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Radiation Protection at EPA

The First 30 Years

...Protecting People and the Environment

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INTRODUCTION

This report describes key accomplishments and program activities during the first thirty years of the U.S. Environmental Protection Agency's (EPA) involvement in radiation protection. It is limited however to activities carried out by the current Radiation Protection Division [1] (RPD) of the Office of Radiation and Indoor Air (ORIA) within the Office of Air and Radiation (OAR) and its earlier organizational formulations. This report provides the context for EPA's key actions and the practical impact of these actions. It does not provide an in-depth policy or scientific discussion; rather, it is intended to introduce Agency staff and other interested parties to historical information on this topic.

The Agency's involvement in radiation protection has both a legal and historical foundation. To better understand the origin of EPA's radiation protection activities, the first part of this report, Authorities and Responsibilities, describes the historical basis. It begins with a description of the ongoing radiation protection activities transferred to EPA when it was established in 1970, and continues with information on the statutes that have been enacted over the past 30 years that provide additional radiation protection authorities and responsibilities to EPA. The second part of this report, Program Activities, provides information on key EPA radiation protection activities carried out in response to these responsibilities, and highlights significant precedents for radiation protection established by these activities.

[1] Both ORIA (and RPD) have been reorganized several times, resulting in many different program names and acronyms. To avoid confusion, this report recognizes all radiation protection work as having been done under RPD auspices.

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AUTHORITIES AND RESPONSIBILITIES

This section reviews the environmental protection authorities and responsibilities transferred to EPA when it was established in 1970, provides information on the statutes that have been enacted over the past 30 years, and the radiation protection responsibilities of other Federal agencies.

The Formation of EPA: Reorganization Plan No. 3

EPA was formed at the direction of President Nixon under Reorganization Plan No. 3, which became law on December 2, 1970. The White House Press Release, dated July 9, 1970, described the need to form EPA as follows:

> *As concern with the condition of our physical environment has intensified, it has become increasingly clear that we need to know more about the total environment – land, water and air. It also has become increasingly clear that only by reorganizing our federal efforts can we develop that knowledge, and effectively ensure the protection, development and enhancement of the total environment itself.*
>
> *The Government's environmentally-related activities have grown up piece-meal over the years. The time has come to organize them rationally and systematically. As a major step in this direction, I am transmitting today two reorganization plans: one to establish an Environmental Protection Agency and one to establish within the Department of Commerce, a National Oceanic and Atmospheric Administration.* [1]

Reorganization Plan No. 3 consolidated the environmental protection functions of several departments and agencies into the newly formed EPA. EPA was generally provided research, monitoring, standard setting, and enforcement authorities for each category of pollutant. However, the transfer of radiation protection responsibilities to EPA was more limited than that of other pollutants, in that the authority for enforcement of radiation standards was retained by the Atomic Energy Commission (AEC). EPA would later gain enforcement authority for the regulation of some radioactive materials under certain environmental statutes.

Functions Transferred to EPA

Selected functions performed by the following Federal agencies and their components were transferred to the newly formed EPA under Reorganization Plan No. 3:

Department of the Interior (DOI)

- Federal Water Quality Administration (FWQA)
- Research on the effects of pesticides on fish and wildlife

Department of Health, Education and Welfare (HEW)

- National Air Pollution Control Administration (NAPCA)
- Bureau of Solid Waste Management (BSWM)
- Bureau of Water Hygiene (BWH)
- Bureau of Radiological Health (BRH)

- Pesticide research tolerance setting

Department of Agriculture (USDA)

- Pesticide registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Executive Office of the President

- Federal Radiation Council (FRC)
- Atomic Energy Commission (AEC) environmental radiation standard setting
- Council on Environmental Quality (CEQ) research on ecological systems [2]

EPA's Radiation Protection Responsibilities

Prior to the formation of EPA, radiation protection standard setting and guidance development authorities were housed in different organizations within the Executive Office of the President and various Federal agencies in the executive branch. In forming EPA, the authors of Reorganization Plan No. 3 created a new national approach for protecting the general public from the harmful exposure to radiation. Two key radiation protection functions would now be housed in a single agency – the promulgation of generally applicable environmental standards to limit man-made radioactive materials in the environment, and the development of national radiation protection guidance for Federal and State agencies to follow in the development of their radiation protection programs and regulations. Along with these responsibilities, EPA was provided extensive research and surveillance capabilities to support the development of national guidance and standards, as well as the authority to provide technical assistance to the States.

This section discusses both the legal and the historical foundation of the radiation protection functions transferred to EPA. The authors of Reorganization Plan No. 3 explicitly stated that the term "functions" referred to an organization's statutory authority as well as its "duties, responsibilities, and activities." [3]

Functions Transferred from HEW-BRH

Several functions vested in the Bureau of Radiological Health under the Public Health Service Act (PHSA) were transferred to EPA, including a broad authority to conduct or promote research, investigations, experiments, demonstrations, and studies relating to the causes, diagnoses, treatments, control, and prevention of diseases. EPA also was transferred BRH's "primary responsibility within the executive branch for the collection, analysis, and interpretation of data on environmental radiation levels" along with three laboratories. The functions transferred to EPA from BRH include the following: development of Protective Action Guides; routine and special surveillance; monitoring, research, and development; environmental impact analysis and evaluation; and administrative and service support, including training. [4]

Under Reorganization Plan No. 3, BRH retained the responsibility to regulate radiation from consumer products and certain non-regulatory functions pertaining to medical and occupational exposures to radiation. BRH also retained the research, technical assistance, and training related to these responsibilities. [2]

Functions Transferred from AEC

Under Reorganization Plan No. 3, EPA was transferred the functions of the Atomic Energy Commission, administered through its Division of Radiation Protection Standards "to

the extent that such functions consist of establishing generally applicable environmental standards for the protection of the general environment from radioactive material." [2] Under the AEA, these standards were defined as "limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material." [2] The AEC (and later the Nuclear Regulatory Commission) retained the responsibility for implementing and enforcing these standards. This AEC authority applies only to exposures resulting from radionuclides from the nuclear fuel cycle.

Functions Transferred from FRC

In 1959, the Federal Radiation Council (FRC) was established by Executive Order (EO) 10831 and was given the authority under the Atomic Energy Act (AEA) to develop Federal guidance. Soon after, Congress provided an identical statutory basis for the FRC. Reorganization Plan No. 3 abolished the FRC and its functions and authorities were transferred to EPA. This included the FRC's primary function to "advise the President with respect to radiation matters directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." [2,5]

New Radiation Protection Authorities

Subsequent to the formation of EPA, Congress enacted several new statutes providing EPA with the authority to regulate hazardous materials in specific environmental media. Through the enactment of these new statutes, most notably the Clean Air Act (CAA); the Safe Drinking Water Act (SDWA); and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the scope of EPA's radiological protection authorities expanded. EPA became responsible for regulating both chemical and certain radiological hazards under the same legislative requirements. As a result of these changes, EPA was faced with the challenge of establishing standards and regulations for radiation that were consistent with its standards and regulations for chemical carcinogens.[2] (See Appendix A "Statutory Authorities" for a summary of statutes providing authorities for EPA's radiation protection activities.)

Radiation Protection at Other Federal Agencies

Several Federal agencies have significant radiation protection responsibilities, including EPA, the Department of Energy (DOE), the Nuclear Regulatory Commission (NRC), the Department of Defense (DoD), the Department of Health and Human Services (DHHS), the Department of Labor (DOL), the Department of Transportation (DOT), and the Federal Emergency Management Agency (FEMA). The overall responsibilities of these organizations are described in Appendix B.

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[2] For an extended analysis of EPA's resolution of the conflicts between the Agency's regulatory policies for chemicals and historical radiation protection policy, see "Regulation of Radiological and Chemical Carcinogens: Current Steps Toward Risk Harmonization." [6]

Summary

Reorganization Plan No. 3 provided EPA with considerable authorities and responsibilities for the development of the Agency's radiation protection program. For the first time, the national radiation protection guidance setting authority and the environmental standard setting authority were housed in a single agency. The authorities transferred to EPA from the FRC, when combined with those of the BRH, gave EPA wide-ranging authority to promote, conduct, or contract for any research to provide needed radiation protection information.

In addition, EPA was transferred authority under the PHSA to provide technical assistance to the States and other Federal agencies having radiation protection programs, and to provide emergency assistance in responding to radiological emergencies.

PROGRAM ACTIVITIES

This section discusses EPA's radiation protection activities from 1970 to 2000 within the following four program areas:

Federal Guidance describes Presidential and Federal radiation protection guidance and supporting EPA technical reports.

Nuclear Fuel Cycle Standards and Regulations describes EPA's regulatory program developed under the authority of the AEA and related statutes. These standards generally apply to source, special nuclear, or byproduct material as defined by the AEA of 1954, as amended.

Environmental Standards describes media-specific (e.g. air, water, etc.) standards developed under a variety of environmental statutes that apply to both chemical and radioactive contaminants.

Emergency Response describes technical support and guidance developed in compliance with the FEMA regulations.

Each of these program areas are discussed in detail below. First an initial background paragraph is provided giving the general context for EPA's actions, then the discussion of each program area contains following subsections:

Legislative Authority describes the authorizing statute and statutory purpose.

Internal/External Triggers describes the reason for RPD's action.

EPA Actions describes RPD's actions to address the problem.

Impact of EPA Actions describes how RPD's actions affected other Federal agencies, other program areas within EPA, and the international radiation protection community.

Federal Guidance

The authority to develop Federal guidance was one of the primary radiation protection authorities transferred to EPA when it was formed in 1970. The purpose of this guidance is to provide a common framework for all Federal agencies to follow to ensure that the regulation of exposure to radiation is carried out in an adequately protective and consistent manner. It is used by Federal agencies as the basis for developing and implementing their own regulatory standards. There are two kinds of Federal guidance publications:

- **Presidential Federal Guidance** provides principles and basic standards for Federal and State radiation protection programs. This guidance is developed by EPA and approved by the President.

- **Federal Guidance** provides current scientific and technical information for radiation dose and risk assessment. This guidance is issued by EPA to support the implementation of Federal and State radiation protection programs.

From 1960 to 1970, the FRC issued three Presidential Federal guidance documents and eight Federal guidance reports. These documents, for the first time, provided broad guidance to Federal agencies for protection of the general public from radiation, and for workers exposed to radiation in the work-place.

Since 1970, EPA has developed four Presidential Federal guidance documents. Two of these replaced guidance developed by the FRC for workers, one provided guidance for medical uses of radiation – an area not previously addressed by Federal guidance – and the last provided guidance for the general population and is still awaiting final action. EPA has developed five Federal guidance reports, including one multi-agency report, and sponsored seven studies by the National Academy of Sciences (NAS) under this authority. These reports are discussed in the following subsections.

Presidential Federal Guidance

Underground Mining of Uranium Ore

Legislative Authority

The AEA and Reorganization Plan No. 3 provide EPA the authority to "...advise the President with respect to radiation matters directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." [2] EPA is authorized to consult with the National Academy of Sciences, the National Council on Radiation Protection and Measurements, and other experts in carrying out this responsibility.

Internal/External Triggers

In the 1960s, the FRC noted an increase in lung cancer among underground uranium miners in the U.S. associated with the inhalation of radioactive materials. The FRC conducted a study of the problem, and in 1967 reported the results in Federal Guidance Report No. 8, *Guidance for the Control of Radiation Hazards in Uranium Mining*. [7] Based on that study, in 1969 the FRC proposed recommendations for miners, including a threefold reduction in the maximum annual radiation exposure to radon and its decay products for miners in underground uranium mines.

EPA Actions

After an extensive review of available scientific and epidemiological information on radiation induced lung cancer, EPA concluded that the recommendations of the FRC should not be modified. On July 9, 1971, EPA finalized the guidance, recommending standards for the protection of underground uranium miners. [8] EPA's primary objective was to protect miners from radiation induced lung cancer. In recommending these standards, EPA considered the protection of the health of uranium miners, technical feasibility of achieving various levels of exposure, and the economic impact

Impact of EPA Actions

This was the first time occupational standards were recommended for Federal agencies to incorporate into their regulations that limited the exposures of uranium miners to the harmful exposures to radiation.

Diagnostic X-Rays

Legislative Authority

See above.

Internal/External Triggers

Although the beneficial uses of diagnostic x-rays were well recognized, by the 1960s there was a growing concern among medical practitioners, medical physicists, and other scientists concerned with radiation protection that medical uses of ionizing radiation represented a significant and growing source of exposure for the U.S. population. Medical exposures to radiation were not controlled by guidance, regulation, or law. [9]

In 1970, at the request of the FRC, the NAS initiated a study on the health effects of exposure to low levels of radiation. (Later that year, the responsibilities of the FRC, including the sponsorship of this study, were transferred to EPA.) In their 1972 report, *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation*, the NAS noted that "...medical diagnostic radiology accounts for at least 90% of the total man-made radiation dose to which the U.S. population is exposed." The Committee recommended that medical radiation exposure be reduced by limiting its use to clinically indicated procedures, using efficient exposure techniques and optimal operation of radiation equipment. [10]

EPA Actions

To address these recommendations, on July 5, 1974, EPA formed an Interagency Working Group on Medical Radiation. The Working Group issued two reports for public comment, and on January 18, 1977, EPA published proposed recommendations. [11] As a part of this process, EPA also entered into a Memorandum of Understanding (MOU) with the Department of Health, Education and Welfare (HEW) defining the responsibilities of the two agencies for the development of Federal guidance on medical uses of radiation. This MOU provided that either agency could develop recommendations, with EPA primarily responsible for broad guidance and HEW primarily responsible for implementing guidance. However, EPA was responsible for the final review of all Federal guidance. Consistent with this agreement, EPA and HEW developed its final recommendations on *Radiation Protection Guidance to Federal Agencies for Diagnostic X Rays*, approved by President Carter and published in the *Federal Register* on February 1, 1978. [9]

Impact of EPA Actions

The 1978 guidance was the first to provide a framework for the development of radiation protection programs for diagnostic uses of x-rays in medicine. It introduced into Federal guidance the concepts of:

- Medical x-ray studies should only be conducted to obtain diagnostic information (i.e., studies were for the benefit of the patient, and not undertaken for other purposes);

- Routine screening exams should be limited to those that have a demonstrated beneficial yield compared to the radiation risk;

- Exams of pregnant or potentially pregnant patients should consider possible fetal exposure;

- Operators of diagnostic equipment should meet or exceed requirements of established credentialing organizations; and

- Specified standard x-ray exams should satisfy maximum numerical exposure criteria.

This guidance provided the basis for subsequent legislation that gave HEW both the authority and the charge to develop regulations to implement most of these recommendations.

Occupational Exposure

Legislative Authority
See above (page 8).

Internal/External Triggers
Occupational exposure to ionizing radiation in the United States is governed by regulations established by a wide variety of Federal and State agencies. To assure uniform protection of workers, the framework for these regulations is set out in Federal guidance.

In 1974, EPA began an evaluation of the magnitude and extent of worker exposure to radiation in the United States. EPA published reports in 1980 and again in 1984 providing comprehensive reviews of the numbers and exposures of workers for the years 1960 to 1980, with projections to the year 1985. These reports demonstrated that the number of workers exposed to ionizing radiation increased significantly since Federal radiation protection guidance for occupational exposure was first issued in l960, and was continuing to increase. The average exposure of workers, however, was decreasing. The mean annual dose to potentially exposed workers decreased by a factor of two between 1960 and 1985. [12]

EPA Actions
EPA began its review of radiation protection guidance for workers by establishing a Federal interagency committee. Final recommendations for increased protection of U.S. workers, *Radiation Protection Guidance to Federal Agencies for Occupational Exposure*, were approved by President Reagan and published on January 27, 1987. [13] This guidance replaced the Federal guidance signed by President Eisenhower and published by the FRC in 1960.

Impact of EPA Actions
EPA's new Federal guidance for occupational exposure made a number of major changes in the protection of workers, including:

- Reducing the annual limit from 12 rem to 5 rem;
- Replacing the "critical organ" approach to radiation limits (that limited only the dose to the most exposed organ) with limits based on the sum of risks to all exposed organs through the introduction of the "effective dose equivalent" as the relevant dose quantity;
- Requiring summing internal and external doses in assessing conformance with dose limits;
- Introducing the use of the "committed dose" to account for future exposure from radionuclides retained in the body;
- Limiting exposure of the fetus through lowered limits, on both a monthly and an annual basis, for declared pregnant workers, and requiring that this be achieved in a non-discriminatory manner;
- Requiring application of the "as low as reasonably achievable" (ALARA) principle to collective, as well as individual, doses;

- Requiring education of workers on the risks from radiation, and that workers be given access to annual records of their exposure and dose commitments; and

- Introducing the concept of "administrative control levels" below the limits for use in the great majority of situations involving radiation exposure that do not warrant use of the full exposure limits.

These recommendations have been implemented by essentially all Federal and State agencies.

Exposure of the General Public

Legislative Authority
See above (page 8).

