CHAPTER 2

HISTORY OF RADIATION PROTECTION IN THE UNITED STATES AND CURRENT REGULATIONS

2.1 INTRODUCTION

Radiation from cosmic rays and naturally occurring radioactivity contained in the earth make up the natural radiation background environment in which all life forms have evolved. Society's recognition of radiation began in 1895 with the discovery of X-rays; naturally occurring radioactivity was observed in 1896. These discoveries marked the beginning of the study and use of radioactive substances in science, medicine, and industry.

The discovery of radioactivity led rapidly to the development of medical radiology, industrial radiography, nuclear physics, and nuclear medicine. By the 1920s, the use of X-rays in diagnostic medicine and industrial applications was widespread. Radium was being routinely used in luminescent dials and by doctors in therapeutic procedures. By the 1930s, biomedical and genetic research scientists were studying the effects of radiation on living organisms, and physicists were beginning to understand the mechanisms of spontaneous fission and radioactive decay. In the 1940s, research in nuclear physics had advanced to the point where a self-sustaining fission reaction was demonstrated under laboratory conditions. These events led to the construction of the first nuclear reactors and the development of atomic weapons.

Today, the use of radiation, be it naturally occurring or man-made, is widespread and reaches every segment of our society. Common examples include:

- Nuclear reactors used: (1) to generate electricity, (2) to power ships and submarines, (3) to produce radioisotopes used for research, medical, industrial, space and national defense applications, and (4) as research tools for nuclear engineering and physics

- Particle accelerators used to produce radioisotopes and radiation and to study the structure of matter, atoms, and common materials

- Radioisotopes used in nuclear medicine, biomedical research, and medical treatment

- X-rays and gamma rays used as diagnostic tools in medicine, as well as in diverse industrial applications, such as industrial radiography, luggage X-ray inspections, and nondestructive materials testing

- Common consumer products, such as smoke detectors, luminous-dial wrist watches, luminous markers and signs, cardiac pacemakers, lightning rods, static eliminators, welding rods, lantern mantles, and optical glass

It was soon recognized that the use of radioactive materials would have to be controlled to protect the public, workers, and the environment from radiation exposures. The following sections present a brief history of the evolution of radiation protection activities, their principles and concepts, and U.S. regulatory programs and strategies. Included in this discussion is the influence that certain international advisory bodies, such as the International Commission on Radiological Protection (ICRP), have had on the development of U.S. radiation protection policies. Chapter 3 presents a summary of spent nuclear fuel and high-level waste disposal programs in other countries.

2.2 THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, THE NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, AND THE INTERNATIONAL ATOMIC ENERGY AGENCY

Initially, the dangers and risks posed by X-rays and radioactivity were poorly understood. By 1896, however, "X-ray burns" were being reported in the medical literature, and by 1910, it was understood that such "burns" could be caused by radioactive materials. By the 1920s, sufficient direct evidence (from radium dial painters, medical radiologists, and miners) and indirect evidence (from biomedical and genetic experiments with animals) had been accumulated to persuade the scientific community that an official body should be established to make recommendations concerning human protection against exposure to X-rays and radium.

In 1928, at the Second International Congress of Radiology meeting in Stockholm, Sweden, the first radiation protection commission was created. Reflecting the uses of radiation and radioactive materials at the time, the body was named the International X-Ray and Radium Protection Commission. It was charged with developing recommendations concerning radiation protection. In 1950, to better reflect its role in a changing world, the Commission was reorganized and renamed the International Commission on Radiological Protection.
During the Second International Congress of Radiology, the newly created Commission suggested to the nations represented at the Congress that they appoint national advisory

committees to represent their viewpoints before the Commission and to act in concert with the Commission in developing and disseminating recommendations on radiation protection. This suggestion led to the formation of the U.S. Advisory Committee on X-Ray and Radium Protection in 1929. In 1964, the Committee was congressionally chartered as the National Council on Radiation Protection and Measurements (NCRP).

Throughout their existence, the ICRP and the NCRP have worked closely together to develop radiation protection recommendations that reflect the current understanding of the risks associated with exposure to ionizing radiation (ICR34, ICR38, ICR51, ICR60, ICR65). Neither organization has official status, in that they do not have authority to issue or enforce regulations. However, their recommendations often serve as the basis for the radiation protection regulations adopted by the regulatory authorities in the United States and most other nations.

The International Atomic Energy Agency (IAEA) was chartered in July 1957 as an autonomous intergovernmental organization under the aegis of the United Nations. The IAEA gives advice and technical assistance to Member States on nuclear power development, health and safety issues, radioactive waste management, and on a broad range of other areas related to the use of radioactive material and atomic energy in industry and government. As is the case for ICRP and NCRP, Member States do not have to follow IAEA recommendations. However, funding for international programs dealing with the safe use of atomic energy and radioactive materials can be withheld if Member States do not comply with IAEA recommendations. In addition, in matters related to safeguarding special nuclear material, the full weight of the UN can be brought to bear to “enforce” UN resolutions pertaining to the use of nuclear materials for peaceful purposes. Many of the IAEA recommendations adopt ICRP recommendations with respect to the Commission’s radiation protection philosophy and numerical criteria.

In 1977, the ICRP released recommendations that are in use today. ICRP Publication No. 26 (ICR77) adopted the weighted, whole-body dose equivalent (defined as the effective dose equivalent) concept for limiting occupational exposures. This approach reflected the increased understanding of the differing radiosensitivities of various organs and tissues and was intended to sum exposures from external sources and from internally deposited nuclides. (Note: The concept of summing internal and external exposures to arrive at total dose had been mentioned as early as ICRP Publication No. 1 [ICR60].)

