

APPROACHES TO RISK MANAGEMENT IN REMEDICATION OF RADIOACTIVELY CONTAMINATED SITES



National Council on Radiation Protection and Measurements



NCRP REPORT No. 146

Approaches to Risk Management in Remediation of Radioactively Contaminated Sites

**Recommendations of the
NATIONAL COUNCIL ON RADIATION
PROTECTION AND MEASUREMENTS**

Issued October 15, 2004

Revised March 1, 2005

**National Council on Radiation Protection and Measurements
7910 Woodmont Avenue, Suite 400 / Bethesda, MD 20814**

LEGAL NOTICE

This Report was prepared by the National Council on Radiation Protection and Measurements (NCRP). The Council strives to provide accurate, complete and useful information in its documents. However, neither NCRP, the members of NCRP, other persons contributing to or assisting in the preparation of this Report, nor any person acting on the behalf of any of these parties: (a) makes any warranty or representation, express or implied, with respect to the accuracy, completeness or usefulness of the information contained in this Report, or that the use of any information, method or process disclosed in this Report may not infringe on privately owned rights; or (b) assumes any liability with respect to the use of, or for damages resulting from the use of any information, method or process disclosed in this Report, *under the Civil Rights Act of 1964, Section 701 et seq. as amended 42 U.S.C. Section 2000e et seq. (Title VII) or any other statutory or common law theory governing liability.*

Library of Congress Cataloging-in-Publication Data

Approaches to risk management in remediation of radioactively contaminated sites.

p. cm. -- (NCRP report ; no. 146)

Includes bibliographical references and index.

ISBN 0-929600-82-7

1. Radioactive waste sites--Risk assessment. 2. Risk management.

I. National Council on Radiation Protection and Measurements. II. Series

TD898.15.A67 2004

363.72'89--dc22

2004019893

Copyright © National Council on Radiation
Protection and Measurements 2004

All rights reserved. This publication is protected by copyright. No part of this publication may be reproduced in any form or by any means, including photocopying, or utilized by any information storage and retrieval system without written permission from the copyright owner, except for brief quotation in critical articles or reviews.

[For detailed information on the availability of NCRP publications see page 266.]

Preface

The issue of dual or multiple regulation by the U.S. Nuclear Regulatory Commission (NRC), the Environmental Protection Agency (EPA), and state agencies of NRC-licensed facilities that are undergoing decommissioning has been a subject of considerable debate and controversy. As a step toward developing consistent approaches to decision making by NRC and EPA on the remediation of radiologically contaminated nuclear sites, the National Council on Radiation Protection and Measurements (NCRP) has been requested by NRC to prepare a report that has two primary goals: (1) identify and summarize current practices used by NRC under the License Termination Rule (10 CFR Part 20) and by EPA under the Comprehensive Environmental Response, Compensation, and Liability Act; and (2) identify, examine and summarize the following aspects of current practices used by NRC and EPA: (a) their historical basis; (b) their commonalities and significant differences; and (c) their current and future implications as they relate to public perception, uncertainty, measurability, and radiation dose and risk estimates.

This Report addresses the above issues and summarizes both their near- and long-term implications for the decommissioning of regulated radiological facilities. To meet the need of various audiences to understand the Report at different levels of detail, the text contains three independent parts: (1) a short Executive Summary that briefly summarizes the purpose of the study and the main conclusions; (2) a longer Extended Summary that provides a complete summary description of the Committee's work, but without many of the supporting technical details; and (3) the main body of the Report.

During the course of preparation of this Report, the NCRP Committee benefited from briefings and discussions with several representatives of government and state organizations. On January 16, 2003, the Committee held informative discussions with representatives of NRC, EPA and the U.S. Department of Energy (DOE). The appreciation of NCRP is extended to the following persons who presented information and answered questions raised by the Committee: Michael A. Boyd, Bonnie C. Gitlin, Stuart Walker, and

Anthony B. Wolbarst (EPA); John T. Greeves and Cheryl A. Trottier (NRC); and Andrew Wallo, III (DOE). On May 28, 2003, the Committee visited the West Valley Demonstration Project (WVDP) in New York. NCRP's appreciation is extended to the following individuals who briefed the Committee on the WVDP: Paul Piciulo, Director of the New York State Energy Research and Development Authority, and Alice C. Williams, Director of the WVDP. Helpful discussions were also held at the West Valley Site with Barbara A. Youngberg of the New York State Department of Environmental Conservation, Dan Sullivan of the DOE West Valley Area Office, and the West Valley Citizens Task Force.

This Report was prepared by NCRP Scientific Committee 87-5 on Risk Management Analysis for Decommissioned Sites. Serving on Scientific Committee 87-5 were:

Daniel J. Strom, *Chairman*
Pacific Northwest National Laboratory
Richland, Washington

Members

Lynn R. Anspaugh
University of Utah
Salt Lake City, Utah

James H. Flynn
Decision Research
Eugene, Oregon

F. Owen Hoffman
SENES Oak Ridge, Inc.
Oak Ridge, Tennessee

David C. Kocher
SENES Oak Ridge, Inc.
Oak Ridge, Tennessee

Paul A. Locke
Johns Hopkins University
Bloomberg School of Public
Health
Baltimore, Maryland

Paul J. Merges
Environment and Radiation
Specialists, Inc.
Londonville, New York

Bruce A. Napier
Pacific Northwest National
Laboratory
Richland, Washington

Consultant

Lauren Zeise
Office of Environmental Health Hazard Assessment
Oakland, California

NCRP Secretariat

E. Ivan White, *Consultant*
Cindy L. O'Brien, *Managing Editor*
David A. Schauer, *Executive Director*

The Council wishes to express its appreciation to the Committee members for the time and effort devoted to the preparation of this Report. NCRP also gratefully acknowledges the financial support provided by the U.S. Nuclear Regulatory Commission.

Thomas S. Tenforde
President

Contents

Preface	iii
Executive Summary	1
Extended Summary	3
1. Introduction	28
1.1 Purpose and Scope	29
1.2 NCRP Process	30
1.3 Outline of the Report	30
2. Current Regulatory Guidance and Practice	31
2.1 Principal Governing Laws and Organizational Structure	32
2.1.1 Governing Laws and Organizational Structure of NRC	32
2.1.2 Governing Laws and Organizational Structure of EPA	34
2.1.3 Relationships Between NRC or EPA and the States	37
2.2 Regulations for Remediation of Radioactively Contaminated Sites	38
2.2.1 NRC Regulations	38
2.2.1.1 10 CFR Part 20, Subpart E	39
2.2.1.2 10 CFR Part 40, Appendix A	42
2.2.1.3 Discussion of NRC Regulations	45
2.2.2 EPA Regulations	46
2.2.2.1 Regulations Developed Under CERCLA (Superfund)	46
2.2.2.2 Groundwater Protection Requirements and Drinking Water Standards	51
2.2.3 Comparison of NRC and EPA Regulations	58
2.2.3.1 Regulations Applicable to Most NRC Licensees	59

2.2.3.2	Regulations Applicable to Other NRC Licensees	63
2.2.4	Decision Process in Decommissioning of Contaminated Sites	65
2.2.4.1	NRC's Decision Process Under the Atomic Energy Act	65
2.2.4.2	EPA's Decision Process Under the Comprehensive Environmental Response, Compensation, and Liability Act	67
2.2.5	Role of States in Remediation of Licensed Facilities	73
2.2.6	Resource Conservation and Recovery Act Impact on Radioactively Contaminated Sites	75
2.3	Methods of Site Characterization and Dose or Risk Assessment	77
2.3.1	EPA Calculation Methods	78
2.3.2	NRC Calculation Methods	87
2.3.3	DOE Methods: The Residual Radiation (RESRAD) Family of Codes	94
3.	Analysis of Regulatory Guidance and Practice	100
3.1	Principal Governing Laws and Organizational Structures	100
3.1.1	Differences in Governing Laws	100
3.1.2	Commonalities in Governing Laws	102
3.1.3	Organizational Structures and Functions	103
3.2	Regulations for Remediation of Radioactively Contaminated Sites	103
3.2.1	Different Approaches to Regulation by NRC and EPA	105
3.2.1.1	Approach to Regulation by NRC	105
3.2.1.2	Approach to Regulation by EPA	108
3.2.1.3	Comparisons of Criteria in Radiation and Chemical Paradigms	110
3.2.2	Commonalities in Approaches to Regulation by NRC and EPA	111
3.2.3	Comparison of NRC and EPA Remediation Standards	113
3.2.4	Discussion of Origins of Different Approaches to Regulation	115

3.3	Methods of Site Characterization and Dose or Risk Assessment.	119
3.3.1	Methods of Site Characterization and Verification.	119
3.3.2	Methods of Dose or Risk Assessment	121
3.3.3	Comparison of EPA Preliminary Remediation Goals with NRC Screening Levels	122
3.3.4	Analysis of ²³⁹Pu Remediation Levels for 10 Cases	133
3.3.5	Uncertainties in Assessments of Dose or Risk at Contaminated Sites	140
3.3.5.1	Uncertainties in Estimating Concentrations of Radionuclides at Contaminated Sites	141
3.3.5.2	Uncertainties in Estimating External Exposures and Intakes of Radionuclides	143
3.3.5.3	Uncertainties in Estimating Dose.	144
3.3.5.4	Uncertainties in Estimating Risk.	146
3.3.5.5	Summary of Estimated Uncertainties	149
4.	Practical Decision Making at Specific Sites	152
4.1	Discussion of Case Studies	152
4.1.1	Fernald and Rocky Flats: End-Use Considerations	154
4.1.2	West Valley Demonstration Project: Multiple Regulation of a Complex Site	155
4.1.3	The Johns Hopkins and the Environmental Law Institute Study.	156
4.1.4	Paducah, Brookhaven and Fernald: The Importance of Trust	157
4.1.5	Case Studies by the Interstate Technology and Regulatory Council	160
4.1.6	Observations on Practical Remediations	160
4.1.6.1	Sites May End Up Less Contaminated Than Required	160
4.1.6.2	ALARA May Have Little Impact.	162
4.1.6.3	Remediation Worker Protection May Differ Under EPA and NRC	162

