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A COMPENDIUM OF MAJOR U.S. RADIATION PROTECTION STANDARDS AND GUIDES: LEGAL AND TECHNICAL FACTS

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Submitted To:

Committee on Interagency Radiation

Research and Policy Coordination

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with the assistance of

Social, Educational Research and Development, Inc.

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TABLE OF CONTENTS

LIST OF TABLES vii

LIST OF FIGURES ix

PART I - COMPENDIUM OF RADIATION PROTECTION STANDARDS

INTRODUCTION I-1

SELECTION OF STANDARDS I-3

COLLECTION OF DATA I-3

FACT SHEET ORGANIZATION AND FORMAT I-6

OVERVIEW OF FACT SHEETS I-6

CONCLUSIONS AND RECOMMENDATIONS I-16

PART II - RADIATION PROTECTION STANDARDS: LEGAL AND TECHNICAL FACTS

LISTING OF FACT SHEETS II-1

FACT SHEETS II-3

USER'S GUIDE II-137

LIST OF TABLES

Table 1. Listing of Titles and Numbers of Fact Sheets I-4

Table 2. Sources of Ionizing Radiation Exposure: Average Annual Effective Dose Equivalent (H_E) in the U.S. Population I-12

Table 3. Fact Sheets Related to Major Radiation Source Categories I-13

Table 4. Fact Sheets Applicable to Sources of Exposure and Modes of Control I-15

LIST OF FIGURES

Figure 1. Standards to Control Occupational Radiation Exposures I-8

Figure 2. Standards to Control Radiation Exposures of the General Public: Emissions and Dose..... I-9

Figure 3. Standards to Control Concentrations of Radioactivity or Radiation Levels in the Environment..... I-10

Figure 4. Mode of Control by Standard According to Type of Application..... I-14

PART I

COMPENDIUM OF RADIATION PROTECTION STANDARDS

COMPENDIUM OF MAJOR U.S. RADIATION PROTECTION STANDARDS AND GUIDES

INTRODUCTION

U.S. standards[1/] to protect workers and members of the general public against any potentially harmful effects of ionizing radiation are numerous and complex. Congress has delegated radiation protection responsibilities to multiple Federal agencies, which, in turn, interpret the authority given to them and issue the appropriate standards. Differences in the radiation protection provisions associated with this authority and in the basic rationales behind these provisions, combined with different interpretations of them and the limited discretionary authority given to the agencies in providing protection, all contribute to the complex network of U.S. radiation protection standards.

During a survey of radiation issues of concern conducted by the Committee on Interagency Radiation Research and Policy Coordination[2/] (CIRRPC), government agencies, the Congress, industry, professional organizations, and individuals in the radiation protection community expressed the need for:

- Consistent Federal radiation policies and reviews of existing standards and regulations;
- Mutually consistent and coordinated radiation regulations and standards, particularly those involving multiple agencies and jurisdictions;
- Establishment of radiation levels below regulatory concern (de minimis);
- Coordination of U.S. policies and positions on radiation issues at international meetings;
- Clarification of an "as low as reasonably achievable" (ALARA) policy;
- Scientifically-based standards;
- Examination of "umbrella" dose limits, dose commitment methodology, collective dose application, etc.; and
- Introduction of a risk-based standards system, standardizing radiation risk estimation techniques and approaches to risk comparability.

In addition to these expressed general needs for CIRRPC to address radiation protection policy, standards and regulations, a June 25, 1985 letter to the Science Advisor to the President from the Secretary of Commerce specifically suggested that

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1/ The term standard is used in a generic sense in this report to refer to not only those standards and regulations that are enforceable, but also to Federal or agency guides.

2/ CIRRPC is an interagency committee of eighteen Federal agencies, represented by senior policy makers, and is complemented by a Science Panel whose members are senior radiation scientists from fourteen member agencies. Oak Ridge Associated Universities provides the necessary administrative and technical support to CIRRPC.

CIRRPC study the problem of inconsistency in regulations and the lack of an agreed upon level of radiation exposure at which "no radiation hazard exists," and that it assist agencies in achieving consistent Federal guidelines. The Secretary stated that, "[t]he Federal Government has an obligation to industry to rationalize its regulatory concerns across all the federal agencies and to avoid over-regulation. . . . CIRRPC should strive for the simplest regulatory posture consistent with protection of the public and the environment."

Likewise, the Director, Office of Energy Research, Department of Energy (DOE), expressed his concerns about radiation standards in an August 12, 1985 letter to the Chairman of CIRRPC by suggesting that CIRRPC

> . . . develop and publish for Federal agency use, a coordinated and modernized guide for the development and implementation of radiation protection standards. A concrete initial step toward realization of this goal would be to coordinate a review of existing and proposed radiation protection standards. The objective of such a review would be to help other organizations and agencies develop standards which provide a technically sound and uniform degree of protection to workers and to the public.

It is against this background and interest that CIRRPC initially considered this issue and how it might enhance its knowledge and understanding of the basis of and the relationship between the principle standards promulgated in the United States to limit and control radiation exposures.

Following discussion of the general issue, the CIRRPC Executive Committee approved, with concurrence of the full Committee, an Oak Ridge Associated Universities (ORAU) staff proposal to develop a compendium of Fact Sheets on the major U.S. radiation protection standards and guides, existing or proposed. The compendium was to contain relevant legal or statutory information and detailed technical requirements that state and describe the protection to be achieved. The report was to provide appropriate legislative citations; note any legislative language that gave direction to the development of standards promulgated under the legislation; cite rationales for the standards promulgated; and provide a listing of related standards. Acting on CIRRPC's directions, ORAU was then tasked by the DOE to develop the compendium.

Two consultants with considerable experience in radiation protection regulations were contracted to assist the ORAU staff in developing the report. The research services of Social, Educational Research and Development (SERD), Inc., were contracted to collect the necessary documents, to provide initial drafts of the Fact Sheets, and to assist in the development of a final ORAU report.

This report has been reviewed twice by the CIRRPC member agencies; once to ensure the accuracy of all the legal and technical facts in the compendium, and once to comment on the entire document, including the accompanying text. This final report reflects consideration of all the agencies' comments received during the reviews.

Part I of this report presents information on the selection, preparation and content of the Fact Sheets; an overview of their scopes, applications and modes of control; and the ORAU conclusions and recommendations. Part II contains the Fact Sheets and a User's Guide to finding relevant information in the Fact Sheets.

SELECTION OF STANDARDS

The following three criteria guided selection of the standards to be included in the collection of Fact Sheets. A standard had to meet each of the three criteria to be included.

1. It must have been published in The Federal Register as a proposed or final standard.

2. It must establish substantive public health protection requirements (i.e., it should not merely implement requirements of another standard).

3. Finally, it cannot be solely an intra-agency standard (i.e., limited to controlling exposures within the agency itself).

For example, transportation standards were omitted because they primarily implement requirements of other standards. The last criterion excluded protection requirements issued as "orders" by DOE that control exposures in its contractor-operated facilities.3/ Finally, standards for limiting diagnostic or therapeutic doses to patients by physicians (except for the Federal Guidance in Fact Sheet 5) were omitted because they apply to special-case situations, which involve consideration of benefit versus risk.

Fact Sheets have been developed for twenty-two existing standards, proposed revisions to two of these, and a proposed new standard (Table 1). Proposed standards included are the Nuclear Regulatory Commission's (NRC) basic radiation protection regulations (10 CFR 20); the Department of Labor (DOL), Mine Safety and Health Administration's (MSHA) regulation to control radon in underground mines (30 CFR 57); and the Environmental Protection Agency's (EPA) proposed guidance on transuranics in the environment. Of the twenty-two final standards, eight are in the form of guides and fourteen are enforceable standards. Seven enforceable standards have been promulgated by the EPA, four by the NRC, two by the DOL, and one by the Food and Drug Administration (FDA). Five of the seven Federal Guides, presently in effect and Presidentially-approved, were recommended by the former U.S. Federal Radiation Council (FRC) and the remaining two by the EPA Administrator, to whom was transferred in 1970 the FRC responsibility to "advise the President on radiation matters directly or indirectly affecting health."

COLLECTION OF DATA

The SERD staff collected materials (technical, legal and background) necessary for development of the Fact Sheets. In addition to collecting the printed materials, a series of visits and telephone and personal interviews were conducted. This included contacts with EPA, the NRC, the Library of Congress, the U.S. Government Printing Office (GPO), the U.S. Senate Committees on Energy and Natural Resources and Environment and Public Works and the U.S. House of Representatives Committee on Energy and Commerce.

3/ Intra-agency requirements for radiation protection are expected to be in accord with Federal guidance, such as that issued in 1960, which places limits on population exposure, and that issued by the Environmental Protection Agency in 1987, which provides the basic guidance for occupational radiation protection.

Table 1. LISTING OF TITLES AND NUMBERS OF FACT SHEETS

FACT SHEET	TITLE
1	Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960)
2	Federal Guidance on Occupational Radiation Exposures (RPGs) (1987)
3	Federal Guidance on Radon Exposures in Uranium Mines (1969)
4	Federal Guidance on Limiting Certain Internal Radiation Exposures (RPGs) (1961)
5	Federal Guidance on Diagnostic X-Ray Exposures (RPGs) (1978)
6	Proposed Federal Radiation Protection Guidance on Transuranics in the Environment (RPGs) (1977)
7	Federal Protective Action Guide (PAG) for I-131 (1964)
8	Federal Protective Action Guides (PAGs) for Sr-89, Sr-90 and Cs-137 (1965)
9	40 CFR 61, EPA Air Emission Standards for Radionuclides (1985, 1986)
10	40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976)
11	40 CFR 190, EPA Environmental Standards for Uranium Fuel Cycle (1977)
12	40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985)
13	40 CFR 191, EPA Environmental Standards for Management and Disposal of High-Level and Transuranic Radioactive Waste (1985)
14	40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982)
15	40 CFR 220-229, EPA Regulations and Criteria for Ocean Dumping of Radioactive Materials (1977)
16A	10 CFR 20, NRC Basic Standards for Radiation Protection (1960)
16B	10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986)
17	10 CFR 60, NRC Requirements for Disposal of High-Level Radioactive Waste in Geologic Repositories (1981)
18	10 CFR 61, NRC Requirements for Land Disposal of Low-Level Radioactive Waste (1975)

Table 1. LISTING OF TITLES AND NUMBERS OF FACT SHEETS (continued)

FACT SHEET	TITLE
19	10 CFR 50, Appendix I, NRC ALARA Design Objectives for Light-Water Reactor Effluents (1975)
20	29 CFR 1910.96, OSHA Ionizing Radiation Protection Standards (1971)
21	21 CFR 1020, FDA Performance Standards for Ionizing Radiation Emitting Products (1973)
22	Advisory FDA Protective Action Guides (PAGs) for Radioactive Contamination in Food (1982)
23A	30 CFR 57, MSHA Safety and Health Radiation Standards for Underground Metal and Nonmetal Mines (1977)
23B	30 CFR 57, MSHA Proposed Ionizing Radiation Standards for Underground Metal and Nonmetal Mines (1986)

FACT SHEET ORGANIZATION AND FORMAT

The Fact Sheets are primarily listed according to whether they contain Federal guidance or to the agency responsible for issuing the standard. Each Fact Sheet covers a single standard, except for Fact Sheet 12 which covers the EPA remedial action and environmental standards for uranium and thorium mill tailings, as well as the NRC conforming regulation.

To be both useful and informative, the Fact Sheets describe the legal and technical information as briefly as possible. The reader is encouraged to refer to the issuances and background documents for more complete information on the standards, e.g., on the accompanying implementing regulations. The Fact Sheets include available information that explains why and how the requirements came into being. For example, they state the relevant statute(s) and statutory purpose(s) and describe the rationale used in developing the detailed requirements. The Fact Sneets also provide relevant supplemental information, including the names of the agencies responsible for promulgation, implementation or enforcement of the standards and related standards.

Specifically, each Fact Sheet includes the:

- Complete title, including number and date of the Federal Register notice;
- Authorizing statute, including its purpose and radiation protection provisions;
- Responsible agency(ies);
- Description of the standard, including the related issuance(s), effective date, background, general radiation protection provisions and rationale and description of the detailed requirements; and
- Related standards.

OVERVIEW OF FACT SHEETS

One problem that arises when trying to review the Fact Sheets is that the sheer number of parameters, variables and dimensions contained in the standards is an obstacle to their effective comparison.

For example, the standards include radiation protection standards for:

- General population;
- Workers;
- Radon in underground mines;
- Internal emitters in the environment, including transuranic nuclides;
- Protective action guides for certain radionuclides;
- Air emissions;

- At-the-tap drinking water;
- Uranium fuel cycle, excepting mines and radon from uranium mill operations;
- Uranium and thorium mill tailings: active and inactive;
- Mining effluents and underground injections;
- High-level and transuranic waste operations and disposal;
- Ocean dumping;
- Low-level waste;
- ALARA design objectives for commercial light-water reactor effluents; and
- Ionizing radiation emitting products.

Possible ways of categorizing the Fact Sheets in order to examine the relationship between them are presented in this section. One method of categorization, based on modes of control for various source categories, may be particularly useful to CIRRPC.

Figure 1 shows the relationship between those standards that apply to occupational radiation protection. The existing occupational radiation protection standards imposed by the NRC (Fact Sheet 16A) and Occupational Safety and Health Administration (OSHA) (Fact Sheet 20) on regulated industries and those related standards applied by other Federal agencies to their own activities are consistent with the 1960 Federal guidance for occupational radiation protection, the so-called Radiation Protection Guides (RPGs), (Fact Sheet 1). In 1987, the Federal radiation protection guidance for occupational exposure was revised to reflect improvements in both the quantitative and qualitative knowledge of radiation health risks and the changes in radiation protection philosophy for controlling occupational exposures (Fact Sheet 2). For example, there is more emphasis on the concept of "as low as reasonably achievable" and internal and external exposures are combined to give a whole body dose equivalent. The NRC proposed revision to 10 CFR 20 (Fact Sheet 16B) would make the NRC occupational radiation protection requirements consistent with the 1987 Federal guidance and would also update those requirements for protection of the general population contained in the 1960 Federal RPGs.

Additional radiation protection for uranium miners (Fact Sheets 3; 23A) is provided due to their occupational exposure to radon and its daughter products. The proposed revision of 30 CFR 57 (Fact Sheet 23B) provides for combining exposures to radon and thoron daughters and whole-body gamma radiation into a sum rule and for examining whether the standard needs to be applied to more than just uranium mines.

Figures 2 and 3 show the relationships between the standards that control radiation exposures of the general public. Figure 2 presents those standards that set limits on operations, doses to people, or emissions into the environment. Figure 3 includes standards for concentrations of radionuclides in the environment. Some standards contain provisions related to both and, consequently, appear in both figures.

Recently, the National Council on Radiation Protection and Measurements (NCRP) categorized the sources of radiation exposure to which members of the U.S. population are exposed and estimated the collective and average effective dose equivalents received

FIGURE 1.

STANDARDS TO CONTROL OCCUPATIONAL RADIATION EXPOSURES

(NUMBER SHOWN: FACT SHEET DESIGNATION)

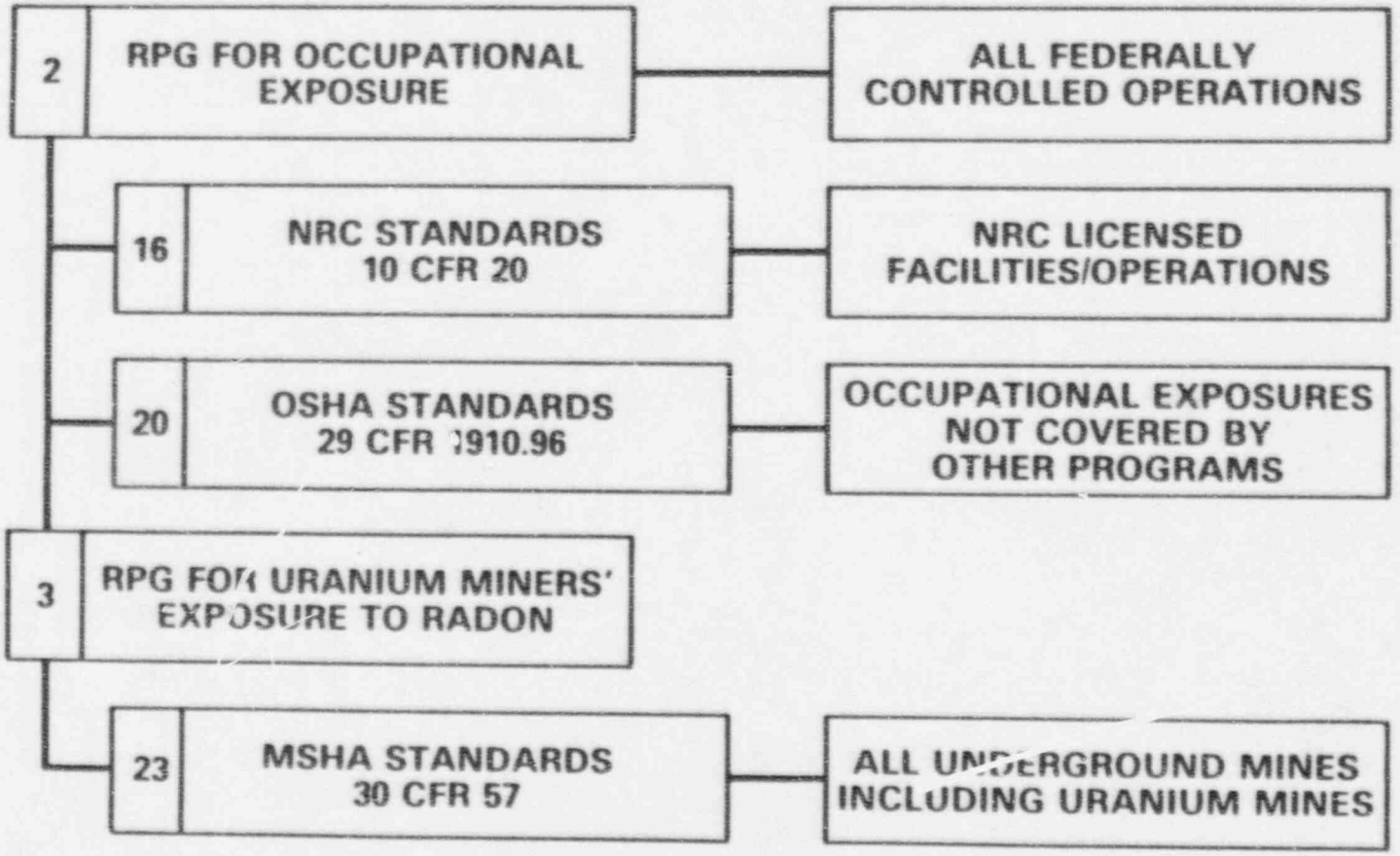


FIGURE 2.

STANDARDS TO CONTROL RADIATION EXPOSURES OF THE GENERAL PUBLIC: EMISSIONS AND DOSE

(NUMBER SHOWN/ FACT SHEET DESIGNATION)

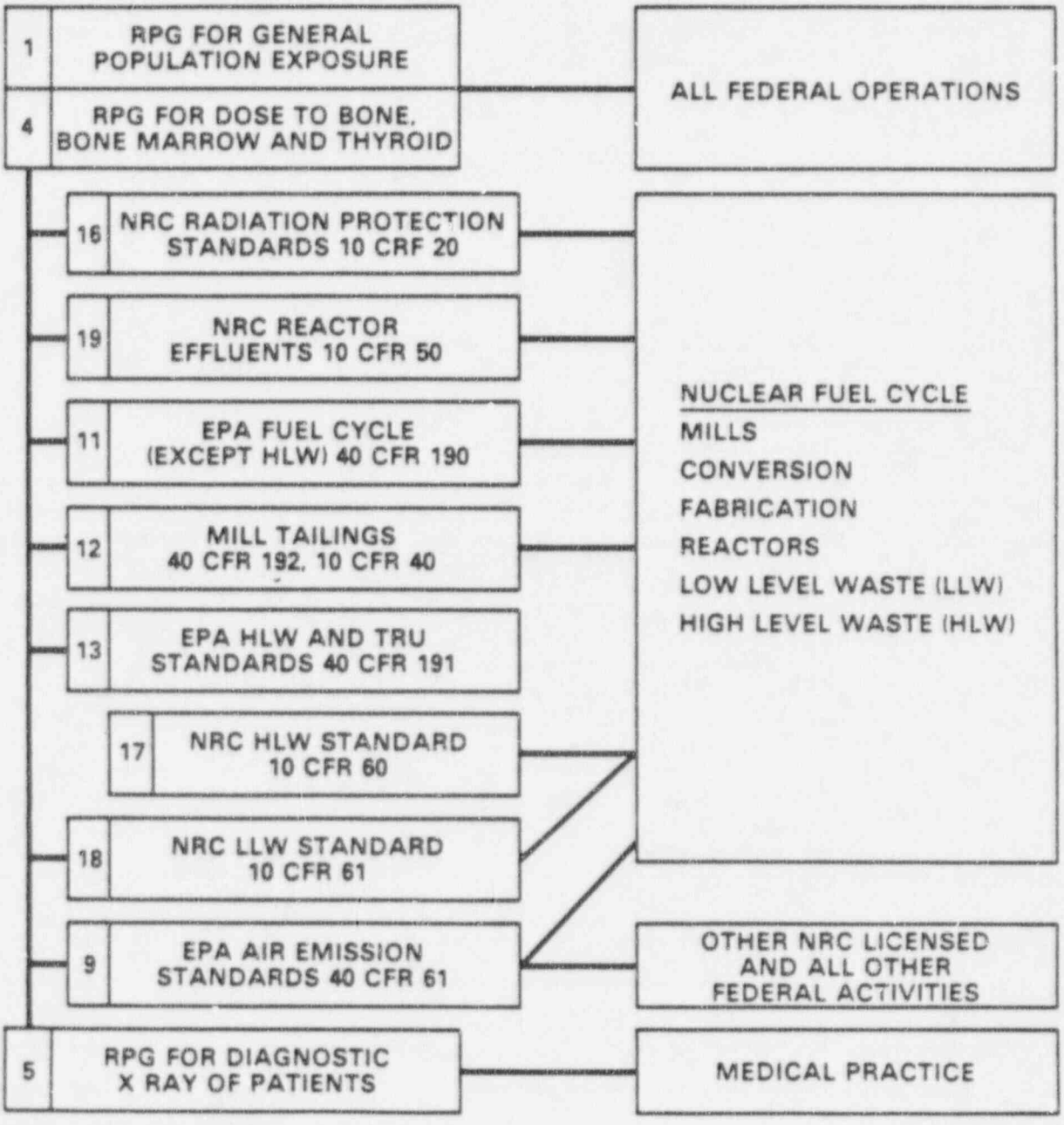
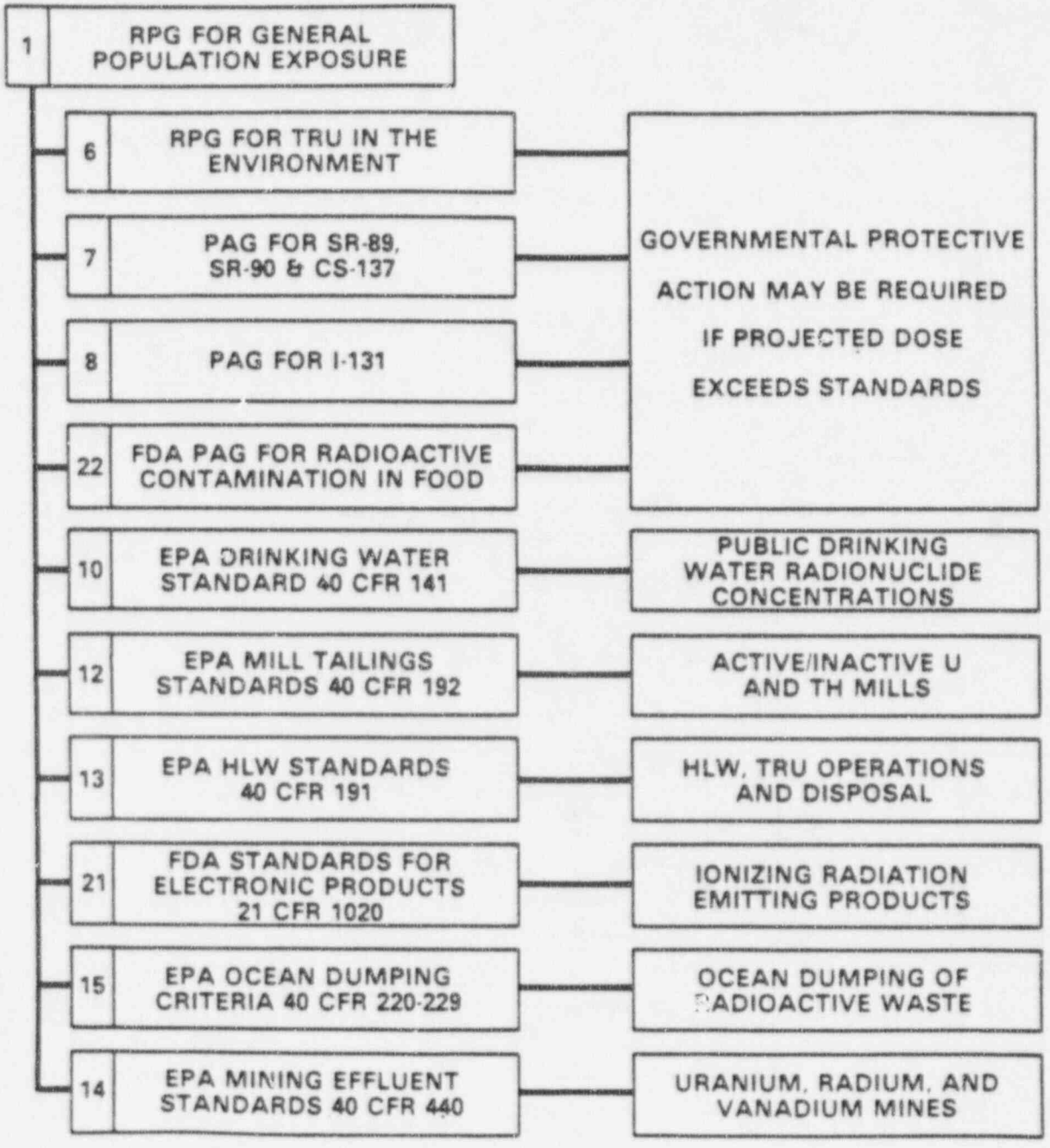


FIGURE 3.

STANDARDS TO CONTROL CONCENTRATIONS OF RADIOACTIVITY OR RADIATION LEVELS IN THE ENVIRONMENT

(NUMBER SHOWN: FACT SHEET DESIGNATION)



from each source category. Their results were issued in the 1987 NCRP Report No. 93, entitled "Exposure of the Population in the United States to Ionizing Radiation." Table 2 showing the average annual effective dose equivalent to the U.S. population from different sources is a modification of a summary table presented in this NCRP Report.

The Fact Sheets were related to the major sources identified in the NCRP report to identify any potential merit in utilizing this relationship in a future CIRRPC study. Table 3 shows, for each NCRP source category, those standards (represented by Fact Sheet numbers) that are applicable to at least some part of the source category. The number of standards applicable to a given source appears to be inversely proportional to the contribution of the source to the exposure of the population. This suggests a possible future evaluation across sources of exposure of the cost-effectiveness achieved in terms of health risk reduction.

Figure 4 categorizes the standards according to their mode(s) of control, that is, whether they apply to: the siting, design or operation of a facility (or activity); releases or emissions of radionuclides from the facility; concentrations or quantities in the environment; or doses to people, either individually or collectively.

Table 4 represents the array considered to have the greatest potential utility to CIRRPC for any future analysis. It relates the applicable standards and their mode(s) of control to some of the specific sources within the NCRP source categories. What remains to be examined is the rationale behind and objective of each standard, the level of constraint imposed by its detailed requirements, and the consistency in protection both within and between the given mode(s) of control. For example, some standards set limits on the basis of acceptable level of risk, others on the application of best control technology or zero degradation of existing conditions. Some standards limit dose from a single source, while others seek to limit dose from multiple sources, a class of sources, or all sources. Some standards set performance requirements (e.g., emission limits), while others specify design or operating features in lieu of performance requirements. With the exception of the standards limiting dose, it is not always clear what level of dose or health risk is implied by the standards. While it should be made clear that all standards are aimed at controlling the exposure of people to radiation, there appears to be no clear intent to be consistent in either the statutory language or the explicit or implicit protection objective of the standards.

Standards are either of the "umbrella" (general) form, such as a 0.5 rem annual population limit for exposure to the individual from all sources in the proposed revision of 10 CFR 20, or are very source specific, such as 20 pCi per meter^2 per second limiting radon emission from a disposal site for uranium mill tailings. The standards may be expressed in a variety of ways: activity per unit volume or mass; dose equivalent or effective dose equivalent; exposure or emission rate; total activity released over a period of time (e.g., 10,000 years); or activity per unit of annual electrical power produced. Furthermore, the numerical limits for the general public vary over a wide range and in some instances are quite low, e.g., the limit for beta particle and photon emitters in at-the-tap drinking water is 4 mrem per year.

While the Atomic Energy Act, under which most of the EPA and NRC standards are established, leaves to the regulatory agencies the manner in which the objective to "protect health or minimize danger to life or property is achieved," the Clean Air Act (Fact Sheet 9) and the Safe Drinking Water Act (Fact Sheet 10) administered by EPA requires them to set limits that would avoid "any adverse effect on the health of persons" and "with an ample margin of safety." As a result of the wide interpretation

TABLE 2.

SOURCES OF IONIZING RADIATION EXPOSURE: AVERAGE ANNUAL EFFECTIVE DOSE EQUIVALENT (H_E) IN THE U.S. POPULATION

	H_E IN MILLISIEVERT** PER YEAR (ROUNDED TOTALS)		PERCENT
TOTAL		3.6	
NATURAL SOURCES		3.0	83
RADON	2		
OTHER	1		
COSMIC	0.27		
COSMOGENIC	0.01		
TERRESTRIAL	0.28		
IN THE BODY	0.39		
OCCUPATIONAL*		0.009	0.2
NUCLEAR FUEL CYCLE		0.0005	0.02
CONSUMER PRODUCTS*		0.09	2
MISCELLANEOUS ENVIRONMENTAL SOURCES*		0.0006	0.02
MEDICAL		0.5	15
DIAGNOSTIC X RAYS	0.39		
NUCLEAR MEDICINE	0.14		

* ESTIMATED NUMBER OF PEOPLE EXPOSED:
OCCUPATIONAL 0.9 MILLION
CONSUMER PRODUCTS 120 MILLION
MISCELLANEOUS ENV. SOURCES 25 MILLION
REF: NCRP REPORT 93 (1987)

** 1 MILLISIEVERT = 100 MILLIREM

TABLE 3.

FACT SHEETS RELATED TO MAJOR RADIATION SOURCE CATEGORIES

SOURCE CATEGORY[1/]	APPLICABLE FACT SHEET (TOTAL NUMBER)
OCCUPATIONAL (0.2%)	2, 3, 16, 20 AND 23 (5)
NUCLEAR FUEL CYCLE (0.02%)	1, 4, 7, 8, 9, 11, 12, 13, 16, 17, 18 AND 19 (12)
CONSUMER PRODUCTS (2%)	1, 10 AND 21 (3)
MISCELLANEOUS ENVIRONMENTAL (0.02%)	1, 4, 6, 7, 8, 9, 14, 15, 16 AND 22 (10)
MEDICAL (15%)	5, 16 AND 21 (3)

[1/] VALUES IN PARENTHESIS SHOW PERCENT OF TOTAL ANNUAL INDIVIDUAL DOSE EQUIVALENT PER CAPITA FOR U.S. POPULATION BASED ON NCRP REPORT #93, 1987.

FIGURE 4.

MODE OF CONTROL BY STANDARD ACCORDING TO TYPE OF APPLICATION

(NUMBERS SHOWN: FACT SHEET DESIGNATION)

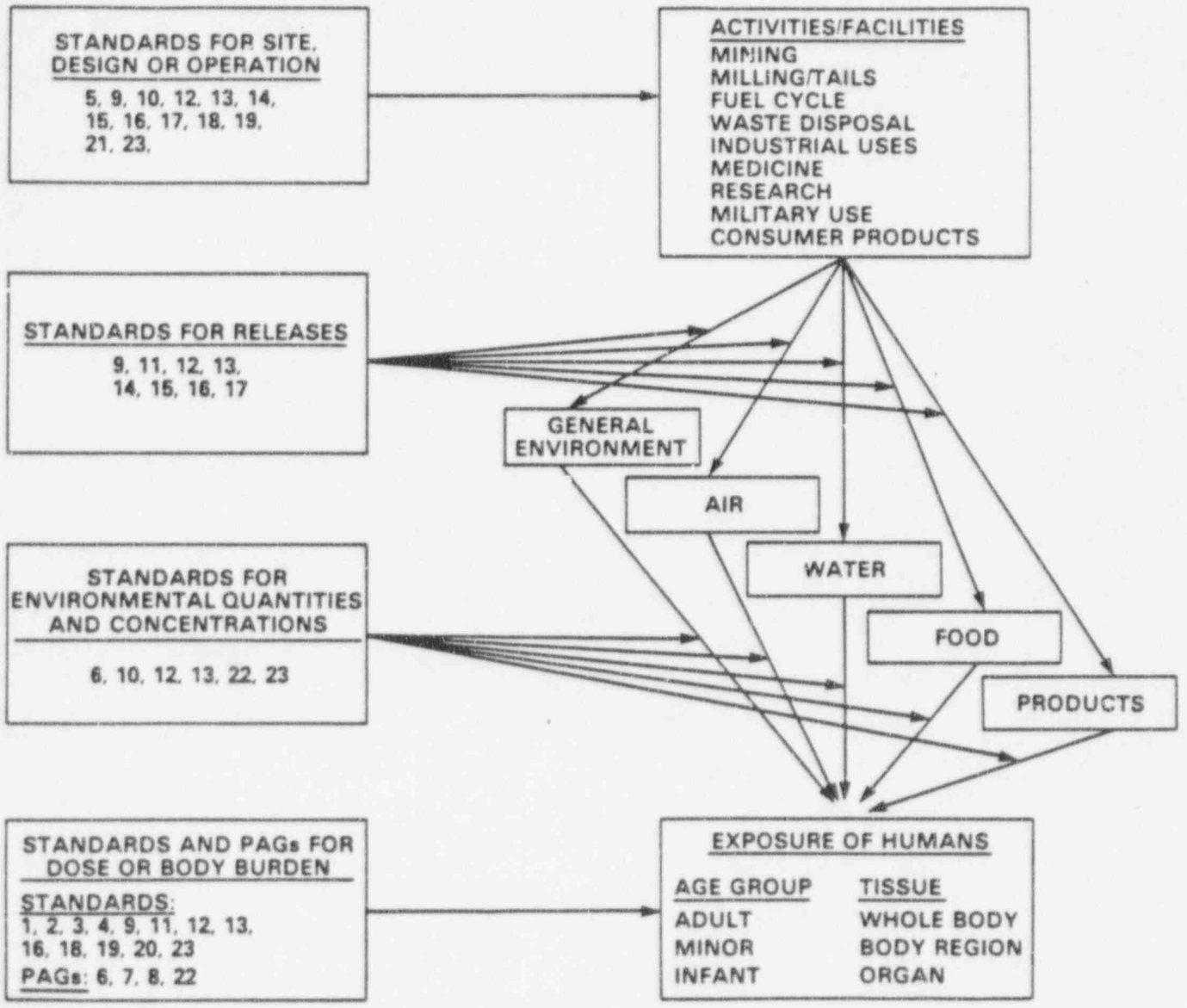


TABLE 4.

FACT SHEETS APPLICABLE TO SOURCES OF EXPOSURE AND MODES OF CONTROL

SOURCES OF EXPOSURE	MODES OF CONTROL			
	SITE, DESIGN AND OPERATION	RELEASES/ EMISSIONS	ENVIRONMENTAL QUANTITIES AND CONCENTRATIONS	DOSE AND BODY BURDEN
FUEL CYCLE				
ALL FUEL CYCLE		11, 16		1, 4, 7, 8, 9, 11, 16
MILL TAILINGS	9, 12	12	12	12
REACTOR EFFLUENT	19			19
LLW DISPOSAL	16, 18			18
HLW & TRU DISPOSAL	13, 17	13, 17	13	13
REMEDIAL ACTION			12	
MISC. ENVIRONMENTAL SOURCES				
ALL MISC. ENV. SOURCES			6	1, 4, 6, 7, 8
MINING & MILLING EFFLTS	9, 14	14		
OTHER NRC LICENSED		16		9, 16
FEDERAL FACILITIES				9
PHOSPHORUS PLANTS		9		
OCEAN DUMPING	15	15		
FOOD			22	22
CONSUMER PRODUCTS				
ALL CONSUMER PRODUCTS				1
DRINKING WATER	10		10	10
ELECTRONIC PRODUCTS	21			
MEDICAL				
DIAGNOSTIC X-RAYS	5, 21			5
NUCLEAR MEDICINE		16		16
OCCUPATIONAL				
ALL OCCUPATIONAL				2
NRC LICENSED				16
OTHER EMPLOYERS				20
UNDERGROUND MINES	23		23	3, 23

of this guidance to agencies provided in these statutes, agencies use an equally wide range of rationales in developing and promulgating standards: control technology capabilities and cost may or may not be a consideration (ALARA); current emission levels may be the basis; or a level of health risk expressed as annual or lifetime risk may be the operative criterion. Overall, ALARA and non-degradation appear to be the principle criteria for protecting members of the general public. A level of lifetime risk no greater than that found in other industries is the principal criterion for protecting workers.

The interplay between standards has resulted in a lowering of the limits over time. This can be illustrated by the relationship among several standards, each of which relates to the limits on effluents from licensed commercial nuclear power plants. The applicable Federal guidance (Fact Sheet 1) sets the annual limit for an individual member of the general population at 500 mrem. Consistent with that guidance, NRC's 10 CFR 20 (Fact Sheet 16A) sets the same limit; however, the individual licensees are held to limits that have been individually determined and are usually implicit in the detailed licensing conditions. The NRC's proposed revision of 10 CFR 20 (Fact Sheet 16B) states explicitly that the applicable annual limit of 500 mrem is based on exposure from all sources, including the sum of internal and external doses. An individual licensee will be in compliance with the annual limit of 500 mrem from all sources if he can demonstrate that sources under his control will not cause any individual to receive an annual dose equivalent in excess of 100 mrem. However, the EPA standard for the NRC-licensed fuel cycle, 40 CFR 190, (Fact Sheet 11) sets an annual limit for individual licensees of 25 mrem for whole body and most body organs, making the NRC limit effectively inoperative for this segment of its licensing purview. In addition to these applicable standards, for nuclear power plants the NRC sets ALARA design and operating conditions at 3 mrem per year for liquid effluents and 5 mrem per year for gaseous effluents.

This suggests that the rationales given in support of whole body dose equivalent limits have generally become more restrictive over time: from "no undue hazard" (Fact Sheet 1, published in 1960), to "no observable health effects" and "ample margin of safety" (Fact Sheet 16A, published in 1960), to ALARA (Fact Sheet 19, published in 1975), and cost effectiveness in risk reduction (Fact Sheet 11, published in 1977).

CONCLUSIONS AND RECOMMENDATIONS

A cursory review of the legal and technical facts contained in many of the basic U.S. radiation protection standards suggests that the standards are numerous and complex, principally control activities that make relatively small contributions to the overall U.S. population dose, have become more restrictive over time, and follow no common rationale in achieving public health objectives. CIRRPC can use the data base in these Fact Sheets to determine whether further review, analysis or coordination of U.S. standards is required to meet its policy coordination responsibilities. For example, using the Fact Sheets to examine protection and/or to compare cost-benefit tradeoffs in greater detail for consistency and trends over time would appear to have merit.

Should revisions of this compendium be undertaken it is recommended that the following suggestions be considered:

1. Consideration should be given to broadening the selection criteria for developing Fact Sheets to include other agency standards that control

basic radiation protection and, perhaps as suggested by one agency, existing memoranda of understanding between agencies.

2. Every two years the existing Fact Sheets should be updated to reflect any proposed or approved changes, and additional Fact Sheets in the same format should be added to reflect new regulations.

3. New or revised Fact Sheets should be reviewed by the responsible agencies so that recommended changes can be incorporated prior to publication.

Implementing these recommendations would enhance the usefulness of the compendium as a reference publication and ensure that it is current and factual.

PART II

RADIATION PROTECTION STANDARDS:
LEGAL AND TECHNICAL FACTS

LISTING OF FACT SHEETS

FACT SHEET		PAGE
1	FEDERAL GUIDANCE ON OCCUPATIONAL AND POPULATION RADIATION EXPOSURES (RPGs) (1960)	II-3
2	FEDERAL GUIDANCE ON OCCUPATIONAL RADIATION EXPOSURES (RPGs) (1987)	II-9
3	FEDERAL GUIDANCE ON RADON EXPOSURES IN URANIUM MINES (1969)	II-15
4	FEDERAL GUIDANCE ON LIMITING CERTAIN INTERNAL RADIATION EXPOSURES (RPGs) (1961)	II-19
5	FEDERAL GUIDANCE ON DIAGNOSTIC X-RAY EXPOSURES (RPGs) (1978)	II-25
6	PROPOSED FEDERAL RADIATION PROTECTION GUIDANCE ON TRANSURANICS IN THE ENVIRONMENT (RPGs) (1977)	II-29
7	FEDERAL PROTECTIVE ACTION GUIDE (PAG) FOR I-131 (1964)	II-33
8	FEDERAL PROTECTIVE ACTION GUIDES (PAGs) FOR Sr-89, Sr-90 AND Cs-137 (1965)	II-37
9	40 CFR 61, EPA AIR EMISSION STANDARDS FOR RADIONUCLIDES (1985, 1986)	II-41
10	40 CFR 141, EPA INTERIM DRINKING WATER STANDARDS FOR RADIONUCLIDES (1976)	II-49
11	40 CFR 190, EPA ENVIRONMENTAL STANDARDS FOR URANIUM FUEL CYCLE (1977)	II-55
12	40 CFR 192, EPA, AND 10 CFR 40, NRC, ENVIRONMENTAL STANDARDS FOR U AND Th MILL TAILINGS (1983, 1985)	II-61
13	40 CFR 191, EPA ENVIRONMENTAL STANDARDS FOR MANAGEMENT AND DISPOSAL OF HIGH-LEVEL AND TRANSURANIC RADIOACTIVE WASTE (1985)	II-69
14	40 CFR 440, EPA MINING EFFLUENT LIMITS FOR U AND Ra (1982)	II-77
15	40 CFR 220-229, EPA REGULATIONS AND CRITERIA FOR OCEAN DUMPING OF RADIOACTIVE MATERIALS (1977)	II-83
16A	10 CFR 20, NRC BASIC STANDARDS FOR RADIATION PROTECTION (1960)	II-87
16B	10 CFR 20, NRC PROPOSED BASIC STANDARDS FOR RADIATION PROTECTION (1986)	II-93

LISTING OF FACT SHEETS (CONTINUED)

FACT SHEET		PAGE
17	10 CFR 60, NRC REQUIREMENTS FOR DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTE IN GEOLOGIC REPOSITORIES (1981)	II-99
18	10 CFR 61, NRC REQUIREMENTS FOR LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE (1975)	II-105
19	10 CFR 50, APPENDIX I, NRC ALARA DESIGN OBJECTIVES FOR LIGHT-WATER REACTOR EFFLUENTS (1975)	II-109
20	29 CFR 1910.96, OSHA IONIZING RADIATION PROTECTION STANDARDS (1971)	II-113
21	21 CFR 1020, FDA PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS (1973)	II-117
22	ADVISORY FDA PROTECTIVE ACTION GUIDES (PAGs) FOR RADIOACTIVE CONTAMINATION IN FOOD (1982)	II-121
23A	30 CFR 57, MSHA SAFETY AND HEALTH RADIATION STANDARDS FOR UNDERGROUND METAL AND NONMETAL MINES (1977)	II-127
23B	30 CFR 57, MSHA PROPOSED IONIZING RADIATION STANDARDS FOR UNDERGROUND METAL AND NONMETAL MINES (1986)	II-131

NOTE: Quoted material contained in the following Fact Sheets was taken from a combination of the Federal statutes, laws, codes and other background documents cited in the particular Fact Sheets. Because the quoted material is extensive and the sources readily apparent, individual passages of material are not footnoted to keep the document as unencumbered and useful as possible.