ICRP No. 26 defined the goal of radiation protection as the prevention or limitation of effects from radiation exposure and the assurance that practices involving radiation exposure are justified. The concept of collective dose equivalent for populations was also discussed. The ICRP No. 26 recommendations represented the first explicit attempt to relate and justify permissible radiation exposures with quantitative levels of acceptable risk. The ICRP concluded that "...the mortality risk factor for radiation-induced cancers is about 10^{-4} per rem, as an average for both sexes and all ages... ." The risks of average occupational exposures (about 0.5 rem/year) are roughly comparable to risks experienced in safe industries, 10^{-4} annually. At the permissible limit of 5 rem/year, the risk is comparable with that experienced by some workers in occupations having higher-than-average risk.

For members of the public, the ICRP considered that an annual risk in the range of 10^{-6} to 10^{-5} would likely be acceptable (ICR77). The ICRP recommended an annual individual dose limit of 100 mrem (1 mSv) from all radiation sources. However, the Commission also recognized that an annual individual dose limit of 500 mrem (5 mSv) may be permissible, provided that the average annual effective dose equivalent over a lifetime does not exceed the principal limit of 100 mrem (1 mSv) (ICR85a). No dose limits for populations were proposed.

In 1979, the ICRP issued Publication No. 30 (ICR79) establishing the Annual Limit on Intake (ALI) system for limiting the intake of radionuclides by workers. The ALI is the activity of a given nuclide that would irradiate a person to the limit set in ICRP No. 26 for each year of occupational exposure. It is a secondary limit, based on the primary limit of equivalent whole-body irradiation, and applies to intake by either ingestion or inhalation. The recommendations of ICRP No. 30 applied only to occupational exposures. In 1983, the ICRP issued a statement (ICR84) clarifying the use of ALIs and Derived Air Concentrations (DACs) for members of the public.

In 1985, the ICRP issued a statement (ICR85a) refining dose limits for members of the public. ICRP No. 26 had endorsed an annual limit of 500 mrem, subject to certain conditions. In making this endorsement, it was assumed that the conditions would, in practice, restrict the average annual dose to about 100 mrem. In its 1985 statement, the Commission stated that the principal limit was 100 mrem, while occasional and short-term exposures up to 500 mrem were thought to be acceptable.

The Commission has also published guidance for waste disposal (ICR85b) and for general radiological protection (ICR91). The first of these, "Radiation Protection for the Disposal of Solid Radioactive Waste," emphasizes an individual-risk approach that considers both the probability of a breach of a disposal site and its consequence upon the critical group.

In 1987, the NCRP issued Report No. 91 (NCR87), which acknowledged the assumptions and the basic thrust of the recommendations in ICRP Reports 26 and 30. In discussing risk estimates, the NCRP noted in its report that new data were becoming available that might require changes in the current estimates. However, the value recommended in ICRP No. 26 of 10^{-4} per rem was retained for a nominal lifetime somatic risk for adults.

The NCRP also noted that continuous annual exposure to 100 mrem gives a person a mortality risk of about 10^{-5} annually, or approximately 10^{-3} in a lifetime (NCR87). Similar to the 1985 ICRP statement, annual limits of 500 mrem were recommended for infrequent exposures and 100 mrem for continuous (or frequent) exposures. These limits do not include natural background or medical exposures.

In 1989, the IAEA issued reports 96 and 99 in its Safety Series (IAE89a, IAE89b). These documents presented criteria and guidance for the underground disposal of nuclear waste. Safety Series No. 99, "Safety Principles and Technical Criteria for the Underground Disposal of High-Level Radioactive Wastes," set out basic design objectives to ensure that "humans and the human environment will be protected after closure of the repository and for the long periods of time for which the wastes remain hazardous." The report went on to state that for releases from a repository due to gradual processes, the dose upper bound should be less than an annual average dose value of 1 mSv (i.e., 100 mrem/yr)[6] for prolonged exposures for individuals in the critical group (defined as the members of the public whose exposure is relatively homogeneous and is typical of individuals receiving the highest effective dose equivalent or dose equivalent from a given radiation source). Finally, it suggested a risk upper bound of 10^{-5} per year for an individual for disruptive events.

In 1990, the ICRP issued Publication 60, which broadened its recommendations to include a wider range of exposure scenarios than had been previously addressed. Publication 60 also gave

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[6] The ICRP has adopted the international system of units (SI). Under this system, 1 Sv equals 100 rem. As such, 1 mSv equals 100 mrem.

support to new concepts in the field of radiation exposure protection, most notably the ALARA (as low as reasonably achievable) concept of worker protection optimization. The ALARA principle suggests dose limits should be set at the lowest levels reasonably possible for a given scenario. In recent years, several international organizations, including the Council of the European Communities (CEC) and the Organization for Economic Cooperation and Development/Nuclear Energy Agency's (OECD/NEA's) Committee on Radiation Protection and Public Health (CRPPH), have worked to interpret this principle and develop guidelines for its practical use (NEA94). The formality with which the ALARA principle has been adopted varies widely internationally. In many cases, the ALARA principle is being applied only as part of a nonquantified conceptual framework within which protection measures are implemented; in other countries, the application of the ALARA approach to worker safety is becoming increasingly formalized (OEC95a).

In recent years, the IAEA has been developing new international safety standards and guidance documents. Foremost among these is "International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources," known as BSS (Basic Safety Standards, Safety Series 115-I). The BSS was approved by the IAEA Board of Governors in 1994 and published as an interim document in December 1995. A joint effort of the Food and Agricultural Organization of the United Nations, the International Labor Organization, the OECD/NEA, the Pan-American Health Organization, and the World Health Organization, the BSS is notable primarily for its movement toward an integrated approach to managing exposure risk in which potential but unlikely events (such as accidents) are evaluated along with comparatively normal, likely scenarios for exposure. Previously, safety assessment had focused only on comparatively normal, likely scenarios (OEC95a). IAEA has also been developing a comprehensive set of safety standards for radioactive waste management called Radioactive Waste Safety Standards (RADWASS). RADWASS includes a safety fundamentals document entitled "The Principles of Radioactive Waste Management" and a safety standard document entitled "Establishing a National Safety Standard for Radioactive Waste Management." Both of these were approved by the IAEA Board of Governors and published in October 1995. Three other safety standards (S-2, S-3, and S-6) addressing predisposal management of radioactive waste, near-surface disposal of radioactive waste, and decommissioning are under review (OEC95b). The entire RADWASS series is currently under review to ensure harmonization with Safety Series Publications and BSS documents.