4.2	Recurrent Themes Observed in the Case Studies	163
4.2.1	Assumptions About Future Use of Sites, as Well as Assessments of Off-Site Risks, Drive Risk Management Decision Making	163
4.2.2	Public Participation, Input and Acceptance are Critical for Successful Risk Management. .	164
4.2.3	Distributive and Procedural Fairness	165
4.2.4	Various Approaches are Used Across Sites to Assess and Manage Risks	168
4.2.4.1	Selection of Contaminates of Concern. .	168
4.2.4.2	Assumptions About Exposure Duration and Site Time Frame	169
4.2.4.3	Establishing Target Remediation Goals (Dose or Risk)	170
4.2.4.4	Risk Management Approaches are Pragmatic	171
4.3	The Role and Scope of Risk Communication	172
4.3.1	A Brief Overview of Risk Communication Development	172
4.3.2	Models for Risk Communication	172
4.3.3	The Status of Risk Communication at NRC and EPA	173
4.3.4	The Social Context for Risk Messages.	175
5.	Implications of Regulatory Guidance and Practice. .	179
5.1	Site Characterization and Measurability of Residual Radionuclides	180
5.2	Estimation of Dose or Risk	182
5.3	Uncertainty in Site Characterization and Dose or Risk Assessment.	184
5.4	Final Decision-Making Authorities.	185
5.5	Consistency of Policies Within NRC and EPA	186
5.6	Comparability of Basic Protection Criteria	187
5.7	Focus of Disagreements Between NRC and EPA. . . .	189
5.8	Language of Risk Management.	190
5.9	Public Perception	193
5.10	Impacts on the States.	194
6.	Conclusions	197

Appendix A. 10 CFR Part 20 Subpart E—Radiological Criteria for License Termination	204
Appendix B. EPA/NRC Memorandum of Understanding	210
Appendix C. ITRC (2002) ²³⁹Pu Data with Risk Normalization	219
Glossary	226
Acronyms and Symbols	236
References	238
The NCRP	257
NCRP Publications	266
Index	277

Executive Summary

For many years, there has been concern on the part of licensees, regulators and stakeholders about multiple agency regulation at radioactively contaminated sites undergoing decommissioning and remediation. In particular, during the development of the License Termination Rule [LTR (10 CFR Part 20, Subpart E)] of the U.S. Nuclear Regulatory Commission (NRC), concern was raised that the U.S. Environmental Protection Agency (EPA) or States might invoke different and sometimes more restrictive regulations at a site. In light of this concern, NRC asked the National Council on Radiation Protection and Measurements (NCRP) to prepare a report that addressed issues of dual or multiple regulation at radioactively contaminated sites licensed by NRC.

This study had two primary objectives. First, NCRP was to identify and analyze current guidance and practices used by NRC under the LTR and EPA under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the National Oil and Hazardous Substances Pollution Contingency Plan [National Contingency Plan (NCP) (40 CFR Part 300)] in the remediation of radioactively contaminated sites. Second, NCRP was to identify, analyze and summarize the significant differences and commonalities in current practices of NRC and EPA, and to identify, examine and summarize current and future implications of current practices as they relate to such issues as public perception, uncertainty, measurability, and estimation of radiation dose and risk.

The issues examined by NCRP arose from the complex history and different regulatory cultures of NRC and EPA as they have affected approaches to regulating nuclear activities and control of radioactively contaminated sites and radioactive waste. While the Report examines these matters in detail, NCRP believes that the seven conclusions set out below capture the themes that delineate similarities and differences in approaches to regulation at radioactively contaminated sites used by the two agencies.

- EPA uses a lifetime cancer risk criterion to determine acceptable levels of residual soil contamination, whereas NRC and most of the States use an annual dose criterion.

The two criteria cannot be compared in a meaningful way without also examining each agency's entire system for protection of public health and the environment, including methods of site characterization, assumptions about future land use, and methods of assessing dose and risk, as well as uncertainties in determining levels of residual contamination and uncertainties in dose and risk assessments.

- In modern legislation established to ensure protection of public health and the environment, concurrent jurisdiction among federal and state agencies is the rule, not the exception.
- Current law, including the National Environmental Policy Act and CERCLA, and their implementations in NRC and EPA regulations recognize that decision making must involve key stakeholders, especially the nearby communities directly impacted by decommissioning and remediation. Public confidence in decision making is enhanced when the process is open and transparent and the need for meaningful stakeholder involvement is embraced by all parties.
- Either the NRC's LTR and accompanying practices or the EPA's NCP and accompanying practices can result in a negotiated remediation decision among stakeholders that is protective of public health and the environment. Under either approach, acceptable residual contamination levels are expected to vary from site to site.
- Practical decision making at specific sites has been driven primarily by the feasibility and costs of alternatives to remediation and the need to achieve negotiated agreements among regulators, site managers, and stakeholders, rather than rigid adherence to dose or risk criteria in regulations.
- State governments have a vital role in determining acceptable remediation of radioactively contaminated sites, including sites licensed by NRC, and the role of the states should be taken into account in efforts to reconcile differences in NRC and EPA regulations.
- Involvement of EPA in remediation decisions at facilities licensed by NRC should not be a significant impediment to remediation and license termination, but can be accommodated with cooperative, site specific, practical decision making.

Extended Summary

Introduction

The U.S. Nuclear Regulatory Commission (NRC) is responsible for developing, implementing and enforcing regulations for remediation of radioactively contaminated sites that are licensed by NRC. Such regulations essentially define radiological conditions at contaminated sites that would permit unrestricted or restricted release for public use following decommissioning and license termination. NRC also is responsible for assuring that contaminated sites that are licensed by the 32 Agreement States are remediated in accordance with regulations that are at least as stringent as those that apply at facilities licensed by NRC.

Under authority of the Atomic Energy Act (AEA), NRC has established regulations that apply to remediation of all facilities licensed by NRC. The License Termination Rule [LTR (10 CFR Part 20, Subpart E)] applies, for example, to nuclear power plants, uranium enrichment facilities, and fuel fabrication facilities, as well as a large number of materials licensees. Regulations that apply to remediation of thorium mills and uranium recovery facilities licensed by NRC have been established in 10 CFR Part 40, Appendix A.

Over the last decade, NRC and the U.S. Environmental Protection Agency (EPA) have been engaged in a disagreement over the adequacy of remediation criteria in the LTR. That disagreement is potentially important to NRC and its licensees because EPA is authorized under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, or “Superfund”) to intervene in decisions by NRC to terminate licenses at contaminated sites following decommissioning if EPA judges that such involvement is warranted to protect public health and the environment. This ability is consistent with EPA’s authority under CERCLA to take response actions at non-NRC sites that are regulated by another entity. At issue is whether remediation criteria in the LTR provides a level of protection of public health and the environment that is consistent with criteria established by EPA under CERCLA in the National Oil and Hazardous Substances Pollution Contingency Plan [National Contingency Plan (NCP) (40 CFR

Part 300)]. The disagreement between NRC and EPA over the adequacy of the LTR is part of a more general debate over differences in radiation standards for many practices and sources established by NRC under AEA and standards established by EPA under several environmental laws and the significance of those differences. The issue of concern in that debate is referred to as “risk harmonization.”

Purpose and Scope of Study

The National Council on Radiation Protection and Measurements (NCRP) was asked by NRC to perform an analysis of current regulatory guidance and practice used by NRC and EPA in remediation of radioactively contaminated sites. Specifically tasks were:

- identify and summarize current regulatory guidance and practice on remediation of radioactively contaminated sites used by NRC under the LTR and by EPA under CERCLA and NCP, including a review of models and tools used to assess regulatory compliance;
- identify, examine and summarize the historical basis for current guidance and practices of the two agencies;
- identify, analyze and summarize the significant differences and commonalities in current guidance and practices of the two agencies; and
- identify, examine and summarize the implications of current guidance and practices of the two agencies as they relate to such issues as public perception, uncertainty, measurability, and dose and risk estimates.

The ultimate objective of such an analysis is to evaluate whether guidance and practice of NRC and EPA can be harmonized to provide reasonably consistent approaches to decision making in remediation of radioactively contaminated sites.

In analyzing current guidance and practice on remediation of radioactively contaminated sites, NCRP considered NRC regulations in 10 CFR Part 40, Appendix A, as well as the LTR. Although the adequacy of criteria that define acceptable remediation at sites regulated under 10 CFR Part 40, Appendix A, has not been called into question by EPA, application of the rule to cleanup of specific sites has been disputed by EPA and state regulatory agencies in some cases. Demonstrations of compliance with those regulations and with the LTR raise many of the same issues in areas of dose

assessment and protection of groundwater resources. In addition, EPA also is authorized under CERCLA to intervene at sites that undergo remediation and license termination under 10 CFR Part 40, Appendix A.

Approach to Analysis of Current Guidance and Practice

NCRP considered current guidance and practice of NRC and EPA on remediation of radioactively contaminated sites at several levels, from basic requirements of governing laws to methods of assessing compliance with applicable regulatory requirements at specific sites. The following aspects of current guidance and practice of the two agencies are considered:

- the principal laws governing remediation of radioactively contaminated sites, and the organizational structures and functions of NRC and EPA;
- regulations that apply to remediation of radioactively contaminated sites and guidance documents to interpret the regulations;
- documents that provide guidance on demonstrating compliance with remediation criteria in regulations and address such issues as methods of characterizing radiological conditions at a site, assumptions about exposure scenarios, and models to estimate dose or cancer risk to representative individuals.

Approaches to practical decision making in remediation of contaminated sites, including involvement by the public and other stakeholders, also are considered. The following sections summarize NCRP's findings.

Governing Laws and Organizational Structures and Functions

NRC regulations for remediation of radioactively contaminated sites are developed under authority of AEA, whereas EPA regulations, which apply to radionuclides and hazardous chemicals, have been developed mainly under CERCLA. EPA regulations developed under the Resource Conservation and Recovery Act (RCRA) may apply to remediation of some facilities licensed by NRC. However, those regulations are not considered in detail, mainly because this Report is concerned primarily with comparisons of

NRC regulations with EPA regulations developed under CERCLA. Furthermore, remediation regulations developed under RCRA incorporate many of the same principles as regulations developed under CERCLA.

An essential commonality in applicable laws is a requirement that remediation of radioactively contaminated sites must ensure adequate protection of public health. As summarized in the following section, the particular approaches to protecting public health in regulations developed under AEA and CERCLA and other environmental laws are quite different, but the desired outcome is the same nonetheless.