FACT SHEET 1

FEDERAL GUIDANCE ON OCCUPATIONAL AND POPULATION RADIATION EXPOSURES (RPGs) (1960)

COMPLETE TITLE

FEDERAL RADIATION COUNCIL, RADIATION PROTECTION GUIDANCE FOR FEDERAL AGENCIES, MEMORANDUM FOR THE PRESIDENT, 25 FR 4402, May 18, 1960

1. AUTHORIZING STATUTE

Executive Order 10831 and Public Law 86-373 (added section 274 to the Atomic Energy Act of 1954).

Effective Date: September 23, 1959.

1.1 Statutory Purpose:

Section 274(h) established the Federal Radiation Council (FRC), noting that the "Council shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. . . . The Council shall 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. . . ."

1.2 Radiation Protection Provisions:

The FRC has published eight staff reports. Three of these reports (3, 4, and 6) deal with doses from atmospheric fallout. The remaining five reports provide background on Federal guidance.

2. RESPONSIBLE AGENCIES

The Federal Radiation Council (FRC). The FRC consisted of the Secretary of Agriculture, the Secretary of Health, Education and Welfare (HEW) [now Health and Human Services (HHS)], the Secretaries of Defense, Labor, and Commerce and the Chairman of the Atomic Energy Commission (AEC) [now Department of Energy (DOE) and Nuclear Regulatory Commission (NRC)].

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88) abolished the FRC and transferred its function to the Administrator of EPA.

All Federal Agencies. Federal guidance applies to all Federal agencies that have radiation protection responsibility.

3. DESCRIPTION OF FEDERAL GUIDANCE ON OCCUPATIONAL AND POPULATION RADIATION EXPOSURES (RPGs) (1960)

Issuances:

25 FR 4402, May 18, 1960.

Effective Date: May 13, 1960, signed by President Dwight D. Eisenhower.

Background:

FRC Staff Report No. 1, "Background Material for the Development of Radiation Protection Standards," May 13, 1960.

3.1 General Radiation Protection Provisions:

Radiation Protection Guides (RPGs) set dose limits for radiation workers and the general population.

3.2 Rationale for Detailed Requirements:

3.2.1 RPGs are established "to allow the beneficial use of ionizing radiation, while assuring that man is not exposed to undue hazard." FRC considered the benefits of energy, industrial, and medical uses of ionizing radiation, balanced with the known health hazards associated with acute or chronic radiation exposure.

3.2.2 FRC assumed a linear relationship between biological effect and the amount of dose, which permits one to relate a very low dose to an assumed biological effect even though the effect is not detectable except at higher doses. In this way the actual biological effect should not exceed the amount assumed.

3.2.3 In addition, FRC, due to the lack of data, especially with respect to the biological effects at very low doses and low dose-rates, found that it could not assume that there is a level of radiation exposure below which there is absolute certainty that no effect may occur.

3.3 Description of Detailed Requirements:

3.3.1 "There should not be any man-made radiation exposure without the expectation of benefit resulting from such exposure. . . . Activities resulting in man-made radiation exposure should be authorized for useful applications provided recommendations set forth herein are followed."

3.3.2 Radiation Protection Guide (RPG). RPG is defined as "the radiation dose which should not be exceeded without careful consideration of the reasons for doing so; every effort should be made to encourage the maintenance of radiation doses as far below this guide as practicable."

3.3.3 The following RPGs apply to normal peacetime operations:

Type of Exposure		Condition	Dose (rem)
Radiation Worker			
(a)	Whole body, head and trunk, active blood-forming organs, gonads, or lens of eye	Accumulated Dose	5 times number of years beyond age 18
		13 weeks	3
(b)	Skin of whole body and thyroid	Year	30
		13 weeks	10
(c)	Hands and forearms, feet and ankles	Year	75
		13 weeks	25
(d)	Bone	Body burden	0.1 microgram of radium-226 or its biological equivalent
(e)	Other organs	Year	15
		13 weeks	5
Population			
(a)	Individual	Year	0.5 (whole body)
(b)	Average	30 years	5 (gonads)

Notes to above detailed requirements:

(1) When "the individual whole-body doses for the population are not known, a suitable sample of the exposed population should be developed whose protection guide for annual whole-body dose will be 0.17 rem per capita per year." (This can be modified to meet special situations.)

(2) "The annual individual whole-body dose of 0.5 rem is likely in the immediate future to assure that the gonadal exposure guide (5 rem in 30 years) is not exceeded."

(3) The "[g]uides do not differ substantially from . . . recommendations . . . made by the National Committee on Radiation Protection and Measurements, the National Academy of Sciences, and the International Commission on Radiological Protection."

(4) "There can be no single permissible or acceptable level of exposure without regard to the reason for permitting the exposure. It should be general practice to reduce exposure to radiation. . . . [E]xposure . . . should result from a real determination of its necessity."

(5) The guides are not intended to apply to natural background radiation exposure or the exposure of patients for medical reasons.

(6) The guides are set well below the level where biological damage has been observed in humans.

(7) There can be different Radiation Protection Guides with different numerical values, depending upon the circumstances.

3.3.4 Radioactivity Concentration Guide (RCG). RCG is defined as "the concentration of radioactivity in the environment which is determined to result in whole-body or organ doses equal to the [RPG]."

No specific RCGs are given. "However, concentration guides now used by the agencies appear appropriate on an interim basis."

3.3.5 The guides may "be exceeded only after the Federal agency having jurisdiction over the matter has carefully considered the reason for doing so in light of recommendations [3.3.1 through 3.3.4 above]."

4. RELATED STANDARDS

Federal Guidance on Occupational Radiation Exposures (RPGs) (1987). (See FACT SHEET 2.)

Federal Guidance on Radon Exposures in Uranium Mines (1969). (See FACT SHEET 3.)

Federal Guidance on Limiting Certain Internal Radiation Exposures (RPGs) (1961). (See FACT SHEET 4.)

Proposed Federal Radiation Protection Guidance on Transuranics in the Environment (RPGs) (1977). (See FACT SHEET 6.)

40 CFR 61, EPA Air Emission Standards for Radionuclides (1985, 1986). (See FACT SHEET 9.)

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 190, EPA Environmental Standards for Uranium Fuel Cycle (1977). (See FACT SHEET 11.)

40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985). (See FACT SHEET 12.)

40 CFR 191, EPA Environmental Standards for Management and Disposal of High-Level and Transuranic Radioactive Waste (1985). (See FACT SHEET 13.)

40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982). (See FACT SHEET 14.)

40 CFR 220-229, EPA Regulations and Criteria for Ocean Dumping of Radioactive Materials (1977). (See FACT SHEET 15.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

10 CFR 61, NRC Requirements for Land Disposal of Low-Level Radioactive Waste (1975). (See FACT SHEET 18.)

10 CFR 50, Appendix I, NRC ALARA Design Objectives for Light-Water Reactor Effluents (1975). (See FACT SHEET 19.)

29 CFR 1910.96, OSHA Ionizing Radiation Protection Standards (1971). (See FACT SHEET 20.)

21 CFR 1020, FDA Performance Standards for Ionizing Radiation Emitting Products (1973). (See FACT SHEET 21.)

40 CFR 141, EPA Advance Notice of Proposed Rulemaking Dealing with Radionuclides Under Safe Drinking Water Act, 51 FR 34836, September 30, 1986. (This will be a revision of the standard described in FACT SHEET 10.)

40 CFR 194, EPA Advance Notice of Proposed Rulemaking: Radiation Protection Criteria for Cleanup of Land and Facilities Contaminated With Residual Radioactive Materials, 51 FR 22264, June 19, 1986.

40 CFR 193, EPA Advance Notice of Proposed Rulemaking for Low-Level Radioactive Waste Disposal, 48 FR 39563, August 31, 1978.

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

30 CFR 57, MSHA Safety and Health Radiation Standards for Underground Metal and Nonmetal Mines (1977). (See FACT SHEET 23A.)

30 CFR 57, MSHA Proposed Ionizing Radiation Standards for Underground Metal and Nonmetal Mines (1986). (See FACT SHEET 23B.)

NRC Safety Goals for the Operations of Nuclear Power Plants; Policy Statement, August 4, 1986.

FACT SHEET 2

FEDERAL GUIDANCE ON OCCUPATIONAL RADIATION EXPOSURES (RPGs) (1987)

COMPLETE TITLE

RADIATION PROTECTION GUIDANCE TO FEDERAL AGENCIES FOR OCCUPATIONAL EXPOSURE, 52 FR 2822, January 27, 1987

1. AUTHORIZING STATUTE

Executive Order 10831 and Public Law 86-373, which added section 274 to the Atomic Energy Act of 1954, and the President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88).

Effective Date: December 2, 1970.

1.1 Statutory Purpose:

Reorganization Plan No. 3 modified Section 274(h) of the Atomic Energy Act to read "the Administrator [of the EPA] shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. . . . The Administrator shall 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. . . ."

1.2 Radiation Protection Provisions:

The Administrator has published two staff reports that apply to all Federal agencies concerned with radiation protection. Recommendations based on one of these reports were published by Presidential Order as Federal Radiation Protection Guidance. The other provided Radioactivity Concentration Guides.

2. RESPONSIBLE AGENCIES

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88) abolished the FRC and transferred its function to the Administrator of EPA.

All Federal Agencies. Federal guidance applies to all Federal agencies that have radiation protection responsibility.

3. DESCRIPTION OF FEDERAL GUIDANCE ON OCCUPATIONAL RADIATION EXPOSURES (RPGs) (1987)

Issuances:

52 FR 2822, January 27, 1987.

Effective Date: January 20, 1987, signed by President Ronald Reagan.

Background:

Federal Guidance Report No. 10, "The Radioactivity Concentration Guides," EPA 520/1-84-010 (December 1984); "Federal Radiation Protection Guidance for Occupational Exposure—Response to Comments," EPA 520/1-84-011 (May 1984); FRC Staff Report No. 1, "Background Material for the Development of Radiation Protection Standards," May 13, 1960 and 24 FR 4402, May 18, 1960; 44 FR 53785, September 17, 1979; and 46 FR 7836, January 23, 1981.

3.1 General Radiation Protection Provisions:

The recommendations replace that part of existing guidance [Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960), see FACT SHEET 1] which applies to workers and includes both qualitative guidance on radiation protection and numerical guides for maximum allowed dose equivalents. The portions of that guidance which apply to the general public are not changed by this guidance. The most significant changes from the 1960 guidance are: the RPG for whole-body dose is reduced by more than half [i.e., from 3 rem per quarter and 5(N-18) (where N is the age of the worker) to 5 rem effective dose equivalent incurred in any year]; the guidance on internal doses takes into account the sum of the risks to all organs, rather than continue to be based only on the most significantly exposed organ; the RPGs for whole-body effective dose equivalent apply to the appropriately weighted sum of the doses from both internal and external exposures; and the dose to the embryo and the fetus is limited to a level well below that for adult workers.

3.2 Rationale for Detailed Requirements:

3.2.1 The 5 rem/year RPG for whole-body exposure complies with the current internationally accepted value; there exist essential jobs requiring near 5 rem per year exposure; and risks to the few workers in these jobs are not high compared to other industrial hazards.

3.2.2 It is assumed that any exposure carries some risk; thus it is important to avoid unnecessary exposures at any level.

3.3 Description of Detailed Requirements:

3.3.1 All occupational exposure should be justified by the net benefit of the activity causing the exposure. The justification should include comparable consideration of alternatives not requiring radiation exposure.

3.3.2 For any justified activity, a sustained effort should be made to ensure the collective dose is "as low as is reasonably achievable" (ALARA).

3.3.3 The radiation dose to individuals should conform to the numerical RPGs specified below. Individual doses should be maintained as far below these RPGs as is reasonably achievable.

Radiation Protection Guides (RPGs):

A. "Radiation doses received as a result of occupational exposure should not exceed the limiting values for assessed dose to individual workers specified below. These are given separately for protection against different types of effects on health and apply to the sum of doses from external and internal sources of radiation."

B. "For cancer and genetic effects, the limiting value is specified in terms of a derived quantity called the effective dose equivalent. For other health effects, the limiting values are specified in terms of the dose equivalent to specific organs or tissues."

C. For cancer and genetic effects, "[t]he effective dose equivalent, H_E, received in any year by an adult worker should not exceed 5 rem (0.05 sievert).[1/] The effective dose equivalent is defined as:

$$H_E = \sum_T w_T \, H_T,$$

where w_T is a weighting factor and H_T is the annual dose equivalent averaged over organ or tissue T. Values of w_T and their corresponding organs and tissues are:

Gonads	0.25
Breasts	0.15
Red bone marrow	0.12
Lungs	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder[2/]	0.30

For the case of uniform irradiation of the whole body, where H_T may be assumed the same for each organ or tissue, the

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1/ The unit of dose equivalent in the system of special quantities for ionizing radiation currently in use in the United States is the "rem." In the recently-adopted international system (SI) the unit of dose equivalent is the "sievert." One sievert = 100 rem.

2/ "Remainder" means the five other organs with the highest doses. The weighting factor for each such organ is 0.06.

effective dose equivalent is equal to the dose equivalent to the whole body."

D. For other health effects, the dose equivalent, H_T, received in any year by an adult worker (in addition to the limitation on effective dose equivalent) should not exceed the following:

Lens of the eye	15 rem
Any other organ or tissue (including the skin)	50 rem
Any extremity[1/]	50 rem

E. The annual intake of radionuclides in the workplace should be limited such that (a) "the anticipated magnitude of the committed effective dose equivalent from such intake plus any annual effective dose equivalent from external exposure will not exceed 5 rem (0.05 sievert); and (b) the anticipated magnitude of the committed dose equivalent to any organ or tissue from such intake plus any annual dose equivalent from external exposure will not exceed 50 rem (0.5 sievert). The committed effective dose equivalent from internal sources of radiation, $H_{E,50}$, is defined as

$$H_{E,50} = \sum_T w_T \; H_{T,50},$$

where w_T is defined as in [3.3.3.C above], and the committed dose equivalent, $H_{T,50}$, is the sum of all dose equivalents to organ or tissue T that may accumulate over an individual's anticipated remaining lifetime (taken as 50 years) from radionuclides that are retained in the body."

F. "Occupational dose equivalents to individuals under the age of eighteen should be limited to one-tenth of the [RPGs] for adult workers."

G. "Exposure of an unborn child should be less than that of adult workers. . . . [I]n any case, it should not exceed 0.5 rem (0.005 sievert) during the entire gestation period."

H. In exceptional circumstances the RPGs may be exceeded, but only if the Federal agency having jurisdiction carefully considers the reasons for doing so and publicly discloses them.

Notes to above detailed requirements:

(1) "Occupational exposure of workers does not include that due to normal background radiation and exposure as a patient" for medical reasons.

(2) "The existing Federal guidance (34 FR 576 and 36 FR 12921) for limiting exposure for underground miners to radon decay products applies

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1/ "Extremity" means the forearms and hands, or the lower legs and feet.

independently of, and is not changed by these recommendations." (See FACT SHEET 3.)

(3) "The values specified by the International Commission on Radiological Protection (ICRP) for quality factors and dosimetric conventions for the various types of radiation, the models for reference persons, and the results of their dosimetric methods and metabolic models may be used for determining conformance to these recommendations."

(4) "'Annual Limits on Intake' (ALIs) and/or 'Derived Air Concentrations' (DACs) may be used to limit radiation exposure from intake of or immersion in radionuclides. The ALI or DAC for a single radionuclide is the maximum intake in a year or average air concentration for a working year, respectively, for a reference person that, in the absence of any external dose, satisfies the conditions on committed effective dose equivalent and committed dose equivalent of Recommendation 4. ALIs and DACs may be derived from different chemical or physical forms of radioactive materials."

(5) "The numerical values provided by these recommendations do not apply to workers responsible for the management of or response to emergencies."

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Federal Guidance on Radon Exposures in Uranium Mines (1969). (See FACT SHEET 3.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

29 CFR 1910.96, OSHA Ionizing Radiation Protection Standards (1971). (See FACT SHEET 20.)

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

FACT SHEET 3

FEDERAL GUIDANCE ON RADON EXPOSURES IN URANIUM MINES (1969)

COMPLETE TITLE

FEDERAL RADIATION COUNCIL REPORT NO. 8, GUIDANCE FOR THE CONTROL OF RADIATION HAZARDS IN URANIUM MINING, 34 FR 576, JANUARY 15, 1969

1. AUTHORIZING STATUTE

Executive Order 10831 and Public Law 86-373 (added section 274 to the Atomic Energy Act of 1954).

Effective Date: September 23, 1959.

1.1 Statutory Purpose:

Section 274(h) established the Federal Radiation Council (FRC), noting that the "Council shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. . . . The Council shall 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. . . ."

1.2 Radiation Protection Provisions:

The FRC has published eight staff reports. Three of these reports (3, 4, and 6) deal with doses from atmospheric fallout. The remaining five reports provide background on Federal guidance.

2. RESPONSIBLE AGENCIES

The Federal Radiation Council (FRC). The FRC consisted of the Secretary of Agriculture, the Secretary of Health, Education and Welfare (HEW) [now Health and Human Services (HHS)], the Secretaries of Defense, Labor, and Commerce and the Chairman of the Atomic Energy Commission (AEC) [now Department of Energy (DOE) and Nuclear Regulatory Commission (NRC)].

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88) abolished the FRC and transferred its function to the Administrator of EPA.

The Mine Safety and Health Administration (MSHA). MSHA, under The Department of Labor (DOL), and formerly known as The Mining Enforcement and Safety Administration (MESA) and The Bureau of Mines, is responsible for promulgating

regulations for the metal and nonmetal mining industry to ensure that the Agency's standards appropriately address the hazards of ionizing radiation.

All Federal Agencies. Federal guidance applies to all Federal agencies that have radiation protection responsibility.

3. DESCRIPTION OF FEDERAL GUIDANCE ON RADON EXPOSURES IN URANIUM MINES (1969)

Issuances:

32 FR 11183, August 1, 1967; 34 FR 576, January 15, 1969; 35 FR 19218, December 18, 1970; 36 FR 9480, May 25, 1971; and 36 FR 12921, July 9, 1971.

Effective Date: July 1, 1971 (signed by President Richard M. Nixon on December 15, 1970).

Background:

FRC Staff Report No. 8, "Guidance for the Control of Radiation Hazards in Uranium Mining," September 1967 (Revised); Interagency Uranium Mining Radiation Review Group Report, summaries of subgroup reports, and conclusions of the National Academy of Sciences/National Research Council report, "Epidemiologic Studies of Uranium Miners," 36 FR 9480, May 25, 1971.

3.1 General Radiation Protection Provisions:

Recommendations are made to control the occupational exposure of miners to radionuclides (radon daughters) that are produced by radon decay in underground uranium mines. This is achieved by a limit on exposure to radon daughters, as well as requirements for recordkeeping and monitoring of mine air.

3.2 Rationale for Detailed Requirements:

3.2.1 "In prior reports the Federal Radiation Council has expressed the philosophy that guidance for radiation protection involves achieving a balance between the risk of radiation-induced injury and the benefits derived from the practice causing the exposure to radiation. An implicit part of such a balance is a necessity for considering the relation between the difficulties involved in reducing radiation exposure by a given amount and the risk that might be associated with that amount of exposure."

3.2.2 "It has been observed that underground uranium miners have a higher incidence of lung cancer than is found in the male population in the same geographic area. Continued exposure to the radioactive decay products of the naturally occurring gas radon-222 has been implicated as an important cause of this increased incidence. The decay products of radon-222 (radon daughters) of interest are: polonium-218, lead-214, bismuth-214 and polonium-214. . . . The principal radiation hazard is associated with the inhalation of mine air containing radionuclides that irradiate lung tissue nonuniformly. The most serious result is the development of lung cancer, which

generally does not appear for 10 to 20 years after the individual started uranium mining."

3.2.3 ". . . available data indicate a higher than expected mortality rate in the lower exposure categories (i.e., less than 840 WLM) as well as in the higher exposure categories (i.e., larger than 840 WLM)."

3.2.4 The EPA Administrator reached the following conclusions:

A. The major areas of consideration in connection with determining radiation protection guidance for uranium mining are:

i. Health protection of uranium miners.

ii. "Technical feasibility of achieving various levels of exposure."

iii. "Economic impact of achieving various levels of exposure."

B. "The primary objective of EPA guidance for underground uranium mining is to protect miners from radiation-induced lung cancer."

C. "A standard of 4 WLM per year is technically feasible."

D. "A standard of 4 WLM per year would not have a severe impact on the underground uranium mining community, provided additional time is allowed for compliance in certain instances."

E. "A standard greater than 4 WLM per year would probably result in dosages exceeding those permitted for other occupational radiation exposure situations."

F. "The risk of lung cancer appears to be enhanced by cigarette smoking in combination with the inhalation of radioactive materials; therefore, smoking by underground uranium miners should continue to be discouraged."

3.3 Description of Detailed Requirements:

3.3.1 Working Level (WL). WL is defined as "any combination of radon daughters in one liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha energy. . . . Inhalation of air containing a radon daughter concentration of 1 WL for 170 hours results in an exposure of 1 Working Level Month (WLM)."

3.3.2 The occupational exposure to radon daughters in underground uranium mines must be controlled so that no individual miner will receive an exposure of more than 4 WLM per year as of January 1, 1971.

3.3.3 "Areas in underground uranium mines, whether normally or occasionally occupied, [must] be monitored for the concentration of radon daughters in mine air."

3.3.4 Appropriate records of the exposure received by individuals working in uranium mines from radon daughters in the mine air must be established and maintained.

4. RELATED STANDARDS

Federal Guidance on Occupational Radiation Exposures (RPGs) (1987). (See FACT SHEET 2.)

30 CFR 57, MSHA Safety and Health Radiation Standards for Underground Metal and Nonmetal Mines (1977). (See FACT SHEET 23A.)

30 CFR 57, MSHA Proposed Ionizing Radiation Standards for Underground Metal and Nonmetal Mines (1986). (See FACT SHEET 23B.)

FACT SHEET 4

FEDERAL GUIDANCE ON LIMITING CERTAIN INTERNAL RADIATION EXPOSURES (RPGs) (1961)

COMPLETE TITLE

FEDERAL RADIATION COUNCIL, RADIATION PROTECTION GUIDANCE FOR FEDERAL AGENCIES, MEMORANDUM FOR THE PRESIDENT, 26 FR 9057, September 28, 1961

1. AUTHORIZING STATUTE

Executive Order 10831 and Public Law 86-373 (added section 274 to the Atomic Energy Act of 1954).

Effective Date: September 23, 1959.

1.1 Statutory Purpose:

Section 274(h) established the Federal Radiation Council (FRC), noting that the "Council shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. . . . The Council shall 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. . . ."

1.2 Radiation Protection Provisions:

The FRC has published eight staff reports. Three of these reports (3, 4, and 6) deal with doses from atmospheric fallout. The remaining five reports provide background on Federal guidance.

2. RESPONSIBLE AGENCIES

The Federal Radiation Council (FRC). The FRC consisted of the Secretary of Agriculture, the Secretary of Health, Education and Welfare (HEW) [now Health and Human Services (HHS)], the Secretaries of Defense, Labor, and Commerce and the Chairman of the Atomic Energy Commission (AEC) [now Department of Energy (DOE) and Nuclear Regulatory Commission (NRC)].

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88) abolished the FRC and transferred its function to the Administrator of EPA.

All Federal Agencies. Federal guidance applies to all Federal agencies that have radiation protection responsibility.

3. DESCRIPTION OF FEDERAL GUIDANCE ON LIMITING CERTAIN INTERNAL RADIATION EXPOSURES (RPGs) (1961)

Issuances:

26 FR 9057, September 26, 1961.

Effective Date: September 20, 1961, signed by President John F. Kennedy.

Background:

FRC Staff Report No. 2, "Background Material for the Development of Radiation Protection Standards," September, 1961.

3.1 General Radiation Protection Provisions:

Recommendations are made "to limit exposure of members of population groups to radiation from radioactive materials deposited in the body as a result of their occurrence in the environment." This is achieved through: "Radiation Protection Guides (RPGs) for certain organs of individuals in the general population, as well as averages over suitable samples of exposed groups; guidance on general principles of control applicable to all radionuclides occurring in the environment; and specific guidance for exposure of population groups to radium-226, iodine-131, strontium-90, and strontium-89."

3.2 Rationale for Detailed Requirements:

3.2.1 ". . . any radiation exposure of the population involves some risk; the magnitude of which increases with increases of exposure."

3.2.2 "Establishment of radiation protection standards involves a balancing of the benefits to be derived from the controlled use of radiation and atomic energy against the risk of radiation exposure."

3.2.3 "Specific attention was directed to problems associated with radium-226, iodine-131, strontium-90, and strontium-89. Radium-226 is an important naturally occurring radioactive material. The other three were present in fallout from nuclear weapons testing. They could, under certain circumstances, also be major constituents of radioactive materials released to the environment from large scale atomic energy installations used for peaceful purposes."

3.2.4 "Concentrations of iodine-131 in the diets of small children, particularly in milk, equal to those permitted under current standards would lead to radiation doses to the child's thyroid which . . . would be too high. In the case of iodine-131 in milk, consumption of milk and retention of iodine by the child may be at least as great as by the adult, while the relatively small size of the child's thyroid makes the radiation dose much larger (10 times) than in the case of the adult." In addition, irradiation of a child's thyroid involves greater risk, due to evidence that the adult thyroid is more radioresistant.

3.3 Description of Detailed Requirements:

3.3.1 Radiation Protection Guide (RPG). RPG is defined as "the radiation dose which should not be exceeded without careful consideration of the reasons for doing so; every effort should be made to encourage the maintenance of radiation doses as far below this guide as practicable."

3.3.2 The following RPGs apply to public exposure during normal peacetime operations:

Organ	RPG for Individuals	RPG for Average of "Suitable Sample" of Exposed Population Group
Thyroid	1.5 rem per year	0.5 rem per year
Bone marrow	0.5 rem per year	0.17 rem per year
Bone	1.5 rem per year	0.5 rem per year
Bone (alternate guide)	0.003 micrograms of Ra-226 in the adult skeleton or the biological equivalent of this amount of Ra-226	0.001 micrograms of Ra-226 in the adult skeleton or the biological equivalent of this amount of Ra-226

Note to above detailed requirements:

RPGs for "suitable sample" are one-third of those applying to individuals.

3.3.3 Control of population exposure to radionuclides in the environment is accomplished either by restricting the entry into the environment of the materials or by limiting the human intake of materials already in the environment. Controls of exposure should be based on an evaluation of population exposure with respect to the RPG. The total daily intake, averaged over periods of the order of a year, constitutes an appropriate criterion.

3.3.4 The radiological health activities of Federal agencies in connection with environmental contamination by radioactive materials should be based on a graded scale of appropriate actions related to ranges of intake of radioactive materials by an exposed population group which, when averaged over periods of time of about a year, do not exceed the upper value of Range II.

Generally the Graded Scale should be as follows:

Ranges of Transient Rates of Daily Intake	Graded Scale of Action
Range I	Periodic confirmatory surveillance as necessary.
Range II	Quantitative surveillance and routine control.
Range III	Evaluation and application of additional control measures as necessary.

3.3.5 The following guidance on daily intake (in micromicrocuries per day) for normal peacetime operations is to be applied to the average of suitable samples of an exposed population group:

Radionuclides	Range I	Range II	Range III
Radium-226	0 - 2	2 - 20	20 - 200
Iodine-131	0 - 10	10 - 100	100 - 1,000
Strontium-90	0 - 20	20 - 200	200 - 2,000
Strontium-89	0 - 200	200 - 2,000	2,000 - 20,000

1/ In the case of iodine-131, the suitable sample would include only small children. For adults, the RPG for the thyroid would not be exceeded by rates of intake higher by a factor of 10 than those applicable to small children.

Note to above detailed requirements:

"The upper limit of Range II is based on an annual RPG . . . considered as an acceptable risk for a lifetime." The upper limit for strontium is even lower because there is no known operational requirement for an intake as high as the RPG. The "values listed in the tables are much smaller than any single intake from which an individual might be expected to sustain injury."

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Proposed Federal Radiation Protection Guidance on Transuranics in the Environment (RPGs) (1977). (See FACT SHEET 6.)

40 CFR 61, EPA Air Emission Standards for Radionuclides (1985, 1986). (See FACT SHEET 9.)

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 190, EPA Environmental Standards for Uranium Fuel Cycle (1977). (See FACT SHEET 11.)

40 CFR 191, EPA Environmental Standards for Management and Disposal of High-Level and Transuranic Radioactive Waste (1985). (See FACT SHEET 13.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

10 CFR 50, Appendix I, NRC ALARA Design Objectives for Light-Water Reactor Effluents (1975). (See FACT SHEET 19.)

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

NRC Safety Goals for the Operations of Nuclear Power Plants; Policy Statement, August 4, 1986.

FACT SHEET 5

FEDERAL GUIDANCE ON DIAGNOSTIC X-RAY EXPOSURES (RPGs) (1978)

COMPLETE TITLE

GUIDANCE TO FEDERAL AGENCIES FOR DIAGNOSTIC X-RAYS, 43 FR 4377, February 1, 1978

1. AUTHORIZING STATUTES:

Executive Order 10831 and Public Law 86-373, which added section 274 to the Atomic Energy Act of 1954, and the President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88).

Radiation Control for Health and Safety Act of 1968, Public Law 90-602; the Public Health Service Act, 42 U.S.C. 351 et seq.; and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq.

Effective Dates:

Public Law 86-373, September 23, 1959; Radiation Control for Health and Safety Act of 1968 (Public Law 90-602), October 18, 1968.

1.1 Statutory Purposes:

1.1.1 Reorganization Plan No. 3 modified Section 274(h) of the Atomic Energy Act to read "the Administrator [of the EPA] shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. . . . The Administrator shall 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. . . ."

1.1.2 The purpose of the Radiation Control for Health and Safety Act is "to provide . . . an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation . . . and the undertaking . . . of research and investigation into the effects and control of such radiation emissions."

1.2 Radiation Protection Provisions:

1.2.1 The Administrator has published two staff reports that apply to all Federal agencies concerned with radiation protection. Recommendations based on one of these reports were published by Presidential

Order as Federal Radiation Protection Guidance. The other provided Radioactivity Concentration Guides.

1.2.2 Under the Radiation Control for Health and Safety Act, the Public Health Service Act, and the Federal Food, Drug, and Cosmetic Act, the Assistant Secretary for Health in the Department of Health and Human Services (HHS), has the responsibility (which has been delegated to the Food and Drug Administration) of developing a program of radiation protection which includes: research and training concerning radiation hazards, recommendations for radiation users, advice to states, information for the public, performance standards for electronic products that emit radiation, and regulations for the sale, distribution, and use of medical devices. (These programs are described in 21 CFR 1000 to 21 CFR 1050 and/or FDA publications.)

2. RESPONSIBLE AGENCIES

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88) abolished the FRC and transferred its function to the Administrator of EPA.

The Department of Health and Human Services (HHS). The Assistant Secretary for Health has delegated the responsibility of setting policy for health care and the use of radiation in the healing arts to The Food and Drug Administration (FDA).

All Federal Agencies. Federal guidance applies to all Federal agencies that have radiation protection responsibility.

3. DESCRIPTION OF FEDERAL GUIDANCE ON DIAGNOSTIC X-RAY EXPOSURES (RPGs) (1978)

Issuances:

43 FR 4377, February 1, 1978.

Effective Date: January 26, 1978, signed by President Jimmy Carter.

3.1 General Radiation Protection Provisions:

Recommendations are made to reduce exposure from diagnostic use of x-rays in Federal facilities and Federally-sponsored programs by eliminating clinically unproductive examinations, assuring the use of optimal examination techniques, and requiring appropriate equipment. Also, Entrance Skin Exposure Guides (ESEGs) are set for various x-ray examinations.

3.2 Rationale for Detailed Requirements:

3.2.1 "Technique appropriate to the equipment and materials available should be used to maintain exposure as low as is reasonably achievable without loss of requisite diagnostic information."

3.2.2 According to a 1972 National Academy of Sciences/National Research Council report, "medical diagnostic radiology accounts for at least 90% of the total man-made radiation dose to which the U.S. population is exposed."

3.3 Description of Detailed Requirements:

3.3.1 "General radiographic or fluoroscopic examinations should be prescribed only by licensable Doctors of Medicine or Osteopathy or, for specified limited procedures, postgraduate physician trainees and qualified allied medical professionals under their direct supervision; specialized studies should be prescribed only by those physicians with expertise to evaluate examinations in the particular specialty. Exception for specified procedures may be made for dentists and podiatrists."

3.3.2 "Prescription of x-ray studies should be for the purpose of obtaining diagnostic information, should be based on clinical evaluation of symptomatic patients, and should state the diagnostic objective and detail relevant medical history."

3.3.3 "Routine or screening examinations, in which no prior clinical evaluation of the patient is made, should not be performed unless exception has been made for specified groups of people on the basis of a careful consideration of the magnitude and medical benefit of the diagnostic yield, radiation risk, and economic and social factors."

3.3.4 "Prescription of x-ray examinations of pregnant or possibly pregnant patients should assure that medical consideration has been given to possible fetal exposure and appropriate protective measures are applied."

3.3.5 "X-ray equipment used in Federal facilities should meet the Federal Diagnostic X-Ray Equipment Performance Standard."

3.3.6 "Techniques appropriate to the equipment and materials available should be used to maintain exposure as low as is reasonably achievable without loss of requisite diagnostic information; measures should be undertaken to evaluate and reduce, where practicable, exposures for routine nonspecialty examinations which exceed the following Entrance Skin Exposure Guides (ESEG):

Examination (Projection)	ESEG (milliroentgens)*
Chest (P/A)	30
Skull (Lateral)	300
Abdomen (A/P)	750
Cervical Spine (A/P)	250
Thoracic Spine (A/P)	900
Full Spine (A/P)	300
Lumbo-Sacral Spine (A/P)	1,000
Retrograde Pyelogram (A/P)	900
Feet (D/P)	270
Dental (Bitewing or Peripheral)	700

* Entrance skin exposure determined by the Nationwide Evaluation of X-Ray Trends program for a patient having the following body part/thickness: head/15 cm, neck/13 cm, thorax/23 cm, abdomen/23 cm, and feet/8 cm."

3.3.7 "X-ray examinations for dental purposes should be prescribed only by licensable Doctors of Dental Surgery or Dental Medicine or properly supervised postgraduate dentists on the basis of prior clinical evaluation or pertinent history."

4. RELATED STANDARDS

21 CFR 1020, FDA Performance Standards for Ionizing Radiation Emitting Products (1973). (See FACT SHEET 21.)

10 CFR 35, Human Uses of Byproduct Material, 30 FR 8200, June 26, 1965. (Prescribes NRC regulations governing the licensing of byproduct material for human uses.)

FACT SHEET 6

PROPOSED FEDERAL RADIATION PROTECTION GUIDANCE ON TRANSURANICS IN THE ENVIRONMENT (RPGs) (1977)

COMPLETE TITLE

PERSONS EXPOSED TO TRANSURANIUM ELEMENTS IN THE ENVIRONMENT, (PROPOSED) FEDERAL RADIATION PROTECTION GUIDANCE ON DOSE LIMITS, 42 FR 60956, November 30, 1977

1. AUTHORIZING STATUTE

Executive Order 10831 and Public Law 86-373, which added section 274 to the Atomic Energy Act of 1954, and the President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88).

Effective Date: September 23, 1959.

1.1 Statutory Purpose:

Reorganization Plan No. 3 modified Section 274(h) of the Atomic Energy Act to read "the Administrator [of the EPA] shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. . . . The Administrator shall 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. . . ."

1.2 Radiation Protection Provisions:

The Administrator has published two staff reports that apply to all Federal agencies concerned with radiation protection. Recommendations based on one of these reports were published by Presidential Order as Federal Radiation Protection Guidance. The other provided Radioactivity Concentration Guides.

2. RESPONSIBLE AGENCIES

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88) abolished the FRC and transferred its function to the Administrator of EPA.

All Federal Agencies. Federal guidance applies to all Federal agencies that have radiation protection responsibility.

3. DESCRIPTION OF PROPOSED FEDERAL RADIATION PROTECTION GUIDANCE ON TRANSURANICS IN THE ENVIRONMENT (RPGs) (1977)

Issuances: 42 FR 60956, November 30, 1977.

Effective Date: The guidance was published in proposed form on November 30, 1977. Public comment deadline was February 28, 1978. The guides have not been signed by the President.

3.1 General Radiation Provisions:

3.1.1 The proposed guidance contains "recommendations intended to assure protection of the public health by limiting the radiation doses persons may receive from transuranium elements present in the environment as a result of existing or possible future unplanned contamination. The guidance considers both the inhalation and ingestion pathway of transuranium elements . . . and establish[es] a maximum dose rate to lung and bone."

3.1.2 "The scope of the proposed guidance includes all transuranium element contamination in the general environment from all sources."

3.2 Rationale for Detailed Requirements:

3.2.1 "Two primary criteria used in deriving the guidance were: that any added risk to an individual from exposure to transuranium elements be very small, and that any actions required by implementation of the guidance be practical in terms of overall economic requirements."

3.2.2 "The agency has found that the costs of remedial actions and benefits of risk reduction differ so greatly between contaminated sites that generic guidance applicable to all sites cannot be provided by formal benefit-cost procedures."

3.3.3 "The [health] risk at the proposed guidance level is estimated to be less than one chance in a million per year and less than ten chances per hundred thousand in a lifetime that an individual would develop a cancer from continuous exposure at the stated dose rates."1/

1/ "The radiation risk due to inhalation of transuranium elements is primarily lung cancer. Additional risks may result from translocation of a small fraction of the transuranium elements from the lung to other body organs, especially to the liver and bone. On the basis of models, it was estimated that, for a cohort of 100,000 persons followed through their entire lifetimes, the continuous inhalation over their lifetimes of transuranium aerosols leading to an average annual [intake] to the pulmonary tissue of 1 mrad/year per person could potentially result in 10 premature cancer deaths. For an average lifespan of 71 years, the annual risk to each person from lifetime exposure at this level is about one per million per year.

"The radiation risk due to ingestion of transuranium elements is primarily bone and liver cancers. In a cohort of 100,000 persons, continuous ingestion over a

3.2.4 "The costs of implementing the guidance can be expected to vary by location, contamination level, and other factors. A minimum cost of $500.00 per acre has been assumed for estimating the total cost . . . [of bringing contaminated] areas . . . into compliance. It can be concluded that the costs of implementing the guidance at the reference level would be reasonable and achievable, but that the cumulative costs increase rapidly when lower guidance limits are considered."

3.3 Description of Detailed Requirements:

3.3.1 "The annual alpha radiation dose to members of the critical segment of the exposed population as the result of exposure to transuranium elements in the general environment should not exceed either:

"1 millirad per year to the pulmonary lung, or
"3 millirad per year to the bone."

3.3.2 "For newly contaminated areas, control measures should be taken to minimize both residual levels and radiation exposures of the general public. The control measures are expected to result in levels well below those specified [above]. Compliance . . . should be achieved within a reasonable period of time."

3.3.3 The recommendations are to be used only for guidance on possible remedial actions in instances of existing, or possible future unplanned contamination. They are not to be used as limits for planned releases.

3.3.4 Definitions:

Critical segment of the exposed population is defined as "that group of persons within the exposed population receiving the highest radiation dose to the pulmonary region of the lung or to the bone."

(cont.)

lifetime of a transuranium radionuclide at a level causing an average skeletal (bone) dose rate of 3 mrad per year 70 years after the start of ingestion could potentially result in less than 6 premature deaths from such cancers.

"Genetic damage is possible as a result of assimilation of transuranium elements in gonadal tissue. . . . [I]t can be estimated [with uncertainty] that, for continuous ingestion at the limits set by this proposed guidance, the total dose to gonadal tissue over 30 years of chronic exposure would be about 10 millirad. Such a gonadal dose to each of the parents is estimated to produce 1 to 20 genetic defects per 100,000 live births in the first generation. This number can be compared to the approximately 6,000 genetic defects normally observed in 100,000 live births.

"It must be recognized that these estimates are not precise, and have an uncertainty of at least a factor of three for cancer risk."

Millirad per year to the pulmonary lung is defined as "the equilibrium dose rate following chronic inhalation. This dose rate is calculated by dividing the alpha energy absorbed per year in the pulmonary lung by its mass."

Millirad per year to the bone is defined as "that dose rate attained after 70 years of chronic exposure. This dose rate is calculated by dividing the alpha energy absorbed in the bone during the 70th year by the bone mass."

General environment is defined as "the total terrestrial, atmospheric, and aquatic environments outside the boundaries of federally licensed facilities or outside the boundaries of sites under the direct control of a Federal agency."

3.3.5 "For practical reasons of facilitating implementation of the proposed guidance, derived numerical values for [transuranic] soil or air concentrations, which can reasonably be predicted to result in dose rates less than the guidance recommendations, could be substituted for site-specific values." The agency suggests the following would establish a reasonable "screening level:"

A. "A soil contamination level of 0.2 $\mu Ci/m^2$, for samples collected at the surface to a depth of 1 cm and for particle sizes under 2 mm."

B. "A derived air concentration based on an activity median aerodynamic particle diameter (AMAD) not to exceed 0.1 µm, which . . . could be equated to a limiting concentration of about 1 fCi/m^3 for alpha emitting transuranium nuclides."

"Areas which do not exceed the 'screening level' would generally be considered in compliance with the guidance. . . . [Areas] that exceed it would require more intensive evaluation to determine actual dose rates to exposed populations."

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Federal Guidance on Limiting Certain Internal Radiation Exposures (RPGs) (1961). (See FACT SHEET 4.)

40 CFR 194, EPA Advance Notice of Proposed Rulemaking: Radiation Protection Criteria for Cleanup of Land and Facilities Contaminated With Residual Radioactive Materials, 51 FR 22264, June 19, 1986.

FACT SHEET 7

FEDERAL PROTECTIVE ACTION GUIDE (PAG) FOR I-131 (1964)

COMPLETE TITLE

FEDERAL RADIATION COUNCIL, RADIATION PROTECTION GUIDANCE FOR FEDERAL AGENCIES, MEMORANDUM FOR THE PRESIDENT, 29 FR 12056, August 22, 1964

1. AUTHORIZING STATUTE

Executive Order 10831 and Public Law 86-373 (added section 274 to the Atomic Energy Act of 1954).

Effective Date: August 23, 1959.

1.1 Statutory Purpose:

Section 274(h) established the Federal Radiation Council (FRC), noting that the "Council shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. . . . The Council shall 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. . . ."

1.2 Radiation Protection Provisions:

The FRC has published eight staff reports. Three of these reports (3, 4, and 6) deal with doses from atmospheric fallout. The remaining five reports provide background on Federal guidance.

2. RESPONSIBLE AGENCIES

The Federal Radiation Council (FRC). The FRC consisted of the Secretary of Agriculture, the Secretary of Health, Education and Welfare (HEW) [now Health and Human Services (HHS)], the Secretaries of Defense, Labor, and Commerce and the Chairman of the Atomic Energy Commission (AEC) [now Department of Energy (DOE) and Nuclear Regulatory Commission (NRC)].

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88) abolished the FRC and transferred its function to the Administrator of EPA.

All Federal Agencies. Federal guidance applies to all Federal agencies that have radiation protection responsibility.

3. DESCRIPTION OF FEDERAL PROTECTIVE ACTION GUIDE (PAG) FOR I-131 (1964)

Issuances:

29 FR 12056, August 22, 1964.

Effective Date: July 31, 1964, signed by President Lyndon B. Johnson.

Background:

FRC Staff Report No. 5, "Background Material for the Development of Radiation Protection Standards," July 1964.

3.1 General Radiation Protection Provisions:

Recommendations are made to limit the exposure of members of the population to iodine-131 due to the ingestion of contaminated food, particularly fresh milk. This is achieved by a Protective Action Guide (PAG) for iodine-131.

3.2 Rationale for Detailed Requirements:

3.2.1 "The Council [FRC] is concerned with a balance between the risk of radiation exposure and the impact on the public well-being associated with alterations of the normal production, processing, distribution, and use of food."

3.2.2 "Protective actions are appropriate when the health benefits associated with the reduction in exposure to be achieved are sufficient to offset the undesirable features of protective actions. The PAG represents the Council's judgement as to where this balance should be for the conditions considered most likely to occur."

3.2.3 "A basic assumption in the development of the guidance in this memorandum is that a condition requiring protective action is unusual and should not be expected to occur frequently."

3.2.4 ". . . the Protective Action Guides are not intended to authorize deliberate releases expected to result in absorbed doses of these magnitudes."

3.2.5 ". . . the relatively high [fission] yield of iodine-131 and the short radioactive half-life (8 days) . . . make it the radionuclide most likely to reach concentrations justifying protective actions. This is especially true if the deposition occurs within a few days after the fission event. Protective action against iodine-131 must be taken promptly to be effective."

3.2.6 ". . . it is assumed that children one year of age . . . are the critical segment of the population."

