White Paper on Risk Harmonization

U.S. Nuclear Regulatory Commission
U.S. Environmental Protection Agency

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1.0 INTRODUCTION

1.1 Statement of the Problem

Authority for protection of members of the public from exposure to radioactive materials was divided in 1970 between the newly-created Environmental Protection Agency (EPA) and the former Atomic Energy Commission (AEC). The Reorganization Plan (No. 3 of 1970, Sec. 3, para. 6) through which EPA was created provided that, henceforth, EPA would set generally applicable environmental standards and that AEC would implement and enforce those standards[1].

Over subsequent years, EPA and NRC have undertaken a number of regulatory initiatives that affect activities licensed or otherwise regulated by the Nuclear Regulatory Commission[2]. In the course of developing these initiatives, substantial disagreements have arisen between the two agencies over (1) the respective roles for EPA and NRC in the regulation of NRC-licensed facilities[3], (2) the benefit of these various initiatives, and (3) the initiatives' relative timing and priority. Furthermore, disagreements have occurred over the underlying bases and approaches used to develop specific standards.

In addition, the enactment of a series of environmental statutes that address hazardous materials (in most cases including radioactive materials) has created the potential for conflicting approaches to environmental protection. These difficulties were focussed when, under the Clean Air Act Amendments of 1977 (CAA), emissions to air of Atomic Energy Act materials became covered under the CAA as hazardous air pollutants, and EPA's

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[1] The President's transmittal of the Reorganization put it as follows: "The AEC is now responsible for establishing environmental radiation standards and emission limits for radioactivity. Those standards have been based largely on broad guidelines recommended by the Federal Radiation Council (FRC). The AEC's authority to set standards for the protection of the general environment from radioactive material would be transferred to the EPA The functions of the FRC would also be transferred [to the EPA]. AEC would retain responsibility for the implementation and enforcement of radiation standards through its licensing authority."

[2] NRC and the Department of Energy are successors to the AEC.

[3] As the term "NRC-licensed" is used throughout this document, it also includes facilities licensed by Agreement States pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

responsibility was expanded to include not only establishment of standards, but also their enforcement[4].

Recognizing the need to assure consistency and avoid unnecessary duplication in Federal regulation of radioactive material, NRC and EPA signed a Memorandum of Understanding (MOU) in March 1992. The MOU provides a formal mechanism for agency cooperation on issues relating to environmental regulation of radionuclides from NRC-licensed facilities. It also commits the agencies to "...actively explore ways to harmonize risk goals and ... [to] cooperate in developing a mutually agreeable approach to risk assessment methodologies for radionuclides."

In this paper, EPA and NRC jointly examine the similarities and differences in their approaches to assessing and managing risks from radioactive materials.

1.2 Background

In 1946, the Atomic Energy Commission (AEC) was created by Congress and given virtually exclusive jurisdiction for regulating all aspects of the use of radioactive materials associated with nuclear fission, namely: source, special nuclear, and byproduct materials[6]. Even the states were preempted in the exercise of their authority to protect health and safety (10 CFR Part 8.4).[7] The comprehensive authority of the AEC under the Atomic Energy Act (AEA) was established early, before widespread use of radioactive materials occurred, and provides broad latitude for implementation.

In contrast, the Congress enacted legislation for Federal control of hazardous chemicals, beginning in the 1970's, only after environmental and health problems resulted in demands for government action, and Congress was often specific in setting forth how national objectives were to be achieved. Responsibility for the regulations governing those controls is vested in EPA and the States under a series of major environmental statutes, which include the CAA; the Federal Water Pollution Control Act (FWPCA); the Toxic Substances Control Act (TSCA); the Safe Drinking Water Act (SDWA); the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); and the Resource Conservation and Recovery Act (RCRA), among others.

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[4] Under the CAA, EPA must implement and enforce its standards governing radioactive air emissions at NRC licensee sites, as well as establish them, unless EPA makes a finding, under amendments to the CAA enacted in 1990, that NRC's regulatory program for such sites provides an ample margin of safety to protect the public health . At the time of writing of this paper, EPA is in the process of reaching such a finding, based on contemplated changes in NRC's regulations.

[6] For definitions and the general body of NRC regulations regarding these materials, see 10 CFR Parts 40, 70, and 30, respectively.

[7] The AEA was amended in 1959 to authorize the NRC to provide the states with authority over radioactive materials under certain circumstances. See S. 274 of the AEA

The AEC's responsibility for regulation of radioactive materials was changed in 1970. That year, responsibility to establish generally applicable environmental standards for AEC sites was transferred to the newly-formed EPA and the AEC was charged to implement and enforce those standards. In addition, the responsibility to provide overall guidance to all Federal agencies on radiation protection standards and in the establishment and execution of programs of cooperation with the states was transferred from the former Federal Radiation Council to EPA.

After the establishment of EPA in 1970, the AEC, and later NRC, continued to exercise its standards function in parallel with EPA's exercise of its authority. In the early to mid-1970s, the agencies attempted to refine their division of responsibilities[7]. During this period, environmental legislation continued to exclude radioactive materials regulated under the AEA (e.g., RCRA). With the 1977 amendments to the CAA, Congress significantly departed from the general concept of a single Federal agency with implementing and enforcement jurisdiction over AEA materials. Congress directed EPA to make a finding as to the carcinogenicity of radionuclides, and to regulate them under the Clean Air Act if this finding were positive.[8] EPA, which was already charged to promulgate National Emission Standards for Hazardous Air Pollutants (NESHAPS), listed radionuclides as a hazardous air pollutant under section 112 of the CAA. Thus, through the CAA, EPA became responsible for implementing and enforcing these standards at NRC licensee sites. In addition, the CAA permits the States to promulgate more restrictive standards. Subsequently, Congress also gave EPA responsibility to establish standards for radioactive materials under several other statutes (e.g., Uranium Mill Tailings Radiation Control Act (UMTRCA), CERCLA, and Waste Isolation Pilot Plant Land Withdrawal Act (WIPPLWA)). Under these last two statutes, EPA was also given responsibility for standards implementation.