Criteria development is also continuing through an IAEA Working Group on Principles and Criteria for Radioactive Waste Disposal. The working group's focus includes post-closure monitoring, optimization, retrievability, dose vs. risk, and safety indicators under different time frames. The group's first report, entitled *Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories,* was published in 1994 (SNI95).

In recent years, the CEC has been developing directives on radiation safety standards for radiation exposures established under European Atomic Energy Community (EURATOM) agreements. In accordance with ICRP recommendations, the CEC suggested in 1993 that doses to members of the public be limited to 100 mrem per year from all sources except medical and that occupational doses be limited to 2,000 mrem annually. The CEC is also expected to propose criteria for the shipment of radioactive waste among member countries and for the export of radioactive waste to nonmember countries (OEC93).

Finally, in 1989, Radiation Protection and Nuclear Safety authorities in Denmark, Finland, Iceland, Norway, and Sweden developed a set of safety criteria for the disposal of high-level radioactive waste. Revised in 1993 after international review, the Nordic Principles are largely consistent with other criteria developed on the international level. The Principles outline a radiation protection approach employing the concept of optimization and an individual dose limit of 0.1 millisievert (10 mrem) per year. Basic guiding objectives for HLW disposal programs include reduction of burden for future generations, long-term environmental protection, and the use of specific safety assurance measures. Finally, the Principles contain technical recommendations for repository design, site geology, and closure (SNI95).

2.3 FEDERAL RADIATION COUNCIL GUIDANCE

The Federal Radiation Council (FRC) was established in 1959 by Executive Order 10831. The Council arose as a result of new information that became available in the 1950s on the effects of radiation. Before that time, only nongovernmental radiation advisory bodies (i.e., ICRP and NCRP) existed, and their recommendations were not binding on users of radiation or radioactive materials. The FRC was established as an official Government entity and included representatives from all Federal agencies concerned with radiation protection. The Council served as the primary coordinating body for all radiation activities conducted by the Federal Government (FRC60a) and was responsible for:

...advising the President with respect to radiation matters, directly or indirectly affecting health, including providing guidance to all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States... .

The Council's first recommendations concerning radiation protection guidance for Federal agencies were approved by President Eisenhower in 1960 (FRC60b). The guidance established exposure limits for members of the general public. These included the yearly radiation exposure of 0.5 rem per year for the whole body of individuals in the general population and an average gonadal dose of 5 rem in 30 years for the general population (exclusive of natural background and the purposeful medical exposure of patients).

The guidance also established occupational exposure limits, which differed only slightly from those recommended by the NCRP and ICRP at the time (NCR54, NCR59). The guidance included:

- Whole body, head and trunk, active blood-forming organs, gonads or lens of the eyes are not to exceed 3 rem in 13 consecutive weeks, and the total accumulated dose is limited to 5 rems multiplied by the number of years beyond age 18, expressed as 5(N-18), where N is the current age

- Skin of the whole body and thyroid are not to exceed 10 rem in 13 consecutive weeks or 30 rem per year

- Hands, forearms, feet, and ankles are not to exceed 25 rem in 13 consecutive weeks or 75 rem per year

- Bone is not to exceed 0.1 microgram of radium-226 or its biological equivalent

- Any other organs are not to exceed 5 rem in 13 consecutive weeks or 15 rem per year

In addition to the formal exposure limits, the guidance also established as Federal policy that any radiation exposure should be justified and that "...every effort should be made to encourage the maintenance of radiation doses as far below this guide as practicable... ." Both of these concepts had previously been proposed by the ICRP. The inclusion of the requirements to consider benefits and keep all exposures to a minimum was based on the possibility that there is no threshold for radiation. The linear, nonthreshold, dose-response relationship was assumed to place an upper limit on the estimate of radiation risk. However, the FRC explicitly recognized that it might also represent the actual level of risk.

Following the issuance of this initial guidance, the FRC continued to provide guidance on a number of radiation protection matters. In 1970, the Council was dissolved, and its functions were transferred to the Environmental Protection Agency under authority of Reorganization Plan No. 3 (NIX70).

2.4 ENVIRONMENTAL PROTECTION AGENCY

Since its creation in 1970, the EPA has issued regulatory standards regarding radiation hazards from a number of different sources, including underground mining (EPA71), the uranium fuel cycle operations (EPA77), uranium and thorium mill tailings (EPA83), radionuclide air emissions (EPA89a), and management and disposal of spent nuclear fuel and high-level and transuranic radioactive wastes (EPA93). Recently, EPA issued compliance criteria for the WIPP (EPA96). EPA is currently developing a standard for the disposal of contaminated soil at decommissioned sites, including Federal facilities.

The Agency has also exercised its authority to issue Federal guidance to limit radiation exposures to workers (EPA87), as well as to the general public. In December 1994, EPA issued proposed Federal guidance to update the previous Federal Radiation Protection Guidance for Exposure to the General Public which was originally adopted in 1960 and 1961 (EPA94). The Agency is now finalizing these new recommendations.

EPA has also provided extensive technical information regarding the assessment of risk from radiation hazards. Specific examples of such information include radionuclide intake limits, occupational radiation doses, biological parameters, and dose conversion factors (EPA88). This information has been used extensively in the development of EPA standards and guidance, as well as specific site assessments.