Another important commonality is that regulatory activities of NRC and EPA are subject to requirements of the National Environmental Policy Act (NEPA). NEPA requires public hearings and opportunities for public comment on regulatory activities that significantly affect the quality of the environment, including decisions to terminate licenses at contaminated sites. Requirements of NEPA are incorporated in NRC and EPA regulations. However, EPA on-site response actions under CERCLA are not subject to NEPA because the CERCLA process is functionally equivalent to NEPA, and CERCLA on-site response actions do not have to follow procedural requirements of other environmental laws.

There also are several differences between AEA and CERCLA and other environmental laws in how they address protection of public health.

- All regulatory authority of NRC, including authority related to radiation protection of the public, is derived essentially from AEA, whereas CERCLA and other environmental laws address only specific areas of concern (*e.g.*, remediation of contaminated sites, protection of groundwater and surface water resources, protection of water or air quality, management of hazardous wastes). Thus, NRC can regulate all activities under its purview in essentially the same way, whereas the multiple legal architectures under which EPA regulates can mandate different approaches to protection of public health in different situations.
- The primary purpose of AEA was to promote peaceful and safe uses of nuclear energy, as well as provide for the common defense and security. In contrast, the essential purpose of CERCLA and other environmental laws was to address existing and pervasive environmental problems associated with ongoing or past activities, and they were not developed

to benefit existing industries or promote new ones. That difference is an important reason for the fundamentally different approaches to health protection of the public that have been taken by NRC and EPA, including approaches to regulating remediation of radioactively contaminated sites.

- AEA charges NRC with the responsibility to protect public health and safety in uses of radioactive materials by its licensees, but particular approaches to regulation that NRC must follow are not prescribed. In contrast, CERCLA and other environmental laws prescribe in some detail how EPA must regulate activities governed by those laws.
- CERCLA mandates opportunities for meaningful participation in decision making by the public and other stakeholders, whereas AEA does not address such participation. Thus, requirements of NEPA and NRC regulations concerning public participation in NRC's licensing activities notwithstanding, EPA is more accustomed to regulating remediation of contaminated sites in an environment where affected parties participate in the decision-making process in meaningful ways.
- Because of the prospective nature of the NRC licensing process, the LTR and several other NRC regulations require financial assurance from licensees that resources will be available for decommissioning and remediation (if needed). Because EPA becomes involved under CERCLA only after there is a threat or potential threat to public health or the environment, no such financial assurance is included in its regulations.

NRC and EPA are similar in their organizational structures and functions in several ways. Each agency is organized into several offices that carry out responsibilities in different programs; the central offices are responsible for developing regulations and agency guidance; and each agency maintains several field offices to assist in meeting the agency's responsibilities.

However, there are important differences in how the two agencies function. Because all NRC activities are carried out under authority of AEA and other laws that further define NRC's responsibilities under the Act, NRC policies and guidance are reasonably consistent across all programs. In contrast, given that different EPA offices carry out their responsibilities under different laws with varying mandates, agency policies and guidance are not consistent across all programs.

Of particular importance to regulation of remediation of radioactively contaminated sites is the role of NRC and EPA field offices. When a decommissioning plan is required at sites licensed by NRC, which is the case, for example, when a site has substantial contamination of soil or groundwater, all decisions about cleanup and license termination are made by the Commission or NRC central office staff. NRC field offices terminate hundreds of licenses each year at sites that possessed sealed sources only or at sites where contamination is not widespread and occurs only at very low levels. Consequently, at sites with substantial contamination, NRC guidance on cleanup is applied reasonably consistently in all cases. However, at sites subject to remediation under CERCLA, EPA's responsibilities in the decision process usually are carried out by the appropriate field office. Although EPA field offices are expected to follow policies and guidance developed by the central office, field offices participate in the decision process in site remediation largely independently of the central office, and different field offices do not always apply agency policies and guidance in the same way. This is partly because state and local governments and communities often play a bigger role in decision making at CERCLA sites than at NRC sites. Also, NRC guidance tends to be written in a more prescriptive manner because NRC staff are not functioning as site managers but rather reviewers of draft decision documents drafted by licensees, while EPA regional staff are functioning as site managers.

Regulations for Remediation of Radioactively Contaminated Sites

The main emphasis of this Report is an analysis of similarities and differences in the LTR, which applies to most NRC licensees, and EPA's remediation regulations developed under CERCLA in the NCP. The significance of differences in regulations and other guidance of the two agencies in regard to protection of public health and the environment in remediation of specific sites also is considered.

NRC's License Termination Rule (10 CFR Part 20, Subpart E)

The NRC's License Termination Rule (LTR) specifies radiological criteria to permit unrestricted use of a contaminated site following decommissioning and license termination and criteria for license termination under restricted conditions. The criteria apply to levels of residual radioactivity distinguishable from background

within the first 1,000 y after decommissioning. The basic criteria for license termination under conditions of unrestricted or restricted use of a site are that:

- the annual total effective dose equivalent (TEDE) from all exposure pathways combined, including the dose from groundwater sources of drinking water, to an average member of the critical group does not exceed 0.25 mSv; and
- concentrations of residual radioactive material have been reduced to levels that are as low as reasonably achievable (ALARA).

The LTR emphasizes that application of the ALARA requirement must include consideration of any detriments, such as deaths from transportation accidents, that are expected to result from decontamination and waste disposal.

Under conditions of restricted use, there are additional provisions concerning doses that could be received if intended institutional controls were no longer in effect, and the LTR also includes provisions for terminating a license using alternate criteria. Annual TEDEs up to 1 mSv generally are allowed under those conditions, as specified in NRC's radiation protection standards for the public elsewhere in 10 CFR Part 20. The LTR also requires NRC to solicit input by stakeholders in such cases.

CERCLA and EPA Regulations in the National Oil and Hazardous Substances Pollution Contingency Plan (40 CFR Part 300)

CERCLA and EPA regulations in the National Oil and Hazardous Substances Pollution Contingency Plan [National Contingency Plan (NCP)] do not specify conditions, such as limits on health risk, that must be met in site remediations under any circumstances. Rather, goals for remediation of contaminated sites are established. CERCLA and NCP specify that remediation goals shall be protective of human health and the environment and shall be developed taking into account:

- applicable or relevant and appropriate requirements (ARARs) established under other federal or state environmental laws, with federal and state drinking water standards established under the Safe Drinking Water Act (SDWA) specified as ARARs for remediation of groundwater or surface waters that are current or potential sources of drinking water;

- for known or suspected carcinogens, including radionuclides, an upper bound on lifetime cancer risk of 10^{-6} to 10^{-4} from all substances and all exposure pathways combined at specific sites; and
- for noncarcinogens, including uranium, a hazard index of one or less.

Drinking water standards for radionuclides have been established by EPA in 40 CFR Part 141. Inclusion of drinking water standards as goals for remediation of contaminated sites illustrates that other environmental laws are important in setting remediation standards under CERCLA.

Guidance documents issued by EPA have clarified various provisions of CERCLA and NCP. EPA has emphasized that a lifetime cancer risk of 10^{-4} is the appropriate goal at most sites, provided that drinking water standards also are met, although lower risk goals can be established on the basis of site-specific conditions. EPA also has emphasized that the upper bound of the risk range is not precisely 1×10^{-4} , but that a risk of “around 10^{-4} ” may be considered acceptable if justified on the basis of site-specific conditions. At radioactively contaminated sites licensed by NRC, EPA guidance has indicated that an annual effective dose equivalent of 0.15 mSv or less would comply with the risk goal of 10^{-4} . If exposure over 30 y at a given location is assumed, that annual dose corresponds to a nominal lifetime risk of fatal cancers of about 2×10^{-4} and a lifetime risk of cancer incidence of about 3×10^{-4} .

CERCLA and NCP also lay out a decision process that must be followed in conducting remedial actions at contaminated sites. Early in the process, a remedial investigation/feasibility study is conducted to select the preferred approach to remediation on the basis of a detailed analysis of alternatives. NCP specifies that an analysis of alternatives shall consider nine evaluation criteria. They include two threshold criteria (overall protection of human health and the environment and compliance with ARARs, unless a waiver is justified on the basis of any of several conditions); five primary balancing criteria (long-term effectiveness and permanence; reduction of toxicity, mobility or volume through treatment; short-term effectiveness; implementability taking into account technical feasibility and other factors; and cost); and two modifying criteria (state and community acceptance). In essence, compliance with ARARs, including drinking water standards in current or potential sources of drinking water, and the goal for limiting lifetime cancer risk of around 10^{-4} is required only to the extent

feasible. If compliance with ARARs and the goal for limiting cancer risk is not feasible when unrestricted release of a site is assumed, NCP specifies that institutional controls may be assumed to limit future use of the site and reduce potential risks to the public and potential exposures to contaminated water resources. EPA considers that use of institutional controls is an important means of meeting cleanup goals at sites where remediation to achieve the goals is not feasible. For example, an inability to comply with an ARAR could result in the site being placed under institutional control, and the site would not be released for unrestricted use by the public. In addition, although the lead agency, which can be EPA, another federal agency, or a state, makes the final remedy-selection decision, input by the state, community and other stakeholders must be weighed. The views of such groups have determined the chosen remedy at some sites.

Disagreements Between NRC and EPA

Disagreements between NRC and EPA over the adequacy of the NRC's LTR have focused on two issues:

- whether NRC's annual dose criterion of 0.25 mSv is consistent with EPA's lifetime cancer risk criterion of 10^{-4} , and
- lack of a separate provision in the LTR concerning protection of groundwater and surface water resources in accordance with standards for radionuclides in public drinking water supplies established by EPA.

In EPA's view, NRC's annual dose criterion is not consistent with an upper bound on acceptable lifetime cancer risk of 10^{-4} , as specified in the NCP. In regard to protection of water resources, EPA's drinking water standards in 40 CFR Part 141 correspond to annual effective dose equivalents of about 0.04 mSv or less for many man-made radionuclides, which means that NRC's annual dose criterion could allow contamination of water resources at levels well above drinking water standards and, thus, would not comply with the goal specified in CERCLA and NCP.

