Conf-9206218-3

PNL-SA--21060

DE92 019130

RISK-BASED CLEANUP STANDARDS

W. E. Kennedy, Jr.

June 1992

Paper presented at
Health Physics Society Summer School
June 15-19, 1992
Columbus, Ohio

Received OSTI
AUG 1 1 1992

Work supported by
the U.S. Department of Energy
under Contract DE-AC06-76RLO 1830

Pacific Northwest Laboratory
Richland, Washington 99352

RISK-BASED CLEANUP STANDARDS

W. E. Kennedy, Jr.
Pacific Northwest Laboratory[a]
P.O. Box 999
Richland, Washington 99352

ABSTRACT

The problems encountered during facility or land cleanup operations will provide challenges both to technology and regulatory agencies. Inevitably, the decisions of the federal agencies regulating cleanup activities have been controversial. The major dilemma facing government and industry is how to accomplish cleanup in a cost-effective manner while minimizing the risks to workers and the public.

In recognition of the potentially complex relationship between science and public policy in several areas, including cleanup of lands and facilities, in 1981 the U.S. Congress directed the Food and Drug Administration (FDA) to contract a study of the institutional means for risk assessment. The National Academy of Sciences conducted the study on behalf of the FDA and reported the results in a document issued in 1983 ([National Research Council] NRC 1983). The document examined and codified past experience with risk assessment and related that experience to potential future patterns and practices. The goal of the effort was to develop a constructive partnership between science and government, and to ensure that government regulation takes the best advantage of scientific knowledge while preserving the integrity of scientific data and judgements in the conflict of diverse interests that generally accompanies regulatory decisions. Specifically, the report examined whether altered institutional arrangements or procedures could improve regulatory performance in controversial areas.

In an ideal world, risks from various sources could be evaluated and risk management decisions could be made in a constant, agreed-upon manner. In the real world, our ability to assess risks is limited by lack of scientific data on the hundreds of chemical and physical agents that must be considered. When data are available, there is great uncertainty in estimating the frequency, types, and magnitude of health effects associated with a given agent.

One of the fundamental needs in managing the risks of facility or site cleanup is to have well-established standards that apply uniformly to a number of situations. Discussions are being conducted between the U.S. Department of Energy (DOE) and the U.S. Environmental Protection Agency (EPA) in the development of risk-based standards for cleanup operations. This paper provides an overview of risk assessment, risk management, and the role and importance of risk-based standards to facility cleanup activities.

(a) The Pacific Northwest Laboratory is operated by Battelle Memorial Institute for the U.S. Department of Energy under Contract DE-AC06-76RLO 1830.

INTRODUCTION

Over the past forty years, national and international authorities have set radiation protection standards in an attempt to limit the potential risk of exposed individuals to radiation-induced health effects. Although the methods for estimating the resultant risk have changed (i.e., controlling whole-body versus critical-organ risk), the objective has remained constant. Under the authority of the Atomic Energy Act of 1954, as amended, the DOE continues to use a risk basis in its public radiation protection Orders (DOE 1990). It is also the EPA's general philosophy that the individual lifetime risk posed by remediated hazardous waste sites be in the range of 10^{-4} to 10^{-6}. The EPA has taken a similar risk-based approach to establishing emission standards for hazardous pollutants in its recent proposal of standards for radionuclides regulated under the Clean Air Act's National Emission Standards for Hazardous Air Pollutants.

The idea of risk-based standards is a potentially broad subject and covers topics including offsite radiological release criteria; radiological criteria for material recycle/reuse; decommissioning criteria (including surface and bulk contamination criteria for soils, buildings, and facilities); radiological "Below Regulatory Concern" (BRC) standards for waste management; and cleanup levels for site remediation under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended, and the Resource Conservation and Recovery Act (RCRA). For each of the potential topics, it is both desirable and possible to protect the environment and public health in a consistent manner through the establishment of a risk-based framework for setting the standards and implementing the process.

As seen from a risk perspective, regulatory actions are based on two elements: 1) risk assessment and 2) risk management (NRC 1983). Risk assessment is the qualitative or quantitative characterization of the potential health effects of particular substances on individuals or populations. The major elements of risk assessment are hazard identification, dose-response assessment, exposure assessment, and risk characterization. By contrast, risk management is the process of evaluating alternative regulatory options and selecting one of them. In addition to risk assessment, risk management includes an evaluation of economic, social, and political consequences of the regulatory options.