In addition to its responsibility to provide Federal guidance on radiation protection, the EPA has various statutory authorities and responsibilities for regulating exposure to radiation. The standards and regulations that EPA has promulgated and proposed with respect to controlling radiation exposures are summarized in the following paragraphs. Their applicability to EPA's proposed standards under 40 CFR Part 197 is also discussed.

2.4.1 Environmental Radiation Exposure

The Atomic Energy Act (AEA) of 1954, as amended, and Reorganization Plan No. 3 granted the EPA the authority to establish generally applicable environmental standards for exposure to radiation (AEA54, NIX70). The AEA is the cornerstone of current radiation protection activities and regulations. In 1977, pursuant to this authority, the EPA issued standards limiting exposures from operations associated with the light-water reactor fuel cycle (EPA77). These standards, under 40 CFR Part 190, cover normal operations of the uranium fuel cycle. The standards limit the annual dose equivalent to any member of the public from all phases of the uranium fuel cycle (excluding radon and its daughters) to 25 mrem to the whole body, 75 mrem to the thyroid, and 25 mrem to any other organ. To protect against the buildup of long-lived radionuclides in the environment, the standards also set normalized emission limits for krypton-85, iodine-129, and plutonium-239 combined with other transuranics with a half-life exceeding one year. The dose limits imposed by the standards cover all exposures resulting from radiation and radionuclide releases to air and water from operations of fuel-cycle facilities. The development of these standards took into account both the maximum risk to an individual and the overall effect of releases from fuel-cycle operations on the population, and balanced these risks against the costs of effluent control.

2.4.2 Environmental Impact Assessments

In 1969, Congress passed the National Environmental Policy Act (NEPA), which declared a national policy that encouraged a productive and enjoyable harmony between the public and the environment (NEP70). The Act recognized the profound impact of human activity on the interrelations of all components of the natural environment and sought to promote efforts to prevent or eliminate damage to the environment. To this end, the national policy is geared towards increasing the understanding of the ecological systems and natural resources important to the United States. In addition, the Act established a Council on Environmental Quality to assist the President in determining the state of the environment and developing environmental policy initiatives.

The Act also directed all Federal agencies to use a systematic, interdisciplinary approach to ensure the integrated use of natural, social, and environmental sciences in support of plans and decisions that have a potential impact on the environment. Specifically, it mandated that a detailed Environmental Impact Statement (EIS) be submitted for any major action proposed by a Federal agency or for legislation that would significantly affect the quality of the environment. The EIS must describe any adverse environmental effects that the proposal would cause, alternatives to the proposed action, effects of the project on the long-term productivity of the environment, and any irreversible and irretrievable commitment of resources involved in the proposed action. The EIS must also be prepared through consultation with any Federal agency having jurisdiction or special expertise regarding the project and its environmental impact.

The Final EIS prepared by the Department of Energy for the Yucca Mountain site must comply with NEPA requirements.

2.4.3 Ground Water Protection

The Safe Drinking Water Act (SDWA) was enacted to assure safe drinking water supplies and to protect against endangerment of underground sources of drinking waters (USDWs). Under the authority of the SDWA, the EPA issued interim regulations (40 CFR Part 141, Subpart B) covering the permissible levels of radium, gross alpha, man-made beta, and photon-emitting contaminants in community water supply systems (EPA76). Similar to hazardous chemical substances, limits for radionuclides in drinking water are expressed as Maximum Contaminant Levels (MCLs). The current MCL for radium-226 and radium-228 combined is 5 picoCuries per liter (5 pCi/L), and the MCL for gross alpha particle activity (including radium-226, but excluding radon and uranium) is 15 pCi/L. For man-made beta particle- and photon-emitting radionuclides (except tritium and strontium-90), individually or in combination, the MCL is set at an annual dose limit of 4 millirem to the total body or any internal organ. For tritium and strontium-90, the MCLs are 20,000 pCi/L and 8 pCi/L, respectively.

In 1991, the EPA issued a Notice of Proposed Rulemaking (NPRM) under 40 CFR Parts 141 and 142 to update the 1976 interim regulations for radionuclide water pollution control (EPA91). The NPRM, under the SDWA, proposed the establishment of Maximum Contaminant Level Goals (MCLGs) and Maximum Contaminant Levels (MCLs). The MCLGs and MCLs target radium-226, radium-228, natural uranium, radon, gross alpha, gross beta, and photon emitters. As proposed, MCLGs are not enforceable health goals. In contrast, MCLs are enforceable standards. The EPA concluded that radionuclide MCLGs should be set at zero to avert known or anticipated adverse health effects while providing an adequate margin of safety. In setting the MCLGs, the EPA also committed itself to evaluating the feasibility, costs, and availability of water treatment technologies, as well as other practical considerations. The proposed regulations state the following MCLs: radium-226, 20 pCi/L; radium-228, 20 pCi/L; radon-222, 300 pCi/L; uranium, 20 micro g/L; adjusted gross alpha, 15 pCi/L; and beta and photon emitters, 4 mrem ede/yr.

Over the past 20 years, the EPA has used two different methods to calculate radioactivity concentrations for beta particle and photon emitting radionuclides in drinking water corresponding to the MCL of 4 mrem/yr. Each method incorporates successive improvements in the risk models and dose conversion factors for ingested radioactivity recommended by national and international advisory committees on radiation protection and adopted by the Agency.

The first method is a requirement (§141.6(b)) of EPA's 1976 Interim Regulations. It specifies that, with the exception of tritium and strontium-90, the concentration of beta/photon emitters causing 4 millirem (mrem) total body or organ dose equivalent shall be calculated on the basis of a 2 liter per day drinking water intake using the 168 hour data listed in Handbook 69 of the National Bureau of Standards (NBS63). The dose models used in preparing Handbook 69 are based on earlier recommendations of the International Commission on Radiological Protection (ICR60). For tritium and strontium-90, the EPA provides derived activity concentrations in Table A of §141.6(b) based on specific dose models for these nuclides.

