the site that require an evaluation of remedial alternatives in the Feasibility Study (FS). Risks are considered to be unacceptable if the non-cancer hazard quotient is above one or if excess cancer risk is above 10^{-4} (40 CFR 300), or if ARARs are exceeded. In the FS remedial

alternatives are developed, screened, and analyzed, and potential remedies are evaluated against the nine criteria outlined in the NCP, as further discussed in Paragraph 9-2.

e. The first two criteria for evaluating remedial alternatives, overall protection of human health and the environment, and compliance with ARARs, relate to protectiveness of the remedy and to determination of remediation goals. The discussion of overall protectiveness in an FS will draw upon the analysis of other criteria, such as long-term effectiveness, short-term effectiveness, and attainment of ARARs. Long-term effectiveness considers the amount of residual risk remaining after a remedial alternative is implemented. For some projects this evaluation may require that a quantitative residual risk assessment be prepared. A residual risk assessment entails estimating residual concentrations of contaminants of concern, with a subsequent calculation of risk from exposures to those levels. For many projects, though, a qualitative evaluation of how remediation goals will be attained will suffice. The FS needs to discuss whether the analyzed remedial alternatives meet the ARAR or risk-based criteria for protectiveness.

5-4. Regulatory Guidance for Risk Assessments and Dose Assessments. EM 200-1-4, Risk Assessment Handbook Volume I: Human Health Evaluation (1999) and EM 200-1-4 Risk Assessment Handbook Volume II: Environmental Evaluation (1996) provide an extensive discussion of available guidance for human health and ecological risk assessments at sites regulated by CERLCA and RCRA. The reader is referred to these documents for more information. The discussion presented in the following paragraphs will focus on issues and guidance that are unique to radiological risk assessments and dose assessments.

5-5. CERCLA.

a. EPA has issued several guidance documents for conducting human health and ecological risk assessments. Chapter 10, “Radiation Risk Assessment Guidance,” of Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (RAGS Pt. A) (EPA 1989) covers data collection and evaluation, exposure and dose assessment, toxicity assessment, and risk characterization for sites contaminated with radionuclides. Chapter 4 of RAGS Pt. B Development of Risk-based Preliminary Remediation Goals (EPA 1991) presents standardized exposure equations for calculating preliminary remediation goals (PRGs) for radionuclides under residential and commercial/industrial land uses. When the PRG document was developed, EPA recommended that the equations be used with default exposure parameters to develop values for screening sites in the initial stages of the CERCLA process, as well as with site-specific information for developing PRGs in the FS. In 1996, though, EPA released Soil Screening Guidance, which gives equations to develop soil screening levels (SSLs) for screening sites with non-radiological contaminants. SSLs are based on residential use and also address contaminants leaching from soil to ground water, whereas the PRG calculations do not consider leachability. In 2000, EPA followed this document up with a document specific for radionuclides, Soil Screening Guidance for

Radionuclides (EPA 2000), which contains equations for calculating screening levels for radionuclides. The equations for exposures to soil supercede the residential equations contained in RAGS Pt. B. An electronic tool for running the calculations, the EPA PRG Calculator, is located at http://epa-prgs.ornl.gov/radionuclides/.

b. An ecological risk assessment must also be conducted on CERCLA sites. The guidance for ecological risk assessments at CERLCA sites is titled Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments (EPA 1997).

c. Information regarding toxicity values for radiological risk assessments, additional models, and other information relative to risk assessment for radionuclides, may be obtained at EPA's radiation website http://www.epa.gov/radiation/.

5-6. RCRA Guidance. As stated above, RCRA human health assessments generally follow CERCLA guidance. There is no guidance regarding risk assessments or dose assessments specific to radionuclides available for the RCRA program.

5-7. NRC Guidance. Standards for Protection Against Radiation, Radiological Criteria for License Termination, and NRC decommissioning standards at 10 CFR 20.1401-1403 give dose requirements for restricted and unrestricted land use. The standard also requires that the dose assessment determine the peak annual total effective dose equivalent (TEDE) to the average member of the critical group expected within the first 1000 years. The NRC has developed draft guidance for performing dose assessments to show compliance with their standards and also developed the D and D computer code to perform dose assessments. Another computer code, RESRAD, is available that may be used to assess doses. RESRAD has certain advantages over D and D and is preferred by health physicists for assessing doses. The model may be downloaded at Argonne National Laboratory's website at http://web.ead.anl.gov/resrad/home2/.

5-8. Considerations for Project Risk Assessments. Since many USACE projects will follow the CERCLA process, the following paragraphs discuss aspects of CERCLA screening-level and baseline risk assessments that will be unique for projects where radionuclide contamination is confirmed or suspected. Further information on risk assessments may be found in Volume I of EM 200-1-4 and Volume II of EM 200-1-4 (USACE 1996, 1999).

a. Screening-Level Risk Assessments. To determine whether a site requires further investigation and to identify areas that may pose an immediate threat to human health and the environment, a screening-level risk assessment is carried out as part of the SI. The first step of this process is preparation of a preliminary conceptual site model (CSM) for both human and ecological receptors. A preliminary CSM should be prepared when scoping the PA/SI, using whatever site information is available at the time, and the CSM should be modified as

more site-specific information is gathered. EM 1110-1-1200 provides guidance for preparing CSMs for human receptors, and integrates ordnance and explosives or hazardous, toxic, and radioactive waste. Guidance for preparing CSMs for ecological receptors with case study examples may be found in EM 200-1-4.