Differences in Approaches to Regulation by NRC and EPA

The apparent differences between the NRC's LTR and EPA regulations for remediation of contaminated sites in the NCP are due in large part to a fundamental difference in approaches to

regulation by the two agencies. The approach used by NRC is referred to in this Report as the “radiation paradigm,” and the approach used by EPA is referred to as the “chemical paradigm.”

The radiation paradigm is based on principles of radiation protection developed over many decades by NCRP and the International Commission on Radiological Protection (ICRP). Given that radiation exposures are justified on the basis that the expected benefits to society exceed the overall societal cost, the radiation paradigm has two basic elements:

- a *limit* on radiation dose to individuals from exposure to all controlled sources combined, corresponding to a maximum allowable risk for routine exposure situations; and
- a requirement to *reduce* exposures to all controlled sources ALARA.

The concepts of a limit on dose (and, therefore, risk) and reductions below the limit using the ALARA principle define a “top-down” approach to control of radiation exposures.

The annual dose limit for the public currently recommended by NCRP and ICRP is 1 mSv, to be applied to the sum of external effective dose and committed effective dose from intakes of radionuclides during the year. The same numerical limit on annual TEDE is specified in NRC’s radiation protection standards for the public in 10 CFR Part 20. One way to ensure that the dose limit for all controlled sources combined will be met is to establish dose constraints on individual sources or practices at a fraction of the dose limit. The annual dose criterion of 0.25 mSv in the LTR is an example of a dose constraint.

For any practice at specific sites, the ALARA principle is applied to reduce doses below the dose limit for all controlled sources combined and applicable dose constraints on the basis of such considerations as the costs of reducing exposures in relation to the benefits in health risks averted in exposed populations and use of good management practices in reducing exposures. At most operating nuclear facilities, vigorous application of the ALARA requirement reduces doses to the public to levels far below the dose limit and applicable dose constraints. The ALARA principle essentially defines a process for risk reduction, and the outcome of that process generally cannot be specified in advance in regulations.

The chemical paradigm used by EPA to control public exposures to radionuclides and hazardous chemicals under authority of several environmental laws, including CERCLA and SDWA, is

fundamentally different from the radiation paradigm (“top-down” approach) used by NRC under AEA. Given that exposures are justified, the chemical paradigm has two basic elements:

- a *goal* for acceptable risk; and
- allowance for an *increase* (relaxation) in risks above the goal, based primarily on considerations of technical feasibility and cost.

Thus, the chemical paradigm is the opposite of the “top-down” approach in the radiation paradigm, and can be thought of as a “bottom-up” approach to control of exposures. The goal for acceptable risk is properly interpreted as a negligible risk, because action to reduce risks below the goal is not required in most circumstances. Justified relaxations above the goal then define acceptable risks for specific exposure situations when achieving the goal is not feasible.

The chemical paradigm for risk management (“bottom-up”) is exemplified by the approach to regulation of contaminants in public drinking water supplies specified in SDWA. The Act requires that EPA first establish nonenforceable health goals for drinking water. The nonenforceable goals must be set at levels at which no known or anticipated health effects occur and which allows an adequate margin of safety. Since any exposure to radionuclides and chemical carcinogens is assumed to impose some cancer risk, the goal for those contaminants must be zero, a level which cannot be achieved at any cost. The Act then requires that enforceable standards for contaminants in drinking water be set as close to the goals as is feasible, taking into account best-available technology for removing contaminants from public drinking water supplies at a reasonable cost.

CERCLA and NCP also provide a clear example of the chemical paradigm. As described previously, CERCLA and NCP establish goals for remediation of contaminated sites—namely, compliance with ARARs, including drinking water standards established by EPA under SDWA in groundwater or surface water resources, and a lifetime cancer risk of 10^{-6} to 10^{-4} —and they allow increases (relaxations) in risks above the goals if, among many factors to be considered, achieving the goals is not feasible.¹

¹EPA and NRC both use the linear-nonthreshold dose-response model adjusted for low doses and low-dose rates, under which any increment of radiation dose implies an increment in risk of radiogenic cancer incidence, as a basis for risk calculations.

Implications of Differences in Approaches to Regulation

The fundamental differences in approaches to regulation used by NRC and EPA, as described above, have important implications for the disagreements between the two agencies over appropriate regulatory criteria for remediation of radioactively contaminated sites. The issue of whether NRC's annual dose criterion of 0.25 mSv is consistent with EPA's lifetime cancer risk criterion of 10^{-4} does not take into account the requirement in the LTR to reduce doses below the criterion in accordance with the ALARA principle and the provisions of CERCLA and NCP (*i.e.*, the various balancing and modifying criteria, including conditions for waiver of ARARs) that allow increases (relaxations) above the goal for limiting cancer risk when achieving the goal is not feasible. Indeed, the balancing and modifying criteria in the NCP are in many ways consistent with or equivalent to the ALARA principle. Taking those factors into account would reduce or eliminate any differences between remediation criteria derived from NRC's annual dose criterion and EPA's lifetime cancer risk criterion, which are small when the latter is around 10^{-4} (*e.g.*, up to about 3×10^{-4}) and the annual dose criterion corresponds to lifetime risks of fatal cancers or cancer incidence of about 4 or 6×10^{-4} , respectively, if exposure duration of 30 y at a given location is assumed.

Similar considerations apply to the issue of appropriate criteria for protection of water resources. Compliance with drinking water standards in groundwater and surface waters that are current or potential sources of drinking water is a goal, not a requirement, of CERCLA and NCP, and the goal can be relaxed if, for example, an ARAR waiver is justified.² Although the LTR does not include a separate provision for protection of water resources, rigorous application of the ALARA requirement should result in compliance with drinking water standards if it is feasible to do so. In addition, NRC's annual dose criterion limits allow increases in levels of contaminants above drinking water standards. Such increases should not be large when doses from all other pathways involving exposure to radionuclides in soil or on surfaces of building structures are taken into account.

On the basis of the previous discussions, NCRP believes that the disagreements between NRC and EPA over the adequacy of the LTR have been misplaced. Rather than debate whether NRC's

²EPA has several areas of flexibility in meeting groundwater cleanup goals (pages 16 to 20 of EPA, 1996a).

annual dose criterion is consistent with EPA's lifetime cancer risk criterion and whether exceeding drinking water standards in current or potential sources of drinking water that would be allowed by the annual dose criterion constitute an unacceptable risk to public health and the environment, NCRP believes that it would be more beneficial to focus on issues of levels of residual contamination that reasonably can be achieved in remediation of specific sites, taking into account the ALARA requirement in NRC regulations and the equivalent balancing and modifying criteria in EPA regulations. Previous studies of differences in regulatory approaches used by NRC and EPA (*i.e.*, differences between the radiation and chemical paradigms for cancer risk management) have concluded that consistent application of the ALARA principle, broadly interpreted, is an important means of harmonizing regulations of the two agencies.

NRC Regulations in 10 CFR Part 40, Appendix A

NRC regulations in 10 CFR Part 40, Appendix A, apply to remediation of contaminated lands and structures at thorium mills and uranium recovery facilities. They are compatible with standards for remediation of uranium and thorium mills established by EPA in 40 CFR Part 192.

Radionuclides of concern at facilities that are subject to remediation under 10 CFR Part 40, Appendix A, are naturally occurring isotopes of radium, thorium and uranium. The remediation standard for radium essentially is a concentration limit of 5 pCi g^{-1} (0.19 Bq g^{-1}) averaged over the first 15 cm of soil below the surface and over any area of 100 m^2 . Remediation standards for other naturally occurring radionuclides then are established on a site-specific basis using the benchmark dose method. In that method, the licensee first calculates the highest annual TEDE within the first 1,000 y to an average member of the critical group that would result from applying the radium soil standard, excluding the dose due to radon, using site-specific assumptions about exposure scenarios, pathways, and pathway models; this is the benchmark dose. The licensee then calculates the concentrations of other naturally occurring radionuclides of concern that correspond to the benchmark dose, using the same site-specific assumptions as in calculating the benchmark dose; those concentrations are the remediation standards for naturally occurring radionuclides other than radium. In addition, levels of residual radionuclides in soil and on remaining structures must be ALARA.

The standard for remediation of radium in surface soil of 5 pCi g^{-1} (0.19 Bq g^{-1}) that provides the basis for determining remediation standards for naturally occurring radionuclides at sites licensed under 10 CFR Part 40, Appendix A, is based directly on an EPA regulation (40 CFR Part 192). The NRC regulation also includes provisions on protection of groundwater essentially in accordance with drinking water standards established by EPA. Thus, the basic criteria for limiting concentrations of radium in surface soil and contamination of groundwater have not been questioned by EPA, as have the annual dose criterion and the lack of separate provisions on protection of water resources in the LTR. However, the benchmark dose method has not yet been applied by NRC to any completed remediations at sites contaminated with radionuclides other than radium. Furthermore, use of the benchmark dose method by other agencies, such as the U.S. Army Corps of Engineers, to establish acceptable levels of other radionuclides (*e.g.*, uranium) in soil has not shown consistency in application at different sites, and its use in those cases has been criticized by EPA regional offices and state regulators.³

EPA has emphasized that the remediation standards in 10 CFR Part 40, Appendix A, should be used only at sites where 40 CFR Part 192 applies or at sites with distributions of naturally occurring radionuclides in surface soil that are similar to those at sites where 40 CFR Part 192 applies. The radium soil standard established by EPA in 40 CFR Part 192 and by NRC in 10 CFR Part 40, Appendix A, also is important to the debate about the adequacy of the annual dose criterion of 0.25 mSv in the NRC's LTR (10 CFR Part 20, Subpart E). At sites where radium is the primary contaminant of concern, EPA and NRC have agreed that a concentration of 5 pCi g^{-1} (0.19 Bq g^{-1}) is a suitable soil screening level. Depending on the extent of contamination at a site and assumptions about exposure conditions, the soil screening level for radium could correspond to an annual effective dose equivalent of about 0.35 mSv, excluding the dose due to indoor radon. The estimated dose assumes that all radium decay products are present and in activity equilibrium, and is due almost entirely to external exposure. Substantially lower annual doses, including values as low as 0.15 mSv, can be obtained only if some combination of lower indoor and outdoor exposure times, higher shielding during indoor residence, and limited areal extent of the source region is assumed. If

³Merges, P.J. (2004). Personal communication, March 9 (Environment and Radiation Specialists, Inc., Londonville, New York).

the dose due to indoor radon were included, acceptable doses at sites contaminated with radium could be about an order of magnitude higher. In comparison, the average annual effective dose to the U.S. population from natural background, excluding indoor radon, is about 1 mSv, and the average annual effective dose from indoor radon alone is about 2 mSv (NCRP, 1987).