The second method is presented in EPA's 1991 proposed rule on final drinking water standards for radionuclides (EPA91). This method is based primarily on the updated dosimetric data in ICRP Publication 30 (ICR79) and uses the Agency's own risk assessment methodology formalized in the RADRISK computer code (DUN80). Under this approach, concentration levels are calculated for each radionuclide individually by limiting the dose to the total body (i.e., the effective dose equivalent or ede) to 4 mrem/yr ede, rather than on a dose rate of 4 mrem/yr to the critical organ. Similar to the first method, the second method assumes continuous intake of activity over a lifetime at a rate of 2 liters of drinking water per day.

2.4.4 Radionuclide Air Emissions

In December 1979, the EPA designated radionuclides as hazardous air pollutants under Section 112 of the Clean Air Act (CAA) Amendments of 1977 (Public Law 95-95) (EPA79). In April 1983, the EPA proposed standards regulating radionuclide emissions from four source categories, one of which included U.S. Department of Energy (DOE) facilities. The rule established annual airborne emission limits for radioactive materials and specified that annual doses resulting from such emissions should not exceed 25 mrem to the whole body and 75 mrem to any critical organ for members of the general public. The EPA also proposed not to regulate several other categories of facilities, including high-level radioactive waste disposal facilities. EPA based its decision with respect to high-level waste disposal facilities on estimated releases from conceptual repositories that indicated that the airborne exposure pathway would not cause doses high enough to warrant regulation.

In October 1984, following a court order, the EPA withdrew the proposed emission standards based on the findings that the control practices already in effect protected the public from radionuclide releases with an ample margin of safety. The Agency also affirmed its position not to regulate other categories of emission sources, including uranium fuel facilities and high-level radioactive waste.

In December 1984, a U.S. District Court found the EPA in contempt of its order and directed the EPA either to issue final radionuclide emission standards or make a finding that radionuclides are not hazardous air pollutants. The EPA complied with the court order in 1985 by issuing standards for selected sources (EPA85a, EPA85b). As a result of the decision in *National Resources Defense Council Inc. v. EPA,* November 1987, the Agency submitted a motion to the court requesting a voluntary remand of its national emission standards for the four original categories of emission sources proposed in April 1983. In December 1987, the Court granted the EPA's motion for voluntary remand and established a schedule to propose new regulatory standards within one year. The Court decision also defined the analytical process under which the EPA was to re-evaluate its standards. Two steps were identified: (1) determine what is safe, based exclusively on health risk, and (2) adjust the level of safety downward to provide an ample margin of safety.

In March 1989, the EPA issued a proposed rule for regulating radionuclide emissions under the CAA following the re-examination of the regulatory issues associated with the use of Section 112 (EPA89a). The rule proposed four policy alternatives to control emissions and risks from 12 categories of sources. Each of the four approaches considered the acceptable risk criterion differently. The four approaches were:

- Case-by-Case Approach: Acceptable risk considers all health information, risk measures, potential biases, assumptions, and quality of the information. The maximum individual lifetime fatal cancer risk must not exceed 1×10^{-4}.

- Incidence-Based Approach: Based on the best estimate of the total incidence of fatal cancer. The proposed acceptable level of incidence must not exceed one fatal cancer per year per source category.

- Maximum Individual Risk Approach (10^{-4} or less): Only risk indicator considered is the best estimate of the maximum individual lifetime risk of fatal cancer. The maximum individual lifetime risk must not exceed 1×10^{-4}.

- Maximum Individual Risk Approach (10^{-6} or less): This approach is similar to the previous one. The maximum individual lifetime risk, however, must not exceed 1×10^{-6}.

Consistent with the two-step process established by the Court, the Agency determined an ample margin of safety after ascertaining a safe level based solely on health risks. In reaching its final decision, the EPA considered all health risk measures, as well as technological feasibility, costs, uncertainties, economic impacts of control technologies, and any other relevant information.

In its radionuclide emission standards, EPA considered a lifetime risk to an individual of approximately 1 in 10,000 as acceptable. The presumptive level provides a benchmark for judging the acceptability of maximum individual risk, but does not constitute a rigid line for making that determination.

In its final rule, EPA concluded that there was no need to establish air emission standards for high-level waste disposal repositories since anticipated operations at the site would be governed by 40 CFR Part 191. Radioactive materials received at such facilities are sealed in containers. Normal operations do not require additional processing or handling because spent nuclear fuel or high-level waste is received and emplaced into the ground in its original containers. Operations at the disposal site, which may require additional waste processing or repackaging before the site is declared a disposal facility, are covered by 40 CFR Part 191 and must comply with Subpart I of the National Emission Standards for radionuclides[7] (EPA89b). Consequently, the Agency believed there is an ample margin of safety since the likelihood of releases, and attendant risks, is very low.

2.4.5 Disposal of High-Level Radioactive Waste and Spent Nuclear Fuel

Congress passed the Nuclear Waste Policy Act (NWPA) of 1982 to provide for the development of repositories for the disposal of high-level radioactive waste and spent nuclear fuel, and to establish a program of research, development, and demonstration regarding this disposal (NWP83). The Act established a schedule for the siting, construction, and operation of repositories that would provide a reasonable assurance that the public and environment would be adequately protected from the hazards posed by high-level radioactive waste. The Secretary of Energy was charged with nominating candidate sites for a repository and following a number of steps through a process of Presidential and Congressional approval, site characterizations, public participation, and hearings. The Act also required the Secretary to adhere to NEPA in considering alternatives and to prepare an EIS for each candidate site.

Initially the Act called for the development of two mined geologic repositories. The first repository was to be selected from nine candidate sites in western states; the second repository was to be located in the eastern United States in crystalline rock. EPA was charged with the responsibility of promulgating generally applicable standards for the protection of public health and the environment from off-site releases from radioactive material in repositories. The NRC, in turn, was responsible for promulgating technical requirements and criteria consistent with EPA's standards to serve as the basis for approving or disapproving applications regarding the use, closure, and post-closure of the repository. The Act also discussed interim waste storage requirements, as well as the payment of benefits to affected States and tribal groups to allow them sufficient resources to participate fully in the process.

