AN EVALUATION OF NRC REGULATIONS AND STAFF POSITIONS RELEVANT TO THE TECHNICAL BASES FOR REPOSITORY STANDARDS

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1 INTRODUCTION AND BACKGROUND

Section 801 of the Energy Policy Act of 1992 (U.S. Congress, 1992) directs the U.S. Environmental Protection Agency (EPA) to contract with the National Academy of Sciences (NAS)/National Research Council for a study to provide findings and recommendations on reasonable safety standards for the disposal of high-level radioactive wastes (HLW) at the proposed Yucca Mountain repository site. Among the general issues to be considered in the NAS study are:

- whether a health-based standard, based on doses to individual members of the public, would be reasonable

- whether postclosure oversight of a repository, based on active institutional controls, can lower the risk of breaching of the repository's barriers or of causing unacceptable radiation doses to the public

- whether it is possible to make scientifically supportable predictions of the probability of human intrusion for 10,000 years

With regard to the formulation of a health-based standard, NAS is seeking to: (i) understand the technical bases for the current EPA standards for disposal of radioactive wastes; (ii) examine populations or individuals at risk, such as global or regional populations or the average or maximally exposed individual; and (iii) understand the development and status of health-based standards in different countries for high-level and alpha-bearing radioactive wastes. After receipt of the NAS findings and recommendations, the EPA is to promulgate regulatory standards for the protection of the public from releases of radioactivity stored or disposed of in the proposed repository at the Yucca Mountain site. The standards are also required to prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment. The U.S. Nuclear Regulatory Commission (NRC) is then required to modify its technical requirements and criteria to be consistent with the EPA standards.

This document summarizes the federal regulations and history of NRC positions and comments related to radiologic protection standards. The regulatory history was developed from a review of the requirements contained in: (i) Title 10 of the Code of Federal Regulations (10 CFR) Parts 20, 60, and 61; (ii) NRC staff positions and comments on the EPA standards for disposal of HLW; and (iii) other documents which may be applied to HLW repository postclosure performance standards, such as 10 CFR Part 40 and the NRC Safety Goals. This document also presents specific recommendations, including their bases, for positions which the NRC may choose to advocate in its interactions with the NAS Committee on Technical Bases for Yucca Mountain Standards (NAS Committee). The recommendations should assure adequate health and safety of the public and lead to regulatory standards which can be implemented by the NRC in a licensing decision for a potential geologic repository. The specific recommendations are based upon existing NRC regulatory rationale and upon Center for Nuclear Waste Regulatory Analyses (CNWRA) independent analysis.

The topics addressed in this report include the following:

- health-based, risk-based, and technology-based standards
- dose limits for individuals
- dose limits for populations

- applicability of as low as reasonably achievable (ALARA) principle
- probabilistic standards for human-induced and natural disruptions
- active and passive institutional controls for preventing human intrusion
- evaluation period for performance assessment (PA)
- overall system and subsystem performance requirements

This report summarizes previous NRC positions and comments related to the following areas:

- Evaluation of the NAS Committee *Consultant Reports*. These reports are expected to address: (i) health-based standards for other countries' HLW disposal; (ii) significance of human intrusion into a HLW repository; and (iii) catastrophic natural phenomena effects on a HLW repository. The *Consultant Reports* are expected to be finalized on or about January 31, 1994.

- Determination of any changes needed in the previous positions of the NRC, so that a *Commission Paper* can be prepared. Such a *Commission Paper* may be prepared if the NRC staff believes that changes in previous positions should be recommended to the Commission or if policy issues are raised by the NAS Committee deliberations.

- Preparation of any comments on the NAS Committee's final recommendations presented to the EPA.

This report also includes recommendations to assist the NRC staff in formulating any potential positions deemed necessary. These recommendations, if adopted by the NRC, will provide a basis for ongoing interactions with the NAS Committee.

2 SUMMARY AND EVALUATION OF REGULATORY HISTORY

The first subsection introduces the essential background information contained in 10 CFR Part 20, Standards for Protection Against Radiation. The second subsection covers the earliest NRC positions and comments on the drafts of the EPA's remanded 40 CFR Part 191, Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level, and Transuranic Radioactive Wastes (EPA, 1985), which were discussed in the NRC development of 10 CFR Part 60, Disposal of High-Level Radioactive Wastes in Geologic Repositories. The third subsection summarizes NRC positions and comments on the EPA's working drafts of 40 CFR Part 191, issued after June 1989; in addition, it presents the applicable and up-to-date NRC positions related to the scope of the NAS Committee task. The fourth subsection summarizes the NRC positions on 10 CFR Part 61, Licensing Requirements for Land Disposal of Radioactive Waste, which may generally apply to HLW disposal standards. The final subsection presents other NRC positions which may be applied to a HLW repository postclosure performance standards.

2.1 STANDARDS FOR PROTECTION AGAINST RADIATION, 10 CFR PART 20

Title 10 of the Code of Federal Regulations, Part 20 (10 CFR Part 20) in § 20.1001 to 20.2402, establishes new standards for protection against ionizing radiation for NRC licensees which become effective January 1, 1994. These regulations are issued under the authority of the Atomic Energy Act of 1954, as amended (U.S. Congress, 1954), and the Energy Reorganization Act of 1974, as amended (U.S. Congress, 1974a). The new sections of 10 CFR Part 20 (§ 20.1001 to § 20.2401) take into account developments in the principle and scientific knowledge underlying radiation protection and implement the 1987 Presidential Guidance on occupational radiation exposure (EPA, 1987). The regulations in 10 CFR Part 20 apply to any persons licensed by the NRC to receive, possess, use, or transfer byproduct, source, or special nuclear material or to operate a production or utilization facility under Parts 30 through 35, 39, 40, 50, 60, 61, 70, and 72 of Title 10.

10 CFR Part 20 controls the receipt, possession, use, transfer, and disposal of licensed material, by any licensee. The total dose to an individual is taken to include doses resulting from licensed and unlicensed radioactive material. The limits in 10 CFR Part 20 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

2.1.1 Health-Based, Risk-Based, and Technology-Based Standards

Health-based standards are those standards which are based primarily on judgments about acceptable risks to the public (Kocher, 1993). The 100 mrem/yr (1 mSv/yr) limit for individual members of the public is a health-based, rather than a technology-based, standard and the limit is broadly applicable to several licensed activities, which suggests that it may be an acceptable health-based standard for a HLW repository. The 100 mrem (1 mSv) value was adopted directly from International Commission on Radiation Protection (ICRP) statements (ICRP, 1985b). The ICRP bases its numerical recommendations on "detriment," which is a quantity related directly to health. Assuming the most recently provided fatal-cancer risk coefficient (ICRP, 1991) of 0.05 Sv^{-1}, an individual in the general population who receives a total lifetime dose of 100 mrem (1 mSv) has a corresponding lifetime probability of fatal cancer of

$$1 \text{ mSv} \times 0.05 \text{ Sv}^{-1} \times 0.001 \text{ Sv/mSv} = 0.00005 \text{ (0.005 percent)}.$$

This may be compared to a natural lifetime fatal-cancer risk of approximately 18 percent. It should be noted that ICRP Publication 60 (ICRP, 1991) uses terminology which is slightly different from that in 10 CFR Part 20, which is based upon ICRP Publication 46 (ICRP, 1985a). These differences in terminology are insignificant.

In the supplementary statement to the new 10 CFR Part 20, the NRC states, "Incorporation of these changes will ensure Part 20 continues to provide adequate protection of public health and safety" (NRC, 1991a). The NRC goes on to state:

> The radiation protection standards in the final rule are based upon the assumptions that:
>
> 1. Within the range of exposure conditions usually encountered in radiation work, there is a linear relationship, without threshold, between dose and probability of stochastic health effects (such as latent cancer and genetic effects) occurring.
>
> 2. The severity of each type of stochastic health effect is independent of dose.
>
> 3. Nonstochastic (nonrandom) radiation-induced health effects can be prevented by limiting exposure so that doses are below the thresholds for their induction.

To a certain extent, technology is taken into account in 10 CFR Part 20 through the ALARA process, rather than numerical limits. NRC defines ALARA in 10 CFR Part 20 as, "making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest." No mention of technology as a basis for limitation was found in 10 CFR Part 20 except in this definition of ALARA.

2.1.2 Dose Limits for Individuals

Various health physics terms (quantities and units) are used in 10 CFR Part 20 to express dose limits for individuals. Dose and radiation dose are generic terms which can be used to express more precise terms which follow.

- Absorbed dose means the energy imparted by ionizing radiation per unit mass of irradiated material.

- Dose equivalent (H_T) is a quantity which accounts for the energy deposited (absorbed dose) and the efficacy of the different types of radiation.

- Deep-dose equivalent (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm.

- Eye dose equivalent applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm.

- Shallow dose equivalent (H_s), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 cm.

- Committed dose equivalent ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) which will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

- Effective dose equivalent (H_E) is a modification of dose equivalent which accounts for the radiosensitivity of the various organs and tissues. It is formally defined as the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues which are irradiated.

- Effective dose equivalent is used primarily for internally deposited radionuclides.

- Committed effective dose equivalent ($H_{E,50}$) 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 to these organs or tissues.

- Total Effective Dose Equivalent (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). TEDE is particularly important for this discussion because it is the quantity used to express the individual dose limit for the public.

In the new 10 CFR Part 20, whole body means (for purposes of external exposure) head, trunk (including male gonads), arms above the elbow, or legs above the knee.

10 CFR Part 20 expresses the various dose quantities in both traditional and System International (SI) units. Absorbed dose is expressed in the traditional unit of rad or the SI unit of Gray (Gy). All the other dose quantities are expressed in the traditional unit of rem or the SI unit of Sievert (Sv). Sub-multiples of the basic units, such as mrem and μSv, are frequently used.

10 CFR Part 20 contains several limits for protection of individuals against radiation. These limits pertain to adult occupational workers, persons under the age of 18 in the workplace, the embryo/fetus, and the general public. Additionally, there are special limits which are applicable only in emergencies. The regulatory definitions of these classes of individuals and pertinent limits for these various classes of individuals (except for emergency limits) are in § 20.1201, § 20.1207, and § 20.1208.

The primary dose limits for individual members of the public (member of the public means an individual in a controlled or unrestricted area, however, an individual is not a member of the public during any period in which the individual received an occupational dose) are presented in § 20.1301:

(a) Each licensee shall conduct operations so that

(1) The total effective dose equivalent to individual members of the public from those operations does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003; and

(2) The dose in any unrestricted area does not exceed 0.002 rem (0.02 mSv) in any one hour.

(b) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

The value of 100 mrem (1 mSv) represents a substantial change from the previous value of 500 mrem (5 mSv). In its response to comments, the NRC (1991c) emphasized that the 100 mrem (1 mSv) value is not to be interpreted as a guideline or as an average annual value to be achieved over the long term, it is an annual limit. In addition to basic dose standards, 10 CFR Part 20 also provides derived standards for the public in Appendix B. These derived standards are expressed in terms of concentrations of radioactive material in air and water which, if ingested continuously over a year, would lead to TEDE of 50 mrem (0.5 mSv). The value of 50 mrem (0.5 mSv) was selected instead of the basic 100 mrem (1 mSv) value so that the derived standards would be applicable to all age groups (NRC, 1991a).

Of the four classes of standards given earlier, only the limits for individual members of the general public are relevant to the standards for workers, minors, embryo/fetus, public, and a HLW repository. Consequently, the rest of the discussion in this subsection focuses on the limits for individual members of the general public.

2.1.2.1 Basis of the Individual Limit of 100 mrem (1 mSv) to the Public

In March 1985, the ICRP held a meeting in Paris, France, to review the work of the various ICRP task groups and committees. One of the outcomes of this meeting was an ICRP statement (ICRP, 1985c) which proposed a principal dose limit for members of the general public to be 1 mSv (100 mrem) in a year, rather than 5 mSv (500 mrem). This clarification was taken into account by the NRC in the limits adopted for members of the public. The NRC was also aware that forthcoming recommendations (ICRP, 1991) would retain the 100 mrem/yr (1 mSv/yr) limit. No specific health-risk analysis for the 100 mrem (1 mSv) limit was performed by the NRC[1] and the NRC simply adopted the ICRP value.

During the comment period for the proposed 10 CFR Part 20, the EPA recommended that the NRC not change the dose limit from 500 to 100 mrem (5 to 1 mSv) until the EPA prepared revised federal guidance on dose limits applicable to the general public (NRC, 1991a). Although the NRC acknowledged that it would be desirable to base its limits on federal guidance, the advantages of having the entire standard based on a consistent set of principles and concepts was deemed more important (NRC, 1991a). Federal guidance on dose limits applicable to the general public has not been published by the EPA as of this report.

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[1] Private communication with R. Alexander, 1993.

2.1.2.2 Applicability of Individual Limits for a HLW Repository

Because any HLW repository would be required to be licensed by the NRC, the dose limits in the 10 CFR Part 20 regulations would be controlling unless other lower dose limits were established in regulations specific to a HLW repository. Furthermore, § 20.1002 of 10 CFR Part 20 specifically mentions applicability to 10 CFR Part 60, Disposal of High-Level Radioactive Wastes in Geologic Repositories. This regulation contains a requirement in § 60.21(c)(7) for:

> A description of the program for control and monitoring of radioactive effluents and occupational radiation exposures to maintain such effluents and exposures in accordance with the requirements of part 20 of this chapter.

It is clear that the individual limits for members of the public, per 10 CFR Part 20, are meant to apply to a HLW repository, until the license is terminated (roughly the preclosure period). It is unclear if these limits can be explicitly applied to postclosure performance after license termination. It seems reasonable that the annual postclosure performance of a repository should at least meet these limits for preclosure performance in order to have an acceptable public health risk.