3.2.7 The transmission of iodine-131 is most likely through the pasture-cow-milk-man food chain.

3.3 Description of Detailed Requirements:

3.3.1 Protective Action Guide (PAG). PAG is defined as "the projected absorbed dose to individuals in the general population which warrants protective action following a contaminating event." The projected dose is the dose that would be received by individuals in the population group from the contaminating event if no protective action is taken.

3.3.2 The PAG for iodine-131 is 30 rad to the thyroid for individuals.

3.3.3 The PAG for iodine-131 is 10 rad to the thyroid of a "suitable sample" of the exposed population group (made up of one-year-old infants).

3.3.4 If the projected dose exceeds the PAG, protective action is indicated.

3.3.5 "A protective action is an action or measure taken to avoid most of the exposure to radiation that would occur from future ingestion of foods contaminated (acute) with radioactive materials."

3.3.6 The types of actions which may be taken are:

A. "Altering production, processing, or distribution practices affecting the movement of radioactive contamination through the food chain and into the human body. This action includes storage of food supplies and animal feeds to allow for radioactive decay."

B. "Diverting affected products to uses other than human consumption."

C. "Condemning [affected] foods."

Measures that require alterations of the diet are generally less desirable than those listed and should not be undertaken except on the advice of competent medical authorities.

3.3.7 Two actions appear to provide the most acceptable combination of maximum effectiveness and minimum undesirable consequences for iodine-131 contamination:

A. Diversion of fresh milk to provide unaffected milk in the contaminated area and to use the affected milk in the production of dairy products that may be stored until the iodine-131 has effectively decayed, a matter of a few weeks.

B. Substitution of stored feed for pasture, until most of the iodine-131 has decayed.

4. RELATED STANDARDS

Federal Protective Action Guides (PAGs) for Sr-89, Sr-90 and Cs-137 (1965). (See FACT SHEET 8.)

Advisory FDA Protective Action Guides (PAGs) for Radioactive Contamination in Food (1982). (See FACT SHEET 22.)

Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, September 1975, Revised June 1980, EPA-520/1-75-001. (Provides action levels and guidance for their use by state and local agencies in developing radiological emergency plans.)

FACT SHEET 8

FEDERAL PROTECTIVE ACTION GUIDES (PAGs) FOR Sr-89, Sr-90 and Cs-137 (1965)

COMPLETE TITLE

FEDERAL RADIATION COUNCIL, RADIATION PROTECTION GUIDANCE FOR FEDERAL AGENCIES, MEMORANDUM FOR THE PRESIDENT, 30 FR 6953, May 22, 1965

1. AUTHORIZING STATUTE

Executive Order 10831 and Public Law 86-373 (added section 274 to the Atomic Energy Act of 1954).

Effective Date: September 23, 1959.

1.1 Statutory Purpose:

Section 274(h) established the Federal Radiation Council (FRC), noting that the "Council shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. . . . The Council shall 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. . . ."

1.2 Radiation Protection Provisions:

The FRC has published eight staff reports. Three of these reports (3, 4, and 6) deal with doses from atmospheric fallout. The remaining five reports provide background on Federal guidance.

2. RESPONSIBLE AGENCIES

The Federal Radiation Council (FRC). The FRC consisted of the Secretary of Agriculture, the Secretary of Health, Education and Welfare (HEW) [now Health and Human Services (HHS)], the Secretaries of Defense, Labor, and Commerce and the Chairman of the Atomic Energy Commission (AEC) [now Department of Energy (DOE) and Nuclear Regulatory Commission (NRC)].

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88) abolished the FRC and transferred its function to the Administrator of EPA.

All Federal Agencies. Federal guidance applies to all Federal agencies that have radiation protection responsibility.

3. DESCRIPTION OF FEDERAL PROTECTIVE ACTION GUIDES (PAGs) FOR Sr-89, Sr-90 and Cs-137 (1965)

Issuances:

30 FR 6953, May 22, 1965.

Effective Date: May 20, 1965, signed by President Lyndon B. Johnson.

Background:

FRC Staff Report No. 7, "Background Material for the Development of Radiation Protection Standards," May 1965.

3.1 General Radiation Protection Provisions:

Recommendations are made to limit the exposure of members of the population to strontium-90, strontium-89, and cesium-137 due to the ingestion of food. This is achieved by establishing Protective Action Guides (PAGs) for these radionuclides for three different dietary pathways of exposure.

3.2 Rationale for Detailed Requirements:

3.2.1 "The PAG represents a consensus as to when, under the conditions considered most likely to occur, intervention is indicated to avoid radiation exposure that would otherwise result from a transient environmental contamination condition. This judgment involves health, economic, sociologic, and political factors for which the relative values are different than for the RPG. These factors for the PAG may include agricultural policies, the known feasibility of protective actions, related health impacts, and similar considerations involved in the national interest."

3.2.2 "Protective actions are appropriate when the health benefits associated with the reduction in exposure to be achieved are sufficient to offset the undesirable features of the protective actions. The PAG represents the Council's judgment as to where this balance should be for the conditions considered most likely to occur."

3.2.3 "The Council [FRC] is concerned with a balance between the risk of radiation exposure and the impact on the public well-being associated with alterations of the normal production, processing, distribution, and use of food."

3.3 Description of Detailed Requirements:

A. Protective Action Guide (PAG). PAG is defined as "the projected absorbed dose to individuals in the general population that warrants protective action following a contaminating event." The projected dose is the dose that would be received by individuals in the population group from the contaminating event if no protective action were taken.

Dietary Pathway		Strontium-89, Strontium-90, Cesium-137
I.	Transmission through pasture-cow-milk-man chain.	
	Individual	10 rad in the first year to the bone marrow or whole body
	Suitable sample of the exposed population (One-year-old infants)	3 rad in the first year to the bone marrow or whole body
	Total dose from Category I not to exceed 15 rad (Total dose for Sr-89 and Cs-137 is assumed the same as the dose in the first year; total dose for Sr-90 is assumed to be five times the dose in the first year.)	
II.	Transmission through feed crops to animals including dairy cattle, and plant crops used directly for human consumption.	
	Individual	5 rad in the first year to the bone marrow or whole body
	Suitable sample of the exposed population (One-year-old infants)	2 rad in the first year to the bone marrow or whole body
III.	Long-term transmission through soil into plants	
	Individual	0.5 rad in the first year to the bone marrow or whole body
	Suitable sample of the exposed population (One-year-old infants)	0.2 rad in the first year to the bone marrow or whole body

The setting of PAGs is not intended to authorize deliberate releases expected to result in absorbed doses of these magnitudes.

4. RELATED STANDARDS

Proposed Federal Radiation Protection Guidance on Transuranics in the Environment (RPGs) (1977). (See FACT SHEET 6.)

Federal Protective Action Guide (PAG) for I-131 (1964). (See FACT SHEET 7.)

Advisory FDA Protective Action Guides (PAGs) for Radioactive Contamination in Food (1982). (See FACT SHEET 22.)

Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, September 1975, Revised June 1980, EPA-520/1-75-001. (Provides action levels and guidance for their use by state and local agencies in developing radiological emergency plans.)

FACT SHEET 9

40 CFR 61, EPA AIR EMISSION STANDARDS FOR RADIONUCLIDES (1985, 1986)

COMPLETE TITLE

40 CFR 61, NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS; STANDARDS FOR RADIONUCLIDES, 50 FR 5190, February 6, 1985; STANDARD FOR RADON-222 EMISSIONS FROM UNDERGROUND URANIUM MINES, 50 FR 15386, April 17, 1985; STANDARDS FOR RADON-222 EMISSIONS FROM LICENSED URANIUM MILL TAILINGS, 51 FR 34056, September 24, 1986

1. AUTHORIZING STATUTE

Section 120 of the Clean Air Act Amendments of 1977 (Public Law 95-95) (42 U.S.C. 7401 et seq.).

Effective Date: Clean Air Act, December 31, 1970; Amendments of 1977, August 7, 1977.

1.1 Statutory Purpose:

The purposes of the Clean Air Act are: "to protect . . . the Nation's air resources . . . to promote public health and welfare and . . . productive capacity; to initiate and accelerate national research and development to achieve the prevention and control of air pollution; to provide technical and financial assistance to State and local governments in connection with the development and execution of their air pollution prevention and control programs; and to encourage and assist . . . regional air pollution control programs."

1.2 Radiation Protection Provisions:

Section 122(a) of the Clean Air Act provides: "the Administrator [of the Environmental Protection Agency (EPA)] shall . . . determine whether or not emissions of radioactive pollutants (including source material, special nuclear material, and by-product material) . . . will cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health. If the Administrator makes an affirmative determination, . . . he shall . . . include such substance in the list published under section . . . 112(b)(1)(A) in the case of a substance which . . . causes, or contributes to air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." This listing for radionuclides was made and issued in 44 FR 76738, December 27, 1979.

Section 112(b) of the Act provides: "The Administrator shall . . . publish (and shall from time to time thereafter revise) a list which includes each hazardous air pollutant for which he intends to establish an emission standard under this section." In addition, the Administrator "shall

publish . . . regulations establishing emission standards for such pollutant . . . and shall establish such standards at the level which in his judgment provides an ample margin of safety to protect the public health."

Section 112(c) provides that any emission standard shall become effective upon promulgation for "new sources," and apply 90 days after promulgation for "existing sources."

Section 112(e) provides: "[if] in the judgment of the Administrator, it is not feasible to prescribe or enforce an emission standard, . . . he may instead promulgate a design, equipment, work practice, or operational standard, . . . which in his judgment is adequate to protect the public health . . . with an ample margin of safety."

2. RESPONSIBLE AGENCIES

The Environmental Protection Agency (EPA). EPA is responsible for listing hazardous air pollutants, and once listed, promulgating, implementing, and enforcing emission standards or design, equipment, work practice, or operational standards.

The Nuclear Regulatory Commission (NRC). Under Clean Air Act §122, the NRC must be consulted by the EPA before any source material, special nuclear material, or by-product material (or component or derivative thereof) is listed. This consultation was noted in 44 FR 76738, December 27, 1979. Pursuant to the Act, the EPA and NRC entered into a Memorandum of Understanding, published in 45 FR 72980, November 3, 1980.

Department of Energy (DOE). DOE facilities are regulated under the Clean Air Act §§112 and 122.

States. Under section 112(d)(1) of the Clean Air Act, any State may develop and submit to the Administrator (of EPA) a procedure for implementing and enforcing emission standards for hazardous air pollution for stationary sources located in such State. If the Administrator finds a State's procedure adequate, the Federal authority is then delegated to the State. (So-called "automatic" delegation, agreed upon between EPA and some States for other pollutants, is not applicable to the "radionuclides" category.)

3. DESCRIPTION OF 40 CFR 61, EPA AIR EMISSION STANDARDS FOR RADIONUCLIDES (1985, 1986)

Issuances:

40 CFR 61, 50 FR 5190, February 6, 1985, for DOE facilities, NRC-licensed facilities and non-DOE Federal facilities, and elemental phosphorus plants; 50 FR 15386, April 17, 1985 for underground uranium mines; and 51 FR 34056, September 24, 1986 for uranium mill tailings.

Effective Dates:

For DOE, NRC-licensed and non-DOE Federal facilities, and elemental phosphorus plants final rules became effective, February 6, 1985 for new sources. For existing sources, the standards did not apply until May 7, 1985.

For underground uranium mines, the final rule became effective on April 17, 1985. For existing sources, the standards did not apply until 90 days after the effective date.

For uranium mill tailings, the final rule became effective on September 24, 1986.

Background:

"Radionuclides: Background Information Document for Final Rules, Volumes 1 and 2," EPA 520/1-84-022-1 (October 1984), EPA 520/1-84-022-2 (October 1984); "Radionuclides Background Information Document: Standard for Radon-222 Emissions for Underground Uranium Mines," EPA 520/2-85-010 (April 10, 1985); "Background Information Document—Final Rule for Radon-222 Emissions from Licensed Uranium Mill Tailings," EPA 520/1-86-009 (August 15, 1986); and "Economic Analysis—Final Rule for Radon-222 Emissions from Licensed Uranium Mill Tailings," EPA 520/1-86-010 (August 1986).

3.1 General Radiation Protection Provisions:

The EPA has promulgated standards under §112 of the Clean Air Act to limit exposure of the public due to emissions from the following source categories: DOE facilities; certain NRC-licensed facilities and non-DOE Federal facilities; elemental phosphorus plants; and underground uranium mines and licensed uranium mill tailings. Excluded from the standards are: facilities regulated under 40 CFR 190, 191, and 192; any low-energy accelerator; or any user of sealed radiation. The standards prescribe dose limits to members of the public from radionuclides emitted into the air from DOE and NRC facilities. The standard for elemental phosphorus plants limits the total emissions of polonium-210 into the air from these plants. The standard for underground uranium mines establishes a work practice that requires the installation of bulkheads in abandoned parts of these mines, to limit radon-222 emissions into the air. The standard for licensed uranium mill tailings also establishes a work practice that requires "phased disposal" or "continuous disposal" of mill tailings in order to limit radon-222 emissions into the air.

3.2 Rationale for Detailed Requirements:

3.2.1 DOE, NRC, non-DOE Federal facilities, and elemental phosphorus plants.

EPA attempted to withdraw its proposed standards for DOE, NRC, and non-DOE Federal facilities and for elemental phosphorus plants on the grounds that current emission control and operational practices provided an ample margin of safety in protecting the public health. However, the Sierra Club filed suit to compel action in U.S. District Court, and the court ordered EPA to promulgate standards or "delist" radionuclides as a hazardous air pollutant. The

EPA believes that although current emission levels for these three source categories represent an ample margin of safety, radionuclides cannot be delisted because radionuclide emissions from underground uranium mines appear to reach levels that warrant regulation.

EPA set limits that reflect current emission levels achieved by existing control technology and operating practices at DOE, NRC-licensed and non-DOE Federal facilities and at elemental phosphorous plants. EPA noted that the DOE and NRC policy of keeping radionuclide emissions "as low as reasonably achievable" (ALARA) has generally led to low emissions, and expects the policy to continue.

3.2.2 Radon-222 emissions from underground uranium mines.

To regulate radon-222 emissions from underground uranium mines, EPA took a risk-benefit approach. EPA cites: "convincing evidence that exposure to radon-222 gas and its decay products causes or contributes to lung cancer"; also "the increased lifetime risk to individuals living near an underground uranium mine could be about one chance in one hundred of incurring lung cancer because of the emissions." In addition, "several fatal cancers per year may result in the total population due to these emissions."

Because conventional radon-222 control technology was either prohibitively expensive, or not particularly effective, and any reduction in risk to the population might be achievable only by increasing the risk to miners, EPA concluded that bulkheading, while not highly effective, would be the least costly practice, and would not significantly increase miner exposure.

3.2.3 Radon-222 emissions from licensed uranium mill tailings.

To regulate radon-222 emissions from licensed uranium mill tailings, EPA also took a risk-benefit approach. Citing lung cancer as the dominant health hazard from tailings, the EPA estimated that the individual lifetime risk of developing a fatal cancer (for individuals living near tailing piles where predicted concentrations of the pollutant are highest) may be as high as 1 in 100, based on median risk estimates assuming 70 years of exposure. The U.S. population risk is estimated to be 1 to 5 deaths per year under current industry and regulatory conditions. EPA believes that these risks are significant and that there is a need for standards under the Clean Air Act to protect public health with an ample margin of safety.

The standard "requires the use of work practices that will reduce radionuclide emissions, and therefore risks, to the practical minimum." The standard "reflects consideration of the magnitude of the risks, the costs and availability of further controls and associated risk reduction potential, and the potential societal impacts of regulatory alternatives."

3.3 Description of Detailed Requirements:

3.3.1 Standards for DOE, NRC-licensed and non-DOE Federal facilities (excluding facilities regulated under 40 CFR 190, 191, or 192; any low-energy accelerator; or any user of sealed radiation sources):

Organ	Dose Equivalent Rate To Any Member of the Public
Whole body	25 mrem/year
Critical organ	75 mrem/year

(Excludes doses due to radon-220, radon-222, and their decay products.)

EPA will grant a waiver of the above limits, and issue alternative standards if a facility operator demonstrates:

No member of the public will receive a continuous exposure, excluding natural background and medical exposures, of more than 100 mrem/year effective dose equivalent and a noncontinuous exposure of more than 500 mrem/year effective dose equivalent from all sources.

3.3.2 Standard applicable to owners and operators of calciners and nodulizing kilns at elemental phosphorus plants:

Emissions of polonium-210 to air shall not exceed a total of 21 curies in a calendar year.

3.3.3 Standard for radon-222 emissions from underground uranium mines.

Applicable to an owner or operator of a mine which:

(1) Has mined or will mine over 100,000 tons of ore during the life of the mine; or

(2) Has had or will have an annual ore production greater than 10,000 tons, unless it can be demonstrated that the mine will not exceed a total ore production of 100,000 tons during the life of the mine.

The owner or operator of an underground uranium mine to which this rule is applicable shall install and maintain bulkheads to isolate all abandoned and temporarily abandoned areas.

The owner or operator of such a mine may apply to the Administrator of EPA for an alternative standard if compliance with the above requirement will result in increased radon-222 exposure in active areas of the mine, will require workers to enter unsafe areas, or will otherwise be impractical to achieve because of unusual circumstances. The alternative standard must be shown by the

applicant to be necessary to provide for the health and safety of the workers and to minimize exposure to the general population to the extent practical.

3.3.4 Standard for radon-222 emissions from licensed uranium mill tailings.

Applicable to licensed sites that manage uranium by-product materials during or following the processing of uranium ores, commonly referred to as uranium mills, and their associated tailings. This subpart applies during the period of operation of the mill.

A. "All new tailings impoundments built after September 24, 1986, shall be designed and constructed to meet one of the two following work practice standards:

i. "Phased disposal in lined tailings impoundments that are not more than 40 acres in area and meet requirements of 40 CFR 192.32(a). The owner shall have no more than two impoundments in operation (open) at any one site at any one time;

ii. "Continuous disposal of tailings such that the tailings are dewatered and immediately disposed with no more than 10 acres being uncovered at any time and operated in accordance with 40 CFR 192.32(a)."

B. Owners who do not intend to build a new tailings impoundment, must certify so within 2 years of September 24, 1986. These owners will be able to use existing piles for new tailings until December 31, 1992, unless they receive an exception or extension from the Administrator.

C. Owners who wish to build new tailings piles must follow the following schedule:

i. Apply for approval of construction as soon as possible, but no later than 2 years from September 24, 1986.

ii. Within 60 days of approval apply to NRC for a license to construct a new tailings impoundment.

iii. Begin construction within 90 days after obtaining a license (season permitting).

In no event shall an owner following this schedule place new tailings on existing tailings piles after December 31, 1992, unless the owner has received an exception or extension from the Administrator.

D. New tailings shall not be placed on any existing tailings pile after December 31, 2001. No exceptions or extensions will be effective after that date.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposure. (RPGs) (1960). (See FACT SHEET 1.)

Federal Guidance on Limiting Certain Internal Radiation Exposures (RPGs) (1961). (See FACT SHEET 4.)

40 CFR 190, EPA Environmental Standards for Uranium Fuel Cycle (1977). (See FACT SHEET 11.)

40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985). (See FACT SHEET 12.)

40 CFR 191, EPA Environmental Standards for Management and Disposal of High-Level and Transuranic Radioactive Waste (1985). (See FACT SHEET 13.)

40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982). (See FACT SHEET 14.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

10 CFR 50, Appendix I, NRC ALARA Design Objectives for Light-Water Reactor Effluents (1975). (See FACT SHEET 19.)

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

FACT SHEET 10

40 CFR 141, EPA INTERIM DRINKING WATER STANDARDS FOR RADIONUCLIDES (1976)

COMPLETE TITLE

40 CFR 141, INTERIM PRIMARY DRINKING WATER REGULATIONS, PROMULGATION OF REGULATIONS ON RADIONUCLIDES, 41 FR 28402, July 9, 1976

1. AUTHORIZING STATUTE

Title XIV - Safety of Public Water Systems of the Public Health Service Act, as amended by the Safe Drinking Water Act (SDWA), as amended, (P.L. 93-523).

Effective Date: December 16, 1974.

1.1 Statutory Purpose:

SDWA applies to public water systems and establishes primary drinking water regulations which specify contaminants that, in the judgment of the Environmental Protection Agency (EPA), "may have any adverse effect on the health of persons." Under the regulations, EPA must set a maximum contaminant level (MCL) for each contaminant.

1.2 Radiation Protection Provisions:

Under the SDWA, the EPA established national interim primary drinking water regulations for radioactivity, setting MCLs for various radionuclides.1/

1/ The EPA published an Advance Notice of Proposed Rulemaking Dealing With Radionuclides Under the Safe Drinking Water Act (51 FR 34836) on September 30, 1986. This provided

> advance notice of a proposed rule for Maximum Contaminant Level Goals (MCLGs) and National Primary Drinking Water Regulations (NPDWR) including Maximum Contaminant Levels (MCLs) for radionuclides in drinking water. MCLGs and MCLs are being considered for radium-226, radium-228, natural uranium, radon, gross alpha, and gross beta and photon emitters. . . . MCLGs are non-enforceable health goals which are to be set at levels which will result in no known or anticipated adverse health effects with an adequate margin of safety. When the MCLGs are proposed, the Agency will also propose MCLs and monitoring requirements. MCLs are enforceable standards and are to be set as close to the MCLGs as feasible, taking into account cost, availability of treatment technologies and other practical considerations.

2. RESPONSIBLE AGENCIES

The Environmental Protection Agency (EPA). The EPA is responsible for the promulgation and enforcement of primary drinking water regulations.

States. The States have primary enforcement responsibility for public water systems during any period for which the EPA determines that such State: has adopted drinking water regulations which are no less stringent than the national regulation; and has adopted and is implementing adequate procedures for the enforcement of such state regulations (including monitoring and inspection activities).

Indian Tribes. The EPA is authorized to treat Indian Tribes as States under the SDWA.

3. DESCRIPTION OF 40 CFR 141, EPA INTERIM DRINKING WATER STANDARDS FOR RADIONUCLIDES (1976)

Issuances:

41 FR 28402, July 9, 1976.

Effective Date: June 24, 1977.

Background:

"National Interim Primary Drinking Water Regulations," Office of Water Supply, EPA 570/9-76-003 (July 1976) (Statement of Basis and Purpose is included therein as appendices).

3.1 General Radiation Protection Provisions:

Under the SDWA, the EPA has established MCLs for radium-226, radium-228, gross alpha particle activity, and beta particle and photon radioactivity from man-made radionuclides in community water systems. EPA has also promulgated monitoring requirements for radioactivity in these community water systems. The EPA maximum contaminant levels apply to the need for treatment by the water supply operator and are not ambient water quality criteria, except for groundwater. A "public water supply" has at least 15 connections or serves at least 25 individuals.

3.2 Rationale for Detailed Requirements:

3.2.1 "Because of these many uncertainties [of data for low-level doses at low dose-rates], it is necessary to rely upon the considered

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(cont.)

The legislative history provides further guidance on selecting MCLGs: "[t]he recommended maximum level . . . must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the level should be set at zero level. (House Report No. 93-1185, July 10, 1974, at 20)."

judgements of experts on the biological effects of ionizing radiation." (UNSCEAR, NAS, NCRP)

3.2.2 "It is the present policy of the EPA to assume a linear, nonthreshold relationship between the magnitude of the radiation dose received at environmental levels of exposure and ill health produced as a means to estimate the potential health impact of actions it takes in developing radiation protection . . . criteria, guides, or standards. This policy is adopted in conformity with the generally accepted assumption that there is some potential ill health attributable to any exposure to ionizing radiation and that the magnitude of this ill health [is] directly proportional to the magnitude of the dose received."

3.2.3 "The linear hypothesis by itself precludes the development of acceptable levels of risk based solely on health considerations. Therefore, in establishing radiation protection positions, the EPA will weigh not only the health impact, but also social, economic and other considerations associated with the activities addressed."

3.2.4 "The MCL of 15 pCi/l for gross alpha particle limit . . . is based on a consideration of the radiotoxicity of other alpha particle emitting contaminants relative to radium. The 15 pCi/l gross alpha particle limit . . . is based on the conservative assumption that if the radium concentration is 5 pCi/l and the balance of the alpha particle activity is due to the next most radiotoxic alpha particle emitting chain starting with lead-210, the dose to bone will not be unduly increased. Though less precise than setting maximum contaminant levels for lead-210 specifically, the establishment of a limit on gross alpha particle activity is more in keeping with the current capability of State laboratories while providing significant public health protection."

3.3 Description of Detailed Requirements:

3.3.1 MCLs for radium-226, radium-228, and gross alpha particle activity in community water systems:

A. Combined radium-226 and radium-228: 5 pCi/l.

B. Gross alpha particle activity (including radium-226, but excluding radon and uranium): 15 pCi/l.

3.3.2 MCLs for beta particle and photon radioactivity from man-made radionuclides in community water systems:

A. "The average annual concentration of beta particle and photon radioactivity from man-made radionuclides in drinking water shall not produce an annual dose equivalent to the total body or any internal organ greater than 4 millirem."

B. "Except for the radionuclides listed in [the table which follows], the concentration of man-made radionuclides causing 4 millirem total body or organ dose shall be calculated on

the basis of a 2 liter per day drinking water intake using the 168-hour data listed in . . . NBS Handbook 69, as amended, August 1963, U.S. Department of Commerce."

TABLE - AVERAGE ANNUAL CONCENTRATIONS ASSUMED TO PRODUCE A TOTAL BODY OR ORGAN DOSE OF 4 MREM/YR:

Radionuclide	Critical Organ	pCi per liter
Tritium	Total body	20,000
Strontium-90	Bone marrow	8

C. "If two or more radionuclides are present, the sum of their annual dose equivalent to the total body or to any organ shall not exceed 4 millirem/year."

D. To determine compliance with B above, the detection limits shall not exceed the concentrations listed below:

Radionuclide	Detection Limit
Tritium	1,000 pCi/l
Strontium-89	10 pCi/l
Strontium-90	2 pCi/l
Iodine-131	1 pCi/l
Cesium-134	10 pCi/l
Gross beta	4 pCi/l
Other radionuclides	1/10 of the applicable limit

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Federal Guidance on Limiting Certain Internal Radiation Exposures (RPGs) (1961). (See FACT SHEET 4.)

40 CFR 190, EPA Environmental Standards for Uranium Fuel Cycle (1977). (See FACT SHEET 11.)

40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982). (See FACT SHEET 14.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

10 CFR 50, Appendix I, NRC ALARA Design Objectives for Light-Water Reactor Effluents (1975). (See FACT SHEET 19.)

40 CFR 141, EPA Advance Notice of Proposed Rulemaking Dealing with Radionuclides Under Safe Drinking Water Act, 51 FR 34836, September 30, 1986. (This will be a revision of this standard.)

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

FACT SHEET 11

40 CFR 190, EPA ENVIRONMENTAL STANDARDS FOR URANIUM FUEL CYCLE (1977)

COMPLETE TITLE

40 CFR 190, ENVIRONMENTAL RADIATION PROTECTION STANDARDS FOR NUCLEAR POWER OPERATIONS, 42 FR 2858, January 13, 1977

1. AUTHORIZING STATUTE

Atomic Energy Act of 1954, as amended (P.L. 83-703), and the President's Reorganization Plan No. 3 of 1970 (5 U.S.C. App. 609, 84 Stat. 2086-88).

Effective Date: August 30, 1954.

1.1 Statutory Purpose:

The policy of the United States under the Atomic Energy Act is:

1.1.1 to develop, use, and control atomic energy so as to maximize its contribution to the general welfare and to make the maximum contribution to the common defense and security of the country; and

1.1.2 to develop, use, and control atomic energy so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise.

1.2 Radiation Protection Provisions:

Section 161 of the Atomic Energy Act of 1954 (The General Authority section) empowers the Atomic Energy Commission (AEC) [Nuclear Regulatory Commission (NRC) and Environmental Protection Agency (EPA)] to establish rules, regulations, and standards to govern the possession or use of nuclear materials as the AEC [(NRC), (EPA)] deems necessary or desirable to "protect health or minimize danger to life or property."

Section 274(b) of the Atomic Energy Act of 1954 authorizes the Commission "to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission . . . with respect to . . . byproduct materials, . . . source materials, . . . [and] special nuclear materials in quantities not sufficient to form a critical mass." However, §274(c) provides that "[n]o agreement entered into pursuant to subsection b. shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of . . . the construction and operation of any production or utilization facility; . . . [and the export, import, and disposal of any nuclear material] as defined in the regulations or orders of the Commission."

2. RESPONSIBLE AGENCIES

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 (5 U.S.C. App. 609, 84 Stat. 2086-88) transferred to EPA from the former Atomic Energy Commission the more explicit responsibility to establish generally applicable radiation standards. The Plan defined standards 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."

The Nuclear Regulatory Commission (NRC). The NRC is responsible for the implementation and enforcement of the radiation standards established by EPA. "The authority to regulate fuel cycle facilities resides in the . . . NRC or, in some cases, the States, under agreement with NRC."

States. As of 1988, twenty-nine States have entered into agreements with NRC under Section 274 of the Atomic Energy Act of 1954, as amended, where the States have assumed jurisdiction to regulate fuel cycle facilities, and other operations consistent with NRC regulations and EPA standards.

3. DESCRIPTION OF 40 CFR 190, EPA ENVIRONMENTAL STANDARDS FOR URANIUM FUEL CYCLE (1977)

Issuances:

Final, 42 FR 2858, January 13, 1977; Proposed, 40 FR 23420, May 29, 1975.

Effective Date:

For the standard in 3.3.1 below, December 1, 1979, except that for doses arising from operations associated with the milling of uranium ore, the effective date is December 1, 1980; for the standard in 3.3.2 below, December 1, 1979, except January 1, 1983 for krypton-85 and iodine-129 generated by the fission process.

Background:

"Environmental Radiation Protection Requirements for Normal Operations of Activities in the Uranium Fuel Cycle," Volumes I, II and III, EPA 520/4-76-016 A, B, C (November 1, 1976); "Environmental Analysis of the Uranium Fuel Cycle, Parts I-IV," EPA 520/4-76-017 (July 1976).

3.1 General Radiation Protection Provisions:

3.1.1 The standards specify the levels below which normal operations of the uranium fuel cycle are determined to be environmentally acceptable. "'Uranium fuel cycle' means the operations of milling uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing uranium fuel, to the extent that these directly support the production of electrical power for public use utilizing nuclear energy, but excludes mining operations, operations at waste disposal sites, transportation of any radioactive materials in support of these

operations, and the reuse of recovered non-uranium special nuclear and by-product materials from the cycle."

3.1.2 The standards are expressed in terms of limits on individual doses to members of the public and on quantities of certain long-lived radioactive materials released to the general environment.

3.2 Rationale for Detailed Requirements:

3.2.1 The EPA has concluded that environmental radiation standards for nuclear power operations (nuclear fuel cycle) should include consideration of:

(1) "the total radiation dose to populations;

(2) "the maximum dose to individuals;

(3) "the risk of health effects attributable to these doses, including the future risks arising from the release of long-lived radionuclides; [and]

(4) "the effectiveness and costs of the technology available to mitigate these risks through effluent control."

3.2.2 EPA assumes "that a potential for health effects due to ionizing radiation exists at all levels of exposure and that at the low levels of exposure characteristic of environmental levels of radiation the number of these effects will be directly proportional to the dose of radiation achieved (a linear non-threshold dose-effect relationship)."

3.2.3 The standards generally represent the lowest radiation levels at which the EPA has determined that the costs of control are justified by the reduction in health risk.

3.2.4 The standard for individual whole-body dose limits the combined internal and external dose equivalent from gaseous and liquid effluents as well as exposure to gamma and neutron radiation from all operations of the fuel cycle. EPA determined that this limit is readily satisfied at all sites by levels of control that are cost-effective for the reduction of potential risk achieved; and, based on present operating experience at existing sites, it can be readily achieved in practice. The dose limit to the thyroid reflects, to the extent that current capability for risk-estimation permits comparison, a level of biological risk comparable to that represented by the standard for the whole body. The principal potential doses to internal organs (other than the thyroid) are to the lung via inhalation of airborne particulates and to bone due to ingestion via water and other pathways. The impact on populations due to effluents from these operations is generally quite small (due to remote locations and lack of widespread dispersion); however, significant lung doses are possible to individuals living or working near these operations, particularly in the case of mills and conversion facilities. EPA

determined that the use of well-established, efficient, and inexpensive control technology for particulate effluents can readily achieve the level of control to meet the dose limit to internal organs.

3.2.5 The long-lived radionuclides produced in the fuel cycle are of particular concern because of their potential for extreme persistance in the environment (iodine-129, half-life 17 million years). The long-lived radionuclides should only be discharged to the environment after careful consideration of the trade-offs between the societal benefits of the power generated, the current and projected health risks to populations, and the costs and effectiveness of methods available to limit their release. Since the anticipated maximum dose to any single individual is very small, the primary concern is the cumulative risk to population groups over long periods of time. It is therefore important to assure that any permitted discharge is offset by a beneficial product, i.e., a quantity of electricity, and that every reasonable effort is made to minimize discharges.

3.3. Description of Detailed Requirements:

3.3.1 The annual dose equivalent to any member of the public as the result of exposures to planned discharges of radioactive materials (radon and its daughters excepted) to the general environment from uranium fuel cycle operations and to radiation from these operations shall not exceed:

Organ	Annual Dose Equivalent (millirem)
Whole body	25
Thyroid	75
Any other organ	25

3.3.2 The total quantity of radioactive materials entering the general environment from the entire uranium fuel cycle, per gigawatt-year of electrical energy produced by the fuel cycle, shall contain less than 50,000 curies of krypton-85, 5 millicuries of iodine-129, and 0.5 millicuries combined of plutonium-239 and other alpha-emitting transuranic radionuclides with half-lives greater than one year.

3.3.3 "The standards . . . may be exceeded if,

A. The regulatory agency has granted a variance based upon its determination that a temporary and unusual operating condition exists and continued operation is in the public interest, and

B. Information is promptly made a matter of public record[.]"

4. RELATED STANDARDS

Federa. Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Federal Gui...ing Certain Internal Radiation Exposures (RPGs) (1961). (See FACT SHEET 2.)

40 CFR 61, EPA Air Emission Standards for Radionuclides (1985, 1986). (See FACT SHEET 9.)

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985). (See FACT SHEET 12.)

40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982). (See FACT SHEET 14.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

10 CFR 50, Appendix I, NRC ALARA Design Objectives for Light-Water Reactor Effluents (1975). (See FACT SHEET 19.)

40 CFR 141, EPA Advance Notice of Proposed Rulemaking Dealing with Radionuclides Under Safe Drinking Water Act, 51 FR 34836, September 30, 1986. (This will be a revision of the standard described in FACT SHEET 10.)

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

NRC Safety Goals for the Operations of Nuclear Power Plants; Policy Statement, August 4, 1986.

FACT SHEET 12

40 CFR 192, EPA, AND 10 CFR 40, NRC, ENVIRONMENTAL STANDARDS FOR U AND Th MILL TAILINGS (1983, 1985)

COMPLETE TITLE

40 CFR 192, HEALTH AND ENVIRONMENTAL STANDARDS FOR REMEDIAL ACTIONS AT INACTIVE URANIUM PROCESSING SITES, 48 FR 590, January 5, 1983; ENVIRONMENTAL STANDARDS FOR URANIUM AND THORIUM MILL TAILINGS AT LICENSED COMMERCIAL PROCESSING SITES, 48 FR 45926, October 7, 1983; and 10 CFR 40, URANIUM MILL TAILINGS REGULATIONS; CONFORMING NRC REQUIREMENTS TO EPA STANDARDS, 50 FR 41852, October 16, 1985

1. AUTHORIZING STATUTE

Section 275 of the Atomic Energy Act (42 U.S.C. 2022), as added by §206 of the Uranium Mill Tailings Radiation Control Act of 1978 (P.L. 95-604) (UMTRCA).

Effective Date: November 8, 1978.

1.1 Statutory Purpose:

1.1.1 In §2 of UMTRCA, Congress stated its finding that uranium mill tailings ". . . may pose a potential and significant radiation health hazard to the public, . . . and . . . that every reasonable effort should be made to provide for stabilization, disposal, and control [of tailings] in a safe and environmentally sound manner . . . in order to prevent or minimize . . . other environmental hazards from such tailings."

1.1.2 Congress further stated that the purposes of the UMTRCA are to provide at inactive mill sites ". . . a program of assessment and remedial action . . . including, where appropriate, the reprocessing of tailings to extract residual uranium and other mineral values where practicable, . . . and a program to regulate mill tailings during uranium or thorium ore processing at active mill operations and after termination of such operations, in order to stabilize and control tailings in a safe and environmentally sound manner and to minimize or eliminate radiation health hazards to the public."

1.2 Radiation Protection Provisions:

1.2.1 "UMTRCA established two programs to protect public health, safety, and the environment from uranium mill tailings, one for certain designated sites which are now inactive (i.e., at which all milling has stopped and which are not under license) and another for active sites" (those sites licensed by the NRC or a State pursuant to §274 of the Atomic Energy Act).

1.2.2 "Tailings at the inactive uranium milling sites are defined in UMTRCA as residual radioactive materials. The program for inactive sites covers the disposal of tailings and the cleanup of onsite and offsite locations contaminated with tailings."

1.2.3 "Tailings in active uranium milling sites are defined in UMTRCA as uranium byproduct materials. The program for active sites covers the final disposal of tailings and the control of effluents and emissions during and after milling operations."

1.2.4 Section 274(b) of the Atomic Energy Act of 1954 authorizes the Commission "to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission . . . with respect to . . . byproduct materials, . . . source materials, . . . [and] special nuclear materials in quantities not sufficient to form a critical mass." However, §274(c) provides that "[n]o agreement entered into pursuant to subsection b. shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of . . . the construction and operation of any production or utilization facility; . . . [and the export, import, and disposal of any nuclear material] as defined in the regulations or orders of the Commission."

2. RESPONSIBLE AGENCIES

Department of Energy (DOE). The UMTRCA directs the DOE to conduct necessary remedial actions at designated inactive processing sites to achieve compliance with the standards established by EPA, with the concurrence of the NRC and in cooperation with the States.

Environmental Protection Agency (EPA). The UMTRCA requires the EPA to set standards for the stabilization, disposal, and control of tailings and the control of effluents and emissions, for inactive and active uranium milling sites.

Nuclear Regulatory Commission (NRC). The NRC is responsible for enforcing compliance with the EPA standards at active uranium mill sites. NRC has amended its regulations governing the disposal of uranium mill tailings found in 10 CFR 40, Appendix A, to conform to certain of EPA's requirements for active uranium processing sites.

States. The State in which the site is located can perform remedial actions in cooperation with the DOE at inactive sites and, pursuant to an NRC-State agreement under §274 of the Atomic Energy Act, be responsible for assuring compliance with EPA standards at active mill sites.

Indian Tribes. DOE must consult affected Indian tribes and the Secretary of the Interior, when appropriate, on remedial actions.

3. DESCRIPTION OF 40 CFR 192, EPA, AND 10 CFR 40, NRC, ENVIRONMENTAL STANDARDS FOR U AND Th MILL TAILINGS (1983, 1985)

Issuances:

48 FR 590, January 5, 1983; 48 FR 45926, October 7, 1983; 10 CFR 40; and 50 FR 41852, October 16, 1985.

Effective Dates:

For standards at inactive sites, March 7, 1983. For standards at active sites, December 6, 1983. For NRC Regulations (10 CFR 40), November 15, 1985.

3.1 General Radiation Protection Provisions:

3.1.1 The standards for inactive sites require two types of remedial actions: control and cleanup. Control is the operation which places the tailings in piles in a stable way that gives reasonable assurances that the health hazards will be controlled and limited for a long period of time, and that the limits on releases of radon from tailings piles are met. Cleanup is the mill tailings removal operation which reduces the potential health consequences of tailings that have been dispersed from tailings piles by natural forces or removed by man and used elsewhere in buildings or land. The standard for cleanup limits the radon decay-product concentration and gamma radiation levels in buildings affected by tailings and the radium-226 concentration in contaminated land.

3.1.2 The standards for active sites are also divided into two parts. "The first part applies to management of tailings during the active life of the pile, and during the subsequent 'closure period,' i.e., after cessation of operations but prior to final disposal, including the period when the tailings are drying out." The standards for tailings at operating mills subject mill tailings to the ground water protection requirements now specified under the Solid Waste Disposal Act (SWDA) and extend these requirements by adding two chemical elements and radioactivity limits. "The second part specifies the conditions to be achieved by final disposal." They contain the same standards for control of uranium tailings after closure, as do the regulations for inactive sites. The standards in both parts apply to thorium mills with only minor modifications.

3.2 Rationale for Detailed Requirements:

3.2.1 EPA chose "optimized cost-benefit" alternatives for standards at inactive processing sites. Their objective was to establish standards that take account of the trade-offs between costs and benefits in a way that assures adequate protection of the public health, safety, and the environment; that can be implemented using presently available techniques and measuring instruments; and that are reasonable in terms of overall costs and benefits. (EPA concluded that "nondegradation" alternatives' small incremental increase in health benefits did not justify large additional costs; that the final standard provided much greater protection at only a small increase

above "least cost" alternatives, and that "least cost" alternatives placed primary emphasis on institutional controls that were not long-term controls.)

3.2.2 EPA considers the single most important goal of control to be the effective isolation and stabilization of tailings for as long a period as is reasonably feasible because tailings will remain hazardous for hundreds of thousands of years. EPA selected the 200- to 1,000-year control period because there is a reasonable expectation that readily achievable controls will remain effective for at least this period of time.

3.2.3 The radon emission limit of 20 $pCi/m^2/s$ was chosen to reduce the excess risk of fatal lung cancer from three to four chances in a hundred to an excess risk level of a few chances in a thousand. EPA set the radon air concentration standard at 0.5 pCi/l at the edge of the tailings, which provides approximately the same protection as the 20 $pCi/m^2/s$ emission standard.

3.3 Description of Detailed Requirements:

3.3.1 Standards for Remedial Action at Inactive Uranium Processing Sites:

Control of Tailings Piles:

A.	Longevity	Up to 1000 years, to the extent reasonably achievable, but at least 200 years.
B.	Radon emissions from disposal site	20 $pCi/m^2/s$ averaged over the entire surface of the disposal site over a one-year period, or 0.5 pCi/liter in air outside the disposal site.
C.	Water protection	Use existing State and Federal standards; apply site-specific measures where needed.

Cleanup of Buildings:

A.	Indoor radon decay products	To the extent practicable achieve 0.02 WL; in no event exceed 0.03 WL; WL (Working Level) is any combination of radon daughters in 1 liter of air which gives rise to the emission of 1.3×10^5 MeV of potential alpha energy.
B.	Indoor gamma radiation	20 microR/hr (above background).

Cleanup of Land:

A.	Surface	The concentration of radium-226 in land averaged over any area of 100 square meters shall not exceed background level by more than: 5 pCi/g averaged over the first 15 cm of soil below the surface; and
B.	Buried	15 pCi/g of radium-226 averaged over 15 cm thick layers of soil more than 15 cm below the surface.

Exceptions:

A.	Procedure	Supplemental standards (may be applied on generic or site-specific basis).
B.	Applicability	Where health and safety would be endangered, or where costs clearly outweigh benefits, or where inaccessible tailings pose minimal hazards.
C.	When radionuclides other than radium-226 are present in sufficient quantity to constitute a significant hazard.	Standards above, and ALARA for other radionuclides.

3.3.2 Environmental Standards for Uranium and Thorium Mill Tailings at Licensed (Active) Commercial Processing Sites:

A. Standards during operations and prior to the end of the closure period.

i. New tailings impoundments must be constructed to meet the requirements of 40 CFR 264.221 of the Solid Waste Disposal Act (except the requirements of 40 CFR 264.228(a)(2)(iii)(E) do not apply).

ii. Uranium by-product materials (tailings) shall be managed to conform to the groundwater protection standards in 40 CFR 264.92 except:

a. molybdenum and uranium are added to the list of hazardous constituents referenced in 40 CFR 264.93.

b. a combined limit for radium-226 and radium-228 of 5pCi/liter, and a limit for gross alpha-particle activity (excluding radon and uranium) of 15

pCi/liter, is added to the concentration limits for radioactive materials in groundwater referenced in Table 1 of 40 CFR 264.94.

c. the NRC may establish alternate concentration limits, provided they are ALARA, and the standards of 40 CFR 264.94(a) are satisfied at all points further than 500 meters from the site boundary.

iii. Uranium by-product material (tailings) shall be managed to conform to the provisions of 40 CFR 190 and 40 CFR 440.

iv. Every effort shall be made to maintain radiation doses from surface impoundments of tailings as far below the Federal Radiation Protection Guides (25 FR 4402, May 18, 1960; see FACT SHEET 1) as practicable.