The development of risk-based public health standards is a key element in the risk-management process, as shown in Figure 1. Without standards and a framework for implementation, the risk-management process is out of control and decisions can be made that result in undue public health risks or economic costs. The logical starting point, as shown in Figure 1, is the identification of existing standards for both radiological and hazardous materials. Once identified, the risk basis (or lack thereof) needs to be determined and potential discrepancies or omissions need to be noted. For example, existing standards may or may not be based on risk and, for those that are, different methods of estimating the risk or different acceptable levels of risk may have been used. In some cases, there may be redundant or contradictory standards that have been applied for similar situations. When this occurs, additional legal opinions concerning the appropriate legal

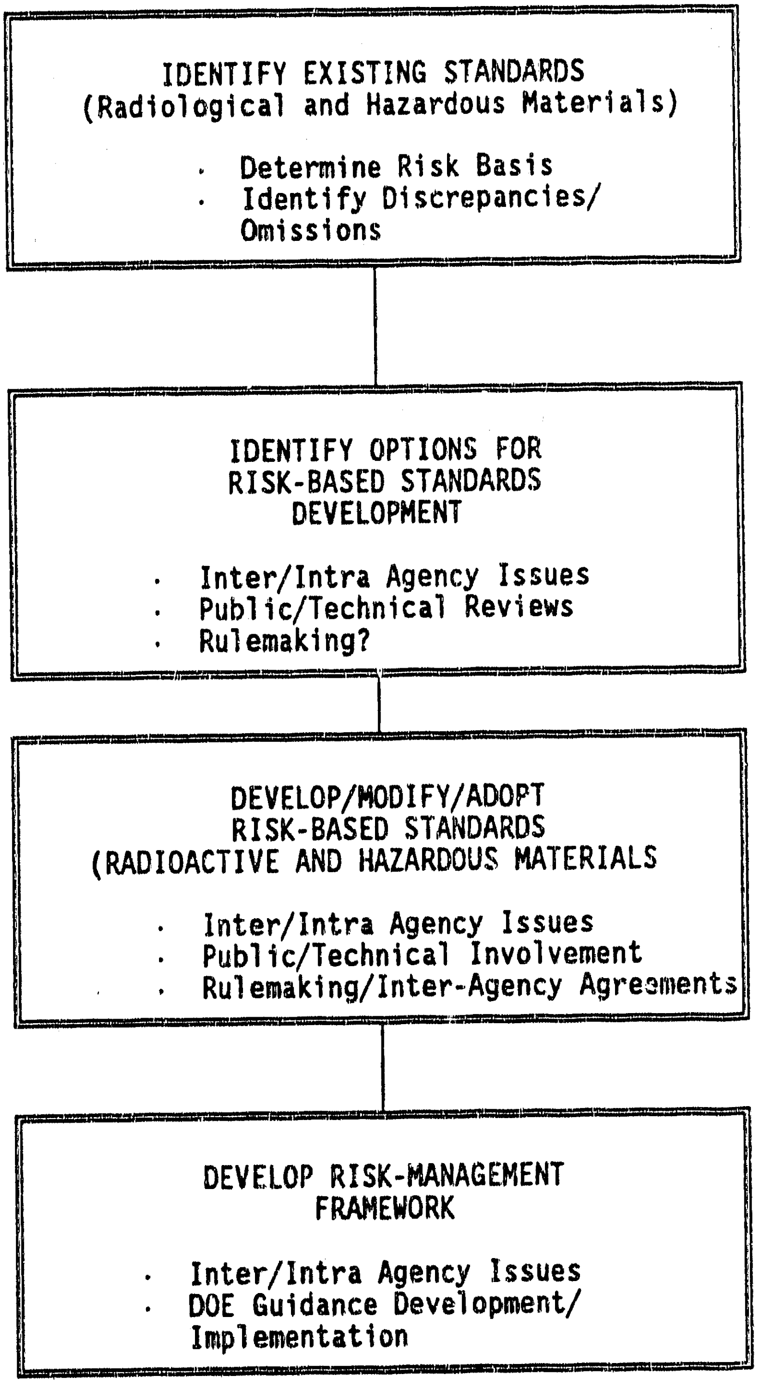

Figure 1. Development of a Risk-Management System

authority may have to be obtained. Three potential types of options exist: develop, modify, or simply adopt existing risk-based standards, as shown in Figure 1. Once the risk-based standards are in place, they can be used in a risk-management framework to add credibility to the regulatory decision-making process.