Methods of Site Characterization and Dose or Risk Assessment

Characterization of radiological conditions at contaminated sites is essential in evaluating the need for remediation, determining appropriate remedial actions, and evaluating compliance with regulatory criteria. Indeed, concentrations of radionuclides in the environment or on surfaces of building structures that are assumed to be equivalent to dose or risk criteria specified in regulations provide the only practical standards for site remediation. EPA and NRC do not use the same guidance in carrying out site characterization activities; EPA's use of guidance developed specifically for CERCLA sites differs from NRC's use of the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM). Modeling then is required to estimate doses or risks that correspond to given concentrations of radionuclides at a site. Modeling also is required to estimate future changes in radiological conditions, such as the potential for contamination of groundwater or surface waters due to migration of radionuclides in surface soil.

NRC typically uses more stringent land use assumptions than EPA. For example, NRC often uses a resident farmer scenario for establishing remediation levels, while EPA often uses a less restrictive suburban resident scenario rather than an agricultural scenario. Both agencies also allow use of site-specific scenarios and assumptions in estimating dose or risk in a given scenario.

However, NRC and EPA do not use the same methods of estimating dose or risk in a given scenario. There can be important differences in assumed exposure pathways, values of model parameters used to estimate external exposure or intakes of radionuclides, and dose coefficients (*i.e.*, doses per unit activity taken in) for inhalation and ingestion. Differences in doses or risks per unit concentration of radionuclides in the environment calculated by the two agencies frequently exceed a factor of 10, and sometimes exceed a factor of 100, when ingestion and inhalation exposure routes are of primary importance. In modeling external irradiation, there can be differences in assumptions about exposure

times, shielding provided by building structures during indoor residence, the spatial extent of contamination, the presence of clean cover to provide shielding of contaminated soil, and erosion of surface soil at future times.

Uncertainties in characterizing radioactive contamination at a site and uncertainties in models used to estimate dose or risk also are important but have not often been taken into account in applying regulatory criteria. Although uncertainties in site characterization may be unimportant if average concentrations of radionuclides over a site are far below a remediation standard, those uncertainties probably are a factor of about two or more, with higher uncertainties applying in cases of heterogeneous contamination with beta- or alpha-emitting radionuclides. Analyses of available data indicate that uncertainties in estimating external exposure are a factor of two to three; uncertainties in estimating intakes of radionuclides by inhalation and ingestion are at least a factor of five and can exceed a factor of 10; uncertainties in dose coefficients for inhalation and ingestion due to uncertainties in dosimetric and biokinetic models are in the range of 2 to 10, and there is additional uncertainty in the biological effectiveness of alpha particles of a factor of about four for solid tumors or seven for leukemias; and the uncertainty in estimating risk per unit dose is a factor of about three or more, depending on the organs irradiated. These uncertainties all are commensurate with or substantially greater than any difference between NRC's annual dose criterion and EPA's lifetime cancer risk criterion when the former is expressed in terms of lifetime risk.

Practical Decision Making at Specific Sites

In many respects, NRC and EPA approach the need for practical decision making at specific sites in similar ways. Both agencies appreciate that resources available for remediation are limited, remediation can be difficult, decisions must be made in the presence of uncertainty, the public wants to be assured that their health and the quality of the environment will be protected, and licensees or other responsible parties desire certainty and finality in remediation decisions.

One area in which NRC and EPA appear to differ somewhat in their approaches to practical decision-making concerns the extent of involvement by the public and other stakeholders. As noted previously, CERCLA requires that the public and other stakeholders be given opportunities to participate in the decision-making

process in meaningful ways, and this requirement is implemented, in part, by the modifying criteria specified in the NCP. Thus, EPA is accustomed to meaningful participation in decision making by other groups, and there have been cases where stakeholder concerns have determined remediation decisions. However, it appears that NRC has been slower to seek out and seriously consider stakeholders' views during their decision-making process. Although NEPA generally requires that there be opportunities for public input to NRC's licensing actions and the LTR includes provisions on public involvement in remediation of contaminated sites, it remains to be seen whether the public and other stakeholders will have meaningful input to remediation decisions at licensed sites.

In an effort to gain some understanding of approaches to practical decision making at specific sites, a series of case studies was reviewed. Additionally, members of NCRP visited a site at West Valley, New York, to meet with responsible federal and state officials, the site operator, and public interest groups. The West Valley Demonstration Project Site is notable for its complexity and the challenges posed by remediation. The U.S. Department of Energy (DOE), NRC, EPA, and the State of New York are all involved at West Valley. NCRP also contacted several EPA field offices. NCRP's various interactions indicated that remediation decisions at specific sites are driven by concerns of practicality, and that when government agencies and other interested parties choose to cooperate, successful remediations that address the concerns of all parties can result.

Recurrent themes from the case studies emerged. Assumptions about future use of a site, as well as assumptions about off-site risks, often drive risk management decision making. Public participation, input and acceptance are critical for successful risk management. Various approaches are used across sites to assess and manage risks. Among the differences in approaches were selection of contaminants of concern; assumptions about the duration of exposures of individuals and the future time period over which doses or risks are assessed; establishment of target remediation goals in terms of dose or risk; and balanced considerations of feasibility and effectiveness of remedies, health and environmental protection, and costs.

Risk communication emerged as a key issue in building public trust, which, in turn, was necessary for satisfactory remediation outcomes. Stakeholder issues of importance include different perceptions of risk by public and experts, public perception that unlikely adverse outcomes are proof of danger, social amplification

of risk, distrust caused by past mismanagement (by current standards) of contamination at many sites, distrust of industry and government along with trust of medicine and research, belief that risk managers value schedule and cost over long-term risk reduction, limited effectiveness of usual approaches to risk communication, and the perception that risk managers engage in one-way communication about risks that do not answer community concerns. Because of these issues, better understanding of risk communication and the way stakeholders understand risk is needed.

Implications of Current Regulatory Guidance and Practice

NCRP has considered implications of current regulatory guidance and practice of NRC and EPA on remediation of radioactively contaminated sites, especially in the areas of site characterization and measurability of residual radionuclides, estimation of dose or risk, uncertainty in site characterization and dose or risk assessment, final decision-making authorities, consistency of policies within each agency, comparability of basic protection criteria, the focus of disagreements between NRC and EPA, the language (terminology) of risk management, public perception, and the role of states in remediation decisions. Implications in some areas have been discussed previously, and the main points are summarized below. It should be recognized that implications in many areas are closely related.

Site Characterization and Measurability of Residual Radionuclides

NRC generally uses MARSSIM as a guide to conducting surveys to characterize radioactive contamination at a site, especially in conducting final site surveys following remediation, whereas EPA's Superfund program has developed a separate, and somewhat different, methodology for characterizing radioactively contaminated CERCLA sites. Differences in methods of site characterization can result in differences in estimates of average concentrations of radionuclides over a site and, potentially, differences in decisions about compliance with site-specific cleanup criteria.

Regardless of the particular approach to site characterization, it is difficult to distinguish reliably between concentrations of particular radionuclides in soil or on building surfaces that correspond to NRC's annual dose criterion of 0.25 mSv and concentrations that

correspond to EPA's lifetime cancer risk criterion of around 10^{-4} when doses and risks are calculated using the same methods. Given that the difference between the two criteria is not large, the two criteria would result in concentrations that are similar when the same methods of deriving equivalent concentrations are used. In addition, inhomogeneities in distributions of radionuclides across a site are likely, and such inhomogeneities would result in significant uncertainty in average concentrations. An ability to distinguish site contamination from background also is a significant issue at sites where radium or thorium is important, and a similar concern could apply to ^{137}Cs due to its presence in fallout from atmospheric testing of nuclear weapons.

Estimation of Dose or Risk

Differences in doses or risks per unit concentration of radionuclides estimated by the two agencies can be much larger than any difference between the annual dose criterion in the LTR and EPA's lifetime cancer risk criterion. Even though EPA's lifetime cancer risk criterion appears to be more restrictive than NRC's annual dose criterion, soil screening levels developed independently by the two agencies indicate that use of EPA's criterion and methods of risk estimation can result in substantially higher equivalent concentrations of radionuclides than use of NRC's criterion and methods of dose estimation.

Uncertainty in Site Characterization and Dose or Risk Assessment

Uncertainty is important in all aspects of determining compliance with regulatory criteria expressed in terms of dose or risk including: estimation of average concentrations of radionuclides over a site at the time decisions about remediation and license termination are made; estimation of concentrations of radionuclides over a site at future times, especially concentrations in groundwater or surface waters that could result from migration from surface soil; modeling of exposure pathways; and models and assumptions used to estimate dose or risk from assumed external exposures and intakes of radionuclides. Estimates of dose can be made without assuming a radiation dose-response model, while estimates of risk currently are based on low-dose and dose-rate adjustments to the linear-nonthreshold dose-response model, which contributes additional uncertainty. Uncertainties in characterizing radioactive contamination at present and future times and

uncertainties in methods of estimating dose or risk resulting from assumed levels of radioactive contamination at specific sites are substantially greater than any differences between NRC's annual dose criterion expressed in terms of lifetime risk and EPA's lifetime cancer risk criterion or drinking water standards.

Final Decision-Making Authorities

NRC licensees prefer that decisions by NRC that remediations are acceptable would not be overturned later by EPA. However, it appears that EPA would be in violation of CERCLA if the possibility of EPA involvement at sites licensed by NRC were waived by agreement between the two agencies. Thus, the possibility remains that EPA could become involved in remediation decisions at sites licensed by NRC. However, EPA has stated that such involvement should be rare and should not normally be opposed by NRC.

NRC and EPA officials have indicated that there are very few sites licensed by NRC where EPA could become involved. When EPA involvement could occur, NCRP believes that it should not impose undue hardships on licensees, because such involvement should occur only in cases where there are important concerns about radiological conditions at a site and there are no significant concerns about remediation of nonradioactive hazardous materials.