There are three areas of concern that arise as a result of the statutory authorities and distribution of responsibilities described above. The first two involve the regulation of radioactive materials only; they are 1) the establishment of inconsistent standards for protection of members of the public and the environment, and 2) the overlapping

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[7] In 1973, AEC turned to the Office of Management and Budget (OMB) to resolve which agency should have the responsibility for issuing standards to define permissible limits on radioactivity that may be emitted from facilities in the nuclear power industry. On December 7, 1973, OMB issued a memorandum to the Administrator of EPA and the Chairman of AEC, stating, in part, that AEC should continue issuing uranium fuel cycle standards, taking into account comments from all sources, including EPA, and that EPA should continue to have responsibility for setting standards "...for the total amount of radiation in the general environment from all facilities combined in the uranium fuel cycle.. ". EPA set such standards in 1977 (40 CFR Part 190), which NRC has incorporated into its regulations.

[8] The Clean Air Act also directed EPA and NRC to cooperate to minimize implementation difficulties.

implementation and enforcement of those standards at individual licensee sites. The third area of concern is: (3) the inconsistency of regulation of chemical carcinogens and radioactive materials. Because these two classes of carcinogenic substances are not differentiated by the majority of environmental statutes, and EPA's risk management under these statutes is strongly driven by policy established for carcinogenic chemicals, the findings of this paper deal with the precedents that exist in those programs, as well as those for conventional radiation protection programs.

Differing agency objectives, priorities, and statutory mandates, together with overlapping enforcement jurisdictions, have resulted in both real and perceived differences between NRC and EPA over the regulation of radiation. Over the last 20 years, the two agencies developed conflicting positions on radiation protection for a range of applications, including standards for radionuclide air emissions under the CAA[9], environmental standards for disposal of low-level radioactive waste, groundwater protection at uranium mill tailings disposal sites, exemption levels for radioactive wastes, and standards for disposal of high-level waste. Resolution and agreement have since been reached on several of these, but others remain unresolved. These differences have consumed limited resources and risked eroding public confidence in the regulation of radioactive materials.

1.3 NRC/EPA 1992 Memorandum Of Understanding

NRC and EPA signed an MOU on March 16, 1992, that established a framework for resolving issues of joint NRC-EPA concern that relate to the regulation of radionuclides in the environment, excluding matters arising under RCRA or CERCLA. Because differences in risk assessment and management approaches appeared to be a root cause for several priority issues, NRC and EPA agreed that exploration of risk harmonization would be beneficial to both agencies. The MOU, therefore, in addition to providing a framework for continued cooperation in resolving high-priority issues, commits the agencies to actively explore ways to harmonize risk goals, and to cooperate in developing a mutually agreeable approach to risk assessment methodologies. To meet this commitment, the two agencies began, in 1992, to explore generically the treatment of risk in their programs.

1.4 Approach and Scope of This Project

We used a two-phased approach for the generic exploration of risk harmonization. The first phase consisted of an examination of approaches to risk assessment (primarily radiological) used in each agency. The second phase involved a similar examination of risk management

[9] This disagreement also involved whether NRC's overall regulatory program (including implementation aspects) or only its enforceable requirements should be considered in demonstrating achievement of the same level of protection as EPA's numerical standards.

approaches. To provide a comprehensive generic review, risk management approaches used by EPA under RCRA and CERCLA were included (although they are excluded from the MOU) because the policies under these statutes strongly influence EPA's risk decisions and reflect the implementation of EPA programs.

For this paper, we define **risk assessment** as an analytical process that includes methods, assumptions, and other considerations involved in the description and quantification of a potential risk from a particular activity or situation. In contrast, **risk management** is the judgmental policymaking process that leads to regulatory decisions, such as: (1) the selection of risk goals, limits, or standards, source or pathway constraints, and the methods to achieve their implementation (including consideration of the robustness, precision, or uncertainties in risk assessments); and (2) the selection of regulatory preferences, among risk reduction alternatives, that may include consideration of costs, as well as other factors.

The concept implicit in this set of working definitions is to differentiate between quantification of risk (**risk assessment**) and the judgmental activity of setting standards and regulations that limit risks and impose costs (**risk management**). In theory, the risk embodied in a given situation would be similarly assessed by different analysts, if certain parameters associated with potential exposure scenarios are defined. However, agencies with different regulatory viewpoints might not necessarily reach the same risk management outcomes.

However, while the distinction between risk assessment and risk management is both useful and important; in fact, the processes are strongly linked. The risk management process depends upon the risk assessment process. The risk assessment process involves some judgment (e.g., in the choice of assumptions). These judgments may be policy-based, and they may drive the risk management decision. All such judgments should be explicit.

Each agency systematically examined the approaches it used in a representative spectrum of its own programs and applications. The approaches were then compared and contrasted to identify similarities and differences in approaches for risk assessment and risk management between the two agencies.