DEVELOPMENT OF RISK-BASED STANDARDS

The development of risk-based standards could potentially cover a number of individual topics. Topics of importance include the following:

- Off-Site Radiological Release Criteria for Materials Management. Since the mid-1970s, surface contamination levels have been controlled using Regulatory Guide 1.86 developed by the U.S. Atomic Energy Agency (AEC) for license termination for commercial facilities (AEC 1974). This guide lists removable and fixed surface-contamination levels, in units of dpm/100 cm^2, for broad groupings of radionuclides. The levels in this guide were based on detectability and do not reflect a uniform level of risk protection. Although these levels have been applied for various DOE-controlled clean-up operations, attempts to include the guidance in Chapter IV of DOE 5400.5 (1990) met with critical comments from several DOE Operations Offices. At issue was the lack of ability to detect the alpha contamination levels (important for ^{239}Pu contamination control) and the lack of a uniform risk basis for the guidance. A uniform risk-management approach would allow the development of consistent, technically credible standards, while considering practical and public concerns.

- Radiological Criteria for the Potential Recycle/Reuse of Tools, Equipment, and Scrap Materials. The release of slightly contaminated equipment and materials for unrestricted recycle/reuse is of continuing concern because of the growing stockpile of such material and the lack of uniform Federal guidance governing its release. The DOE has an estimated $60 million worth of slightly contaminated smelted alloys. Additional costs are incurred through loss of land because of unnecessary burial and the perpetual care of such burial grounds. Recent international efforts, led by the International Atomic Energy Agency (IAEA), are attempting to set uniform guidance for material recycle/reuse. However, beyond the surface-contamination guidance contained in Regulatory Guide 1.86, there are no applicable regulations in the United States. For recycle or reuse of radioactively contaminated materials, a risk-management system would allow consideration of health risks and costs, and the potential for other effects like the potential effects of low levels of radiation from important industrial products, including electronics equipment.

- Residual Radioactivity Criteria for Decommissioning of Retired Facilities Including Criteria for Release of Lands and Buildings. Release of slightly contaminated lands and buildings after decontamination and decommissioning have occurred largely on a case-by-case basis. The U.S. Nuclear Regulatory Commission (U.S. NRC) is in the process of developing a revised policy regarding residual radioactive materials after decommissioning. The revised policy will use three levels of screening, from highly generic to site-specific, in determining risk-based release criteria (Kennedy and Peloquin 1990). The DOE established guidelines for residual soil radioactivity in DOE 5820.2A (DOE 1988) and a methodology for deriving soil guidelines, the RESRAD computer program (DOE 1989). These guidelines are based on a radiation dose of 100 mrem/yr plus the application of the "as low as reasonably achievable" (ALARA) principle for limiting radiation dose.

- Below Regulatory Concern Criteria for Low-Level Radioactive Waste (LLW) Management. Both the NRC and EPA have published background materials concerning the establishment of BRC criteria; however, the approaches offered by these agencies differ. The NRC favors setting an individual dose limit (10 mrem/yr) and a collective dose criteria (500 person-rem/yr) to assure that the overall population risks are managed. The NRC proposal has been abandoned because of unfavorable comments from the public and agreement states. The EPA favors setting a single individual dose limit of 4 mrem/yr. Both the NRC and EPA draft numbers are within the range of dose values suggested by the IAEA for exemption of radiation sources and practices from regulatory control (IAEA 1988). This subject is of potentially great importance because, through appropriate waste segregation, use of BRC criteria could help conserve the limited LLW disposal space.

- Non-Radioactive Hazardous Materials Criteria. A slightly different situation exists for non-radioactive hazardous materials because of the role of the EPA under CERCLA and RCRA. Neither DOE nor NRC has the authority to set regulations for non-radioactive hazardous materials. However, a clear risk-management framework for implementing standards should include these non-radioactive hazardous materials because doing so would help standardize the process of identifying which regulations contain the applicable, or relevant, and appropriate requirements for a particular site's cleanup.

For cleanup of both radiological and hazardous materials, it will be necessary for Federal and State agencies and members of the public to interact. Those interactions may be more credible if the resultant actions are seen in an overall risk-management context.