Internal/External Triggers
In 1960, the FRC issued its first recommendations, which established limits for exposure of the public, and included an annual limit of 500 mrem to the whole body and a 5 rem limit over 30 years to the gonads. During the years following EPA's creation in 1970, the Agency decided to concentrate its energies on establishing more protective limits for the most important specific kinds of exposure sources, such as the nuclear power industry and sources of emissions to air, rather than on revising the 1960 FRC general guidance on limits for members of the public. All of these environmental radiation standards, as well as the corresponding risk levels involved in the Agency's standards for other pollutants, were much lower than the 1960 FRC limits. In addition, new reviews of radiation risks by the NAS found that radiation risks were significantly higher than had been assumed by the FRC in 1960. By 1986, it had become apparent that the old FRC limits were anachronisms that should be addressed.

EPA Actions
In 1986, EPA began a long series of meetings with the eleven Federal agencies that have responsibilities for controlling exposure of the public, and with representatives of State radiation control programs. By 1993, in cooperation with these agencies and the States, EPA developed draft recommendations for new Federal guidance to replace the old 1960 FRC guidance for members of the public. EPA proposed *Federal Radiation Protection Guidance for Exposure of the General Public* in 1994. [14] The proposed guidance contained the following major changes: it reduced the former limits to a single limit of 1 mSv/y, and limited its use to that of a cap on the sum of exposure from *all* man-made sources of exposure; it introduced the use of source-related limits (e.g., those already established under the environmental statutes) as the primary basis for control of exposure; and it replaced use of dose to critical organs with effective dose and the use of committed dose.

During the period following publication of these recommendations, EPA conducted extensive negotiations but was unable to resolve the outstanding issues.

Federal Guidance Reports

Legislative Authority
See above (page 8).

Internal/External Triggers
To implement radiation protection guidance on standards and regulations for radionuclides and for sources of x-ray and gamma external

radiation, it is necessary to relate dose and risk to quantities of radioactivity in the environment through various exposure pathways, and to the intensity of external radiation sources. Prior to EPA's formation, there were only a few incomplete sources of Federally approved technical information available for these purposes.

EPA Actions

Since the mid-1980s, EPA has published five Federal guidance reports on a variety of technical matters to provide Federal and State agencies dose and risk information for use in the development and implementation of their radiation protection programs.

Federal Guidance Technical Report No. 9, *Radiation Protection Guidance for Diagnostic X Rays.* This report, prepared in cooperation with an Interagency Working Group on Medical Radiation, provides the basis for the *Radiation Protection Guidance to Federal Agencies for Diagnostic X Rays*. [15]

Federal Guidance Technical Report No. 10, *The Radioactivity Concentration Guides*. This report presents numerical values for the concentrations of radioactivity in air and water, corresponding to the limiting annual doses recommended for workers in 1960. [16]

Federal Guidance Technical Report No. 11, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion*. This report provides derived guides (limiting values) of radionuclide intake and air concentration for control of occupational exposure that are consistent with 1987 Federal radiation protection guidance. The derived guides serve as the basis for regulations setting upper bounds on the inhalation and ingestion of, and submersion in, radioactive materials in the workplace. The report also includes tables of exposure-to-dose conversion factors for general use in assessing average individual committed doses in any population that is adequately characterized by Reference Man. This report supercedes Federal Guidance Report No. 10. [17]

Federal Guidance Technical Report No. 12, *External Exposure to Radionuclides in Air, Water, and Soil*. This report provides tables of exposure-to-dose conversion factors for external exposure to photons and electrons emitted by radionuclides in air, water, and soil. It is intended to be a companion to Federal Guidance Report No. 11 (see above). The dose coefficients for exposure to external radiation are intended for the use of Federal agencies in calculating the dose equivalent to organs and tissues of the body. Dose coefficients for air submersion in Report No. 12 update those given in Report No. 11. [18]

Federal Guidance Technical Report No. 13, *Cancer Risk Coefficients for Environmental Exposure to Radionuclides.* This report provides, for the first time, comprehensive tables of health risks due to ingestion, inhalation, external exposure, or submersion for over 800 different radionuclides. It uses nationally accepted biokinetic models to incorporate age-, gender-, and organ-specific intakes and risks to determine lifetime cancer risks. [19]

Impact of EPA Actions

Federal Guidance Technical Report No. 11, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,* has been adopted by Federal agencies and the States as the standard source

for calculating radiation doses from radionuclides in the human body.

Federal Guidance Technical Report No. 12, *External Exposure to Radionuclides in Air, Water, and Soil,* is used by Federal and State agencies and others as the standard source for exposure-to-dose conversion factors for external exposure of human from radiation and radionuclides in air, water, and soil.

Federal Guidance Technical Report No. 13, *Cancer Risk Coefficients for Environmental Exposure to Radionuclides* is used by Federal and State organizations to assess risks from exposure to radionuclides in a wide variety of applications. These range from environmental impact analyses of specific sites to the general analyses that support rulemaking.

NAS Reports

In support of all Federal and State radiation protection activities, EPA has sponsored seven major reviews of radiation risks by the National Academy of Sciences-National Research Council (NAS-NRC) during the past 30 years under its Federal guidance authority. Most of these studies have been carried out by the NAS-NRC Committee on the Biological Effects of Ionizing Radiation (BEIR). Four of these reviews, the BEIR Reports I, II, V, and the in-progress BEIR VII Report, address low level effects of radiation in general, and two of these reviews, BEIR IV and VI, deal with more specialized risk assessments for alpha-emitting radionuclides and for radon, respectively. BEIR II addressed the use of cost/benefit analysis in radiation risk management. [10,20,21,22,23, 24]

Taken together, the NAS BEIR reports are the United States' most authoritative and comprehensive source of reliable information and opinion on the health effects of exposure to radiation.

Nuclear Fuel Cycle Standards and Regulations

Prior to the formation of EPA, radiation protection activities for the nuclear industry were primarily the responsibility of the AEC. The AEC was charged, under the 1954 amendments of the AEA, to both promote peaceful uses of nuclear energy and regulate the nuclear industry. With the passage of time, the dual role of the AEC as both regulator and advocate of the use of atomic energy came into question.

In 1970, under Reorganization Plan No. 3, the responsibility to develop Federal guidance and establish generally applicable environmental standards for radioactive materials was transferred from the AEC to the EPA; however, AEC retained its responsibilities to simultaneously promote and regulate the nuclear industry. The controversy surrounding this dual role reached its height during the Arab oil embargo and the energy crisis of 1973-74. Additional factors included the growth of the nuclear industry; an increasingly active anti-nuclear movement; and growing concern among citizens groups, Congress, and scientists about the perceived environmental threat from reliance on nuclear energy. In 1974, Congress passed the Energy Reorganization Act (ERA), which abolished the AEC and split its remaining responsibilities among two new entities: the Nuclear Regulatory Commission (NRC) and the Energy, Research and Development Administration (ERDA). The AEC's authority to regulate civilian nuclear power operations was transferred to the NRC, and AEC's responsibilities for producing nuclear weapons and promoting peaceful uses of atomic energy were transferred to ERDA, which became DOE in 1977.

Under the AEA and subsequently enacted nuclear statutes, EPA developed a comprehensive set of standards addressing environmental issues for all phases of the uranium fuel cycle, including: uranium milling; chemical conversion; fuel fabrication and reprocessing; power plant operations; waste management, storage, and disposal; and site cleanup for milling operations. These standards apply to exposures due to releases of radioactive material into the accessible environment. Implementing agencies (primarily EPA, NRC, and DOE) incorporate them into their site-specific or facility-specific regulations, which promotes consistency in radiation protection.

Under the WIPP Land Withdrawal Act (WIPP LWA), EPA developed a facility-specific regulation for the Waste Isolation Pilot Plant (WIPP) that certifies the facility to open and accept transuranic radioactive waste. The Agency also proposed a facility-specific standard for Yucca Mountain.

The Uranium Fuel Cycle (40 CFR Part 190)

From the late 1950s through the early 1970s, nuclear power emerged as a significant source of energy for the United States. By the late 1960s, it became apparent, to both the public and the Federal government, that the growing industry supporting nuclear power – the production, management, and use of uranium fuel – could pose a significant risk to

the environment and public health. In 1970, seventeen nuclear power plants were in operation, forty- nine were under construction, and an additional forty-eight were in the planning stage. These 114 plants were to be located in twenty-nine States and were expected to provide over 85 million kilowatts of electric generating capacity. The AEC estimated nuclear power would generate 150 million kilowatts by 1980 and one billion kilowatts by the year 2000. These expectations have not been met, however, and today there are only about 100 commercial nuclear power plants in operation.

Legislative Authority

The AEA provides EPA the broad authority to develop generally applicable environmental radiation standards. [25]

Internal/External Triggers

As the technology to generate electricity using nuclear energy became more sophisticated and widespread, concern over potential public health and environmental impacts of radioactive materials also increased. The fission of nuclear fuel was a fairly recent discovery, and as a consequence the health and environmental implications were only beginning to be understood. At the time this standard was developed, environmental contamination resulting from the nuclear power industry was minimal. Therefore, the opportunity and the challenge existed to manage future growth of this industry in a preventive, rather than remedial, context, which is the best situation for environmental protection.

EPA Actions

On August 13, 1973, EPA developed proposed standards for nuclear power plants that set separate exposure and release limits for the three classes of facilities in the uranium fuel cycle: fuel supply operations (e.g., uranium mills, chemical processing, isotopic enrichment, and fuel fabrication), light water reactor plants, and fuel reprocessing plants. The AEC challenged EPA's legal authority to set these standards, arguing that standards for separate classes of facilities in the fuel cycle encroached on AEC's authority to license and regulate such facilities individually, and that such standards were not "generally applicable" standards.

This dispute was referred to President Nixon, who asked the Office of Management and Budget (OMB) to further clarify the responsibilities of the EPA and AEC. The decision was defined in a memorandum from Roy L. Ash, Director of the Office of Management and Budget, dated December 7, 1973. [26] Although OMB supported AEC's position against separate standards for classes of facilities within a given industry, it confirmed that EPA could set different generally applicable environmental standards for broad classes of activities, such as the uranium fuel cycle, taken as a whole.

Based on this OMB decision, EPA revised its approach and in 1975 proposed standards applicable to normal operations of the entire uranium fuel cycle. This approach included four basic considerations: the total radiation dose to populations; the maximum dose to individuals; the risk of health effects attributable to these doses, including the future risks arising from the release of long-lived radionuclides to the environment; and the effectiveness and costs of the technology available to mitigate these risks. [27]

On January 13, 1977, the uranium fuel cycle standard was promulgated at 40 CFR Part 190.

This two-part standard, entitled *Environmental Radiation Protection for Nuclear Power Operations*, sets generally applicable environmental limits for the entire uranium fuel cycle. The first part limits individual exposures from planned discharges of radioactive materials, and the second part addresses population exposure and buildup of environmental burdens by limiting discharges of certain long-lived radionuclides. [28] These were the first U.S. radiation standards to be based on explicit estimates of the associated health risks, and contain provisions that limit the total impact on health in populations. The latter provisions, which required severely limiting emissions of certain long-lived radionuclides, were based on the calculation of a new radiation protection quantity, the "environmental dose commitment." [29] Calculation of population dose commitments has since become a standard part of risk assessments for environmental impact statements, rulemakings, and international assessments of radiation doses, such as those prepared by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

The uranium fuel cycle standard does not apply to mining operations, transportation of radioactive material, or waste disposal operations. These activities are regulated under subsequent standards. Nuclear power generation from recycled plutonium or thorium was excluded from this standard because sufficient operating data and experience with fuel cycles utilizing these fuels were not available at the time. These activities are also regulated under subsequent standards.

Impact of EPA Actions

The uranium fuel cycle standards had the following critical impacts on the regulation of radiological contamination:

- These were the first U.S. radiation standards to be based on explicit estimates of individual health risks, and to contain provisions that limit the total impact on health in populations. They address both discharges of radioactive materials into the environment and the accumulation of long-lived materials by limiting discharges of certain long-lived radionuclides.

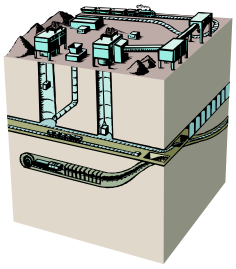
- The standards set a precedent for setting limits that take into account both individual exposures and general population exposures.

- These standards set generally applicable environmental limits for the entire uranium fuel cycle, applicable to areas outside the boundaries of those facilities.

- NRC later selected the same individual exposure levels for their low-level waste requirements (10 CFR Part 61).

- The issuance of the Ash Memorandum in 1973 clearly defined the roles of both EPA and the AEC in the regulation of nuclear fuel facilities. The directive set the future direction of RPD rulemaking.

Uranium and Thorium Mill Tailings (40 CFR Parts 192 and 61)



In the 1940s, the U.S. government began to purchase uranium for defense purposes. To meet the demand, the uranium milling industry began to generate large quantities of uranium mill tailings, the waste byproduct of the extraction of uranium from ore ("yellowcake production"). This sand-like material, produced predominantly in the West, was stored in surface impoundments (piles) amounting to thousands of tons of waste and covering up hundreds of acres of land.

Historically, uranium mill tailings were not covered under the AEA since they were not considered to be hazardous. They were, however, highly contaminated with radionuclides, particularly radium-226, and heavy metals such as arsenic, molybdenum, and selenium.

With the passage of Uranium Mill Tailings Radiation Control Act (UMTRCA), uranium and thorium mill tailings were for the first time subject to regulation under the AEA.

Legislative Authority

Section 275 of the AEA, as amended by Section 206 of UMTRCA (1978), directed EPA to set generally applicable health and environmental standards to govern the stabilization, restoration, disposal, and control of effluents and emissions at both active and inactive mill tailings sites. [30]

The Clean Air Act Amendments (CAAA) of 1979 gave EPA the authority to develop National Emission Standards for Hazardous Air Pollutants (NESHAPs), including radionuclides.

Internal/External Triggers

Prior to the 1970s, uranium mill tailings had been removed from storage piles and used in construction and soil conditioning. During the late 1970s, the lack of controls over uranium mill tailings piles was identified as a major health risk, particularly in the West. Elevated levels of indoor radon gas and gamma radiation were found in western communities where housing developers had used uranium mill tailings for fill material, road construction aggregate, and other purposes. The associated long-term health risks to families living in these homes (termed "vicinity properties") were high enough to warrant cleanup actions.

The source of the radiation exposure hazard from tailings piles lasts for tens of thousands of years. Some of the non-radioactive toxic chemicals persist indefinitely, along with their potential to contaminate groundwater. The tailings, therefore, posed both an immediate threat to human health and a very long-term threat of extensive environmental contamination if allowed to disperse through human misuse or by natural forces.

To address these problems, Congress passed UMTRCA. EPA initially developed standards for the regulation of uranium and thorium mill tailings under UMTRCA. Subsequently, EPA developed additional standards for the regulation of mill tailings to meet the statutory requirements of the CAAA. Ultimately, EPA amended the UMTRCA standards to incorporate these additional limitations required by the CAA. (See Hazardous Air Pollutants section on page 33)

EPA Actions

On January 5, 1983, EPA issued 40 CFR Part 192, *Standards for Remedial Actions at Inactive Uranium Processing Sites* (the Title I sites). These standards were developed to govern the stabilization and cleanup of uranium mill tailings at the twenty-four inactive sites designated under Section 102(a)(1) of UMTRCA and at associated vicinity properties. [32]

On October 7, 1983, EPA issued *Environmental Standards for Uranium and Thorium Mill Tailings at Licensed Commercial Processing Sites* (the Title II sites). This standard governs the stabilization and control of by-product materials (primarily mill tailings) at commercial uranium and thorium processing sites licensed by the NRC or the States under Title II of UMTRCA. The standards for disposal require stabilization of the tailings and separate ground water limits. [33]

Standards for both Title I and Title II sites were subsequently challenged in the Tenth Circuit Court of Appeals by several parties. The Court upheld all aspects of the rules, except the ground water provisions of the Title I regulations.

On September 24, 1987, EPA proposed new standards to replace those that had been remanded. [34] On January 11, 1995, EPA issued final ground water standards for the Title I sites. [35] These ground water standards were essentially identical to existing RCRA requirements but with a precedent-setting new provision – the regulation, for the first time, permitted the use of institutional controls under specified conditions to meet the ground water criteria. This resulted in a reduction in the cost of compliance by a factor of two, at no increase in risk to health.

The Title I and II standards address both cleanup and disposal. The disposal standards deal with the long-term control of radium and hazardous chemicals in uranium and thorium tailings piles. In light of the long half-life of radium (1,600 years), EPA's primary objective for the disposal standards was to isolate and stabilize the piles to prevent the release of radon, misuse of tailings by humans, and dispersal by natural forces for the longest feasible period of time, which the Agency decided was 1,000 years, or at a minimum 200 years. The standards generally limit emissions of radon from the piles to a lifetime individual risk of 10^{-4}.

A distinguishing characteristic of these disposal standards is that they apply to the performance of the disposal facility for an unprecedented time period of 1,000 years. Active institutional controls are to be implemented in perpetuity to ensure the disposal facilities continue to perform as designed.

In 1989, EPA promulgated additional standards, under the authority of the CAAA, at 40 CFR Part 61 Subpart T for inactive Title I and II uranium mill tailings sites, and at Subpart W for operational Title II uranium mill tailings sites. Issues that these standards addressed that the UMTRCA standards did not include are: establishing compliance schedules to ensure a timely closure of the tailings piles; ensuring the standard would be met within a reasonable period of time; and requiring monitoring to verify initial compliance with the radon flux standard.