B. Standards for after the closure period.

i. Disposal areas shall comply with the closure performance standards in 40 CFR 264.111 with respect to nonradiological hazards, and

ii. Disposal areas shall be designed to provide reasonable assurances of control of radiological hazards to be effective for one-thousand years, to the extent reasonably achievable, in any case, for at least 200 years, and

iii. Radon-222 emissions from tailings to the atmosphere will not exceed an average of 20 pCi/m^2/s over the entire surface of the disposal site over periods of at least one year, but short compared to 100 years.

iv. The requirements of B(i) above (the closure requirements of 40 CFR 264.11) shall not apply to any portion of a site which contains a concentration of radium-226 in land, averaged over areas of 100 square meters, which does not exceed background level by more than:

a. 5 pCi/g averaged over the first 15 cm below the surface, and

b. 15 pCi/g averaged over 15 cm-thick layers more than 15 cm below the surface.

v. Corrective actions shall be taken within 18 months of finding that EPA groundwater protection levels of 40 CFR 264.100 are exceeded.

C. Environmental standards for thorium mill tailings at licensed (active) commercial processing sites.

i. The provisions in A and B above apply to thorium by-product material tailings with the following additions: provisions applicable to uranium shall also apply to thorium; provisions applicable to radon-222 shall also apply to radon-220; and provisions applicable to radium-226 shall also apply to radium-228.

ii. Operations under A above shall be conducted in such a manner as to provide a reasonable assurance that the annual dose equivalent to any member of the public does not exceed:

Organ	Dose
Whole body	25 millirem
Thyroid	75 millirem
Any other organ	25 millirem

as a result of exposure to the planned discharge of radioactive materials (radon-220 and its daughters excepted) to the general environment.

3.3.3 10 CFR 40, Uranium Mill Tailings Regulations; Conforming NRC Requirements to EPA Standards:

The requirements of 10 CFR 40 are identical to those found in B and C above. In addition 10 CFR 40, Appendix A, requires milling operations to be conducted so that all airborne effluent releases are reduced to ALARA levels.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

40 CFR 61, EPA Air Emission Standards for Radionuclides (1985, 1986). (See FACT SHEET 9.)

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 191, EPA Environmental Standards for Management and Disposal of High-Level and Transuranic Radioactive Waste (1985). (See FACT SHEET 13.)

40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982). (See FACT SHEET 14.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

10 CFR 61, NRC Requirements for Land Disposal of Low-Level Radioactive Waste (1975). (See FACT SHEET 18.)

40 CFR 141, EPA Advance Notice of Proposed Rulemaking Dealing with Radionuclides Under Safe Drinking Water Act, 51 FR 34836, September 30, 1986. (This will be a revision of the standard described in FACT SHEET 10.)

40 CFR 194, EPA Advance Notice of Proposed Rulemaking: Radiation Protection Criteria for Cleanup of Land and Facilities Contaminated With Residual Radioactive Materials, 51 FR 22264, June 19, 1986.

40 CFR 193, EPA Advance Notice of Proposed Rulemaking for Low Level Radioactive Waste Disposal, 48 FR 39563, August 31, 1978.

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

FACT SHEET 13

40 CFR 191, EPA ENVIRONMENTAL STANDARDS FOR MANAGEMENT AND DISPOSAL OF HIGH-LEVEL AND TRANSURANIC RADIOACTIVE WASTE (1985)

COMPLETE TITLE

40 CFR 191, ENVIRONMENTAL STANDARDS FOR THE MANAGEMENT AND DISPOSAL OF SPENT NUCLEAR FUEL, HIGH-LEVEL AND TRANSURANIC RADIOACTIVE WASTES, 50 FR 38066, September 19, 1985

1. AUTHORIZING STATUTE

The Atomic Energy Act of 1954 (AEA), as amended (P.L. 83-703); Reorganization Plan No. 3 of 1970 (35 FR 15623); and the Nuclear Waste Policy Act of 1982 (NWPA).

Effective Date: Atomic Energy Act, August 30, 1954; Nuclear Waste Policy Act, January 7, 1983.

1.1 Statutory Purpose:

The purposes of the NWPA are to:

1.1.1 Establish a schedule for the siting, construction, and operation of repositories which will provide reasonable assurance that the public and the environment will be adequately protected from the hazards posed by high-level radioactive waste and spent nuclear fuel disposed of in these repositories;

1.1.2 Establish Federal responsibility and policy for disposal of such waste;

1.1.3 Define the relationship between Federal and State governments and Indian tribes with respect to waste disposal; and

1.1.4 Establish a nuclear waste fund, composed of payments made by generators and owners of such waste, that will insure that the costs of the disposal of the waste are borne by the persons responsible for generating it.

1.2 Radiation Protection Provisions:

Section 121 of the NWPA gives the Environmental Protection Agency (EPA) the responsibility to "promulgate generally applicable standards for protection of the general environment from offsite releases from radioactive material in repositories."

2. RESPONSIBLE AGENCIES

The Environmental Protection Agency (EPA). The President's Reorganization Plan No. 3 (5 U.S.C. App. 609, 84 Stat. 2086-88) transferred to EPA from the former Atomic Energy Commission the responsibility to establish generally applicable radiation standards. Under this authority, EPA is responsible for promulgating generally applicable standards for the management and disposal of spent nuclear fuel and high-level and transuranic wastes, including radiation protection standards for members of the public.

The Nuclear Regulatory Commission (NRC). The NRC is responsible for the implementation and enforcement of the radiation standards established by EPA under the Atomic Energy Act at NRC-regulated DOE High-Level Waste (HLW) facilities.

The Department of Energy (DOE). DOE is responsible for development of guidance for site selection, site characterization, waste package and repository design, construction, operation, decommissioning and permanent closure of HLW repositories.

States and Indian Tribes. Affected States and Indian Tribes are granted automatic party status in NRC licensing proceedings.

3. DESCRIPTION OF 40 CFR 191, EPA ENVIRONMENTAL STANDARDS FOR MANAGEMENT AND DISPOSAL OF HIGH-LEVEL AND TRANSURANIC RADIOACTIVE WASTE (1985)

Issuances:

50 FR 38066, September 19, 1985.

Effective Date: November 18, 1985.

Background:

"High-level and Transuranic Radioactive Wastes—Background Information Document for Final Rule," EPA 520/1-85-023 (August 1985); "High-level and Transuranic Radioactive Wastes—Response to Comments for Final Rule," Volumes I, II, EPA 520/1-85-024 (August 1985).

3.1 General Radiation Protection Provisions:

3.1.1 The first part of the EPA standards limits the radiation exposure of members of the public from the management and storage of spent fuel or high-level or transuranic wastes at NRC and DOE facilities.

3.1.2 The second part establishes several different types of requirements for disposal of these materials. They include: long-term containment standards which limit projected releases of radioactivity for 10,000 years after disposal; a set of six qualitative assurance requirements designed to provide adequate confidence that containment requirements will be met; limitations on exposures to individual

members of the public for 1,000 years after disposal; and a set of groundwater protection requirements.

3.1.3 Although disposal of these materials in geological repositories has received the most attention, the regulations apply to disposal by any method, except ocean disposal which is prohibited under the Marine Protection, Research, and Sanctuaries Act of 1972, as amended (P.L. 93-254). (See FACT SHEET 15.)

3.2 Rationale for Detailed Requirements:

3.2.1 "Disposal in compliance with the containment requirements is projected to cause no more than 1,000 premature cancer deaths over the 10,000 year period from disposal of all existing high-level wastes and most of the wastes yet to be produced by currently operating reactors, an average of 0.1 fatality per year. This level of residual risk to future generations would be comparable to the risks that those generations would have faced from the uranium ore used to create the wastes if the ore had never been mined."

3.2.2 EPA felt that the risks of public exposure during management and storage (prior to disposal) were very small, and therefore made the public exposure limits for 40 CFR 191 comparable with other related radiation protection standards. The combined exposure to the public from NRC facilities under 40 CFR 190, and Subpart A of 40 CFR 191, cannot exceed limits equal to those found in Part 190. (This includes all operations prior to final closure at high-level waste disposal facilities.) For DOE management and storage operations, the limits are equivalent to standards found in 40 CFR 61 which were promulgated under the Clean Air Act. (See FACT SHEET 9.)

3.2.3 The groundwater protection standards that apply after disposal are designed to protect individuals in the vicinity of a disposal system and are similar to those established for the output of community water systems in 40 CFR 141. (See FACT SHEET 10.)

3.2.4 The individual protection requirements after disposal of the wastes of 25 millirem/year to the whole body and 75 millirem/year to any organ during the first 1,000 years after disposal are estimated to "cause a 5×10^{-4} chance of incurring a premature fatal cancer." This level of protection was considered sufficiently stringent in this situation, where no more than a few individuals are likely to receive this exposure.

3.3 Description of Detailed Requirements:

40 CFR 191 applies to the management and disposal of spent nuclear fuel, high-level radioactive waste (defined by the NWPA as follows: 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 NRC determines by rule requires permanent isolation), and transuranic wastes containing more than 100 nanocuries per gram of alpha-emitting

transuranic isotopes, except wastes that either the NRC or EPA determines do not need the degree of isolation required by this rule.

3.3.1 Subpart A - Environmental Standards for Management and Storage

A. Management and storage at facilities regulated by NRC or Agreement States shall be conducted in such a manner as to provide reasonable assurance that the combined annual dose equivalent to any member of the public from all NRC-licensed facilities covered by 40 CFR 190, the EPA uranium fuel cycle standards, will not exceed:

Organ	Dose
Whole body	25 millirem
Thyroid	75 millirem
Any other organ	25 millirem

B. For management and storage at DOE disposal facilities annual doses to members of the public are limited to:

Organ	Dose
Whole body	25 millirem
Any other organ	75 millirem

C. Alternative Standards may be set at DOE facilities if the EPA determines they will prevent any member of the public from receiving a dose exceeding:

Type of Exposure	Dose Equivalent
Continuous	100 millirem/year
Infrequent	500 millirem/year

(from all sources except natural background and medical procedures).

3.3.2 Subpart B - Environmental Standards for Disposal

A. Containment requirements:

Disposal systems shall be designed to provide a reasonable expectation, based upon performance assessments, that the cumulative releases of radionuclides to the environment for 10,000 years after disposal shall:

i. Have a likelihood of less than one chance in ten of exceeding the quantities below; and

ii. Have a likelihood of less than one in 1,000 of exceeding ten times the quantities below:

Cumulative Releases to the Environment for 10,000 Years After Disposal

Radionuclide	Release limit: curies per 1,000 MTHM[1/] or other unit of waste
Americium-241 or -243	100
Carbon-14	100
Cesium-135 or -137	1,000
Iodine-129	100
Neptunium-237	100
Plutonium-238, -239, -240, or -242	100
Radium-226	100
Strontium-90	1,000
Technetium-99	10,000
Thorium-230 or -232	10
Tin-126	1,000
Uranium-233, -234, -235, -236, or -238	100
Any other alpha-emitting radionuclide with a half-life greater than 20 years	100
Any other radionuclide with a half-life greater than 20 years that does not emit alpha particles	1,000

1/ MTHM means metric tons of heavy metal. The above table is found in 40 CFR 191, Appendix A, Table 1. "To develop Release Limits for a particular disposal system, the quantities in Table 1 shall be adjusted for the amount of waste included in the disposal system compared to the various units of waste defined in Note 1" following Table 1, in Appendix A.

B. Individual protection requirements.[1/]

Disposal systems shall be designed to provide a reasonable expectation that for 1,000 years after disposal, undisturbed performance of the system shall not cause the annual dose equivalent to any member of the public in the accessible environment to exceed:

Organ	Dose
Whole body	25 millirem
Any other organ	75 millirem

All potential pathways from the disposal system to people shall be considered, including the assumption that individuals consume 2 liters per day of drinking water from any significant source of groundwater outside the controlled area.

C. Groundwater protection requirements.

i. Disposal systems shall be designed to provide a reasonable expectation that for 1,000 years after disposal, the system shall not cause the radionuclide concentrations averaged over any portion of a special source of groundwater to exceed:

a. 5 picocuries per liter of radium-226 and radium-228;

b. 15 picocuries per liter of alpha-emitting radionuclides (including radium-226 and radium-228, but excluding radon); or

c. The combined concentrations of radionuclides that emit either beta or gamma radiation that would produce an annual dose equivalent to the total body or any internal organ greater than 4 millirem per year (if an individual consumed 2 liters of groundwater per day).

1/ On July 17, 1987, in a suit filed by environmental groups, the U.S. Court of Appeals for the First Circuit nullified EPA's 40 CFR 191 on the basis that it is not consistent with EPA's drinking water standard (Fact Sheet 10). Specifically, the individual dose limit of 25 mrem per year was struck down, since no rationale was provided for departing from the 4 mrem per year limit previously established for drinking water. The court also found that no basis had been provided for establishing a limit of only 1000 years for application of the individual protection criteria. EPA has petitioned the court to reinstate the unaffected sections of 40 CFR 191.

ii. If any of the average annual radionuclide concentrations existing in groundwater before construction of the disposal system already exceed the limits in (C)(i) above, the system shall not increase the existing average concentrations by more than the limits in (C)(i) above.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985). (See FACT SHEET 12.)

40 CFR Parts 220-229, EPA Regulations and Criteria for Ocean Dumping of Radioactive Materials (1977). (See FACT SHEET 15.)

10 CFR 61, NRC Requirements for Land Disposal of Low-Level Radioactive Waste (1975). (See FACT SHEET 18.)

40 CFR 193, EPA Advance Notice of Proposed Rulemaking for Low-Level Radioactive Waste Disposal, 48 FR 39563, August 31, 1978.

10 CFR 60, NRC Requirements for Disposal of High-Level Radioactive Wastes in Mined Geological Repositories. (See FACT SHEET 17.)

FACT SHEET 14

40 CFR 440, EPA MINING EFFLUENT LIMITS FOR U AND Ra (1982)

COMPLETE TITLE

40 CFR 440, ORE MINING AND DRESSING POINT SOURCE CATEGORY EFFLUENT LIMITATIONS, GUIDELINES AND NEW SOURCE PERFORMANCE STANDARDS, 47 FR 54598, December 3, 1982

1. AUTHORIZING STATUTE

Sections 301, 304, 306, 307, 308 and 501 of the Clean Water Act (CWA) [The Federal Water Pollution Control Act Amendments of 1972 (P.L. 92-500), as amended (P.L. 95-217).]

Effective Date: P.L. 92-500, October 18, 1972; P.L. 95-217, December 27, 1977.

1.1 Statutory Purpose:

The objective of the CWA is to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" through: elimination of the discharge of pollutants into navigable waters; interim goals of water quality; prohibiting the discharge of toxic pollutants in toxic amounts; research and construction grants; and Congressional and Presidential actions to insure to the extent possible that foreign countries shall also take action to improve water quality.

1.2 Radiation Protection Provisions:

Under the CWA, the Environmental Protection Agency (EPA) has established regulations that limit the discharge of pollutants into navigable waters of the United States from existing and new sources in the ore mining and dressing industry. One subcategory of this industry--uranium, radium and vanadium ores--is relevant to radiation protection.

2. RESPONSIBLE AGENCIES

The Environmental Protection Agency (EPA). Under the CWA, EPA is required to issue effluent limitation guidelines, pretreatment standards, and new-source performance standards for industrial discharges. The regulations will be applied to individual ore mines and mills through National Pollution Discharge Elimination System (NPDES) permits issued by EPA or approved State agencies.

States. The States may administer their own permit programs for discharges into navigable waters within their jurisdictions (or by interstate compact) with approval by the EPA.

3. DESCRIPTION OF 40 CFR 440, EPA MINING EFFLUENT LIMITS FOR U AND Ra (1982)

Issuances:

47 FR 54598, December 3, 1982.

Effective Date: January 17, 1983.

3.1 General Radiation Protection Provisions:

The provisions are applicable to discharges from (a) mines either open-pit or underground, from which uranium, radium and vanadium ores are produced; and (b) mills using the acid leach, alkaline leach, or combined acid and alkaline leach process for the extraction directly from the ground of uranium, radium and vanadium. Only vanadium by-product production from uranium ores is covered under this subpart. The regulations set effluent limitations for existing mines and mills representing best practicable control technology currently available (BPT) and best available technology economically achievable (BAT). The regulations also set effluent limitations for new sources, representing best available demonstrated technology (BADT).

3.2 Rationale for Detailed Requirements:

3.2.1 Best Practicable Control Technology Currently Available (BPT)
"[l]imitations are based on the average of the best existing performance at plants of various sizes, ages and unit processes within the industry or subcategory. In establishing BPT limitations, [EPA] considers the total control of applying the technology in relation to the effluent reduction derived, the age of equipment and facilities involved, the process employed, the engineering aspects of the control technologies, process changes and the nonwater-quality environmental impacts (including energy requirements)."

3.2.2 Best Available Technology Economically Achievable (BAT)
"[l]imitations . . . represent the best existing performance in the industrial category or subcategory. [CWA] establishes BAT as the principal national means of controlling the direct discharge of toxic and nonconventional pollutants to navigable waters. In arriving at BAT, EPA considers the age of the equipment and facilities involved, the process employed, the engineering aspects of the control technologies, process changes, the cost of achieving such effluent reduction and nonwater-quality environmental impacts. [The EPA] retains considerable discretion in assigning weight to these factors."

3.2.3 "EPA established BAT equal to BPT either because BPT already specified zero discharge, . . . or because application of . . . BAT did not reduce the level of toxic or nonconventional pollutants, or because BPT removed a very high percentage of all relevant pollutants."

3.2.4 EPA excluded the mill subpart in the uranium, radium and vanadium subcategory from development of BAT regulations because there is only one discharger.

3.2.5 "New Source Performance Standards (NSPS) are based on the best available demonstrated technology. New plants have the opportunity to install the best and most efficient production processes and wastewater treatment technologies." EPA proposed NSPS equal to BAT limitations for all elements of the ore mining and dressing industry except for the uranium mill subcategory. EPA proposed NSPS requiring "zero discharge for new uranium mills based on data demonstrating 18 of 19 existing mills do not discharge wastewater. The single mill which discharges recycles over 80 percent of the requirement for its intake water. Zero discharge is based on recycle, evaporation, and a combination [of the two.]"

3.3 Description of Detailed Requirements:

The standard establishes limits for non-radiological characteristics (e.g., total suspended solids) as well as radiological characteristics. Only the limits for radionuclides are discussed below. The limits on radioactive effluents are the same for existing point sources and new sources. However, different levels of control technology are required to reach the levels.

3.3.1 "Any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction after application" of BPT:

The concentration of pollutants discharged in mine drainage from either open-pit or underground uranium, radium, and vanadium mines (excluding mines using in-situ leach methods); and from mills using acid leach, alkaline leach, or combined alkaline and acid leach process to extract uranium, radium, and vanadium, including mine-mill facilities using in-situ leach methods, shall not exceed:

Radionuclide	Effluent Limitations	
	Maximum For Any 1 Day	Average of daily values for 30 consecutive days
Ra-226 (dissolved)	10 pCi/l	3 pCi/l
Ra-226 (total)	30 pCi/l	10 pCi/l
U	4 milligrams/liter	2 milligrams/liter

3.3.2. Any existing point source subject to this subpart must achieve the above limitations representing the degree of effluent reduction attainable by application of BAT:

The concentration of pollutants discharged in mine drainage from open-pit or underground mines that produce uranium ore, including mines using in-situ leach methods, shall not exceed the limits in the table above.

3.3.3 Any new source subject to this subpart must achieve the following NSPS representing the degree of effluent reduction attainable by the application of Best Available Demonstrated Technology (BADT):

A. The concentration of pollutants discharged in mine drainage from open-pit or underground mines that produce uranium ore (excluding mines using in-situ leach methods) shall not exceed the limits in the table above.

B. Except as provided in C below, there shall be no discharge of process wastewater to navigable waters from mills using the acid leach, alkaline leach, or combined acid and alkaline leach process for the extraction of uranium or from mines and mills using in-situ leach methods. (EPA recognizes this may result in an increase in discharges of some pollutants in other media.)

C. In the event annual precipitation and surface runoff exceeds annual evaporation at a treatment facility, a volume of water equal to the excess may be discharged subject to the limits in the table, above.

3.3.4 General Provisions

A. Combined Waste Streams: The quantity and concentration of each pollutant or pollutant property in the combined discharge from waste streams from various subparts or segments, shall not exceed the quantity and concentration of each pollutant had each waste stream been treated separately.

B. Storm Exemption: If, as a result of precipitation or snowmelt, a source with an allowable discharge has an overflow or excess discharge of effluent which does not meet the limitations of 40 CFR 440, or a source which is not permitted to discharge has an overflow or discharge that violates the limitations of 40 CFR 440, the facility may qualify for an exemption if:

i. The facility is designed to accommodate a 10-year, 24-hour precipitation event.

ii. The facility takes all reasonable steps to maintain treatment of the wastewater and minimize overflow.

iii. The facility complies with notification requirements.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 190, EPA Environmental Standards for Uranium Fuel Cycle (1977). (See FACT SHEET 11.)

40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985). (See FACT SHEET 12.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

40 CFR 141, EPA Advance Notice of Proposed Rulemaking Dealing with Radionuclides Under Safe Drinking Water Act, 51 FR 34836, September 30, 1986. (This will be a revision of the standard described in FACT SHEET 10.)

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

FACT SHEET 15

40 CFR Parts 220-229, EPA REGULATIONS AND CRITERIA FOR OCEAN DUMPING OF RADIOACTIVE MATERIALS (1977)

COMPLETE TITLE

40 CFR PARTS 220-229, OCEAN DUMPING; FINAL REVISION OF REGULATIONS AND CRITERIA, 42 FR 2462, January 11, 1977; CONVENTION ON THE PREVENTION OF MARINE POLLUTION BY DUMPING OF WASTES AND OTHER MATTER, London 1972, effective August 30, 1975

1. AUTHORIZING STATUTE

Marine Protection, Research, and Sanctuaries Act of 1972 (MPRSA), as amended, Public Law 92-532, October 23, 1972; 33 U.S.C. 1401 et seq., 86 Stat. 1052 ("The Ocean Dumping Act").

Effective Date: April 23, 1972.

1.1 Statutory Purpose:

"The [MPRSA] declares that it is the policy of the United States . . . to prevent or strictly limit the dumping into ocean waters of any material which would adversely affect human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities."

1.2 Radiation Protection Provisions:

1.2.1 MPRSA empowers the Environmental Protection Agency (EPA) to promulgate regulations and issue permits for the dumping of materials into the territorial waters of the United States, "when the EPA determines that such dumping will not unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities."

1.2.2 Section 102 of the Act prohibits the issuing of a permit for, and therefore bans, the dumping of radiological, chemical, and biological warfare agents, and high-level radioactive waste. High-level radioactive waste is defined as ". . . the aqueous waste resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated waste from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuels, or irradiated fuel from nuclear power reactors."

1.2.3 The 1982 amendments to MPRSA (P.L. 97-424, January 6, 1983) added to Section 104, a "Permit Conditions" section which put a two-year moratorium on permits for ocean disposal of all radioactive waste. (The moratorium ran from January 6, 1983 to January 5, 1985.) Thereafter, a permit may not be issued until the applicant

prepares a Radioactive Material Disposal Impact Assessment and Congress authorizes the EPA to grant a permit by a joint resolution.

1.2.4 The MPRSA also requires the EPA to apply the standards and criteria of the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (London Dumping Convention), including its Annexes, to the extent that they can do so without relaxing the standards of the MPRSA. The London Convention is an international agreement signed by the United States and 70 other countries on ocean dumping. The U.S. has signed the agreement making it legally binding. Specifically, the definition of high-level radioactive waste unsuitable for sea disposal is binding upon signatories to the Convention. As of October 1986, the definition is both qualitative and quantitative.

2. RESPONSIBLE AGENCIES

The Environmental Protection Agency (EPA). EPA is responsible for issuing permits, promulgating regulations, conducting research, and enforcing the MPRSA.

The Secretary of the Army and Army Corps of Engineers. These agencies can issue permits for dredged material.

The Department of the Coast Guard. The Coast Guard is responsible for enforcement activities and surveillance to prevent unlawful transportation of material for dumping.

The Department of Commerce. This department is responsible for monitoring and research regarding the effects of ocean dumping.

The District Courts of the United States. These courts have jurisdiction over actions arising under the MPRSA.

3. DESCRIPTION OF 40 CFR Parts 220-229, EPA Regulations and Criteria for Ocean Dumping of Radioactive Materials (1977)

Issuances:

42 FR 2462, January 11, 1977; Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matters (London, 30 October to 13 November 1972).

Effective Dates:

40 CFR 220-229, February 10, 1977; London Convention, August 30, 1975.

3.1 General Radiation Protection Provisions:

Both 40 CFR 227 and the London Convention ban the dumping of high-level radioactive waste. Other radioactive materials must be containerized for disposal at sea under 40 CFR 227 and are also allowed to be dumped, with special care, under the terms of the London Convention.

3.2 Rationale for Detailed Requirements:

Only a qualitative definition of high-level radioactive waste is given in 40 CFR 220-229. The London Dumping Convention defers to the IAEA to define high-level waste. The IAEA originally developed a quantitative definition. However, in 1985 the IAEA added a qualitative element to their quantitative definition of high-level waste. (A dose of 1 mSv/annum to individuals was used to arrive at the quantitative definition. The Convention went on to state that although the 1 mSv/annum dose was used as a reference, it does not imply an acceptable dose.)

3.3 Description of Detailed Requirements:

3.3.1 40 CFR 227

A. High-level radioactive waste is defined as, "the aqueous waste resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated waste from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuels, or irradiated fuel from nuclear power reactors."

B. High-level radioactive wastes cannot be dumped into the ocean under any circumstances.

C. Materials produced or used for radiological warfare cannot be dumped into the ocean under any circumstances.

D. Radioactive materials, other than those described above, must be contained to prevent their direct dispersal or dilution in ocean waters in accordance with the following provisions:

i. The materials to be disposed of decay, decompose, or radiodecay to environmentally innocuous materials within the life expectancy of the containers and/or their inert matrix; and

ii. Materials to be dumped are present in such quantities and are of such nature that only short-term localized adverse effects will occur should the containers rupture at any time; and

iii. Containers are dumped at depths and locations where they will cause no threat to navigation, fishing, shorelines, or beaches.

3.3.2 London Convention

A. High-level radioactive waste or other high-level radioactive matter unsuitable for dumping at sea is defined as follows:

i. Irradiated reactor fuel; liquid wastes from the first solvent extraction cycle of chemical reprocessing of irradiated reactor fuel, or equivalent processes; solidified forms of such waste; and

ii. any other waste or matter of activity concentration exceeding:

a. 5×10^{-5} TBq/Kg (1.35×10^{-3} Ci/Kg) for alpha-emitters;

b. 2×10^{-2} TBq/Kg (0.54 Ci/Kg) for beta/gamma-emitters with half-lives of greater than 1 year (excluding tritium); and

c. 3 TBq/Kg (81 Ci/Kg) for tritium and beta/gamma-emitters with half-lives of 1 year or less.

The above activity concentrations shall be averaged over a gross mass not exceeding 1000 tons.

B. Materials of activity concentration less than those in (ii) above shall not be dumped except under a special permit. The maximum dumping rate into a single ocean basin of volume of at least $10^{17} m^3$ shall not exceed 10^8 Kg per year.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985). (See FACT SHEET 12.)

40 CFR 191, EPA Environmental Standards for Management and Disposal of High-Level and Transuranic Radioactive Waste (1985). (See FACT SHEET 13.)

10 CFR 61, NRC Requirements for Land Disposal of Low-Level Radioactive Waste (1975). (See FACT SHEET 18.)

40 CFR 193, EPA Advance Notice of Proposed Rulemaking for Low-Level Radioactive Waste Disposal, 48 FR 39563, August 31, 1978.

10 CFR 60, NRC Requirements for Disposal of High-Level Radioactive Waste in Geologic Repositories (1981). (See FACT SHEET 17.)

FACT SHEET 16A

10 CFR 20, NRC BASIC STANDARDS FOR RADIATION PROTECTION (1960)

COMPLETE TITLE

10 CFR 20, STANDARDS FOR PROTECTION AGAINST RADIATION, 25 FR 10914, November 17, 1960

1. AUTHORIZING STATUTE

Atomic Energy Act (AEA) of 1954, as amended, and the Energy Reorganization Act (ERA) of 1974, as amended.

Effective Date: Atomic Energy Act, August 30, 1954; Energy Reorganization Act, January 19, 1975 .

1.1 Statutory Purpose:

The policy of the United States under the Atomic Energy Act is:

1.1.1 to develop, use, and control atomic energy so as to maximize its contribution to the general welfare, subject to making the maximum contribution to the common defense and security of the country; and

1.1.2 to develop, use, and control atomic energy so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise.

1.2 Radiation Protection Provisions:

Section 161 of the Atomic Energy Act of 1954 (The General Authority section) empowered the Atomic Energy Commission (AEC) to establish rules, regulations, and standards to govern the possession or use of nuclear materials as the AEC deemed necessary or desirable to "protect health or minimize danger to life or property." This authority was transferred to the Nuclear Regulatory Commission (NRC) by the Energy Reorganization Act of 1974, as amended.

Section 274(b) of the Atomic Energy Act of 1954 authorizes the Commission "to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission . . . with respect to . . . byproduct materials, . . . source materials, . . . [and] special nuclear materials in quantities not sufficient to form a critical mass." However, §274(c) provides that "[n]o agreement entered into pursuant to subsection b. shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of . . . the construction and operation of any production or utilization facility; . . . [and the export, import, and disposal of any nuclear material] as defined in the regulations or orders of the Commission."

2. RESPONSIBLE AGENCIES

The Nuclear Regulatory Commission (NRC). These regulations apply to all persons who receive, possess, use or transfer byproduct, source or special nuclear material pursuant to the regulations in 10 CFR 30 through 35, 40, 60, 61, 70, or 72, including persons licensed to operate a production or utilization facility pursuant to 10 CFR 50, and persons licensed to possess power reactor spent fuel pursuant to 10 CFR 72.

States. As of 1988, 29 States have entered into agreements with NRC under section 274 of the Atomic Energy Act of 1954, as amended, where the States have assumed jurisdiction over many uses of byproduct, source, and small amounts of special nuclear material which are regulated by NRC.

3. DESCRIPTION OF 10 CFR 20, NRC BASIC STANDARDS FOR RADIATION PROTECTION (1960)

Issuances:

22 FR 548, January 29, 1957; and 25 FR 10914, November 17, 1960.

Effective Date: November 17, 1960 (ongoing revisions).

Background:

National Committee on Radiation Protection and Measurement (NCRP) Handbook 52, "Maximum Permissible Amounts of Radioisotopes in the Human Body and Maximum Permissible Concentrations in Air and Water" (Revised June 1959, NBS Handbook 69); and FRC Staff Report No. 1, (May 13, 1960) and 25 FR 4402, May 18, 1960.

3.1 General Radiation Protection Provisions:

10 CFR 20 contains standards for the protection of licensees, their employees, and the general public against radiation hazards arising out of the possession or use of special nuclear, source, or byproduct material under a license issued by the NRC. These regulations prescribe limitations which govern: occupational exposure to radiation and concentrations of radioactive material; concentrations of radioactive material which may be discharged into air or water; and limits on levels of radiation to the general population.

3.2 Rationale for Detailed Requirements:

3.2.1 Limits were established at levels for which biological damage or health effects would not be observed. The standards provide what, at that time (1960 and following revisions), was considered to be "a very substantial margin of safety for exposed individuals."

3.2.2 Internal exposure limits were based on the critical organ concept developed by the International Commission on Radiological Protection (ICRP). Tables of "Maximum Permissible Concentrations" (MPC)

were based on the calculated dose to the most irradiated organ using the method published by the ICRP in 1959 (ICRP-2).

3.2.3 In addition to complying with the detailed requirements set forth in 10 CFR 20, licensees should make every reasonable effort to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable (ALARA).

3.3 Description of Detailed Requirements:

3.3.1 Dose limiting requirements of current 10 CFR 20:

Individuals in Restricted Areas[a] (Occupational)

	Limiting Dose in any Calendar Quarter (Rem/Quarter)
Whole body[b] Head and trunk Active blood forming organs[c] Lens of eyes Gonads	1-1/4[d]
Hands and forearms Feet and ankles	18-3/4
Skin of whole body	7-1/2
Individuals under 18 years of age	10 percent of above limits
Concentrations of radioactive materials in air or water	Not to exceed levels in Table I of Appendix B of 10 CFR 20[e]

Individuals in Unrestricted Areas (General Population)

Whole body	(1) 0.5 rem per calendar year, (2) levels which could exceed 2 millirem in any one hour (for an individual continuously present), or (3) levels which could exceed 100 millirem in any seven consecutive days (for an individual continuously present).
Concentrations of radioactive materials in air or water	Not to exceed levels in Table II of Appendix B of 10 CFR 20[f]

Notes to above detailed requirements:

(a) "Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.

(b) Whole-body exposures in excess of this dose may be permitted provided that (1) the whole-body dose does not exceed 3 rem per calendar quarter, and (2) the dose to the whole body, when added to the accumulated occupational dose to the whole body does not exceed 5(N-18) rem, where "N" equals the individual's age at his last birthday.

(c) The blood-forming organs are generally assumed to include the red bone marrow, lymph nodes, the thymus gland, and the spleen.

(d) For the purposes of computing the 5(N-18) rem calculation in footnote (a) and in lieu of actual exposure data, exposure after January 1, 1961 will be assumed to have been 1.25 rem per quarter. Prior to that, 3.75 rem per quarter should be assumed.

(e) The concentrations in Table I of Appendix B of 10 CFR 20 are based on an exposure period of 40 hours per week and 50 weeks per year.

(f) For effluents released to unrestricted areas, the limiting concentrations given in Table II of Appendix B are based upon continuous exposure for 168 hours per week and 52 weeks per year.

3.3.2 Waste Disposal Requirements of 10 CFR 20:

No licensee shall dispose of licensed material except by:

A. Transfer to an authorized recipient as provided in the regulations in 10 CFR 30, 40, 60, 61, 70, or 72.

B. Obtaining approval by the NRC of disposal procedures not otherwise authorized in 10 CFR.

C. Disposal by release into sanitary sewage systems only if:

i. The material is readily soluble or dispersible in water; and

ii. "The quantity of licensed or other radioactive material released in any one day (1) should not exceed ten times the quantity of such material specified in Appendix C, or (2) if diluted by the average amount of non-radioactive sewerage, will not result in an average concentration exceeding that specified in Appendix B, Table I, Column 2.

"The quantity of licensed or other radioactive material released in any one month, if diluted by the average monthly quantity of water released, will not exceed

the concentrations specified in Appendix B, Table I, Column 2.

"The gross quantity of licensed or other radioactive material released in any one year shall not exceed one curie in total, except for tritium (not to exceed 5 curies) and carbon-14 (not to exceed one curie)."

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Federal Guidance on Occupational Radiation Exposures (RPGs) (1987). (See FACT SHEET 2.)

Federal Guidance on Limiting Certain Internal Radiation Exposures (RPGs) (1961). (See FACT SHEET 4.)

40 CFR 61, EPA Air Emission Standards for Radionuclides (1985, 1986). (See FACT SHEET 9.)

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 190, EPA Environmental Standards for Uranium Fuel Cycle (1977). (See FACT SHEET 11.)

40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985). (See FACT SHEET 12.)

40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982). (See FACT SHEET 14.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

10 CFR 50, Appendix I, NRC ALARA Design Objectives for Light-Water Reactor Effluents (1975). (See FACT SHEET 19.)

29 CFR 1910.96, OSHA Ionizing Radiation Protection Standards (1971). (See FACT SHEET 20.)

40 CFR 141, EPA Advance Notice of Proposed Rulemaking Dealing with Radionuclides Under Safe Drinking Water Act, 51 FR 34836, September 30, 1986. (This will be a revision of the standard described in FACT SHEET 10.)

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

10 CFR 35, Human Uses of Byproduct Material, 30 FR 8200, June 26, 1965. (Prescribes NRC regulations governing the licensing of byproduct material for human uses.)

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

NRC Safety Goals for the Operations of Nuclear Power Plants; Policy Statement, August 4, 1986.

FACT SHEET 16B

10 CFR 20, NRC PROPOSED BASIC STANDARDS FOR RADIATION PROTECTION (1986)

COMPLETE TITLE

10 CFR 20, STANDARDS FOR PROTECTION AGAINST RADIATION; PROPOSED RULE, 51 FR 1092, January 9, 1986

1. AUTHORIZING STATUTE

Atomic Energy Act (AEA) of 1954, as amended, and the Energy Reorganization Act (ERA) of 1974, as amended.

Effective Date: Atomic Energy Act, approved August 30, 1954; Energy Reorganization Act, January 19, 1975.

1.1 Statutory Purpose:

The policy of the United States under the Atomic Energy Act is:

1.1.1 to develop, use, and control atomic energy so as to maximize its contribution to the general welfare, subject to making the maximum contribution to the common defense and security of the country; and

1.1.2 to develop, use, and control atomic energy so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise.

1.2 Radiation Protection Provisions:

Section 161 of the Atomic Energy Act of 1954 (The General Authority section) empowered the Atomic Energy Commission (AEC) to establish rules, regulations, and standards to govern the possession or use of nuclear materials, as the AEC deemed necessary or desirable, to "protect health or minimize danger to life or property." This authority was transferred to the Nuclear Regulatory Commission (NRC) by the Energy Reorganization Act of 1974, as amended.

Section 274(b) of the Atomic Energy Act of 1954 authorizes the Commission "to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission . . . with respect to . . . byproduct materials, . . . source materials, . . . [and] special nuclear materials in quantities not sufficient to form a critical mass." However, §274(c) provides that "[n]o agreement entered into pursuant to subsection b. shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of . . . the construction and operation of any production or utilization facility; . . . [and the export, import, and disposal of any nuclear material] as defined in the regulations or orders of the Commission."

2. RESPONSIBLE AGENCIES

The Nuclear Regulatory Commission (NRC). These regulations apply to all persons who receive, possess, use or transfer byproduct, source or special nuclear material pursuant to the regulations in 10 CFR 30 through 35, 40, 60, 61, 70, or 72, including persons licensed to operate a production or utilization facility pursuant to 10 CFR 50, and persons licensed to possess power reactor spent fuel pursuant to 10 CFR 72.

States. As of 1988, 29 States have entered into agreements with NRC under Section 274 of the Atomic Energy Act of 1954, as amended, where the States have assumed jurisdiction over many uses of byproduct, source, and small amounts of special nuclear material which are regulated by NRC.

3. DESCRIPTION OF 10 CFR 20, NRC PROPOSED BASIC STANDARDS FOR RADIATION PROTECTION (1986)

Issuances:

51 FR 1092, January 9, 1986.

Effective Date: The comment period expired October 31, 1986.

Background:

International Commission on Radiological Protection (ICRP) publications: ICRP Publication 26, "Recommendations of the International Commission on Radiation Protection," adopted January 17, 1977; ICRP Publication 30, "Limits for Intake of Radionuclides by Workers," adopted July 1978; ICRP Publication 32, "Limits for Inhalation of Radon Daughters by Workers," adopted March 1981; National Academy of Sciences/National Research Council, Advisory Committee on the Biological Effects of Ionizing Radiations, "The Effects on Populations of Exposures to Low Levels of Ionizing Radiation," (BEIR I), National Academy Press, Washington, D.C. 1972; and National Academy of Sciences/National Research Council, Committee on the Biological Effects of Ionizing Radiations, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980," (BEIR III), National Academy Press, Washington, D.C., 1980.

3.1 General Radiation Protection Provisions:

The proposed regulations constitute a major revision of 10 CFR 20, which provides the requirements for the protection of individuals who are exposed, both within and outside the workplace, to ionizing radiation from routine activities (normal operations) which are licensed by the NRC. This protection is achieved through the setting of occupational and general public dose limits, as well as limits for effluent releases into air, water, or sanitary sewage systems.

3.2 Rationale for Detailed Requirements:

3.2.1 The proposed revision reflects developments in the principles that underlie radiation protection and advances in related sciences that have occurred since the promulgation of 10 CFR 20 in 1960. The

revision would put into practice many of the more recent recommendations of the ICRP.

3.2.2 "In the proposed revision, limits are derived explicitly by quantifying risk, and then by judging the acceptability of the risk through a comparison of risks experienced by workers in industries not involving radiation exposures or a comparison of risks normally encountered by the general public." The "acceptable" risk used as a basis for the limits is 10^{-4} per year for workers, and 10^{-6} to 10^{-5} per year for members of the public, based on estimated radiation-induced fatal cancers and serious hereditary disorders. The upper limits for organs were set to avoid non-stochastic (threshold) effects, such as cataracts.

3.2.3 Each licensee shall ensure that the dose to individuals receiving occupational doses and to members of the public is as low as is reasonably achievable (ALARA) and does not exceed the appropriate limits.

3.3 Description of Detailed Requirements (refer to footnote 1, page II-96):

Dose-Limiting Requirements of Proposed 10 CFR 20:

3.3.1 Occupational Limits

A. External Exposure

Whole body, head, trunk, arm above elbow, and leg above knee	5 rem/year (0.05 Sv/year) includes summation of (external) deep dose equivalent and (internal) committed effective dose equivalent 3 rem (0.03 Sv) (external) maximum deep dose equivalent in any quarter
Lens of eye	15 rem/year (0.15 Sv/year)
Hand, elbow, arm below elbow, foot, knee, and leg below knee	50 rem/year (0.5 Sv/year)
Skin (10 cm^2)	50 rem/year (0.5 Sv/year)
Minors	1/10 of annual limits for adults
Embryo/fetus	0.5 rem (5mSv) during the entire pregnancy due to occupational exposure of the "declared" pregnant woman

Planned special exposures

Annual limit from all events	1 x annual limits
Lifetime limit from all events	5 x annual limits

B. Internal Exposure

The proposed 10 CFR 20, Appendix B, Table 1, has three columns captioned "Oral Ingestion ALI" (Annual Limit of Intake), "Inhalation ALI," and "DAC" (Derived Air Concentration), which are applicable to occupational exposure to radioactive material and may be used in demonstrating compliance with the occupational dose limits above. The ALIs in this appendix are the annual intakes of given radionuclides by a "Reference Man" which would result in either (1) a committed effective dose equivalent[1/] of 5 rem (stochastic ALI), or (2) a committed dose equivalent of 50 rem to an organ or tissue (non-stochastic ALI). The DAC values are derived limits intended to control chronic exposures. An ALI is equivalent to 2000 derived air concentration (DAC)-hours/year. Note that the values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides, or when the individual is exposed to both external and internal irradiation. In such a case the method of summation in Appendix E of 10 CFR 20 shall apply.

C. Radiation protection program is required, including consideration of ALARA.

3.3.2 Public Limits

A. Explicit limit of 0.5 rem/year (5 mSv/year) for individuals from all sources. Includes summation of external and internal doses and food pathways.

B. A licensee will be in compliance with the 0.5 rem annual limit if he can demonstrate that sources under his control will not result in an individual member of the public receiving

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1/ Definitions:
"Dose Equivalent" means the product of absorbed dose, quality factor, and all other necessary modifying factors at the location of interest in tissue. The units of dose equivalent are the rem and the sievert [1 sievert (Sv) = 100 rem].
"Committed Dose Equivalent" ($H_{c,T}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake ($H_{50,T}$).
"Effective Dose Equivalent" (H_E) is the sum of the products of the dose equivalent (H_T) to the organ or tissue (T) and the weighting factors (W_T) applicable to each of the body organs or tissues which are irradiated. ($\sum W_T H_T$).
"Committed Effective Dose Equivalent" ($H_{E,c}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues which are irradiated and the committed dose equivalent.

a dose in excess of the 0.1 rem (1 mSv) annual reference level. A licensee may demonstrate compliance with the annual reference level by:

i. Demonstrating that the sum of the external dose equivalent and internal committed effective dose equivalent to the individual likely to be the highest exposed does not exceed 0.1 rem; or

ii. Demonstrating that the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area are not greater than the values specified in 10 CFR 20, Appendix B, Table 2; and dose rates in unrestricted areas are not greater than 0.002 rem/hour and not more than 0.05 rem/year.

C. Doses less than 0.001 rem/year (0.01 mSv/year) per person need not be included in evaluating collective doses to the general population.

D. A licensee may apply for prior authorization of operations which may result in exposure of individual members of the public in excess of the 0.1 rem annual reference level, but within the 0.5 rem annual limit. The following should be included in the application: demonstration of a clear need to operate in excess of the reference level; an acceptable program to assess and control doses under the 0.5 rem annual limit; and acceptable procedures followed to maintain public exposures ALARA.