In profiling risk assessment and management methods, NRC and EPA agreed that the scope would be broad, but not totally inclusive, in terms of program areas and types of assessments. Several different types of risk assessment and management applications were identified, generally including those in support of rulemakings and compliance determinations, but, at this point, excluding programs directed solely at preventing accidents or abnormal events.

Tables A and B show the programs from each agency that were reviewed for this project, paired when both EPA and NRC have programmatic responsibilities with corresponding or similar scopes.

Table A - Paired Programs Assessed

NRC	EPA
Decommissioning	Superfund (CERCLA)
Low-Level Waste Disposal	Low-Level Waste Standards
High-Level Waste Disposal	High-Level Waste Standards
Byproduct and Source Material, and Reactor and Fuel Cycle Air Emissions	NESHAPs (40 CFR Part 61)
Uranium Mill Tailings Licensing	Uranium Mill Tailings Standards
Reactor and Fuel Cycle Licensing	Uranium Fuel Cycle Standards

Table B - Other Programs Assessed

NRC	EPA
Radiation Protection Standards (Part 20)	Federal Radiation Protection Guidance for Occupational and for Public Exposure
Byproduct Material Licensing	Drinking Water Standards
	Groundwater Protection Strategy
	Protective Action Guides

The comparison between agencies focused on health risk assessment approaches and techniques. It did not address engineering risk assessment, which considers the probability and consequences of failure of components and structures, although such assessments can affect environmental decisions.

1.5 Organization of the Report

Section 2 presents findings and conclusions in the comparison of **risk assessment** approaches used by the two agencies. Similarly, Section 3 contains a discussion of **risk management** approaches. The concluding section summarizes what has been learned from this investigation.

2.0 RISK ASSESSMENT

The objective of the risk assessment comparison was to identify significant similarities and differences in the approaches used by EPA and NRC in the quantification of risk (primarily radiological), and to highlight issues that require further exploration.

Staff from both agencies first identified NRC and EPA programs with largely similar or corresponding scopes (i.e., those shown in Table A), then addressed the other programs identified in Table B. Each program was examined according to a list of characteristics that form the basis for risk assessment in each program area:

- Application of the risk assessment (e.g., compliance assessment or rulemaking)[10]
- Assessment methodology: (e.g., deterministic or probabilistic)
- Exposed population considered (e.g., type of maximum exposed individual, the extent to which other populations considered)
- Exposure scenario(s) considered (e.g., onsite resident, nearest individual)
- Critical pathways (e.g., inhalation, resuspension, direct radiation, ingestion)
- Critical assumptions: (key factors, driving parameters)
- Computer codes employed
- Other issues or important aspects

The remainder of this section discusses the key similarities and differences between the agencies and, in some cases, between programs within an agency.

2.1 Similarities

[10]The term "rulemaking" includes the establishment of both regulations and standards.

The comparison showed that, in many respects, EPA and NRC assess risk in the same way. The specific similarities identified are outlined below:

Both agencies use cancer mortality as the primary measure of risk.

Both agencies report numerical values of risk primarily in terms of cancer fatalities. While acknowledging that other risks exist (e.g., non-fatal cancer, genetic effects, birth defects), they are often not quantified in the risk assessments. Superfund is the major exception, it assesses risk in terms of morbidity, which, in general, results in numerical values 50% higher than those for mortality (with a few exceptions). The Protective Action Guides for accidents, the Federal Radiation Protection Guidance for Occupational Exposure, and the proposed Federal Radiation Protection Guidance for Exposure of the General Public explicitly report risks for other endpoints, and, in the case of the occupational guidance, specify limits to protect the unborn against birth defects due to radiation exposure of the declared pregnant worker. NRC's 10 CFR Part 20 implements those limits.

Translations between dose and risk usually use international consensus factors.

In analyses done by NRC and EPA, the conversions of unit intake of a radionuclide through inhalation or ingestion into a dose or risk rely, for the most part, on factors that are broadly accepted. Both agencies make use of publications from the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), and the National Academy of Sciences (the Biological Effects of Ionizing Radiation (BEIR) reports). Differences between the two agencies usually involve minor variations, although some significant differences in dose conversion factors for a few radionuclides (primarily α-emitters) exist, and are discussed in Section 2.2.

Both agencies assess exposure to a "reasonably" maximum exposed individual for most generic rulemaking and standard setting activities[11].

The primary approach of both agencies, for assessments used in limiting risk to individuals, is to calculate the exposure to a hypothetical "reasonably maximum exposed individual.[12]" Conceptually, such an approach endeavors to strike a balance between limiting the maximum

[11] However, NRC effluent concentrations for air, water, and sewers (10 CFR Part 20.1302(b)(2) and referenced Appendix B values), for use in compliance demonstrations for certain licensees, are based on a theoretical maximum individual located at the boundary of the unrestricted area.

[12] Also characterized as the average member of a "critical group" or the "95th percentile" individual, depending on the program involved.

risk to most of the population, without resorting to a highly unlikely or implausible scenario that incorporates extreme conservatism. As difficult as it may be to define the term "reasonably," this approach acknowledges the need for credibility in the scenario. A *hypothetical* individual is assumed because of uncertainties about whether an identifiable individual will actually be subjected to the risk. For example, in evaluating potential exposures to residual contamination, it is typically assumed that an individual may, in the future, be exposed to the contamination through a variety of pathways (e.g., as a resident farmer).

However, when assessing the cost-effectiveness of control for reducing the total public health impact of a site, both agencies have used realistic assumptions and average characteristics of the relevant populations.