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[7] Subpart I of the National Emission Standard can be found in 40 CFR Part 61.101 and is entitled “National Emission Standard for Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission (NRC) and Federal Facilities Not Covered by Subpart H.” Subpart H of the National Emission Standard addresses radionuclide standards for DOE facilities.

In 1987, the NWPA was amended to reflect a redirection of the nuclear waste program. The generic nature of the original act was changed to reflect the selection of the Yucca Mountain site in Nevada as the only candidate site for the repository (NWP87). The State of Nevada was also identified as the affected community. All site-specific activities at other candidate sites were phased out, and the Final EIS, necessary for compliance with the NEPA, was to be prepared specifically for the Yucca Mountain site without further consideration of alternative sites. The redirection charged DOE with reporting to Congress on the potential social, economic, and environmental impacts of locating the repository at Yucca Mountain.

2.4.5.1 Generic Disposal Standards for High-Level and Transuranic Wastes

As discussed in Chapter 1, the First Circuit Court of Appeals remanded Subpart B of EPA's standards for the management and disposal of spent nuclear fuel and high-level and transuranic waste (40 CFR Part 191) in 1987. (See Section 1.3.4 for additional detail regarding the Court's action on 40 CFR Part 191.) The Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA) of 1992 reinstated all of the disposal standards remanded by the First Circuit Court of Appeals in 1987 except the three aspects of the individual and ground water protection requirements that were the subject of the court remand (WIP92). It then put the Agency on a schedule for issuing the final disposal standards. They were published in December 1993. The law also provided an extensive role for EPA in reviewing and approving various phases of DOE activities at the WIPP and required EPA to certify whether the WIPP repository would meet the final 40 CFR Part 191 standards. Finally, and of greatest importance to the current rulemaking, the WIPP LWA exempted radioactive waste disposal activities at Yucca Mountain from compliance with the generic standards set forth under the 40 CFR Part 191 standards.

2.4.5.2 Site-Specific Disposal Standards for High-Level Radioactive Waste

The Energy Policy Act (EnPA) of 1992 addressed energy efficiency throughout the United States in different situations and for various types of fuel. Title VIII of the Act dealt specifically with high-level radioactive waste. Section 801 of the EnPA assigned EPA the responsibility of promulgating public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of in the repository at the Yucca Mountain site. EPA is to prescribe a maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository (EnPA92). The Act also requires that the standards developed be based upon and consistent with the findings and recommendations of the NAS. Specifically, the NAS was charged with considering: the use of a dose-based standard, the reasonableness of post-closure oversight in preventing breaches, and the predictability of human intrusion over a period of 10,000 years. NAS's findings and recommendations were published on August 1, 1995, in its report *Technical Bases for Yucca Mountain Standards* (NAS95). These standards will apply only to Yucca Mountain.

2.4.6 Evaluation of Radiation Dose

The radiation dose incurred by an exposed individual is evaluated using the "committed effective dose equivalent" (CEDE) concept. The CEDE is the weighted sum of the "committed dose equivalent" to specified organs and tissues. The committed effective dose equivalent is the total effective dose equivalent, averaged over a given tissue or organ, that is deposited in the 50-year period following the intake of a radionuclide.

The CEDE approach to dose evaluation therefore takes into account the differing dose effects of various radionuclides in specific parts of the body over time, and the differing dose effects of external exposure to ionizing radiations of different types and energy levels. It accounts, for example, for the fact that some radionuclides that are taken into the body will be rapidly excreted after ingestion or inhalation, so that the dose effect is small. Other radionuclides may be retained indefinitely in specific organs so that if the decay rate is low and exposure continues over time, the body burden of the dose source, and therefore the dose committed to the organ, will continually increase with time. In general, the dose incurred will depend on the types and concentrations of radionuclides present, the conditions and duration of exposure, the biological half-life of the radionuclide in the body, and the effects of exposure on organs and tissues of the body.

Ability to apply the CEDE approach to dose evaluation is the result of a decades-long evolutionary process which has developed a data base for, and an understanding of, the physiological effects of radiation exposure. A brief history of the evolution of information and methodology for radiation dose evaluation, and a description of the CEDE methodology, are set forth in EPA's Federal Guidance Report No. 11 (EPA88). This document also contains tables of values for the committed dose equivalents per unit uptake for various radionuclides taken into the body and for various body organs and tissues.

In 1993, EPA issued a companion report, Federal Guidance Report No.12 (EPA93a), which tabulates dose coefficients for external exposure to photons and electrons emitted by radionuclides distributed in air, water, and soil. The dose coefficient values provided in this document are, like those in Federal Guidance Report No.11, intended to be used by government agencies to calculate the dose equivalent to organs and tissues of the body for given exposure conditions.

2.5 NUCLEAR REGULATORY COMMISSION

The NRC was created as an independent agency by the Energy Reorganization Act (ERA) of 1974 (ERA74), which abolished the AEC and moved the AEC's regulatory function to the NRC. This Act, coupled with the AEA, as amended, provided the foundation for regulation of the nation's commercial nuclear power industry. NRC regulations are issued under the U.S. Code of Federal Regulations Title 10 Chapter 1.

The mission of the NRC is to ensure adequate protection of public health and safety, the national defense and security, and the environment in the use of nuclear materials in the United States. The NRC's scope of responsibility includes regulation of commercial nuclear power reactors; nonpower research, test, and training reactors; fuel cycle facilities; medical, academic, and industrial uses of nuclear materials; and the transport, storage, and disposal of nuclear materials and waste. In addition to licensing and regulating the use of byproduct, source, and special nuclear material, the NRC is also responsible for assuring that all licensed activities are conducted in a manner that protects public health and safety. The NRC assures that none of the operations of its licensees expose an individual of the public to more than 100 mrem/yr from all pathways (NRC91).