E. In addition to the requirements of 10 CFR 20, a licensee engaged in uranium fuel cycle operations must comply with the relevant provisions of 40 CFR 190.

3.3.3. Sanitary Sewerage Disposal

A licensee may discharge licensed material into a sanitary sewerage system if each of the following conditions are satisfied:

A. The material is readily soluble in water;

B. The quantity of licensed or other radioactive material released in one month divided by the average monthly volume of water released does not exceed the concentrations listed in 10 CFR 20, Appendix B, Table 3. [The concentration limits are equivalent to a whole body dose of 0.5 rem/year (5 mSv/year) by potential ingestion.]

C. The gross quantity of licensed and other radioactive material released in a year does not exceed 5 curies of hydrogen-3, 1 curie of carbon-14, and 1 curie of all other radioactive materials.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Federal Guidance on Occupational Radiation Exposures (RPGs) (1987). (See FACT SHEET 2.)

Federal Guidance on Limiting Certain Internal Radiation Exposures (RPGs) (1961). (See FACT SHEET 4.)

40 CFR 61, EPA Air Emission Standards for Radionuclides (1985, 1986). (See FACT SHEET 9.)

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 190, EPA Environmental Standards for Uranium Fuel Cycle (1977). (See FACT SHEET 11.)

40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985). (See FACT SHEET 12.)

40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982). (See FACT SHEET 14.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 50, Appendix I, NRC ALARA Design Objectives for Light-Water Reactor Effluents (1975). (See FACT SHEET 19.)

29 CFR 1910.96, OSHA Ionizing Radiation Protection Standards (1971). (See FACT SHEET 20.)

40 CFR 141, EPA Advance Notice of Proposed Rulemaking Dealing with Radionuclides Under Safe Drinking Water Act, 51 FR 34836, September 30, 1986. (This will be a revision of the standard described in FACT SHEET 10.)

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

10 CFR 35, Human Uses of Byproduct Material, 30 FR 8200, June 26, 1965. (Prescribes NRC regulations governing the licensing of byproduct material for human uses.)

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

NRC Safety Goals for the Operations of Nuclear Power Plants; Policy Statement, August 4, 1986.

FACT SHEET 17

10 CFR 60, NRC REQUIREMENTS FOR DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTE IN GEOLOGIC REPOSITORIES (1981)

COMPLETE TITLE

10 CFR 60, DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES, 46 FR 13971, February 25, 1981 (LICENSING PROCEDURES); 48 FR 28194, June 21, 1983 (TECHNICAL CRITERIA)

1. AUTHORIZING STATUTE

Atomic Energy Act (AEA) of 1954, as amended, and the Energy Reorganization Act (ERA) of 1974, as amended; and the Nuclear Waste Policy Act of 1982.

Effective Date: Atomic Energy Act, approved August 30, 1954; Energy Reorganization Act, January 19, 1975.

1.1 Statutory Purpose:

The policy of the United States under the Atomic Energy Act is:

1.1.1 to develop, use, and control atomic energy so as to maximize its contribution to the general welfare, subject to making the maximum contribution to the common defense and security of the country; and

1.1.2 to develop, use, and control atomic energy so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise.

1.2 Radiation Protection Provisions:

Section 161 of the Atomic Energy Act of 1954 (The General Authority section) empowered the Atomic Energy Commission (AEC) to establish rules, regulations, and standards to govern the possession or use of nuclear materials as the AEC deemed necessary or desirable to "protect health or minimize danger to life or property." This authority was transferred to the Nuclear Regulatory Commission (NRC) by the Energy Reorganization Act of 1974, as amended.

Section 274(b) of the Atomic Energy Act of 1954 authorizes the Commission "to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission . . . with respect to . . . byproduct materials, . . . source materials, . . . [and] special nuclear materials in quantities not sufficient to form a critical mass." However, §274(c) provides that "[n]o agreement entered into pursuant to subsection b. shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of . . . the construction and operation of any production or

utilization facility; . . . [and the export, import and disposal of any nuclear material] as defined in the regulations or orders of the Commission."

2. RESPONSIBLE AGENCIES

The Nuclear Regulatory Commission (NRC). The NRC issues licenses to the Department of Energy (DOE) "to receive and possess source, spent nuclear, and byproduct materials at a geologic repository operations area sited, constructed, or operated in accordance with the Nuclear Waste Policy Act of 1982 (NWPA) (42 U.S.C. 1010 et seq.)."

States and Indian Tribes. A state in which a high-level waste facility is proposed to be located and affected Indian tribes have a legal right to party status in review of license applications for such a facility.

3. DESCRIPTION OF 10 CFR 60, NRC REQUIREMENTS FOR DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTE IN GEOLOGIC REPOSITORIES (1981)

Issuances:

46 FR 13971, February 25, 1981; 47 FR 13774, March 31, 1982; 48 FR 28194, June 21, 1983; 50 FR 29641, July 22, 1985; 51 FR 22288, June 19, 1986; 51 FR 27158, July 30, 1986; 52 FR 5992, February 27, 1987.

Effective Date: Procedural Rule, March 27, 1981; Technical Criteria, July 21, 1983.

Background:

The NRC regulations in 10 CFR 60 establish procedures for the licensing of geologic repositories and provide technical criteria (subpart E) to be used in the evaluation of license applications submitted under the procedural rules.

3.1 General Radiation Protection Provisions:

10 CFR 60 "prescribes rules governing the licensing of the U.S. Department of Energy to receive and possess source, spent nuclear, and byproduct materials at a geologic repository operations area sited, constructed, or operated in accordance with the Nuclear Waste Policy Act of 1982." (NWPA) (42 U.S.C. 1010 et seq.)

The regulations do not apply to (1) land disposal of low-level waste as provided for in 10 CFR 61; (2) disposal of uranium or thorium tailings or wastes as provided for in 10 CFR 40; or (3) disposal of licensed material by means provided for in 10 CFR 20.

3.2 Rationale for Detailed Requirements:

3.2.1 Subpart E - Technical Criteria prescribes standards for licensing geologic repositories for disposal of high-level waste.[1/] In particular, it requires "a finding that the issuance of a license will not constitute an unreasonable risk to the health and safety of the public. The purpose of this subpart is to set out performance objectives and set site and design criteria which, if satisfied, will support such a finding of no unreasonable risk."

3.2.2 Because a complete assurance cannot be presented, a reasonable assurance that the objectives and criteria will be met is the general standard that is required.

3.2.3 Where criteria are set for repository performance "over a long time in the future, there will inevitably be greater uncertainties. Proof of future performance . . . over time periods of many hundreds or many thousands of years is not to be had in the ordinary sense of the word. . . . [W]hat is required is reasonable assurance, making allowance for the time period, hazards, and uncertainties involved."

3.3 Description of Detailed Requirements:

3.3.1 Performance Objectives:

A. Performance objective for the geologic repository area through permanent closure.

"The geologic repository operations area shall be designed so that until permanent closure has been completed, radiation exposures and radiation levels, and release of radioactive materials to unrestricted areas, will at all times be maintained within the limits specified in [10 CFR 20] and such generally applicable environmental standards for radioactivity as may have been established by the Environmental Protection Agency."

"Repository operations must be conducted so as to make it possible to retrieve the wastes throughout the period during which they are being emplaced." Also, waste must be retrievable on a reasonable schedule "starting at any time up to 50 years after waste emplacement operations are initiated." A "reasonable schedule" for retrieval "would permit retrieval in about the same time as that devoted to constructions of the geologic repository area and the emplacement of wastes."

1/ " 'High-level radioactive waste' or 'HLW' means: (1) Irradiated reactor fuel, (2) liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel, and (3) solids into which such wastes have been converted."

B. Performance objective for the geologic repository area after permanent closure.

The geologic setting must be chosen, and shafts designed, to assure that "release of radioactive materials to the accessible environment following permanent closure conforms to such generally applicable environmental standards for radioactivity as may have been established by the Environmental Protection Agency with respect to both anticipated processes and events and unanticipated processes and events."

C. Performance of particular barriers after permanent closure.

Engineered barriers must be designed to effect substantially complete containment while "radiation and thermal conditions in the engineered barrier system are dominated by fission product decay." Also, any release of radionuclides must be small, and occur over long periods of time.

i. Containment of HLW within the waste packages must be substantially complete for a period to be determined by the Commission of "not less than 300 years nor more than 1,000 years after permanent closure of the facility."

ii. Release rate of any radionuclides following the containment period must not exceed one part in 100,000 of "the inventory of that radionuclide calculated to be present at 1,000 years following permanent closure," or such other fraction approved by the Commission. "[T]his requirement does not apply to any radionuclide which is released at a rate less than 0.1% of the calculated total release limit." The calculated release limit is one part in 100,000 per year of the radionuclide that remains after 1,000 years of radioactive decay. The geologic setting must be such that radionuclides will not be transported by groundwater, along the fastest path likely, to the accessible environment in less than 1,000 years.

iii. The Commission may approve other radionuclide release rates on a case-by-case basis provided that the overall system performance objective is met. The Commission may take into account such factors as: any generally applicable environmental standard for radioactivity established by the Environmental Protection Agency; the age and nature of the waste; the geochemical characteristics of the host rock; particular sources of uncertainty in predicting performance; and any additional requirements made necessary by unanticipated factors.

3.3.2 Design criteria for the geologic repository operations area:

"The geologic repository operations area shall be designed to maintain radiation doses, levels, and concentrations of radioactive materials in air in restricted areas within the limits specified in [10 CFR 20]." Design must include:

A. Means to limit concentrations of radioactive material in air;

B. Means to limit time required to perform work in the vicinity of radioactive materials;

C. Suitable shielding;

D. Means to control access to high radiation areas or airborne radioactivity areas.

3.3.3 Additional design criteria for surface facilities:

The surface facilities must be designed to control the release of radioactive materials in effluents within the limits specified in 10 CFR 20 and such generally applicable environmental standards for radioactivity as may have been set by the Environmental Protection Agency (EPA).

3.3.4 Design criteria for the waste packages for High-Level Waste:

Waste packages for HLW must be designed so that the chemical, physical and nuclear properties of the waste package and its interaction with the site environment do not compromise the performance of the waste package or the underground facility or geologic setting.

3.3.5 Siting Criteria:

A geologic setting must exhibit an appropriate combination of favorable conditions to reasonably assure that the performance objectives relating to isolation of the waste will be met. Favorable conditions are enumerated in 10 CFR 60.122(b).

4. RELATED STANDARDS

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 191, EPA Environmental Standards for Management and Disposal of High-Level and Transuranic Radioactive Waste (1985). (See FACT SHEET 13.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 61, NRC Requirements for Land Disposal of Low-Level Radioactive Waste (1975). (See FACT SHEET 18.)

10 CFR 40, NRC Regulations for Domestic Licensing of Source Material (1961).

FACT SHEET 18

10 CFR 61, NRC REQUIREMENTS FOR LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE (1975)

COMPLETE TITLE

10 CFR 61, LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE, 47 FR 57446, December 27, 1982

1. AUTHORIZING STATUTE

Atomic Energy Act (AEA) of 1954, as amended, and the Energy Reorganization Act (ERA) of 1974, as amended.

Effective Date: Atomic Energy Act, approved August 30, 1954; Energy Reorganization Act, January 19, 1975.

1.1 Statutory Purpose:

The policy of the United States under the Atomic Energy Act is:

1.1.1 to develop, use, and control atomic energy so as to maximize its contribution to the general welfare, subject to making the maximum contribution to the common defense and security of the country; and

1.1.2 to develop, use, and control atomic energy so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise.

1.2 Radiation Protection Provisions:

Section 161 of the Atomic Energy Act of 1954 (The General Authority section) empowered the Atomic Energy Commission (AEC) to establish rules, regulations, and standards to govern the possession or use of nuclear materials as the AEC deemed necessary or desirable to "protect health or minimize danger to life or property." This authority was transferred to the Nuclear Regulatory Commission (NRC) by the Energy Reorganization Act of 1974, as amended.

Section 274(b) of the Atomic Energy Act of 1954 authorizes the Commission "to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission . . . with respect to . . . byproduct materials . . . source materials . . . [and] special nuclear materials in quantities not sufficient to form a critical mass." However, §274(c) provides that "[n]o agreement entered into pursuant to subsection b. shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of . . . the construction and operation of any production or

utilization facility; . . . [and the export, import, and disposal of any nuclear material] as defined in the regulations or orders of the Commission."

2. RESPONSIBLE AGENCIES

The Nuclear Regulatory Commission (NRC). The NRC issues licenses for land disposal facilities and promulgates, implements, and enforces regulations for the siting, constructing, and operating of these facilities.

States. Under §274 of AEA, states can, under Agreement State status, license a low-level waste disposal facility. Upon formal request, a state or tribal government may participate in the review of a license application for a land disposal facility.

3. DESCRIPTION OF 10 CFR 61, NRC REQUIREMENTS FOR LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE (1975)

Issuances:

47 FR 57446, December 27, 1982.

Effective Date: January 26, 1983.

3.1 General Radiation Protection Provisions:

10 CFR 61 provides specific requirements for the near-surface disposal of low-level radioactive wastes (LLW) containing source, special nuclear, or byproduct material. The regulations establish performance objectives for land disposal of waste and technical requirements for the siting, design, operation, closure and long-term control for a near-surface disposal facility. Waste classification is defined in the regulations. Institutional control of access to the site is required for up to 100 years.

The regulations do not apply to (1) disposal of high-level waste as provided for in 10 CFR 60; (2) disposal of uranium or thorium tailings or wastes as provided for in 10 CFR 40; or (3) disposal of licensed material by means provided for in 10 CFR 20.

3.2 Rationale for Detailed Requirements:

3.2.1 "Disposal of [LLW] in near-surface disposal facilities has [these] objectives: protection of the general population from releases of radioactivity, protection of individuals from inadvertent intrusion, and protection of individuals during operation. A fourth objective is to ensure stability of the site after closure."

3.2.2 Presently there are no Environmental Protection Agency (EPA) standards that set limits for releases of radioactivity from (LLW) disposal facilities to the environment. In the absence of such a standard, the [NRC] examined a range of limits which bound that expected for the EPA standard and selected a proposed performance

objective that establishes a release limit for the site boundary. . . ." The EPA "stated that the range of 1 to 25 mrem/year analyzed by the [NRC] was a reasonable range and should encompass any standard which EPA might derive. . . ."

3.2.3 Every reasonable effort should be made to limit releases of radioactivity in effluents, and radiation exposure during operations as low as is reasonably achievable (ALARA).

3.3 Description of Detailed Requirements:

3.3.1 Performance Objectives:

A. General requirement: Land disposal facilities must be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to humans are within the limits established in the performance objectives below. Free-standing liquids in waste delivered to the site are limited to one percent (0.01) by volume.

B. Protection of the general population: Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants, or animals must not result in an annual dose to any member of the public exceeding:

Organ	Annual Dose
Whole body	25 millirem
Thyroid	75 millirem
Any other organ	25 millirem

Also, every reasonable effort should be made to limit releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

C. Protection to individuals from inadvertent intrusion: Design, operation, and closure of facilities must ensure protection of individuals inadvertently intruding onto disposal sites after active institutional controls are removed.

D. Protection of individuals during operations: Operations must be conducted in compliance with radiation protection standards in 10 CFR 20, except for releases of radioactivity in effluents, which are governed by the standards in B above.

Also, every reasonable effort should be made to maintain radiation exposure as low as is reasonably achievable.

E. Stability of the disposal site after closure: The facility must be sited, designed, used, operated, and closed to achieve long-term stability of the site and to eliminate to the extent practicable the need for ongoing active maintenance of the

site following closure so that only surveillance, monitoring, or minor custodial care are required.

3.3.2 Waste Classification:

Waste is classified on two considerations: (1) the concentration of long-lived radionuclides, whose potential hazard will persist beyond the effective life of institutional controls, and (2) the concentration of shorter-lived radionuclides. Classifications from Class A to Class C are set out in 10 CFR 61.55.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1987). (See FACT SHEET 1.)

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 192, EPA, and 10 CFR 40, NRC, Environmental Standards for U and Th Mill Tailings (1983, 1985). (See FACT SHEET 12.)

40 CFR 191, EPA Environmental Standards for Management and Disposal of High-Level and Transuranic Radioactive Waste (1985). (See FACT SHEET 13.)

40 CFR 220-229, EPA Regulations and Criteria for Ocean Dumping of Radioactive Materials (1977). (See FACT SHEET 15.)

40 CFR 141, EPA Advance Notice of Proposed Rulemaking Dealing with Radionuclides Under Safe Drinking Water Act, 51 FR 34836, September 30, 1986. (This will be a revision of the standard described in FACT SHEET 10.)

40 CFR 193, EPA Advance Notice of Proposed Rulemaking for Low-Level Radioactive Waste Disposal, 48 FR 39563, August 31, 1978.

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

FACT SHEET 19

10 CFR 50, APPENDIX I, NRC ALARA DESIGN OBJECTIVES FOR LIGHT-WATER REACTOR EFFLUENTS (1975)

COMPLETE TITLE

10 CFR 50, APPENDIX I, NUMERICAL GUIDES FOR DESIGN OBJECTIVES AND LIMITING CONDITIONS FOR OPERATION TO MEET THE CRITERION "AS LOW AS IS REASONABLY ACHIEVABLE" FOR RADIOACTIVE MATERIAL IN LIGHT-WATER-COOLED NUCLEAR POWER REACTOR EFFLUENTS, 40 FR 19442, May 5, 1975

1. AUTHORIZING STATUTE

Atomic Energy Act (AEA) of 1954, as amended; Energy Reorganization Act (ERA) of 1974, as amended.

Effective Date: Atomic Energy Act, approved August 30, 1954; Energy Reorganization Act, January 19, 1975.

1.1 Statutory Purpose:

The policy of the United States under the Atomic Energy Act is:

1.1.1 to develop, use, and control atomic energy so as to maximize its contribution to the general welfare and to make the maximum contribution to the common defense and security of the country; and

1.1.2 to develop, use, and control atomic energy so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise.

1.2 Radiation Protection Provisions:

Section 161 of the Atomic Energy Act of 1954 (The General Authority section) empowered the Atomic Energy Commission (AEC) to establish rules, regulations, and standards to govern the possession or use of nuclear materials as the AEC deemed necessary or desirable to "protect health or minimize danger to life or property." This authority was transferred to the Nuclear Regulatory Commission (NRC) by the Energy Reorganization Act of 1974, as amended.

2. RESPONSIBLE AGENCY

The Nuclear Regulatory Commission (NRC). The NRC issues licenses for nuclear power plants and promulgates, implements, and enforces safety regulations for their siting, construction and operation.

3. DESCRIPTION OF 10 CFR 50, APPENDIX I, NRC ALARA DESIGN OBJECTIVES FOR LIGHT-WATER REACTOR EFFLUENTS (1975)

Issuances:

40 FR 19442, May 5, 1975.

Effective Dates:

June 4, 1975, for permit applications filed after January 2, 1971. Applications filed prior to January 2, 1971 must file additional material with NRC within 12 months of June 4, 1975.

Background:

Effective Rule Published, 40 FR 19439, May 5, 1975; amended 40 FR 40516, September 4, 1975; 40 FR 33029, December 19, 1975.

Proposed Rule Published for Public Comment; 36 FR 11113, June 9, 1971. AEC published new sections of 10 CFR 50.34a and 50.36a; 35 FR 18385, December 3, 1970, which specified the quali[illegible] requirement for keeping radioactive material effluents "as low as possible" [illegible]ow "as low as is reasonably achievable" (ALARA).]

3.1 General Radiation Protection Provisions:

10 CFR 50, Appendix I, provides quantitative design objectives for radioactive material in light-water-cooled (LWR) reactor effluents. Guidelines are promulgated for liquid and gaseous effluents, and for radioactive iodine and radioactive material in particulate form. Conforming to the guidelines is deemed a conclusive showing of compliance with the "as low as is reasonably achievable" (ALARA) requirement of 10 CFR 50.34a and 50.36a.

3.2 Rationale for Detailed Requirements:

ALARA is defined in 10 CFR 50.34a(a) as: "as low as is reasonably achievable" taking into account the state of technology, and the economics of improvements in relation to the benefits to public health and safety and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest. The guidelines quantify the qualitative ALARA criterion.

3.3 Description of Detailed Requirements:

3.3.1 Guides on design objectives for LWRs licensed under 10 CFR 50:

The following numerical guides are based on estimated annual dose or dose commitments for any individual in an unrestricted area from all pathways of exposure from each LWR reactor.

Liquid effluents

- 3 mrem total body or
- 10 mrem any organ

Gaseous effluents

- 10 mrad from gamma radiation or
- 20 mrad from beta radiation

Notwithstanding these air doses, the following apply:

- 5 mrem total body or
- 15 mrem skin

Radioactive iodine/radioactive material in particulate form

- 15 mrem any organ

3.3.2 In addition to the provisions in 3.3.1 above, the licensee must include in the radwaste system all items of reasonably demonstrated technology that, when added to the system sequentially and in order of diminishing cost-benefit return, can for a favorable cost-benefit ratio effect reductions in dose to the population reasonably expected to be within 50 miles of the reactor. The values of $1000 per total body man-rem and $1000 per man-thyroid-rem shall be used on an interim basis in this cost-benefit analysis (lesser values may be determined on a case-by-case basis).

3.3.3 Guides on technical specifications for limiting conditions for operation for LWRs licensed under 10 CFR 50:

A. The quantity of radioactive material released in effluents to unrestricted areas during any calendar quarter shall be such that the calculated resultant radiation exposure does not exceed one-half the design objective annual exposure.

B. Establish a monitoring program of radionuclide releases in effluents and measurable levels of radiation and radioactive materials in the environment to evaluate doses to individuals from principal exposure pathways.

C. If data developed in monitoring shows that the relationship between material released and individual doses in the unrestricted area is significantly different from that assumed in calculating design objectives, the Commission may modify the quantities in the technical specifications defining the limiting conditions for operating a light-water-cooled nuclear power reactor.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Federal Guidance on Limiting Certain Internal Radiation Exposures (RPGs) (1961). (See FACT SHEET 4.)

40 CFR 61, EPA Air Emission Standards for Radionuclides (1985, 1986). (See FACT SHEET 9.)

40 CFR 141, EPA Interim Drinking Water Standards for Radionuclides (1976). (See FACT SHEET 10.)

40 CFR 190, EPA Environmental Standards for Uranium Fuel Cycle (1977). (See FACT SHEET 11.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

40 CFR 141, EPA Advance Notice of Proposed Rulemaking Dealing with Radionuclides Under Safe Drinking Water Act, 51 FR 34836, September 30, 1986. (This will be a revision of the standard described in FACT SHEET 10.)

DOE Manual Chapter XI, DOE Limits on Occupational and General Population Exposure to Radiation, April 29, 1981.

Great Lakes Water Quality Agreement: Specific Water Quality Objectives; Radiological. April 15, 1972; renewed November 22, 1978.

NRC Safety Goals for the Operations of Nuclear Power Plants; Policy Statement, August 4, 1986.

FACT SHEET 20

29 CFR 1910.96, OSHA IONIZING RADIATION PROTECTION STANDARDS (1971)

COMPLETE TITLE

29 CFR 1910.96, IONIZING RADIATION: OSHA RADIATION PROTECTION STANDARDS, 36 FR 10466, May 29, 1971 (and later amendments)

1. AUTHORIZING STATUTE

Occupational Safety and Health Act of 1970, 29 U.S.C. 651 et seq., P.L. 91-596, 84 Stat. 1590, December 29, 1970.

Effective Date: April 27, 1971.

1.1 Statutory Purpose:

To assure insofar as is possible that every worker in the Nation has safe and healthy working conditions and to preserve human resources.

1.2 Radiation Protection Provisions:

Regulations concerning radiation protection of workers were established under Sections 6(a) and 8(g) of the Act, which broadly empower the Secretary of Labor to promulgate occupational safety and health standards.

2. RESPONSIBLE AGENCIES

U.S. Department of Labor, Occupational Health and Safety Administration (OSHA). The Secretary of Labor sets mandatory occupational health and safety standards. The Secretary is authorized to set standards regarding labels showing exposure limits, protective equipment, medical examinations, recordkeeping, and reporting and is empowered to conduct inspections and investigations.

Occupational Health Review Commission. A 3-member board, appointed by the President carries out adjudicatory functions under the Act.

The Secretary, U.S. Department of Health and Human Services (HHS) (formerly Health, Education and Welfare). The Secretary of HHS conducts research, experiments, and studies of exposure levels; recommends regulations regarding records, medical examinations, and toxic substances; conducts annual studies and inspections and has contracting authority, all of which are delegated to the Director of the National Institute for Occupational Safety and Health.

3. DESCRIPTION OF 29 CFR 1910.96, OSHA IONIZING RADIATION PROTECTION STANDARDS (1971)

Issuances:

36 FR 10466, May 29, 1971; 39 FR 23502, June 27, 1974, as amended at 43 FR 49746, October 24. 1978; 43 FR 51759, November 7, 1978; and 49 FR 18295, April 30, 1984.

Effective Date: August 27, 1971, or February 15, 1972, in situations where time was necessary to adjust to the standards.

3.1 General Radiation Protection Provisions:

Radiation protection standards promulgated under OSHA are designed to protect workers from exposure to radiation in programs other than those regulated by MSHA, those specifically covered by the Atomic Energy Act of 1954, as amended, and those in specific situations covered by other Federal regulatory agencies. Also excluded from direct OSHA jurisdiction are States which maintain NRC agreements or which have OSHA State plans. OSHA sets exposure limits; requires the monitoring of individual exposure; requires evacuation warning signals; sets standards for posting, storage, notification, and reporting of incidents; establishes requirements for recordkeeping and surveying; and requires education of employees on exposure hazards and safety procedures.

3.2 Rationale for Detailed Requirements:

No specific rationale was provided in the regulations.

3.3 Description of Detailed Requirements:

3.3.1 The requirements are almost identical to those found in 10 CFR 20.

3.3.2 The regulations define: radiation, radioactive material, restricted area, unrestricted area, dose, rad, rem, radiation area, high radiation area, airborne radiation area, and neutron flux dose equivalents.

3.3.3 Exposure to individuals in restricted areas may not exceed the following doses:

		rem/calendar quarter
A.	Whole body	1-1/4
	Hands and forearms Feet and ankles	18-3/4
	Skin of whole body	7-1/2

B. The above doses may be exceeded if: the dose to the whole body does not exceed 3 rem in any calendar quarter and the dose to the whole body does not exceed 5 times (age at last birthday minus 18) rem when added to the accumulated

occupational dose, and employer maintains past and current exposure records to show the addition of such a dose will not exceed the limits set above.

C. No employers shall permit employees under 18 to receive in any period of a calendar quarter a dose in excess of 10% of the above limits.

3.3.4 Exposure to Airborne Radioactive Materials:

No employer shall possess, use or transport radioactive material in such manner as to cause any employee to be exposed to airborne radioactive material in an average concentration in excess of limits specified in:

A. Table I of Appendix B to 10 CFR 20 if an individual is over 18 years old, and

B. Table II of Appendix B to 10 CFR 20 if an individual is under 18 years old.

NOTE: Exposure means an individual is present. No allowance is made for protective clothing or equipment or particle size.

3.3.5 Instruction of Personnel:

All employers, except employers regulated by the Atomic Energy Commission (Nuclear Regulatory Commission), governed by 10 CFR 20 standards, or employers regulated under AEC(NRC)-State agreements, are regulated by the following:

A. Individuals working or frequenting any portion of a radiation area must be informed of the occurrence of radioactive materials and be instructed in the safety problems associated with exposure, and be instructed in precautions and devices to minimize exposure; and

B. Employers shall conspicuously post current regulations and operating procedures or keep these documents for examination on request.

3.3.6 Waste Disposal:

No employer shall dispose of radioactive materials except by transfer to an authorized recipient or in a manner approved by the Atomic Energy Commission (Nuclear Regulatory Commission) or Agreement State programs under the Atomic Energy Act.

3.3.7 Records:

A. Employers shall maintain records for employees under Paragraph 3.3.5.A above that are exposed to radiation at levels in excess of 25 percent of the applicable value in 3.3.3 above for adults, and in excess of 5 percent of the limits in 3.3.3 for minors. Employers shall also advise employees of their individual exposure on at least an annual basis.

above for adults, and in excess of 5 percent of the limits in 3.3.3 for minors. Employers shall also advise employees of their individual exposure on at least an annual basis.

B. Employers shall maintain records in the same units used in Paragraph 3.3.3 above, and Appendix B to 10 CFR 20.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Federal Guidance on Occupational Exposures (RPGs) (1987). (See FACT SHEET 2.)

Guidance on Radon Exposures in Uranium Mines (1969). (See FACT SHEET 3.)

10 CFR 20, NRC Basic Standards for Radiation Protection (1960). (See FACT SHEET 16A.)

10 CFR 20, NRC Proposed Basic Standards for Radiation Protection (1986). (See FACT SHEET 16B.)

Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, September 1975, Revised June 1980, EPA-520/1-75-001. (Provides action levels and guidance for their use by state and local agencies in developing radiological emergency plans.)

FACT SHEET 21

21 CFR 1020, FDA PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS (1973)

COMPLETE TITLE

21 CFR 1020, PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS, 38 FR 28632, October 15, 1973

1. AUTHORIZING STATUTE

Section 358 of the Radiation Control for Health and Safety Act of 1968 (RCHSA), 42 U.S.C. 263f, P.L. 90-602.

Effective Date: October 18, 1968.

1.1 Statutory Purpose:

The purpose of the RCHSA is "to provide . . . an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation . . . and the undertaking . . . of research and investigation into the effects and control of such radiation emissions." Electronic product radiation means:

(1) Any ionizing or non-ionizing electromagnetic or particulate radiation; or

(2) Any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of an electronic circuit in such product.

1.2 Radiation Protection Provisions:

Under Section 358 of the RCHSA, the Assistant Secretary for Health in the Department of Health and Human Services (HHS) shall prescribe regulations for performance standards for radiation emitting products to control electronic product radiation.

2. RESPONSIBLE AGENCIES

Department of Health and Human Services (HHS). This department has authority under RCHSA to prescribe performance standards for radiation emitting products. HHS has delegated this responsibility to the:

Food and Drug Administration (FDA). The FDA has set performance standards for electronic products.

States. Whenever a performance standard is prescribed under Section 358, no State shall have any authority to either establish, or to continue in effect, any standard which is applicable to the same aspect of performance which is not identical to the Federal standard. States may impose a more restrictive standard than the Federal standard for electronic products procured for their own use.

Technical Electronic Products Radiation Safety Standards Committee (TEPRSSC). The Secretary of HHS must consult the Committee before prescribing a standard. The 15 member Committee is appointed by the Secretary and is made up of experts on electronic product radiation safety as follows:

—five members from governmental agencies (State and Federal);

—five members selected from affected industries; and

—five members selected from the general public (at least one from organized labor).

The Committee may propose standards to the Secretary for his consideration.

3. DESCRIPTION OF 21 CFR 1020, FDA PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS (1973)

Issuances:

38 FR 28624, October 15, 1973.

Effective Date: October 15, 1973.

3.1 General Radiation Protection Provisions:

Performance standards have been established for ionizing radiation emitting products: television receivers, cold-cathode gas discharge tubes, diagnostic x-ray systems (radiographic equipment, fluoroscopic equipment, and CT x-ray systems), and cabinet x-ray systems (including airport security).

3.2 Rationale for Detailed Requirements:

No specific rationale was provided in the regulations.

3.3 Description of Detailed Requirements:

NOTE: The Standards below are ionizing radiation emission limits found in the regulations. Standards for implementation have been omitted.

3.3.1 Radiation exposure rates produced by a television receiver shall not exceed 0.5 milliroentgens per hour at a distance of 5 centimeters from any external surface of the receiver, measurement averaged over 10 square centimeters with no linear dimension greater than 5 centimeters.

3.3.2 Radiation exposure rates produced by cold-cathode gas discharge tubes shall not exceed 10 milliroentgens per hour at a distance of 30 centimeters from any point on the external surface of the tube.

3.3.3 The leakage of radiation from the diagnostic source assembly of an x-ray diagnostic system shall not exceed 100 milliroentgens in one hour, measured at a distance of 1 meter in any direction from the source; measurements shall be averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

3.3.4 The radiation emitted by a component other than the diagnostic source assembly of an x-ray diagnostic system shall not exceed 2 milliroentgens in one hour at 5 centimeters from any accessible surface of the component.

3.3.5 Radiation emitted from a cabinet x-ray system, such as those used in airports for security, shall not exceed an exposure of 0.5 milliroentgens in one hour at any point 5 centimeters outside the external surface, measurement averaged over 10 square centimeters with no linear dimension greater than 5 centimeters.

4. RELATED STANDARDS

Federal Guidance on Occupational and Population Radiation Exposures (RPGs) (1960). (See FACT SHEET 1.)

Federal Guidance on Occupational Radiation Exposures (RPGs) (1987). (See FACT SHEET 2.)

29 CFR 1910.96, OSHA Ionizing Radiation Protection Standards (1971). (See FACT SHEET 20.)

FACT SHEET 22

ADVISORY FDA PROTECTIVE ACTION GUIDES (PAGs) FOR RADIOACTIVE CONTAMINATION IN FOOD (1982)

COMPLETE TITLE

ACCIDENTAL RADIOACTIVE CONTAMINATION OF HUMAN FOOD AND ANIMAL FEEDS; RECOMMENDATIONS FOR STATE AND LOCAL AGENCIES, 47 FR 47073, October 22, 1982

1. AUTHORIZING STATUTE

Public Health Service Act of 1944, as amended, 42 U.S.C. 241, 242, and 243, and authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10).

Effective Date: March 11, 1982.

1.1 Interagency Assignment:

44 CFR 351 sets out Federal agency roles and assigns tasks regarding Federal assistance to State and local governments in radiological emergency planning activities. Federal Emergency Management Agency (FEMA) assigned the task of issuing Protective Action Guides for human food and animal feeds to the Department of Health and Human Services with the cooperation of the Environmental Protection Agency.

1.2 Applicability:

The FDA Protective Action Guides are applicable to radiological accidents at fixed nuclear facilities and transportation accidents involving radioactive material.

2. RESPONSIBLE AGENCIES

The Department of Health and Human Services (HHS). HHS has the responsibility to develop and specify to State and local governments protective actions and associated guidance for human food and animal feed. This responsibility was delegated to the Food and Drug Administration (FDA).

State and Local Governments. The FDA Protective Action Guides are recommendations for when State and local agencies should take voluntary action to protect the public from food contaminated with radiation.

3. DESCRIPTION OF ADVISORY FDA PROTECTIVE ACTION GUIDES (PAGs) FOR RADIOACTIVE CONTAMINATION IN FOOD (1982)

Issuances:

47 FR 47073, October 22, 1982; and 43 FR 58790, December 15, 1978.

Effective Date: October 22, 1982.

3.1 General Radiation Protection Provisions:

FDA recommendations, Protective Action Guides (PAGs), establish the level of radioactive contamination in human or animal feeds at which actions should be taken to protect the public health and assure the safety of food. The PAGs are recommendations only, which State and local agencies should, but are not required, to follow.

3.2 Rationale for Detailed Requirements:

3.2.1 "The PAGs represent FDA's judgment as to that level of food contamination resulting from radiation incidents at which action should be taken to protect public health. This is based on the agency's recognition that safety includes the degree to which risks are judged acceptable. The risk from natural disasters (approximately one in a million annual individual risk of death) and the risk from variations in natural background radiation have provided perspective in selecting PAG values. The recommendations are based on the assumption that . . . contamination requiring protective actions . . . is an unlikely event, that most individuals will never be so exposed, and that any individual is not likely to be exposed at the PAG level more than once in his or her lifetime."

3.2.2 The basis for the Preventive PAG involves consideration of the risk from natural disasters, the variation in the population-weighted natural background radiation dose to the total population, and the variation in dose due to ingestion of food.

3.2.3 "The basis for the Emergency PAG involves consideration of (1) the ratio between average and maximum individual radiation doses (taken as 1 to 10), (2) the cost of low- and high-impact protective actions, (3) the relative risks from natural disasters, (4) health impact, (5) the upper range of the PAGs proposed by EPA (5 rem projected radiation dose to the whole body and 25 rem projected dose to the thyroid), and (6) radiation doses from multiple pathways."

3.2.4 The PAGs issued by the Federal Radiation Council for I-131 in 1964 (see FACT SHEET 7) and for Sr-89, Sr-90, Cs-137 in 1965 (see FACT SHEET 8) were considered in developing these PAGs.

3.3 Description of Detailed Requirements:

These recommendations are for use by appropriate State or local agencies in response planning and radiation protection activities in the event of an incident resulting in the release of radioactivity to the environment. FDA

recommends that the guidance be used on a case-by-case basis. If, in a particular situation, effective action with low total impact is available, initiation of such action at a projected dose lower than the PAG may be justifiable. If only high impact action would be effective, initiation at a projected dose higher than the PAG may be justifiable.

NOTE: PAGs are not intended to authorize deliberate releases expected to result in doses of these magnitudes.

3.3.1 Definitions:

Protective Action is an action or measure taken to avoid most of the radiation dose "that would occur from future ingestion of foods contaminated with radioactive materials."

Preventive PAG "is the projected dose commitment value a which . . . officials should take protective actions having minimal impact. . . ."

Emergency PAG "is the projected dose commitment value at which officials should isolate food containing radioactivity. . . ."

Response Level "means the activity of a specific radionuclide (1) initially deposited on pasture; or (2) per unit weight or volume of food or animal feed; or (3) in the total dietary intake which corresponds to a particular PAG." (Specific radionuclide concentrations upon which to initiate protective actions.)

3.3.2 The following Preventive and Emergency PAGs for an exposed individual in the population are adopted:

A. Preventive PAG: ". . . 1.5 rem projected dose commitment to the thyroid; or 0.5 rem projected dose commitment to the whole body, bone marrow or any other organ."

B. Emergency PAG: ". . . 15 rem projected dose commitment to the thyroid; or 5 rem projected dose commitment to the whole body, bone marrow, or any other organ."

C. Response Levels for Preventive and Emergency PAGs: (see chart on following page).

Response Levels for Preventive PAG: Infant[1/]

	I-131[3/]	Cs-134[5/]	Cs-137[5/]	Sr-90	Sr-89
Initial Activity Area Deposition (microcuries/sq. meter)	0.130	2.00	3.00	0.500	8.00
Forage Concentration[4/] (microcuries/kilogram)	0.050	0.80	1.30	0.180	3.00
Peak Milk Activity (microcuries/liter)	0.015	0.15	0.24	0.009	0.14
Total Intake (microcuries)	0.090	4.00	7.00	0.200	2.60

Response Levels for Emergency PAG

	I-131[3/]		Cs-134[5/]		Cs-137[5/]		Sr-90		Sr-89	
	Infant[1/]	Adult	Infant[2/]	Adult	Infant[2/]	Adult	Infant[2/]	Adult	Infant[2/]	Adult
Initial Activity Area Deposition (microcuries/sq. meter)	1.3	18	20.0	40	30.0	50	5.00	20.0	80.0	1,600
Forage Concentration (microcuries/kilogram)	0.5	7	8.0	17	13.0	19	1.80	8.0	30.0	700
Peak Milk Activity (microcuries/liter)	0.15	2	1.5	3	2.4	4	0.09	0.4	1.4	30
Total Intake (microcuries)	0.9	10	40.0	70	70.0	80	2.00	7.0	26.0	400

1/ Newborn Infant as critical segment of population, includes fetus (pregnant women) as critical segment for I-131.

2/ Infant refers to child less than 1 year of age.

3/ From fallout, iodine-131 is the only radioiodine of significance with respect to milk contamination beyond the first day. In case of a reactor accident, the cumulative intake of iodine-133 via milk is about 2 percent of iodine-131 assuming equivalent deposition.

4/ Fresh Weight.

5/ Intake of cesium via [illegible] meat/person pathway for adults may exceed that of the milk pathway; therefore, such levels in milk should cause [illegible]veillance and protective actions for meat as appropriate. If both cesium-134 and cesium-137 are equally present, as might be expected for reactor accidents, the response levels should be reduced by a factor of 2.

D. To obtain the Response Level (microcuries/kilogram) equivalent to the Protective Action Guide for other specific foods:

$$\text{Response Level} = \frac{\text{Total Intake (microcuries)}}{\text{Consumption (kilograms)}}$$

where: Total intake for the appropriate PAG and radionuclide is given in the chart above, and consumption is the product of the average daily consumption and the days of intake of contaminated food.

4. RELATED STANDARDS

Federal Protective Action Guide (PAG) for I-131 (1964). (See FACT SHEET 7.)

Federal Protective Action Guides (PAGs) for Sr), Sr-90 and Cs-137 (1965). (See FACT SHEET 8.)

Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, September 1975, Revised June 1980, EPA-520/1-75-001. (Provides action levels and guidance for their use by state and local agencies in developing radiological emergency plans.)

FACT SHEET 23A

30 CFR 57, MSHA SAFETY AND HEALTH RADIATION STANDARDS FOR UNDERGROUND METAL AND NONMETAL MINES (1977)

COMPLETE TITLE

30 CFR 57.5037-5047, SAFETY AND HEALTH STANDARDS -UNDERGROUND METAL AND NONMETAL MINES-RADIATION-UNDERGROUND ONLY

1. AUTHORIZING STATUTES

Federal Metal and Nonmetallic Mine Safety Act, 30 U.S.C. 721, P.L. 89-577 § 6, 80 Stat. 774. Repealed by P.L. 95-164, Title III, §306(a), November 9, 1977. Replaced by 30 U.S.C. 801, pursuant to P.L. 95-164.
Federal Mine Safety and Health Act of 1977 (P.L. 91-173) as amended by P.L. 95-164, 30 U.S.C. 957, 83 Stat. 803.

Effective Date: Repeal and replacement effective March 9, 1978.

1.1 Statutory Purpose:

1.1.1 To establish interim mandatory health and safety standards and to direct the Secretary of Health, Education and Welfare [later Health and Human Services (HHS)] and the Secretary of Labor to develop improved mandatory health or safety standards to protect the nation's miners.

1.1.2 To require mine operators and miners to comply with such standards.

1.1.3 To cooperate with the States in development of effective mine safety programs.

1.1.4 To improve and expand training programs aimed at preventing accidents and occupationally-caused diseases in the mining industry.

1.2 Radiation Protection Provisions:

Under the Federal Metal and Nonmetallic Mine Safety Act, the Department of the Interior, through the Mining Enforcement Safety Administration (MESA), established regulations governing health and safety standards. One set of regulations, governing exposure to ionizing radiation (radon daughters and gamma rays) is relevant to radiation protection.

When the original §§721-740 of the Federal Metal and Nonmetallic Mine Safety Act were repealed and replaced by §§801 et seq., the Department of Labor received the Department of the Interior's rulemaking authority, and delegated it to the Mine Safety and Health Administration (MSHA).

2. RESPONSIBLE AGENCIES

The Department of the Interior. Under 30 U.S.C. 721, the Secretary of the Interior was authorized to promulgate mandatory mine health and safety standards. Authority was delegated to the Mining Enforcement and Safety Administration.

The Department of Labor. Under 30 U.S.C. 801, authority over mine safety standards was transferred to the Secretary of Labor. This brought operation of all mines under a single legislative canopy. The Secretary delegated the rule-making authority to the Mine Safety and Health Administration created by 30 CFR I, under the authority of the Federal Mine Safety and Health Act of 1977.

The Secretary, U.S. Department of Health and Human Services (HHS) (formerly Health, Education and Welfare). The Secretary of HHS conducts research, experiments, and studies of exposure levels; recommends regulations regarding records, medical examinations, and toxic substances; conducts annual studies and inspections and has contracting authority, all of which are delegated to the Director of the National Institute for Occupational Safety and Health.

The States. One purpose of 30 U.S.C. 801 was to promote cooperation by Federal agencies with the states in developing health and safety standards.

3. DESCRIPTION OF 30 CFR 57, MSHA SAFETY AND HEALTH RADIATION STANDARDS FOR UNDERGROUND METAL AND NONMETAL MINES (1977)

Issuances:

42 FR 5546, January 28, 1977; 42 FR 29418, June 8, 1977.

Effective Date: July 18, 1977 (revisions currently proposed).

3.1 General Radiation Protection Provisions:

30 CFR 57 prescribes limitations which govern radon daughter exposure monitoring, annual exposure limits, maximum permissible concentration, exposure records, smoking prohibition, revised exposure levels, posting of inactive workings, protection against radon gas, and gamma radiation surveys and exposure limit.

3.2 Rationale for Detailed Requirements:

3.2.1 The existing mining standard for gamma radiation was set at 5 rem in 1977 (42 FR 29418). This level was based on the recommendations first made by the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP) in the mid-1950s.