2.1.3 Dose Limits for Populations

Collective dose is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation. Although collective dose is defined in 10 CFR Part 20, no numerical limits are given. The NRC does, however, reserve the right to impose additional limits to restrict collective dose in § 20.1301(e). In general, the basis of collective dose limits is the limitation of population risk, as opposed to individual risk. In order for the collective dose limiting concept to be valid, it must be assumed that a linear, no-threshold relationship exists between any dose and individual risk. An illustration can be given for a collective dose of 10,000 person rem (100 person Sv). The total risk (for example, the number of cancer deaths induced) in a population is assumed to be the same regardless of whether 1,000 people are exposed to 10 rem (100 mSv) each, 1,000,000 to 10 mrem (100 μSv) each, 1,000,000,000 to 0.01 mrem (0.1 μSv) each, etc. Although the NRC has not set any collective dose limits in 10 CFR Part 20, it is implicit in the regulations that the NRC believes that restriction of collective dose is a potential regulatory tool. This inference is made from the inclusion of a definition for collective dose and the statement that collective dose to the public may be restricted by the NRC.

2.1.4 Applicability of ALARA Principle

The term ALARA means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest. It is clear that ALARA is a process and not a set of numerical limits. Nevertheless, the outcome of applying the ALARA process may be numerical guidelines. In the supplementary information to 10 CFR Part 20 (NRC, 1991a), the NRC states:

In adopting the basic tenets of the ICRP system of dose limitation, the Nuclear Regulatory Commission recognizes that, when application of the dose limits is combined with the principle of keeping all radiation exposures "as low as is reasonably achievable," the degree of protection could be significantly greater than from relying upon the dose limits alone.

ALARA is explicitly required to be applied to dose to the public. Within the paragraph on radiation protection programs, 20.1101(b), it is stated that: "The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA)."

The fundamental basis of the ALARA philosophy is similar to that for the collective dose concept. Although a linear, no-threshold relationship between dose and individual risk must be assumed in order for the collective dose to relate quantitatively to risk, the ALARA concept only requires that risk be assumed to increase with dose above some level (which could be zero). Above this level, any increase in dose carries a concomitant increase in risk and, if reasonably achievable, should be avoided or reduced. 10 CFR Part 20 requires that ALARA be applied to doses to members of the public and 10 CFR Part 20 is applicable to a HLW repository at least until license termination. Until the technology and cost bases for postclosure performance of a given site are defined, the applicability of ALARA concepts after license termination would be difficult to determine.

2.1.5 Probabilistic Standards for Human-Induced and Natural Disruptions

10 CFR Part 20 and the supplemental information do not make reference to probabilistic standards.

2.1.6 Active and Passive Institutional Controls for Preventing Human Intrusion

10 CFR Part 20 applies to licensed operating facilities where institutional control is assumed, rather than to closed repositories or abandoned or decommissioned facilities. Inadvertent and intentional intrusion during operations are dealt with through requirements for posting, interlocks, and physical security, which include:

> § 20.1801 Security of stored material.
>
> The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or restricted areas.
>
> § 20.1802 Control of materials not in storage.
>
> The licensee shall control and maintain constant surveillance of licensed material which is in a controlled or unrestricted area and which is not in storage.

The requirements for controlled and restricted areas in which high or very high radiation fields are present allow the licensee to use one or a combination of several approaches. The acceptable means of controlling access are given in Subpart G of 10 CFR Part 20 and are summarized as follows: (i) a control device which, upon entry into the area, causes the level of radiation to be reduced; (ii) a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; (iii) entryways which are locked, except during periods when access to the areas is required, with positive control over each individual entry; and (iv) continuous direct or electronic surveillance which is capable of preventing unauthorized entry.

2.1.7 Evaluation Period for Performance Assessment

This topic is not addressed in 10 CFR Part 20 or the supplemental information.

2.1.8 Overall System and Subsystem Performance Requirements

Licensees are subject to a dose rate limit in unrestricted areas. The dose in any unrestricted area must not exceed 0.002 rem (0.02 mSv) in any 1 hour, and dose rates higher than 2 mrem/hr (20 μSv/hr) are not permitted even if the licensee could demonstrate that no individual member of the public would be exposed for a sufficient time to exceed 100 mrem/yr (1 mSv/yr). As discussed in Subsection 2.1.1, 10 CFR Part 20 provides derived limits for the public in Appendix B. These derived limits are expressed in terms of concentrations of radioactive materials in air and water which, if ingested continuously over a year, would lead to TEDE of 50 mrem (0.5 mSv). The value of 50 mrem (0.5 mSv) was selected instead of the basic 100 mrem (1 mSv) value so that the derived standards would be applicable to any age group (NRC, 1991a).

Disposal of radionuclides to sewerage represents a potential for dose to the public, but this practice has its own limits which are separate from the 100 mrem/yr (1 mSv/yr) limit. In a sense, sewerage disposal should be considered as a separate system requirement, rather than a subsystem requirement, because any dose delivered to members of the public through sewerage disposal is not to be included in the 100 mrem/yr (1 mSv/yr) limit. For sewerage disposal, a complex system of requirements is given in § 20.2003(a). Medical licensees have sewerage disposal exemptions for patient excreta under § 20.2003(b).

Certain NRC licensees are also subjected to additional total system performance requirements by EPA regulations which are identified in § 20.1301 and 20.2203. The referenced EPA regulation, 40 CFR Part 190, (EPA, 1992a) limits doses to individual members of the public to 25 mrem/yr (0.25 mSv/yr). 10 CFR Part 20 specifically requires affected licensees to comply with the requirements of 40 CFR Part 190, and requires that affected licensees report to the NRC if the limits of 40 CFR Part 190 are exceeded.

Although not specifically called out in 10 CFR Part 20, some licensees are also subject to 40 CFR Part 61, National Emission Standards for Hazardous Air Pollutants (EPA, 1992c) or are affected by the Safe Drinking Water Act (U.S. Congress, 1974b) and 40 CFR Part 141, Interim Drinking Water Standards for Radionuclides (EPA, 1992b).

The basis of the 2 mrem/hr (20 μSv/hr) dose rate limit is not discussed in recent NRC literature, but appears to be a defense-in-depth measure. By limiting the maximum dose rate to 2 mrem/hr (20 μSv/hr), an individual member of the public would have to spend at least 50 hours per year in an unrestricted area to reach the basic limit of 100 mrem/yr (1 mSv/yr). The requirements expressed as derived limits for the public in Appendix B of 10 CFR Part 20 correspond to an annual limit of 50 mrem

(0.5 mSv) instead of the basic 100 mrem (1 mSv) so that the derived standards would be applicable to other age groups (NRC, 1991a). The separate system requirement for disposal to sewerage appears to be based on practicality. By providing limits in the form of quantities of specific radionuclides, NRC relieves the licensee of performing potentially complex modeling and calculation to demonstrate compliance with a dose limit. The EPA limits which apply to NRC licensees are specialized standards which address certain practices and environmental media.

2.2 DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES, 10 CFR PART 60

As mandated by Congress, the NRC and EPA have very distinct roles and responsibilities to regulate the disposal of HLW in a geologic repository. Each of these federal agencies has a unique, yet integrated, role to play in assuring the health and safety of the public from the disposal of HLW. The NRC has promulgated its regulatory requirements in 10 CFR Part 60, Disposal of High-Level Radioactive Wastes in Geologic Repositories. The EPA issued its Final Rule for HLW disposal standards in 40 CFR Part 191, Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Waste (EPA, 1985).

Section 121 of the Nuclear Waste Policy Act (NWPA) of 1982 (U.S. Congress, 1982) most clearly defines the roles of the two regulatory agencies. The EPA is to promulgate generally applicable standards for protection of the general environment from offsite releases from radioactive material in repositories. The NRC is to promulgate technical requirements and criteria which apply to approving or disapproving: (i) applications for authorization to construct repositories; (ii) applications for licenses to receive and possess spent nuclear fuel and HLW in such repositories; and (iii) applications for authorization for closure and decommissioning of such repositories. These NRC technical requirements and criteria shall provide for the use of a system of multiple barriers in the design of a repository and shall include such restrictions on the retrievability of the solidified HLW and spent fuel emplaced in a repository, as the NRC deems appropriate. The NRC requirements and criteria shall not be inconsistent with any comparable standards promulgated by the EPA; if the EPA promulgates standards after the NRC has issued its technical requirements, these requirements shall be revised, if necessary, to comply with EPA standards.

Providing clarification of the different roles of these two agencies, the statement of considerations for the Advanced Notice of Proposed Rulemaking for 10 CFR Part 60 (NRC, 1980) states:

1. Under Reorganization Plan Number 3 (35 FR 15623, October 6, 1970), the Environmental Protection Agency (EPA) was given the authority under the Atomic Energy Act of 1954 as amended to set the generally applicable standards for radiation in the environment. Such standards represent the amount of radioactive materials and levels of radioactivity in the general environment that are compatible with protection of the health and safety of the public. This EPA authority extends to setting of the standards or to establishing of requirements concerning how they are to be met. The Commission is bound to implement these standards in its regulations, thus assuring they be met by the activities authorized by the Commission's licensing decisions. The Commission may not substitute its judgement for that of the EPA, but the Commission may, and must, determine whether particular proposed disposal activities will conform to the EPA standard.

2. As noted above, although the Commission is bound to implement the EPA HLW standard, it has the authority and discretion to determine how that standard will be achieved. In particular the Commission must decide how it will develop its regulatory requirements, viz., the technical criteria of 10 CFR Part 60, and carry out its decision process to show that in each particular licensing case, the EPA standards will be met.

The NRC used a rulemaking approach which solicited and considered comments of the U.S. Department of Energy (DOE), the EPA, and the public. The NRC, through a series of rulemaking publications, sought comments on its proposed concepts and publicly addressed all comments received, either on a collective or individual comment basis. This process, though lengthy, resulted in regulations which have avoided or withstood any legal challenges. The evidence of the lengthy and public process which the NRC underwent to develop sound regulations is demonstrated in the numerous Federal Register publications, given in the References (Section 4), which ultimately led to the existing 10 CFR Part 60.

The regulations of 10 CFR Part 60 are relevant to the formulation of the EPA standards for a HLW repository because they address in general and specific terms the concepts which the NRC deems necessary and sufficient for such standards.

2.2.1 Health-Based, Risk-Based, and Technology-Based Standards

The NRC did not make any direct statements regarding a preference for a technology-based or a health-based standard in 10 CFR Part 60 or its supporting documentation. However, prior to issuing its radioactive waste disposal standards, the NRC indicated that it anticipated the EPA waste standard to be compatible with that for other fuel cycle facilities, such as 40 CFR Part 190 (EPA, 1992a). This EPA standard has a dose limit of 25 mrem/yr (0.25 mSv/yr) whole body exposure. Also, the NRC discussion about ALARA, subsystem performance criteria, and collective dose (i.e., population dose) criteria relate to the desirability of an EPA standard which is primarily health-based, and one which addresses overall system performance.

When the EPA issued its proposed standards (EPA, 1982), it was indicated that the activity limits were based on total health effects of 1,000 cancer deaths over 10,000 years, for 100,000 metric tons of spent fuel. This is estimated to be equivalent to the risk which would be expected from the source uranium, if never mined and left *in situ*. The EPA Final Rule for 40 CFR Part 191 (EPA, 1985) had limits for a repository, which are stated in the terms of not exceeding cumulative activity limits for key isotopes, which appear to be a combination of health-based and technology-based standards. The activity limits (curies released) were related to the 1,000 total health effects through PA modeling for hypothetical repository performance limits that may technically be achieved (EPA, 1993). The NRC commented that these activity limits and the 1,000 total health effects are such low limits and stringent geologic performance requirements that it is doubtful that the ALARA concept could be applied in a meaningful way (NRC, 1983a). The NRC and EPA have apparently agreed on the concept that the ALARA process is not applicable to the postclosure performance objectives of a HLW repository. This is evidenced by withdrawal of such standards from the EPA Final Rule for 40 CFR Part 191 (EPA, 1985) after NRC commented to EPA on this subject.

The long-term population distribution near a repository is most uncertain and, if a geologic repository performs as anticipated, is generally immaterial. The majority of the collective dose will be to that segment of the population which is closest to a repository, due to the tendency for most radioisotopes to remain in the local vicinity. A possible exception may be for some gaseous releases where the world population may contribute to the majority of the collective dose. It is the view of the NRC that it makes little sense to attempt to limit consequences by means of a population-related siting criterion, since long-range demographic forecasts are inherently speculative and unreliable.

NRC in 10 CFR Part 60 has included individual subsystem technical criteria and has criteria which address minimizing the collective dose, where possible. In 10 CFR Part 60, individual subsystems are required to meet given numerical criteria in order to provide the assurance that the assessment of the overall system performance standard is adequate.

2.2.2 Dose Limits for Individuals

There are no individual dose criteria in 10 CFR Part 60 which are directly related to the EPA standards, but 10 CFR 60.111(a) references 10 CFR Part 20, which is only applicable to the preclosure period (the period of repository operations prior to permanent closure). Also, 10 CFR Part 60 references such generally applicable environmental standards for radioactivity as may have been established by the EPA, in both 10 CFR 60.111(a) and 60.112. The individual dose criteria of 10 CFR Part 20 are discussed in Subsection 2.1 of this report. The applicable environmental standards for radioactivity, established by the EPA, are in 40 CFR Part 191, Subparts A and B. 40 CFR Part 191, Subpart A has radiation standards which apply only to the preclosure period, and are the same as those which are in 40 CFR Part 190 (EPA, 1992a). Three specific aspects of 40 CFR Part 191, Subpart B, were remanded by the U.S. Court of Appeals for the First Circuit (Natural Resources Defense Council, Inc., 1987).