After promulgating Subpart T, EPA received petitions for reconsideration from NRC and the industry, arguing that there was an overlap between EPA's UMTRCA regulations and Subpart T of the radionuclide NESHAP. [36]

EPA worked closely with these stakeholders to resolve the issues. In October 1991, EPA, NRC, and the relevant NRC Agreement States entered into a MOU to resolve the deficiencies in compliance with EPA's Title II UMTRCA standards that had led to the promulgation of Subpart T. As a result, in 1993 EPA amended the UMTRCA standards and NRC amended their implementing regulations to address the above deficiencies. Subsequently, EPA rescinded Subpart T. [37,38]

Impact of EPA Actions

UMTRCA and the uranium and thorium mill tailings standards set important precedents:

- These standards provided the basis for DOE's program for protection of human health and the environment at inactive uranium mill tailings sites and vicinity properties. There are twenty-four inactive uranium sites designated as Title I sites. [39] To date, tailings stabilization has been completed at all twenty-four sites, and ground water restoration is underway.

- These standards also provided the basis for NRC's program for protection of human health and the environment at operating sites licensed by NRC or Agreement States. There are twenty-seven operating sites designated as Title II sites. [40] To date, four are still considered to be operational, and the remainder are in some stage of closure.

- This was the first EPA regulatory program to establish standards applicable for more than a few decades – in this case for 1,000 years.

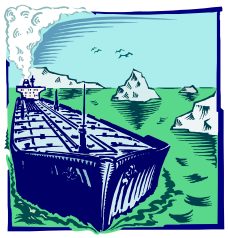
- It was the first regulatory program to set ground water standards for radionuclides.

- It was the first regulatory program to permit the use of institutional controls to limit the costs of remediating contaminated groundwater.

Low-Level Wastes

LLW is defined as radioactive material that is not HLW, spent nuclear fuel (SNF), transuranic (TRU) waste, or byproduct material as defined in section 112(2) of the AEA of 1954. It is also radioactive material that the NRC, consistent with existing law, classifies as LLW. [41] LLW is comprised of a large volume of radioactive wastes produced by a variety of different processes including the nuclear fuel cycle, medical or biotechnological research, the production of radioactive chemicals, the manufacture of commercial products, and government military operations. Radioactive waste resulting from the operations, decontamination, and decommissioning of fuel cycle facilities is also classified as LLW. LLW varies widely in the hazard it poses. This section discusses both ocean disposal and land disposal, as well as the disposal of mixed waste.

Ocean Disposal (40 CFR Part 220)



In the 1950s and 1960s, the United States disposed of some LLW in the deep ocean. At the time, this activity, while not specifically regulated, was an accepted method for managing low-level radioactive waste.

Legislative Authority

The Marine Protection, Research, and Sanctuaries Act of 1972 (MPRSA) authorizes EPA to issue permits and promulgate regulations for disposing of materials into the territorial waters of the United States, when it will not degrade or endanger human health, welfare, ecological systems, the marine environment, or the economy. It specifically prohibits ocean disposal of HLW. Any request for ocean disposal of LLW requires a permit that must be approved by both houses of Congress. [42]

EPA Actions

EPA undertook a series of studies to determine the impact of ocean dumping on the marine environment. Based on these studies, EPA issued a proposal in 1973 specifying conditions for permits for ocean disposal of LLW. The final rule for such permits was issued on January 11, 1977. [43] To date, no applications for this type of permit have been submitted to EPA.

Impact of EPA Actions

With the severe national and international restrictions placed on ocean disposal, commercial generators and EPA accelerated the search for acceptable radioactive waste disposal alternatives. Ocean disposal of LLW has effectively stopped.

Land Disposal

In the 1950s and early 1960s, most of the nation's LLW, generated at both commercial and Federal facilities, was buried at Federal disposal facilities. When the Federal government closed its disposal facilities to commercial LLW, several private disposal facilities were constructed. By 1970, six private facilities were accepting LLW from commercial sources. These facilities were located in Hanford, Washington; West Valley, New York; Maxey Flats, Kentucky; Barnwell, South Carolina; Sheffield, Illinois; and Beatty, Nevada. By the end of the decade, three of the facilities were closed – Sheffield was filled to capacity, and West Valley and Maxi Flats were closed due to containment problems. All three of these sites caused extensive environmental contamination requiring cleanup. In 1986, Maxi Flats was listed on Superfund's National Priorities List (NPL). By the late 1970s, all commercial LLW in the United States was being disposed of in the remaining three facilities - in Nevada, South Carolina, and Washington. The closure of three disposal facilities and the slow development of new disposal capacity caused a significant increase in the volume of stored LLW. This waste is frequently being stored at sites away from the generation or disposal facility.

By 1992, the Nevada site closed permanently. There remained only a few facilities that accepted LLW – Barnwell in South Carolina, the commercial disposal facility in Hanford, Washington, and a new facility, Envirocare, in Utah. [45]

Legislative Authority

The Atomic Energy Act of 1954 provides EPA broad authority to develop generally applicable environmental radiation standards.

The Low-Level Radioactive Waste Policy Act of 1980 (LLRWPA), as amended, required each State to be responsible for providing disposal capacity for commercial LLW generated within its borders by January 1, 1986. It also encouraged States to form regional compacts to develop new disposal facilities. By

1984, it became evident that no new disposal facilities would be opened before the deadline. The LLRWPA was amended in 1985 to provide States more time to develop facilities, and to provide incentives for volume reduction of LLW. [44] To date, ten interstate compacts have been developed, covering 44 States, to build new disposal facilities; however, none of these facilities have been licensed to accept waste. [45]

Internal/External Triggers

During the late 1980s, the governors of Nevada, South Carolina, and Washington urged Congress to take action to improve packaging requirements for LLW and to relieve their States of the burden of providing LLW disposal for the entire United States. When Congress did not respond, both Nevada and Washington temporarily closed their disposal facilities, and South Carolina significantly reduced the amount of waste it would accept. This was the catalyst for enactment of the LLRWPA in 1980.

EPA Actions

In 1988, EPA developed a proposed rule for the management, storage, and disposal of LLW for both commercial and Federal facilities. This rule encountered significant opposition during the OMB review due to interagency concerns over the ground water protection standards, and OMB suspended review. The rule languished until 1993 when EPA initiated the development of standards to regulate the cleanup of Federal facilities (see Cleanup Rule on page 40). The cleanup effort would generate large volumes of LLW.

In 1994, EPA developed a LLW pre-proposal that included individual protection limits for management and storage of the waste, and individual protection limits and ground water protection requirements for waste disposal. This pre-proposal was consistent with EPA's ground water protection policy which says that, "maximum contaminant limits (MCLs) under the Safe Drinking Water Act (shall be used) as 'reference points' for water resource protection efforts when the groundwater in question is a source of drinking water."

In November 1994, the LLW pre-proposal was circulated for review and comment on major policy issues prior to beginning the formal rulemaking process. One major concern identified during the public comment period was that a new LLW standard for commercial waste would further delay the development of the new State compact disposal sites. It was also noted that large amounts of LLW were anticipated from the cleanup of DOE sites. To ensure the standard would not be disruptive to States, in 1995, EPA limited the applicability of the rule to Federal facilities. In 1996, when EPA withdrew the Cleanup Rule, it effectively halted the development of the LLW regulation as well.

Impact of EPA Actions

There is no generally applicable standard for the management and disposal of LLW.

Low-Activity Mixed Wastes

Low-Activity Mixed Waste (LAMW) is produced commercially at industrial, medical, and nuclear power facilities. There are several thousand cubic meters of this mixed waste held in storage, and the amount is increasing each year. This waste is being stored, indefinitely in many cases, by small commercial generators because the

current regulatory framework severely limits disposal options.

EPA is working with NRC to develop a mixed waste rule for the management, storage, and disposal of commercially generated LLW mixed with RCRA hazardous waste. Disposal alternatives are being evaluated for mixed waste minimally contaminated with radionuclides. This rule will propose a more economic and efficient regulatory framework for the disposal of commercially generated LAMW that is protective of human health and the environment.

Legislative Authority

The AEA provides EPA broad authority to develop generally applicable environmental radiation standards.

RCRA gives EPA the authority to regulate hazardous waste from "cradle-to-grave." The definition of hazardous waste under RCRA specifically excludes source, special nuclear, or byproduct material as defined by the AEA. [47]

Internal/External Triggers

The regulation of commercially generated LAMW is both complex and expensive. LAMW is comprised of both hazardous and radioactive wastes. For a waste to be considered hazardous it must be specifically listed as a hazardous waste by EPA or exhibit one or more of the characteristics of hazardous waste – ignitability, corrosivity, reactivity, and/or toxicity. [46] The hazardous chemical component is regulated by EPA under RCRA and the LLW component is regulated by NRC under the AEA. Management and storage costs are high and disposal options are limited.

EPA Actions

In August 1995, EPA and NRC published the *Draft Joint Guidance on the Storage of Mixed Low-Level Radioactive and Hazardous Waste*. [48] This guidance describes the applicable regulatory requirements under both RCRA and the AEA, the procedures that are generally acceptable to both NRC and EPA, and resolves issues of concern which have been identified to the agencies by licensees and generators.

On November 19, 1999, EPA proposed a rule to provide increased flexibility to facilities that manage low-level mixed waste and naturally occurring and/or accelerator produced radioactive material (NARM) mixed with hazardous waste. The proposal aims to reduce dual regulation of LAMW, which is subject to RCRA and AEA. This rule is designed to lower cost and reduce the paperwork burden while improving or maintaining protection of human health (including worker exposure to radiation) and the environment. [49]

Impact of EPA Actions

EPA intends, by rule, to increase disposal options and reduce disposal costs for mixed waste minimally contaminated with radionuclides. EPA intends that improved, affordable access to approved disposal facilities will induce the thousands of generators currently storing mixed waste to dispose of it in ways that are more protective human health. [50]

Spent Nuclear Fuel, High-Level, and Transuranic Wastes

EPA has the responsibility to establish general environmental standards for SNF, HLW, and TRU, and to develop regulations at specific

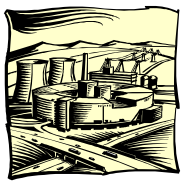
waste disposal sites (e.g, the WIPP repository and the proposed Yucca Mountain repository).

SNF is produced by the fission of nuclear fuel in nuclear reactors. Although little commercially generated SNF has been reprocessed in the United States, SNF from nuclear weapons production reactors was routinely reprocessed to recover unfissioned uranium and plutonium for use in weapons programs. Most of this spent fuel is currently being stored in water pools at the reactor sites where it is produced.

HLW is defined by the Nuclear Waste Policy Act of 1992 (NWPA) as "the highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and other highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation." [41] HLW is a mixed waste containing radionuclides that remain radioactive for thousands of years, as well as highly corrosive components, organics, and heavy metals that are regulated under RCRA. Since the 1940s and 1950s, HLW has been stored in various liquid and solid forms in underground tanks at the Hanford Reservation, Richland, Washington; Idaho National Engineering and Environmental Laboratory, Idaho Falls, Idaho; and Savannah River Site, Aiken, South Carolina.

Most TRU wastes are contaminated items (e.g., rags, equipment, and organic and inorganic sludges) resulting from nuclear weapons production, dismantling, and cleanup. The radioactive components are radionuclides with an atomic number greater than 92, and are created during nuclear fission – primarily isotopes of plutonium and americium. TRU is often mixed with hazardous chemicals. Until 1970, TRU was disposed of along with low-level waste by shallow land burial at Federal reservations. In 1970, the AEC issued a directive that TRU could no longer be disposed of by shallow land burial. Since then, TRU wastes have been stored at Federal facilities in Colorado, Idaho, Nevada, New Mexico, Ohio, South Carolina, Tennessee, and Washington. Currently, WIPP, located in New Mexico, is accepting defense-related TRU waste for disposal (see WIPP section on page 26)

Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes Management and Disposal (40 CFR Part 191)



This generally applicable standard provides limits for the release of radionuclides into the accessible environment for management and disposal of spent nuclear fuel, high-level waste, and transuranic radioactive waste. It applies to most such wastes generated by both commercial activities regulated by the NRC, and defense activities under the jurisdiction of DOE (see Yucca Mountain, on page 28, for the exception).

Legislative Authority

The AEA provides EPA broad authority to develop generally applicable environmental radiation standards.

The NWPA directed EPA to utilize its existing authority, pursuant to the AEA, to "promulgate generally applicable standards for the protection of the general environment from offsite releases from radioactive materials...in repositories" by January 7, 1984. [41]

The Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA) reinstated most of the disposal standards issued by the Agency in 1985 and remanded in 1987 (see WIPP section on page 26). It also exempted Yucca Mountain from the 40 CFR Part 191 disposal standard. [51]

Internal/External Triggers

In 1976, OMB established an interagency task force on commercial wastes to define the responsibility of each Federal agency involved in HLW management. The EPA was tasked with establishing general environmental standards governing waste disposal activities.

Presidents Ford, Carter, and Reagan were committed to the development of a permanent storage facility for HLW. Presidents Ford and Carter directed EPA to develop general environmental standards governing releases from nuclear waste facilities to the biosphere, including a numerical limit on long-term radiation releases outside the boundary of the repository. In 1982, as the study of this issue progressed, President Reagan recommended the development of temporary storage and long-term monitored retrievable facilities to manage these wastes until a permanent repository becomes available.

EPA Actions

In 1978, as a first step in response to President Ford's directive, EPA published a proposed Federal guidance, *Criteria for Radioactive Waste*, intended as generic guidance for storage and disposal of all forms of radioactive wastes. [52] EPA withdrew the proposal in 1981 because the many different types of radioactive wastes made this generic approach to disposal impractical. [53]

On September 19, 1985, EPA promulgated generally applicable environmental standards for the management and disposal of HLW, SNF, and TRU wastes. The management standards limit the radiation exposure of the public from the management and storage of these wastes prior to disposal at waste management and disposal facilities regulated by the NRC. They also limit waste emplacement and storage operations at DOE disposal facilities that are not regulated by the NRC.

The primary disposal standards are the long-term containment requirements that limit projected releases of radioactivity to the accessible environment for 10,000 years after disposal. The disposal standard also establishes six qualitative assurance requirements (e.g., multiple barriers – both engineered and natural to better isolate the wastes, and institutional controls) to provide additional certainty that the containment requirements will be met. In addition, the disposal standards set limits on exposures to individual members of the public, and separate ground water protection requirements for 1,000 years after disposal. [54,55]

In 1986, several States and environmental groups petitioned for review of the rule because the individual protection requirements were modeled for 1,000 years, whereas the containment requirements were modeled for 10,000 years. Additionally, they claimed the rule was not consistent with the underground injection requirements of SDWA. In July 1987, the Court of Appeals remanded the individual protection requirements (§191.15), the ground water protection requirements (§191.18), and the rest of 40 CFR Part191. [56]

The government requested reinstatement of all unchallenged sections. In September 1987,

the court reinstated the management and storage standards but left the entirety of the disposal standards in remand.

On October 30, 1992, the WIPP LWA was enacted. The law reinstated all of the disposal standards issued by the Agency in 1985 that had been remanded by the court in 1987 except the individual and ground water protection requirements which were the basis of the remand.

On December 20, 1993, EPA issued revised individual and ground water protection standards at 40 CFR Part 191. The time frame for applicability of the individual protection standards was increased to 10,000 years, and the whole body/specific organ dose limits were updated, based on more recent methodology[3], in terms of an annual committed effective dose. The revised ground water standards require compliance with the SDWA MCLs for 10,000 years. [57,58]

Impact of EPA Actions

EPA has set containment, individual protection, and ground water standards for SNF, HLW, and TRU to protect current and future populations and the environment for at least 10,000 years after disposal. These requirements are complimented by six qualitative assurance requirements designed to provide confidence that the standards will be met given the substantial uncertainties inherent in predictions of systems performance over 10,000 years.

The promulgation of 40 CFR Part 191 set the stage for one of EPA's most prominent regulatory programs for radioactive waste disposal – the WIPP, constructed by DOE and regulated by EPA, for disposal of TRU waste from DOE sites.

This standard extended the precedent first established by the uranium and thorium mill tailings regulations for standards requiring design performance far into the future – in this case, for 10,000 years.

Deep Geologic Repositories

Since the mid to late 1940s, the Federal government has assumed ultimate responsibility for the management and disposal of defense generated radioactive wastes. The AEC began conducting research as far back as the mid to late 1940s on processes to stabilize high-level liquid wastes. With the support from the NAS, the AEC evaluated the feasibility of different disposal media, including geologic repositories for long-term disposal of radioactive wastes. The 1957 NAS report recommended naturally occurring salt formations as promising disposal media for disposal of these wastes. [59]

From 1965 to 1970, the AEC tested an abandoned salt mine in Lyons, Kansas to determine the safety and feasibility of handling and storing radioactive waste in such a facility. By 1970 the AEC believed they had adequately demonstrated the safety of the mine and announced its preliminary selection for the establishment of a national radioactive waste repository. However, growing public opposition and concerns that nearby drilling

[3]EPA revised the risk assessment methodology used in the final rule to be consistent with Federal Guidance Report No. 11, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion*. The limit for doses to individuals of 25 mrem/yr to the whole body or 75 mrem/yr to any organ, in the 1985 rule, was replaced with an annual limit of 15 mrem/yr committed effective dose, in the 1993 final rule. [17]

had compromised the geologic integrity of the mine prompted the AEC to withdraw this selection and pursue other options.