3.2.2 In 1970, the Bureau of Mines (predecessor to MESA and MHSA) had established 12 working level months (WLM) as the Federal exposure limit to radon daughters in underground mines. In 1971, the Environmental Protection Agency (EPA) issued a Federal Radiation Protection Guidance for radon daughters, which specified a limit of

4 WLM per year. (See FACT SHEET 3.) That annual limit applied to underground mines as a mandatory standard through 30 CFR 57.5042, which incorporates EPA radon daughter recommendations approved by the President. The 4 WLM limit was later explicitly adopted.[1/]

3.3 Description of Detailed Requirements:

3.3.1 Radon Daughter Exposure Monitoring: In all mines at least one sample must be taken of mine exhaust air.

A. Uranium mines: If the concentration in the initial sample is less than 0.1 WL, mines must be sampled monthly thereafter. If the concentration is more than 0.1 WL, samples must be taken every two weeks thereafter. If a concentration in excess of 0.3 WL is found, monitoring must be done weekly until the concentration is less than 0.3 WL for five consecutive weeks.

B. All other mines: If the concentration in the initial sample is less than 0.1 WL, no further samples need be taken. If the concentration is more than 0.1 WL, samples must then be taken at least every three months. If the concentration in the initial sample is greater than 0.3 WL, sampling must be done at least every week until the concentration is less than 0.3 WL for five consecutive weeks.

3.3.2 Annual Exposure Limits: No person shall be permitted to receive an exposure in excess of 4 WLM in any calendar year.

3.3.3 Maximum Permissible Concentration: No one may be exposed to air containing concentrations of radon daughters exceeding 1.0 WL in active workings, except as provided by standard 30 CFR 57.5005: ". . . [W]here accepted engineering control measures have not been developed or when necessary by the nature of work involved (for example, while establishing controls or occasional entry into hazardous atmospheres to perform maintenance or investigation), employees may work for reasonable periods of time in concentrations of airborne contaminants exceeding permissible levels if they are protected by appropriate respiratory protective equipment."

3.3.4 Radon daughter exposure monitoring and records are required. A higher level of scrutiny is required where uranium is mined.

3.3.5 Smoking is prohibited in all areas of a mine where exposure records are required to be kept.

1/ To calculate an individual's exposure to WLM under this standard, multiply the total exposure time (hours to the nearest half-hour) by the average concentration of airborne radon daughters for the applicable active working area (average working level calculated to the nearest hundredth working level) and divide the product by the constant 173 hours per month. (This 173 hours per month standard differs from the NRC and international standard of 170 hours per month.)

3.3.6 Revised Exposure Levels: If maximum exposure levels to concentrations of radon daughters are recommended by the EPA and approved by the President, no employee shall be permitted to receive exposures in excess of those levels after the effective dates established by the Agency.

3.3.7 Respirators are required in compliance with §57.5005 in environments exceeding 1.0 WL.

3.3.8 Inactive Workings in which radon daughter concentrations are above 1.0 WL shall be posted against unauthorized entry, and identified by signs as an area in which respirators are required.

3.3.9 Protection Against Radon Gas: Where radon daughter concentrations exceed 10 WL, respirator protection against radon gas must be provided in addition to protection against radon daughters.

3.3.10 Gamma Radiation

A. Gamma radiation surveys must be conducted annually in all underground mines where radioactive ores are mined.

B. Surveys must be in accordance with American National Standards (ANSI) Standard N13.8-1973 ("Radiation Protection in Uranium Mines"), section 14.1, page 12, which is incorporated in this standard by reference.

C. Where average gamma radiation measurements are in excess of 2.0 milliroentgens per hour in the working place, gamma radiation dosimeters must be provided for all persons affected, and records of cumulative gamma radiation exposure must be kept.

D. Annual individual gamma radiation exposure must not exceed 5 rem.

4. RELATED STANDARDS

Federal Guidance on Occupational Radiation Exposures (RPGs) (1987). (See FACT SHEET 2.)

Federal Guidance on Radon Exposure in Uranium Mines (1969). (See FACT SHEET 3.)

40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982). (See FACT SHEET 14.)

30 CFR 57, MSHA Proposed Ionizing Radiation Standards for Underground Metal and Nonmetal Mines (1986). (See FACT SHEET 23B.)

FACT SHEET 23B

30 CFR 57, MSHA PROPOSED IONIZING RADIATION STANDARDS FOR UNDERGROUND METAL AND NONMETAL MINES (1986)

COMPLETE TITLE

30 CFR 57, IONIZING RADIATION STANDARDS FOR UNDERGROUND METAL AND NONMETAL MINES; PROPOSED RULES, 41 FR 45678, DECEMBER 19, 1986.

1. AUTHORIZING STATUTES

Federal Metal and Nonmetallic Mine Safety Act, 30 U.S.C. 721, P.L. 89-577 §6, 80 Stat. 774. Repealed by P.L. 95-164, Title III, §306(a), November 9, 1977. Replaced by 30 U.S.C. 801, pursuant to P.L. 95-164.
Federal Mine Safety and Health Act of 1977, P.L. 91-173 as amended by P.L. 95-164, 30 U.S.C. 957, 83 Stat. 803.

Effective Date: Repeal and replacement effective March 9, 1978.

Statutory Purpose:

1.1.1 To establish interim mandatory health and safety standards and to direct the Secretary of Health, Education and Welfare [later Health and Human Services (HHS)] and the Secretary of Labor to develop improved mandatory health or safety standards to protect the nation's miners.

1.1.2 To require mine operators and miners to comply with such standards.

1.1.3 To cooperate with the States in development of effective mine safety programs.

1.1.4 To improve and expand training programs aimed at preventing accidents and occupationally-caused diseases in the mining industry.

1.2 Radiation Protection Provisions:

Under the Federal Metal and Nonmetallic Mine Safety Act, the Department of the Interior, through the Mining Enforcement Safety Administration (MESA), established regulations governing health and safety standards. One set of regulations, governing exposure to ionizing radiation (radon daughters and gamma rays) is relevant to radiation protection.

When the original §§721-740 of the Federal Metal and Nonmetallic Mine Safety Act were repealed and replaced by §§801 et seq., the Department of Labor received the Department of the Interior's rulemaking authority, and delegated it to the Mine Safety and Health Administration (MSHA).

2. RESPONSIBLE AGENCIES

The Department of the Interior. Under 30 U.S.C. 721, the Secretary of the Interior was authorized to promulgate mandatory mine health and safety standards. Authority was delegated to the Mining Enforcement and Safety Administration.

The Department of Labor. Under 30 U.S.C. 801, authority over mine safety standards was transferred to the Secretary of Labor. This brought operation of all mines under a single legislative canopy. The Secretary delegated the rule-making authority to the Mine Safety and Health Administration created by 30 CFR I, under the authority of the Federal Mine Safety and Health Act of 1977.

The Secretary, U.S. Department of Health and Human Services (HHS) (formerly Health, Education and Welfare). The Secretary of HHS conducts research, experiments, and studies of exposure levels; recommends regulations regarding records, medical examinations, and toxic substances; conducts annual studies and inspections and has contracting authority, all of which are delegated to the Director of the National Institute for Occupational Safety and Health.

The States. One purpose of 30 U.S.C. 801 was to promote cooperation by Federal agencies with the states in developing health and safety standards.

3. DESCRIPTION OF 30 CFR 57, MSHA PROPOSED IONIZING RADIATION STANDARDS FOR UNDERGROUND METAL AND NONMETAL MINES (1986)

Issuances:

50 FR 4144, January 29, 1985, 50 FR 47700, November 19, 1985, 51 FR 45678, December 10, 1986.

Effective Date: The comment period expired February 14, 1987.

Background

Sum rule: ICRP Publication 2, "Report of Committee II on Permissible Dose from Internal Radiation" (1959); Nuclear Regulatory Commission, proposed revision to Part 20 of Code of Federal Regulations (50 FR 1092, January 9, 1986); ICRP Publication 32, "Limits for Inhalation of Radon Daughters" (1982); ICRP Publication 47, "Radiation Protection of Workers in Mines" (1985).

Monitoring: Schiager et al., "Radiation Monitoring for Uranium Mines: Evaluation and Optimization" (1981).

3.1 General Radiation Protection Provisions:

The proposed standards would revise large portions of 30 CFR 5037-5047, which set standards for limits on annual exposure to, and recording standards for, occupational exposure to ionizing radiation in underground mines.

3.2 Rationale for Detailed Requirements:

3.2.1 Scope. MSHA continues to limit the scope of the rule to underground mines because "MSHA found no significant radiation hazard at surface operations which was not already adequately addressed by other

State or Federal agencies." Nor does the rule cover use of x-radiation equipment, because such exposure is low, isolated to specific parts of the body, and adequately regulated by State and local governmental agencies.

3.2.2 Control of exposure to radiation-Sum rule: "The most significant departure from the Agency's existing ionizing radiation standards in this proposed rule is the establishment of a combined exposure limit or sum rule for radon daughters, thoron daughters, and gamma radiation. . . .

"The guiding principle is that the total risk of radiation-induced fatal cancers for an individual should be limited."

3.2.3 Monitoring for radon daughters and thoron daughters: The proposed rule would reduce the action level for radon daughters for weekly sampling from 0.3 WL to 0.2 WL, and would institute an action level for thoron daughters of 0.6 WL. This reflects the concern for the effects of combined radiation resulting in increased fatal cancer risk.

3.2.4 Gamma ray dosimetry: The threshold level for required gamma ray dosimetry would also be changed, from an average of 2.0 milliroentgens per hour to an average of 0.75 millirem per hour. This was intended to prevent any miner from exceeding 30% (1.5 rem) of the annual allowed exposure (5 rem) without his exposure being recorded.

3.2.5 Records: Two levels of record-keeping are proposed for radon daughters, based on the level of gamma radiation present. This reflects the same whole-risk concern as does the recommendation of the sum rule.

3.2.6 Calculation of exposure to individuals: This section "clarifies the methodology for calculating individual radon daughter exposure in existing 30 CFR 57.5040, and contains provisions for calculating exposure to thoron daughters." Although no thoron daughter concentrations approaching the action level have been recorded in any working mine in the United States, such levels have been found in some inactive mines.

3.2.7 Smoking prohibition: The smoking prohibition has been maintained because removing it "would be a step back from sound health protection." There is no evidence of the exact relationship between smoking and radiation-induced lung cancer.

3.2.8 ALARA: "A widely-held, basic tenet for minimizing harm from radiation is that exposures should be kept as low as reasonably achievable (ALARA). Effective implementation of the principle involves: education of workers, . . . training in regulatory requirements, . . . establishment of appropriate exposure limits, . . . monitoring, . . . and implementation of radiation control measures. [To this end] the mining act contains specific provisions for training miners in health and safety. This proposal would put into effect

other facets of ALARA by setting requirements for monitoring and record-keeping."

3.3 Description of Detailed Requirements:

3.3.1 Control of exposure to radiation.

A. Ceiling limits. The proposed regulation requires that no person be exposed to air containing concentrations of radon daughters exceeding 1.0 WL or thoron daughters exceeding 3.0 WL unless the person is wearing approved respiratory protection. Areas where concentrations exceed these limits must be barricaded or posted. If radon-daughter concentration exceeds 10 WL, supplied-air type respirators must be used.1/

B. Combined limit. Combined radiation exposure for any person during any calendar year may not exceed 1.0 as determined by the following formula:

$$\text{Combined radiation exposure} = \frac{R}{4\ \text{WLM}} + \frac{T}{14\ \text{WLM}} + \frac{G}{5\ \text{rem}}$$

Where:
R = the recorded calendar-year radon-daughter exposure in WLM.2/

T = the recorded calendar-year thoron-daughter exposure in WLM.

G = the recorded calendar-year whole-body gamma dose in rem.

C. Declared pregnancy. The occupational whole-body dose of gamma radiation of a declared pregnant woman (one who has been diagnosed as pregnant and has informed the mine-operator) shall not exceed 0.50 rem during the entire pregnancy.

1/ WL, WLM, and rem are the traditional measures in the mining industry. Conversion to the International System of Units (SI), involving joules and sieverts, can be accomplished with the following conversion factors:
1.0 WL=2.08 x 10^{-5} J/m^3
1.0 WLM=3.6 x 10^{-3} J per m^3
1.0 rem=10 mSv.

2/ To calculate an individual's exposure to WLM under this standard, multiply the total exposure time (hours to the nearest half-hour) by the average concentration of airborne radon daughters for the applicable active working area (average working level calculated to the nearest hundredth working level) and divide the product by the constant 173 hours per month. (This 173 hours per month standard differs from the NRC and international standard of 170 hours per month).

3.3.2 Monitoring for airborne radiation.

A. Action level. Monitoring standards apply to any mine identified as having radon daughter concentrations above 0.20 WL or thoron daughter concentrations above 0.60 WL, unless levels can be promptly reduced and maintained, or the areas are barricaded or posted.

B. Frequency. Areas with concentration levels above the action level must be sampled weekly. Where areas have concentrations below the action level, but are entered by persons whose exposures are monitored because of their exposures in other areas of the mine, these areas shall be sampled on a monthly basis. Sampling frequency may be lowered either for weekly or monthly areas, subject to guidelines concerning the consistency of the levels in the last four regular samples.

3.3.3 Gamma ray dosimetry.
The mine operator must provide gamma-ray dosimeters for all persons with an average whole-body gamma-ray dose rate of more than 0.75 millirem per hour during any shift, and for the term of the pregnancy if the whole-body dose rate from gamma radiation of a declared pregnant woman exceeds an average of 0.33 millirem/hour during any shift.

3.3.4 Records. Two levels for recordkeeping of individual exposure to radon daughters are proposed. Where gamma ray dosimetry is required, calendar-year radon exposure levels are required where radon daughter concentrations exceed 0.2 WL. Where gamma dosimetry is not required, yearly records are only required where radon-daughter exposure exceeds 0.3 WL.

3.3.5 Calculation of exposure to individuals.

A. The average radon or thoron daughter concentration for an area is determined by averaging two consecutive samples.

B. For each person the exposure time (to the nearest half-hour) is multiplied by the average concentration (WL) to arrive at the person's exposure in working level hours (WLH) to the nearest hundredth.

The quarterly WLH are added together and divided by 173 to calculate the person's quarterly exposure in working level months (WLM). The quarterly exposure in WLM are added together to calculate the calendar-year exposure.

C. Where respiratory protective equipment is used for short-term entry for inspection, maintenance, or installation of controls, or to supplement feasible controls as required by 30 CFR 57.5701(d), the following adjustments may be made in calculating exposure:

i. For approved respirators that remove airborne nuclides, the wearer's exposure may be considered to be 10% of the last radon daughter and thoron daughter concentration in the area prior to the respirator use.

ii. For approved supplied-air respirators, exposure may be calculated on the basis of radon daughter and thoron daughter concentrations present in the supplied air for the time the respirator is worn.

3.3.6 Smoking prohibition. Smoking would be prohibited underground in mines where airborne radiation exposure records are required.

3.3.7 30 CFR 57.5042, which incorporated any standard for radon daughter exposure proposed by the Environmental Protection Agency (EPA) and approved by the President, has been removed.

4. RELATED STANDARDS

Federal Guidance on Occupational Radiation Exposures (RPGs) (1987). (See FACT SHEET 2.)

Federal Guidance on Radon Exposure in Uranium Mines (1969). (See FACT SHEET 3.)

40 CFR 440, EPA Mining Effluent Limits for U and Ra (1982). (See FACT SHEET 14.)

30 CFR 57, MSHA Safety and Health Radiation Standards for Underground Metal and Nonmetal Mines (1977). (See FACT SHEET 23A.)

USER'S GUIDE

1. ACTS.

	FACT SHEET
Atomic Energy Act	1-8, 11-13, 16A and B, 17-19
Clear Air Act Amendments	9
Clean Water Act	14
Energy Reorganization Act	16A and B, 17-19
Federal Food, Drug, and Cosmetic Act	5
Federal Metal and Nonmetallic Mine Safety Act	23A and B
Federal Mine Safety and Health Act	23A and B
Federal Water Pollution Control Act Amendments	14
London Dumping Convention	15
Marine Protection, Research and Sanctuaries Act	15
Nuclear Waste Policy Act	13, 17
Occupational Safety and Health Act	20
Ocean Dumping Act	15
Public Health Service Act	5, 10, 22
Radiation Control for Health and Safety Act	5, 21
Reorganization Plan No. 3	2, 5, 6, 11, 13
Safe Drinking Water Act	10
Solid Waste Disposal Act	12
Uranium Mill Tailings Radiation Control Act	12

2. AGENCIES.

Army, Secretary of the	15
Army Corps of Engineers	15
Department of the Coast Guard	15
Department of Commerce	15
Department of Energy	9, 12, 13, 17
Department of Health and Human Services	5, 20-22, 23A and B
Department of Interior	23A and B
Department of Labor	3, 20, 23A and B
District Courts of the United States	15
Environmental Protection Agency	1-15
Federal Radiation Council	1, 3, 4, 7, 8
Food and Drug Administration	5, 21, 22
Indian Tribes	10, 12, 13, 17
Local Governments	22
Mine Safety and Health Administration	3, 23A and B
Mining Enforcement and Safety Administration	3, 23A and B
National Institute for Occupational Safety and Health	20
Nuclear Regulatory Commission	9, 11-13, 16A and B, 17-19
Occupational Safety and Health Administration	20
States (including NRC-Agreement States)	9-14, 16A and B, 17, 18, 21, 22, 23A and B

3. RADIONUCLIDES.

	FACT SHEET
Cesium	8, 10, 13, 22
Iodine	4, 7, 10, 11, 13, 19, 22
Krypton	11
Plutonium	11, 13
Polonium	3, 9
Radium	1, 4, 10, 12-14
Radon	2, 3, 9, 12, 23A and B
Strontium	4, 8, 10, 13, 22
Thorium	12, 13
Thoron	23B
Transuranics	6, 11, 13
Tritium	10, 15, 16A
Uranium	3, 9, 11-14, 23A and B

4. MAJOR RADIATION SOURCE CATEGORIES.

Consumer Products	1, 10, 21
Medical	5, 16, 21
Miscellaneous Environment	1, 4, 6-9, 14-16, 22
Nuclear Fuel Cycle	1, 4, 7-9, 11-13, 16-19
Occupational	2, 3, 16, 20, 23

5. SPECIFIC ORGANS OR TISSUES.

Active Blood-Forming Organs	1, 16A
Ankle	1, 16A, 20
Arm	1, 16A and B, 20
Bone	1, 2, 4, 6
Bone Marrow	2, 4, 8, 10, 22
Breast	2
Elbow	16B
Extremity	2
Eye, Lens	1, 2, 16A and B
Foot	1, 16A and B, 20
Gonads	1, 2, 6, 16A
Hand	1, 16A and B, 20
Head	1, 16A and B
Knee	16B
Leg	16B
Liver	6
Lung	2, 3, 6, 9, 12
Skin	1, 2, 5, 16A and B, 19, 20
Thyroid	1, 2, 4, 7, 11-13, 18, 22
Trunk	1, 16A and B
Whole Body	1, 2, 8-13, 16A and B, 18-20, 22

6. TERMS.

	FACT SHEET
Annual Limit of Intake (ALI)	2, 16B
As Low As Reasonably Achievable (ALARA)	2, 5, 9, 12, 16A and B, 18, 19, 23B
Best Available Technology (BAT)	14
Best Practicable Technology (BPT)	14
Best Available Demonstrated Technology (BADT)	14
Derived Air Concentration (DAC)	2, 16B
Entrance Skin Exposure Guides (ESEG)	5
High-Level Waste (HLW)	13, 15, 17
Light-Water-Cooled Reactor (LWR)	19
Low-Level Waste (LLW)	18
Maximum Contaminant Level (MCL)	10
Maximum Permissible Concentration (MPC)	16A
New Source Performance Standard (NSPS)	14
Protective Action Guide (PAG)	7, 8, 22
Radiation Protection Guide (RPG)	1, 2, 4-6
Radioactivity Concentration Guide (RCG)	1
Working Level (WL)	3, 12, 23A and B
Working Level Month (WLM)	3, 23A and B
Working Level Hour (WLH)	23B

7. TOPICS.

Air	
emission standards	9
particulates	19
Alpha-emitting radionuclides	
air emissions	9
mill tailings	12
mines	3, 23A and B
ocean dumping	15
radioactivity in drinking water	10
radionuclides in groundwater	13
transuranics	6
Cancer	
lung	3, 6, 9, 12
risk	2, 6, 9, 12, 13, 23B
Contamination	
animal feed	7, 22
environmental	4, 6-8, 22
food	7, 8, 22
milk	4, 7, 22
transuranics	6
Cost-benefit	19
Dose	
committed effective dose equivalent	2, 16B
dose equivalent	2, 16B
effective dose equivalent	2, 16B
summation	2, 16B, 23B

7. TOPICS (CONTINUED).	FACT SHEET
Effluents	
gaseous	16A and B, 19
light-water reactor	19
limits for uranium fuel cycle	11
liquid	16A and B, 19
mining limits for U and Ra	14
Electronic product	5, 21
Environmental	
radionuclides	4, 6-9, 12, 13, 17
standards for uranium fuel cycle	11
transuranics	6
Embryo/fetus	2, 16B, 22, 23B
Exposure	
internal	2, 4, 6, 16A and B
radon	3, 23A and B
thoron	23B
Gamma	
limits for LWR gaseous effluents	19
ocean dumping	15
radiation in underground mines	23A and B
radioactivity in drinking water	10
radionuclides in groundwater	13
Genetic damage	2, 6
Medical	
diagnostic x-ray	5, 21
Mines	
metal and nonmetal	23A and B
uranium (see Uranium, mines)	
Minors	2, 16A and B, 20, 22
Occupational	
limits	1, 2, 16A and B, 20
miners	3, 23A and B
Ocean Dumping	15
Photons (see Gamma)	
Population	
general limits	1, 16A and B
internal exposure limits	4, 16A and B
limits from air emissions	9
limits from mill tailings	12
limits from waste disposal	13, 17, 18
limits from nuclear fuel cycle	11, 19
Pregnant female (see Embryo/Fetus)	
Radionuclides	
air emission standards	9
drinking water standards	10
mining effluent limits for U and Ra	14
ocean dumping	15
Sewage systems	
disposal of NRC-licensed material	16A and B
Smoking	3, 23A and B
Thorium	
mill tailings	12

7. TOPICS (CONTINUED).	FACT SHEET
Uranium	
mill tailings	9, 12
mills	9, 12, 14
mines	3, 9, 14, 23A and B
Waste	
disposal into sewage systems	16A and B
geologic repository	17
high-level	13, 15, 17
land disposal	18
low-level	18
ocean dumping	15
spent nuclear fuel	13, 17
transuranic	13
Water	
drinking	10
groundwater	12, 13, 17

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July 17, 1989

VIA HAND DELIVERY

TO: Tim Smith

FROM: Phil Cummings

Re: Attached §112 memo

Attached is a draft of the memorandum you requested on section 112 of the Clean Air Act. Sorry it did not reach you before your vacation.

I'll be back in my office Wednesday afternoon (July 19). Let me know if you want this expanded, modified, etc.

P. T. C.

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July 17, 1989 DRAFT

VIA HAND DELIVERY

PRIVILEGED AND CONFIDENTIAL
ATTORNEY-CLIENT PRIVILEGE

To: Timothy Smith

From: Philip T. Cummings

Re: Regulation of radionuclides under section 112 of the Clean Air Act

You asked for a discussion of how section 112 of the Clean Air Act, providing for national emission standards for hazardous air pollutants, operates with respect to the regulation of radionuclides. Among the questions you asked me to address are the role of cost considerations in standard-setting, how States will be involved in regulation under section 112, what is likely to happen once EPA completes the pending rulemaking on radionuclides, and what options will be available to ANEC and its members.

Decision to list radionuclides under §112

The Clean Air Act Amendments of 1977 (P.L. 95-95) resolved a controversy about EPA's failure to regulate a number of substances of concern by enacting section 122, requiring the "Listing of Certain Unregulated Pollutants". This section and an amendment including radioactive substances in the definition of "air pollutant" were originally contained in the House bill. As the Statement of Managers accompanying the Conference Report explains, "This provision makes it clear that the full regulatory framework of the Act is available for radioactive pollutants." House Report No. 95-564, p. 142.

Section 122 required EPA to make a determination within two years after enactment as to whether air emissions of radioactive pollutants (including source material, special

nuclear material, and byproduct material) will cause or contribute to air pollution which may reasonably be anticipated to endanger public health. In the case of an affirmative determination, EPA was required to simultaneously decide whether to regulate radioactive pollutants as criteria pollutants subject to ambient air quality standards under sections 108 and 109, as hazardous air pollutants under section 112, under new source performance standards under section 111, or under some combination of regulations.

Pursuant to this requirement, on December 27, 1979, EPA listed radionuclides as a hazardous air pollutant under section 112. This was based on a determination that radionuclides are a known cause of cancer and genetic damage, that they meet the statutory definition of a hazardous air pollutant, and that they present a risk warranting regulation under section 112. (Since the listing of a hazardous air pollutant is not considered to be a final agency action, judicial review of the basic listing decision is part of the challenge to the emissions standards themselves, when promulgated. As a result of challenges to earlier regulations, the reaffirmation of the original decision to list radionuclides as a hazardous air pollutant is part of the pending rulemaking.)

Section 112 rulemaking for radionuclides

Emission standards under section 112 were promulgated for several categories of sources of radionuclides in 1985, after protracted litigation and the publication in 1984 of final decisions not to regulate several other source categories (including uranium fuel cycle facilities). These were challenged by EDF, NRDC and the Sierra Club. After the decision in the Vinyl Chloride case (discussed below), on November 16, 1987, EPA moved for a voluntary remand of all the radionuclide emission standards and decisions. The Court has now established a deadline for final action of August 31, 1989. EPA met an earlier Court deadline by proposing emission standards for radionuclides on February 28, 1989 (appearing in the March 7, 1989, Federal Register). This same deadline for final promulgation of emission standards applies to a pending rulemaking for benzene emissions from various source categories, some of which were also voluntarily remanded in 1987.

The regulatory standard under section 112 is "to establish any such standard at the level which in [the Administrator's] judgment provides an ample margin of safety to protect the public health from such hazardous air pollutant". Prior to the Vinyl Chloride decision, the Agency had decided

that this standard was difficult to apply to carcinogens and other pollutants without a "threshold" level below which no adverse health effects could be expected. EPA had issued several regulations based on judgments of risk in which the costs and benefits of the standard and the technical availability of controls were considered. In fact, the Agency was well along toward converting the "ample margin of safety" standard to one regulating carcinogens on the basis of the best available control technology.

In Natural Resources Defense Council, Inc. v EPA, 824 F.2d 1146, decided en banc July 28, 1987, the U.S. Court of Appeals for the D.C. Circuit remanded to EPA the section 112 emission standard for vinyl chloride. The Court ruled that EPA improperly considered cost and technological feasibility, without first making a determination based exclusively on the risk to health. This requires EPA to make a two-stage decision on emission standards for listed hazardous air pollutants:

> - First, the Agency must make an initial determination as to what level of emissions is safe, or will result in an acceptable risk to health. How to do this was left to EPA's expert judgment, but the Administrator must base this determination on risk to health exclusively and may not consider cost or technological feasibility.
>
> - Then, EPA may set a lower level of emissions in order to provide an ample margin of safety. In deciding whether to establish this lower level, and in determining what it should be, EPA can consider costs of control, technological feasibility, the benefits of the activity, and other balancing factors.

In trying to interpret this decision and develop emission standards for radionuclides and benzene sources, EPA has proposed four alternative approaches for determining acceptable risks to health. Several of these alternatives set specific levels of individual or population risk (as calculated through EPA's risk assessment methodology) that would be deemed to be acceptable. One, Approach A, uses a case-by-case approach considering multiple factors including risk information and estimation uncertainties, without a firm decision rule on acceptable risk levels. While EPA has proposed emission standards based on each of the four approaches, the final promulgation will select one approach (or a standard based on some combination of the approaches).

In the pending rulemaking, EPA has reconsidered its

earlier decision not to regulate uranium fuel cycle facilities and subjects them to the same analysis and consideration of these four approaches as other radionuclide sources. Under Approach A, the case-by-case approach, EPA proposes an emission standard that would result in no more than 10 mrem/year effective dose equivalent (ede). The current standard set by EPA under the Atomic Energy Act and enforced by the NRC is 25 mrem/year whole body dose. EPA's analysis and argument, however, is that the Approach A proposed emission standard represents the baseline level, or the level currently attained by sources in the category.

The most likely other alternative, Approach C, would set emission standards at the level necessary to assure that risk of cancer does not exceed one in 10,000, or 1 x 10^{-4}. EPA's proposed standard under Approach C is 3 mrem/year ede. (In both cases, EPA has determined that no further reductions below the acceptable risk to health level is necessary to provide an ample margin of safety.)

Although the final regulations will not be promulgated until August, it appears that Administrator Reilly has decided to use a combination of Approach A and Approach C, establishing a "fuzzy bright line" which presumes a risk level of 10^{-4}, but is not absolute. This is apparently a stronger disposition toward 10^{-4} as the ordinary standard than the case-by-case approach in which 10^{-4} is the "preferred level". (This information is considered to be reliable with respect to the benzene rule, and ought to apply to the radionuclides rule as well.) Based on the EPA rulemaking, this could result in an emission standard for uranium fuel cycle facilities of between 3 and 5 mrem/year ede. This would result in some additional controls for some power reactors beyond current levels, according to the EPA analysis. Uranium mills and conversion plants would require additional controls.

(As indicated below, pending legislation would change the basis for emission standards under section 112 to a maximum available control technology (MACT) approach. Although it is difficult to be certain, one can infer from the EPA analysis of alternatives for ample margin of safety for UFC facilities that MACT might be 1 mrem/year for power reactors. That would achieve a residual risk level of about 3 x 10^{-5}.)

Implementation of §112 emission standards for radionuclides

Standards under section 112 are national emission standards, enforced by EPA. Once promulgated, emission standards must be complied with by new or modified facilities before they begin operation. In essence, an EPA permit is

required. Existing sources must comply within 90 days, unless EPA establishes a compliance period of up to 2 years after promulgation.

Under section 112(d), States may develop and submit to EPA programs for implementing and enforcing emission standards for hazardous air pollutants. If the State program is adequate, EPA delegates its authority to implement and enforce the emission standards to the State. This can be done on a pollutant-specific basis. EPA retains the authority to enforce the emission standards, but permitting is done by the State. This is unrelated to the agreement State provisions of the Atomic Energy Act; separate delegation would be required under section 112. Many States have delegated programs for the current hazardous air pollutant emission standards.

If EPA had chosen the ambient air quality standard approach for radionuclides in 1979, all the regulation and emission limitations would have been developed and enforced by the States through State implementation plans under section 110. This is the reason section 122(c)(3) was included in the Act. Under this provision, if the NRC determines that a standard or emission limitation promulgated by EPA under the Clean Air Act or by a State under an implementation plan would endanger public health or safety at a facility within NRC jurisdiction, the standard or emission limitation would not apply unless the President determines that it should apply.

This provision allows the NRC to disapprove any EPA, State or local standard promulgated under the Clean Air Act. The President may overturn this disapproval, upon appeal by the agency that promulgated the standard. As the Statement of Managers accompanying the Conference Report notes,

> "Under this provision, radioactive pollutants, including source material, special nuclear material, and byproduct material are covered under section 116 of the Clean Air Act. Thus, any State, or political subdivision thereof, may establish standards more stringent than Federal, or where a Federal standards [sic] has not been established, may establish any standards they deem appropriate. Thus the provision would not preempt States and localities from setting and enforcing stricter air pollution standards for radiation than the Federal standards, and would not follow the holding of Northern States Power Co. v. State of Minnesota, 447 F.2d 1143 (8th Cir. 1971) aff'd 405 U.S. 1035 (1972) in the context of radioactive air pollution."

House Report No. 95-564, p. 143. Apparently more stringent standards set by States under State law, and protected under section 116, cannot be disapproved by the NRC under section 122(c)(3).

Pending §112 legislation

Several bills have been proposed to modify section 112: H.R. 4 (Dingell, drafted by EPA in 1988), S. 816 (Durenberger, Baucus, Breaux, et al), H.R. 2585 (Leland, Waxman, Molinari, et al), and title III of the President's proposal. Each of these proposals follows a two-stage process that is quite different than the court established in the Vinyl Chloride case. The first stage is the regulation of any major source of any of about 187-200 listed hazardous air pollutants. This regulation would be done on the basis of categories of industries, requiring the level of control that represents the maximum available control technology (MACT).

Conceptually, this is similar to BAT requirements for toxic pollutants under the Clean Water Act. There are minor differences among the bills as to the stringency of MACT, and as to how many categories of sources would be covered. The first categories would have MACT emission standards set within 2 years after enactment, and existing sources would have to comply within 3 years after promulgation (or about 5 years after enactment). The standard-setting process for all categories covered would cover 8 to 10 years.

The second phase in each bill involves assessing the residual risk to human health that remains after MACT standards are implemented. Under the President's proposal, if there remains an "unreasonable risk", balancing cost and technological feasibility, EPA must set additional emission standards for the industrial category to reduce that risk. H.R. 2585 would require any risk beyond 10^{-6} to be eliminated by the risk-based standards. With extensions, the deadline for this standard is 16 years after enactment for the first group of sources. S. 816 requires compliance by existing sources with a 10^{-4} standard 15 years after enactment; the 10^{-6} standard can be indefinitely postponed. Under both S. 816 and H.R. 2585, new sources must immediately meet a 10^{-6} standard, if that level of risk would remain after meeting a MACT standard. Cost and technological feasibility cannot be considered.

It is very likely EPA will interpret the risk-based standard-setting under new legislation in a manner similar to their interpretation of the Vinyl Chloride decision: if S. 816 or H.R. 2585 were enacted, EPA would use its Approaches C or D, and an unreasonable risk standard would resemble the case-by-case evaluation of Approach A with the inclusion of cost, technological feasibility, and other balancing factors

The more pertinent question is how a "best technology" MACT would be interpreted. Each bill contains language suggesting MACT has to be based on the best performers in the industrial category.

The pending bills differ in how EPA is expected to treat emission standards that are promulgated under section 112 prior to amendment. This includes the older standards such as vinyl chloride and asbestos, as well as those expected to be promulgated in the next few months (radionuclides and benzene). S. 816 "grandfathers" previously promulgated standards. H.R. 2585 continues the effectiveness of previous emission standards "until modified in accordance with [the amended section 112]", and the bill can be read to require review of all standards on a periodic basis.

The President's proposal apparently takes a more complicated approach. Prior section 112 standards remain in effect, unless modified in accordance with the amended language. This appears to be discretionary. If there is a petition for review of the emission standard pending as of the date of enactment, the regulation is considered under the old language of section 112 (the Vinyl Chloride standard). If the court remands the emission standard to EPA, EPA can then act under either the old or amended language of section 112.

This provides several choices for ANEC, in the legislative process and in weighing its reaction to the expected August '89 emission standards for radionuclides. First, ANEC will want to follow the Congressional deliberations on which risk-based standard-setting approach is selected. For power reactors this does not appear to be as critical a question. The definition of MACT could prove to be more important, particularly in deciding whether an emission standard under the old or the new section 112 is better. It is also possible the Congress will include "anti-backsliding" language to prevent any standard from being weakened.

If the readionuclides emission standard is promulgated by September 1, it is unlikely that the new amendments will be enacted within the period for seeking judicial review. If the President's proposal on "old" standards is followed, ANEC will have to evaluate its chances for succeeding on the basis of the old law. Obviously, some in Congress will be weighing EPA's decisions in the benzene and radionuclides standards in selecting the final amendments to standard-setting, as well as the manner in which the "old" standards are preserved.

Please let me know if I can provide further information or analysis.

P. T. C.

4/4/88

FEDERAL AGENCY VALUATIONS OF HUMAN LIFE

A Report to
the Administrative Conference of the United States

Clayton P. Gillette* & Thomas D. Hopkins**

April 1988

This report was prepared for the consideration of the Administrative Conference of the United States. The views expressed are those of the authors, and do not necessarily reflect those of the Conference or its committees.

I. Introduction

Regulation of health and safety hazards provides protection at a price. Using regulation to decrease the number or severity of accidents, injuries, and illnesses typically requires the expenditure of societal resources. Notwithstanding the benefits that can be conferred by these expenditures, the limited nature of available resources entails that their dedication to this purpose requires forgoing alternative uses. Thus, decisions to take advantage of an opportunity for risk reduction necessarily confronts the issue: is the reduction worth the cost? Put in the extreme, this question asks what we as a society are willing to invest in order to save lives, or -- more crudely -- what price we place on human life. As harsh or cold-blooded as this inquiry might seem, it is both a common and necessary part of government regulation of hazards.

The inevitability of this issue does not suggest, however, that all regulators will define the "value of life" equally or even similarly. Indeed, there is substantial evidence that federal agencies differ widely on life valuation questions that determine the propriety of a particular regulation. Some agencies adopt explicit valuations of life to use in determining the relative benefits of a proposed regulation, while other agencies eschew any such calculation. Even then, of course, an implicit value can be reached by computing the cost of a regulation and the number of lives that would be saved through its adoption. Our discussions with agency officials suggest that there has recently been some convergence around a figure of $1-2 million per statistical life. For instance, economists at the Consumer Product Safety Commission have employed a $1-2 million range.[1] Nevertheless, agencies have used substantially different numbers in calculating the benefits of particular regulations. For instance, EPA staff have employed figures between

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[1] See, e.g., Memorandum from Paul Rubin to L.J. Sharman, May 27, 1987.

$400,000 and $7 million.[2] The Nuclear Regulatory Commission has adopted a somewhat different approach; it evaluates the "value-impact" of proposed regulations by assigning a monetary value of $1000 per person-rem that would averted by a given proposal.[3] NRC's figure appears to translate into a very wide range of values per life -- from $4 million to $100 million -- depending on assumptions made.[4]

For those agencies that do not adopt explicit values for life, there is a similar range in implicit values that can be deduced from regulations that are proposed or adopted. For example, the Office of Management and Budget[5] has documented values per life saved in discrete rulemakings ranging as low as $70,000 (in a 1980 Consumer Product Safety Commission regulation of space heaters) and as high as $132,000,000 (in a 1979 regulation of the Food and Drug Administration banning DES in cattle feed). In another investigation of rulemakings concerning environmental carcinogens at four agencies -- Environmental Protection Agency, Consumer Product Safety Commission, Occupational Safety and Health Administration, and Food and Drug Administration -- researchers found that, at least in this important class of health regulation, we as a society tend to regulate vigorously if lives can be protected at less than $2 million per life saved, but not if costs are significantly higher.[6]

While different circumstances may justify the use of different valuations of lives, there appears to be a more troublesome divergence among agencies in the effort expended

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[2] Conversation of authors with Ralph A. Luken, Chief, Economic Studies Branch, Environmental Protection Agency.

[3] See 10 C.F.R. §50, Appendix I; Division of Risk Analysis, Office of Nuclear Regulatory Research, Nuclear Regulatory Commission, A Handbook for Value-Impact Assessment 3.15 (1983).

[4] See NRC, Analysis of a Proposed $1000 Per Man Rem Cost Effectiveness Criterion ( ).

[5] See Office of Management and Budget, Regulatory Program of the United States Government, 1987-1988 xx.

[6] Travis et al., Cancer Risk Management: A Review of 132 Federal Regulatory Decisions, 21 Environmental Science and Technology (1987).

to derive meaningful figures. Some agencies -- notably EPA[7] and the Federal Highway Administration[8] -- have commissioned extensive studies that seek to draw on and expand existing knowledge about life valuation, our research reveals less intense documentation efforts at the vast majority of agencies. Some agencies appear willing to accept a figure, notwithstanding the absence of any independent evaluation of its veracity or its application to the borrowing agency's regulatory task.[9]

Given the range of figures and methodologies employed in the valuation of human life, there is a justifiable concern that selections based on the regulator's predisposition about a proposal's desirability rather than on the merits. Certainly valuations can be set purposefully as one of several criteria guiding decision makers. For instance, Viscusi, in surveying available normative studies of life valuation, found that (depending on the particular circumstances) plausible justifications are available for values from $600,000 (where individuals place themselves voluntarily in high risk situations) to $7 million (where risks are involuntary and remote).[10] Recent reviews of valuation studies support a range of $1.6 to $8.5 million.[11] But, of course, value of life outcomes also may be a by-product of decision making that is guided by other considerations entirely. Indeed, as we shall see,

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[7] See EPA, Valuing Reductions in Risks: A Review of the Empirical Estimates -- Summary (1983).

[8] See Federal Highway Administration, Alternative Approaches to Accident Cost Concepts -- State of the Art (1984).

[9] In hearings concerning EPA's asbestos regulations, Jack Campbell, Deputy Assistant Administrator for Policy, Planning, and Evaluation at EPA, stated: "The $1 million per life saved figure is in essence an arbitrary figure in any (regulatory) analysis, and it is used basically as a baseline to judge whether there are positive or negative net benefits to society as a result of a particular action." EPA's Asbestos Regulations, Hearings Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, 99th Cong., 1st Sess., April 16, 1985, at 455.

[10] See Viscusi, The Valuation of Risks to Life and Health: Guidelines for Policy Analysis 201-02 n.5, in J. Bentkover et al., Benefits Assessment: The State of the Art (1986).

[11] Fisher, Chestnut, & Violette, The Value of Reducing Risks of Death: A Note on New Evidence (forthcoming).

some argue that such numbers are largely devoid of meaning and, in any event, repugnant or irrelevant.

Why life saving values differ across types of rulemakings and agencies, whether they should vary, and how agencies derive and utilize them comprise the focus of this report. We begin in Section II with a discussion of the Executive Orders and statutory and case law which define the parameters for agency valuation practices. Section III then turns to a broad array of issues that arise in the valuation process, including philosophical reservations about any explicit valuation efforts and more pragmatic questions concerning valuation techniques. Finally, Section IV provides our concluding observations and recommendations for improvements in agency practice.

II. Legal Bases for Agency Valuation of Human Lives.

Administrative agencies that possess statutory authority to promulgate health and safety regulations face a variety of constraints on what and how they may regulate. The most obvious and direct of these are contained in certain generic laws such as the Administrative Procedure Act[12] and in each agency's organic statute. While the generic laws are silent on life valuation matters, a number of specific statutes limit and guide agencies in ways that affect any attempt to value human life, as discussed in Section II.B. We also examine in that section an additional array of life valuation constraints appearing in judicial decisions. First, however, we review in Section II.A the tier of requirements that has emanated from the executive branch and been superimposed on the more traditional statutory and judicial constraints.

A. Overview of Executive Orders Mandating Cost/Benefit Analysis and Associated OMB Guidance

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12 5 U.S.C. §§ 551-59, 701-06, 3105, 3344, 5362, 7521.

Most statutes allow agencies considerable discretion in the design and implementation of new regulations. Such agency discretion is substantially narrower where the Congress specifically designates the regulatory action to be taken by an agency, but congressional intervention in the minutae of implementation is uncommon. In the main, Congress provides fully detailed mandates only where it lacks confidence in how an agency has proceeded (as with NHTSA's auto ignition/seat belt interlock regulation) or is likely to proceed (as with deadlines imposed to accelerate some EPA regulation). Even then, however, agencies are left with responsibility for a host of practical decisions that usually prove necessary in translating a statutory design into an implemented regulation. Thus, managing the regulatory process requires much agency judgment, often extending to basic decision criteria and priorities in addition to the unavoidable details of implementation.

When Congress delegates to an administrative agency the duty to regulate a health or safety problem, it typically is expressing its intent that the agency's specialized expertise guide regulatory action. The Congress, that is, looks to the head of the designated agency, and not to the President, for the solution to a problem. This creates a natural tension, or at least an added decision complexity, for those agencies that are subject to White House supervision (i.e., those agencies whose heads serve at the pleasure of the President). For inherent in the executive function of the Presidency is the obligation to ensure the faithful execution of the law, which unavoidably entails responsibility for agency exercise of discretion.

Recent Administrations have taken progressively increased cognizance of this responsibility. A White House managerial process has evolved to guide agency use of whatever discretion exists in the regulatory statutes. The Reagan Administration in particular has made vigorous use of the Executive order mechanism and of the 1980 Paperwork Reduction Act in managing the issuance of regulations. It has articulated a

distinctive set of regulatory principles and established a more potent central oversight process than existed previously.

The current process grew out of several years of experimentation with shifting White House review mechanisms.[13] The most noteworthy antecedent prior to 1974 was the "Quality of Life Review" process started in 1971 by the Office of Management and Budget.[14] Motivated principally by concern about rising budgetary and industrial compliance costs of new environmental regulations, OMB Director George Schultz signed memoranda directing agencies to submit significant regulatory proposals to OMB for review. In practice, this review process focused on proposals from only one agency, the Environmental Protection Agency. The process involved interagency meetings, convened by OMB, at which EPA defended its intended actions in a hostile forum dominated by staff from OMB and the Department of Commerce. This mechanism had narrow scope and dubious authority, but it continued to operate until 1977, when EPA declared that it would no longer participate.