Regarding the individual dose standards related to 10 CFR Part 60, the NRC indicated in the statement of considerations for the Advanced Notice of Proposed Rulemaking for 10 CFR Part 60 (NRC, 1980):

> The EPA has published its generally applicable environmental standard for all of the fuel cycle except waste storage and disposal, 40 CFR (Part) 190, which expresses the limit in the form of a quantitative dose limit to the individual. The EPA is in the process of developing its HLW standard. The Commission expects this standard to be similar in approach to that followed in 40 CFR (Part) 190.

Since the limits established for any operating fuel cycle facility have been determined to provide adequate protection for the health and safety of the public from radiation exposure, it seems logical that these same limits, for an individual's annual exposure, would be applicable as a standard to protect the public from radioactive materials released from a repository. The public's exposure from a facility that is assumed to operate for a very long period of time, or which is replaced by a similar facility with uninterrupted production, would result in the same potential risk as any other facility, including a geologic repository.

2.2.3 Dose Limits for Populations

There are no collective dose or population dose criteria applied in 10 CFR Part 60, but the NRC did address this matter in the statement of considerations for the Final Rule of 10 CFR Part 60 (NRC, 1983a). The NRC states:

The proposed rule (NRC, 1981a) did not include any siting requirements which dealt directly with population density or proximity of population centers to a geologic repository operations area. The Commission indicated its belief that a more realistic approach, given the long period of time involved, would be to address the issue indirectly through considerations of resources in the geologic setting.

Population distribution over the long term is immaterial if the geologic repository operates (performs) as anticipated. Demographic factors could nevertheless be of concern to the extent that they could increase the probability or the consequences of releases associated with unanticipated processes and events. As to probability, it is difficult to relate the likelihood of releases to population factors; it is the view of the Commission that it is more realistic, as originally stated, to reduce the probability by avoiding sites with significant resource potential and by using records and monuments to caution future generations. Consequences of unanticipated releases would be greater only if they occurred in densely populated areas. Nevertheless, it is the view of the Commission that it makes little sense to attempt to limit such consequences by means of a population-related siting criterion, since long-range demographic forecasts are inherently speculative and unreliable; instead, the Commission is taking the approach that releases that result from the occurrence of unanticipated processes and events must be evaluated and must satisfy the EPA standard.

The Commission anticipates that the selection of a densely populated area would be unlikely even in the absence of express constraints in NRC regulations. For one thing, such a site would be disqualified under the guidelines to be developed (by the DOE) under the Nuclear Waste Policy Act.

It should be noted that the DOE did not include any population related criteria under Subpart C, Postclosure Guidelines, of 10 CFR Part 960, General Guidelines for the Recommendation of Sites for Nuclear Waste Repositories (DOE, 1992). However, Yucca Mountain, the only site currently under consideration per the Nuclear Waste Policy Amendments Act (U.S. Congress, 1987), has a low population density and is remote from any existing large population center.

In 10 CFR 60.122(b)(6), the NRC identified that a low population density within the geologic setting and a controlled area which is remote from population centers is a favorable condition for a repository to exhibit. This approach to controlling (minimizing) the population dose for a geologic repository will help to assure that the collective dose will be as low as possible, should the population distribution remain fairly constant.

2.2.4 Applicability of ALARA Principle

The NRC has taken a position that the radiological requirement to keep exposures ALARA does not apply as a postclosure requirement for a HLW repository. In the statement of considerations for the Advanced Notice of Proposed Rulemaking for 10 CFR Part 60 (NRC, 1980) the NRC stated, "ALARA (as low as reasonably achievable) principles have not been applied to the natural features of a site because they are not amenable to modification once a site is chosen." Also, the NRC in the statement of considerations for the Final Rule of 10 CFR Part 60 (NRC, 1983a) stated:

Based in part upon the standard recently proposed by EPA, (47 FR 58196-58206, December 29, 1982) the Commission considers it reasonable to anticipate that the permissible amounts of radioactivity in the general environment will be established at a very low level. In fact, the statement of considerations accompanying the EPA proposed rule (47 FR 58196) explains that EPA has chosen to propose disposal standards that limit the risks to future generations to a level no greater than the risks which these generations would be exposed to from equivalent amounts of unmined uranium ore and thus, any risks to future generations from the disposal of high-level wastes would be no greater than, and probably much less than, risks which those generations would face if the wastes had not been created in the first place. Efforts to reduce the releases further would have little, if any, demonstrable value commensurate with their costs.

The EPA limits require the performance of geologic repositories to be effective over a long period of time. There will always be substantial uncertainties in predicting the long-term performance of geologic repositories. The Commission will insist upon the adoption of a variety of design features, tests, or other measures in order to be able to conclude with confidence that the EPA standard is met. The result may be the same as if the Commission were to impose similar requirements in the name of keeping releases as low as reasonably achievable. Given the substantial uncertainties involved in predicting long term performance, the already low EPA limits and the already stringent geologic performance requirements, it is doubtful that the ALARA concept could be applied in a meaningful way.

The Commission is recommending to EPA that the assurance requirements, including the ALARA provision, be omitted from the final rule. The Commission emphasizes that its (the NRC) rules accommodate the underlying concerns of EPA, as articulated in its (EPA's) statement of considerations, that measures must be taken to assure that the numerical release limits will be met.

The approach the NRC has taken is that a requirement for maintaining the public's radiation exposures and releases of radioactive material to the environment ALARA applies to the operations of any NRC licensed facility, but the concepts for ALARA do not apply to the postclosure aspects of a geologic repository. The basis for this is in the large uncertainties associated with determining the postclosure performance of a HLW repository.

2.2.5 Probabilistic Standards for Human-Induced and Natural Disruptions

The NRC rulemaking process is based on the concept that the standards must address low and extremely low probability events in the evaluation of the adequacy of a repository. The NRC addresses the concepts of the probabilistic-disruptive events of human intrusion in the section titled, Human Intrusion, within the statement of considerations for the Final Rule for 10 CFR Part 60 (NRC, 1983a).

The Commission explained that inadvertent intrusion was highly improbable, at least for the first several hundred years during which time the wastes are most hazardous; and even if it should occur, it is logical to assume that the intruding society would have the capability to assess the situation and mitigate consequences.

> Although the discussion accompanying the proposed rule (NRC, 1981a) indicated that intrusion scenarios need not be considered, the rule itself was not explicit on this point. The Commission considers it necessary to clarify its position and, in doing so, allows for examination of intrusion under appropriate bounding conditions. ... Its objective is to provide a means for evaluating events that are reasonably of concern, while at the same time excluding speculative scenarios that are inherently implausible. The Commission will not require this generation to design for fanciful events which the Commission has an abiding conviction will never occur; on the contrary, it will grant a license if it is satisfied that the risk to the health and safety of future generations is not unreasonable. The rule now incorporates a definition of "unanticipated processes and events" which are reviewable in a licensing proceeding; such processes and events expressly include intrusion scenarios that have a sufficiently high likelihood and potentially adverse consequence to exceed the threshold for review. The scenarios must be "sufficiently credible to warrant consideration."
>
> The definition of "unanticipated processes and events" (includes and) also implicitly bounds the consequences of intrusion scenarios. This is accomplished not only by the assumption of continued understanding of radioactivity and survival of records, but also by the further assumptions that if there are institutions that can cause intrusion at depth in the first place, there will also be institutions able to assess the risk and take remedial action.

The NRC addresses the concepts of probabilistic-disruptive events of natural origin primarily in the section titled, Anticipated/Unanticipated Processes and Events, within the statement of considerations for the Final Rule for 10 CFR Part 60 (NRC, 1983a). It should be noted that the distinction between anticipated and unanticipated processes and events relates solely to natural processes and events affecting the geologic setting. Numerical performance objectives are established for particular barriers for anticipated processes and events, but numerical criteria are not established for unanticipated processes and events. However, additional requirements may be found to be necessary to satisfy the overall system performance objective as it relates to unanticipated processes and events. The NRC relates anticipated with the assumption of Quaternary events continuing to operate during the period of PA. Identification of such events will require considerable judgment and not be amenable to accurate quantification, by statistical analysis, of their probability of occurrence. The license review will determine reasonable assurance of compliance with EPA standards for both anticipated and unanticipated processes and events by two principal elements: (i) the PA indicates the likelihood of exceeding the EPA standards is low; and (ii) the PA is sufficiently conservative and its limitations are sufficiently well understood to assure the repository performance is within applicable limits.

2.2.6 Active and Passive Institutional Controls for Preventing Human Intrusion

The NRC position applicable to human intrusion was clearly summarized in its statement of considerations for the Final Rule for 10 CFR Part 60 (NRC, 1983a). Excerpts of the most pertinent statements are given in the following.

> The Commission observed, in the preamble of the proposed rule, that everything that is reasonable should be done to discourage people from intruding into the geologic repository. Those measures which it believed to be reasonable included directing site

selection toward sites having little resource value and marking and documentation of the site. Beyond that, the Commission felt there would be no value in speculating on the "virtual infinity of human intrusion scenarios and whether they will or will not result in violation of the EPA standard."

After careful consideration of the public comments received on questions relating to human intrusion, the Commission is of the view that while the passive control measures it is requiring will reduce significantly the likelihood of inadvertent intrusion into a geologic repository, occasional penetration of the geologic repository over the period of isolation cannot be ruled out, and some provision should be made in the final rule for consideration of intrusion should these measures fail.

In summary, the Commission has retained the principle that highly speculative intrusion scenarios should not be allowed to become the driving force in license reviews, but has introduced some flexibility to permit consideration of intrusion on a case-by-case basis where circumstances warrant.

The NRC position allows for the consideration of human intrusion and its resultant exposures (consequences) in a reasonable approach. This will assure public health and safety while not allowing the postulation of extremely low probability intrusion scenarios to delay the licensing process for a potential geologic repository.

2.2.7 Evaluation Period for Performance Assessment

In NUREG-0804 (NRC, 1983b), the NRC presents its responses to the individual comments received on the Proposed Rule for 10 CFR Part 60 (NRC, 1981a). These responses indicate that the NRC will leave the decision on the adequacy of a 10,000-year period to evaluate the overall system performance of a repository to the EPA. The NRC responses to Comments Nos. 119, 264, 280, 291, 375, 386, and 403 clarify the NRC position on this issue, and three specific responses are given in the following.

Staff Response to Comment No. 264: Long-term performance of a repository must be evaluated against the EPA standard. If the EPA standard were to specify environmental radioactivity levels over a period of 100,000 years, for example, then it would be necessary to predict performance over that period. We recognize that the degree of uncertainty may increase over time, at least as to some processes and events, but this should not preclude the making of required findings with reasonable assurance.

Staff Response to Comment No. 291: The issue of an appropriate cut-off (10,000 or 100,000 years, for example) must in the first instance, be resolved by EPA. However, we have assumed for purposes of developing performance objectives for particular barriers, the EPA standard will provide a 10,000-year cutoff.

Staff Response to Comment No. 386: The NRC will apply the EPA standard to whatever interval the EPA finally establishes. It would not be appropriate for our rule to specify an interval, but we have used 10,000 years in our analyses.

2.2.8 Overall System and Subsystem Performance Requirements

The NRC has taken a position that a HLW repository will apply a defense-in-depth or multiple barrier approach in meeting the EPA standard. In the statement of considerations for the Advanced Notice of Proposed Rulemaking for 10 CFR Part 60 (NRC, 1980), the NRC stated, "the Commission staff believes that it is reasonable to couple a prudently and cautiously selected geologic setting (natural barrier) with a set of engineered barriers capable of performing or assisting in the performance of the functions..." and, "a defense-in-depth approach to provide assurance and confidence that the EPA standard can be met."

The NRC position on overall system and subsystem performance limits was also clearly summarized in its statement of considerations for the Final Rule for 10 CFR Part 60 (NRC, 1983a). Excerpts of the most pertinent statements are given in the following.

> The Commission identified two potential viable approaches to assuring achievement of the desired isolation goal of controlling releases so as to assure that radioactivity in the general environment is kept to sufficiently low levels. The Commission suggested that a course that would be "reasonable and practical" would be to adopt a "defense-in-depth" approach that would prescribe minimum performance standards for each of the major elements of the geologic repository, in addition to prescribing the EPA standard as a single overall performance standard.

Arguments were made that the NRC should not establish fixed numerical values for subsystem performance; if the subsystem performance criteria were derived from the overall system performance objectives they would effectively be *de facto* regulations which could not be violated without violating the overall objective. The NRC responded to these arguments in the Final Rule for 10 CFR Part 60 (NRC, 1983a) with the following:

> The proposed rule (NRC, 1981a) defined anticipated processes and events as "those natural processes and events that are reasonably likely to occur during the period the intended performance objective must be achieved and from which the design bases for the engineered system are derived." At the same time, the Commission was requiring that the facility be designed so as to assure that long-term releases conform to standards established by EPA. The statement of considerations pointed out that if the process or event is unlikely, the overall system must still limit the release consistent with the EPA standard as applied to such events. This created a contradiction because on the one hand it was stated that the design bases should be derived from anticipated processes and events while, on the other hand, the design was to meet an EPA standard as applied to what was unanticipated.
>
> The Commission has resolved this conflict by eliminating the reference to design bases from the definition of "anticipated processes and events." It has also included a definition of "unanticipated processes and events." In the final rule, numerical performance objectives are established for particular barriers, assuming "anticipated processes and events." Such numerical criteria are not established for "unanticipated processes and events." Rather, additional requirements may be found to be necessary

> to satisfy the overall system performance objective as it relates to unanticipated processes and events.
>
> Nevertheless, if the Commission were simply to adopt the EPA standard as the sole measure of performance, it would have failed to convey in any meaningful way the degree of confidence which it expects must be achieved in order for it (NRC) to be able to make the required licensing decisions. ... To that end, the Commission considers it appropriate to include reasonable generic requirements that, if satisfied, will ordinarily contribute to meeting the standards even though modifications may need to be made for some designs and locations.
>
> The Commission is also concerned that its final judgments be made with a high degree of confidence. Where it is practical to do so, the Commission can and will expect barrier performance to be enhanced so as to provide greater confidence in its licensing judgments. Accordingly, a variation between actual and assumed EPA standards will not necessarily require a change of corresponding magnitude in the individual barrier performance requirements.
>
> While use of an assumed EPA standard provides a basis for specifying anticipated performance requirements for individual barriers, it does not deal with the concern about undue restriction upon the applicant's flexibility. The Commission's response to this has not been to abandon the values altogether, but rather to allow them to be modified as the particular case warrants.
>
> There is nothing inconsistent between the multiple barrier, defense-in-depth approach and a unitary EPA standard; on the contrary, in view of the many possible circumstances that must be taken into account, the Commission firmly believes that the performance of the engineered and natural barriers must each make a definite contribution in order for the Commission to be able to conclude the EPA standard will be met.