Identification of Need

The overall need for the development of risk-based standards for site cleanup stems from the overall responsibility to maintain public health and safety for cleanup and post-cleanup operations. In this context, the goal is to provide a technically credible, risk-based framework to serve as an "umbrella" of safety over operational and management decisions. Development of risk-based standards should serve as the basis or starting point; however, the process of risk management, by necessity, includes community involvement. Community involvement (i.e., public opinion including those expressed through public reviews, or hearings, and by State agencies) may ultimately control many of the regulatory decisions that are reached. This is especially important when site cleanup operations are considered. For example, the overall site cleanup for DOE is estimated to cost many tens of billions of dollars over the next 20 years. Although the cost estimates produced to date vary, in light of the expected high costs, DOE must develop a program of cost reduction while assuring that public health and safety are maintained. Known methods of cost reduction include the use of standardized procedures for site characterization and cleanup, and application of standardized engineering technology; however, the identification and implementation of appropriate standards, including community involvement, are essential to the reduction of costs. Unless acceptable cleanup criteria are established early in the process, cost control will be very difficult.

Discussion of Risk-Based Standards

The term "risk" means different things to different individuals. Before risk-based standards can be promulgated, a consensus must be obtained on what constitutes "risk" for the purposes of the standards. In general, a risk-based standard restricts the probability of occurrence of an event to some predetermined acceptable level (or range of levels). However, the standard can be expressed in a variety of ways. For example, it could be used to limit the risk of cancer in individuals to 1 in 100,000 over their lifetime, or the total incidence of cancer in a population to 1 incidence of fatal cancer per year. Although the standard has risk as its basis, it could also be expressed in other terms, for example the radiation dose in rems that will result in an individual lifetime risk of 1 in 10,000. Agreement on the definition and context of the term "risk" should involve inter-agency discussions and community interactions.

A risk-based standard might also include the probability of a release occurring from a waste site as part of the standard. For example, the high-level waste repository standards limit the maximum release rate, as well as the estimated health risk. This situation may cause a direct conflict because the same quantity of release in different environmental settings will lead to different values of estimated public risk.

The development of risk-based standards requires the selection of an agreed upon target risk level, as shown in Figure 2. Figure 2 shows a general flow chart for the development of risk-based standards and includes a "reality check" to evaluate the reasonableness and technical feasibility of the proposed criteria. This figure is a simplified representation of the steps necessary to establish risk-based standards. There are numerous optional ways to proceed with each of the identified steps in Figure 2. For example, it is not an easy matter to establish the risk term of the standard as indicated by the current debate over the need to establish individual and/or collective dose standards for BRC radioactive wastes. The selection of target risk values is a complex task because it is difficult to get regulatory and societal agreement on what constitutes an acceptable risk. One potential method is to establish a range of risk values that encompasses a generally

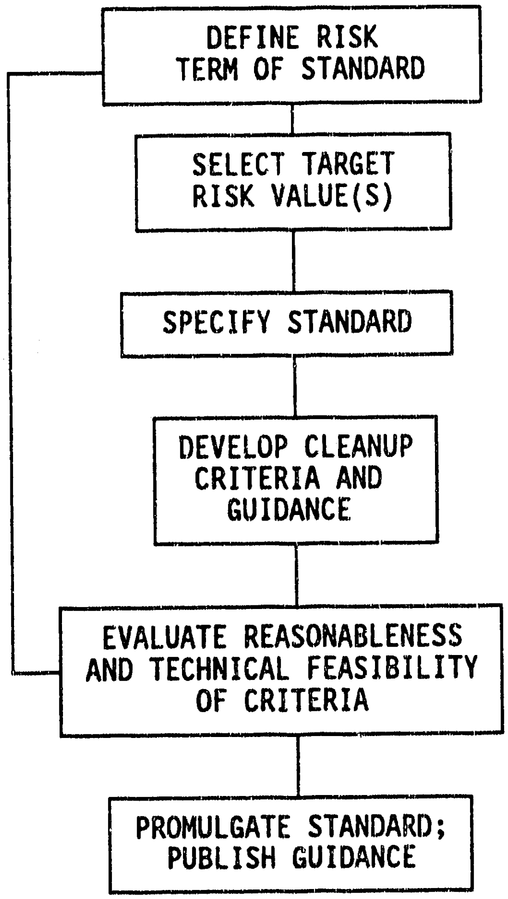

Figure 2. Flow Chart for the Development of Risk-Based Standards

agreed-upon range; however, this may have the disadvantage of relegating related topics to different risk levels. The standard itself may be expressed in terms of dose, contaminant concentration level, cancer incidence, or other units that can be converted to risk only through modeling or other secondary methods. Cleanup criteria may specify technological or engineering methods for decontamination or cleanup, or may include performance statements that define their effectiveness. Finally, there may not be a clear jurisdictional authority for promulgating the standard, as witnessed by the sometimes redundant roles of Federal and State agencies; thus, some level of review and cooperation among all parties is essential.