It also should be recognized that the history of regulation of nuclear activities, including management and disposal of radioactive waste, has often been characterized by concurrent involvement of more than one federal or state agency. Indeed, this situation is typical of current approaches to protection of human health and the environment in many areas. Therefore, the possibility of EPA involvement in decisions by NRC to terminate licenses at contaminated sites presents a situation that has been addressed successfully in other areas.

Consistency of Policies Within NRC and EPA

NRC applies its policies and guidance on decommissioning and license termination reasonably consistently at all sites with substantial contamination, whereas EPA regional offices that are responsible for decision making at specific CERCLA sites are afforded considerable flexibility and do not necessarily apply EPA policies and guidance in the same ways. Especially when faced with complex and difficult remediation situations, EPA regional offices often focus on practical aspects of decision making.

Comparability of Basic Protection Criteria

An important focus of this Report is a comparison of the basic protection criterion specified in the NRC's LTR, which is a limit on annual TEDE of 0.25 mSv, with EPA's upper bound on lifetime cancer risk of 10^{-4} , as specified in the NCP. Such comparisons are central to the issue of whether NRC's annual dose criterion is consistent with EPA's lifetime cancer risk criterion and, therefore, whether remediation of radioactively contaminated sites under the LTR would be considered adequately protective under CERCLA and NCP.

NRC's annual dose criterion and EPA's lifetime cancer risk criterion can be compared by making simple assumptions about the duration of exposure (*e.g.*, 30 y) and a nominal risk coefficient (*e.g.*, 0.05 Sv^{-1} for fatal cancers or 0.076 Sv^{-1} for cancer incidence). However, it is important to emphasize that any such comparisons are complicated by several factors including:

- perhaps most importantly, the strong dependence of estimated doses or risks per unit concentration of radionuclides in the environment on the assumed exposure scenario and assumed parameters in exposure pathway models in a given scenario (*e.g.*, doses or risks per unit concentration can be much higher in a resident farmer scenario, as often assumed by NRC, than in a suburban resident scenario, as often assumed by EPA, with the result that limits on acceptable concentrations of radionuclides obtained using NRC methods often can be much lower, and therefore more protective, than limits obtained using EPA methods; there also can be large differences in doses or risks per unit concentration of radionuclides in the same scenario estimated by the two agencies);
- the nonunique correspondence between committed effective dose equivalents from intakes of radionuclides by inhalation or ingestion used by NRC and EPA's methods of estimating risk from intakes of radionuclides in Federal Guidance Report No. 13 (*i.e.*, committed effective dose equivalents are not related to lifetime risks calculated by EPA by a nominal risk coefficient that applies to all radionuclides), and the outcome that EPA's methods of estimating risk from intakes of radionuclides often result in lower estimates of risk, and by more than an order of magnitude in some cases;
- variations in the assumed duration of exposures, which is not relevant in applying NRC's annual dose criterion but

can affect estimates of the corresponding lifetime risk by a factor of two or more (*e.g.*, an assumption of exposure over 30 versus 70 y);

- the half-lives of particular radionuclides of concern at a site, *i.e.*, when the half-life is considerably less than an assumed duration of exposures, a limit on annual dose can correspond to an average annual dose over that period, and therefore lifetime risk, that is substantially less than is obtained by assuming that exposure at NRC's annual dose criterion occurs every year, as could occur when long-lived radionuclides are present;
- the particular interpretation of EPA's lifetime cancer risk criterion, *i.e.*, is the appropriate upper bound on lifetime cancer risk at 1×10^{-4} , or can a cancer risk of *around* 10^{-4} (*e.g.*, up to about 3×10^{-4}) be considered acceptable in some cases, as suggested in EPA guidance on cleanup of radioactively contaminated sites.

Comparisons of NRC's annual dose criterion with EPA's lifetime cancer risk criterion are difficult essentially because any comparison involves dissimilar quantities and, therefore, many assumptions about conditions of exposure are required. As indicated above, simple comparisons of the two criteria based on an assumed exposure time and a nominal risk coefficient can be misleading, and it is difficult to formulate general conclusions about differences in levels of health protection that would be obtained by applying the two criteria at specific sites. In making comparisons, it is important to realize that it is the residual concentrations of radionuclides at a site and assumptions about conditions of exposure that determine doses and risks, not the basic protection criteria themselves. Therefore, basic protection criteria can be compared in meaningful ways only if the many assumptions used to estimate doses or risks corresponding to given concentrations of radionuclides in the environment are taken into account.

Focus of Disagreements Between NRC and EPA

NCRP believes that the focus of disagreements between NRC and EPA over appropriate regulatory criteria for remediation of radioactively contaminated sites has been misplaced. Debates about whether NRC's annual dose criterion of 0.25 mSv is consistent with EPA's lifetime cancer risk criterion of around 10^{-4} and whether lack of a separate provision in the LTR concerning protection of groundwater and surface water resources in accordance

with drinking water standards, as specified in EPA's remediation regulations, constitutes an unacceptable risk to public health and the environment focus on relatively unimportant issues. Such debates do not take into account two considerations of potentially greater importance. The first is that doses and risks that are achieved by applying NRC's annual dose criterion or EPA's lifetime cancer risk criterion are determined by the residual concentrations of radionuclides at a site and assumptions about conditions of exposure, not by the basic protection criteria themselves. This is important because NRC and EPA often use substantially different assumptions about exposure scenarios and exposure pathways, and the resulting differences in cleanup levels of radionuclides derived from the basic protection criteria can be much larger than any difference between NRC's annual dose criterion and EPA's lifetime cancer risk criterion. The second consideration is the requirement in NRC regulations to apply the ALARA principle in reducing doses below the criterion and the provisions of CERCLA and EPA regulations that allow increases (relaxations) above ARARs, including drinking water standards in water resources, and the lifetime cancer risk criterion or that allow restrictions on land use to meet the protection criteria when compliance with those criteria is not feasible under conditions of unrestricted use. Thus, NCRP believes that it would be more helpful, first, to focus on methods used to derive acceptable cleanup levels of radionuclides and, second, to emphasize the essential equivalence of the ALARA principle in NRC regulations and the balancing and modifying criteria in EPA regulations and focus on how those principles should be applied in determining acceptable remediations at specific sites.

Language of Risk Management

As a result of the fundamental difference between the radiation and chemical paradigms for risk management (*i.e.*, use of limits and an ALARA requirement versus use of goals and allowance for increases above the goals), the two paradigms generally attach different meanings to the terms "unacceptable" and "acceptable" used to describe doses or risks at various levels. In the radiation paradigm, "unacceptable" denotes doses so high that they are regarded as intolerable and must be reduced regardless of cost or barely tolerable doses that are not ALARA, and a dose is "acceptable" if it is below intolerable levels and is ALARA. In contrast, "unacceptable" in the chemical paradigm generally means "non-negligible" and denotes a risk sufficiently high that consideration must be given to whether it is feasible to reduce risk. The

term “acceptable” then denotes a negligible risk because action to reduce risk below “acceptable” levels usually is not required. The concept of an intolerable risk that generally requires action to reduce risk is not explicit in the chemical paradigm. Comparisons of criteria in NRC and EPA regulations would be facilitated considerably if consistent and reasonable meanings of those terms were used in both paradigms.

It also could be beneficial if a common terminology were developed to describe the concepts of ALARA in the radiation paradigm and the equivalent considerations in the chemical paradigm to permit increases (relaxations) above specified goals for protecting public health and the environment, such as the balancing and modifying criteria used under CERCLA. NCRP believes that a terminology that emphasizes an optimization of risk management based on all relevant considerations, including stakeholder concerns, would be appropriate.

Public Perception

The public probably is largely unaware of differences in current NRC and EPA guidance and practice on remediation of radioactively contaminated sites. However, awareness of the differences may increase as public involvement in remediation decisions increases, and questions may arise concerning why the differences exist and what they mean in regard to protection of public health and the environment at specific sites. It therefore will be important for regulatory authorities to address the differences and their significance in a forthright manner and to give proper emphasis to their more important similarities.

Impacts on States

Differences in current NRC and EPA guidance and practice on remediation of radioactively contaminated sites and disagreements between the two agencies over the adequacy of the LTR have potentially important impacts on the states, because essentially the same differences occur in guidance and practice of many state radiation and environmental protection programs. In addition, many states have stringent standards on protection of groundwater resources that can impact remediations at all sites, including those licensed by NRC; states are likely to assume ultimate responsibility for sites that have been released for public use; and states are the only authorities that have assumed responsibility for regulating all radioactive materials. Thus, as NRC and EPA

have attempted to resolve their disagreements over appropriate remediation standards through interagency agreements, with only limited success, states understandably have not taken kindly to being excluded from agreements that directly affect their responsibilities.

Conclusions

As a result of this study, NCRP has reached several conclusions which are summarized in the Executive Summary and detailed in Section 6.

1. Introduction

In the United States, a spectrum of laws, regulations, guidance and practice apply to regulation of the nuclear fuel cycle and associated radioactive materials, nuclear materials for national defense, and naturally occurring and accelerator-produced radioactive materials. These laws and regulations exist at both the federal and state levels and are intended to protect public health and the environment from the harmful effects of ionizing radiation. This Report is concerned with the regulations that apply to decommissioning and remediation of radioactively contaminated sites.

The U.S. Nuclear Regulatory Commission (NRC) and the U.S. Environmental Protection Agency (EPA) are the two principal federal agencies that regulate remediation and decommissioning of radioactively contaminated sites. Both agencies function under a variety of laws and have promulgated a variety of regulations. The states also play an important role which varies from state to state.

Important issues include the choice to regulate based on radiation dose or on risk of cancer, whether radioactive materials are to be regulated separately from other toxic materials, whether groundwater is to be regulated separately from other exposure pathways, and what future site uses are planned. Involvement of stakeholders other than licensees and regulators is another important issue.

There is not always agreement on these issues among the various agencies. In particular, in 1997 EPA questioned whether NRC's remediation criteria [10 CFR Part 20, Subpart E (NRC, 2004a), also see NRC (1997); known as the "License Termination Rule" (LTR); reproduced as Appendix A of this Report]⁴ were adequately protective of public health. In 2002, NRC and EPA signed a Memorandum of Understanding (MOU; reproduced as Appendix B of this Report) on cooperation between the two agencies in the case of termination of NRC licenses. Despite the existence of the MOU, there are many aspects of regulation of remediation and decommissioning on which disagreements between the two agencies remain.