Overall system performance is an important element used in assessing the ability of a HLW repository to meet the regulatory standards and thus protect the health and safety of the public. The use of regulatory requirements applied to individual barriers or pathways to provide containment and isolation is needed to have confidence that the overall system performance will be met, given the uncertainties of long-term isolation. This use of overall system and subsystem performance criteria is based upon the need to have reasonable assurance that adequate public health and safety will be provided.

2.3 SUMMARY OF RECENT NRC STAFF COMMENTS ON THE EPA STANDARDS FOR DISPOSAL OF HIGH-LEVEL WASTE

The EPA has issued three working drafts of 40 CFR Part 191, Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes. The NRC, in its comments on these drafts, has expressed and refined its positions on the issues being addressed by the NAS Committee. This subsection focuses on the NRC comments issued after June 1989, when the EPA distributed the first of its working drafts[2] for amending the remanded 40 CFR Part 191 (EPA, 1985). The NRC comments on 40 CFR Part 191, prior to its being remanded (Natural Resources Defense Council, Inc, 1987) are addressed in Subsection 2.2 of this report.

Each of the eight topics identified in the introduction have been addressed by the NRC staff comments on the EPA working drafts and are summarized in this subsection. Concise statements on the NRC staff views on the EPA HLW standards were prepared for a presentation to the NAS Committee (Federline, 1993). These statements are based upon several documents which are cited in Subsections 2.3.1 through 2.3.8. A summary of the concise statements (Federline, 1993) is presented in the following paragraphs.

The NRC has a strong interest in the form and content of HLW standards, and the NRC's first interest is protection of the public health and safety; however, the NRC is also concerned with the clarity of the standards and the practicality of evaluating compliance during licensing. The NRC also recognizes a strong national interest in proceeding with HLW disposal and is concerned that standards should provide a level of safety which is adequate to protect future generations, but not so stringent that demonstrating compliance becomes needlessly costly or time-consuming.

The NRC believes the basis for HLW regulation is that future societies will be just as concerned about the potential health hazards of radiation exposure as society is today and that future societies should be provided the same level of protection from radiation exposures as we would expect for ourselves. Furthermore, HLW disposal should not impose burdens on future societies, and these societies should not have to take special precautions to protect themselves from radioactive materials disposed of today. The NRC also believes that the standard should assume that human beings and their societal institutions remain much as they are today and that speculation about the ways in which societies and humans might change over thousands of years is a very difficult undertaking with little chance of predictive accuracy.

In the NRC view, the EPA should reduce the emphasis placed on technical achievability when deriving its standards. For a new undertaking such as a HLW repository, there is a real potential for technology-based standards to be unreasonably stringent if all significant releases and exposure pathways cannot be identified and included in the derivation of the standards. There is also no guarantee which technology-based standards will provide adequate protection. For these reasons, the NRC has recommended to the EPA that much more emphasis should be placed on a health-based approach when HLW standards are developed.

The NRC believes that radiation protection for individuals, applied in a reasonable manner, should be a part of the HLW standards. An individual protection standard should not attempt to protect all individuals, under all conceivable circumstances, at all times in the future. Rather, a standard should protect critical groups based on reasonable, realistic exposure scenarios. The NRC has supported a derived standard, such as a limit on radionuclide releases, because such a standard would be easier to implement during licensing then a fundamental standard expressed in terms of dose or health risks. However, if a derived standard is to be used, it would be necessary to avoid unrealistic assumptions in the derivation of the standard. A fundamental dose or health risk standard would also be acceptable, provided that such a standard could be implemented using some type of reference biosphere. The NRC

[2] EPA Working Draft No. 1, dated June 2, 1989

would discourage a fundamental standard which would permit unlimited speculation about human locations, lifestyles, and societal conditions.

The NRC regulations for a geologic repository have not assumed that active institutional controls would be effective in preventing human intrusion for more than 100 years after facility closure. This assumption appeared to be prudent for a HLW repository because no practical method has been identified to guarantee which active institutional controls will persist or will continue to be effective. Passive institutional controls, such as monuments, markers, and land use records, are likely to persist and be effective in deterring future human intrusion into a repository. Concerns about the scientific predictability of human intrusion are reflected in the Energy Policy Act of 1992 identification of postclosure oversight and human intrusion as subjects for NAS Committee review. Predicting the probabilities of rare geologic events, such as volcanic activity at Yucca Mountain, could prove nearly as challenging as predictions of human intrusion. Therefore, the NRC believes that rare geological events, along with human intrusion, be included when considering whether it is possible to make scientifically supportable predictions of potential repository disruptions.

In probabilistic risk assessments, the probability that an event will occur cannot always be determined from the historical frequency of occurrence of similar events. For rare events, the probabilities are often values which represent an individual's degree of belief that an event will occur. Although such probability estimates may not be scientifically verifiable in the most rigorous sense, they have provided an adequate basis for past regulatory decisions such as seismic potential in the eastern United States. Thus, it is reasonable to expect that a probabilistic standard will prove workable during licensing. Nevertheless, some of the events of concern for predicting the performance of the repository may be even more speculative then events dealt with in the past and could be difficult to evaluate during licensing. In the NRC view, implementing probabilistic standards during repository licensing would be challenging, but should ultimately prove to be feasible.

The NRC regulations now contain a requirement for consideration of alternatives to the major design features of a repository. Any additional extensive ALARA analysis is likely to prove speculative and unworkable, in light of the large uncertainties in projected repository performance. The NRC would object to any broad-based requirement that repository releases be demonstrated to be ALARA, especially if such a requirement were applied to site selection.

The NRC has recommended to the EPA that any numerical HLW standards be applied only for a limited time after disposal, such as 10,000 years. In the NRC view, the large uncertainties inherent in estimating releases over long times make it impractical to make a scientifically rigorous demonstration of compliance with numerical regulatory limits. Instead, potential releases that might occur should be estimated and disclosed in a suitable format, such as an Environmental Impact Statement. These statements (Federline, 1993) are based upon several sets of the NRC comments on the EPA working drafts of their proposed HLW standards.

2.3.1 Health-Based, Risk-Based, and Technology-Based Standards

The advantages and disadvantages of the different bases for HLW standards are discussed in Appendix A of SECY-91-242 (NRC, 1991b). The NRC positions on the possible alternatives for HLW standards are concisely summarized in this document, and thus, are directly quoted.

EPA's containment requirements are expressed in terms of allowable releases of radioactive materials from a repository. EPA's release limits were derived from a health-effects goal, using a generic biosphere model with world-average characteristics. An alternative format would explicitly limit the doses (or health risks) that might result from those releases. For example, the recommendations of ICRP Publication 46 (ICRP, 1985a) include application of basic dose limits for expected releases (an average dose to the critical group of 100 mrem/yr or 1 mSv/yr), as well as limits on projected health risks for releases that are not likely to occur.

The advantage of the release-limit format is that it provides a usable measure of repository performance while significantly simplifying demonstrations of compliance. Regardless of the form of the standards, a major part of an analysis of compliance will consist of evaluating the ability of the repository barriers to reduce releases of radioactive material to the environment. If the standards place limits on releases, the evaluation is complete to that point.

If, however, the standards limit doses or health effects, an additional evaluation is needed to estimate the environmental transport and human uptake of the released material. Over the long time period of concern in repository licensing (10,000 years), the parameters involved in dose or health effects estimates can be highly uncertain. For example, the locations where people might live, their dietary habits, the amount of their food obtained locally, and even metabolic characteristics could change, as they have in the past. Elimination of such speculative parameters from a licensing review would be beneficial in terms of reaching a timely licensing decision that adequately protects public health and safety.

One disadvantage of the release-limit format is that it is difficult to compare such a standard with other radiological impacts (e.g., background radiation) or other radiation protection standards. Another disadvantage is that the actual number of health effects to be expected for a repository will probably vary from EPA's goal, since few actual repository sites will conform to the world-average biosphere model used by EPA to derive the release limits.

A standard expressed directly in terms of doses or health effects would have the advantage of facilitating comparison with other radiological impacts and radiation-protection standards. Another advantage is that such a standard would directly limit the potential doses or health risks of concern at a specific site. As noted above, a release-limit standard might allow the actual public-health risk from a repository to vary from EPA's goal if the characteristics of the biosphere surrounding the repository are significantly different from the generic biosphere used by EPA to derive its release limits.

An intermediate alternative would be to express the standards in terms of doses or health effects and to specify, by rule, the assumptions to be made in projecting the doses or health effects associated with releases of radioactive materials to the environment. For example, either EPA or the Commission would specify a "static biosphere," in which current population locations, lifestyles, and metabolic characteristics would be assumed to remain unchanged for the indefinite future.

However, such an approach would merely substitute an assumption that present site-specific biosphere conditions are representative of the future in place of the EPA assumption that current world-wide averages are an adequate representation. While this approach would eliminate potential uncertainties, the staff is not convinced that such a specification would be any more accurate than EPA's world-average model. Thus, the staff continues to favor retention of the release-limit format of EPA's standards.

The NRC staff has long supported EPA's release-limit format for the standards, because it would eliminate many potentially contentious issues from a licensing review. The staff continues to believe that the implementation advantages of the release-limit format far outweigh the disadvantages.

Further support for a risk-based or health-based standard is expressed in SECY-91-218 (NRC, 1991c).

> Regarding the stringency and the technical-achievability basis underlying the standards, the staff believes that EPA should place more emphasis on comparisons with other risks experienced by society and the risk levels used as the basis for other safety standards, particularly those for the uranium fuel cycle. EPA's analyses of hypothetical repository performance should play a less prominent role in supporting the standards.

2.3.2 Dose Limits for Individuals

The advantages and disadvantages of a standard based on protection of individuals are discussed in Appendix A of SECY-91-242 (NRC, 1991b). The comments presented in this document again concisely summarize the alternatives for HLW standards, and are quoted.

> EPA's standards emphasize protection of populations by imposing "containment requirements" that limit the cumulative amount of radioactive material released over 10,000 years. The cumulative release limits correspond to EPA's population-impacts goal of 1,000 premature cancer deaths for a 100,000 metric ton (MTHM) repository. Additional(ly), limited protection of individuals is provided for "undisturbed performance" during the first 1,000 years. Thus, while the population is protected for most of the circumstances and time period of concern, radiation doses to particular individuals could be either very high or very low, depending on specific circumstances. The alternative to EPA's cumulative release limits, as recommended in ICRP Publication 46 (ICRP, 1985a), would be limits that emphasize protection of individuals rather than populations.
>
> EPA's decision to base its standards on population impacts rather than on protection of individuals was EPA's most significant departure from the traditional concepts of radiation protection, from the recommendations of international advisory groups, and from the practices of other nations. All national and international criteria and guidance of which the staff is aware use protection of individuals as the primary safety criteria. Evaluation of population impacts is generally required to determine whether such

impacts are "as low as is reasonably achievable (ALARA)," but not as a primary measure of facility acceptability. EPA argued that compliance with limits corresponding to protection of individuals might be very difficult to demonstrate and that cumulative release limits would be more practical[3]. It is also noted that standards based on protection of individuals might encourage selection of disposal sites where any release of wastes would be substantially diluted, even if such sites offered less than optimal containment of wastes.

Many existing radiation-protection standards, including EPA's environmental standards for the uranium fuel cycle, limit radiation doses received by the maximally exposed individual. An estimate of the maximum individual dose begins with a projection of the location, timing, and rate of release of radioactive material to the human environment. For most releases, the concentration of released material must also be projected. Then, potential pathways of exposure (e.g., drinking water and food chains) must be defined along with the usage rates (e.g., drinking water and food consumption) of the maximally exposed individual. The following are pertinent quotes from SECY-91-242 (NRC, 1991b).

> Estimation of the maximum individual dose is strongly dependent on the rate of release of radioactive material to the environment, since the rate of release will largely determine the concentrations of radioactive material ultimately reaching an individual. The relative timing of releases of different radionuclides will also be important, since simultaneous release of two or more radionuclides will cause higher doses than would sequential releases. Finally, the estimated doses will depend strongly on whether the location and characteristics of the exposed individual are taken to be projections of current demographics and lifestyles or are defined in a manner that maximizes the doses that reasonably could be hypothesized to occur in the future.
>
> Average Critical Group Dose The fundamental radiation protection recommendations of the ICRP now include the concept of the "critical group," (i.e., those who are expected to receive the greatest exposure). The ICRP recommends that its dose limits be applied to the average dose within the critical group, rather than to the maximally exposed individual. Application of the ICRP concept would require essentially the same information as the maximum individual-dose standard discussed above. However, it would also be necessary to define the critical group in terms of size, location, and usage rates for the potential pathways of exposure, and to determine the average dose expected within this group.