At this time, the AEC also requested the NAS to again evaluate the feasibility of disposing of radioactive waste in salt formations, and to advise them on long-range management of radioactive waste. In the 1970 report, *Disposal of Solid Radioactive Wastes in Bedded Salt Deposits*, the NAS concluded that salt formations are satisfactory for long-range disposal of radioactive waste since they are generally located in geologically stable areas. The salt beds indicate an absence of flowing fresh water that would have dissolved them. Salt is relatively easy to mine, and salt will eventually "creep" and fill in mined areas and further seal the radioactive waste. [60] Plans for the development of the WIPP for long-term storage of TRU waste, followed in the next two decades.

Waste Isolation Pilot Plant
(40 CFR Part 194)

Once the decision to establish a repository in Lyons, Kansas, was rejected, the U.S. Geological Survey continued to conduct studies to identify a new site. In 1975, at the invitation of local officials, a salt formation east of Carlsbad, New Mexico, was explored. By 1979, DOE completed the initial environmental studies of the site, and in 1980, Congress authorized construction of the WIPP.

WIPP is DOE's geologic repository for TRU wastes. It is located on 10,240 acres of land in a salt deposit 2,150 feet below the surface. It was developed to store TRU and mixed wastes that are currently being stored on Federal reservations across the United States.

Legislative Authority

The Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1979 provided the authorization for the development of the WIPP. This repository was to be developed to "demonstrate the safe disposal of radioactive wastes resulting from the defense activities and programs of the United States." The Act also specified that only certain amounts and types of defense-generated TRU could be disposed of at the WIPP. [63]

The 1982 NWPA also supported the use of mined geologic repositories for the safe storage and/or disposal of radioactive waste, and established formal procedures to evaluate and select sites for geologic repositories. Based on the criteria defined in the NWPA, DOE selected the WIPP as the first potential deep geologic repository. The NWPA also required EPA to develop generally applicable environmental standards for off-site releases from radioactive material in repositories. [41]

The 1992 WIPP LWA effected a legislative withdrawal of the land surrounding WIPP for purposes of developing and building a TRU waste repository, and required EPA to finalize the generally applicable disposal standards at 40 CFR Part 191, establish a process to certify that the WIPP facility was technically adequate to meet the disposal standards established at 40 CFR Part 191, and reevaluate the WIPP every five years to determine whether it should be recertified. [51]

Internal/External Triggers

In 1982, DOI initially withdrew the land surrounding the WIPP for an eight year period

for the purpose of performing initial site and design characterization activities. In 1983, DOI issued a second eight-year administrative land withdrawal for the purpose of construction of the WIPP. The 1983 withdrawal provided that the withdrawn area was not authorized for use for burial or storage of any radioactive materials. In 1991, DOI modified the 1983 withdrawal to permit DOE to conduct a "test phase" involving placement of TRU waste in the WIPP, and extending the term of the withdrawal through 1997. DOI's extension was found unlawful by a U.S. District Court. [61] The Court's order was upheld on appeal. [62] Congress subsequently effected a legislative withdrawal of this land in perpetuity in the WIPP LWA. [51]

EPA Actions

As directed by WIPP LWA, EPA finalized the generally applicable standards for the disposal of spent nuclear fuel, transuranic, and high-level radioactive wastes. These regulations limit the amount of radioactive material that may escape from a disposal facility and protect individuals and ground water resources from dangerous levels of radioactive contamination (see 40 CFR Part 191 on page 23).

Next, EPA developed criteria to implement and interpret these generic radioactive disposal standards specifically for the WIPP. In 1996, EPA promulgated the "Criteria for the Certification and Re-certification of the Waste Isolation Pilot Plant's (WIPP) Compliance with the 40 CFR Part 191 Disposal Regulations" at 40 CFR Part 194. This rule described the information DOE must submit in any certification application and clarifies the basis on which EPA's WIPP compliance determination would be made. [64]

As a companion to this rule, EPA developed the Compliance Application Guidance (CAG) to "assist DOE with the preparation of any Compliance Certification Application (CCA) for the WIPP and, in turn, to assist in EPA's review of the CCA for completeness and generally to enhance the readability and accessibility of the CCA for EPA and public scrutiny." [65] The criteria were challenged in the Court of Appeals for the District of Columbia and upheld in their entirety on June 6, 1997.

DOE studied the WIPP site for a decade. The Department conducted field studies, laboratory tests, and computer modeling to gain a clearer understanding of the WIPP's ability to isolate waste. In 1996, DOE submitted a Compliance Certification Application (CCA) for WIPP to EPA. After a careful review of the CCA, supplementary materials, and additional information, on May 13, 1998, EPA certified that the WIPP likely will comply with 40 CFR Part 191 as well as other relevant environmental and public health and safety regulations. [66]

Since TRU may be either a radioactive waste or a mixed radioactive and chemical waste, DOE was required to obtain a RCRA Permit (40 CFR Parts 264 and 270) for disposal of hazardous wastes from the New Mexico Environment Department (NMED). NMED granted a Hazardous Waste Facility Permit for the WIPP in October 1999, specifying the conditions under which DOE may dispose of mixed radioactive and chemical waste in the WIPP. The WIPP received its first shipment of TRU radioactive waste in March 1999. EPA will continue to regulate the WIPP, through inspections, recertification, and other actions, through the operational phase (i.e., as long as DOE is emplacing waste in the repository – about 35-40 years).

Impact of EPA Actions

The WIPP is both the nation's and the world's first facility certified for the deep geological disposal of TRU waste.

The WIPP provides a long-term disposal facility for TRU waste that is temporarily stored at Federal facilities. Most of the waste proposed for disposal at the WIPP will be generated in the future as nuclear weapons are disassembled.

Yucca Mountain, Nevada (40 CFR Part 197)

In 1980, DOE performed an analysis of disposal alternatives for spent nuclear fuel and high-level waste. This study evaluated possible disposal options, including ejection into space, elimination by transmutation to other elements, disposal in polar ice sheets, engineered disposal in a deep geologic repository, and burial in the ocean floor. Disposal in a deep geologic repository was determined to be the safest option.

Legislative Authority

The NWPA of 1982 provides DOE the responsibility of siting, building, and operating a deep geologic repository for the disposal of HLW and SNF. It directs EPA to "by rule promulgate generally applicable standards for protection of the general environment from offsite releases of radioactive material in repositories." NRC is required to license DOE to operate a repository that meets EPA's standards and all other relevant requirements. [41]

In 1987, Congress enacted the NWPAA that directed DOE to consider Yucca Mountain as the primary site for the first HLW and SNF repository in the United States and to phase out activities at other potential sites. [69]

The WIPP LWA of 1992 reinstated most of EPA's generally applicable disposal standards at 40 CFR Part 191, and exempted Yucca Mountain from those disposal standards. [51]

The Energy Policy Act of 1992 (EnPA) directed EPA to "promulgate, by rule, 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 was required to contract with NAS to conduct a study and make recommendations on the suitability of Yucca Mountain as a disposal site. EPA's standards were to be "based upon and consistent with the findings and recommendations of the NAS," and "shall prescribe the maximum annual effective dose equivalent of individual members of the public." [70]

Internal/External Triggers

A process for the selection of potential sites for disposal of HLW and SNF was established in the 1982 Nuclear Waste Policy Act. DOE was given the responsibility for conducting the siting process. The first steps were to identify potentially acceptable sites and develop general guidelines for siting repositories. In February 1983, DOE identified nine sites in six States as potentially acceptable for the first deep geologic repository. Yucca Mountain was one of those sites. [67] After further consideration and environmental assessment, DOE determined that three sites, Yucca Mountain, Nevada; Deaf Smith County, Texas; and Hanford, Washington, were suitable for development as repositories. [68]

The 1987 Nuclear Waste Policy Act Amendments (NWPAA) directed DOE to study only one candidate site, Yucca Mountain, Nevada, as the primary location for the first HLW and SNF deep geologic repository in the United States. It is located about 100 miles northwest of Las Vegas on Federally owned land on the western edge of the DOE's Nevada Test Site.

EPA is responsible for developing site-specific radiation protection standards and DOE is responsible for the construction, management, and operation of the facility. Since about 90% of the waste proposed for disposal is commercially generated, with the remainder coming from defense programs, NRC is responsible for implementing the EPA standard.

EPA Actions

To better understand the technical aspects of Yucca Mountain, EPA conducted extensive information gathering activities and analyses. These activities included contracting with the NAS Committee on Radioactive Waste Management to conduct the study and make recommendations on the suitability of Yucca Mountain as a disposal site, as required by the EnPA. The NAS completed the study and published the report, *Technical Bases for Yucca Mountain Standards.* [71] EPA solicited comments on this report from stakeholders and the scientific community, had technical discussions with NRC and DOE and its scientists, and worked with the President's Office of Science and Technology Policy. In addition, other Federal agencies' actions, other countries' regulations, and guidance from national and international organizations were considered. Based on the NAS report and the information received from the public, EPA proposed "Environmental Radiation Protection Standards for Yucca Mountain, Nevada" on August 27, 1999. [72,73]

Impact of EPA Actions

If approved, Yucca Mountain will be the nation's first deep geological disposal facility for the permanent disposal of HLW and SNF.

Environmental Standards

An important activity of the national radiation protection program has been the development of national standards and regulations to protect the general public from exposure to radiation in the environment. The environmental statutes discussed below apply to both chemical and radioactive contaminants.

Drinking Water (40 CFR Part 141)

Through the 1960s, both surface water and groundwater had generally degraded to the point that drinking water quality was becoming compromised in the United States – particularly in heavily populated urban areas. In 1960, the FRC, for the first time, established drinking water guidelines for selected radionuclides, including Ra-226, I-131, Sr-90, and Sr-89. The U.S. Public Health Service (PHS) established drinking water standards for these same radionuclides in 1962. In 1976, EPA revised these standards and developed drinking water standards for a host of other radionuclides under the authority of the Safe Drinking Water Act (SDWA). Through SDWA, Congress intended to improve the quality of drinking water and throughout the United States and prevent its further contamination.

Radionuclides Other than Radon

Legislative Authority

The Public Health Service Act, as amended in 1974 by SDWA, required EPA to establish primary drinking water standards for contaminants in public water systems. EPA was directed to set protective limits on drinking water contaminants that water systems can achieve using the best available technology; set water-testing schedules and methods that water systems must follow; and establish acceptable techniques for treating contaminated water. [75]

SDWA, as amended in 1986, declared the 1976 interim standards to be final National Primary Drinking Water Regulations (NPDWRs), required EPA to set Maximum Contaminant Level Goals (MCLGs) and MCLs[4], and directed EPA to develop procedures to assure drinking water supplies dependably comply with the MCLs. The standards were to be promulgated for 83 contaminants, including two additional radionuclides, uranium and radon, which may cause adverse health effects in humans and are known to occur in public water systems.

SDWA, as amended in 1996, directed EPA to withdraw the proposed MCL for radon due to a controversy over the cost-benefit basis for the proposed standard; required the NAS to conduct a formal study of the issue; and required assurance that any revised drinking water standards will maintain or increase public health protection. These amendments also provide for a cost-benefit analysis when publishing a proposal for new NPDWRs pursuant to SDWA section 1412(b)(6).

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[4] MCLGs are non-enforceable health based goals, set where no anticipated health effects would occur, with an ample margin of safety. For known carcinogens, the MCLG is set at zero, the assumption is that any exposure could present a cancer risk. MCLs are legally enforceable standards set as close to the MCLGs as possible, considering cost and technical feasibility.

Internal/External Triggers

Although radium may occasionally be found in surface water due to man's activities, it is usually found in groundwater where it is the result of geological conditions. In contrast to radium, man-made radioactivity is ubiquitous in surface water because of fallout radioactivity from nuclear weapons testing. In some localities radioactivity in surface or groundwater may be increased by small releases from nuclear facilities, hospitals, and scientific and industrial users of radioactive materials. EPA recognizes that, for both man-made and naturally occurring radioactivity, a wide range of both controllable and uncontrollable sources can influence the concentrations of radioactivity in water served by public water systems. Regulation of these contaminants under the authority of SDWA provides protection of human health from the harmful effects of exposure to radiation in drinking water. [74]

EPA Actions

In 1976, EPA established National Interim Primary Drinking Water Regulations (NIPDWRs) that included interim limits for the following categories of radionuclides: radium-226 and radium-228 combined at 5 pCi/l, gross alpha emitters at 15 pCi/l, and all beta particles and photon emitters (referred to as "man-made" radionuclides) at a total dose equivalent of 4 mrem/yr to any organ or the whole body. Standards for uranium and radium were not developed at this time since the Agency did not have sufficient health and occurrence data to establish standards. [76]

The NIPDWRs became final NPDWRs under the 1986 amendments to SDWA.

In 1986, EPA also published an Advanced Notice of Proposed Rulemaking (ANPRM) requesting additional information and comments on radionuclide contaminants in drinking water.

In 1991, EPA proposed a revision to the 1986 NPDWRs, including separate MCLs for radium-226 and radium-228; new standards for radon-222 and uranium; and revised standards for the gross alpha emitters and beta and photon emitters. The proposed limit for uranium was based on toxicity to the kidney as well as consideration of the cancer risk it poses. This proposed regulation also included monitoring, reporting, and public notification requirements. [77]

In 1996, the U.S. District Court for the District of Oregon issued an order that directed EPA, by November 2000, to either finalize the 1991 proposed radiation standards; state its reasons for not taking final action; or develop revised standards. The Court also directed EPA to establish a final standard for uranium by November 2000.

In 1999, EPA released *Cancer Risk Coefficients for Environmental Exposure to Radionuclides*, providing dose and risk data for each radionuclide based on updated scientific data. These values have been used to update the MCLs promulgated in 1986. In April 2000, EPA proposed revised NPDWRs which would result in the same or greater level of human health protection. [78]

Impact of EPA Actions

These drinking water standards replace those set by the PHS in 1962, setting legal limits on the levels of radionuclide contaminants in drinking water. The MCLGs reflect the level that is protective of human health; the MCLs reflect the level that water systems can achieve using current technology. These rules

set water-testing schedules and methods, and list acceptable techniques for treating contaminated water.

As described in *Protecting the Nation's Groundwater: EPA's Strategy for the 1990s: The Final Report of the EPA Ground-Water Task Force*, EPA will use MCLs as reference points when the groundwater in question is a potential source of drinking water. [81]

Radon

Legislative Authority
See above (page 30).

Internal/External Triggers
National and international scientific organizations have concluded that radon causes lung cancer in humans. According to the NAS, breathing indoor radon in homes is estimated to cause about 15,000 to 22,000 lung cancer deaths each year in the United States. [22] That makes radon in indoor air the second leading cause of lung cancer in the United States after cigarette smoking. In most cases, radon in soil under homes is the biggest source of exposure and radon from tap water is a small source of radon in indoor air, generally contributing about 1-2 percent of the total radon exposure from indoor air. In a second report in 1999, *Risk Assessment of Radon in Drinking Water*, the NAS estimated that lung cancer accounts for about 89 percent of the fatal cancers resulting from exposure to radon released from water into indoor air. The remaining fatal cancers, primarily stomach cancer, result from ingestion of radon in water. [79] Based on this report and other updated information, EPA estimates that uncontrolled levels of radon in public drinking water supplies cause 168 fatal cancers each year in the United States.

EPA Actions
In November 1999, EPA proposed new regulations to protect people from exposure to radon. The proposed regulations will provide the States flexibility in how to limit the public's exposure to radon by focusing their efforts on the greatest public health risks from radon - those in indoor air - while also reducing the highest risks from radon in drinking water. SDWA provides a unique framework for a multi-media approach, and is intended to promote a more cost-effective way to reduce the greatest risks from radon. The proposed rule applies to all community water systems (CWSs) that use groundwater or mixed ground and surface waters. [80]

The multi-media approach is based in part on the goals, program strategies, experience, and successes of existing national and State programs working to achieve indoor radon risk reduction through voluntary public action. Given the much greater potential for risk reduction in indoor air, EPA expects that greater overall risk reduction will result from this proposal than from an approach that solely addresses radon in community drinking water supplies.

Impact of EPA Actions
Once finalized, this rule would limit the public's exposure to radon by reducing the greatest public health risks from radon – those in air – while also reducing the greatest risks from radon in water.

The proposed radon in drinking water rule is one of EPA's first multi-media rules, and presents a unique multi-media risk management approach.

Hazardous Air Pollutants

Radionuclides are emitted into the air from many sources, including nuclear power plants, facilities relating to the nuclear fuel cycle, national defense facilities, research and development laboratories, medical facilities, industrial users, some mining and milling operations, and fossil fuel combustion plants. The CAAA of 1977, for the first time, provided EPA the specific authority to limit radionuclide emissions to the air.