In certain programs, the reasonably "maximum exposed individual" construct is replaced by a less-ambiguous, although highly time-dependent, definition for the purpose of demonstrating compliance. EPA's uranium fuel cycle standards[13], although they were derived on the basis of reasonably maximum exposed individuals, specify limits that apply to *actual* individuals, based on the situation at the time of the evaluation (i.e., actual location and appropriate exposure scenario, with the use of "standard man" parameters), to determine compliance. Similarly, the NESHAPs standards program applies to actual individuals[14]. In both cases, however, since identifying an actual exposed individual may be practically difficult, the individual targeted by the relevant EPA standard can be replaced, at the discretion of the licensee, by a more conservative "maximum exposed individual." Similar flexibility exists for demonstrating compliance with NRC's public dose limits[15]

Both agencies use deterministic risk (dose) assessments, but each also uses probabilistic assessments in selected programs.

Both EPA and NRC use deterministic exposure scenarios (i.e., combinations of exposure assumptions and presumptions on populations exposed) in performing dose/risk assessments in most of their programs. For a specific application in a given program (e.g., decommissioning, Superfund), appropriate scenarios are usually defined. These scenarios are frequently deterministic; there is no explicit accounting for probabilities of occurrence. Instead of incorporating probability distributions into the algorithms used for

[13] See 40 CFR Part 190.

[14] See 40 CFR Part 61.

[15] See 10 CFR 20.1302(b)(1)

dose/risk assessment, both agencies address uncertainties in the exposure situation by examination of alternative deterministic scenarios to reflect situations with different likelihoods.

In contrast to the above, certain programs explicitly use or are planning to consider probabilistic methods in their risk/dose assessments. High- and low-level radioactive waste disposal programs in both agencies use or are considering the use of sophisticated stochastic modeling, to express a full range of anticipated and projected events and parametric variations, as well as their probabilities of occurrence. The high-level waste programs in both agencies review repository designs against man-caused and natural processes and events (external events). These analyses assess behavior of the repository, and resulting doses, for a range of possible release scenarios, over an assumed 10,000-year lifetime of the repository. Although not specifically considered in this paper, it should be noted that NRC's reactor program evaluates reactor designs by assessing possible releases from a design-specific probabilistic risk assessment. These assessments are used by EPA in deriving protective action guides for accidents.

Both agencies usually consider the same pathways of exposure.

In general, both agencies draw from the same possible exposure pathways for their analyses. The relative significance of a particular pathway in the risk assessments depends on source, environmental, and population characteristics. Frequently, one pathway will "dominate" the analysis (i.e., contribute the most to the potential dose or risk). In those cases, that pathway may become the target for sensitivity analyses, or may be the controlling pathway that results in a recommended specific regulatory action (e.g., inhalation of radon).

For many NRC programs, the pathways and parameters considered in dose assessment are those outlined in NRC's Regulatory Guide 1.109 or NUREG/CR-5512. These programs include nuclear power plants, decommissioning, and low-level and high-level waste disposal. NRC regulations also include some concentration limits for specific pathways, e.g., for air and water, as well as for sewer disposal, as a mechanism for demonstrating compliance with their dose limits for the general public.[16]

[16]The concentration limits can be applied at the unrestricted area boundary, but, in practice, are frequently compared with concentrations at points of discharge. Their use is conditional (i.e., external dose rates cannot exceed 2 millirem/hour (0.02 mSv/hour) or 50 millirem/year (0.5 mSv/year)) and procedures and engineering controls must be used to achieve doses that are as low as is reasonably achievable (ALARA).

EPA's standards require consideration of all significant pathways - the best example for air and related pathways is the collection of computer codes used for compliance with 40 CFR Part 61. The CERCLA (Superfund) and RCRA programs have published extensive guidance for pathways relevant to contaminated soil and buildings, and ground and surface water contamination. Some EPA regulations also specify concentration limits for specified pathways (e.g., the drinking water standards at 40 CFR Part 141).

Both agencies truncate risk assessments *in time.*

Although both agencies truncate dose calculations in time, this is usually carried out only when this action is demonstrated to have no significant impact on the regulatory decision being made. For example, certain programs have made general decisions to truncate assessments of collective doses at times beyond which the effectiveness of control options ceases or is no longer assessable. Among NRC programs, decommissioning and uranium mill tailings truncate their analyses at 1000 years. EPA truncated its analysis for uranium mill tailings at 1000 years and, in 1993, EPA determined in its high-level and transuranic waste standards at 40 CFR Part 191, applicable to the Waste Isolation Pilot Plant and sites other than Yucca Mountain, that individual and collective doses, and the associated groundwater concentrations and cumulative releases could be usefully assessed over 10,000 years[17]. EPA truncates all of its low-level and high-level waste standards analyses at 10,000 years. Although EPA's uranium fuel cycle standards calculated doses over a period of 100 years, that choice was precedent-setting when those standards were published in 1977, and choice of a longer period would not have changed the regulatory outcome.

In conducting risk assessments, both agencies similarly truncate the analyses they use to identify maximum exposed individuals. The relevant distance used in an analysis is predicated by the scenario(s) selected; the time period for analysis of individual dose is generally 1,000 years (except for EPA's low-level and high-level waste standards, as mentioned above). This truncation is done for computational efficiency, and the period is chosen so that the doses after truncation are well below those of interest for limiting individual dose.