NRC commented on individual dose limits in SECY-91-218 (NRC, 1991c), and is quoted.

> The staff recognizes that protecting individuals, rather than populations, would make EPA's standards consistent with other national and international radiation protection standards and guidance. However, the staff is not convinced that implementation of the standards in an NRC licensing review would be affected if EPA were to emphasize protection of individuals. Accordingly, the staff has not objected to EPA's decision to derive the containment requirements from a population impacts goal.

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[3] 50 FR 38077, dated September 19, 1985.

More detailed comments on the specific individual dose limits for a HLW repository are presented in a set of joint comments by the NRC and the Advisory Committee on Nuclear Waste (ACNW), on page 1 of the Proposed Combined Responses to EPA's Six Questions, an Attachment to SECY-91-266 (NRC, 1991d), which states the following.

> ACNW View: 10 mrem/yr (0.1 mSv/yr)
>
> NRC View: 25 mrem/yr (0.25 mSv/yr) for 191.03 and 10 mrem/yr (0.1 mSv/yr) for 191.14
>
> Combined Comment: The International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP) recommend an overall dose limit of 100 mrem/yr (1 mSv/yr) averaged over the lifetime of an individual. This limit applies to the total radiation exposure received from all sources and practices excluding medical and natural sources. Exposures of short duration are permitted to be larger, provided that the lifetime average remains within the recommended limit. Because postclosure radionuclide releases from a high-level waste repository, if they occur, could continue for a number of years, EPA's dose limits should be apportioned from the 100 mrem/yr (1 mSv/yr) recommended list.
>
> Limits for specific sources of exposure, such as a repository, are to be apportioned in a way that ensures that combined doses from all sources will not exceed 100 mrem/yr (1 mSv/yr). For EPA's HLW standards, the proper apportionment must take into account the range of facilities to which the dose limits would be applied. EPA proposes to apply the dose limits of Section 191.03 (of 40 CFR Part 191) to the combined doses from HLW facilities and all other uranium fuel cycle facilities. Since the uranium fuel cycle includes several potential sources of exposure, it seems reasonable to allow a relatively large fraction of the overall dose limit for these facilities. Absent a clear demonstration by EPA that the 10 mrem/yr (0.1 mSv/yr) limit is necessary to protect public health and safety, 25 mrem/yr (0.25 mSv/yr) would be the more appropriate dose limit for the combined doses addressed by Section 191.03.
>
> The proposed dose limit of Section 191.14 would apply only to the projected postclosure performance of a repository - not to be combined doses from a repository and other sources. For this section, a dose limit of 10 mrem/yr (0.1 mSv/yr) would allow an ample margin so that other future sources of radiation exposure would not cause total doses to exceed the limits recommended by ICRP and NCRP.

2.3.3 Dose Limits for Populations

In addition to the population-related aspects of a HLW repository discussed in Subsections 2.3.1 and 2.3.2, advantages and disadvantages of a standard based on collective doses are discussed in Section 3 of Appendix A to SECY-91-242 (NRC, 1991b). The comments in Appendix A present a very good summary of the alternatives for HLW standards.

Recently, the ACNW commented on the population-impacts basis underlying EPA's standards[4]. ACNW stated, in part:

> The projection of collective dose estimates far into the future (as is necessary to comply with the high-level radioactive waste repository standards as proposed by EPA) is extremely difficult. Factors that complicate such estimates include errors in predictions of regional and global population demographics (size and location) and of potential radionuclide pathways (groundwater flow and agricultural practices). In contrast, long-range projections of the locations and living habits of individuals who may reside near a repository are relatively straightforward, and estimates of their potential doses can be made with greater certainty.

The staff agrees that long-term projections of collective doses are extremely difficult. As discussed in Section 2 above (quoted in Subsection 2.3.2 of this report), a fundamental feature of EPA's standards is the use of limits on the amounts of radioactive material released to the environment. This feature of the standards eliminates the need for difficult dose calculations, and has long been supported by the staff. Nevertheless, ACNW's comment raises a valid question — would EPA's derivation of the release limits have been more technically rigorous if those release limits had been based on protection of individuals rather than populations? ACNW argues ... that, when monitoring releases from operating facilities, collective doses are more difficult to estimate than are individual doses. The staff agrees. However, when projecting hypothetical impacts far into the future, the staff is not convinced that there is a significant difference between release limits based on individual protection versus release limits derived from a population-protection goal. The following discussion examines four measures of repository performance that could have been used by EPA in developing its standards.

<u>Summation (of the topic) Collective Dose</u> The most obvious way to estimate the collective dose associated with a repository is to determine the individual dose anticipated for each person exposed to releases from the facility, and then to sum those individual doses. Estimation of the collective dose in this way requires fairly detailed demographic information about the population exposed to a release, including the number of individuals exposed, their locations, and the usage rates for each person for each pathway of exposure. As a practical matter, a truncation of the summation of individual doses may be necessary, either as a function of distance from the facility or at some <u>de-minimis</u> or "negligible risk" individual dose rate. Some radiation-protection experts extend the "negligible-risk" concept to conclude that truncation is necessary, as a matter of principle, arguing that collective doses composed of very small individual doses are meaningless for regulatory purposes. For example, EPA's release limit for carbon-14 was based on a world-wide collective dose estimate in which each individual dose is only a tiny fraction of natural background radiation levels. However, there is no consensus within the radiation protection

[4] January 29, 1991, letter from Dade W. Moeller to Chairman Carr.

community regarding truncation, as illustrated by the directly contradictory advice offered by radiation protection advisory organizations.

The National Council on Radiation Protection and Measurements (NCRP), in its 1987 recommendations (Report No. 91), recommends truncation of collective dose estimates for individual dose contributions below 1 mrem/yr, arguing that such dose rates represent a "negligible individual risk level." The NCRP describes this risk level as ". . .trivial compared to the risk of fatality associated with ordinary, normal societal activities," and recommends that such risks "be dismissed from consideration." In contrast, the 1990 recommendations of the ICRP state that "The Commission does not recommend the use of this technique" (Publication 60, Paragraph 293). Instead, the ICRP recommends truncation in only two situations: "when the subsequent [individual dose] contributions are common to all alternatives or it is no longer possible to distinguish between options" (Publication 55, Paragraph 149). Perhaps the most practical course of action would be similar to that of NUREG-1150 where collective doses were estimated both within a 50-mile radius of a facility and to the entire regional site population. Differences in the two estimates generally were not substantial. As discussed below, the method used by EPA in deriving its standards did not involve any truncation of individual doses.

Collective dose estimates are not as sensitive as individual dose estimates to the location, timing, and rate of release of radioactive materials to the environment. For example, the sequential release of two radionuclides will produce essentially the same collective dose as simultaneous release of those nuclides, even though individual doses might differ significantly. Therefore, although collective dose estimates require more detailed estimates of biosphere characteristics, there is an offsetting reduction in the needed precision of release estimates derived from geosphere and engineered barrier analyses.

Collective Dose by EPA's Method The collective dose estimates used by EPA to develop its high-level waste standards were not produced by summing individual dose estimates. Instead, EPA defined a "world-average" biosphere model, with specified fractions of released radioactive material entering each exposure pathway of the model[5]. For example, EPA estimated that 1.3×10^{-4} of the world-wide river flow is consumed as drinking water, and EPA assumed that the same fraction would apply to releases of radioactive material to a river near a repository. Thus, EPA assumed that the release of one curie of any radionuclide results in consumption of 1.3×10^{-4} curies via drinking water, without regard to whether that activity is consumed by a small or a large number of individuals. Similar assumptions were made for other exposure pathways, allowing EPA to estimate collective doses without first calculating individual doses.

Overall Evaluation Any of the four measures of repository performance discussed above could have been used by EPA in deriving its HLW standards. Individual dose estimates do not require extensive demographic projections of the populations affected

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[5] EPA, "Environmental Pathway Models for Estimating Population Health Effects . . ," EPA 520/5-85-026.

by potential releases, including the location, timing, and rate of release. In contrast, population dose estimates do require demographic projections, but are less sensitive to uncertainties in the nature of the release. Given the sizeable uncertainties in projections of either individual or population doses, EPA's "world-average" biosphere model appears to be a workable approach for deriving generic release standards for HLW disposal.

The principal advantage of EPA's cumulative release limits, as contrasted with release rate or concentration limits derived from an individual protection goal, is that such limits encourage isolation, rather than dilution, of wastes. A significant disadvantage of EPA's cumulative release limits is inconsistency with more commonly applied radiation protection standards, which emphasize protection of individuals. Another disadvantage may be that EPA's cumulative release limits do not recognize any de-minimis level of radiation exposure. Thus, releases that cause very small doses to large numbers of people are considered equivalent to releases that cause larger doses to smaller populations.

The NRC staff has not previously objected to the population-impacts basis for EPA's standards. EPA's decision to protect populations rather than individuals was viewed as a decision properly within EPA's discretion, given EPA's authority to develop generally applicable environmental radiation-protection standards. Moreover, the staff does not believe that the derivation of release criteria corresponding to protection of individuals would be any more technically rigorous than EPA's derivation of its current release limits from a population-protection goal.

The NRC staff does not perceive any significant implementation differences for standards, based on protection of populations or on protection of individuals. If EPA were to base its standards on protection of individuals, a generic biosphere model could be used to translate its radiation-protection objectives into allowable concentrations of radioactive materials permitted to be released to the environment. Such a translation would be very similar to EPA's previous conversion of a population-protection goal into allowable cumulative releases of radionuclides. In either case, the important implementation concern is conversion of a radiation-protection goal to a release-limit format, eliminating speculative long-term environmental transport and dosimetry issues from a licensing review.

2.3.4 Applicability of ALARA Principle

The need for explicit or implicit ALARA criteria in the HLW standards is discussed on page A-7 of Appendix A of Enclosure 1 of SECY-91-242 (NRC, 1991b). The comments presented here concisely summarize the NRC position concerning ALARA, and are quoted in the following.

EPA's standards are notable for the absence of a specific requirement that projected releases be ALARA. EPA's containment requirements, which were derived from analyses of the waste-isolation capabilities of hypothetical HLW repositories, are effectively "generic" ALARA levels. In contrast, an explicit ALARA requirement is a prominent feature of the recommendations of ICRP Publication 46.

The principal advantage of an explicit ALARA requirement would be consistency with other radiation-protection standards. The disadvantage would be significant difficulties in evaluating compliance with such a criterion. In the NRC staff's view, the large uncertainties in projected repository performance would make any case-specific ALARA analysis highly speculative. The NRC staff remains opposed to adoption of an ALARA requirement as a standard for post-closure performance of an HLW repository.

2.3.5 Probabilistic Standards for Human-Induced and Natural Disruptions

The probabilistic aspects of HLW standards are discussed on pages A-9 and A-10 of Appendix A of Enclosure 1 of SECY-91-242 (NRC, 1991b). These quoted comments concisely summarize the NRC position concerning a probabilistic format.

> The "containment requirement" of EPA's standards prescribe two sets of release limits. Releases more likely than 1 chance in 10 (over 10,000 years) must not exceed the levels specified in a table of release limits, whereas releases less likely than 1 chance in 10 may be up to 10 times larger. Releases less likely than 1 chance in 1,000 are not restricted at all by the standards. EPA's standards required that the probabilities of disruptive processes and events be estimated with sufficient precision to determine that a projected release falls within one of the two ranges of likelihood addressed by the standards. Uncertainty exists regarding acceptable methods for estimating the probabilities of potentially disruptive processes and events.
>
> In contrast to EPA's dual-release limits, ICRP Publication 46 recommends that the risk to any individual be limited to a specified level. In this context, "risk" means the product of the probability that an individual will receive a radiation exposure, and the probability that the resulting exposure will cause a fatal health effect. Thus, ICRP recommends a continuum of acceptable release levels, dependent on the likelihood that a release will occur.
>
> EPA's containment requirements have been criticized by NRC and by others, because they require numerical predictions of the probabilities of human-initiated disruptions and of rare geologic events (those with probabilities on the order of one chance in 1,000 over 10,000 years). EPA's critics believe that the inability to estimate such probabilities in a scientifically rigorous way will preclude determination of compliance with the standards in a licensing review.
>
> A range of alternatives exists for the probabilistic format of EPA's containment requirements. For example, EPA could limit applicability of the standards to relatively likely releases, as is the case for EPA's uranium fuel cycle standards. NRC would then need to develop some type of implicit or explicit safety standard for evaluating the acceptability of unlikely releases. Alternatively, EPA could replace its dual category standard with a pure risk standard, as recommended by the ICRP in its Publication 46. Such a standard would benefit from conforming more closely with other radiation protection standards. However, it would require probability estimates for disruptive processes and events that are at least as precise as the probability

estimates required by the current standards. Other alternatives include a qualitative (rather than a numerical) description of the release categories, or elimination of release categories so that a single release limit would apply to any release regardless of its likelihood.

The NRC staff believes that some type of probabilistic formulation is needed for EPA's standards in order to accommodate the large uncertainties in potential geologic evolution, climate change, and human activities. At the same time, the staff is sensitive to the difficulties that would be associated with the numerical probability estimates required by the current EPA standards and, perhaps to an even greater extent, by ICRP Publication 46. As an alternative, the staff has suggested to EPA wording for the containment requirements that would retain essentially the same level of safety sought by EPA, but would eliminate the need for precise numerical predictions of the probabilities of unlikely processes and events.