The dose limits imposed by the EPA's standards for uranium fuel-cycle facilities (40 CFR Part 190) apply to the fuel-cycle facilities licensed by the NRC. These facilities are prohibited from releasing radioactive effluents in amounts that would result in doses greater than the 25 mrem/yr limit imposed by that standard. Currently, NRC-licensed facilities are also required to operate in accordance with the requirements of the CAA (40 CFR Part 61), which limits radionuclide emissions into the air (EPA89b).[8]

The NRC exercises its statutory authority over licensees by imposing a combination of design criteria, operating parameters, and license conditions at the time of construction and licensing. It assures that the license conditions are fulfilled through inspection and enforcement activities.

2.5.1 Fuel Cycle Licensees

The NRC licenses and inspects all commercial fuel cycle facilities involved in the processing and fabrication of uranium ore into reactor fuel. NRC regulations require an analysis of probable radioactive effluents and their effects on the population near fuel cycle facilities. The NRC also assures that all exposures are maintained as low as reasonably achievable (ALARA) by imposing design criteria for effluent control systems and equipment. After a license has been issued, fuel-cycle licensees must monitor their emissions and set up an environmental monitoring program to assure that the design criteria and license conditions have been met.

2.5.2 Radioactive Waste Disposal Licenses

The NWPA, as amended, specifies a detailed approach for high-level radioactive waste disposal. DOE has operational responsibility and the NRC has licensing responsibility for the transportation, storage, and geologic disposal of the waste. The disposal of high-level radioactive waste requires a determination of acceptable health and environmental impacts that may occur over a period of thousands of years. Current plans call for the ultimate disposal of waste in solid form in a licensed, geologic disposal system. The NWPA, as amended, designates Yucca Mountain, Nevada, as the candidate site for the high-level waste repository.

The EnPA provides additional direction to the NRC as to its role in the licensing of a specific disposal site at Yucca Mountain. Section 801 of the EnPA requires the Commission to modify its technical requirements and criteria under section 121(b) of the NWPA of 1982, as necessary, to be consistent with EPA's standards for the Yucca Mountain site. The NRC's requirements

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[8] Pursuant to Section 112(d)(9) of the CAA Amendments of 1990, EPA is proposing to rescind Subpart I as it applies to NRC-licensed facilities. The NRC is proposing to adopt a constraint level rule which would limit radionuclide airborne emissions to 10 mrem/yr.

and criteria shall assume that engineered barriers and post-closure oversight provided by the DOE will be sufficient to: (1) prevent any activity at the site that poses an unreasonable risk of breaching the repository's engineered or geological barriers and (2) prevent any increase in the exposure of individual members of the public to radiation beyond allowable limits (EnPA92).

NRC's original generic regulations governing deep geologic disposal (which were largely developed prior to the EnPA) are contained in 10 CFR Part 60 entitled *Disposal of High-level Radioactive Wastes in Geologic Repositories* (NRC81, NRC83). However, since the EnPA specifies that sites for consideration be limited to Yucca Mountain and since the legislation specifies the types of standards the Commission is to implement, NRC decided to promulgate site specific standards for Yucca Mountain at 10 CFR Part 63. The proposed rule is entitled *Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada* (*Federal Register*, February 22, 1999). The proposed rule applies only to Yucca Mountain. The generic rule at 10 CFR Part 60 will be modified to indicate that does not apply to Yucca Mountain nor can it be used as a basis for litigation in NRC's Yucca Mountain licensing procedures. The proposed 10 CFR Part 63 regulations are summarized below. In addition, the NRC promulgates (under 10 CFR Part 71) packaging criteria for the transportation of spent nuclear fuel and high-level and transuranic radioactive wastes. Under 10 CFR Part 72, the NRC licenses independent spent nuclear fuel storage facilities (NRC88).

Under the proposed 10 CFR Part 63, DOE is required to conduct site characterization activities prior to submitting a license application and to regularly report on these activities to NRC. When DOE submits the license application it must contain certain prescribed general information and a Safety Analysis Report. The license application must be accompanied by an environmental impact statement. The prescribed general information includes:

- A general description of the proposed geologic repository
- Proposed schedules for construction, receipt of waste, and emplacement of wastes
- A detailed plan to provide physical protection of the waste
- A description of the material control and accounting program
- A description of the site characterization work

The Safety Analysis Report is a comprehensive document with 22 prescribed elements including such items as a description and discussion of the engineered barriers system, an assessment of the expected performance after closure, an explanation of how expert elicitation was used, and a description of the quality assurance program.

After review of the license application and the environmental impact statement, NRC may authorize construction of the geologic repository operations area. In deciding whether to provide such authorization to DOE, NRC will examine safety, common defense and security and environmental values in making its determination that construction can begin.

The NRC may subsequently issue a license to DOE to receive nuclear waste if it finds that construction has been substantially completed, that the proposed activities in the operations area are in conformity with the application, that the issuance of a license is not inimical to common defense and security and will not constitute and unreasonable risk to public health and safety, and that adequate protective measures can be taken in the event of a radiological emergency at any time before permanent closure. The NRC license will contain a variety of conditions relating to:

- Restrictions on the physical and chemical form and radioisotopic content of the waste

- Restrictions on the size, shape, and materials and methods of construction of the waste packages

- Restrictions on the volumetric waste loading

- Testing and inspection requirements to assure that any restrictions are met

- Controls to limit access and prevent disturbance of the site

- Administrative controls to assure that site activities are conducted in a safe manner and in accordance with license requirements

Once the waste has been emplaced, DOE is required to file an application to amend the license for permanent closure. The DOE submission shall include, inter alia, a updated performance assessment of the geologic repository, and a detailed plan for post-closure monitoring of the site including land use controls, construction of monuments and preservation of records. Upon completion of permanent closure activities and D&D of surface facilities, DOE can then apply for an amendment to terminate the license.