Legislative Authority

Section 122 of the CAA Amendments of 1977 directed EPA to review all relevant information and determine whether emissions of radioactive pollutants will cause or contribute to air pollution that may reasonably by anticipated to endanger public health. Section 112 of the CAA required EPA to publish and periodically revise a list of HAPs that cause or contribute to an increase in mortality or serious illness and to which no national ambient air quality standard apply. Under Section 112(b), EPA was directed to publish regulations establishing NESHAPs for each listed HAP. The EPA was required to "establish such standards at the level that in his judgement provides an ample margin of safety to protect public health." [82]

Internal/External Triggers

On December 27, 1979, EPA added radionuclides to the list of HAPs under the CAA. [31] Among the radionuclides included were those defined by the AEA as source material, special nuclear material, and by-product materials as well as TENORM. In accordance with the requirements of Sections 122 and 112 of the CAA, EPA found that exposure to radionuclides increases the risk of human cancer and genetic damage. Also, the Agency found that emission data indicate radionuclides are released into air from thousands of sources. Based on this information, EPA concluded that emissions of radionuclides may reasonably be anticipated to endanger public health, and that radionuclides constitute HAPs within the meaning of the CAA.

EPA Actions

In 1983, EPA proposed NESHAPs for elemental phosphorus plants, DOE facilities, NRC-licensed facilities and non-DOE Federal facilities, and underground uranium mines. Simultaneously, the Agency proposed decisions not to regulate coal-fired boilers, the phosphate industry, other extraction industries, uranium fuel cycle facilities, uranium mill tailings, high-level radioactive waste facilities, and low-energy accelerators. [83] These standards were finalized in 1985. [84,85] A new standard for uranium mill sites was promulgated in 1986. [86]

Vinyl Chloride Decision

In July 1987, the U.S. Court of Appeals for the District of Columbia remanded the vinyl chloride NESHAP. The Court found that costs and technological feasibility had been improperly considered in setting the standard. According to Section 112 of the CAA, the Administrator is first required to make a determination based exclusively on risk to health. In light of that decision, EPA concluded the radiological NESHAPs should be reconsidered. The Court agreed, and on December 8, 1987, granted EPA's motion for a voluntary remand.

The Court, in the vinyl chloride decision,

established a two-step process to establish a safe level under Section 112 of the Act. First, it said, "the Agency must determine the level of emissions considered 'safe or acceptable,' without regard to control costs." Second, the Agency must achieve an ample "margin of safety" – considering both cost and technology. This approach was first expressed in the NESHAP for benzene, and became known as the "benzene policy."

For the first step, to determine "safe or acceptable," the Agency compared risks from many different sources, evaluated risks accepted in other Agency programs (e.g., Superfund and drinking water), and accepted public comments. EPA also considered several measures of risk including individual exposure, population exposure, numbers of people in various risk ranges, and non-fatal health effects. EPA defined "safe or acceptable" as:

- An individual lifetime risk of no greater than approximately 1 in 10,000 of contracting fatal cancer;
- The majority of people within 80 km of the facility at a less than 1 in 1,000,000 lifetime risk; and
- A small total estimated number of cases of death or disease.

The second step, an "ample margin of safety," involves establishing the actual level of public protection. It must be at least as protective as the level determined to be "safe" in step one. EPA defined the factors to be considered in setting an "ample margin of safety" to be:

- Costs and economic impacts of controls,
- Technological feasibility,
- Uncertainties, and
- Any other relevant factors.

All subsequent radionuclide NESHAPs have been promulgated through this process. These individual and population risk criteria (10^{-4} and 10^{-6} lifetime risk) correspond to the bounds of acceptable risk employed for all carcinogens, chemical or radioactive, by the Agency in its drinking water, Superfund, and CAA programs.

Radionuclide NESHAPs

On December 15, 1989, EPA published NESHAPs for eight radionuclide source categories, covering an estimated 6,300 sources. The revised rules were more prescriptive, based primarily on the decision-making framework outlined in the vinyl chloride decision and the benzene policy. They included radionuclide emissions other than radon from DOE facilities; NRC-licensees and non-DOE Federal facilities; elemental phosphorus plants; radon emissions from underground uranium mines; DOE facilities; phosphogypsum stacks; inactive uranium mill tailings facilities; and operating mill tailings facilities. [36]

Legal Actions

Eleven parties, primarily representing the regulated community, sued EPA during the development of the radionuclide NESHAPs promulgated in 1989. Several environmental organizations sued EPA over the level it chose as a benchmark for acceptable risk.

The NRC and the National Institutes of Health (NIH) petitioned for reconsideration of the NESHAP for NRC-licensed facilities, on

the basis that this regulation duplicated NRC's regulatory program. However, NRC did not have data from these facilities to verify the emissions, and did not constrain emissions below the EPA limit. Between 1992 and 1996, EPA evaluated the NRC program at thousands of facilities. Based on the data collected, EPA concluded that radionuclide emissions from NRC- and Agreement State-licensees did not exceed the 10 mrem/yr standard established in the NESHAP. NRC issued a "constraint rule" that required licensees to maintain emissions below that standard. EPA found that NRC's regulatory program protects the public health to a safe level with an ample margin of safety and the NESHAP regulating air emissions from NRC-licensees was rescinded on December 30, 1996. [87]

EPA was also petitioned by The Fertilizer Institute (TFI), Consolidated Minerals, Inc. (CMI), and U.S. Gypsum Co. (USG) to reconsider the portion of the NESHAP for phosphogypsum that required disposal into stacks or mines, thereby preventing any alternative uses of the material. EPA received more information on the proposed uses of phosphogypsum and on June 3, 1992, revised the rule to provide for limited uses for both agriculture, research and development, and other alternative uses on a case-by-case basis. [88]

EPA was petitioned by the NRC and industry stating that the operating uranium mills NESHAP overlapped EPA's uranium fuel cycle standard at 40 CFR Part 192, resulting in duplicative, burdensome regulations. EPA amended 40 CFR Part 192 to incorporate the additional requirements defined in the NESHAP, the NRC incorporated the additional requirements into its regulations, and this NESHAP was withdrawn (see the Uranium and Thorium Mill Tailings section on page 17). [37]

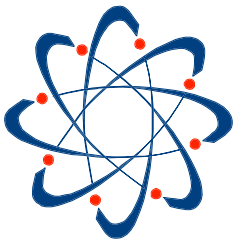
Impact of EPA Actions

These NESHAP standards limited releases of radionuclides from a variety of sources, protecting people and the environment from the harmful effects of ionizing radiation, including an increased risk of human cancer and genetic damage.

Radionuclides in air were regulated for the first time under a legislative authority other than that provided by the AEA. This meant that States and localities could set standards more stringent than the NRC standards; citizens could sue the government to provide and enforce standards; and policies for development of standards for radioactive materials could be established consistent with standards for the regulation of chemicals.

The vinyl chloride decision provided the decision-making framework for the NESHAPs independent of, yet consistent with, the risk management approach adopted by many EPA's programs.

Technologically Enhanced Naturally Occurring Radioactive Materials



Over the past 20 years, EPA and other Federal and State agencies, industries, and other organizations have identified an array of naturally occurring materials that, because of human activity, may present a radiation hazard to people and the environment. These materials are known as technologically enhanced naturally occurring radioactive

materials, or TENORM.[5] In general terms, TENORM is material containing radionuclides that are present naturally in rocks, soils, water, and minerals and that have become concentrated and/or exposed to the accessible environment as a result of human activities such as manufacturing, water treatment, or mining operations. The NAS defines TENORM as "any naturally occurring material not subject to regulation under the Atomic Energy Act whose radionuclide concentrations or potential for human exposure have been increased above levels encountered in the natural state by human activities." [89] Much TENORM contains only trace amounts of radiation and is part of our everyday landscape. Some TENORM, however, contains very high concentrations of radionuclides that can produce harmful exposure levels. EPA is concerned about TENORM because of this potential for harmful exposure to humans and the environment.

The radionuclide radium-226, a decay product of uranium and thorium with a radiation decay half-life of 1,600 years, is commonly found in TENORM materials and wastes and is the principal source of radiation doses to humans from natural surroundings. While normally occurring in soils of the United States at concentrations ranging from less than 1 to slightly more than 4 picocuries per gram (pCi/g, where picocuries are a measure of radiation content in a material), Radium-226 in TENORM materials can occur in concentrations ranging from undetectable amounts to as much as several hundred thousand pCi/g. In comparison, EPA has issued guidance that recommends that radioactively contaminated soils should be cleaned up so remnant radium concentrations are 5 pCi/g or less. This level would provide for a reasonably reduced risk from long term exposure. [90,91] Total amounts of TENORM wastes produced in the United States annually may be in excess of 1 billion tons.

Environmental Regulations

Legislative Authority

The CAA provides EPA the authority to set NESHAPs at 40 CFR Part 61. This authority applies to any TENORM sources specified by EPA that engage in activities resulting in emissions of a hazardous air pollutant into ambient air. [82]

The SDWA provides EPA the authority to set standards for radioactivity in community drinking water systems at 40 CFR Part 141. This authority applies to all TENORM; the principal concern is radium, but may also include uranium. [75]

The CWA provides EPA the authority to protect the waters of the United States (e.g., rivers, lakes, and wetlands) from pollution. The CWA is implemented through the National Pollutant Discharge Elimination System (NPDES). This system requires all pollutant discharges to the waters of the United States to comply with certain pollutant discharge criteria. EPA has the authority under the CWA to regulate non-AEA radioactive materials (e.g., TENORM). [95]

CERCLA provides broad Federal authority to respond directly to releases or threatened

[5] Before 1998, the term used for these materials was "Naturally Occurring Radioactive Materials" (NORM). Based on more current industry and regulatory practice, the term "TENORM" now is considered more appropriate. TENORM is used throughout this report.

releases of hazardous substances that may endanger public health or the environment, and to assure permanent cleanup of contaminated sites listed on the NPL. Radionuclides are considered hazardous substances under CERCLA by virtue of their listing as HAPs under the CAA, and are treated the same as any other carcinogen under Superfund regulations. Although CERCLA excludes source, byproduct, or special nuclear materials from the definition of "release," TENORM is subject to CERCLA. [96]

RCRA applies to active and future facilities, and provides EPA the authority to regulate hazardous wastes from "cradle-to-grave," including minimization, generation, transportation, treatment, storage, and disposal. RCRA exempts solid waste, including TENORM produced, from the extraction, beneficiation, and processing of ores and minerals (Bevill exclusion) and oilfield wastes from regulation as hazardous wastes. Additionally, source, special nuclear, or byproduct material as defined by the AEA of 1954 as amended, are exempt. [47]

Internal/External Triggers

In 1978 and 1983, the Conference of Radiation Control Program Directors (CRCPD) published reports titled *Natural Radioactivity Contamination Problems*, Numbers 1 and 2, providing recommendations for the protection of public health from exposure to TENORM. These reports recommended that EPA study the risk assessment and management of TENORM. [92,93]

The issue was further highlighted by the following two events:

- In 1986, significant levels of radioactivity were found at the Street facility in Mississippi. This facility removed scale and residue from salvaged oilfield equipment for Chevron and Shell Oil Co[6]. Street and its employees filed a suit against Chevron alleging personal injury and property damage resulting from the company's "failures to conduct reasonable inspections of the equipment and to warn the employees of the associated dangers." The Federal District Court found Chevron liable for damages to workers at the facility. [94]

- Following the discovery of TENORM at the Street facility, playground equipment and fences were found to be contaminated with TENORM at a number of locations in Mississippi and Louisiana. This equipment was made from oilfield equipment donated by the industry. [94]

Finally, as directed by Congress, EPA contracted with the NAS for a comprehensive review of guidance and regulations, developed by regulatory and advisory organizations, for indoor radon and other sources of TENORM. The 1999 NAS study found Federal and State organizations used the same scientific and technical information as the basis for their risk estimates. The differences in individual organizations numerical guidelines, which may vary significantly, were attributed to different risk management strategies and organizational missions. [89]

EPA Actions

EPA initiated studies in the 1970s to assess the risk to human health and the environment from industrial releases of TENORM. EPA

[6] Shell settled its claims prior to trial.

began with an evaluation of mining, milling, and smelting operations since they processed large quantities of ore, and there was little information about how these activities release radioactive emissions. EPA continued the evaluation of other NORM producing industries, and developed the following regulations under CAA, SDWA, CWA, and CERCLA to control exposures to these low levels of radiation.

Clean Air Act

In 1989, EPA promulgated the NESHAPs for radionuclides including four standards for releases of TENORM from both surface and underground mines as well as the production of phosphoric acid as follows:

Elemental Phosphorus Facilities – To gain a better understanding of TENORM releases, EPA conducted extensive radiological surveys of airborne releases at three elemental phosphorus plants: FMC Thermal Processing Plant, Pocatello, Idaho; Stauffer Elemental Phosphorus Plant, Silver Bow, Montana; and Monsanto Company Plant, Columbia, Tennessee. The significant releases of radionuclides for this industry were polonium-210 and lead-210 that were volatilized by the high temperatures in the calciner stacks. [97] Although significant amounts of radium were contained in the slag, the radon emanation rate was very low since the radium was encapsulated. However, the gamma exposure was found to be fifteen times that of background. [98,99] The NESHAP standard, promulgated in 1989, regulates polonium-210 emissions from elemental phosphorus plants. [36] No separate standard was promulgated for lead-210 since control of polonium ensures control of lead as well. Gamma radiation is not regulated since it is not considered a HAP under the CAA.

Phosphogypsum Stacks – Phosphogypsum is the primary byproduct generated from the wet-acid process of producing phosphoric acid. To protect human and environmental health, the EPA required the placement of phosphogypsum wastes in isolated "stacks" or piles. There are about sixty-three phosphogypsum stacks in the United States, ranging in size from 2 to almost 300 hectares, and from 3 to about 60 meters high. After an extensive study, EPA found that the radon released from the stacks present low levels of risk to millions of people. Subsequently, a NESHAP standard was promulgated to regulate radon emissions from phosphogypsum stacks. [34]

Surface Uranium Mines – Until the early 1960s, uranium was commonly mined in open pit mines from ore deposits near the surface. During this process, the topsoil (overburden) is piled on land beside the pit and saved for reclamation. The large surface area created by the pit and overburden, both of which contain elevated levels of radium, allowed higher than normal radon emissions to be released into the atmosphere. In 1988, EPA surveyed two active mines in Texas and Wyoming and 25 inactive mines in Arizona, New Mexico, Colorado, South Dakota, Texas, and Wyoming and determined health risk to be very low. Since these mines were already regulated by State and Federal mine reclamation laws and there was no reason to believe that new mines would be constructed since the industry was depressed, EPA decided not to set a NESHAP regulating emissions from surface mines. [36]

Underground Uranium Mines – EPA conducted a site-by-site assessment of operating or operable underground uranium mines, and found that the risk to nearby

individuals from exposure to the radon emissions from mine vents, in some cases, may be relatively high. The 1989 NESHAP regulates radon emissions from underground uranium mines. [83]

Safe Drinking Water Act

Water used for municipal purposes comes from lakes, streams, reservoirs, and aquifers that contain varying amounts of naturally occurring radionuclides. This water is generally treated to ensure its safety. The sludge generated from the treatment process may contain elevated levels of TENORM. EPA has developed a draft document, *Suggested Guidelines for Disposal of Drinking Water Treatment Wastes Containing Radioactivity*, to provide assistance to drinking water treatment facilities for the disposal of wastes resulting from the treatment of drinking water. These guidelines are intended to fill the gaps in State regulations for disposal of TENORM wastes. [99]

Clean Water Act

CWA provides EPA the authority to set standards for liquid discharges of TENORM from mines or mills. In 1982, EPA set standards for releases from the production of uranium, radium, and vanadium into surface waters. These limits are based on "best available control technology." [100]

Comprehensive Environmental Response, Compensation, and Liability Act

CERCLA addresses TENORM within the same risk management scheme as chemicals (see Superfund Program on page 42).

Diffuse Norm Scoping Document

In the mid-1980s to the mid-1990s, EPA began developing a report to characterize and evaluate the potential risks from TENORM generated from a variety of common activities. The draft report, *NORM Waste Characterization*, presented a preliminary risk assessment, NORM waste characterization, and generic risk assessment information for generation, handling, disposal, and use in each of the identified NORM sectors. This report also summarized the literature for several major industrial sectors that produce NORM, including industries EPA has previously evaluated (discussed above) as well as the following industries: metal mining and processing other than uranium, oil and gas production and processing, and geothermal energy production. In 1999, the Agency decided to concentrate its efforts on issuing technical reports on one sector at a time.

Impact of EPA Actions

EPA has developed regulations, under several different environmental laws, limiting TENORM releases to air and water, and establishing cleanup goals for contaminated soil. The implementation of these regulations has protected people and the environment from the harmful effects of ionizing radiation.

Indoor Radon Exposure in Florida

In 1975, approximately 83 percent of U.S. phosphate rock was mined in Florida, with the remainder in Tennessee and several western States. Uranium and radium-226 are present in the phosphate ore and the overburden. The presence of radium-226 and its decay products is a potential source of gamma exposure, but of greater concern is exposure to radon gas. [102]

Legislative Authority

See above (page 30).