2.2 Differences

[17] In accordance with Section 801 of the Energy Policy Act of 1992, as of December 20, 1993, 58 FR 66398, 40 CFR Part 191 does not apply to the high-level waste program for Yucca Mountain, pending EPA's rulemaking following recommendations of the National Academy of Sciences on the adequacy of health based standards based on dose to the individual.

The risk assessment methodologies of the two agencies are similar. However, we identified three differences that are described below.

Different models for relating dose to risk are used.

In their formal regulations and guidance, both agencies express *dose* using ICRP 26 methodology. However, EPA and NRC use different detailed methods for calculating *risks* due to radionuclide intakes and exposures. Some differences between the Agencies occur because they have made different compromises between regulatory stability and conformance with the continually evolving science of radionuclide risk assessments.

In many cases, the agencies have used a nominal dose/risk conversion factor to calculate cancer risk. Both agencies currently use biokinetic models based on ICRP Publication 30, and similar risk-per-unit-dose values for uniform whole-body, low-linear energy transfer (LET) radiation (approximately 5×10^{-2} Sv^{-1}); however, differences in methodology for risks due to internal exposure can often result in risk estimates that differ by a factor of 2, and in a few cases, for specific nuclides, by much more. The essential differences are summarized as follows:

1. Organ-specific risks v. risks estimated from effective dose equivalent (EDE). In developing rules, NRC estimates risk using the effective dose equivalent (EDE), a standardized weighting of doses in selected organs devised for regulatory use, [18] coupled with a single whole body risk factor. EPA risks are calculated explicitly for each cancer site and then summed for all organs in the body. For example, the implied risk of bone cancer using the EDE methodology is over 6 times larger than that currently used by EPA.

2. Decay product ingrowth model for calculating dose. NRC uses the ICRP Publication 30 ingrowth model, which assumes that almost all decay products (often with different chemical behavior) in tissues are retained exactly as would be the original intake radionuclide. Although this approach was embodied in EPA's 1988 Federal Guidance Report No. 11, for most radionuclides, EPA's current ingrowth model assumes that decay products arising in tissues are redistributed and retained according to their own retention models. [19]

[18] ICRP replaced these standardized weighting factors with revised values in 1990. Current EPA and NRC organ-specific risk estimates would result in yet another set of weighting factors.

[19] The ICRP is also currently updating its treatment of these radionuclides.

3. Absorbed dose v. dose equivalent. The dose equivalent concept used in NRC dose calculations assumes that the relative biological effectiveness (RBE)[20] of alpha radiation is always 20 times that of low-LET radiation. Based on the findings of BEIR III, in recent assessments EPA has used an alpha radiation RBE of 1.1 for leukemia and 8 for all other radiation induced cancer risks.

4. Age-specific dose rates versus dose commitments. EPA calculates the risk of each type of cancer location based on age-specific dose rates and age-specific cancer radiation risks. These risks are age-averaged, using U.S. life-table data. NRC risks are usually calculated using the product of 50-year dose commitments for a "reference man," and a nominal risk per unit dose.

For short-lived low LET-emitting radionuclides that are nearly uniformly distributed in the body, the differences between NRC and EPA estimates, because of the above factors, are small. In other cases, especially those of long-lived bone-seeking alpha emitters, NRC's risk estimates can exceed EPA's by a factor of 3 or more[21]. The extreme example of this is Th-232, for which the difference is a factor is 66.

However, NRC allows different approaches for estimating risks from exposure under specific circumstances. For example, for evaluation of actual accidents involving known individuals or where a more precise evaluation is desired, NRC uses age- and organ-specific risk factors. On the other hand, for rulemaking or development of measures to prevent or control exposures, NRC considers the approach described above using EDE appropriate, because planning and design normally include conservatisms and include large safety factors[22].

Different exposure scenarios are used in some programs.

Earlier discussions (Section 2.1) stated that EPA and NRC generally draw from the same group of scenarios for their analyses of individual exposures. However, scenarios used by each agency show some differences. One important difference is that for assessments involving *radioactive* waste disposal (other than uranium mill tailings), although both

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[20] The more recent term for RBE is Quality Factor (QF).

[21] Although EPA has recently revised its risk calculations, most of these differences remain. [See Estimating Radiogenic Cancer Risk, J.S. Puskin and C.B. Nelson, U.S. EPA 402-R-93-076, June, 1994.] New organ-specific risk models are based largely on more recent assessments of the Japanese atomic bomb survivors.

[22] See NUREG/CR-4214, Revision 1, Part II, Addenda 1 and 2, "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis," regarding the estimation of low and high LET health effects.

agencies routinely assume individuals will intrude into the waste at some point in the future, EPA does not generally assume intrusion in solid waste programs (municipal waste disposal, hazardous waste disposal, and site remediation in some cases) because EPA assumes the integrity of institutional controls over the hazardous life of these wastes. If different assumptions were made, different site assessments and regulatory requirements might result.

Exposure scenarios also differ in terms of the assumed duration of human exposure. Although NRC programs and most EPA radiation programs assume a 70-year exposure for a maximum exposed member of the general public, the EPA Superfund program typically uses 30 years of exposure. However, that program uses cancer incidence, not cancer fatality, as its risk indicator, so the net effect on the numerically-assessed health risk measure is small. In addition, EPA currently takes into account the distribution of risk with age, and assumes 30-year exposures occurring early in life, which further reduces the significance of differences in exposure duration.