In Comment 7 on the second working draft of EPA's HLW standards, found on pages 4 and 5 of the first enclosure to SECY-91-168, Potential Issues For Negotiated Rulemaking on High-Level Waste Standards, (NRC, 1991e) the NRC presented the recommended alternative to the probabilistic issues of repository performance.

As EPA is aware, the Commission continues to be concerned about the workability of standards that require numerical probability estimates for very unlikely processes and events. In our formal comments on EPA's (1982) proposed standards, we suggested alternative wording for the containment requirements that would ease potential implementability problems while retaining approximately the same level of safety sought by EPA. That alternative would have required development of a complementary cumulative distribution function (CCDF) only for the more likely disruptive processes and events (those now defined as "anticipated" in 10 CFR Part 60). Very unlikely processes and events ("unanticipated" in Part 60 parlance) would be restricted by a release limit applied event-by-event, rather than cumulatively. With this structure for the containment requirements, there would be no need to develop precise numerical probability estimates for very unlikely processes and events. The following text for 40 CFR 191.13 illustrates the concept recommended in the Commission's earlier comment:

191.13 Containment Requirements:

(a) Disposal systems . . . shall be designed to provide a reasonable expectation that, for 10,000 years after disposal:

(1) anticipated performance will not cause cumulative releases of radionuclides to the accessible environment to have a likelihood greater than one chance in 10 of exceeding the quantities calculated according to Table 1 (Appendix B).

(2) the releases resulting from any process, event, or sequence of processes and events that is (are) sufficiently credible to warrant consideration will not

exceed ten times the quantities calculated according to Table 1 (Appendix B).

We, the NRC staff, strongly recommend that EPA reconsider adopting this concept for the containment requirements, because it would impose almost exactly the same level of safety on a repository, while avoiding the potential pitfalls of probability estimation for very unlikely and speculative events that could be far in the future.

Further detail on an approach to assessing the probabilistic nature of human intrusion is expressed in Enclosure 1, Comment No. 17, of SECY-91-218 (NRC, 1991c).

We (the NRC staff) recommend that EPA reevaluate the technical base underlying the guidance on frequency and severity of [human] intrusion. It is our understanding that EPA has, to date, limited its consideration to petroleum exploration. Exploration for non-petroleum resources may take much different forms. For example, multiple, closely-spaced boreholes may be drilled, the frequency of drilling will be highly site-specific, and borehole sealing may be absent or ineffective. Guidance based on petroleum industry practice may not be representative of other exploratory drilling practices — especially for borehole sealing.

2.3.6 Active and Passive Institutional Controls for Preventing Human Intrusion

In a response to questions raised by Commissioner Curtiss, the NRC prepared a letter, dated August 10, 1992 (NRC, 1992), which addressed active and passive institutional controls. The letter stated the following.

The 100-year limit for reliance on active institutional controls emerged, in part, as a consensus position from a series of public workshops on low-level radioactive waste disposal held by NRC in the 1970s. Those workshops resulted in an NRC requirement [10 CFR 61.59(b)] that institutional controls may not be relied upon for more than 100 years following transfer of control of a low-level waste disposal site to the owner. In response to comments that the period of institutional control should be raised from 100 to 300 years, the Commission said "it is not a question of how long the government can survive (that determines the institutional control period), but how long should they be expected to provide custodial care." The Commission went on to note that "a clear consensus was developed which supported the 100 year limit." (Supplementary Information for Part 61 Final Rule, 47 FR 57,446 dated December 27, 1982.)

The NRC's repository regulations in 10 CFR Part 60 do not contain an explicit limit on the duration of active institutional control. However, the provision (in 10 CFR 60.52) for termination of a repository license indicates that long-term reliance on active institutional controls is not anticipated.

Further detail on the effectiveness of passive institutional control is given in Enclosure 1, Comment No. 15, of SECY-91-218 (NRC, 1991c). Here the NRC recommended "that EPA reexamine the reasonableness of the part of the individual protection requirement that specifies an assumption of continual ground water use at the boundary of the controlled area. The passive institutional controls permitted by the standards would seem to provide at least some protection against such uninterrupted ground water use. The effectiveness of such controls is in any event a matter of implementation committed to the independent judgement of the Commission."

2.3.7 Evaluation Period for Performance Assessment

The NRC states, on page 4 of Enclosure 2 of SECY-91-218 (NRC, 1991c), that "some projections of the performance of repositories have shown the most significant releases of waste occurring after the 10,000 year cut-off of the current standards." The appropriate evaluation period for a HLW repository is discussed in Section 4 of Appendix A of SECY-91-242 (NRC, 1991b). These brief comments summarize the NRC position about using a 10,000-year period or another time period to assess the performance of a HLW repository, and are thus quoted.

> Applicability of the containment requirements of EPA's standards is limited to the first 10,000 years after repository closure. In contrast, the recommendations of ICRP Publication 46 are open-ended, restricting individual doses and risks in perpetuity.
>
> The advantage of a 10,000-year limit on releases is that very speculative long-term disruptions need not be evaluated in a licensing review. The disadvantage is the possibility that a significant release might occur after the 10,000-year cut-off, although the subsystem performance objectives and the qualitative siting criteria of 10 CFR Part 60 would limit the potential for, and the size of any such releases.
>
> The NRC staff has supported EPA's 10,000-year limit on the period of concern. Projections of repository performance for a 10,000-year period will be uncertain, but such projections become significantly more uncertain as the projections are extended over longer periods of time. The staff agrees with EPA that a 10,000-year regulatory test is generally sufficient to evaluate the acceptability of repository performance.

Further considerations of alternatives for the time period of evaluation of the performance of a HLW repository are summarized on page 2 of the Proposed Combined Responses to EPA's Six Questions, an Attachment to SECY-91-266 (NRC, 1991d).

> ACNW View: Agreement that 100,000 year evaluations are helpful for site comparisons, but not for evaluating the suitability of a single site.
>
> NRC View: Alternative site comparison is a National Environmental Policy Act (NEPA) issue and is not an appropriate subject to be addressed in EPA's HLW standards. EPA might want to consider whether an environmental standard should be developed for the post-10,000 year performance of a repository.
>
> Combined Comment: We recognize that the specification of the 10,000-year time limit is somewhat arbitrary. It is important that geologic or climatic changes do not occur in the near-term period following the 10,000-year limit if such changes could cause significant releases of radioactive material. The siting criteria and performance

objectives of 10 CFR Part 60 are intended to reduce the potential for, and the consequences of, such disruptive changes. Thus, the NRC is sympathetic to EPA's concerns about repository performance in the post-10,000 year period. However, EPA's HLW standards are being promulgated under Atomic Energy Act authority. Accordingly, they should be "generally applicable environmental standards" as defined in Reorganization Plan No. 3 of 1970, that is, "limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment..." Therefore, we do not believe that a requirement for comparison of alternative sites is an appropriate subject for EPA to address in these standards. Any long-term comparison of candidate sites should be part of a broader evaluation of alternatives under the provisions of the National Environmental Policy Act.

If EPA is concerned that the post-10,000 year performance of a repository could cause significant releases of radioactive material to the environment, an environmental standard, rather than an "assurance requirement," should be considered. Such an environmental standard would provide a basis for judging the acceptability of a single proposed repository site, rather than comparing the merits of alternative sites. However, the large uncertainties in projections of post-10,000 year performance raise questions about the practicality of such a standard. Because 10 CFR Part 60 already contains siting criteria and performance objectives that reduce the potential for significant post-10,000 year releases, NRC recommends that EPA limit application of its standards to 10,000 years.

2.3.8 Overall System and Subsystem Performance Requirements

Support for HLW standards which only address overall system performance is presented in Enclosure 1 of SECY-91-218 (NRC, 1991c), on page 6.

NRC Comment No. 12. The NRC staff prefers those options . . . that would combine the individual and ground water protection requirements into a single standard. Separate ground water protection standards would not provide any significant improvement in public health or environmental protection, but would add substantial complexity to the standards, with a resulting potential for increased difficulties in implementing the standards.

EPA Response. Working Draft 3[6] retains separate ground water protection standards. However, those standards are stated more simply than in Draft 2[7]. In particular, the multiple classes of ground waters (and multiple protection standards) of Draft 2 have been replaced by a single standard for a single type of ground water.

A recommendation that the EPA HLW standards should contain only an overall system performance limit is presented on page 4 of the Proposed Combined Responses to EPA's Six Questions, an attachment to SECY-91-266 (NRC, 1991d). The NRC states:

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[6] EPA Working Draft No. 3, dated April 26, 1991

[7] EPA Working Draft No. 2, dated January 31, 1990

> We (the NRC staff) believe it is important to recognize that the dose rate from underground sources of drinking water, even if contaminated to the limits specified in the National Primary Drinking Water Regulations, would still contribute only a small fraction (4 percent) of the current long-term dose rate limit (100 mrem/yr or 1 mSv/yr) for members of the public. Even if EPA adopts a 10 mrem/yr (0.1 mSv/yr) individual protection standard for an HLW repository, groundwater complying with the Drinking Water Regulations would contribute no more than 40 percent of the dose rate limit. In this sense, application of the Drinking Water Regulations to a repository represents additional stringency, especially because the primary pathway for public exposures from undisturbed performance of such facilities is through drinking water.

The NRC has begun the process of questioning: (i) whether the subsystem performance is an integral part (sum of the whole) of the overall system performance; or (ii) whether the performance of the subsystems can be evaluated independently of the overall system performance. This question was raised as a regulatory uncertainty by the NRC, on pages 3 and 7 and Enclosure 3 of SECY-91-225 (NRC, 1991f). No resolution to this uncertainty has been prepared, although the statement of considerations for the Final Rule for 10 CFR Part 60 (NRC, 1983a) indicate the latter is the Commission's position (see the discussion in Subsection 2.2.8).

2.4 LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE, 10 CFR PART 61

10 CFR Part 61 is the NRC standard which establishes the requirements for licensing the land disposal of low-level radioactive waste. The standard is not legally applicable to a HLW repository, but the standard is an example of an environmental radioactive waste disposal standard which contains concepts that may be useful in the development of HLW disposal standards. The standard is comprised of: (i) performance objectives; (ii) technical requirements for siting, design, operations, and closure; (iii) technical requirements concerning waste form; (iv) waste classification limits; (v) institutional requirements; and (vi) administrative and procedural requirements. The performance objectives in 10 CFR Part 61 include requirements for: (i) protection of the general public from releases of radioactivity (§ 61.41); (ii) protection of individuals from inadvertent intrusion (§ 61.42); (iii) protection of individuals during operations (§ 61.43); and (iv) stability of the disposal site after closure (§ 61.44).

2.4.1 Health-Based, Risk-Based, and Technology-Based Standards

Technology-based standards are those standards which are based primarily on judgments about system performance which are reasonably achievable using currently available technology (Kocher, 1993). In this context, 10 CFR Part 61 is primarily a technology-based radiation protection standard because in the development of the performance objectives contained in 10 CFR Part 61, the costs and impacts of a wide range of alternative low-level waste disposal technologies were examined and performance objectives which were compromises between costs and impacts were established. It should be noted that the distinction between health-based and technology-based standards is somewhat artificial because technology-based standards often take into account health risks to the public (Kocher, 1993).

In the development of the performance objectives contained in 10 CFR Part 61, four alternatives were examined in the Final Environmental Impact Statements for 10 CFR Part 61 (NRC, 1982).

(i) Disposal at a near-surface facility using past waste disposal practices. This alternative reflects past practices with respect to poor waste form characteristics and properties and an absence of facility design or operational practices directed at long-term stability.

(ii) Disposal at a facility using today's waste disposal practices. This alternative characterizes and reflects today's practices in the near-surface disposal of low-level waste. As the industry gained experience and as regulatory agencies acted with respect to identified problems in past operations, changes and modifications were made in past disposal practices. These included limits on the contents, type and form of waste acceptable for disposal, and improvements in design and operational practices. Several waste streams were required to be stabilized prior to disposal, mainly by means of containers providing stability, and concentrated liquids from power plants were solidified. A limit of 10 nCi/g (370 Bq/g) was also placed on the transuranic content of waste. In addition, several design and operational improvements were carried out to reduce contact of the waste by water and to improve site stability. These include compaction of backfill material and trench caps, use of a permeable backfill, use of a thick clay cap, and improved surface drainage to reduce infiltration.

(iii) Disposal at a facility using the 10 CFR Part 61 requirements. This alternative reflects disposal practices developed using three key waste disposal principles identified in the Draft Environmental Impact Statement for 10 CFR Part 61 (NRC, 1981b). These principles are:

(a) Long-term stability of the disposal facility and disposed waste. Stability helps to reduce trench cover collapse, subsidence, water infiltration, and the need to care for the facility over the long-term.

(b) The presence of liquids in waste and the contact of water with waste both during operations and after the site is closed. Water is the primary vehicle for waste transport and its presence in and contact with waste can contribute to accelerated waste decomposition and increased potential for making the waste available for transport off site.

(c) Institutional, engineering, and natural controls that can be readily applied to reduce the likelihood and impacts of inadvertent intrusion. For example, segregation or layering of particular waste streams reduces the impacts of intrusion.

(iv) Disposal at a facility using extensive improvements over today's practices. This alternative analyzes technology that could be used to achieve long-term stability. The principle alternative is to place all unstable waste into a stable form; other alternatives involve the use of facility design and operation options to achieve stability including grouted disposal, disposal into grouted concrete-walled trenches, or extreme compaction.