Issues Related to Implementation

Implementation of risk-based standards can be accomplished through an overall risk-management framework. The two major issues to be addressed, as shown in Figure 1, are resolution of inter/intra agency issues and the development of standardized guidance. Inter/intra agency issues include compatibility with other regulations, development of compliance schedules, and reaching agreements on appropriate regulatory actions. The standardized guidance should establish a framework that accounts for the process of weighing policy alternatives and selecting the most appropriate regulatory actions. This framework needs to be based on high-quality technical information, balanced with community interactions, to assure that credible and defensible regulatory actions are undertaken. The framework should consider engineering data and societal, economic, and political concerns as well. The elements of risk assessment and risk management are shown in Figure 3 (summarized from National Research Council 1983).

Risk assessment is only one aspect of the process of regulatory control for hazardous substances. Risk assessment includes hazard identification and establishing dose-response relationships using research information and data extrapolations. Although the EPA established guidelines for determining the hazard of numerous chemical agents, there will likely be some chemicals encountered during site cleanup that will require further research to determine dose-response relationships. The relationship between generic and site-specific risk assessments using data from field measurements is shown in Figure 3 as risk characterization.

Improvements in risk-assessment methods and risk-characterization methods, and the establishment of risk-based standards, may not eliminate the controversy over risk-management decisions; however, such decisions will be better supported through documentation of the decision process. It is important that agency decisions and actions rely on best data from site characterization (i.e., the use of field measurements to conduct site-specific exposure and risk assessments). Regulatory compliance and agency decisions and actions can be coupled to the site characterization data through statistical methods. For example, at the Hanford Site, the allowable residual contamination level method for decommissioning provides a statistical method for determining the "Upper Confidence Limit" associated with site characterization data (Napier et al. 1988). That is, for a selected compliance confidence limit (like 90 or 95%) the method helps determine the amount of sampling data necessary to support an unrestricted release decision. This approach helps assure a direct link between site-specific data and the agency decision and actions, while optimizing the often expensive site characterization process.

SUMMARY

Because of the responsibility of government agencies and private industry to maintain public health and safety for all cleanup operations, a major goal of cleanup should be to provide a technically credible, risk-based framework to serve as an "umbrella" of safety over all operations. This framework should include the process of weighing policy alternatives and selecting the most appropriate regulatory action using the results of risk assessment and the best engineering data, while considering social, economic and political concerns. The use of risk-based standards in a consistent manner will help streamline and support the decision-making process. The topics of importance to be addressed within the development of risk-based standards include: 1) offsite radiological release criteria for materials management;