Starting well before 1977, however, the Quality of Life Review process came to be superseded gradually by oversight mechanisms with stronger legal footholds. In 1974, President Ford signed the first of what has turned out to be a very significant series of Executive Orders on the regulatory process. As it came to be implemented, his 1974 Executive Order 11821 required that those agencies whose heads serve at the pleasure of the President prepare an Inflation Impact Statement ("IIS") for every new regulation likely to have a substantial economic effect. Although the Office of Management and Budget

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[13] The following discussion of the 1975-81 period is drawn from Hopkins, Social Policy and the Regulatory Process, A 1986 Working Paper of the Project on the Federal Social Role. See also, Baram; Cost-Benefit Analysis: An Inadequate Basis for Health, Safety, and Environmental Regulatory Decisionmaking, 8 Ecol. L. Q. 473, 502-15 (1980); OMB, supra note .

[14] See Eads & Fix, Relief or Reform? 46-50 (1980); National Academy of Public Administration, Presidential Management of Rulemaking in Regulatory Agencies 9 (1987).

approved several different criteria for agencies to use in deciding which regulations would have large enough effects to warrant an IIS, the standard most heavily relied on involved imposing aggregate compliance costs on those regulated in excess of $100 million in any single year.

The IIS was to include a full appraisal of the benefits and costs of the rule relative to those of promising alternatives, but the agency did not have to base its decisions about design or issuance of the rule on the IIS, or even use it in the decision process. An inadequate (or non-existent) IIS posed no direct legal problems, and afforded private parties no new grounds for litigation. The courts saw it as an internal managerial tool clearly within the discretion of the President to apply as he saw fit.

Essentially the IIS analysis provided contending interests added targets or support and served as a key resource for White House overseers. During its seven-year existence, the Council on Wage and Price Stability ("CWPS") served as the principal regulatory monitoring unit within the Executive Office of the President and used the IIS to shift the regulatory debate toward efficiency concerns. (The initial labels did not suggest this emphasis; indeed, both the IIS and the creation of the CWPS had reflected renewed worry about inflation.) With no powers to coerce, the CWPS' influence derived from its access to agency decision makers and its broad statutory authority[15] to issue public statements on pending rulemaking proceedings.

The efficiency perspective advocated by CWPS gradually came to be accepted as legitimate and potentially powerful. During the Ford years, CWPS prepared and publicized policy papers sharply critical of many regulatory proposals. This stimulated greater public debate and increasingly put regulators on the defensive. In response, some regulators began to take the IIS requirements much more seriously, seeking to explain more explicitly

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[15] See P.L. 93-387, §3(a)(7).

the effects of their proposals. Near the end of the Ford Administration, Executive Order 19949 changed the IIS label to Economic Impact Statement to reflect its true focus.

The incoming Carter Administration, after more than a year of debate about the CWPS program, decided to continue the CWPS with basically the same role on regulatory matters, and to create a new player, the Regulatory Analysis Review Group ("RARG"). The Office of Management and Budget monitored implementation and also participated in RARG. Chaired by the Council of Economic Advisers, the RARG provided a forum for executive branch agencies to discuss the economic analysis of 10 to 20 key regulatory proposals each year. While many agencies were RARG members, it was dominated by staff drawn from units of the Executive Office of the President who were skeptical of traditional regulation.

For major new regulations, the analysis required by President Carter's Executive Order 12044 was renamed Regulatory Analysis ("RA") and slightly recast. Each RA was to contain

> a succinct statement of the problem; a description of the major alternative ways of dealing with the problem that were considered by the agency; an analysis of the economic consequences of each of these alternatives and a detailed explanation of the reasons for choosing one alternative over the others.[16]

The Executive Order also added a number of features to regulatory oversight, including a semiannual agenda alerting the public to all nontrivial rules under development, and tighter management of the major rule analysis process. RA's were to be issued in draft form at the rule proposal stage and in final form when the rule was promulgated.

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16 Executive Order 12044, §3(b)(1).

Noteworthy by its absence from the Carter Executive Order was any reference to "benefit cost analysis," which Administration officials thought many perceived as unbalanced and anti-regulatory, in that the less readily quantifiable social benefits would be slighted by benefit-cost analysts. Yet the distinction between that mode of analysis and the "analysis of the economic consequences of . . . alternatives" required for a RA is largely one of semantics and emotions.

The Ford Executive Order had called for analysis to be performed but was silent on how if at all that analysis would be used in actual decisionmaking. The Carter Executive Order moved toward requiring some use of analysis in making decisiions, however cautiously: each agency was to select, in any manner it wished, alternative actions it found acceptable; it then was directed to adopt the least burdensome of these alternatives.

The Carter program featured extensive consultation among agencies that tried to reach consensus on the analysis and shaping of key regulatory proposals under the leadership of CEA and, to some extent, OMB. However, OMB drew narrow limits around its role in this process: "...for OMB to approve or provide appellate review of the substance of individual regulations would be inappropriate and counter to the emphasis on agency accountability in the Executive Order."[17] The consultations held under RARG auspices produced, for each of the small number of regulatory proposals reviewed, a public report that, as a consensus document, was perhaps less strident than many CWPS reports of the Ford period. But in any event such reports continued to be merely advisory.

Within weeks of President Reagan's inauguration, Executive Order 12291 made benefit-cost analysis a key determinant of agency decisions, and assigned pre-clearance responsibilities to OMB -- in both cases, to the extent permitted by law. Major regulations continue to face an economic analysis requirement, now renamed Regulatory Impact

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[17] 43 Fed. Reg. 126691.

Analysis (RIA), and OMB took over and expanded the oversight duties previously shared by CWPS and RARG, both of which were eliminated in 1981.

The Reagan regulatory principles declare that, to the extent permissible under law, regulation should satisfy two primary criteria: first, only use regulation where it will resolve a problem more effectively than would market forces, and secondly, structure regulation to maximize net benefits to society. This position, articulated initially in Executive Order 12291, has been amplified in subsequent White House documents, including most notably in the Regulatory Program of the United States Government, April 1, 1987-March 31, 1988. On the theory that one can only determine whether net benefits are maximized through the use of benefit-cost analysis, the Reagan regulatory principles constitute an endorsement of this analytical tool.

This Presidential requirement for the use of benefit/cost analysis in regulatory decisionmaking, except where precluded by statute, necessarily carries with it an understanding that those lives at stake in regulatory outcomes will be evaluated in some fashion. Otherwise, any calculation of a regulation's net benefits will exclude what often is its most fundamental objective -- lessening the risk of fatalities. An estimate of the net benefits of a health or safety regulation that takes into account factors such as property damage averted, medical costs avoided, and compliance burden imposed certainly will be misleading and incomplete unless it also includes some valuation of fatalities prevented or of life-years extended.

The Executive Order and related documentation recognize that not all effects of a regulation can be translated into a dollar metric, but they do establish a presumption that much can be accomplished in presenting more comprehensive dollar measurements of both benefits and costs. The concept of net social benefits found in the Reagan regulatory principles is a broad one. It includes any consequence of a regulation that alters the level of

material affluence or welfare. Some such consequences are difficult or impossible to measure unambiguously -- e.g., the climate for innovation -- while others can be measured by physical attributes that are difficult at best to convert into dollar terms -- e.g., miles of cleaner waterways. The message conveyed by the Reagan principles is that agencies should attempt to go further than they did previously in quantifying all such effects, whether benefits or costs, and in expressing these effects in dollar terms. The contention is that such explicitness will facilitate arriving at optimal policy decisions.

Once an agency has pushed quantification and monetization of regulatory effects as far as is practicable, the Reagan principles then require the agency to present its conclusions about net benefits in a way that will not slight those remaining effects that cannot be monetized. There of course always is a temptation for the reader of a partly numerical and partly qualitative analysis to be overly swayed by the former. Nonetheless, the current Administration's principles cannot fairly be construed as condoning disregard of qualitative effects.

As to human life, two obvious questions arise in connection with the President's regulatory principles. When a regulatory initiative is being contemplated to lessen a health or safety hazard, with what confidence can the agency estimate the number and time pattern of fatalities avoided or deferred? And what, if any, monetary value can be placed on this reduction in fatality risk? The former question is left entirely to the regulatory agency to address; the White House merely encourages the agency to go as far as it prudently can in making such estimates. The latter also is largely -- but not entirely -- delegated to the individual agencies.

As the chief player in the Presidential regulatory oversight process, OMB does not endorse any particular number as a suitable statistical value of life for agency benefit-cost analyses. And other White House participants, most notably the Vice President in his

capacity as chair of the Presidential Task Force on Regulatory Relief, have distanced themselves from placing any numerical value on human life. There are large political problems -- to say nothing of the philosophical and economic issues -- associated with appearing to assert that a human life can be reduced to a particular dollar value. Explanations that the value is established for analytical purposes and is for a statistical life (or for a measurable though small reduction in the risk of fatality) are insufficiently saleable to avert political damage.

Nonetheless, OMB has an important influence on how agencies do value life in their Regulatory Impact Analyses (the formal analysis that the Executive Order requires for every major regulatory initiative). That influence derives in part from generic guidance offered agencies by OMB on a hortatory basis and in part from the OMB regulatory clearance process. As to generic guidance, the opening sections of the Regulatory Program issued by the White House in the spring of 1987 contain considerable discussion of what OMB views to be the soundest methodology for selecting statistical values of life, as well as evaluative commentary on the range of life values implicit in several agencies regulatory decisions. That preferred methodology, discussed more fully in Section III.B of this report, is usually termed willingness-to-pay, and is based typically on labor market studies of wage variation across jobs with differing riskiness. While this procedure has not led OMB to endorse a particular value for human life, our interviews with staff of that agency indicate they they would generally accept regulations that cost out to less than $2 million per life, but would look askance at regulations that required expenditures in excess of that figure.

The regulatory clearance process is also an important avenue through which OMB influences agency valuation decisions. Under the 1981 Executive Order, virtually every regulatory proposal (from any agency subject to Executive Order jurisdiction) must be reviewed by OMB at two (or more) junctures before it takes effect. Moreover, Executive

Order 12498, issued in 1985, provides that, for all important contemplated regulations, agencies are to consult with OMB prior to beginning work on their design, and out of that consultative process emerges an annual publication of Administration-endorsed regulations under development.

Before an agency publishes a covered regulation in proposed form to obtain public comment (even those too minor to warrant inclusion in the Regulatory Program), it must secure OMB review. At this point, OMB is in a position to object to any aspect of the draft proposal, including whatever value of life the agency may be utilizing in its analysis supporting the proposal. On occasion, disagreement over this value reportedly has been sharp and has led to delay. Under certain circumstances, OMB can block an agency from proceeding until it satisfies OMB that the proposal is consistent with the President's regulatory principles. Finally, before an agency can publish any regulation in final form, it must again go to OMB for a further review round. Thus OMB has ample opportunity -- both on and off the record -- to communicate its views to the regulatory agency on the suitability of any particular value of life.

Not all health and safety regulation encounters this manner of OMB review, because not all regulatory agencies are obliged to conform to Executive Order requirements. Traditionally, the "independent" agencies, whose heads are not subject to Presidential removal, have regarded themselves as exempt from the kind of OMB review discussed above. OMB has a negligible influence on such agencies' practices in valuing life, although some have adopted analytical approaches quite consistent with the basic Executive Order (e.g., the Nuclear Regulatory Commission's internal requirements for economic analysis correspond quite closely with that established by OMB).

Nonetheless, there is one important respect in which OMB does influence regulation at independent agencies. Under the Paperwork Reduction Act of 1980, no

agency (independent or otherwise) can enforce a new regulation containing paperwork requirements (information collection elements) until it has obtained OMB concurrence. It is possible but not likely that issues touching on life valuation have important bearing on this OMB/agency interaction, which turns mainly on questions of the reasonableness of the time necessary to supply the information mandated.

B. Constraints of Statutory and Case Law

The executive branch's endorsement of cost-benefit analysis has not achieved universal acceptance within the legislative and judicial branches. Nevertheless, these branches must often wrestle with the issue of whether a particular regulatory effort is appropriate or authorized. Even if these inquiries are not answered by reference to a strict cost-benefit analysis, some consideration of the relevant adverse and positive effects of the proposed regulation would appear necessary for a rational decision. For instance, assume that we must choose between two methods of implementing a program (e.g., a program of vaccination against an anticipated epidemic), each of which would save the same number of lives, but each of which would also produce some new level of risk. The first would present a low level risk (e.g., short term non-fatal disease due to vaccination) to numerous persons. The second would produce a high level risk (death) to a very small number of persons (e.g., those with severe abreactions) and produce no adverse reactions for anyone else. Can it be said to be illogical or unethical to consider expected losses of each policy in trying to determine which one is superior? Any such process, however, at least implicitly places a value on the lives saved or expended in the decision whether or how to regulate.

The need for agencies generally to balance the positive and negative effects of a proposed regulation -- and hence to evaluate the worth of human life -- is apparent from an examination of the statutes that authorize agency intervention. Most of these statutes confer on administrators some discretion in determining whether to promulgate a particular

regulation, but constrain that discretion by reference to regulatory effects on human welfare. These constraints, however, typically are not expressed in terms of an explicit cost-benefit analysis.

In rare cases congressional standards for regulatory action are sufficiently specific that an agency need only determine whether the congressional judgment has been satisfied. Thus, a statute that requires specific agency action when a calculable threshold is passed[18] does not confer on the agency any discretion to determine whether that particular standard is reasonable, necessary, or useful. The agency need strike no calculus in which human life would be a necessary factor. Similarly, if congressional judgment required regulation as long as any threat to human life existed, computation of human life values would be unnecessary. Any threat to life would be considered too substantial, so the monetized value of benefits preserved through regulation would be irrelevant. The most celebrated instance of such a provision may be found in the Delaney Clause of the Federal Food, Drug, and Cosmetic Act.[19] The Clause prohibits the use as a food additive, animal drug, or color additive of any substance found to induce cancer in humans or animals.[20] No threshold finding is required; when it comes to cancer, the specified additives and drugs are expected to produce zero risk.

Alternatively, statutes may go so far as to require explicitly that costs and benefits of proposed agency action be compared before any regulation proceeds.[21] These

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18 See, e.g., Cotton Standards Act, 7 U.S.C. 51 - 65 (setting forth official cotton standards' names and descriptions).

19 21 U.S.C. §§301 - 92.

20 21 U.S.C. §§348(c)(3)(a), 360b(d)(1)(H), 37b(b)(5)(B). Richard Merrill suggests that the Delaney Clause is less inclusive or absolute than the debate surrounding its propriety would suggest. See Merrill, Risk-Benefit Decisionmaking by the Food and Drug Administration, 45 Geo. Wash. L. Rev. 994, 998 (1977). On the difficulty of administering such a specific standard, see Merrill, FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?, 5 Yale J. Reg. 1 (1988).

21 See, e.g., § 9(f) of Consumer Product Safety Act; § 3 (i) of FHSA; § 4(j) of FFA. The Clean Air Act, 42 U.S.C. §§7401- , requires a benefit-cost analysis for any regulation

provisions indicate congressional realization that achieving zero risk is infeasible; at some point the costs of further risk reduction will not be worth the attendant benefits. Thus, regulation depends on some comparison of the two. Since regulation in these areas returns substantial benefits to human welfare, however, a meaningful determination of relative costs and benefits requires that some value be assigned to that welfare so that it can by properly incorporated into the calculus.

More frequently, however, congressionally granted authority confers on agencies substantial discretion in the decision to regulate. This discretion may be bounded by standards such as "reasonableness" that permit, but do not require the agency to engage in some sort of comparison of costs and benefits of a proposed regulation in determining its effects on human welfare. For instance, the Federal Insecticide, Fungicide, & Rodenticide Act (FIFRA)[22] permits the Administrator of the Environmental Protection Agency to take protective action with respect to a pesticide that causes "unreasonable adverse effects" on the environment.[23] Similarly, the Atomic Energy Act[24] requires the Nuclear Regulatory Commission to ensure that production of nuclear material will provide "adequate protection" to the health and safety of the public;[25] and the Federal Highway Administration is empowered to publish "reasonable rules" for the safe operation of motor carriers, e.g., driver qualifications, maximum hours, and equipment standards.[26] The Motor Vehicle Safety Act[27] requires that motor vehicle safety standards be "practicable, "[28]

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intended to control the effectiveness of motor vehicle fuel emission control systems. See Clean Air Act §211(c)(2)(B).

22 7 U.S.C. §§136 - 136y.

23 7 U.S.C. §136d(b).

24 42 U.S.C. §§2011 -

25 42 U.S.C. 2232(a). This provision has been construed in Union of Concerned Scientists v. Nuclear Regulatory Commission, F.2d (D.C. Cir. 1987), discussed at text accompanying notes - infra.

26 49 U.S.C. §§304(a), (e).

27 15 U.S.C. §1391-

28 15 U.S.C. §1392.

a term that the Department of Transportation suggests requires consideration of both technological and economic soundness.[29]

Most of the statutes that are administered by the EPA similarly require attention to some of the elements of a cost-benefit analysis.[30] For instance, the agency interprets the statutory directive concerning primary National Ambient Air Quality Standards[31] to permit attention only to public health, and thus EPA sets these standards without consideration of analyses that evaluate costs or nonhealth benefits.[32] The agency, however, interprets the statutory mandate concerning establishment of performance standards for new stationary sources of pollution as requiring consideration of costs, but not air quality benefits. Thus, EPA sets the relevant standards after consideration of costs, cost-effectiveness, and economic impacts and not air-quality-related benefits.[33] Alternatively, EPA believes that it is permitted to consider all aspect of cost-benefit analysis in determining standards under the Uranium Mill Tailings Radiation Control Act, an amendment to the Atomic Energy Act. That broad-ranging amendment requires EPA to "consider the risk to the public health, safety, and the environment, the environmental and economic costs of applying such standards and such other factors as the Administrator determines to be appropriate."[34]

Judicial solicitude for strict agency cost-benefit analysis in the absence of an explicit legislative requirement was tested in a duet of Supreme Court cases, Industrial Union

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29 Letter of April 2, 1979, from Linda Heller Kamm, Department of Transporation,.Office of General Counsel, to Ron Lewis.

30 See Environmental Protection Agency, EPA's Use of Benefit-Cost Analysis: 1981-1986 at 3-1 - 3-7 (August 1987).

31 Clean Air Act §109(b)(1).

32 Environmental Protection Agency, sup.a note , at 3-3.

33 Id.

34 Public Law 97-415, January 4, 1983. See EPA, supra note , at 3-7. EPA may consider all aspects of cost-benefit analysis under the similarly broad language of the Toxic Substances Control Act, 15 U.S.C. §§2601 - , which permit consideration of health and environmental effects as well as economic consequences.

Department v. American Petroleum Institute[35] (the Benzene Case), and American Textile Mfrs., Inc. v. Donovan (the Cotton Dust Case).[36] In each case, the Court was considering whether standards promulgated by the Occupational Safety and Health Administration (OSHA) satisfied the statutory obligation of that agency to assure "to the extent feasible" that no employee would suffer material impairment of health or functional capacity.[37]

In the Benzene case, the Court considered whether a statutory directive that OSHA standards assure, as far as possible, that employees not be impaired by exposure to hazards precluded any cost-benefit analysis in the formulation of regulations. The agency had determined that, in the case of exposure to the carcinogen benzene, this directive required the most stringent limitation that was technologically and economically possible. Thus, cost-benefit analysis was unnecessary, if not outright prohibited. The Supreme Court, however, affirmed a determination by the Fifth Court of Appeals that some relationship between costs and benefits had to be made. While no opinion garnered a majority of the high court, a plurality did determine that the issue of cost-benefit comparison had to be deferred until the Secretary of Labor decided expressly whether issuance of a standard would be appropriate and necessary to deal with the particular health issue.

Though there were hints in the plurality and concurring opinions that cost-benefit analysis was congressionally mandated, and explicit statements in the dissent that reliance on cost-benefit was unauthorized, no final determination of the issue was made until the Cotton Dust Case. There the Court focused on the "feasibility" language of the statute and decided that that requirement displaced the obligation to undertake a cost-benefit analysis of a proposed regulation. Instead, a different, and presumably less rigorous, "feasibility"

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35 448 U.S. 607 (1980).
36 452 U.S. 490 (1981).
37 29 U.S.C. §655(b).

analysis was required. The functon of the latter procedure was to determine that implementation of a proposed standard is "capable of being done."[38]

This semantic exercise, unfortunately, does little to displace the need for some comparative consideration of the costs and benefits of a proposed regulation. Numerous safety standards can be implemented at some cost, and are thus "capable of being done" within the narrow meaning of the Supreme Court's mandate. Less certain is whether the benefits obtained by implementing any standard are worth the commensurate costs. Unless the congressional directive is to take all precautions that are technologically possible, the absence of some standard by which to determine whether marginal advances in safety are worthwhile is likely to generate either overinvestment or underinvestment in accident avoidance from a societal perspective.

Our point at present, therefore, is to suggest that the obligation to consider values for human life is not implicated only where an agency is required specifically to compare costs and benefits. Statutory provisions may require particular attention to specific regulatory effects rather than a strict analysis that sanctions only those regulations whose benefits exceed costs. The FIFRA provision referred to above, for instance, requires the Administrator to take into account the impact of proposed final action on production and price of agricultural commodities, retail food prices, and the agricultural economy.[39] Similarly, where noncarcinogens are concerned, the Food and Drug Administration is required to determine whether food additives are "safe" for their intended use, a standard that does not necessarily implicate a finding of benefits in excess of costs or require banning additives whose costs exceed marginal benefits.[40]

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[38] 452 U.S. at 509.
[39] 7 U.S.C. §136d(b).
[40] 21 U.S.C. §348(c)(3)-(4). See Merrill, supra note , at 999.

Indeed, concerns for factors that might escape a naked comparison of costs and benefits have generated statutes that mandate reliance on less quantitative variables. For instance, the Federal Mine Safety and Health Amendments Act,[41] albeit less explicit than its predecessors,[42] demonstrated concern for the safety of miners by requiring closure of mines notwithstanding that the consequent costs might exceed expected losses to miners. Nor do these nonquantitative concerns consistently demonstrate solicitude for safety. Richard Merrill recounts congressional intervention to delay FDA programs designed to reduce the risk of adverse health effects related to shellfish, presumably to satisfy industry concerns.[43] While these programs may require that certain factors on either the cost or benefit side of the calculus be ignored. insofar as they eschew any absolute benchmark by which to determine the propriety of a particular regulation they require some synthesis of costs and benefits. Effective implementation of that mandate, therefore, requires some valuation of human costs saved or lost by the decision to regulate.

Even the emerging judicial antipathy towards cost-benefit analysis does not preclude the necessity to have regulation predicated on some rational basis that includes human life valuations. This is most evident in recent decisions of the District of Columbia Court of Appeals that reflect inconsistent constructions of congressional grants of regulatory authority that affect human welfare.

In Natural Resources Defense Council v. EPA,[44] the District of Columbia Court of Appeals heard an appeal concerning standards for the emission of vinyl chloride promulgated by the Administrator of the EPA. Vinyl chlorides are carcinogens with no known threshold and a twenty-year latency period. Given the uncertainty of the hazards of

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41 30 U.S.C. §§801-78.

42 See Neely, Statutory Inhibitions to the Application of Principles of Cost/Benefit Analysis in Administrative Decision Making, 23 Duq. L. Rev. (1985).

43 See Merrill, supra note , at 1000.

44 824 F. 2d 1146 (D.C. Cir. 1987)(en banc).

a particular emissions level, the Administrator had required that emissions be reduced to the lowest level attainable by the best available control technology. The petitioner contended that the statutory basis for regulation, section 112 of the Clean Air Act,[45] precluded consideration of cost or technological feasibility. Instead, the petitioner argued, that provision, which requires emission standards be set at a level that creates "an ample margin of safety to protect the public health," permitted consideration only of health-related factors. Thus, in the face of uncertainty, the Administrator was constrained to require a zero-emissions level.

In a decision by Judge Bork, a three-judge panel of the court upheld the authority of the Administrator to withdraw proposed regulations of vinyl chlorides by relying solely on economic and technological factors.[46] Congressional delegation of discretionary authority to the Administrator, in Bork's view, permitted the delegate to select the factors that would guide the exercise of that discretion. In a subsequent en banc decision also authored by Judge Bork, however, the court created a standard for "ample margin of safety" that precluded a strict cost-benefit analysis. The court adhered to the view that safety did not require zero-risk and thus dismissed the NRDC position. But it found that the Administrator could not simply define the appropriate margin of safety by reference to what was cost-effective; the Administrator was constrained by the primacy that Congress intended be given to health effects.[47] The court characterized the EPA's position as permitting a standard that would prohibit emissions to a point where marginal costs of additional controls exceeded marginal reductions in risk to health. Thus, definitions of "safety" were not made by reference to the Administrator's expertise, scientific risk assessments, or risks to health at particular emission levels, but only to a naked comparison

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45 42 U.S.C. §7412(b)(1)(b).
46 804 F.2d 710 (D.C. Cir. 1987).
47 824 F.2d at 1163.

of "technological and cost feasibility." The court rejected any such approach.[48] While the court was willing to permit consideration of these cost and technological factors, and specifically rejected the view that a "safe" level of emissions was one that was "risk-free," the court did mandate an initial, independent judgment of safety predicated on risks to health at particular emission levels.[49] Determinations of risks to health could be based on both scientific data and non-quantifiable factors such as risks deemed "acceptable in the world in which we live."[50] The "risk to health" decision, however, could not consider cost and technological feasibility. Nevertheless, once the safety threshold had been crossed, the Administrator could address remaining uncertainties by considering those economic factors in determinations of an "ample margin" of safety.[51]

The ability to engage in an explicit cost-benefit analysis became more doubtful under the approach taken most recently by the court in Union of Concerned Scientists v. Nuclear Regulatory Commission.[52] That case concerned the authority of the Nuclear Regulatory Commission to consider economic costs when deciding whether to require safety-enhancing modifications for previously licensed nuclear power plants. The Commission had proposed a rule that would require so-called "backfits" only when their direct and indirect costs were justified by a substantial increase in protection to health and safety.[53] Rather than accept or reject economic costs as the talisman for nuclear regulation, the court attempted a Solomonic compromise: economic costs could not be considered in determining whether regulation was necessary to satisfy the statutory mandate that the

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48 824 F.2d at 1164.
49 824 F.2d at 1164.
50 824 F.2d at 1165.
51 824 F.2d at 1165 ("Once 'safety' is assured, the Administrator should be free to diminish as much of the statistically determined risk as possible by setting the standard at the lowest feasible level.").
52 824 F.2d 108 (D.C. Cir. 1987).
53 10 C.F.R. 50 .109(a)(3) (1986).

Commission provide "adequate protection" to public health and safety.[54] The Commission, however, could consider economic costs, "even to the extent of conducting strict cost-benefit analysis"[55] in establishing safety requirements beyond those necessary to meet the adequate safety requirements. Since the court understood that this interpretation meant that adequate protection was not synonymous with risk-free or absolute protection, the Commission presumably must engage in some sort of analysis of whether costs of regulation are worth incurring in order to render the level of safety "adequate." While the District of Columbia Circuit indicated that strict cost-benefit analysis is not appropriate to the task, and, indeed, has prohibited consideration of costs in the establishment of the adequate protection standard,[56] it seems logically impossible for the Commission to derive a standard of adequacy without paying some attention to the relative costs and benefits of a proposed regulation. To the extent that even"adequate protection" leaves some lives exposed, any meaningful decision concerning the desirability of a proposed regulation must implicitly, if not explicitly, value those lives relative to the cost of the proposal.

These recent cases suggest that application of cost-benefit analysis and the need for valuation of life to test the propriety of a regulatory effort are not coterminous. Even where courts have rejected the propriety of the former, they have not compelled regulations that create a "risk-free" society. The result is the need for regulations that provide "reasonable," "ample," or "adequate" levels of safety. Yet such phrases cannot be defined or applied without some reference to the relative effects of alternative policies. In a situation where human lives are put at risk, any such reference compels agencies to decide whether proposed standards will save sufficient lives to justify the commensurate expenditure. That justification may be predicated on considerations additional to technological or cost feasibility. But at some point, presumably most individuals in society would cease

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54 42 U.S.C. 2232(a).

55 F.2d at .

56 Id. at (3d para. before conclusion of opinion)

investing in safety. It is the derivation of that point that ultimately drives the quest for some valuation of life.

III. Issues in the Valuation of Human Life

A. Introduction

As we noted at the outset, our purpose in this report is to examine the processes through which government, implicitly or explicitly, values human life for purposes of regulation. Stating our purpose in this way, however, necessarily accepts the propriety of the effort at valuation and seeks only to refine it. Such a strategy threatens to ignore an important and cogent response to the entire effort at valuation, i.e., that any attempt to quantify the value of human life is inherently inappropriate, not because of the difficulty of the task or the intangibility of various factors that must be considered, but because the very process of quantification ignores and violates the sanctity of human life.

In its broadest formulation, the opposition to quantifying human life is based on the assertion that human life has a "sacred" value that cannot be reflected in monetized or quantified terms.[57] Douglas MacLean, the primary proponent of this view, means by this phrase that we adhere to certain ritualistic beliefs and practices in a manner that expresses "the special value of human life in our culture."[58] By so doing, we signal the community that saving lives has merit that exceeds even a precisely computed value. Any attempt to quantify human value is inconsistent with the symbols and rituals that we use to signal life's special meaning within the society.

Alternatively, commentators suggest that the very process of attempting to quantify the value of human life diminishes that value by suggesting that human life is exchangeable

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57 MacLean, Social Values and the Distribution of Risk, in D. MacLean, Values at Risk 85-93 (1986) (hereinafter, Social Values); MacLean, Comparing Values (manuscript).
58 MacLean, Social Values, supra note 35, at 86.

in a manner akin to commodities. Regardless of our ability to consider a commodity as a substitute for human life (one can, after all, compare apples and oranges), some suggest that there may be reasons not to admit our lack of uniqueness.[59] We may, for instance, wish to signal to ourselves the intrinsic worth of certain aspects of life in order to indicate that they are not reducible to monetized values. Such arguments have been put forward to explain a desire to invest in clean air beyond an optimal point.[60] We are, in this argument, entitled to "breathing rights" without making any purchase or engaging in conduct that gives rise to a claim of desert. Similarly, we may wish to signal similar entitlements to a "safe" life, a signal that would be subject to substantial static should we admit openly that life can be balanced against other resources. Such an admission necessarily dehumanizes the subject, and reifies the intangibles of life by placing them on a parallel with commodities subject to market transactions.

Finally, there is a concern that the very process of quantification alters the conclusions that one reaches about the value of human life and thus violates the precepts of neutrality that allegedly underlie any concerted effort to address the issue. For instance, some argue that attempts to quantify the value of individual lives necessarily treats individuals separate and apart from the communities in which they live and "reinforces self-interest as a correct or worthy index of value."[61]

Notwithstanding the cogency of these remarks, we proceed, somewhat unabashed, to analyze efforts to value human life. Our failure to be convinced by the above arguments is based largely on the following responses. First, as a pragmatic matter, it is clear that -- even if we reject the assignment of explicit values -- we as a society constantly engage in

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59 See, e.g., Solow, Defending Cost/Benefit Analysis: Replies to Steven Kelman, 5 Regulation 2 (May/June 1981).
60 Tribe, Policy Science at 88-89.
61 Swartzman, Sources of Controversy, in Cost-Benefit Analysis and Environmental Regulations: Politics, Ethics, and Methods 72 (1982).

the implicit valuation of human life. When we create new technologies that are risk producing, whether they be new machines or drugs to combat disease, we know that the benefits of those technologies carry some degree of cost. Accidents in the production of those technologies, abreactions in consumers, and foreseeable injuries that will result from the negligence of users all reveal that these advances are not risk-free. Nevertheless, we proceed because we believe that even risky technologies may be (net) risk reducing, i.e., they may eliminate a greater quantum of risk than they create. [Huber] Even if they do not displace greater risks to human life, they may possess other compensating features, e.g., convenience, that offset the risks they pose. Thus, our decision to proceed in the face of known risks reveals that we believe those risks that remain are "worth taking." To the extent that those risks involve threats to human life, we implicitly concur that the value of risks reduced exceed the value of the lives lost. When we (a term that does not necessarily implicate governmental agencies although it has increasingly come to connote them) decide to regulate certain activities or not to regulate others, we are implicitly determining that the costs of regulation do or do not exceed the value of lives saved as a result of regulation.

Second, and related to the first, our implicit decisions about human life may be susceptible to some level of quantification. Presumably, we would desire to make the tradeoff between lives and other resources as accurately as possible. If that is the case, failure to attempt any such effort at quantification causes us to miss opportunities to generate either too much or too little risk. While one may respond that such a belief ignores the lessons derived from the theory of the second best -- that in the absence of the ability to quantify all variables, it is not necessarily second best to quantify as many as possible -- that theory suggests only that second best solutions may not be preferable to inaction, not that they cannot be preferable.

Third, while there may be something invidious in the quantification process, e.g., in reifying human life or in risking the omission of nonquantifiable variables from the

ultimate decision, we do not believe these effects to be inexorable. The effort at determining whether regulations are "worthwhile" in terms of cost per life saved is not necessarily dehumanizing if decision makers are ultimately attentive to both the valuation process and its limits. The desire to consider these factors may help to determine the identity of the ultimate decision maker. For instance, one may consider courts rather than agencies to be more receptive to nonquantifiable variables.[62]

Finally, at the very least, efforts at quantification provide regulators with a common metric and thus permit both regulators and those to whom they are accountable with some measure of the consistency of regulatory action. If one agency refuses to propose regulations on the theory that they will be too costly at a rate of $X while another agency promulgates regulations that will cost $2X per life saved, those who participate in the regulatory process have a comparative basis for inquiring into the propriety of regulatory action. Similarly, Paul Rubin has suggested that explicit valuations may enhance regulatory goals of maximizing benefits to consumers for the level of spending that society is willing to invest in safety. Rubin suggests if an agency with a fixed budget can spend $20,000,000 on safety in a given year and can select either a method of safety that saves lives at a cost of $1 million per life or a method that saves lives at a cost of $2 million per life, explicit recognition of these values will increase total lives saved (by concentrating all resources into the first method) over random selection of the alternatives (e.g., by investing $10 million in the first method and $10 million in the second).[63]

Our review of federal agency practices reflects these concerns. Not all agencies accept the view that quantification of human life is an appropriate governmental enterprise. The most forthright rejection can be found at the National Highway Traffic Safety

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62 See Gillette & Krier, Risk and Hubris (forthcoming).

63 See Memorandum from Paul Rubin to Consumer Product Safety Commission, Feb. 25, 1986.

Administration ("NHTSA"), despite its location with a department, the Department of Transportation, whose regulatory procedures call for quantitative benefits analysis (DOT's "Guidance for Regulatory Evaluations"). NHTSA strongly objects to full benefits analysis of fatality avoidance: "It should be noted that this Agency does not consider it appropriate to place a dollar value on human life or injuries."[64] NHTSA believes that it is useful to quantify the clearly monetizable consequences of accidents, particularly property damage, lost productivity, and medical and legal costs. It acknowledges that these constitute only a subset of all benefits from accident reduction, but it chooses not to value other benefits explicitly. It merely states the number of lives or injuries at risk.

Other agencies appear to use explicit values sporadically. For instance, memoranda from the Consumer Product Safety Commission reveal use of a $1-2 million valuation of life in discussions concerning regulation of disposable cigarette lighters and bunk beds.[65] Other memoranda reveal no explicit valuation of life, but only elaboration of the per life costs that would have to be incurred in a regulatory effort. For instance, discussions concerning a particular regulation assume a variety of accident avoidance measures with varying costs. On the assumptions stated in the discussion, these cost estimates range from $2.6 million to $312.5 million per life saved. While the discussion does not incorporate any assignment of value for life, one would infer that proceeding with the more expensive regulatory effort reflects a judgment that life is worth that much, while failure to utilize a more expensive alternative that would save more lives reflects a judgment that the expenditure is not justified, i.e., that saving the marginal lives is simply not worth the necessary added expenditure.

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64 NHTSA, The Economic Cost to Society of Motor Vehicle Accidents 1-2, DOT HS 806342, January 1983.

65 See Memo from Dale Ray to Paul Rubin, May 5, 1987 (cigarette lighters); Memo from Dale Ray to David Thorne, September 23, 1987 (bunk beds).

None of the above suggests that valuation is a task void of computational, ethical, or legal difficulties. Indeed, extraordinary difficulties in any of the above may render the results of any computation so suspect as to undermine the propriety of the effort. In the remainder of this report, we will investigate the extent of those difficulties. At this point we only conclude that those inquiries should not be precluded by any threshold aversion to quantification.

Nevertheless, there may be situations in which monetization of human life makes little sense, given the computational and ethical difficulties associated with the project. For instance, where other factors of uncertainty are so dominant as to dwarf the potential scope of values for life, paying much attention to the latter factor seems unproductive. Assume, for instance, that a particular regulation is anticipated to lessen a risk, but available scientific evidence is too weak to permit reliable quantification of the risk reduction, e.g., the evidence permits only a range of probable reduction at somewhere between 1:10,000 and 1:1,000,000. In this situation, application of a precise figure for human life to diffuse estimates of risk reduction will do little to resolve the question of the proposed regulation's cost-effectiveness. Thus, little is to be gained by evaluating the value of lives saved in this context alone. Short of such situations, however, we believe that the valuation process theoretically generates a more informed and effective quantum of risk-reducing regulations.

B. Problems of Quantification.

If we knew with certainty the costs of regulation and the number of lives that could be saved by implementing a given proposal, quantifying the value of individual human lives would be unnecessary to achieve the most cost-effective level of regulation. Instead, we could determine an appropriate "live-saving budget" and adopt regulations seriatim, starting with the one that saved the most lives per dollar, until the funds allocated to live-saving were exhausted. Unfortunately, this happy scenario is unlikely to materialize as

long as implementation costs are uncertain and are calculated differently among agencies. Indeed, even if we could impose some uniform calculus on agencies, we might fear that its wooden application would fail to recognize that we do not treat all deaths equally. Avoidance of cancer deaths might warrant expenditure of more resources than avoidance of an equal number of deaths in automobile accidents, simply because we dread the painful and extended deterioration that accompanies the former. Thus, some mechanism that reflects our treatment of different deaths should augment initial rankings of the "most effective" regulations.

On its face, a procedure that values both the costs and benefits of regulation would appear appropriate. Any such procedure would ideally quantify all the consequences of implementing a particular level of life saving. Thus, it would permit a differentiated view of the effects of regulations not possible if all deaths are treated equally. Applying such a mode of analysis to the area of health and safety regulation, however, creates an additional set of difficulties. Cost-benefit analysis poses relatively little difficulty where components of the calculus constitute commodities that are exchanged at competitively negotiated prices in established markets or that are otherwise susceptible to socially acceptable quantification.[66] Thus, a decision by a rational, self-interested, profit-maximizing entity to invest in a device that will cost $X and will replace current production modes that cost $X+1 seems relatively straightforward. The difficulty that pervades cost-benefit analysis involving human life is the absence of any reliable "market price" that can be used as a standard for fair exchange. In the absence of a market, some alternative means must be found for establishing the upper bound of what we are willing to invest in order to save a human life. Human life has value not simply because of the ability of humans to produce

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[66] See Baram, Cost-Benefit Analysis: An Inadequate Basis for Health, Safety, and Environmental Regulatory Decisionmaking, 8 Ecol. L. Q. 377, 387 (1980); Zeckhauser, Measuring Risks and Benefits of Food Safety Decisions, 38 Vand. L. Rev. 539, 544 (1985).

goods that do have market values (a function that does permit some measure of human life, i.e., human capital[67]) but also because life generates additional values less susceptible to quantification. Within this category lie such factors as "community," "friendship," and the "hedonic" value of life.

In this section we consider the primary approaches that federal agencies have adopted to address this difficult issue of quantification. We trace the history of their use and the relevant methodology. Finally, we consider some of the critiques of each approach and attempt to reach some conclusions about whether those critiques are so substantial as to undermine any utility that the quantification effort might otherwise possess.

1. Initial Efforts; Human Capital Reasoning.

However one might choose to characterize its overall impact, loss of life does have the quite tangible consequence of lessened production and consumption of goods and services. This fact forms the basis for one longstanding approach to the valuation of life, which is often referred to as the human capital approach. Premature destruction of a productive machine would deprive society of whatever output it was capable of yielding over its remaining years of usefulness. The human capital approach relies on an analogy between such productive physical capital and the economic productivity of people and equates the value of life with the dollar value of goods that can be produced by the person whose life is at risk. In particular, one can estimate the amount of future income that will be forgone if a person's productive effort comes to an early end due to death. This provides one measure of the value of a life.

The human capital concept is quite useful for a number of policy questions. For example, consider the issue of setting priorities for types of capital spending to stimulate

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67 See discussion at text accompanying notes - infra.

economic growth. Not recognizing that human productivity can be increased by outlays on training could lead to an overemphasis on acquiring physical capital. Similarly, if one were concerned with the issue of optimal investment of life insurance to assure a given income stream in the event of one's death, a human capital approach would be appropriate.[68] Moreover, the concept has practical appeal -- say in debating the merit of further education -- both at the level of the identifiable individual and for large group decisions.

But in the context of fatality-risk reduction, human capital thinking can at best provide incomplete answers as it considers only losses in national income and fails to consider other losses that impute value to life, including the at-risk individual's own desire to live.[69] Eliminating productive human effort has a significance that includes but transcends measurable output effects. Mishan reviews some of the early efforts to base life valuation on expected future earnings, and finds them flawed conceptually.[70] As an indication of their limitations, Mishan notes the commonly articulated but rarely satisfied need to buttress estimates of forgone earnings with values for consequences such as pain and suffering and family bereavement. As appealing as this might seem, it moves the analyst well beyond readily available and verifiable data sources. Other than jury verdicts relating to pain and suffering, there exists little basis to assess the amount of money that would compensate for suffering and bereavement.

On the other hand, restricting our measure to forgone earnings, while assuredly facilitating objective estimations, carries with it certain ethically troublesome implications. Any approach based on lost earnings will place low valuations on the lives of those who are neither wage earners nor producers of goods or services in developed markets, for

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68 See L. Dublin & A. Lotka, The Money Value of a Man (1930); M. Jones-Lee, The Value of Life: An Economic Analysis 21-22 (1976); Linnerooth, The Value of Human Life: A Review of the Models, 17 Econ. Inquiry 52, n.1 (1979).
69 Id. at 53.
70 E. Mishan, Cost-Benefit Analysis 320-45 (3d ed. 1982).

example, retirees and homemakers (although markets have developed for some homemaking functions, e.g., child care and cooking). This can lead to any number of objectionable policy outcomes. Suppose two alternative strategies for hazard reduction would avert the same number of total deaths, but one would disproportionately benefit retirees (which could happen if the region benefiting most from one strategy had an older population). An application of a human capital approach to benefits valuation would make the latter strategy look less warranted. Yet few would find this an acceptable basis on which to make a choice between the two alternatives.[71]

Whether as a matter of social policy we would prefer the alternative that protects a more youthful subgroup may be an unavoidable decision. But using a monetization process that neglects everything but future individual productivity would not clarify or inform the decision; it would merely mask its real implications with the appearance of quantitative objectivity. The underinclusiveness of the human capital approach would be exacerbated if it systematically excluded or undervalued particular components of a "valuable" life. The approach appears to suffer from just such a defect insofar as it provides no mechanism (such as shadow prices) for losses that are unrelated to production or market forces and that are, therefore, difficult to quantify. Examples include pain and suffering, psychic harms, and dread of catastrophic or involuntary risks.

Advocates of cost-benefit analysis are not oblivious to the concerns about nonquantifiable variables. Their response, however, seems largely to take two forms. One is urging those who employ cost-benefit analysis to be sensitive to additional variables not

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71 This is not to suggest that alternative methodologies are free of such skews. For instance, in a willingness-to-pay approach, discussed infra, it might be that younger people would be willing to pay more than older people to avoid risks of fatality. See Arthur, The Economics of Risks to Life, 71 Am. Econ. Rev. 54 (1981).

considered in the quantification process.[72] The other is to separate formally the process of quantification from decision making, or risk assessment from risk management.[73]

Unfortunately, neglect at quantification stages of what Lawrence Tribe early described as "soft variables" may preclude their subsequent reintroduction into the policy decision.[74] Decision makers who would ideally reconcile quantifiable data and more ephemeral considerations may be driven by the "hardness" of the former and the abstraction of the latter to rely solely on the data. Quantifiable variables give the decision maker something concrete to point to in order to justify a particular decision and creates an impression of scientific impartiality and certainty. Simultaneously, reliance on quantifiable variables, such as expected earnings over a given number of years in a particular occupation, avoids the need to consider other values that compete with economic utility. Thus, Thomas Nagel writes that attempts to resolve conflicts by reference to a single general system, e.g., a quantitative one, bars as "irrelevant or empty all considerations that cannot be brought within the scope of that system."[75]

Indeed, to some extent, legal doctrine invites regulators to ignore certain "soft variables," notwithstanding the very real costs that they involve. For instance, the Supreme Court has determined that the National Environmental Policy Act of 1969[76] did not require the Nuclear Regulatory Commission to evaluate psychological effects on nearby

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72 See Arthur, supra note , at .