In deriving the concentration values listed in Appendix B, 10 CFR Part 20, that are provided to facilitate demonstrations of compliance with the dose limits for members of the public, NRC considered only direct continuous ingestion or inhalation of effluents at the boundary of the unrestricted area. Because of these conservative exposure pathway assumptions, no reconcentration or food pathways were considered. Since EPA's NESHAPS regulations (40 CFR Part 61) allow compliance demonstrations for the maximum exposed actual individual, the regulations consider additional exposure pathways from airborne releases (e.g., ground deposition) that, for certain nuclides and specific scenarios, could be important to the potential doses received by these individuals. Although, within the range of application of the NRC effluent release values, the difference in assessed dose to an individual may not be significant, the scenarios addressed by EPA are more extensive.

Truncation with distance or magnitude of dose affects consideration of population doses.

EPA usually assesses population risk without truncation in distance. For example, EPA's high-level waste standards, fuel cycle standards, and uranium mill tailings standards considered global population doses. However, one EPA program, NESHAPS, did truncate its assessments in distance (100 km), using the precedent set for chemical contaminants, but made the judgment that the regulatory outcome would not be affected by that decision.

In contrast, NRC generally truncates estimation of doses to population in terms of distance. (Examples range from NRC's generic assessment of fuel cycle impacts for use in EIS's for nuclear power plants to the use of a 50-mile radius from the site as a safety goal for severe accident analysis.) Most programs either implicitly (via choice of scenarios) or explicitly determine a distance beyond which doses and affected populations are not considered.

Truncation based on magnitude of dose (or distance) is not carried out by EPA because it is inconsistent with the linear, no-threshold dose-response assumption (i.e., it would ignore the cumulative population risk below the truncation threshold). NRC's technical basis for truncation is that, beyond a certain distance, the uncertainties in both the data and models can undermine the reliability of the calculated results at very low dose levels. In 1990, NRC issued a "Below Regulatory Concern" (BRC) policy statement that provided for truncating very small doses, on the basis of magnitude, when calculating collective risk. However, in response to public concerns about the implications of such a policy, NRC placed a moratorium on use of the BRC concept the following year, and, after Congressional revocation, formally withdrew the BRC policy in 1993.

3.0 RISK MANAGEMENT

Risk management encompasses the value judgments and pragmatic tradeoffs made by regulators who must make policy decisions in the face of different statutory mandates, imperfect information, limited resources (both of the regulator and of the entity responsible for creating the risk situation), institutional precedents, and other limitations.

Each program was characterized according to the following program elements:

- risk identification: individual dose, health risk; population dose, health detriment; exposure probability
- risk/dose objective: objective sought under program
- basis for objective: policy or other considerations
- implementation: regulatory mechanisms to achieve objective
- compliance: method for determining compliance with regulations
- exceptions: basis for granting exceptions
- uncertainty: method for addressing uncertainties in compliance

3.1 Similarities

The agencies usually achieve similar levels of protection, despite fundamental differences in approaches.

Although the two agencies differ conceptually in their approaches to risk goals and dose limits (see the discussion below), EPA and NRC programs often achieve similar levels of protection. The apparent difference between the lifetime risk (3.5×10^{-3}) implied by NRC's annual dose limit and EPA's lifetime risk objective (10^{-4} to 10^{-6}) can be misleading, because the application of ALARA for NRC licensees almost always results in significant reductions in actual risk levels. On the other hand, many EPA standards allow risks greater than 10^{-6} and a few permit risks greater than 10^{-4}, when justified based on feasibility considerations.[23] Despite this similarity in achieved levels of protection, NRC's radiation protection programs are perceived as less protective than EPA's, when the focus is limited to a comparison between numerical EPA goals and NRC limits (see discussion under Section 3.2, "Differences").

[23]The extreme example of this is EPA's indoor radon program, which provides guidance for remedial action by property owners at risk levels on the order of 10^{-2}, but this is not a regulatory program in the licensing/permitting sense, and significantly lower risks are difficult and costly to achieve. However, an annual average radon decay product concentration, equivalent to the indoor radon program level, is applied at 40CFR Part 192 as a cleanup standard for remediation of any occupied or habitable buildings contaminated with residual radioactive materials from inactive uranium processing sites.

Federal Guidance for Occupational and Public Exposure

Federal Radiation Protection Guidance, which is developed by EPA and contained in a series of documents approved by the President, sets forth general policy for Federal agencies on the formulation of radiation standards.[24] Both NRC and EPA regulatory and standards-setting activities are consistent with existing guidance. [25] NRC has, for example, fully implemented the 1987 occupational guidance in its 10 CFR Part 20 standards, including instituting the use of committed dose and new provisions for protecting pregnant women. EPA requirements for its workers contain similar provisions. Both agencies observe the upper bounds for exposure of members of the public, and, in different ways, assure that doses are as low a reasonably achievable. A potential difference in application of the proposed new guidance for members of the public when regulating individual sources is discussed in Section 3.2 Diffferences below under the heading "Different views of the 100 millirem/year dose limit."

Similar array of decision mechanisms to demonstrate compliance.

EPA and NRC rely on modeling, monitoring, or design to determine whether compliance has been achieved. Compliance requirements often include modeling or design specifications. Monitoring (e.g., radiological monitoring or environmental sampling) is frequently used by both agencies, to ensure that compliance goals are achieved.

3.2 Differences

Different primary risk management approaches.