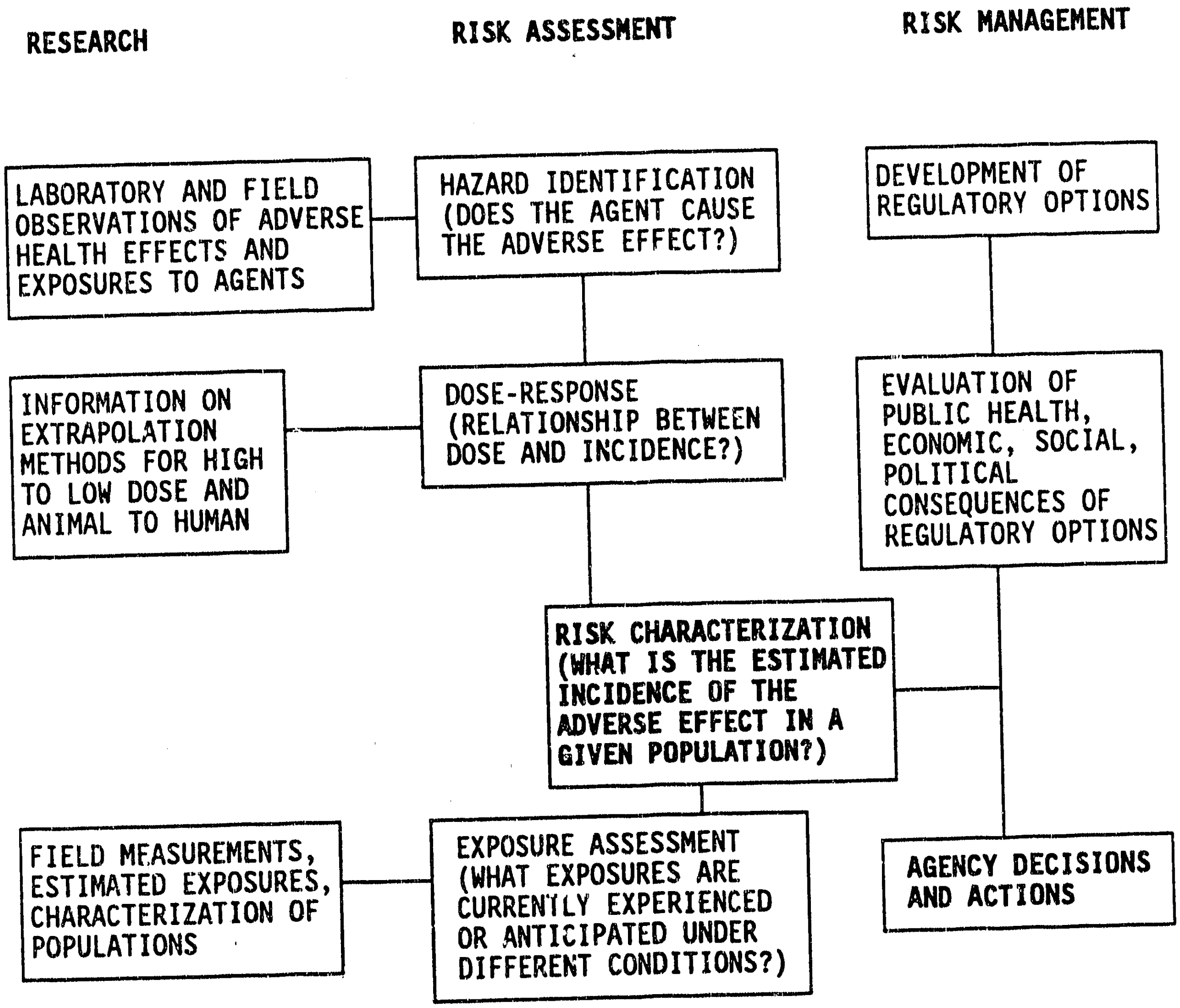

Figure 3. Elements of Risk Assessment and Risk Management

2) radiological criteria for the potential recycle/reuse of tools, equipment, and scrap materials; 3) residual radioactivity criteria for decommissioning of retired facilities including criteria for release of lands and buildings; 4) BRC criteria for LLW management; and 5) non-radioactive hazardous materials criteria. The development of consistent risk-based standards for these topics should serve as a starting point for overall environmental risk management, with recognition that the final regulatory decisions made for the various topics may well be driven by community involvement and inter-agency discussions.

REFERENCES

International Atomic Energy Agency (IAEA). Principles for the exemption of radiation sources and practices from regulatory control. Vienna, Austria: IAEA Safety Series 89; 1988.

Kennedy, W. E., Jr.; Peloquin, R. A. Residual radioactive contamination from decommissioning, technical basis for translating contamination levels to annual dose. Richland, WA: Pacific Northwest Laboratory; NUREG/CR-5512; 1990.

Napier, B. A.; Piepel, G. F.; Kennedy, W. E. Jr.; Schreckhise, R. G. A manual for applying the allowable residual contamination level method for decommissioning facilities on the Hanford Site. Richland, WA: Pacific Northwest Laboratory; PNL-6348; 1988.

National Research Council (NRC). Risk assessment in the federal government: managing the process. Washington, D.C.: National Academy Press; 1983.

U.S. Atomic Energy Agency (AEC). Termination of operating licenses for nuclear reactors. Washington, D.C.: Regulatory Guide 1.86; 1974.

U.S. Department of Energy (DOE). Radioactive waste management: Chapter V, decommissioning of radioactively contaminated facilities. Washington, D.C.: DOE Order 5820.2A, Chapter V; 1988.

U.S. Department of Energy (DOE). A manual for implementing residual radioactive material guidelines; a supplement to U.S. Department of Energy guidelines for residual radioactive material at formerly utilized sites remedial action program and remote surplus facilities management program sites. Washington, D.C.: DOE/CH-8901; 1989.

U.S. Department of Energy (DOE). Radiation protection of the public and the environment: Chapter IV, residual radioactive material. Washington, D.C.: DOE Order 5400.5, Chapter IV; 1990.

END

DATE
FILMED
10/23/92