73 See Ruckelshaus, Risk in a Free Society. On this view, risk assessment is a neutral process, informed solely by pure and objective scientific investigation and measurement. Risk managers, on the other hand, filter the objective data provided by risk assessment through their political roles to determine the proper social policy. Commentators have recognized the difficulty of separating these functions. Uncertainties inherent in the scientific investigation, degrees of confidence in results, and ranges of probability that risks will materialize all raise risk assessment issues that can only be resolved through incorporating the values of the investigator. See Latin, Good Science, Bad Regulation, and Toxic Risk Assessment, 5 Yale J. Reg. 89 (1988).

74 Tribe, Policy Science: Analysis or Ideology, 2 Phil. & Pub. Aff. 66 (1972).

75 Nagel, Fragmentation of Value 137, in T. Nagel, Mortal Questions (198).

76 42 U.S.C. §§ 4321-

residents prior to approving operation of the Three Mile Island nuclear power plant after a major incident at that facility.[77] Although the Court recognized the existence of such effects, it determined that the statute addressed solely effects of conduct on the physical environment rather than to perceptions of risk.[78]

There is some evidence that soft variables or those external to the general system do not get completely ignored. Social or political values may cause regulators to resist decisions that appear mandated by reference to quantified values alone. Some commentators have explained this phenomenon by reference to the existence of "trumps" in the risk management process.[79] But given the politics of regulation, intervention of trumps would seem fortuitous rather than systematic. Their introduction may depend on whether the affected population has sufficient political power to persuade legislators or regulators of the need or irrelevance of regulation. Political capacity may turn on such issues as discreteness of injury and diffusion of the affected population rather than on any merit-based criterion. Thus we are left with a general concern that quantifiable variables take on a life of their own and override other, less quantifiable concerns. Leonard and Zeckhauser similarly suggest that these effects are inevitable.[80] They take comfort, however, in the fact that the skews are not unidirectional. They state:

> But this limitation is itself ethically neutral unless it can be shown that the quantifiable considerations systematically push decisions in a particular direction. In other words, it is not sufficient to argue that cost-benefit analysis does not handle perfectly what is obviously a very hard task;

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[77] Metropolitan Edison Co. v. People Against Nuclear Energy, 460 U.S. 766 (1983).
[78] The Court did suggest that risk perception raises an issue of whether a particular technology should be utilized. 460 U.S. at 776. The Court held, however, that any such issue was not implicated in the statutory issue before it.
[79] Leonard & Zeckhauser, Cost-Benefit Analysis Applied to Risks: Its Philosophy and Legitimacy 31-42, in D. MacLean, Values at Risk (1986).
[80] Id. at 44-45.

> rather, its detractors must show that its errors are systematically unjust or inefficient -- for example, that it frequently helps the rich at the expense of the poor, or that the environment is systematically disadvantaged to the benefit of industry. We have not seen any carefully researched evidence to support such assertions.[81]

Three problems exist with this reasoning. First, those errors that exist do not cancel each other out. If two decisions are made, one of which adversely affects the rich and the other which adversely affects the poor, there is no reason to believe that the same parties will be affected or that the inefficient or unfair effects of each decision will precisely (or remotely) offset the other. Second, it is unclear why the burden of proof is on the dissenters. Why not place it on those who desire to use cost-benefit rather than on those who oppose it? Given uncertainty about the validity of an analytical tool, placement of the burden of proof may be determinative of outcome. While there may well be substantial ethical and pragmatic justifications for using some form of cost-benefit analysis, it is unclear why they need not be explicitly proffered by those who would employ such methods. Third, the discussion implies that the process of risk assessment is readily separable from that of risk management. On this view, risk assessors are apolitical technocrats who generate quantitative data based on value-neutral processes and deliver it in pristine fashion to political decision makers.[82] These risk managers then filter the information through a political process that responds to political trumps. Unfortunately, this ideal remains distant from the actual process of risk assessment. As we shall discuss later in this report, political and scientific values are inherent in the decisions of risk assessors to employ certain test procedures, to present data in certain forms, and to select or ignore certain hypotheses. Thus, what risk managers receive, and what they can

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81 Id. at 44.

82 See Rowe, Government Regulation of Societal Risks 45 G.W.L. Rev. 944 (1977).

therefore subject to political trumps, has already been filtered through a rigorous value system.

Additionally, human capital approaches may incorporate invidious social effects that reflect lower productive values for persons kept from highly productive jobs for reasons having little to do with ability to perform those jobs. For instance, assume that a segment of the population is the subject of employment discrimination. Thus, members of this segment either cannot obtain certain jobs or can obtain them only by accepting a wage less than that of similar workers outside the discriminated group. Assume further that this group is found to be particularly susceptible to a certain disease or injury (e.g., sickle-cell anemia for blacks, Tay-Sachs disease for Jews, breast cancer for women). Finally, assu ne that these risks could be avoided at a cost of $X. If $X is weighted against the human capital costs of the at-risk group, without taking into account the effects of invidious discrimination on the productive capacity of the group, then the cost effectiveness of the curative will be grossly understated.[83] One variant of the human capital approach common in highway policy circles until 1984 employed an even more offensive assumption that the value attached to a life (reflecting future wages) should be lessened by that individual's future consumption.[84] Then having in the analyzed group some elderly people who consume but do not work would have the bizarre effect of actually lowering the calculated benefits of reduced fatality risks.

Notwithstanding these critiques, human capital approaches provide the benefit of administrative ease.[85] Actuarial tables provide justifiable estimates of life expectancy and projected earnings for those placed at risk. In addition, the ethical concerns have not been as strong as to preclude the widespread use of human capital approaches in a variety of

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83 See Rice & Cooper, The Economic Value of Human Life, 57 Am. J. Pub. Health 1954, 1960 ((1967).
84 Miller, Accident Costs and Safety Policy Decisions 2.
85 See Arthur, supra note , at .

situations. Perhaps most commonly, expected earnings remains the primary component of compensation in wrongful death actions in the judicial system.

2. Toward Willingness-to-Pay Approaches.

The inherent limitations on the utility of human capital approaches have led policy makers to seek more acceptable alternatives to the valuation of life. Following a 1968 article by Thomas Schelling,[86] researchers have seized on a theory of valuing life by determining what individuals would be willing to pay in order to reduce the probability of death or what they would accept to have that probability increased. This method, known as the willingness-to-pay approach, assumes that one can get a sense of how people will value a small reduction in the risk of accidental death by examining their behavior in the marketplace. To the extent that it is successful, the willingness-to-pay approach avoids many of the obstacles associated with human capital valuations. For instance, willingness-to-pay assumes that people internalize the "soft variables" excluded from human capital and express a monetized value for those factors, e.g., concern for pain, dread of particular types of death, in their marketplace choices for goods, services, and occupation.

As illustrated in EPA's 1983 review of the literature, if individuals voluntarily take precautionary steps costing each one $10 and if this reduces the probability of death in a particular situation from 10 in a million to 5 in a million, then the implied value of life can be computed as $10/.000005 = $2 million.[87] The data most commonly relied on for these purposes are drawn from labor market studies of the wage premium observed in comparisons of jobs varying in their fatality risks (using multivariate regression analysis to isolate the influence of risk). However, other data sources also have been tapped. For example, some studies have drawn inferences from consumer choices ranging from seat

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[86] Schelling, The Life You Save May Be Your Own, reprinted in T. Schelling, Choice and Consequence 113 (1984).
[87] EPA, Valuing Reductions in Risk 1-2.

belt usage to willingness to take risks through speeding or not using crosswalks (sometimes called hedonic approaches to willingness to pay). Others have relied on surveys of consumer attitudes toward actions that lessen risk (sometimes referred to as contingent valuation approaches to willingness-to-pay).

Numerous willingness-to-pay studies have been completed. Viscusi concludes that for typical risk situations, a range of about $2-3 million can be defended, as can higher values for involuntary risk situations. Miller finds credible values of $1.4 million plus or minus 40%.[88] The Environmental Protection Agency's own conclusions about value of life are more guarded, suggesting a range of $400,000 to $7 million in 1982 dollars.[89] Elsewhere, however, EPA staff have suggested $1.5 to $2 million as a reasonable norm,[90] and an EPA staff draft recently identifies $1.6 million to $8.5 million as supportable.[91]

3. The Limits of Willingness-to-Pay.

Economic reasoning suggests that willingness-to-pay is a superior mechanism for valuing human life. A person's willingness to pay to avoid a risk presumably incorporates that individual's valuation of factors that are difficult to measure independently, and thus this approach necessarily considers nonquantifiable variables that cost-benefit analysis is typically accused of ignoring. For instance, consider an individual who could purchase either of two gasoline lawn mowers that are identical in all respects other than that one of them contained a one-gallon tank of gas and the other contained a two-gallon tank. If a consumer were willing to pay $10 more for the latter, we could infer that the convenience of less frequent fillups was worth $10 to that consumer. Thus, we could quantify a soft variable, convenience, that is easily overlooked and for which there is no market for

88 Miller, supra note , at 15.
89 EPA, supra note , at 6-3.
90 Luken, National Research Council at 13.
91 See note supra.

exchange from which to derive an explicit value. Similarly, willingness-to-pay may reveal values for aspects of safety not otherwise readily quantifiable.

This advantage of the willingness-to-pay approach, however, should not be understood as a panacea for the problem of the immeasurable. The limitations of willingness-to-pay fall into four general categories. The first is mobility. Information extracted from labor studies must assume jobs and wage rates that are accepted volitionally, without exogenous constraints. In fact, however, jobs and wage rates may be accepted under conditions in which alternatives are restricted by mobility or cultural considerations that limit the horizons of workers.

The second problem is informational. Willingness-to-pay serves as a useful measure of value only where the expressed preferences are based on knowledge that accurately reflects both the payer's probability of death and the losses that will occur should that risk materialize. The need for such information suggests that willingness-to-pay approaches may be of limited utility where actors are ignorant of or systematically miscalculate the relevant variables. Because this information may be difficult to obtain, investment in search may be rational only where decisions that incorporate the information occur with some regularity. In short, repeat players may be willing to obtain the relevant information, while single- or infrequent-play players may not. For instance, individuals may want to seek out risk information in decisions to engage in particular occupations, since those risks will be confronted continuously during the course of employment. Thus, Viscusi and O'Connor report that chemical workers perceive occupational risks that do not deviate significantly from objective measures.[92] A consumer considering which hedge trimmer to purchase, however, may avoid inquiries into relative risk among models as the

92 Viscusi & O'Connor, Adaptive Responses to Chemical Labeling: Are Workers Bayesian Decision Makers?, 74 Am. Econ. Rev. 942 (1984).

search for that information will seem too costly given the infrequent use the consumer expects to make of the product.

Nevertheless, repeat players such as employees may be subject to other biases that cause them to misapprehend the level of risk to which they are exposed and thus to misstate what they would be willing to pay or accept to reduce that risk. The literature of cognitive dissonance suggests that those who find themselves in risky situations without an easy way of escape are prone to deny the existence of the risk. Any alternate view would require the actor to recognize that he or she has made a choice that is inconsistent with the actor's preference for thinking well of himself or herself, e.g., made a decision about employment that is personally safe.[93] Note that this phenomenon is likely where actors discover risks of choices previously made; known risks of future projects can be factored into the the decision whether to undertake the project. Nevertheless, where workers become aware of risks that attend the jobs they have held, or become aware of risk-reducing technology that they could employ at their jobs, they may fail to adjust their behavior to take into account the risks or the new technology.[94] Similarly, they are likely to understate their willingness to pay to avoid those risks, as such payments would implicitly recognize the hazards of their occupation. Thus, willingness-to-pay evidence obtained from such individuals cannot be equated with rational decisions about the value one places on one's life.

The third problem of willingness-to-pay is the presence of externalities. Even an accurately computed willingness-to-pay amount predicated on all available information will reflect only those losses that the payer seeks to avoid. Thus, externally imposed losses, e.g., losses suffered by those other than the payer and his or her immediate family, may not be reflected in the calculation at all. Assume, for instance, that an individual is willing

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93 See Akerlof & Dickens, The Economic Consequences of Cognitive Dissonance, 72 Am. Econ. Rev. 307, 308 (1982).
94 Id. at 316.

to take a slightly more risky job, but only if it pays a somewhat higher wage. The wage differential will reflect the value to the worker of the change in risk of death. If the worker were to fall victim to an accident of the type that made the job risky, however, all the consequent losses might not be internalized by the worker. While the potential loss shared by close relatives and friends might be reflected in the worker's decision, and the loss felt by the employer might be reflected in market transactions with consumers of the goods produced by the employer, the loss felt by others -- co-workers, more distant relatives and acquaintances -- would not be reflected in the worker's calculations at all. Nevertheless, these individuals could feel real and substantial losses. Thus, the willingness-to-pay approach, while generally rendering a higher value for life than the human capital approach, will systematically undervalue life.[95]

Infrequency of exposure suggests the fourth problem of the willingness-to-pay approach: cognitive limits on the information utilized in the underlying calculus. For the most part, the risk of death related to products or to occupations is quite small. Infrequency does not affect either the desirability of considering the risk or the technical ability to calculate its value.[96] Even with small risks, expected losses can be derived by multiplying the probability times the loss that will occur should the risk materialize.

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[95] We are not here concerned with a second type of external effect, i.e,. the failure of wage rates to reflect risks of death that workers may impose on others. For instance, the Environmental Protection Agency's analysis of vinyl chloride, discussed above, was based on additional cancers that would be suffered by residents living near plants rather than by workers. It is unlikely that even fully informed employees not at risk would demand wages that reflected risks imposed on non-workers. To the extent that those at risk are not consumers of the risky product, consumer prices are similarly unlikely to reflect amounts that those at risk would be willing to pay to avoid a hazard. Nevertheless, those at risk would presumably be willing to pay something to reduce their risk, if only there were a market in which they could effect the transaction. In a recent article, Viscusi, Magat, & Forrest, Altruistic and Private Valuations of Risk Reduction, 7 J. Pol. Anal. & Management 227 (1988), the authors relate evidence that individuals are willing to act altruistically to reduce risks to others. The level of altruism, however, is limited and dissipates with the geographical distance between the actor and the beneficiary.

[96] On the error of ignoring remote probabilities, see D. Parfit, Reasons and Persons 73-75 (1986).

Expected utility theory suggests that rational decision making would be guided by these precepts.[97] Developments in cognitive theory, however, suggest that individuals seriously deviate from results dictated by expected utility theory where probabilities are small.[98] These errors may at times generate underassessment of a risky event's occurrence and at times may generate overassessment. If the risk is not salient to the actor, as may be the case where injuries materialize only after significant latency periods, then actors are unlikely fully to consider the risk in determining what wage to demand in return for the exposure. This may particularly be a problem where risks are infinitesimal, notwithstanding that they create substantial losses should they, in fact, materialize.

If, on the other hand, the actor can readily call to mind examples of a risk's materialization, the actor is likely to demand compensation in excess of the expected loss of the risk. In this latter situation, known in cognitive theory as the "availability" heuristic,[99] the actor may designate recent or easily recalled events as common, notwithstanding that their appearance does not affect their statistical infrequency. Whether risks are recalled with too much or too little frequency, it can be anticipated that the expressed willingness of individuals to pay to avoid the risk will fail to reflect the actual probability of the risk and will thus deviate from what those same individuals would have been willing to pay had they been cognizant of more accurate probabilities. Here again, there is some evidence that those with frequent exposure to risks or information about risks ("experts") may more accurately predict the probability that a remote risk will materialize. Thus, willingness-to-

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97 See K. Arrow, Essays in the Theory of Risk-Bearing 52-68 (1974).

98 See, e.g., Kahneman & Tversky, Prospect Theory: An Analysis of Decision Under Risk, 47 Econometrica 263 (1979). But see Brookshire, Thayer, Tschirart & Schulze, A Test of the Expected Utility Model: Evidence from Earthquake Risks, 93 J. Pol. Econ. 369 (1985) (property values in California reflect reaction to low-probability risks consistent with expected utility model).

99 Tversky and Kahneman, Judgment Under Uncertainty: Heuristics and Biases, 185 Science 1124, 1127 (1974); Taylor, The Availability Bias in Social Perception and Interaction 190, in D. Kahneman, P. Slovic & A. Tversky, Judgment Under Uncertainty: Heuristics and Biases (1982). For applications to legal theory, see Robinson, Schwartz, Gillette.

pay evidence may be more credible when derived from experts than from those whose data base is suspect.[100]

Finally, preferences for particular actions may depend on the context in which a decision arises or the manner in which a particular decision is framed. The acceptability of social policies may even vary depending on whether the results are classified in terms of lives lost or lives saved, notwithstanding that the social consequences are identical in each case.[101] Similarly, individuals may vary in their expressions of willingness-to-pay depending on whether their purchase is considered as a gain or a loss. From an economic perspective, these values should be identical. But there is evidence that individuals have assymetric attitudes towards gains and losses.[102] Thus, an abutter of a pristine lake might demand more of a potential polluter than the same person would spend to clean the lake if it were already polluted.

Some risks present both the externalities problem and the informational problem. For instance, the Nuclear Regulatory Commission must determine whether proposed measures are necessary to ensure "adequate protection" of human health from the risks created by nuclear power plants.[103] A willingness-to-pay basis for measuring the cost effectiveness of a proposed improvement would confront two difficulties. First, those affected by a nuclear accident will not necessarily be limited to "expert" workers or others

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100 See Slovic, Fischhoff, & Lichtenstein.

101 Tversky & Kahneman, The Framing of Decisions and the Psychology of Choice, 211 Science 453 (1981). In this work, the authors relate an experiment in the consequences of framing in which a group of students were asked to choose between two alternative programs to combat an expected outbreak of a disease from which 600 people would die unless one alternative program was adopted. The first alternative was stated as one that would save 200 people while the second alternative was stated as one that caused a 1/3 probability of saving 600 people and a 2/3 probability of saving no one. Seventy two percent of the group chose the first alternative. Another group was presented with the same threat and the following alternatives: one that would cause 400 deaths and one that created a 1/3 probability that nobody would die and a 2/3 probability that 600 people would die. Seventy-eight percent of this group selected the second alternative.

102 Kelman, 52 S. Cal. L. Rev. 669; Hoffman & Spitzer, 53 S. Cal. L. Rev. 1187

103 42 U.S.C. §2232(a).

who have information about the risk they face. Thus the low probability of such an accident is likely to distort the relationship between expressed willingness-to-pay and the actual risk. Second, any such accident will likely generate substantial external effects that will not be included in willingness-to-pay evidence. The person placed at risk will not necessarily discriminate between the consequences of death in a nuclear holocaust and death in an automobile accident. Either case poses similar consequences for friends, relatives, and others who depend on the victim. The former risk, however, constitutes a catastrophe that threatens additional injuries through the loss of community, monumental stresses on medical and social facilities, and the possibility of substantial economic dislocations in the larger society.[104] While some have suggested that catastrophe poses no greater costs than the aggregate of an equivalent number of individual losses,[105] there is some evidence that total losses are greater in the former case.[106]

4. Ex Ante/Ex Post Losses and the Use of Jury Awards.

Our discussion to this point has underscored on particular feature of hazard rulemaking -- its focus on statistical lives. That is to say, these rules recognize that a particular activity puts life at risk; based on historical experience, some projections can reliably be made concerning the number of lives so risked. Regulation, however, takes place ex ante, before any of the people actually placed at risk can be identified individually. Although ex ante regulation may be able to narrow the group from which the ultimate victims will come, e.g., workers in a particular industry or consumers of particular products, we cannot more precisely predict who will fall victim to society's desire to

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104 See Spangler, A Critique of Methods in the Quantification of Risks, Costs and Benefits in the Societal Choice of Energy Options 119, 125, in 10 Annals of Nuclear Energy (1983).

105 See Nichols and Zeckhauser, supra note , at 23.

106 See, e.g., Erikson, Everything in its Path; Rabin.

pursue the activity, notwithstanding its inevitable human cost. It is within this context that regulators assign values to life and consider the offsetting benefits.

Once the risk materializes, however, we typically are able to identify the individual victim. At this point, a particular application of the "soft variables" discussed above comes into play. Once we must make a decision ex post whether to save an individual life, we do not withdraw to a naked statistical analysis of the cost effectiveness of the effort. Certainly, our attitude is not, "if the risk was not worth saving prior to its materialization, it is not worth saving now." Instead, we appear willing to invest almost limitless resources in saving identifiable individuals who, from an ex ante perspective, were not worth saving from exposure to risk. Readily available examples include miners trapped in mines that might have been made safer (at a cost earlier deemed unwarranted), earthquake victims buried under the rubble of buildings (previously considered safe enough), or children trapped in well (theretofore considered not worth plugging). Numerous commentators have suggested that the kinds of regulatory calculations that generate safety and health standards have no applicability to these ex post cases.[107] We seem not only to recognize the "sacred value" of human life when it is made so salient. We may also be moved by some sense of equity to attempt a rescue the cost of which exceeds the ex ante statistical value of the victim. Having rejected (at least implicitly) precautionary action as too costly, we subsequently have a particular threatened victim on our hands. Once we know who must pay the cost of conferring the benefits (namely, avoiding costs of ex ante reduction of hazards) on the rest of us, it seems appropriate to reduce the burden to that threatened victim, especially when we can do so without losing all the benefits that we have captured by imposing the obligation to sacrifice on someone. It may well be for these reasons that

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107 See Calabresi & Bobbit, Tragic Choices; Mishan; Schelling, The Life You Save May Be Your Own; Sagoff, Sense and Sentiment in Occupational Safety and Health Programs, 179, 183, in D. Nelkin (ed.), The Language of Risk: Conflicting Perspectives on Occupational Health (1985).

the Environmental Protection Agency, in its thorough 1983 survey of risk reduction valuation approaches, states that: (a)lthough there is not a clear consensus in the literature, the arguments for the use of ex ante, unidentified risk valuations in policy evaluation are persuasive."[108]

This ex ante/ex post distinction suggests why jury verdicts and settlements in wrongful death cases might be an inappropriate basis for regulatory life valuations. Those awards focus on the particular earnings and family situation of a known individual, for quite plausible reasons. It is commonplace in these proceedings for evidence on income loss to figure importantly in outcomes. Yet certain factors imply that juries would use their substantial discretion, especially where they may consider pain and suffering, to assign high values to life. Juries in such cases will be determining damages only after a finding of liability, of wrongdoing by a defendant. It is conceivable that, faced with a negligent or otherwise blameworthy actor, juries will tend towards overcompensation as a punitive measure.

In addition, juries are not repeat players; they look only at the effects of a particular case. Each jury that considers damages may fail to consider the cumulative effects of overcompensation in the aggregate of cases. Thus, total or average jury awards is likely to represent an example of the "tragedy of the commons" phenomenon in which individual action -- while relatively harmless in isolation -- can accumulate to produce major social dislocations.

Interestingly, while these biases suggest that jury verdicts will produce ex post life valuations that are "too high," existing research indicates that verdicts are uniformly below the generally accepted willingness-to-pay figures. Machol states:

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108 EPA, Valuing Reductions in Risks: A Review of the Empirical Estimates at 5-2. Much the same point is made in OMB, supra note , at xix-xxii.

> All such methods come out with values under one million dollars per life. In the case of settlements by insurance companies in major aircraft accidents, the average 10 years ago was under $200,000 and is now several times as large, though still less than one million dollars.[109]

Viscusi reports that: "The average bodily injury payment for fatalities in product liability cases is about $212,000 (1982 dollars) . . . ."[110] Finally, Miller found that "the average jury award for wrongful death . . . has risen to about $1,000,000."[111] Nevertheless, Miller believes that as the willingness-to-pay approach becomes more firmly established in the regulatory area, it will have the indirect effect of driving up jury awards in wrongful death cases, substantially narrowing currently observable valuation discrepancies.[112]

Values derived for wrongful death purposes are not frequently utilized now in regulatory settings, but they nevertheless continue to attract some regulatory attention. In its current guidance (issued in 1981) for valuing life, the Federal Aviation Administration noted approvingly that, while the FAA valuation methodology is not a human capital one, the value it yields "approximates the average 1979 judicial settlement of $503,000, after making an allowance for inflation."[113] Moreover, vestiges of human capital reasoning linger on in some regulatory areas, mainly at the National Highway Traffic Safety Administration according to Miller.[114] But on the whole, human capital valuation in regulatory situations has lost whatever adherents, e.g., OSHA, it formerly had.

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109 Machol, How Much Safety?, 16 Interfaces 4 (Nov./Dec. 1986).
110 Viscusi, in Bentkover at 202.
111 Miller, Accident Costs and Safety Policy Decisions unpublished papers, January 12, 1986 at 5.as well as Federal Highway Administration, Alternative Approaches to Accident Cost Concepts: State of the Art.
112 Id.
113 FAA, Economic Values for Evaluation of FAA Investment and Regulatory Programs 27.
114 Miller, supra note, at Table 1.

III. Discounting -- A Hybrid Philosophical and Economic Issue

1. Introduction.

The decision to regulate a suspected health or safety hazard represents a judgment that some mandated change in behavior or circumstance will lessen the risk of illness or accident. The decreased risk constitutes a social benefit, valuation of which constitutes the central concern of this report. The mandated change typically imposes burdens on those required to comply with the regulation. (If it did not, i.e., if the benefits of the risk reducing measures could be captured by those required to take them, presumably they would do so voluntarily.) These benefits and burdens, however, may occupy very different temporal frames. The benefits of regulation often will not be realized until a substantial period of time after their costs have been incurred. This is particularly the case where benefits take the form of avoiding injuries or illnesses characterized by long latency periods. For instance, in reviewing a proposed rulemaking concerning coke ovens, OMB assumed that cancers would typically not materialize for seven years after the exposure that would be avoided through regulation. If one defines the "injury" that regulation addresses as the manifestation of the cancer rather than the initial exposure, there is a significant temporal gap between the period in which the costs necessary to avoid the exposure are incurred and the point at which benefits of injury avoidance materialize. In cases of substantial latency periods, e.g., storage of nuclear waste where current regulations may prevent harms from materializing in 10,000 years,[115] the benefits of current regulations may be conferred on those who have little relationship to the individuals who incur the attendant costs.

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115 See Murauskas & Shelly, Local Political Responses to Nuclear Waste Disposal, Cities 157 (May 1986).

This temporal disparity of costs and benefits raises issues of both philosophical and economic importance. These issues center on the use of "discounting" to enhance the comparability of regulatory options. Discounting attempts to factor into any regulatory analysis the assumption that dollars invested in regulation presumably would otherwise have been invested in productive ventures with a positive rate of return. Thus, during the period between imposition of costs and realization of benefits, the dollars invested in regulation bear an opportunity cost equivalent equal to the productive value they would have generated through an alternative investment. As an economic matter, any comparison between the costs and benefits of a particular regulation should place these effects on a common basis by referring to their values at the same point in time. Discounting accomplishes that task by reducing the expected benefits to their present value or increasing the value of current costs to the period when benefits will be realized.

A simple example may illustrate the point. Adoption of one regulatory alternative may impose $10 million in compliance costs this year and none thereafter, while a second imposes $5 million this year and $5.5 million in two years. If both yield much the same payoff in social benefits (e.g., either measure would prevent 10 deaths in 10 years), how do we decide between the two. To say that the second alternative is $500,000 more costsly ignores the fact that deferral lightens any burden, because interest can be earned until the cost is imposed. Discounting provides a sounder basis for comparison, as it takes into account the forgone earnings that the first alternative entails. We need "only" know the applicable interest rate to complete the analysis.

Obviously, discounting can have substantial impact on the relative merits of a proposed regulation. For instance, in the coke oven example cited above, OMB estimated that the proposed regulations would cost approximately $2.2 million per life saved. These savings, however, would not be realized, under OMB calculations, for approximately seven years. Assuming an interest rate of 10%, the value of a current expenditure of $2.2

million per life doubles to $4.4 million over that seven year period. Thus, if one were to assume that a statistical life were worth approximately $2 million, the regulation might appear reasonable under a regime that compared undiscounted costs and benefits, but not once discounting entered the picture.

Alternatively, one may reduce (discount) future benefits to their present value to equate temporally costs and benefits. Thus, if a life worth $2 million will only be saved seven years hence, its discounted value today (again assuming a 10% interest rate) will be worth only $1 million. Thus, a regulation that requires current expenditures in excess of $1 million per expected life saved would not be worth implementing on a pure cost effectiveness rationale. While this procedure may crudely be referred to as "discounting lives," it may more euphemistically be considered a comparison of the benefits of regulation with the benefits forgone by not investing the same dollars in some alternative enterprise. As a matter of economics, consideration of these opportunities is appropriate, as they constitute a loss of welfare from rendering the benefits of an investment unavailable for immediate consumption or reinvestment.[116]

2. The Arguments Against Discounting.

Notwithstanding the economic logic of discounting, the procedure has met with considerable philosophical debate. To some extent, the temporal divergence of those who benefit from injury avoidance and those who pay for it suggest that discounting may be necessary to reduce intergenerational inequities. As latency periods increase, the question of discounting raises the issue of the extent to which we owe obligations to future generations. Should full costs of injury avoidance be incurred by the present generation while benefits are realized only in the future, those future individuals who benefit from current investment in safety will bear none of the commensurate burden. Simultaneously,

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116 See Baumol, On the Social Rate of Discount, 58 Am. Econ. Rev. 788 (1968).

injury avoidance costs borne by the present generation will constitute forgone opportunities for current consumption.

For the most part, however, the philosophical debate reflects a different view of intergenerational justice. For instance, some commentators contend that since the question of when one exists is purely a matter of fortuity, discounting benefits to justify current consumption at the expense of future generations accords to the latter an insufficient level of respect.[117] Implicit in this view is the (debatable) view that future generations will share the preferences of the current generation. Thus, it is anticipated that they will value the same amenities of life that are currently cherished. Should preferences change in some unexpected way, we would be faced with the extraordinary difficulty of comparing the worth of intertemporal preferences. Assume, for instance, that future generations value wilderness areas less highly than the current generation does. If that change were to materialize, future generations would look askance at current decisions to forgo technological advances in order to preserve natural settings for posterity.

Putting to one side the difficulties of changed preferences, discounting raises serious issues of the relative importance of succeeding generations. Derek Parfit has argued, for instance, that applying a social discount rate of x percent per year tends to ignore future events as "morally trivial."[118] Parfit postulates a scenario in which nuclear waste causes one billion deaths in 500 years. At a discount rate of only 5%, those deaths

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117 The debate about this attitude is evidenced in a dialogue between a geologist who wishes to mine in the Cascade Mountains and a conservationist who wishes to preserve them, as recounted in J. McPhee, Encounters with the Archdruid: Narratives About a Conservationist and Three of His Natural Enemies 74 (1971):

> "The future can take care of itself," Park said. "I don't condone waste, but I am not willing to penalize present people. I say they're penalized if they don't have enough copper. Dave says they're penalized if they don't have enough wilderness."

Implicit in this statement is the important lesson that all courses of action impose costs. The issue then, is not cost avoidance, but cost optimization.

118 See D. Parfit, supra note , at 357.

are equivalent to a single death today. Thus, if we would not be willing to expend the resources necessary to avoid one death today, discounting suggests that we should be similarly unwilling to spend that sum, even though the benefit would instead be the certain saving of one billion deaths in 500 years. For Parfit, discounting in this manner suggests that the moral significance of these future deaths has declined, a conclusion he deems unjustifiable.

Parfit concludes that the opportunity cost explanation for discounting does not justify the use of the procedure. He posits a case in which benefits would be consumed, rather than reinvested, e.g., the natural beauty of the countryside that would be destroyed by construction of a proposed airport.[119] In Parfit's view, future generations do not receive any increased value from a reinvestment of the current generation's appreciation of the countryside. Thus, the future's enjoyment of the view cannot be discounted to reflect any present value.

This is not to say that Parfit believes that future benefits must always be weighed against current costs as if the two were contemporaneous. Instead, he argues that:

> conclusions that are established by such (opportunity cost) calculations could be re-expressed in a temporally neutral way. When describing the effects of future policies, economists could state what future benefits and costs there would be, at different times, in a way that used no discount rate. The arguments that appeal to opportunity costs could be stated in those terms.[120]

Parfit's suggestion is somewhat confusing. It is unclear whether he is permitting decision makers to consider at all the issue of <u>when</u> the costs and benefits of a policy will

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119 Id. at 483.
120 Id. at 484.

materialize. Further, his conception of a "temporally neutral" decision ignores the fact that while discounting favors present benefits over future ones, failure to discount does just the opposite. "Neutrality" in this situation seems rather fictitious. At a minimum, however, Parfit seems concerned that formal calculations of a discount rate and current valuations of future benefits will interfere with, rather than assist, intuitive judgments concerning alternative policies. Even here, though, intuitions are not unidirectional. Substantial writing suggests that we have obligations to those with whom we are in a special relationship that exceeds our obligations to strangers.[121] As a legal matter, some special relationships trigger obligations not present to the public at large.[122] The temporal extension of this view would hold that we have obligations to those who currently exist that do not necessarily extend to those yet to be born.

In a vein similar to Parfit, Peter Railton has argued that discounting produces perverse effects insofar as it favors policies that produce short-term benefits while imposing long-term costs.[123] Railton's argument is a direct attack on those who, apart from discounting, contend that it is sensible to impose costs, e.g., environmental harms, on future generations because they are likely to possess technological advances necessary to bearing those costs. Railton argues instead that caution is appropriate when considering future effects -- particularly in the environmental area -- because "(i)t is . . . almost always easier to do than to undo ecological damage."

Railton attempts to demonstrate the perversity of discounting by postulating two policies, A and B. The former will save 8 "present" lives while causing 12 "surplus" deaths in 15 years. The latter has only future effects: it will save the lives of 14, and cause the death of 12, both in 15 years. Railton suggests that discounting would favor the former

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121 See Anderson essay at 58; MacLean draft at 12; Nagel.
122 Cases.
123 See Railton, The Search for a Single Metric (unpublished manuscript 1987).

policy, notwithstanding that it causes more "actual" deaths than it saves, because (assuming a discount rate in which money doubles every 15 years) the 8 current lives have a dollar equivalent of 16 lives when the costs materialize. (Railton's argument is couched largely in terms of the propriety of monetizing human life, an approach that he implies necessarily entails some use of human capital evaluations. As we find that approach inappropriate, but unnecessary, we couch his argument in more generic terms of numbers of lives). He seconds Parfit's view that discounting provides little basis for deferring adverse effects that have no economic value and, thus, cannot appreciate: "the gain in happiness to a family that does not lose a beloved member in, say 1987, will not compound at a social rate of interest to become an amount of well-being large enough to offset the bereavement of two families, each of whom loses a beloved member in 2002."[124]

The lesson learned from this critique is not that discounting is always inappropriate. Both Parfit and Railton suggest that discounting may be useful, as when there exist predictable technological improvements that will render future generations better able to deal with costs while still enjoying benefits conferred by the present. Rather, the appeal of the critique lies in its implicit rejection of a unitary conception of societal assets. Some assets increase in value over time and are thus susceptible to discounting. Others, however, may be so idiosyncratic, irreplaceable, or external to market transactions that they are less vulnerable to the arguments (compounding interest and opportunity costs) that underlie discounting. The important regulatory implication, therefore, is that a uniform approach to the issue of discounting may not be suitable; some analysis will first be needed of the types of future costs and benefits and their susceptibility to intertemporal comparisons.[125]

3. OMB Discounting Guidance and Agency Practice.

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[124] Id. at 37.

[125] See recent Public Choice piece re: effect of discounting on intergenerational equity.

In 1972, the Office of Management and Budget issued Circular No. A-94 to establish a common discount rate for use throughout government, except where statutes prescribed alternative rates. OMB selected a rate of 10%, which remains unchanged, as "an estimate of the average rate of return on private investment, before taxes and after inflation".[126]

While much discussion has ensued over the years about the suitability of this rate, a topic we take up in the next section, OMB has continued to urge use of the 10% rate in agency analyses of both the costs and benefits of regulations, as well as of other agency programs. However, since 1981, OMB has taken the position that any agency should feel free to supplement use of the 10% rate with analysis showing the sensitivity of the outcomes to selection of any other rates the agency thinks applicable.[127]

Moreover, in the current edition of the Regulatory Program of the United States,[128] OMB's discussion of discounting practices and objectives calls attention in non-judgmental fashion to cases in which agencies have relied on rates other than 10%, and OMB is silent on whether use of that figure continues to be desirable. Indeed, in our discussions OMB staff indicated that, in light of work done by Lind and others, 10% is not always the best choice.

Whatever the particular discount rate selected, OMB has argued consistently that the same rate should be applied to benefits and to costs. This normally involves computing the present values of each (although OMB points out that alternatively agencies can annualize the benefit and cost streams over the same time frame).[129] Nonetheless, agencies not

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126 Circular No. A-94 at 4.
127 See OMB's Interim Regulatory Impact Analysis Guidance.
128 See note supra at xxi.
129 Id. at xxii.

infrequently depart from this practice, declining to apply discounting to future benefits at all, or using a lower discount rate for benefits.

The Regulatory Program cites two OSHA rulemakings (for asbestos and ethylene oxide) where the agency applied a 10% discount rate to costs but did not discount benefits at all, and another EPA rulemaking (for lead phasedown) where discounting occurred at a three percent rate.[130] By contrast, EPA, in its December 1986 analysis of drinking water lead risks, used a five percent discount rate for benefits from reducing lead in drinking water, while adhering to the 10% rate for costs.[131] At NHTSA, the preferred discount rate is seven percent,[132] although its parent Department of Transportation suggests that all parts of the department should be complying with the OMB prescribed rate.[133] Actual discounting practices are indeed diverse.

4. Choosing the Discount Rate.

As noted in earlier sections, discounting may not always be suitable in evaluating fatality reduction benefits. But where discounting is desirable, the question remains of how best to choose the rate. Little agreement exists about the proper number or even about the correct methodology for finding the number. Under these circumstances, sensitivity analysis is particularly inviting. The idea is to show how much the results would differ by switching to alternative discount rates. Then, if the regulation looks appealing for a range of discount rates, it matters little which rate is optimal, and the discount rate choice can be side-stepped.

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130 Id. at xvii.
131 EPA, Reducing Lead in Drinking Water: A Benefit Analysis, III-58, IV-49.
132 The Economic Cost to Society of Motor Vehicle Accidents at V-4.
133 See DOT, Guidance for Regulatory Evaluations: A Handbook for DOT Benefit-Cost Analysis at 17.

One obvious starting point for discount rate choice is OMB's current guidance. As noted above, OMB based its choice on the rate of return available on private investment. The logic is that a government project (or mandated expenditure for regulatory compliance) draws funds away from private investment projects, depriving society of the related productive activity. The pre-tax rate of return then is relevant, because society also experiences a loss of tax revenues if the capital investment is not made. Thus the discount rate is chosen to reflect the real opportunity cost of capital, and as such a 10% rate is not unreasonable. Indeed, some have suggested a rate anywhere in the range of 10 to 25% could be justified.[134]

However, the costs of regulation may take various forms, forgone capital investment being only one. In particular, the costs may show up as reduced consumption (through higher consumer product prices). Then a different conceptual framework is needed, and much work has been done in recent years to develop a suitable one.[135] To the extent that the compliance cost takes the form of reduced consumption, the regulation should be evaluated in terms of how people value a loss of present consumption. This we can accomplish by identifying the interest rate level high enough to induce people to postpone consumption, i.e., to save. While one can debate the precise number for this interest rate, often termed the "social rate of time preference," certainly the range is considerably lower than that for capital rates of return.[136]

The most promising discounting framework now appears to be one which in essence combines these two approaches, recognizing that both investment and consumption may decline near-term when regulation is imposed. The intent is to identify the portion of

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134 R. Tresch, Public Finance: A Normative Theory.

135 See Bradford, Constraints on Government Investment Opportunities and the Choice of the Discount Rate, Am. Econ. Rev. 887 (1975); Lind, Discounting for Time and Risk in Energy Policy (1982).

136 Tresch puts the range at 3 to 6 percent for the social rate. See .

compliance cost that does displace private investment and then to translate that displacement into a corresponding forgone future stream of consumption -- consumption that will not take place because the capital investment necessary to generate it never took place. These "consumption-equivalent" costs of the regulation thencan be added to the compliance costs that do not come at the expense of investment (that is, costs born by consumers right from the start). All costs thus can be portrayed as lost consumption, some now and some later. The final step then is to utilize the social rate of time preference as the discount rate in computing the present value of this stream of future effects.[137]

This falls short of providing a firm answer to the question of "What number?," in part because the most satisfactory approach conceptually (the framework just discussed) is not easy to apply empirically. But most would agree that 10% is too high a rate.

Recommendations

The foregoing discussion leads us to recommend a series of measures for agency regulations that affect human life. Our recommendations are predicated on the belief that the uncertainty underlying valuations of human life provide agencies with substantial discretion in justifying decisions to implement or reject proposed regulations based on factors only tangentially related to the relative benefits that would be conferred through regulation. We are not suggesting that agencies have failed to adopt more precise measures that would improve the quality of their life valuations. To the contrary, we recognize that given the embryonic state of knowledge on this issue, both methodologies and results are likely to vary across agencies. In this environment, however, we believe it would be

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137 Fuller discussions of this approach appear in Lind, supra note ; Staiger & Richardson, A Discounting Framework for Regulatory Impact Analysis, 18 Policy Sciences 33; EPA, Guidelines for Performing Regulatory Impact Analysis, Appendix C.That the same rate should be applied to benefits as to costs is discussed in DOT, 1 Methods for Economic Assessment of Transportation Industry Regulations III-17.

useful for agencies to take measures that would reveal publicly the processes through which they have determined the valuation of life incorporated in policy decisions. In this way, agency practice can be measured against developments in the valuation area and evaluated for consistency with other agencies and other regulations in the same agency. Toward this end, we recommend the following procedures.

1. Regulations that are adopted on the justification that they will save lives should state an explicit valuation utilized, or should disclose the value per statistical life implicit in that determination. Such a procedure will provide useful clarification and exposition of the unavoidable tradeoffs involved in regulating hazards and assist in drawing attention to those hazards where further protection may be feasible at acceptable cost. This is not to say that decisions about relative costs and benefits of a proposed regulation cannot be trumped by other variables. We believe, however, that the explicit values used by an agency is a relevant datum to be used by political decision makers in determining whether to employ those trumps. Exceptions to this principal might exist where empirical information about either the regulation's costs or benefits is highly conjectural or where the benefits include a variety on non-market improvements where benefits are not obvious, e.g., decreased non-fatal illness or aesthetic gains. In such cases, efforts to characterize accurately the imprecision of the valuation process may minimize the perception of substantial uncertainty.

2. We endorse the trend we have observed toward agency acceptance of willingness-to-pay methodology in placing value on human life, but with fuller regard for the limitations of that approach. We believe that this approach provides the most inclusive analysis currently available for evaluating the beenfits derived from regulatory reduction of fatalities. Nevertheless, we recognize that these procedures are still in their infancy and that the precise methodology varies among researchers. Additionally, we believe that there remain substantial limitations on the ability of even the most complete willingness-to-pay

study to incorporate all the variables that affect social valuations of human life. We recommend, therefore, that any valuation based on willingness-to-pay be accompanied by a statement of variables that the agency believes to have been slighted or omitted from consideration but that would affect (positively or negatively) the explicit values derived. The agency also should explain how it takes account of any such additional factors.

3. OMB'S Circular A-94 concerning the use of a discount rate should be revised to reflect learning on the subject since the time of its promulgation. We do not endorse the adoption of a specific discount rate. Rather, we recommend that a revised Circular articulate the various methods by which a discount rate can be derived and the scope of subjects to which it can be applied. However agencies choose to discount costs and beneftis, they should clearly and fully disclose what rates they are using, the methodology that generated those rates, and the sensitivity of outcomes to the particular rates applied.

4. While uniform practices in the life valuation area may not be warranted (because of the diversity of hazard situations, as well as the inconclusive nature of much of the empirical information on which decisions are based), there is justification for greater interchange of information among agencies on how decisions are made and utilized in this contentious area. Thus, we recommend the creation of a central clearing house for research on valuation issues. To this end, we suggest that OMB expand and regularize its discussion of agency practices, initiated in the 1987-88 volume of the annual Regulatory Program.