EPA Actions

In 1975, EPA initiated a pilot study to

examine the radiological impact of living in structures built on reclaimed phosphate land. The field investigations identified high levels of radon in some structures built on reclaimed phosphate land in Florida when compared with structures built on unmined land. In September 1975, EPA informed the Governor of Florida that the Agency had found elevated radon decay product levels in these homes, noting that the primary health concern is increased risk of lung cancer to the occupants. The EPA recommended that "as a prudent interim measure the start of construction of new buildings on land reclaimed from phosphate mining area be discouraged." Florida requested a follow-up investigation and guidance from EPA. [102]

In 1978, the Florida Department of Health and Rehabilitative Services (HRS) issued the results of an additional study of indoor radon and gamma radiation levels in houses located in phosphate mining areas; this report confirmed the earlier results reported by the EPA.

EPA conducted a more comprehensive study, and in February 1979 published the results in *Indoor Radiation Exposure Due to Radium-226 in Florida Phosphate Lands*. This report provided an estimate of the radiation levels in existing structures, an evaluation of cost-effectiveness of controls, an evaluation of the social and economic impact of potential radiation protection controls, and a delineation of the alternatives available for radiation protection to minimize adverse risk to the public. [103] Governor Bob Graham directed HRS to appoint a task force to further investigate the issue and recommend policies to address the health risks of people living on reclaimed phosphate land.

Impact of EPA Actions

The three above-mentioned studies, which examined the radiological impacts of living in structures built on reclaimed phosphate land, led to the promulgation of a new Florida statute, which effectively changed the way mined land is managed in the State. [103]

These were among the first studies to be conducted to evaluate the impact of living in structures built on reclaimed land, and they launched the U.S. program to identify and limit exposure of the U.S. population to indoor radon.

The numerical level recommended for radon in this study became the national action level that is still in effect today (albeit expressed in different units). [102]

Cleanup Rule

By 1990, it was evident that the Federal government needed more and consistent guidance for cleaning up radioactively contaminated sites. Although clean-up activity was ongoing in all environmental media (e.g. soil, groundwater, air) by several different Federal agencies, progress was slow due to public concerns, technical complexity, and the lack of consistent regulations.

Legislative Authority

The Atomic Energy Act provides EPA the broad authority to develop generally applicable environmental radiation standards. [1]

CERCLA authorizes EPA to take corrective action whenever a site has been listed on the

National Priorities List (NPL). [96] This can occur due to contamination by any hazardous substance, including radionuclides.

Internal/External Triggers

In the early 1990s, Senator John Glenn (D-Ohio) held a series of hearings that highlighted problems experienced by EPA, DOE, DoD, and NRC at sites contaminated with radiation. As an outcome, in late 1991, EPA began to develop a "Cleanup Rule" to reduce the uncertainty associated with determining the cleanup level needed to protect human health and the environment. DOE was committed to the rule's development and provided funds to EPA to cover the cost of development. This approach held the promise of providing a precedent for interagency cooperation.

In March 1992, the Administrator of EPA and the Chairman of NRC signed a MOU, "Guiding Principles of EPA/NRC Cooperation and Decisionmaking." The goal of this MOU was to define the division of responsibilities and to foster cooperation between the organizations in fulfilling their responsibilities to ensure protection of human health and the environment. Principles in the MOU included conformance with the radiation protection responsibilities set out in Reorganization Plan No. 3, and avoiding unnecessary, duplicative, or piecemeal regulatory requirements for NRC-licensees. It was envisioned that this MOU would expedite the development of the Cleanup Rule.

EPA Actions

In 1993, EPA developed the *Issues Paper on Radiation Site Cleanup Regulations*, and made it available for public comment. [104] During this period, EPA sought input from individuals actively involved in environmental and radioactive materials management through the establishment of a subcommittee under the National Advisory Council on Environmental Policy and Technology (NACEPT) that met several times in 1993 and 1994. During the last NACEPT meeting, EPA released an early draft of the proposed rule for public comment. [59] In addition, EPA requested comments from the EPA Science Advisory Board (SAB) concerning approaches for developing and implementing the standard.

The goals of the draft proposed rule were to: provide clear, consistent, and protective health-based cleanup standards; promote beneficial land uses; facilitate consistent radiation site cleanup; be implementable; and promote innovative technologies. It was to be applicable to all sites contaminated with radioactive material subject to the AEA and to sites covered under the authority of CERCLA, including the land and structures at Federal facilities, Superfund sites, and NRC- and Agreement State-licensees. The draft proposed rule assumed the property would ultimately be released to the public. It specified an individual protection limit of 15 mrem/yr ground water standards based on the SDWA MCLs, and provided flexibility with respect to land use.

During the OMB review, there was disagreement between the Federal agencies on both the proposed level of individual protection and the use of MCLs for ground water protection. In December 1996, EPA withdrew the proposed rule.

Impact of EPA Actions

NRC, DOE, and EPA each continued development of separate regulations or guidance for their own agencies to follow in cleaning up sites contaminated with radioac-

tive materials.

On August 22, 1997, EPA issued an OSWER Directive *Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination*. This directive clarified cleanup criteria for radiation consistent with the criteria for hazardous chemicals. [105]

On February 12, 1998, EPA issued an OSWER Directive, *Use of Soil Cleanup Criteria in 40 CFR Part 192 as Remediation Goals for CERCLA Sites*. This directive addresses the use of the soil cleanup criteria in 40 CFR Part 192 when setting remediation goals at CERCLA sites contaminated with radioactive materials. [106]

Superfund Program

The Superfund program applies to contaminated sites listed on the NPL based on criteria for the degree of hazard they pose under provisions of the National Contingency Plan (NCP). Fifty-five of these are Federal sites, most of which are associated with past DOE weapons operations. These DOE sites comprise over 98% of the total volume of soils contaminated with man-made radioactive materials in the United States. [107]

The Radiation Protection Division (RPD) works closely with the Superfund Program to ensure that radioactive contaminants at Superfund sites are addressed in a protective manner. RPD assists in two primary areas: site-specific support, such as site monitoring programs, analysis and interpretation of site data, and work on emergency removal actions; and program-wide efforts such as development of technical and policy guidance, technology reviews, and training in assessing and addressing radiological hazards.

Legislative Authority

CERCLA provides EPA broad Federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment, and to assure permanent cleanup of contaminated sites listed on the NPL. CERCLA excludes source, byproduct, or special nuclear material from the definition of "release."[7] [96]

Internal/External Triggers

Radionuclides are considered hazardous substances under CERCLA by virtue of their listing as HAPs under the CAA, and are treated the same as any other carcinogen under Superfund regulations. The majority of radioactively contaminated sites (i.e., those administered by DOE) were listed on the NPL in the years immediately following 1989, when Congress mandated that DOE enter into cleanup agreements with EPA and the States under CERCLA.

EPA Actions

Guidance Development

In 1988-1989, EPA developed Section 7 of Superfund's Hazard Ranking System Rule, which is the schematic for "ranking" or placing sites on the NPL. This rule, finalized on March 8, 1990, provided guidance for the consistent scoring of sites contaminated with radiation. [108]

[7] See 42 USC 9601(22) for definition of "release."

In the late 1980s and early 1990s, RPD collaborated with Superfund in the development of a series of documents collectively entitled *Risk Assessment Guidance for Superfund* (RAGS). [109,110,111] RAGS provide guidance to evaluate risks to human health and the environment from exposure to radioactive and nonradioactive hazardous substances at CERCLA sites. It provides guidelines for assessing baseline risks, developing preliminary remediation goals, and evaluating risks for remedial action alternatives.

RPD also developed the *Radiation Exposure and Risk Assessment Manual: Risk Assessment Using Radionuclide Slope Factors* (RERAM), which provides detailed documentation of the methodology used by EPA to develop health risk assessments. [112] These slope factors are incorporated into the *Health Effects Assessment Summary Tables* (HEAST) and are used to estimate excess cancer risks associated with radiation exposure at Superfund sites. [113] RERAM was developed as a supplement to the RAGS.

When the Cleanup Rule effort stalled, RPD continued to work with the Superfund program to incorporate guidance for cleanup of radioactive materials into Superfund guidance. This effort led to the development of the 1997 OSWER Directive *Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination*. [105] This guidance reaffirms that protective cleanup criteria for radioactive contamination at CERCLA sites are the same as those for all other carcinogens, and specifies that 15 mrem/y satisfies these criteria.

The *Superfund Soil Screening Level Guidance* (SSLG), developed by OSWER in 1996, provides a methodology for evaluating the risk at Superfund sites. [106] This evaluation considers the concentration of the hazardous contaminants present, and guidance on the number and location of samples to be taken to determine if cleanup is needed.

In 1998, EPA issued the directive titled *Use of Soil Cleanup Criteria in 40 CFR Part 192 as Remediation Goals for CERCLA Sites.* [106] It addressed the use of the soil cleanup criteria in 40 CFR Part 192 as an ARAR at Superfund sites.

The *Multi-Agency Radiation Survey and Site Investigation Manual* (MARSSIM), issued in 1997, is a multi-agency consensus document that was developed to provide a single Federal basis for designing protocols to investigate, characterize, and remediate radioactive contamination in the environment. It provides information on how to plan, conduct, evaluate, and document environmental radiological surveys of surface soil and building surfaces for demonstrating compliance with regulations. [114]

On-Site Support

RPD's radiation laboratories, the National Air and Radiation Environmental Laboratory (NAREL) in Montgomery, Alabama and the Radiation and Indoor Environments National Laboratory (RI&ENL) in Las Vegas, Nevada provide on-site support for site assessment and characterization. The laboratories' unique fleet of mobile radiological laboratories and support vehicles provide sample collection, analyses, and comprehensive cleanup support activities. The labs provide assistance to the Superfund and RCRA programs, DOE, and DoD.

Impact of EPA Actions

Risks associated with exposure to chemical

and radioactive contamination have traditionally been evaluated and managed using different methods and risk management criteria. RPD's work with the Superfund program has helped to develop a consistent national approach to the remediation of chemical and radioactive contamination. This work helped ensure that radioactive contamination is addressed early and consistently in the Superfund process.

The MARSSIM manual provides, for the first time, a uniform approach to assessment and verification for all Federal site decontamination and cleanup activities regardless of the cleanup level desired.

Emergency Response

Working closely with its partners in other Federal agencies as well as State and local governments, ORIA is prepared to respond to radiological emergencies including accidents at nuclear power plants, transportation accidents, and deliberate acts of nuclear terrorism. In the event of a nuclear emergency, EPA employs specially trained Regional, Headquarters, and Laboratory staff, sophisticated equipment, and mobile and fixed laboratories to provide crucial scientific and technical support to State and local governments, and other Federal agencies.

EPA's two radiological laboratories, the Radiation and Indoor Environments National Laboratory (R&IENL) in Las Vegas, Nevada and the National Air and Radiation Environmental Laboratory (NAREL) in Montgomery, Alabama, provide the majority of the EPA personnel and field and lab equipment in support of a Federal response to a nuclear emergency. The lab's unique fleet of mobile radiological laboratories and support vehicles provide the capability for on-site sample collection, analyses, and comprehensive cleanup support.

Legislative Authority

The AEA provides EPA the authority to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and executions of programs of cooperation with the states."

The Public Health Service Act (PHSA) provides EPA: the primary responsibility within the executive branch for the collection, analysis, and interpretation of data on environmental radiation levels; the authority to develop protective action guides; conduct routine and special surveillance and monitoring; and to provide technical assistance to the States in responding to an emergency affecting public health.

CERCLA provides EPA a broad Federal authority to respond directly to releases or threatened releases of hazardous substances, including radionuclides that may endanger public health or the environment. CERCLA does not apply to radiological accidents indemnified by the Price Anderson Amendments to the AEA (i.e., commercial nuclear facilities). DoD is the lead for any response at a DoD facility.

The Clean Water Act (Section 311) provides EPA the authority similar to CERCLA, but specific to navigable waterways.

Radiological Emergency Response

This section discusses EPA's role in responding to radiological emergencies, including those at nuclear power plants as well as lost or abandoned sources.

Three Mile Island - Emergency Response at the Cross Roads

On March 28, 1979, a series of mechanical, electrical, and human failures led to a partial meltdown of the reactor core of the Three Mile Island (TMI) nuclear power plant in Harrisburg, Pennsylvania, allowing a release of radioactive coolant to the atmosphere.

There were no injuries. This accident did however, identify significant coordination issues within the different Federal and State agencies responsible for responding to a radiological emergency, and led to a complete overhaul of the Federal emergency response system. (This is discussed in more detail in the Radiological Emergency Response Plan section.)

Legislative Authority
See above (page 45).

EPA Actions
EPA played a significant role in response to the accident at TMI, primarily by supporting the Federal effort to characterize the radioactive releases after the accident. EPA assumed responsibility for off-site environmental monitoring and analysis for nine years. In 1988, this monitoring responsibility was transferred to the State of Pennsylvania.

Impact of EPA Actions
EPA's radiation monitoring and assessment activities provided the information needed to assure the public that the release of radioactive was minimal, and there was no threat to public health. EPA continued monitoring for nine years after the accident.

Radiological Emergency Response Plan
The accident at TMI had a profound effect on the way the Federal government responds to radiological emergencies. Prior to TMI, Federal agencies developed individual plans for a response to a radiological emergency. There was no coordinated plan or overall organization, leading to confusion during the response. In the aftermath of TMI, President Carter created the Federal Emergency Management Agency (FEMA) to lead the effort to reorganize the Federal emergency response.

Legislative Authority
On July 20, 1979, President Carter issued Executive Order 12148, transferring the Federal lead role in off-site radiological emergency planning and preparedness activities from the NRC to the newly formed FEMA. FEMA's responsibilities encompass activities that take place beyond the boundaries of the nuclear power plant. On-site activities continued to be the responsibility of the NRC. [115]

On September 29, 1980, President Carter issued Executive Order 12241, directing FEMA to develop a National Contingency Plan.

Internal/External Triggers
As directed by President Carter, FEMA developed a National Contingency Plan (NCP) called the Federal Radiological Emergency Response Plan (FRERP). FEMA published the plan in November 1985, establishing an organized, integrated response by Federal agencies to peacetime radiological emergencies in the United States. The FRERP specified the roles and responsibilities of Federal, State, and local government; required Federal agencies to develop agency-specific response plans called the Radiological Emergency Response Plans (RERPs); and provided for the Radiological Emergency Response Team (RERT), a designated special response force as the primary mechanism to respond to nuclear emergencies.

In March 1982, FEMA issued regulations establishing the Federal Radiological Preparedness Coordinating Committee (FRPCC) to coordinate all Federal

responsibilities and to assist State and local governments in radiological emergency planning and preparedness. [116]

There are currently 17 Federal agencies that have a role in responding to a nuclear emergency; the major players are FEMA, NRC, DOE, DoD, and EPA.

EPA Actions

EPA's RERP, first published in 1986, defined EPA's authorities, organization, responsibilities, and capabilities for responding to radiological emergencies in the environment. The plan was revised in January 2000. The current plan describes EPA's role in developing and implementing training programs for State and local officials on protective action guides, radiation dose assessment, and decision making and effective use of Agency assets in the event of a nuclear accident. [117]

RERT capabilities include conducting environmental monitoring, performing laboratory analyses, and providing advice and guidance on measures to protect the public. When required, the RERT may also exercise EPA's authority under the FRERP to coordinate the Federal response to a nuclear emergency. The RERT works with other Federal agencies and State and local governments to plan and participate in nuclear emergency response exercises. Additionally, RERT personnel continually update their multidisciplinary skills and provide training to other organizations charged with responding to nuclear emergencies.

EPA also has participated in the first major Federal radiological exercises – Full Field Exercises (FFEs) 1 and 2. These exercises examined the ability of Federal agencies to support a State response to simulated nuclear power plant accidents.

Impact of EPA Actions

EPA is prepared to respond in the event of a radiological emergency, and provides training and support to assist States in preparing for a radiological emergency response.

Chernobyl - An International Incident

On April 26, 1986, unauthorized testing of reactor number four at the Soviet Union's Chernobyl nuclear power station caused it to explode and burn, emitting large quantities of radioactive material into the environment.

Internal/External Triggers

The White House designated EPA to lead the Federal response to this emergency.

EPA Actions

EPA began to monitor and assess radioactivity in the United States, based in part on daily samples from its Environmental Radiation Ambient Monitoring System (ERAMS) stations. EPA's monitoring activities first detected radiation from the Chernobyl power station, at ground level on the West Coast, one week after the accident, well below levels requiring protective action.

EPA also dispatched response personnel to Europe to monitor and assess levels of radioactivity in the U.S. embassies.

Impact of EPA Actions

EPA's radiation monitoring and assessment activities provided the information needed to assure the nation that radiation levels in the United States remained below levels requiring protective actions.

Lost and Abandoned Radiation Sources

Legislative Authority
See above (page 45).

Internal/External Triggers
The FRERP was modified after the accident at Chernobyl to include responses to smaller emergencies such as lost radiation sources or lost radioactive material. In the revised FRERP, EPA was assigned Lead Federal Agency (LFA) for coordinating the Federal response to lost and abandoned radiological materials. [118]

EPA Actions
EPA utilized its authorities under CERCLA to respond to lost and/or abandoned radiation sources that present an imminent danger to public health and safety. The first of these types of responses was conducted in 1989 at the abandoned Radium Chemical Company facility located in a light industrial area in New York City. Thousands of curies of radium were abandoned because the owner did not have the financial capability to clean up the facility. EPA successfully removed all the hazardous and radioactive material and cleaned up the facility.