⁴The Code of Federal Regulations (CFR) is published annually by the U.S. Government Printing Office, Washington [<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1> (accessed September 2004)].

There is a general awareness that resolution of real or apparent disagreements is needed. For example, EPA's Science Advisory Board, Radiation Advisory Committee has addressed the notion of harmonization of standards and risk assessment approaches for radiation and chemicals, but this statement applies equally well to harmonization of radiation standards and practices among various regulators. The Radiation Advisory Committee stated, "[h]armonization' does not mean that all decisions involving chemical and radiological hazards require identical treatment in all situations. Instead, it refers to fitting risk management decisions into a common policy framework aimed at aggregate risk reduction and public health protection, but not necessarily achieving such reduction and protection in identical ways or with identical risk criteria in every case" (EPA/SAB, 1992). This statement can be applied to the regulatory practices of EPA and NRC in remediating radioactively contaminated sites, and, as will be shown, the two agencies are not as far apart as first appearances may suggest.

1.1 Purpose and Scope

The National Council on Radiation Protection and Measurements (NCRP) was asked by NRC to perform an analysis of current regulatory guidance and practice used by the two agencies in remediation of radioactively contaminated sites. NCRP was specifically asked to:

- identify and summarize current regulatory guidance and practice on remediation of radioactively contaminated sites used by NRC under the LTR and by EPA under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the National Oil and Hazardous Substances Pollution Contingency Plan [National Contingency Plan (NCP)], including a review of models and tools used to assess regulatory compliance;
- identify, examine and summarize the historical basis for current guidance and practices of the two agencies;
- identify, analyze and summarize the significant differences and commonalities in current guidance and practices of the two agencies; and
- identify, examine and summarize the implications of current guidance and practices of the two agencies as they relate to such issues as public perception, uncertainty, measurability, and dose and risk estimates.

The ultimate objective of such an analysis is to evaluate whether the different guidance and practices of NRC and EPA can be harmonized to provide reasonably consistent approaches to decision making in remediation of radioactively contaminated sites.

1.2 NCRP Process

Members of NCRP examined laws, regulations, guidance and practices applicable to risk management in remediation and decommissioning of radioactively contaminated sites. NCRP contacted various EPA regions, and solicited presentations from the major federal regulatory agencies. NCRP visited the West Valley Demonstration Project (WVDP) to gain insight into the complex interplay of the stakeholders and regulators at a specific site with intricate remediation challenges. Individual members contributed their expertise and experience in a variety of areas, including regulatory analysis, risk analysis, risk management, regulation, environmental law, public health, risk perception, and risk communication.

1.3 Outline of the Report

The Report begins with an Executive Summary that highlights the major conclusions. A longer Extended Summary provides a complete summary description of this study and its findings, but without giving many of the supporting technical details. Section 2 summarizes current laws, regulations, guidance and practices for risk analysis and risk management decisions at decommissioned sites as implemented by NRC and EPA, along with environmental modeling and dose assessment by NRC, EPA, and the U.S. Department of Energy (DOE). Section 3 is an analysis of those laws, regulations, guidance and practices. Section 4 contains a description of practical decision-making issues and discusses common themes that emerged from case studies of cleanup decisions at several sites, as well as risk communication issues. Section 5 discusses implications of the differences and commonalities in the approaches of the two agencies.

The Report contains three appendices, including the NRC License Termination Rule (LTR), the EPA/NRC MOU, and an analysis of acceptable residual radioactivity levels from 10 case studies. A glossary follows the appendices.

2. Current Regulatory Guidance and Practice

This Section discusses current regulatory guidance and practices used by NRC and EPA to address remediation of radioactively contaminated sites. Regulatory guidance and practice is considered at several levels, from basic requirements of governing laws to methods of assessing compliance with applicable regulatory requirements at specific sites. The discussions in this Section and Section 3 consider the following aspects of current guidance and practice:

- the principal laws governing remediation of radioactively contaminated sites, and the organizational structures and functions of NRC and EPA;
- regulations that apply to remediation of radioactively contaminated sites and associated guidance documents that interpret the regulations;
- supporting documents to provide guidance on evaluating compliance with regulatory criteria that define radiological conditions at contaminated sites following decommissioning and license termination that would permit unrestricted or restricted use by the public, and address such issues as methods of site characterization, assumptions about exposure scenarios, and models used to estimate doses or health risks to representative individuals.

Discussions of applicable regulations and associated guidance documents particularly emphasize their historical development. An understanding of how current regulations were developed is important in gaining an understanding of differences in approaches to regulation taken by NRC and EPA, the significance of those differences in regard to levels of protection of public health and the environment⁵ that would be achieved in remediation of contaminated sites, and ways in which the different regulatory approaches can be reconciled.

⁵The term “environment” includes air, soil and groundwater. As discussed below, NRC’s approach to protecting groundwater differs significantly from EPA’s approach.

Approaches to practical decision making at specific sites and issues that arise in involving stakeholders in the decision process are discussed in Section 4.

2.1 Principal Governing Laws and Organizational Structure

NRC and EPA are federal agencies with different origins and responsibilities. NRC was created in 1974 when the former Atomic Energy Commission (AEC) was abolished, and NRC was established to assume AEC's responsibilities to regulate radioactive materials associated with operations of commercial nuclear fuel cycle facilities. AEC had been established in 1946 to provide civilian oversight and direction to the nation's nuclear weapons program, and its role was greatly expanded in 1954 when the use of radioactive materials for peaceful purposes was first authorized. Thus, the regulatory programs for which NRC assumed responsibility were well established before a strong tradition of public participation in regulatory affairs of federal agencies had developed.

In contrast, EPA was created in 1970 by consolidating many parts of other federal agencies to address increasing public concerns about the need to protect human health and the environment from the deleterious effects of a wide variety of pollutants. Thus, from the outset, EPA has operated under a tradition of public scrutiny and involvement.

The following sections consider the governing laws and organizational structures of the two agencies as an introduction to more specific discussions on regulations that apply to remediation of radioactively contaminated sites.

2.1.1 *Governing Laws and Organizational Structure of NRC*

NRC's regulatory authority is derived from the Atomic Energy Act (AEA, 1954). Under the Act, NRC is authorized to regulate certain radioactive materials, *i.e.*, source, special nuclear, and byproduct materials associated with operations of the nuclear fuel cycle, in the commercial sector to protect the health and safety of workers and the public. NRC is not authorized to regulate any other radioactive materials such as naturally occurring and accelerator-produced radioactive materials not associated with operations of the nuclear fuel cycle, nor is it authorized to regulate radiation-producing machines, *e.g.*, x-ray machines or particle accelerators.

NRC is also not authorized to regulate nonradioactive hazardous materials.

Certain regulatory responsibilities of NRC have been specified in other laws including, for example, the Nuclear Waste Policy Act (NWPA, 1982), Uranium Mill Tailings Radiation Control Act (UMTRCA, 1978), and West Valley Demonstration Project Act (WVDPA, 1980). However, other laws do not define regulatory authorities over radioactive materials that go beyond those that are generally defined in AEA. The Uranium Mill Tailings Radiation Control Act, which was an amendment to AEA, is particularly relevant to this Report because it directed EPA to develop standards for remediation of uranium and thorium mill tailings sites, and those standards provided the basis for NRC regulations on remediation of contaminated lands and structures at licensed thorium mills and uranium recovery facilities (Section 2.2.1.2).

All regulatory activities of NRC also must comply with provisions of the National Environmental Policy Act (NEPA, 1970) that require evaluations of environmental impacts of any federal actions that significantly affect the quality of the environment. NRC regulations to implement requirements of NEPA are given in 10 CFR Part 51 (NRC, 2004b). Those regulations address such issues as requirements for preparation of environmental impact statements and other environmental reports on significant licensing and other regulatory actions and requirements for public hearings and opportunities for public comment on draft environmental impact statements. Requirements to hold public hearings and to provide opportunity for public comment on proposed regulations also are specified in NRC's rules of practice for domestic licensing proceedings [10 CFR Part 2 (NRC, 2003a)].

Much of the organizational structure of NRC is specified in the Energy Reorganization Act (ERA, 1974) which abolished AEC and transferred licensing responsibilities for commercial nuclear activities to NRC. All decision-making authority on matters concerning regulation of activities of NRC licensees is vested in the five members of the Commission, who are appointed by the President. NRC is organized into several functional offices including, for example, the Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Regulatory Research, and the Office of Enforcement. Those offices support the Commission in formulating policies and regulations governing nuclear reactor and materials safety, issuing licenses and other orders to licensees, and adjudicating legal matters brought before it.

NRC also maintains four regional offices which, as part of the regulatory process, conduct inspection, enforcement, and emergency response programs for licensees within their borders. Regional offices are dependent on the central office for their technical and policy direction, and they tend to follow such directions consistently. Decisions about license termination at radioactively contaminated sites licensed by NRC are made either by a regional office or by the Commission or NRC staff at the central office. Regional offices terminate hundreds of licenses each year at smaller sites where the decision process is simple, such as sites that possessed sealed sources only or sites where contamination occurs only at very low levels and is not widespread. However, when contamination at a site is more complex and a decommissioning plan is required by NRC, all decisions about license termination are made by the Commission or staff at the central office. A decommissioning plan is required, for example, when a site has substantial and widespread contamination of soil or when contamination of groundwater is a concern (Smith *et al.*, 2003). It is this type of site that is of interest to this Report.

2.1.2 *Governing Laws and Organizational Structure of EPA*

EPA carries out its regulatory responsibilities under several independent laws including, for example, the Clean Air Act (CAA, 1963), Clean Water Act (CWA, 1972), CERCLA (1980) or “Superfund,” Resource Conservation and Recovery Act (RCRA, 1976), Safe Drinking Water Act (SDWA, 1974), and Toxic Substances Control Act (TSCA, 1976). In addition, Reorganization Plan No. 3 (White House, 1970) which established EPA, transferred to EPA from the former AEC the responsibility for establishing generally applicable standards⁶ for radiation in the environment. Thus, EPA is authorized under AEA to establish environmental radiation standards that apply to NRC licensees. An example of importance to this Report is standards for remediation of uranium and thorium mill tailings sites established in 40 CFR Part 192 (EPA, 2004a) under authority of UMTRCA (1978).