With regards to the performance objective contained in 10 CFR Part 61 for protection of the general public (§ 61.41), the costs and impacts of these alternatives were determined for dose limits which ranged from 1 to 25 mrem/yr (10 to 250 μSv/yr). As part of the development of 10 CFR Part 61, discussions were held with the EPA regarding the NRC development of an interim standard and the ultimate development of the EPA general standard. During these discussions, the EPA indicated that they expected that their general environmental release standard would end up in the same approximate range, from about 1 to 25 mrem/yr (10 to 250 μSv/yr). The analysis was then reduced to a question of what can be achieved at what price. Based on these considerations, a dose limit of 25 mrem/yr (250 μSv/yr) was chosen, consistent with the dose limit contained in 40 CFR Part 190 (EPA, 1992a).

For the performance objective contained in 10 CFR Part 61 for protection of individuals from inadvertent intrusion (§ 61.42), the costs and impacts of these alternatives were determined for whole body dose limits of 25 mrem, 500 mrem, and 5 rem (250 μSv, 5 mSv, and 50 mSv). A dose limit of 25 mrem (250 μSv) was judged to result in considerably more costs, more change in existing practices, and greater reduction in disposal efficiency than the other two alternatives. The 5 rem (50 mSv) alternative was judged to result in approximately the same costs as the 500 mrem (5 mSv) alternative, but could result in moderately higher intruder hazards which could extend for longer time periods. Based on these considerations, a dose limit of 500 mrem (5 mSv) was chosen. At the time, this limit was equal to the dose limit for individual members of the public contained in 10 CFR Part 20. It should be noted that the 500 mrem (5 mSv) dose limit is not expressly stated in § 61.42, but instead was used to derive the waste classification concentration limits in § 61.55.

In the Draft and Final Environmental Impact Statements for the Proposed Rule for 10 CFR Part 61 (NRC, 1981b), the performance objective for protection of the general public contained a requirement that concentrations of radioactive material in groundwater must not exceed the maximum contaminant levels in 40 CFR Part 141, National Primary Drinking Water Regulations, nominally equivalent to a dose limit of 4 mrem/yr (40 μSv/yr). However, the EPA commented that it was inappropriate to apply the EPA drinking water standard in this manner. In the Final Environmental Impact Statements for 10 CFR Part 61 (NRC, 1982), this apportionment of the drinking water pathway was removed. However, the NRC will still assess the potential impact on drinking water as part of licensing review.

Although the apportionment of the drinking water pathway was originally contained in the Proposed Rule, it was subsequently removed as a result of the EPA comments and is not contained in the Final Rule. Since apportionment of the drinking water pathway was removed, it appears that the NRC does not favor apportionment.

2.4.2 Dose Limits for Individuals

The individual dose limits for protection of the general public are 25 mrem/yr (250 μSv/yr) to the whole body, 75 mrem/yr (750 μSv/yr) to the thyroid, and 25 mrem/yr (250 μSv/yr) to any other organ (§ 61.41). These dose limits are numerically equivalent to the dose limits in 40 CFR Part 190. As mentioned previously, the NRC analyzed limits in the 1 to 25 mrem/yr (10 to 250 μSv/yr) range for various disposal technologies. In addition, the NRC did not anticipate any need to change the dose limit in 10 CFR Part 61 to meet a future EPA low-level waste standard.

The dose assessments in the Draft and Final Environmental Impact Statements for 10 CFR Part 61 (NRC, 1981b; 1982) were performed using a dosimetry system which used the concept of whole body dose, not the more current concept of effective dose equivalent. Both the Draft and Final Environmental Impact Statements for 10 CFR Part 61 used reference sites to evaluate site performance; this is equivalent to creating reference biospheres. No long-term climate changes were incorporated into the analyses. Dose assessments were done in a highly stylized manner with precise definition of scenarios.

The individual dose limits in 10 CFR Part 61 provide an example of technology-based dose limits applied to a waste disposal activity.

2.4.3 Dose Limits for Populations

There are no specific collective or population dose criteria in 10 CFR Part 61. However, in § 61.50, Disposal Site Suitability Requirements for Land Disposal, it states that "... a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives..." [§ 61.50(a)(3)]. It should also be noted that collective doses for short-term exposures were calculated as part of the evaluations conducted in the Draft and Final Environmental Impact Statements for 10 CFR Part 61 (NRC, 1981b; 1982).

Although the NRC did not establish collective dose limits in 10 CFR Part 61, it is clear that the NRC believes that population may have an impact on the calculated assessments of meeting the performance objectives and should be factored into the site selection process.

2.4.4 Applicability of ALARA Principle

In § 61.41, it states that, "Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as reasonably achievable." It should be noted that ALARA was intended to apply to long-term environmental release and protection of individuals during site operations and was not intended to apply to intruders, per Appendix F of the Final Environmental Impact Statements for 10 CFR Part 61 (NRC, 1982).

The concept of ALARA during site operations is applicable to a HLW repository. However, 10 CFR Part 61 also applies ALARA to long-term environmental releases, an approach at odds with 10 CFR Part 60.

2.4.5 Probabilistic Standards for Human-Induced and Natural Disruptions

In 10 CFR Part 61, protection of inadvertent intruders is provided by meeting waste classification limits in § 61.55. Waste was classified into Classes A, B, and C based on the radionuclide concentrations of the waste. Limiting radionuclide concentrations were calculated based on acute and chronic intrusion scenarios and a dose limit of 500 mrem/yr (5 mSv/yr) to the whole body. Class A waste assumes 100 years of institutional control and Class C waste concentrations were calculated from Class A concentrations with an additional 10 times credit for greater confinement and 400 more years of radioactive decay.

10 CFR Part 61 is a deterministic radiation protection standard which does not require evaluations of probability for human induced and natural disruptions, however, a wide range of intruder scenarios was evaluated in the Draft and Final Environmental Impact Statements for 10 CFR Part 61 (NRC, 1981b; 1982). The concept of reasonable assurance is part of the standard (§ 61.40) and could be applied to a HLW repository. For example, using the concept of reasonable assurance, highly unlikely scenarios or processes could be removed from consideration in the PA. This has the potential for simplifying the licensing process.

2.4.6 Active and Passive Institutional Controls for Preventing Human Intrusion

10 CFR Part 61 states that, "...institutional controls may not be relied upon for more than 100 years..." (§ 61.59). However, in public comments there were a number of suggestions that the period of institutional control be raised from 100 to 300 years. There appear to be two basic reasons for these suggestions. One reason is that institutions such as a state or the Federal government can reasonably be expected to survive for much longer than 100 years. A second reason is that the 100-year restriction on institutional care affects the waste concentrations acceptable for disposal as Class A waste with resultant higher costs to the waste generator. With respect to the first reason, NRC feels that it is not a question of how long the government can survive, but how long they should be expected to provide custodial care. Based on work done by the EPA, public comments on a preliminary draft of 10 CFR Part 61 and an advanced notice of proposed rulemaking, and four regional workshops, a clear consensus was developed which supported the 100-year limit.

After the institutional control period, intruder protection measures may be used to prevent an intruder from coming in contact with Class C waste. Intruder protection may be provided by designing and constructing an intruder barrier system with material which will provide protection against inadvertent intrusion for at least 500 years following site closure.

10 CFR Part 61 has established precedence for the duration of institutional controls. However, this precedence is limited because it applies to near-surface disposal, not deep geologic disposal.

2.4.7 Evaluation Period for Performance Assessment

There is no time of compliance mandated for the projection of the general public dose limits in 10 CFR Part 61. However, dose calculations in the Draft and Final Environmental Impact Statements for 10 CFR Part 61 (NRC, 1981b; 1982) were carried out for 10,000 years. As mentioned previously, intruder dose assessments were carried out at 100 years after site closure for Class A waste concentration limits and Class C waste concentration limits were calculated from Class A concentrations with an additional 10 times credit for greater confinement and 400 more years of radioactive decay.

10 CFR Part 61 has established precedence for using a 10,000-year evaluation period. However, this precedence is limited because the sites and disposal technologies evaluated in the Draft and Final Environmental Impact Statements for 10 CFR Part 61 (NRC, 1981b; 1982) are fundamentally different from Yucca Mountain.

2.4.8 Overall System and Subsystem Performance Requirements

There are no specific subsystem performance objectives contained in 10 CFR Part 61. However, there are requirements for site suitability (§ 61.50), site design (§ 61.51), site operations and closure (§ 61.52), environmental monitoring (§ 61.53), waste classification (§ 61.55), and waste characteristics (§ 61.56) that provide defense-in-depth to ensure that the overall system requirements are met.

2.5 OTHER PERTINENT DOCUMENTS

This section addresses 10 CFR Part 40, Domestic Licensing of Source Material, and the NRC Safety Goals for the Operation of Nuclear Power Plants, Policy Statement (NRC, 1986). 10 CFR Part 40 establishes procedures and criteria for the issuance of licenses to receive title to, receive, possess, use, transfer, or deliver source material, and byproduct materials, and gives the conditions upon which the NRC will issue these licenses. The regulations also provide for the disposal of byproduct material and for the long-term care and custody of byproduct material and residual radioactive material. In this context, byproduct material consists of tailings or wastes produced by the extraction or concentration of uranium or thorium from ore. The DOE and the EPA are heavily involved in tailings remediation, but this discussion focuses on the NRC regulations.

Of particular interest here is the NRC approach to disposal of byproduct material and the long-term care and custody of byproduct material and residual radioactive material. No license is required for possession of residual radioactive materials, as defined above, provided several conditions are met: (i) the materials are located at a site where milling operations are no longer active; (ii) the site is covered by the remedial action program of Title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended; and (iii) remedial action has not been completed. Instead of licensing during the remediation process, the NRC exerts its regulatory role primarily through concurrence and consultation in the execution of the remedial action pursuant to Title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended (U.S. Congress, 1978). After remedial actions are completed, NRC will license the long-term care of sites. The NRC can regulate byproduct material which is located at a site where milling operations are no longer active, and the criteria in Appendix A of 10 CFR Part 40 apply to such sites.

2.5.1 Health-Based, Risk-Based, and Technology-Based Standards

Although the basic health-based standards of 10 CFR Part 20 apply, 10 CFR Part 40 also contains technology-based standards. These technology-based standards are not expressed in terms of dose, however, but as numerical limits on effluents, design standards intended to limit effluents, and numerical limits on environmental concentrations. 10 CFR Part 40 incorporates some of the EPA standards which include design standards as well as concentration limits for groundwater.

10 CFR Part 40, Appendix A contains several pertinent technical criteria. Criterion 1 addresses the general goal or broad objective in siting and design decisions for permanent isolation of tailings and associated contaminants by minimizing disturbance and dispersion by natural forces without ongoing maintenance. Criterion 4 enumerates desirable design features of tailings disposal which are summarized as follows: (i) upstream rainfall catchment areas must be minimized to decrease erosion and floods; (ii) topographic features should provide good wind protection; (iii) embankment and cover slopes must be relatively flat; (iv) a full self-sustaining vegetative cover must be established or rock cover employed to reduce wind and water erosion to negligible levels; (v) the impoundment may not be located near a fault which could cause a maximum credible earthquake larger than which the impoundment could reasonably be expected to withstand; and, (vi) the impoundment, where feasible, should be designed to incorporate features which will promote deposition. Deposition would enhance the thickness of cover over time.

Groundwater protection is achieved by design standard as well as by numerical limits placed upon concentrations of radioactivity in groundwater. Criterion 5A(1) addresses the primary groundwater protection standard as a design standard for surface impoundments used to manage uranium and thorium byproduct material. Unless exempted, surface impoundments (except for an existing impoundment) must have a liner to prevent any migration of wastes out of the impoundment to the adjacent subsurface soil, groundwater, or surface water at any time during the active life (including the closure period) of the impoundment. With reference to groundwater which might become contaminated, Criterion 5B(5) states the following.

> At the point of compliance, the concentration of a hazardous constituent must not exceed:
>
> (a) The Commission approved background concentration of that constituent in the ground water
>
> (b) The respective value given in the table in paragraph 5C if the constituent is listed in the table and if the background level of the constituent is below the value listed
>
> (c) An alternate concentration limit established by the Commission.
>
> The values in the table in paragraph 5C are the EPA drinking water limits.

A numerical limit of 20 picocuries per square meter per second (pCi m^{-2} s^{-1}) is placed upon release of radon from covered tailings piles.

2.5.2 Dose Limits for Individuals

An NRC position on individual dose criteria is outlined in the Safety Goals for the Operation of Nuclear Power Plants, Policy Statement (NRC, 1986). It states, "The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that may result from reactor accidents should not exceed one-tenth of one percent (0.1 percent) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed." An increase in 0.1 percent in the early fatality risk to an average individual is approximately equivalent to 5×10^{-7} per reactor year (NRC, 1992).

The individual dose criteria of 10 CFR Part 20 apply to 10 CFR Part 40. A specific standard is also given for the active phase of milling or producing thorium byproduct material. 10 CFR Part 40, Appendix A, Criterion 8 states the following.

> Milling operations producing or involving thorium byproduct material must be conducted in such a manner as to provide reasonable assurance that the annual dose equivalent does not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public as a result of exposures to the planned discharge of radioactive materials, radon-220 and its daughters excepted, to the general environment.

The limits of 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public are identical to the limits in 40 CFR Part 190 (EPA, 1992a).

2.5.3 Dose Limits for Populations

An NRC position on collective dose criteria is outlined in the Safety Goals for the Operation of Nuclear Power Plants, Policy Statement (NRC, 1986). It states, "The risk to the population in the area near a nuclear power plant of cancer fatalities which might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1 percent) of the sum of cancer fatality risks resulting from all other causes." An increase in 0.1 percent in the risk of latent cancer fatality to the average individual within 10 miles of a plant site boundary would be a risk of 2×10^{-6} per reactor year (NRC, 1992).