b. Human Health Screening. Human health screening level risk assessments are typically conducted by comparing the highest detection against health-based screening levels. Screening levels are media concentrations derived by back-calculating from protective risk values and conservative exposure parameters. To develop screening levels for radionuclides and other carcinogens, the risk value is set at the lower (most protective) end of the acceptable risk range, 1×10^{-6}, one in one million excess cancer risk. Screening levels are frequently called risk-based concentrations (RBCs), or PRGs. The EPA's PRG calculator should be used to develop radionuclide screening levels for this purpose. At this stage it is appropriate for screening levels to be conservative and it is important to note that that they should not be used as remediation goals for cleaning up a site, as they do not consider site-specific factors. Remediation goals should be based upon results of a site-specific risk assessment or ARARs. Owing to the nature of their effects on biological organisms, radionuclides present at background concentrations may fail a screen against health-based levels. Therefore, it is imperative that the assessment determines whether radionuclides have be released and whether they are present above background levels before a recommendation is given for further investigation or for a removal action.

c. Guidance for Conducting Screening Level Ecological Assessments. Guidance for conducting screening level ecological assessments may be found in ERAGS (EPA 1997) and in Volume II of EM 200-1-4 (USACE 1996). An excellent discussion of screening level and baseline ecological risk assessments is presented in the Tri-Service Remedial Project Manager's Guide for Ecological Risk Assessment (Simini et al. 2000). The DOE (DOE 2002) has developed a technical standard that contains spreadsheets that are useful for calculating dose to ecological receptors. The standard and spreadsheets can be downloaded at http://tis.eh.doe.gov/techstds/standard/std1153/1153.htm. The standard includes a graded method for evaluating sites that starts with a very generic whole-site approach. This is not in strict accordance with USACE and EPA guidance, and it is not necessary to follow the standard's approach in its entirety. The DOE recently published a companion software tool, RESRAD-BIOTA Release 1.0, to assist in implementing the technical standard and will be useful for many projects. It would be uncommon for an ecological risk assessment to go beyond the screening-level stage on a radionuclide site. If a baseline ecological risk assessment is performed, it needs to follow USACE and EPA guidance.

d. Baseline Risk Assessment. Baseline risk is defined as risk that might exist if no remediation or institutional controls were applied to the site (EPA 1989). Baseline risk assessments are a required element of CERCLA remedial investigations, whose results help determine whether remedial alternatives need to be evaluated in the FS to mitigate risk. A

well-designed risk assessment will provide the project manager with sufficient information to make future risk management decisions regarding the site. Such information that should clearly be presented are the media, contaminants, exposure pathways, and specific areas at the site that are contributing to unacceptable risk. The primary adverse effect associated with most radionuclides are their potential for causing cancer; however, there are others, such as uranium that may cause other effects based upon its non-radiological chemical properties, in this case causing kidney damage. The risk assessment needs to express both excess cancer risk and non-cancer risks posed by potential exposures to contaminants at the site.

e. Dose Assessment. A dose assessment may be run concurrently with the risk assessment, and it is recommended that this be done if 10 CFR 20 Subpart E is a potential ARAR for the site. The preferred tool for assessing dose is RESRAD. RESRAD is widely accepted by the health physics community and has the capability to calculate risk and dose as well as modeling fate and transport in a single model. This model has been used on many USACE projects for estimating both dose and risk posed by radionuclides. However, there are differences between using this model and CERCLA guidance for risk assessments that the project delivery team needs to be aware of; these are discussed below. The EPA has recently developed an electronic calculator, similar to the risk-based radionuclide PRG calculator, to provide dose compliance concentrations for demonstrating compliance with dose-based ARARs at CERCLA sites. The dose calculator is located on-line at http://epa-dccs.ornl.gov/radionuclides/. As USACE health physicists and risk assessors gain experience with these new tools, the lessons learned will be shared through the appropriate communities of practice.

f. RESRAD. Within a single interface, RESRAD has the capability to account for factors such as erosion, leaching, and radiological decay and in-growth that are involved with predicting risk of future exposures, also termed a prospective risk assessment. While it is common to consider such factors as contaminants leaching from soil to ground water, ground water movement and ground water discharge in CERCLA risk assessments, it is not standard practice to erode surface soils to reveal contaminants in the subsurface. RESRAD default parameters will model exposures out to 1000 years to demonstrate compliance with NRC and DOE regulatory requirements. For a CERCLA baseline risk assessment, this is not necessary, though estimating the year of peak risk attributable to radionuclide decay alone may be useful. Another factor that must be considered is that RESRAD defaults to conservative exposure scenarios, such as a subsistence farmer and fisherman, while CERCLA risk assessments generally do not include such scenarios unless there is site-specific information suggesting that these are likely future land uses. The project risk assessor, health physicist, and hydro geologist need to work together with regulatory stakeholders to determine the appropriate parameters for the risk assessment and to determine if other fate and transport models are preferred to those in RESRAD before doing the radiological risk assessment.