NRC and EPA use fundamentally different risk management approaches. In protecting individual members of the public, NRC imposes a dose limit with an implied risk of 5×10^{-5} risk/year, or about 4×10^{-3} lifetime[26], and then applies the ALARA concept below this limit. ALARA is usually **applied on a site-specific basis**, but has been applied generically in assessments supporting some rulemaking activities. The projected facility-specific risk can vary as a function of the ALARA process, because this process takes into account the state of

[24]The first Federal guidance was established in 1960 by President Eisenhower. The most recent revisions, proposed by EPA on December 24, 1994, would bring the existing guidance for members of the general public into accordance with the current recommendations of the ICRP.

[25]Also, in their regulatory and standards setting activities, both NRC and EPA take into account the recommendations of the ICRP and NCRP.

[26] When expressed as a dose limit, this is 100 mrem/year (1 mSv/year) for 70 years..

technology, the economics of improvements, and other societal and socioeconomic considerations. NRC does not, in general, generically exempt licensees from the provisions in its regulations.

EPA uses a **fixed risk objective** (approximately 10^{-4} lifetime), and considers further risk reduction if it is cost/benefit justified. Only in cases of clearly unbearable economic costs or excessive environmental consequences may the risk objective not be met. EPA standards are usually derived and **applied generically to classes of sources**, and usually contain provisions for exceptions (which, however, are rarely used).

Different views on the 100 mrem/year dose limit

EPA and NRC have fundamentally different views as to whether the 100 millirem/year annual public dose limit is sufficient. In ICRP 60, NCRP Report No. 116, and proposed Federal Radiation Protection Guidance for Members of the Public,[27] the 100 millirem/year limit is described as the upper limit for exposures from all man-made controllable sources combined.[28] Both ICRP and NCRP have introduced the concept of "constraints" below the 100 millirem/year limit. Both organizations discuss the potential for multiple exposures and ICRP identifies the potential for inequities in the optimization process.

In EPA's view, no single regulated entity (source) should be allowed 100 millirem/year; authorized numerical limits that are a fraction of the 100 millirem should be established for all significant classes of sources.[29] EPA takes this view, in part, because of EPA's responsibility to implement environmental statutes under which the acceptable risk range has been determined to be 10^{-4} to 10^{-6}, and, in part, because of its view of ICRP 60's recommendations on the application of constraints to sources.

In NRC's view, the 100 mrem/year dose limit in 10 CFR 20.1301 for each individual licensee is acceptable. To NRC, the application of ALARA and the combined effects of the regulatory program usually achieve exposures of a few millirem/year for most licensees and are an acceptable alternative to codification of limits less than 100 millirem/year.

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[27]It should be noted that these documents are still under consideration by Federal agencies and have not been adopted as Federal policy.

[28]Medical and background exposures are excluded.

[29]In some instances, EPA has the authority to *require* such limits (e.g., the Clean Air Act.)

Statutory basis for development of radiation policy

A key difference between the two agencies lies in the statutory basis for actions taken to affect radiation policy. While both agencies draw authority from the Atomic Energy Act, the nature of that authority is somewhat different. Under the Atomic Energy Act, as amplified by discussions subsequent to the creation of EPA (e.g., the Ash memorandum), NRC has regulatory, licensing, and enforcement authority over licensed facilities, including both public and occupational exposure from such facilities. Typically, this has led NRC to focus on site-by-site regulation under the "umbrella" of basic dose limits.

In contrast, under the AEA, EPA is primarily a policy and standard setting agency. Also, under the AEA, Executive Order 10831, and Reorganization Plan No. 3 of 1970, EPA is responsible for developing Federal policy and guidance to help ensure that the regulation of exposure to ionizing radiation is carried out by Federal agencies in a consistent and adequately protective manner. As a standard-setting Agency, EPA tends to develop AEA standards that apply to a class of facilities and which do not require that additional site-specific conditions be imposed (as NRC can do in a license.)

An additional difference in the statutory basis for each Agency's radiation policy is the fact that while NRC is governed primarily by the AEA, EPA has multiple statutes under which it has responsibility for radiation policy. This includes the AEA and several environmental statutes including the Clean Air Act, the Clean Water Act, the Safe Drinking Water Act, and CERCLA.

EPA's implementation of these multiple statutes accentuates differences between EPA and NRC in two key ways. First, EPA's management of radiation risk is shaped by the statutory requirements, regulatory decisions, and policy determinations that are associated with those statutes and which stem primarily from a consideration of non-radioactive pollutants. As noted above, EPA typically considers a standard for a non-radioactive carcinogen to be adequately protective if it ensures that the resulting individual lifetime risk falls within a 10^{-6} to 10^{-4} range. Second, in developing standards, EPA focuses on specific pathways of exposure, such as ground water or air. Such a pathway-specific focus is required, for example, by the NESHAPS program under the Clean Air Act, and is Agency policy for the protection of groundwater.

EPA's use of a risk range derived from consideration of non-radioactive carcinogens, and of a statutorily encouraged focus on specific pathways, creates a number of areas in which NRC

and EPA have regulated the same sources in ways that specify or imply different numerical levels of protection.

Use of risk vs. dose as the risk reduction objective.

NRC has traditionally used radiological **dose** as the endpoint for rulemaking and compliance assessment. That is, most regulatory decisions are related to the acceptability of dose as a surrogate for risk (e.g., in relation to ICRP and NCRP recommendations on dose limits). In the past, the risks involved were not calculated, although in all recent rulemakings, NRC has made explicit estimates of the relationship between risk and dose.