EPA responds to dozens of requests for assistance annually from State and local officials that discover radioactive material in local landfills or scrap metal recycling facilities.

Impact of EPA Actions
EPA works closely with the scrap metal industry, States, and other Federal regulatory agencies to identify the source of the lost or abandoned radioactive material, and to address the impact on humans and the environment.

Radiological Emergency Preparedness

Since the early 1970s, EPA has been involved in numerous radiological emergency preparedness activities both nationally and internationally. EPA has supported State preparedness and planning for responding to nuclear incidents through the development of State plans and emergency response guidance. EPA also has participated in emergency response drills and exercises. The most significant activities are briefly discussed below.

Protective Action Guides
One of EPA's most important emergency preparedness activities is the development of Protective Action Guides (PAGs). PAGs are projected levels of radiation at which State and local officials should take action to protect the public from radiation exposure. They are used by Federal, State, and local officials with responsibility for emergency response planning in the event of a nuclear incident. [119]

Legislative Authority
See above (page 45).

Internal/External Triggers
In 1975, the General Services Administration (GSA) outlined the responsibilities of various Federal agencies for radiological emergency response planning. EPA was given the responsibility to establish PAGs for the levels at which protective actions should be taken by governmental authorities to minimize the consequences of a radiological incident. [120]

EPA Actions

Manual of Protective Action Guides and Protective Actions for Nuclear Incidents
This manual was developed to provide State, local, and other officials criteria to use in the development of their State radiological emergency response plans for nuclear power reactors. It provided information for both evacuation and sheltering of the public during a nuclear incident, and included PAGs for exposure to airborne radioactive materials. This document recognized the need for, but did not establish, PAGs for exposure from radioactively contaminated food or water, and radioactive material deposited on property or equipment. [121]

In 1980, this manual was updated. PAGs for an airborne plume were revised to apply to a much broader range of situations. However, the recommendations still applied only to nuclear power reactors.

The *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents* was revised again in 1991 after extensive consultation with all affected Federal agencies. The new recommendations adopted lower, more protective values, and now applied to all types of nuclear incidents. This guidance has been accepted by all Federal agencies and States and applies to all nuclear sites, both Federal (including military) or commercial, nationwide. [119]

PAGs for Accidents from Nuclear Powered Satellites
After the 1978 crash Cosmos 954, the Soviet nuclear powered satellite, in a remote part of Canada, the U.S. became concerned about accidents with satellites containing radioactive material. EPA began working with NASA to develop PAGs for accidents during the launch of nuclear powered satellites and took part in the deployment of emergency response assets during the launch of the Ulysses and Galileo space craft. Because of the potentially wide distribution of radionuclides during an aborted launch or reentry, this effort required considerable coordination between EPA and other Federal, State, and local government agencies and the international community.

Impact of EPA Actions
PAGs are used to guide decision makers in determining the most prudent action to take in the event of a radiological emergency – no action, seek shelter, or evacuate.

The PAGs are incorporated into all State plans for responding to a radiological emergency at a nuclear power plant.

EPA was on-site during preparations for several spacecraft launches involving radioactive materials, including the Cassini mission to Saturn and the Galileo and Ulysses missions to Jupiter. In the event of an accident, EPA was prepared to respond.

Working with International Organizations

Legislative Authority
See above (page 45).

Internal/External Triggers
As a result of EPA's response to the accident at the Chernobyl, the scope of the FRERP was expanded to include responses to accidents in foreign countries that may impact the United States. EPA was assigned LFA for coordinating the Federal response foreign radiological emergencies.

EPA Actions

EPA is working with the International Atomic Energy Agency (IAEA) and the Nuclear Energy Agency (NEA) to improve the ability to respond to nuclear accidents that have transboundary impacts. To better prepare for such an incident, EPA has participated in the NEA's International Nuclear Emergency Exercise (INEX) series of exercises in 1995 and again in 1999.

EPA has organized and conducted RADEX 94 in Anchorage, Alaska in 1994 under the auspices of the Arctic Environmental Protection Strategy. This international exercise involved Russia, Canada, Norway, Sweden, Denmark, Finland, and the United States, and examined the issues surrounding a nuclear accident that had an impact on the Arctic environment.

Impact of EPA Actions

EPA is better prepared to coordinate with international organizations in the event of a transboundary radiological emergency response.

Counterterrorism

Legislative Authority

The *U.S. Policy on Counter-Terrorism* (PDD-39), issued June 21, 1995, established how the United States will respond to the use of weapons of mass destruction by terrorists. EPA has the responsibility to provide support to the FBI during crisis management operations and to FEMA during consequence management operations. EPA assistance may include threat assessment, agent identification, hazard detection and mitigation, environmental monitoring, and long-term site restoration. [122]

Protection Against Unconventional Threats to the Homeland and Americans Overseas (PDD-62) issued May 22, 1998, directed EPA to provide support to FEMA for consequence management. EPA is further directed to support State and local responders plan for terrorist events, coordinate activities with key Federal partners, and provide training to emergency responders. [123]

Presidential Decision Directive 63, *Critical Infrastructure Protection*, issued May 22, 1998, ensures the continuity and viability of the United States' critical infrastructure. EPA, and all other Federal departments and agencies, are required to: develop a Critical Infrastructure Protection Plan (CIPP) to protect its critical infrastructure; conduct an assessment of infrastructure vulnerabilities; and develop a plan to address all the vulnerabilities in a timely manner.

Enduring Constitutional Government and Continuity of Government, PDD-67, issued October 21, 1998 directs the development of plans and capabilities to assure the continuity of government, at all levels, in any national security situation that might confront the Nation.

Internal/External Triggers

In response to the Tokyo subway sarin gas attack in March 1995 and the bombing of the Murrah Building in 1995 in Oklahoma City, the United States government increased its efforts to combat terrorism.

EPA Actions

Because of its role in responding to terrorist events, EPA is working closely with the FBI and FEMA to develop plans and procedures that implement the instructions contained in the Presidential guidance addressing terrorist activities. EPA has also participated in terrorist

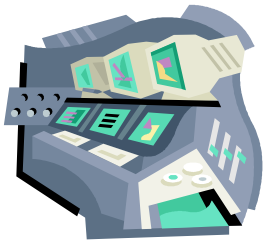
training exercises such *Mirrored Image* in preparation for the Atlanta Olympic Games and *Exercise TopOff* which involved Cabinet-level officials in an exercise for the first time.

EPA has been working with DoD to prepare for accidents involving nuclear weapons in their custody and has participated in exercises such as *Diagram Jump* in Seattle, *Display Select* in Virginia.

Impact of EPA Actions
As a result of EPA's participation in numerous planning and preparedness work groups, training activities, exercises and drills, and responses to real events, the Agency is prepared to coordinate effectively with our partners in other Federal agencies as well as State and local governments to ensure a timely and effective response to a radiological emergency involving terrorist activities.

The development of PAGs has led to a consistent national approach to protecting both nuclear emergency response personnel and the general public in the event of a nuclear incident. PAGs are used by all Federal agencies and States.

Environmental Radiation Ambient Monitoring System



The Environmental Radiation Ambient Monitoring System (ERAMS) is the nation's most comprehensive means of acquiring and analyzing environmental radiation data. ERAMS stations are distributed across the nation and regularly sample the nation's air, precipitation, drinking water, and milk. Station locations provide broad geographical and optimal population coverage. All station operators are volunteers provided mainly by State agencies, or, in some cases, local governments.

Legislative Authority
See PHSA above (page 45).

Internal/External Triggers
Following the 1963 moratorium on atmospheric nuclear weapons testing, the focus of many radiological environmental monitoring systems shifted to baseline, trend analysis, and emergency preparedness.

EPA Actions
In 1973, EPA established ERAMS by consolidating various components of existing radiation monitoring networks into one system. These components included the Radiation Alert Network, the Tritium Surveillance System, the Interstate Carrier Drinking Water Network, and the Pasteurized Milk Network.

ERAMS operates in either an emergency or routine mode. During routine conditions, samples are collected and analyzed on established schedules, producing data that can be used to perform baseline and trend analysis of radioactivity in the environment. During emergency conditions, the sampling schedule is accelerated to daily sampling and the data are used to determine the immediate and long-term environmental and public health impacts.

EPA compiles the ERAMS data quarterly and publishes it in *Environmental Radiation Data (ERD)* reports.

Impact of EPA Actions
During its more than twenty years of operation, ERAMS has been most successful in developing an important environmental

radiation database, providing information about weapons tests, and reporting upon significant releases of radioactivity into the environment such as the Chinese weapons tests of 1976 and 1977, Three Mile Island in 1979, and the Chernobyl incident in 1986. ERAMS was the nation's principal source of comprehensive data for those events.

Data generated by ERAMS have been published in the quarterly data-only journal *Environmental Radiation Data* (ERD). Each issue of the ERD is entered into the National Technical Information Service (NTIS) clearinghouse.

Appendix A: Statutory Authorities, Executive Orders, and Other Reference Documents

The mission of the radiation protection program is derived from numerous statutory authorities, Executive Orders, Presidential Decision Directives, and Federal plans. Some of these documents, such as the Clean Air Act, address radioactive emissions only as part of the much larger problem of air pollution, whereas other documents, such as the Waste Isolation Pilot Plant Land Withdrawal Act, directly address EPA's role in the disposal of radioactive waste. The radiation protection program has evolved significantly over the last thirty years as these documents have been implemented. EPA's radiation protection authorities are briefly described below.

1944 - Public Health Service Act (42 USC 201 et seq.)

The PHSA provides EPA with the authority to conduct monitoring of environmental radiation, perform research on the environmental and human health effects of exposure to radiation, and provide training and technical assistance to the States. Under Reorganization Plan No. 3 of 1970, EPA was assigned the authority of Section 311(c)(1) to develop, and implement as needed, a plan to effectively provide personnel, equipment, medical supplies, or other Federal resources to respond to health emergencies.

1946 - Atomic Energy Act, as amended in 1954 (42 USC 2011 et seq.)

The AEA established the Atomic Energy Commission (AEC) to promote the "utilization of atomic energy for peaceful purposes to the maximum extent consistent with the common defense and security and with the health and safety of the public." Under Reorganization Plan No. 3, EPA was transferred the authority of the AEC for "establishing generally applicable environmental standards for the protection of the general environment from radioactive materials. As used herein, standards mean limits on radiation exposures or levels, concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material." EPA also was transferred the authority of the Federal Radiation Council (FRC) under the AEA to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and executions of programs of cooperation with the states."

1959 - EO 10831, Establishing the Federal Radiation Council

The Federal Radiation Council (FRC) was issued July 24, 1959, by President Eisenhower. The FRC was composed of the Secretary of Defense, the Secretary of Commerce, the Secretary of Health, Education, and Welfare, and the Chairman of the AEC. It was established to "advise the President with respect to radiation matters directly or indirectly affecting health ..." The Council was given the authority to seek technical advice, in respect of its functions, from any source it deems appropriate. These authorities were transferred to EPA under Reorganization Plan No. 3, 1970.

1963 - Clean Air Act, as amended in 1970, 1977, 1990 (42 USC 7401 et seq.)

Section 122 of the CAAA of 1977 directed EPA to review all relevant information and determine whether emissions of radioactive pollutants into ambient air will cause or contribute to air pollution that may reasonably be anticipated to endanger public health. Section 112 required EPA to publish and, from time-to-time, revise a list of hazardous air pollutants (HAPS), and to develop a program to promulgate, implement, and enforce emission standards for listed pollutants. The Administrator was directed to establish national emission standards "at the level in his judgement provides an ample margin of safety to protect public health." This gave EPA the authority to develop NESHAPs for radionuclides. In addition, the listing of radionuclides as hazardous pollutants meant that the emergency response requirements of CERCLA also applied to accidental releases of radioactive material.

Section 103 of the CAA provides EPA broad authority to gather information, provide grants, to conduct or promote research, and to coordinate and accelerate training.

1972 - Marine Protection, Research, and Sanctuaries Act, as amended in 1977 (32 USC 1401 et seq.)

The MPRSA authorizes EPA to issue permits and promulgate regulations for disposing of materials into the territorial waters of the United States when it will not degrade or endanger human health, welfare, ecological systems, the marine environment, or the economy. It specifically prohibits ocean disposal of HLW and requires a permit for any other ocean disposal activity. Any request for ocean disposal of LLW requires a permit that must be approved by both houses of Congress.

1972 - Federal Water Pollution Control Act, as amended by the Clean Water Act of 1977, as amended in 1987 (33 USC 1251 et seq.)

The primary objective of the CWA is to restore and maintain the integrity of the nation's waters. The CWA requires major industries to meet performance standards to ensure pollution control; charges States and Tribes with setting specific water quality criteria appropriate for their waters and developing pollution control programs to meet them; provides funding to States and communities to help them meet their clean water infrastructure needs; and protects valuable wetlands and other aquatic habitats through a permitting process that ensures development and other activities are conducted in an environmentally sound manner. Section 311 of the CWA provides the Administrator with the authority to initiate and direct responses to any accidental releases of oil or hazardous substances when there is a substantial threat to the public health or welfare. The NCP implements the emergency response requirements of Section 311 of the CWA.

1974 - Safe Drinking Water Act, as amended in 1986, 1996 (43 USC s/s 300f et seq.)

SDWA requires EPA to promulgate and enforce primary standards for contaminants in public water systems, including radionuclides. Initially, EPA was to set interim regulations for a limited group of contaminants and later revise those regulations and set standards for the remaining contaminants. The 1986 amendments required EPA to develop MCLGs and MCLs concurrently and to finalize the interim regulations. Under this statute EPA may delegate program enforcement authority to the States.

The 1996 amendments to the SDWA directed EPA to: withdraw the proposed NPDWR, including the proposed MCLG and MCL and monitoring, reporting, and public notification requirements for radon, due to the controversy over the cost-benefit basis for the proposed standard; arrange for the NAS to conduct a formal study of radon in drinking water; publish a risk reduction and cost analysis for possible radon MCLs by February 1999; promulgate the radon MCLG and NPDWR for drinking water by the year 2000; develop an alternative MCL for radon, as directed to ensure that any revised drinking water standard will maintain or increase public health protection; and review all drinking water regulations every six years.

SDWA also provides EPA with emergency response authority. Section 1431(a) directs the Agency to take the necessary actions to protect the public health during emergencies that affect public drinking water supplies.

1976 - Resource Conservation and Recovery Act, as amended in 1984, 1986 (42 USC 6901 et seq.)

RCRA gives EPA the authority to regulate hazardous waste from "cradle-to-grave." This authority includes the minimization, generation, transportation, treatment, storage, and disposal of hazardous waste. RCRA also set forth a framework for the management of non-hazardous solid wastes. RCRA focuses only on active and future facilities. It does not address abandoned or historical sites. Source, special nuclear, or byproduct material as defined by the AEA is specifically excluded from RCRA.

1978 - Uranium Mill Tailings Radiation Control Act (42 USC 2022 et seq.)

UMTRCA amended the AEA by directing EPA to set generally applicable health and environmental standards to govern the stabilization, restoration, disposal, and control of effluents and emissions at both active and inactive mill tailings sites.

Title I of the Act covers inactive uranium mill tailing sites, depository sites, and vicinity properties. EPA was directed to set standards to provide protection consistent with the requirements of RCRA to the maximum extent possible, and to include ground water protection limits. DOE was directed to implement these standards for the tailings piles and the vicinity properties. Upon completion of site cleanup and uranium mill tailings stabilization work, NRC was directed to review the completed actions for compliance with EPA standards. NRC licenses the site for perpetual care to the State or DOE.

Title II of the Act covers operating uranium processing sites licensed by the NRC. EPA was directed to promulgate disposal standards in compliance with Subtitle C of the Solid Waste Disposal Act, as amended, to be implemented by NRC or the Agreement States. The 1993 Amendments to UMTRCA further directed EPA to promulgate general environmental standards for the processing, possession, transfer, and disposal of uranium mill tailings. NRC was required to implement these standards at Title II sites.

1979 - EO 12148, Federal Emergency Management

EO 12148 was issued on July 20,1979, by President Carter in response to the accident at the Three Mile Island Nuclear Power Plant. It assigned FEMA the responsibility for developing a National Contingency Plan for responding to accidents at nuclear power plants. FEMA published the first version of the FRERP in 1985. An updated FRERP was published on May 1, 1996.

1980 - Low-Level Radioactive Waste Policy Act, as amended in 1985 (42 USC 2021b et. seq.)

The LLRWPA requires each State to be responsible for providing disposal capacity for commercial LLW generated within its borders by January 1, 1986. It encouraged States to form regional compacts to develop new disposal facilities. The LLRWPA was amended in 1985 to provide States more time to develop facilities and to provide incentives for volume reduction of LLW.

1980 - Comprehensive Environmental Response, Compensation, and Liability Act, as amended, 1986, 1990 (42 USC 9601 et seq.)

CERCLA (commonly known as Superfund) created a tax on the chemical and petroleum industries and provided broad Federal authority to respond directly to releases or threatened releases of hazardous substances, pollutants, and contaminants that may endanger public health or the environment. CERCLA defines hazardous substances by reference to other lists. Since the CAAA list radionuclides as hazardous substances, they are covered by CERCLA.