EPA has developed regulations for remediation of contaminated sites, potentially including radioactively contaminated sites

⁶In this Report, the term “standard” often is used to denote a regulation or a numerical criterion, such as a limit on dose or limit on concentration of a radionuclide in an environmental medium, specified in a regulation.

licensed by NRC, mainly under authority of CERCLA (1980).⁷ CERCLA was developed to address problems of environmental contamination that was not properly regulated under other laws, such as CAA, CWA, SDWA, RCRA and AEA. Furthermore, the need for, and acceptability of, responses to environmental contamination under CERCLA often are based, at least in part, on standards specified in regulations developed under other laws. The authority for EPA to regulate remediation of radioactively contaminated sites under CERCLA derives from, first, the stated purpose of the Act to address unpermitted and uncontrolled releases or threats of release of hazardous substances and remediation of inactive hazardous waste disposal sites and, second, the definition of “hazardous substance” in CERCLA to include substances that are declared to be hazardous air pollutants under CAA (1963) and the specification of radionuclides as hazardous air pollutants therein.

Provisions of RCRA (1976) and its implementing regulations that are concerned with corrective actions can be important in remediation of radioactively contaminated sites licensed by NRC, even though source, special nuclear, and byproduct materials regulated by NRC under AEA are specifically excluded from regulation under RCRA. RCRA requirements can apply when a licensed facility has operated under a RCRA permit for treatment, storage or disposal of hazardous chemical waste, as is frequently the case, and they can affect remediation of radioactive materials that are mixed or co-located with hazardous chemical waste.⁸ At many radioactively contaminated sites that also contain RCRA hazardous waste, RCRA requirements will apply to site remediations—and *de facto* remediation of radioactive materials—because remedial actions will generally involve treatment, storage or disposal of RCRA waste from which radioactive materials cannot be separated. RCRA and its implementing regulations are not considered in any detail, mainly because this Report is concerned primarily with comparisons of NRC regulations with EPA regulations developed under CERCLA, and RCRA regulations incorporate many of the same principles as regulations developed under CERCLA.

⁷EPA also developed a draft regulation for remediation of radioactively contaminated sites under authority of AEA (EPA, 1994a). However, a proposed regulation was not issued and all EPA regulations on remediation of radioactively contaminated sites have been developed under CERCLA or other environmental laws.

⁸See NCRP (2002) for a discussion of impacts of dual regulation under RCRA and AEA on management and disposal of mixed radioactive and hazardous chemical waste and references to joint EPA and NRC guidance documents on complying with requirements of the two agencies.

EPA standards that apply to remediation of uranium and thorium mill tailings sites have been developed under UMTRCA (1978). The Act addressed problems of environmental contamination at specific sites, nearly all of them in the western United States, where large volumes of waste materials were produced as a result of processing of ores to extract source material (uranium or thorium). Although control of exposures to radioactive material, primarily radium and radon, is the main concern, the Act recognizes the presence of elevated levels of hazardous chemicals, especially heavy metals, in tailings materials, and it requires that standards for protection of human health and the environment developed under RCRA, especially standards for protection of groundwater, be applied in controlling exposures to hazardous chemicals at mill tailings sites.

EPA is organized, in part, into program offices that are responsible for carrying out the mandates of particular laws. Examples include the Office of Radiation and Indoor Air (CAA and AEA), the Office of Water (CWA and SDWA), and the Office of Solid Waste and Emergency Response (RCRA and CERCLA). Those program offices operate largely independently of each other in response to different mandates of the various environmental laws that govern EPA activities. EPA is headed by a single administrator, who is nominated by the President and confirmed by the Senate.

EPA also maintains ten regional offices that have responsibilities within their borders in several areas including, for example, monitoring compliance with environmental laws and regulations, enforcement actions against violators, and compliance assistance and pollution prevention. Each major program office in EPA's central office has a corresponding branch in most regional offices. EPA regional offices operate somewhat independently of the central office and independently of each other, although guidance issued by the central office is expected to be implemented by regional offices and there is frequent communication between the central office and regional offices and among regional offices on issues of mutual interest.

In regard to remediation of contaminated sites under CERCLA, it is important to note that whenever EPA is the lead or support agency at a site (Section 2.2.4.2), the appropriate regional office, rather than the Office of Solid Waste and Emergency Response (OSWER) in EPA's central office, normally assumes that responsibility. Thus, in such cases, decisions about remediation of sites and compliance with CERCLA and its implementing regulations are made by regional offices, with general guidance provided by the

central office, and the different regional offices do not necessarily use consistent policies and approaches in meeting this responsibility. If NRC were to consult with EPA on remediation of licensed sites in accordance with the recent MOU (EPA/NRC, 2002), the central OSWER office would be the initial point of contact. However, subsequent discussions normally should involve the appropriate regional office and the regional office normally would assume responsibility if CERCLA were applied to remediation of a site licensed by NRC. EPA's decentralized approach to decision making in remediation of contaminated sites under CERCLA is intended to provide flexibility in addressing the wide variety of environmental problems that are likely to be encountered and to facilitate interactions and negotiations with local communities and other stakeholder groups.

2.1.3 *Relationships Between NRC or EPA and the States*

In accordance with Agreement State provisions of AEA (1954), NRC may relinquish to a state its regulatory authority over source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass. NRC relinquishes its regulatory authority only if regulations established by a prospective Agreement State are compatible with, or more restrictive than, regulations that would be applied by NRC; and the state has an adequate radiation control program. There are 33 Agreement States as of July 2004.

AEA also specifies several types of nuclear facilities over which NRC may not relinquish its regulatory authority to Agreement States. These types of facilities include nuclear power plants, uranium enrichment and fuel fabrication facilities, facilities for disposal of spent fuel and high-level waste, and any other disposal facilities for waste containing source, byproduct or special nuclear material that the Commission determines should not be operated without a license from NRC. Thus, remediation of the largest commercial nuclear facilities will be regulated by NRC, but remediation of a much greater number of smaller sites and facilities where lesser quantities of radioactive material were handled will be regulated by Agreement States. This is an important consideration when agreements between NRC and EPA on issues involving remediation of radioactively contaminated sites that are licensed by NRC, such as the recent MOU (EPA/NRC, 2002), do not apply to Agreement States (NRC regulates cleanup of such smaller sites and facilities in non-Agreement States).

Several environmental laws that govern EPA activities include provisions for delegation of EPA's regulatory authority and other responsibilities to the states including, for example, RCRA (1976) and SDWA (1974). In general, state regulations must be at least as restrictive as those established by EPA, EPA is authorized to provide grants to states to continue a program as an enticement to accept delegation of regulatory responsibility, programs delegated by EPA mandate specific public participation processes, and EPA funds training programs for state personnel who are responsible for a delegated program. A state can assume responsibility for one EPA program without necessarily seeking delegation of other programs, and multiple state agencies may participate in a particular program.

An important exception to environmental laws that provide for delegation of EPA's regulatory authority and other responsibilities to the states is CERCLA (1980). Although states can (and often do) participate in the decision process in remediation of contaminated sites in their roles as stakeholders (Section 2.2.4.2), EPA's authority and responsibilities as a lead or support agency may not be delegated to a state. However, if a state has a remediation program, EPA works with that state to assure compliance with CERCLA and RCRA. As noted in the previous section, a regional office usually carries out EPA's responsibilities under CERCLA.

2.2 Regulations for Remediation of Radioactively Contaminated Sites

This Section discusses regulations for remediation of radioactively contaminated sites established by NRC and EPA. Selected guidance documents on interpreting applicable regulations are also discussed.

2.2.1 NRC Regulations

NRC regulations that apply to remediation of radioactive contamination at most licensed facilities are given in 10 CFR Part 20, Subpart E (NRC, 1997; 2004a). Those regulations, which are referred to as the License Termination Rule (LTR), apply to remediation of all facilities licensed by NRC except thorium mills and uranium recovery facilities (*i.e.*, conventional uranium mills and uranium solution extraction facilities). NRC regulations that apply to remediation of thorium mills and uranium recovery facilities are given in 10 CFR Part 40, Appendix A (NRC, 2004c).

An essential characteristic of NRC's approach to decommissioning of licensed facilities is the financial assurance requirements that are imposed on all licensees in 10 CFR Part 30.35 and 30.36, 10 CFR Part 40.36, 10 CFR Part 50.75, and 10 CFR Part 70.25 and 70.38 (NRC, 1997; 2004c; 2004d; 2004e; 2004f). The purpose of those requirements is to ensure that adequate funds will be available to meet the future costs of decommissioning at the time the process of license termination is undertaken by currently operating facilities. The particular financial assurance requirements depend on whether a site is licensed under regulations that apply to byproduct material [10 CFR Part 30 (NRC, 2004d)], source material [10 CFR Part 40 (NRC, 2004c)], or special nuclear material [10 CFR Part 70 (NRC, 2004e)], or under regulations that apply to production facilities (*i.e.*, facilities to produce plutonium or ^{233}U , uranium enrichment facilities, or fuel reprocessing facilities) or nuclear power plants [10 CFR Part 50 (NRC, 2004f)].

2.2.1.1 10 CFR Part 20, Subpart E. The NRC's LTR applies, for example, to nuclear power plants and licensed uranium enrichment and fuel fabrication facilities, as well as a large number of materials licensees such as hospitals, medical schools, universities, radiochemical manufacturers, research laboratories, and industrial production facilities. The regulations specify radiological criteria to permit unrestricted use of a contaminated site after license termination and criteria for license termination under restricted conditions. The criteria include limits on annual total effective dose equivalent⁹ (TEDE) to an average member of the critical group, due to levels of residual radioactive material distinguishable from background, that are expected to occur within the first 1,000 y after decommissioning.

A site is considered acceptable for unrestricted use if:

- the annual TEDE from all exposure pathways combined, including the dose from groundwater sources of drinking water, does not exceed 0.25 mSv; and

⁹The term "annual total effective dose equivalent" means the sum of the deep-dose equivalent (*i.e.*, dose equivalent at a depth of 1 cm in tissue) from external exposure during a year and the 50 y committed effective dose equivalent from intakes of radionuclides during that year. The tissue weighting factors used to calculate effective dose equivalent are given in 10 CFR Part 20.1003 (NRC, 2004a), and were originally published in ICRP Publication 26 (ICRP, 1977).