In contrast, EPA programs have always used health **risk** as part of the basis for rulemakings and policies, and most use dose only as a measure of compliance. However, the definition of the health risk to be quantified has varied somewhat, depending on the regulation[30]. For example, cleanup decisions under Superfund are based on cancer incidence rather than fatalities; the risk factor for incidence is about 150% of that for fatalities.

Uses of population risk.

EPA standards almost always include individual dose limits, but population risk may lead to additional regulations requiring more control than that required to satisfy individual dose limits. Examples are population-based limits on quantities of specified long-lived radioisotopes released from high-level waste repositories under 40 CFR Part 191, and of Kr-85, I-129, Pu-239, and other α-emitting transuranics from uranium fuel cycle facilities, under 40 CFR Part 190.

NRC does not specify numerical requirements specifically based on collective risk in populations, but either generally limits public exposure through individual dose limits or incorporation of EPA standards into its regulations. Consideration of population risk can affect the choice of individual dose limits in NRC programs. Examples include: ALARA assessments for effluents, National Environmental Policy Act (NEPA) assessments, consumer product design and distribution, and backfitting reviews.

[30] See "Issues Paper on Radiation Site Cleanup Regulations." EPA 402-R-93-084, September 1993.

Thus, both agencies consider population risk. However, EPA's consideration of population risk is more likely to lead to additional regulatory requirements.

Explicit disagreements on risk objectives.

There are a number of areas in which NRC and EPA programs, which apply to the same sources, specify or imply different numerical levels of risk for protection of the public. These differences are usually based on the different regulatory approaches used by the agencies.

For example, groundwater protection in EPA's draft low-level waste standards is specified at the level of drinking water standards (4 mrem/year (0.04 mSv/yr); about a 10^{-4} lifetime risk), as is the policy for all other EPA groundwater protection programs[31], but is absent, as specific limits, in NRC regulations for low-level wastes[32]. NRC limits the combined hazard from all pathways (except direct radiation) to an implied lifetime risk level of about 10^{-3}, or 25 mrem/year (0.25 mSv /year) whole body dose, but does not specify separate limits for doses resulting from transport of radionuclides in groundwater.

As another example of numerical differences in the standards established by the agencies, NRC's radiation protection standards require that air emissions, when combined with the doses from all other pathways, meet the 100 mrem/year (1 mSv/year) public dose limit and that procedures and design controls limit releases and doses to ALARA. In contrast, EPA standards under the CAA limit the dose from air emissions to 10 mrem/year (0.1 mSv/year) and no more than 3 mrem/year (0.03 mSv/year) for radioiodine.

4.0 CONCLUSIONS AND FINDINGS

The examination of programs in the two agencies demonstrated that, despite differences in the history and regulatory approaches of the two agencies, they often achieve comparable results in their regulatory programs, and are currently embarked on paths that should reduce remaining differences. The similarities in approaches to risk assessment and management have been addressed in the previous sections of this report. Here we summarize the differences.

4.1 Risk Assessment

[31] See "Protecting The Nation's GroundWater: EPA's Strategy for the 1990s." July 1991.

[32] This may reflect the fact that while both agencies are responsible for the protection of public health and safety, EPA also has responsibility for resource protection (e.g., water as a resource).

Although the two agencies carry out risk assessment from different viewpoints, they commonly arrive at similar outcomes. That is, if EPA and NRC were to assess a defined environmental hazard, the two agencies would likely calculate a similar level of implied risk. Nonetheless, differences were found in some program areas. They are:

- Different models are used for relating dose to risk for certain radionuclides; this is particularly significant for α-emitters. Much of the basic difference stems from use of a single whole-body dose-to-risk conversion factor vs. multiple organ-specific dose-to-risk conversion factors.

- A different biological endpoint (cancer incidence, instead of cancer mortality) is used as a risk basis in some programs (e.g., Superfund).

- Different exposure scenarios (e.g., intruder protection, presumed exposure times) are sometimes used.

- Truncation of population dose analyses is performed differently.

The comparison of risk assessment approaches has helped the agencies gain a better understanding of each other's internal practices and procedures for estimating doses and risks associated with radiation in the environment. Although resolution of these differences in risk assessment approaches is unlikely to significantly affect the outcome of agency regulatory decisions, unresolved differences can affect public perception of the scientific credibility of the two agencies.

4.2 Risk Management

Although there is, currently, movement toward more consistent approaches to regulation, the two agencies have traditionally used fundamentally different approaches. In this section, we summarize the current state of differences found in risk management.

- In protecting individual members of the public, NRC imposes a dose limit with an implied risk of about 4×10^{-3} lifetime, and then applies the ALARA concept below this limit. EPA uses a fixed risk objective (approximately 10^{-4} lifetime) and considers further risk reduction if it is cost-benefit justified.

- EPA constrains classes of sources to less than the 100 millirem per year individual dose limit; many NRC programs do not independently impose such constraints (although ALARA is always applied), while others rely on reference to relevant EPA standards for particular classes of sources.

- EPA believes that continued exposure of an individual over substantial portions of a lifetime at or near 100 mrem/year should be avoided. In NRC's view, the 100 mrem/year dose limit in 10 CFR 20.1301 for individual licensees is acceptable.

- NRC programs use *dose* limits and ALARA, whereas EPA programs frequently use a single *risk* objective or range as a basis for regulation.

- EPA's consideration of population risk is more likely to lead to additional regulatory requirements.

- EPA's use of a risk range derived from consideration of non-radioactive carcinogens, and of a statutorily encouraged focus on specific pathways, creates a number of areas in which NRC and EPA have regulated the same sources in ways that specify or imply different numerical levels of protection.