2.5.3 Repository Licensing Support Activities

The current NRC repository licensing program consists of both proactive and reactive activities. Proactive activities include developing and reviewing regulatory requirements and guidance to identify and resolve regulatory and technical uncertainties. Regulatory uncertainties exist where regulatory requirements are ambiguous and could be subject to various interpretations. Technical uncertainties are related to demonstrating compliance with a particular regulation.

The NRC staff is currently developing and implementing performance assessment models using Yucca Mountain site data. The models will assist the NRC in performing a technical assessment of the site, as well as identifying areas of regulatory and technical uncertainty during the license application review process. The uncertainties identified must be addressed in a timely fashion so that the NRC can meet the three-year license review schedule mandated by the NWPA. Additional details are provided in Chapter 7.

These activities have produced licensing review plans in anticipation of the DOE submissions. They include review of the SCP, Study Plan, and Quality Assurance Plan (QAP).

The major focus of pre-licensing activities has been on 10 key technical issues (KTIs) that NRC has identified as being most important to repository performance. NRC's objective is to seek staff-level resolution of these issues during pre-licensing consultation with DOE although the procedure does not preclude rasing the issues during the licensing process. These issues are:

- Total system performance assessment
- Unsaturated and saturated flow under isothermal conditions
- Evolution of the near-field environment
- Container life and source term
- Repository design and thermal-mechanical effects
- Thermal effects on flow
- Radionuclide transport
- Structural defomation and seismicity
- Igneous activity
- Activities related to NRC high-level radioactive regulations

NRC periodically publishes Issue Resolution Status Reports (IRSRs) which provide DOE with feedback on KTI subissues. For example, NRC published IRSR Revision 1, on total system performance assessment and integration, in November 1998 (NRC98). The report documents the acceptance criteria NRC proposes to use for addressing each identified KTI subissue and the review method NRC plans to use in determining whether or not the each acceptance criterion has been met. As of the November date, 18 subissues relating to total system performance assessment and integration had been resolved and 13 remained open.

Reactive activities of the repository licensing program consist of pre-licensing reviews that follow DOE's sequence and schedule of activities. To date, the NRC has reviewed a number of the QAPs proposed by DOE and its contractors for Yucca Mountain. Any quality assurance issues identified must be resolved before significant data collection activities are performed at the Yucca Mountain site.

The NRC has also provided formal comments to DOE on the 1998 TSPA Viability Assessment (NRC99).

As site characterization activities proceed, the NRC will review DOE's semiannual progress reports on the site characterization program. The review will focus on the resolution of previously identified concerns and will evaluate new information about the site and repository design. In addition, the NRC will review selected DOE study reports and position papers that document the results of work performed to date, and topical and issue resolution reports that summarize the site characterization work for specific licensing topics. These reviews will be used to evaluate compliance with NRC regulations.

All concerns identified by the NRC will be tracked by its staff. The tracking system now being implemented will focus not only on the issues identified, but also on DOE's progress towards their resolution. The system also provides a licensing record of all NRC and DOE actions related to resolving specific issues.

2.6 DEPARTMENT OF ENERGY

DOE operates facilities for the production and testing of nuclear weapons; for the management and disposal of radioactive waste generated in national defense activities; for research and development; and for the storage of spent nuclear fuel. In addition, DOE is conducting several remedial action programs, such as the program for the management of uranium mill tailings and the cleanup of sites formerly used for nuclear activities. These facilities and activities are not licensed by the NRC. However, to protect public health and the environment, DOE has implemented orders and procedures that are consistent with NRC regulations under 10 CFR Part 20 (NRC60), standards promulgated by the EPA, and other applicable Federal regulations and guidelines.

DOE is also responsible for the disposal of spent nuclear fuel from the generation of electricity by commercial nuclear reactors and high-level radioactive waste from defense activities. The facilities developed by the DOE for the management and disposal of these wastes must be licensed by the NRC. The Yucca Mountain site in Nevada is the candidate location for disposal of these wastes.

DOE is responsible for operating its facilities in a manner that is environmentally safe and sound, as stated in DOE Orders 5400.1 (DOE88) and 231.1 (DOE95a). In meeting this mandate, DOE has issued a number of orders specifying environmental standards and procedures. Many of these orders are currently under review to determine their conformance with NRC and EPA regulations and standards and will be revised in accordance with the applicable NRC or EPA guidance. Key DOE orders pertaining to the management of radioactive and hazardous materials include:

- DOE Order 460.1A (DOE96b), which establishes administrative procedures for the certification and use of radioactive and other hazardous materials packaging by the DOE.

- DOE Order 460.2 (DOE95b), which specifies DOE's policies and responsibilities for coordinating and planning base technology for radioactive material and transportation packaging systems. (Cancels DOE Orders 1540.1A, 1540.2, and 1540.3A-Change 1.)

- DOE Order 451.1A (DOE97), which establishes procedures for implementing the requirements of NEPA (NEP70). The order requires new facilities and existing facilities with proposed modifications to submit EISs with their proposed facility design or design modification. In addition, the facilities are subject to extensive design criteria reviews to determine compliance. (Cancels DOE Order 451.1.)

In addition to the above orders, in March 1993, DOE published a Notice of Proposed Rulemaking for 10 CFR Part 834, entitled *Radiation Protection of the Public and the Environment* (58 FR 16268) (DOE93). The proposed rule contains DOE's internal primary standards for the protection of the public and environment against radiation. The requirements would be applicable to control of radiation exposures from normal operations under the authority of DOE and DOE contractor personnel. In December 1996, DOE proposed revisions to its siting guidelines in 10 CFR Part 960 which were specific to the Yucca Mountain site (DOE96a). DOE has not yet taken final action on its proposal.

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