CERCLA authorizes two kinds of response actions: short-term removals where actions may be taken to address releases or threatened releases requiring prompt response; and long-term remedial response actions that permanently and significantly reduce the dangers associated with releases or threats of releases of hazardous substances that are serious, but not immediately life threatening. Long-term remedial response actions can only be conducted only at sites listed on EPA's NPL.

Short-term removal actions (emergency responses) may be taken at any site at which a release or threatened release occurs. These response actions are conducted in accordance with the concept of operations contained in the NCP (40 CFR Part 300). Section 105 of CERCLA requires the development of the NCP. CERCLA applies to radiological events at DoD and DOE facilities, but does not apply to releases from NRC-licensed facilities subject to the requirements of the Price Anderson Amendments (Section 170) of the AEA.

1982 - Nuclear Waste Policy Act (42 USC 10101 et seq.)

The NWPA provides the basis for the current national program for the disposal of SNF and HLW. The Act established formal procedures to evaluate and select sites for geologic repositories, as well as procedures for the interaction of State and Federal governments. It provides a timetable of key milestones the Federal agencies must meet in carrying out the program.

The NWPA provides DOE with the responsibility for siting, building, and operating a deep geologic repository for the disposal of HLW and SNF. It directs EPA to "by rule promulgate generally applicable standards for protection of the general environment from offsite releases of radioactive material in repositories." NRC is required to license DOE to operate a repository that meets EPA's standards and all other relevant requirements.

1985 - Federal Radiological Emergency Response Plan, as revised in 1996

The FRERP established an organized and integrated capability for a timely, coordinated response by Federal agencies to assist State and local governments as they respond to peacetime radiological emergencies (e.g., nuclear power plant accidents, lost radioactive sources, foreign nuclear accidents, transportation accidents, etc.). The FRERP is an interagency agreement that has no statutory authority of its own. Each

signatory agency uses its own authorities when implementing a FRERP response. The FRERP covers any peacetime radiological emergency that has actual, potential, or perceived radiological consequences within the United States, its territories, possessions, or territorial waters and that could require a response by the Federal government. The FRERP assigns EPA as the Lead Federal Agency (LFA) to lead and coordinate the activities of other Federal agencies for foreign radiological accidents that may have an impact on the United States and for accidents involving radioactive material that is not owned, licensed, or regulated by another Federal agency.

1987 - Nuclear Waste Policy Amendments Act (42 USC 10101 et seq.)

The NWPAA directs DOE to consider Yucca Mountain as the primary site for the first geologic repository for HLW and SNF, and prohibits DOE from conducting site specific activities at a second site, unless authorized by Congress. It also requires the Secretary of Energy to develop a report on the need for a second repository no later than January 1, 2010.

The NWPAA also established a commission to study the need and feasibility of a monitored retrievable storage facility.

1988 - EO 12656, Assignment of Emergency Preparedness Responsibilities

This Executive Order, issued in November 1988, delineates the roles and responsibilities of the various Federal agencies in preparing for and responding to national security emergencies. These roles and responsibilities are based on the existing statutory authorities and capabilities of the agencies.

1992 - Waste Isolation Pilot Plant Land Withdrawal Act, as amended in 1996 (PL 102-579)

The WIPP LWA reinstated the disposal standards that were issued by the Agency in 1985 and remanded in 1987, except for §191.15 and §191.16, and directed EPA to issue final disposal standards. It also directed that the disposal standards at 40 CFR Part 191 would not apply to any site characterized under section 113(a) of the NWPA (e.g., Yucca Mountain).

This Act also provided an extensive role for EPA oversight of DOE activities at WIPP. Specifically, EPA was required to: issue final standards for disposal of spent nuclear fuel, high-level radioactive waste, and TRU waste (see 40 CFR Part 191 on page 23); develop criteria specifically for the WIPP that implement the final disposal standards; certify that the WIPP is in compliance with 40 CFR 191 if DOE satisfies the criteria; reevaluate the WIPP every five years to determine whether it should be recertified; and ensure that the WIPP complies with other environmental and public health and safety regulations every two years.

The 1996 WIPP LWA Amendments (PL104-201) dictated three major items. The WIPP LWA Amendments specified November 30, 1997 as a non-binding date for the WIPP site to open, pending certification by EPA that the site meets environmental regulatory requirements; exempted the WIPP from RCRA Land Disposal Requirements; and withdrew requirements in the original Act that required DOE to conduct underground tests on-site with transuranic waste to determine whether it could be disposed of safely.

1992 - Energy Policy Act (PL 102-186)

This act requires EPA to "promulgate standards to ensure protection of public health from high-

level radioactive wastes in a deep geologic repository that might be built under Yucca Mountain in Nevada." EPA is further directed to issue these site-specific public health and safety standards, "based upon and consistent with the findings and recommendations of the National Academy of Sciences..."

1992 - Federal Response Plan, as revised in 1999

The FRP outlines how the Federal government implements the Robert T. Stafford Disaster Relief and Emergency Assistance Act to assist State and local governments when a major disaster or emergency (e.g., a natural catastrophe; fire, flood, or explosion, regardless of cause; etc.) overwhelms their ability to respond effectively to save lives; protect public health, safety, and property; and restore their communities. It describes the policies, planning assumptions, concept of operations, response and recovery actions, and responsibilities of twenty-seven Federal departments and agencies, including the Red Cross, that guide Federal operations following a Presidential declaration of a major disaster or emergency.

1994 - National Oil and Hazardous Substances Pollution Contingency Plan (40 CFR Part 300)

The purpose of the NCP is to provide the organizational structure and procedures to prepare for and respond to discharges of oil and releases of hazardous substances, pollutants, and contaminants which may present an imminent and substantial danger to public health or welfare of the United States. The NCP provides for a national response organization that may be activated in response actions and specifies the roles and responsibilities of Federal, State, and local governments. Because radionuclides are listed as hazardous substances in the Clean Air Act, the NCP applies to releases of radioactive material.

1995 - PDD 39, U.S. Policy on Counter-Terrorism

President Clinton issued PDD-39 on June 21, 1995. It establishes how the United States will respond to the use of weapons of mass destruction by terrorists. It assigns specific preparedness and response duties to a limited number of Federal agencies based upon their existing statutory authorities and response capabilities. The FBI is the Federal lead for the crisis management phase of a response to a terrorist incident, and FEMA is the lead for coordination of Federal response activities during the consequence management phase of the response. EPA has been directed to provide support to the FBI during crisis management operations and to FEMA during consequence management operations. EPA assistance may include threat assessment, consultation, agent identification, hazard detection and reduction, environmental monitoring, decontamination, and long-term site restoration (environmental cleanup). It may also include participation on the Domestic Emergency Support Team (DEST) and regional response team deployment. The CTPCT coordinates all Agency activities involving preparing for and responding to terrorist events.

1998 - PDD 62, Protection Against Unconventional Threats to the Homeland and Americans Overseas

PDD-62, issued by President Clinton on May 22, 1998, directs the establishment of an integrated program to increase the effectiveness of the United States in countering terrorist threats and to prepare to manage the consequences of attacks against U.S. citizens or infrastructure. Lead agencies, such as EPA, designate a Senior Program Coordinator who will coordinate this effort with the U.S. Government. This PDD complements the

directives contained in PDD-39. PDD-62 also requires each agency to maintain a viable Continuity of Operations Plan and to have a Critical Infrastructure Protection Plan (CIPP).

1998 - PDD 63, Critical Infrastructure Protection

PDD-63 was issued by President Clinton on May 22, 1998, to ensure the continuity and viability of United States critical infrastructure. Critical infrastructures are those physical and cyber-based systems essential to the minimum operations of the economy and government. These systems are highly automated and inter-connected, and thus are vulnerable to physical and cyber attacks. PDD-63 required EPA and all other Federal agencies to: develop a CIPP to protect its critical infrastructure; conduct an assessment of infrastructure vulnerabilities; and develop a plan to address all vulnerabilities in a timely manner.

1998 - PDD 67, Enduring Constitutional Government and Continuity of Government

PDD-67 was issued by President Clinton on October 21, 1998 and directs the development of plans and capabilities to assure the continuity of government at all levels in any national security situation that might confront the nation. It assigns specific essential functions to be performed by Federal agencies based on existing statutory authorities and response capabilities.

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Appendix B: Federal Agency Radiation Responsibilities

The mission of the U.S. Environmental Protection Agency is to protect human health and to safeguard the natural environment — air, water, and land — upon which life depends on both national and global levels. EPA's radiation protection responsibilities originate from both the AEA and related statutes, as well as the environmental statutes. Under the authority of the AEA and related statutes, EPA develops generally applicable environmental standards for Federal and State organizations to incorporate into the development of their regulations; develops regulations that implement these standards (e.g., Criteria for Certification and Re-Certification of WIPP Compliance with 40 CFR 191 Disposal Regulations); and is responsible for developing guidance for all Federal agencies in the formulation of radiation standards and the establishment and execution of programs of cooperation with the States. Under the authority of the environmental statutes, EPA develops, implements, and enforces media-specific regulations for both chemical and radioactive environmental pollutants.

The mission of the Department of Energy (DOE) is to develop and implement a coordinated national energy policy to ensure the availability of adequate energy supplies and to develop new energy sources for domestic and commercial use. In addition, DOE is responsible for developing, constructing, and testing nuclear weapons for the U.S. military; for managing low- and high-level radioactive wastes generated by past nuclear weapons and research programs; and for constructing and maintaining a repository for civilian radioactive wastes generated by commercial nuclear reactors. DOE develops its own standards under the authority of the AEA (known as DOE Orders) and is responsible for enforcing those as well as EPA regulations at DOE facilities.

The mission of the U.S. Nuclear Regulatory Commission (NRC) is to ensure adequate protection of public health and safety, the common defense and security, and the environment in the use of certain radioactive materials in the United States. The NRC licenses commercial facilities including nuclear power reactors; non-power 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.

Under the authority of the AEA, NRC is responsible for developing, implementing, and enforcing NRC licensing criteria, EPA standards and regulations, and other Federal regulations at these facilities.

The Federal Emergency Management Agency (FEMA) is responsible for planning for and responding to all types of disasters in the United States, including nuclear incidents. EPA, through its Emergency Response Team, is one of several agencies providing guidance and coordination

to the FEMA activities.

The Department of Health and Human Services (DHHS) is the principal agency for protecting the health of all Americans and providing essential human services. The Food and Drug Administration (FDA) assures the safety of foods and cosmetics, pharmaceuticals, biological products, and medical devices. It is responsible for setting policy for health care and the use of radiation in the healing arts.

The mission of the Department of Defense (DoD) is to provide the military forces needed to deter war and protect the security of the United States. DoD is responsible for the safe handling and storage of nuclear weapons and other military uses of nuclear energy.

The Department of Transportation (DOT) is responsible for the coordinated national transportation policy. It proposes transportation legislation, coordinates transportation issues with other concerned agencies, and provides technical assistance to States and cities in support of transportation programs. DOT works with Federal and State agencies to govern the safe packaging and transport of radioactive materials.

The Department of Labor (DOL) is responsible for preparing the American workforce for new and better jobs, and ensuring the adequacy of America's workplaces. Within DOL, the Occupational Safety and Health Administration (OSHA) is responsible for protecting the health of the American workforce. It develops and enforces radiation exposure regulations, protecting workers who are not expressly covered by other Federal agency regulations.

Appendix C: Acronyms

AEA	Atomic Energy Act of 1954
AEC	Atomic Energy Commission
ALARA	As Low As Reasonably Achievable
ANPRM	Advanced Notice of Proposed Rulemaking
ARAR	Applicable, Relevant, and Appropriate Regulation
BEIR	Committee on the Biological Effects of Ionizing Radiation
BRH	Bureau of Radiological Health
BSWM	Bureau of Solid Waste Management
BWH	Bureau of Water Hygiene
CAA	Clean Air Act
CAAA	Clean Air Act Amendments
CAG	Compliance Application Guidance
CCA	Compliance Certification Application
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CEQ	Council on Environmental Quality
CIPP	Critical Infrastructure Protection Plan
CMI	Consolidated Minerals, Inc.
COOP	Continuity of Operations
CRCPD	Conference of Radiation Control Program Directors
CWA	Clean Water Act
CWS	Community Water Systems
DHHS	Department of Health and Human Services
DoD	Department of Defense
DOE	Department of Energy
DOI	Department of the Interior
DOL	Department of Labor
DOT	Department of Transportation
EO	Executive Order
EPA	Environmental Protection Agency
ER	Emergency Response
ERA	Energy Reorganization Act of 1974
ERAMS	Environmental Radiation Monitoring System
ERD	Environmental Radiation Data
ERDA	Energy, Research and Development Administration
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FRC	Federal Radiation Council
FEMA	Federal Emergency Management Agency
FFE	Full Field Exercises
FRERP	Federal Radiological Emergency Response Plan
FRMAC	Federal Radiological Monitoring and Assessment Center
FRP	Federal Response Plan
FRPCC	Federal Radiological Preparedness Coordinating Committee

FWQA	Federal Water Quality Administration
GERMON	Global Environmental Radiation Monitoring Network
GSA	General Services Administration
HAP	Hazardous Air Pollutant
HEAST	*Health Effects Assessment Summary Tables*
HEW	Health Education and Welfare
HLW	High-Level Waste
HRS	Florida Department of Health and Rehabilitative Services
IAEA	International Atomic Energy Agency
INEX	International Nuclear Emergency Exercise
LAMW	Low Activity Mixed Waste
LFA	Lead Federal Agency
LLRWPA	Low-Level Radioactive Waste Policy Act
LLW	Low-Level Waste
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MOU	Memorandum of Understanding
MPRSA	Marine Protection, Research, and Sanctuaries Act of 1972
NACEPT	National Advisory Council on Environmental Policy and Technology
NAPCA	National Air Pollution Control Administration
NAREL	National Air and Radiation Environmental Laboratory
NARM	Naturally Occurring and/or Accelerator Produced Radioactive Material
NAS	National Academy of Sciences
NASA	National Aeronautics and Space Administration
NAS-NRC	National Academy of Sciences - National Research Council
NCP	National Contingency Plan
NEA	Nuclear Energy Agency
NESHAPs	National Environmental Standards for Hazardous Air Pollutants
NIH	National Institutes of Health
NIPDWR	National Interim Primary Drinking Water Regulation
NORM	Naturally Occurring Radioactive Material
NPDES	National Pollutant Discharge Elimination System
NPDWR	National Primary Drinking Water Regulation
NPL	National Priorities List
NRC	Nuclear Regulatory Commission
NRDC	National Resources Defense Council
NRS	National Response System
NSPS	New Source Performance Standards
NWPA	Nuclear Waste Policy Act
NWPAA	Nuclear Waste Policy Act Amendments
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
OCRWM	Office of Civilian Radioactive Waste Management
OMB	Office of Management and Budget
ORIA	Office of Radiation and Indoor Air

OSWER	Office of Solid Waste and Emergency Response
PAG	Protective Action Guide
PDD	Presidential Decision Directives
PHSA	Public Health Service Act
POTWS	Publicly-Owned Treatment Works
RAGS	*Risk Assessment Guidance for Superfund*
RCRA	Resource Conservation and Recovery Act
RERAM	*Radiation Exposure and Risk Assessment Manual: Risk Assessment Using Radionuclide Slope Factors*
RERT	Radiological Emergency Response Team
R&IENL	Radiation and Indoor Environments National Laboratory
RPD	Radiation Protection Division
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
SNF	Spent Nuclear Fuel
SSLG	*Superfund Soil Screening Level Guidance*
TENORM	Technologically Enhanced Naturally Occurring Radioactive Materials
TFI	The Fertilizer Institute
TMI	Three Mile Island
TRU	Transuranic Waste
TSCA	Toxic Substances Control Act
UMTRCA	Uranium Mill Tailings Radiation Control Act
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
USG	U.S. Gypsum Co.
USDA	Department of Agriculture
WIPP	Waste Isolation Pilot Plant
WIPP LWA	Waste Isolation Pilot Plant Land Withdrawl Act
YM	Yucca Mountain

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Appendix D: Organizational History

	EPA Administrator	Assistant Administrator over Radiation Programs	Office Director for Radiation Protection (and Predecessor Orgs.)
1970	William D. Ruckleshaus	David Dominick	Joseph A. Lieberman
1971		Donald M. Mosiman	
1972		Robert L. Sansom	
1973			William D. Rowe
1974	Russell E. Train	Roger Strelow	
1975			
1976			
1977	Douglas M. Costle	David G. Hawkins	
1978			
1979			William A. Mills (Acting)
1980			David M. Rosenbaum
1981	Ann M. Gorsuch	Kathleen M. Bennett	Gordon Burley (Acting)
1982			
1983			Glen J. Sjoblom
1984	William D. Ruckleshaus	Joseph A. Cannon	
1985	Lee M. Thomas	Charles L. Elkins (Acting)	Sheldon Meyers
1986		J. Craig Potter	
1987			
1988		Don R. Clay (Acting)	Richard J. Guimond
1989	William K. Reilly	William G. Rosenberg	
1990			
1991			Margo T. Oge
1992			
1993	Carol Browner	Michael H. Shapiro (Acting)	
1994		Mary D. Nichols	
1995			E. Ramona Trovato
1996			
1997		Richard D. Wilson (Acting)	Larry Weinstock (Acting)
1998		Robert Perciasepe	
1999			Stephen Page
2000			

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