No specific citation of collective dose is made in 10 CFR Part 40 and the only mention of the older term, population exposure, is made in reference to active uranium milling. 10 CFR Part 40, Appendix A, Criterion 8 also states: "Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are reduced to the maximum extent reasonably achievable and to avoid site contamination."

2.5.4 Applicability of ALARA Principle

ALARA has the same meaning in 10 CFR Part 40 as it does in 10 CFR Part 20. Practical and reasonably achievable are considered as having equivalent meaning. 10 CFR Part 40 requires the licensee to use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to ensure that occupational doses and doses to members of the public are ALARA. In Appendix A of 10 CFR Part 40, the NRC goes on to state that: "Decisions involving these terms will take into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest." ALARA is required in Criterion 5 and Criterion 8 of Appendix A.

2.5.5 Probabilistic Standards for Human-Induced and Natural Disruptions

No mention of probabilistic standards is made in 10 CFR Part 40.

2.5.6 Active and Passive Institutional Controls for Preventing Human Intrusion

The terms active institutional control and passive institutional control are not defined or mentioned in 10 CFR Part 40. Institutional control and human intrusion are also not defined but are mentioned in the context of milling operations, not waste disposal or remediation. Appendix A, Criterion 8 states, "Milling operations must be conducted so that all airborne effluent releases are reduced to levels as low as is reasonably achievable. The primary means of accomplishing this must be by means of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practicable measures have been taken to control human intrusion and emissions at the source."

There are, however, provisions in 10 CFR Part 40 which contribute to intruder prevention and protection in the broad sense of the term. These include:

- transfer of ownership and, if possible, subsurface rights to a Federal Agency (usually DOE) for long-term custody

- as a minimum, annual site inspections conducted by the government agency responsible for long-term care of the disposal site to confirm its integrity and to determine the need, if any, for maintenance and/or monitoring

- a requirement that the final disposition of tailings, residual radioactive material, or wastes at milling sites should be such that ongoing active maintenance is not necessary to preserve isolation

- a requirement that final rock covers be designed to avoid displacement of rock particles by human and animal traffic

- a requirement for a cover which limits radon emission

- a requirement that sites be stabilized for at least 200 years and preferably for 1,000 years

- environmental monitoring including groundwater monitoring

The basis of the controls listed above is to ensure which uranium mill tailings disposal sites will be cared for in such a manner as to protect the public health, safety, and the environment after remedial action has been completed.

2.5.7 Evaluation Period for Performance Assessment

10 CFR Part 40 requires that waste byproducts be closed with a cover designed to control radiological hazards for a minimum of 200 years and, to the extent reasonably achievable, up to 1,000 years. The exact language of Appendix A, Criterion 6 states the following.

> In disposing of waste byproduct material, licensees shall place an earthen cover over tailings or wastes at the end of milling operations and shall close the waste disposal area in accordance with a design which provides reasonable assurance of control of radiological hazards to (i) be effective for 1,000 years, to the extent reasonably achievable, and, in any case, for at least 200 years ...

2.5.8 Overall System and Subsystem Performance Requirements

The system limits can be taken as the individual dose limits listed above. Although the term subsystem is not used in 10 CFR Part 40, there are additional standards which could be considered subsystem requirements or separate system requirements. The subsystem requirement is related to groundwater. A radon emission standard could be considered to be a separate system requirement because dose from radon is not included in the individual dose standard.

With reference to groundwater which might become contaminated (EPA drinking water limits) and radon emissions from the waste, Appendix A, Criteria 5B(5) and 6 state the following.

> At the point of compliance, the concentration of a hazardous constituent must not exceed:

(a) The Commission approved background concentration of that constituent in the ground water;

(b) The respective value given in the table in paragraph 5C if the constituent is listed in the table and if the background level of the constituent is below the value listed; or

(c) An alternate concentration limit established by the Commission.

In disposing of waste byproduct material, licensees shall place an earthen cover over tailings or wastes at the end of milling operations and shall close the waste disposal area in accordance with a design which provides reasonable assurance of control of radiological hazards to: (i) be effective for 1,000 years, to the extent reasonably achievable, and, in any case, for at least 200 years; and (ii) limit releases of radon-222 from uranium byproduct materials, and radon-220 from thorium byproduct materials, to the atmosphere so as to not exceed an average release rate of 20 pCi m^{-2} s^{-1} to the extent practicable throughout the effective design life determined pursuant to (i) above.

3 RECOMMENDATIONS FOR POSITIONS ON RADIOLOGIC STANDARDS FOR YUCCA MOUNTAIN

The fundamental safety goal for any facility where radioactive material is stored, disposed, or utilized is to protect public health and safety. In the case of common nuclear facilities, this goal is achieved by complying with acceptable radiation protection dose limits, which are generally consistent with the ALARA principle. For a facility such as a HLW repository, the setting of radiologic standards is a challenging task because of: (i) the first-of-a-kind nature of the facility; (ii) the uncertain nature of future geologic and climatic conditions as well as that of future human activities; and (iii) the broad uncertainties in predicting repository performance over thousands of years. In this report, the existing radiological standards were reviewed for the purpose of providing possible or alternative bases for formulating standards for the proposed repository for Yucca Mountain. Specific recommendations are presented in the following subsections.

3.1 HEALTH-BASED, RISK-BASED, AND TECHNOLOGY-BASED STANDARDS

In establishing regulations for nuclear facilities and operations, the NRC has used both technology-based and health-based standards. For example, the limits of 10 CFR Part 61 and the concept of ALARA are technology-based (see Subsections 2.1.4 and 2.4.1). Similarly, the radiation exposure limits of 10 CFR Part 20 are directly related to health effects (see Subsections 2.1.1 and 2.1.2). Development of technology-based standards for a HLW repository, however, does not appear to be supportable because of the: (i) first-of-a-kind nature of the repository; (ii) evolving design of the repository facility and engineered barrier system; and (iii) large uncertainties associated with the isolation capability of the site. It is recommended that the NRC adopt the position of opposing technology-based standards for the proposed repository, but continue to support the development of health-based standards.

The NRC has previously used risk-based analyses to ensure the health and safety of the public. For example, the exposure limits of 10 CFR Part 20 can be taken to have an annual probability of occurrence of exposure equal to one (i.e., each year's exposure is assumed to be at the regulatory limit). The NRC regulations allow for lower-probability events to have larger levels of exposure than normally anticipated releases (10 CFR 100.11 and 10 CFR 72.106). When both the annual probability of an event and the limit of exposure are considered simultaneously, the risk to the public health and safety should be no more than any routine annual exposure limits. It is recommended that the NRC adopt the position that the standards for a HLW repository should be risk-based. In addition, consideration should be given to proposing a lower limit on annual probability of occurrence.

With regard to derived limits, the NRC regulations used such limits for control of annual exposures for air, water, and sewerage releases of radioactive materials in 10 CFR Part 20 (see Subsections 2.1.2 and 2.1.8). In addition, the NRC has supported the use of derived release-limits for a HLW repository because it simplifies the licensing process (refer to Subsection 2.3.1). The NRC has also contended that health-based (dose-based) regulatory limits can be compared to other standards and would have a more supportable basis than limits derived for a repository (see Subsections 2.2.1, 2.2.2, and 2.3.1). However, it is recommended that NRC adopt a position of opposing the use of derived limits. This recommendation is made because, for a HLW repository, derived limits would be based on generic and/or extremely speculative estimates of the potential performance of a hypothetical repository and biosphere. This speculation can lead to large uncertainties or conservatisms being incorporated into the derived limits. Additionally, it is recommended that NRC support a health-based standard which can be directly compared to annual standards of risks that have been accepted for controlling the public's exposure. A health-based standard could be achieved by specifying a few key parameters associated with annual dose determinations (i.e., the limit is for an average dose to a critical group and a static biosphere is used for dose modeling).

3.2 DOSE LIMITS FOR INDIVIDUALS

The NRC generally applies an annual individual dose limit in its regulations (see Subsections 2.1.2, 2.4.2, and 2.5.2), but has supported alternative limits (see Subsections 2.2.2 and 2.3.4). However, it is recommended that the risk-based standards include only an individual annual dose limit, based upon the average dose to a critical group. This criterion should be consistent with other radiation protection standards, thus assuring an acceptable level of protection and avoiding challenges by those seeking either more-stringent or less-stringent standards. Combining a dose criterion with the probability of occurrence will determine the potential risks (projected health effects) of a geologic repository. The risks should be expressed as the product of the probability of occurrence and the average dose to a critical group, while assuming a static biosphere.

A fundamental safety goal of any facility where radioactive material is possessed is to protect the public health and safety. This is achieved by complying with acceptable radiation protection dose limits. Any facility, including a HLW repository, must demonstrate that the probable consequences or risks of the public's radiation doses are at or below currently accepted protection standard limits. Exposures to the critical group should be based on a static biosphere, because projecting changes in an assumed biosphere only complicates the performance analyses without affecting repository isolation or containment characteristics.

3.3 DOSE LIMITS FOR POPULATIONS

The NRC has avoided collective dose standards (see Subsection 2.1.3 and 2.4.3) and has supported collective doses as a means to minimize the impact of a facility (see Subsections 2.2.3, 2.3.3, and 2.5.3). However, it is recommended that a collective dose standard is not necessary. If it is assumed that the dose limit to an individual is determined by the average exposure of a critical group, the dose of such a hypothetical individual and the collective or population dose will thus be proportional, and there is no need for both individual and collective dose limits.

Calculation of worldwide collective doses from releases of HLW is of little use in setting regulatory standards, because every man, woman, and child receives about 200–300 mrem/yr from background radiation, which yields an extremely large collective dose. The increment in collective dose to the world's population, which may be caused by HLW releases, can appear to be a large collective dose, while in perspective this incremental dose is trivial and meaningless when compared to the total collective dose from background radiation.

3.4 APPLICABILITY OF ALARA PRINCIPLE

Based upon the arguments and resolutions of applicability of ALARA for a HLW repository (see Subsections 2.2.4 and 2.3.4), it is recommended that the average individual dose limit be sufficiently stringent so as not to require the application of the ALARA principle for postclosure performance.

ALARA is a technology-based concept and "reasonably achievable" cannot be defined in the absence of technology considerations. Because it is not known what the capabilities of repository technology are, postclosure ALARA would appear to be undefinable.

3.5 PROBABILISTIC STANDARDS FOR HUMAN-INDUCED AND NATURAL DISRUPTIONS

It is recommended that the standards should be probabilistic for all events, and thus risk-based, because both the probability of occurrence and level of consequences for performance need to be integrally evaluated. This is required because of the extremes in the possible values for the probability of occurrence of a given release and the consequences (health effects) of that release for long-term geologic disposal (see Subsections 2.2.5 and 2.3.5). The standards may need to be divided into three components: (i) expected conditions and events, where the probability of occurrence is equal to one; (ii) unexpected conditions, events, and disruptions, which include both human intrusions and rare geological events; and (iii) events that are so rare they do not require any consideration.

3.6 ACTIVE AND PASSIVE INSTITUTIONAL CONTROLS FOR PREVENTING HUMAN INTRUSION

Based upon the arguments for relying upon a robust site and not upon institutional controls (see Subsections 2.2.6, 2.3.6, and 2.4.6), it is recommended that the standards should not require long-term (postclosure) active institutional controls for preventing human intrusion, because of the uncertainties associated with the perpetual active institutional controls. Also, a site which must rely on active institutional controls to meet the regulatory standards should be disqualified because of the uncertainties and unknown costs associated with perpetual caretaking.

3.7 EVALUATION PERIOD FOR PERFORMANCE ASSESSMENT

Based upon the discussions for a reasonable period for PA for demonstration of regulatory compliance (see Subsections 2.2.7 and 2.3.7), it is recommended that the standards should limit the evaluation period to 10,000 years because little is gained by longer analyses, given the increased uncertainties associated with longer time periods. Analysis may be carried out to the time of maximum impact, but 10,000 years should be the time period of compliance demonstration for a repository.

3.8 OVERALL SYSTEM AND SUBSYSTEM PERFORMANCE REQUIREMENTS

It is recommended that the EPA standards should only state an overall system performance limit because the route of exposure has no bearing on the resultant dose from the overall system. The NRC should be free to regulate subsystem performance limits in order to have: (i) defense-in-depth consistent with the multiple barriers requirement of Section 121 of the NWPA (U.S. Congress, 1982); and (ii) high confidence in its decision to license a repository. The NRC subsystem performance limits do not necessarily have to be exact fractions that sum to the overall system performance limit to meet these two goals.

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APPENDIX A

DEFINITIONS

APPENDIX A — DEFINITIONS

Accessible Environment	(i) The atmosphere, (ii) the land surface, (iii) surface water, (iv) oceans, and (v) the portion of the lithosphere which is outside the controlled area. (10 CFR Part 60)
Active Institutional Control	Deliberate human actions physically carried out at the waste site to restrict access and use of the site and to maintain disposal systems. Active institutional controls involve some form of human activity to ensure effectiveness of controls. Active controls can be ongoing such as environmental monitoring or security surveillance or may be limited to infrequent activity such as one-time repair of a disposal unit cover. (Note: adapted from the draft NRC document on institutional control provided by Jim Firth of the NRC on October 5, 1993.)
Adult	An individual 18 or more years of age. (10 CFR Part 20)
As Low as Reasonably Achievable (ALARA)	Making every reasonable effort to maintain exposures to radiation as far below dose limits as is practical consistent with the purpose for which the activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and radioactive materials in the public interest. (10 CFR Part 20)
Background Radiation	Radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. (10 CFR Part 20)
Exposure	Being exposed to ionizing radiation or to radioactive material. (10 CFR Part 20)
Barrier	Any material or structure which prevents or substantially delays movement of water or radionuclides. (10 CFR Part 60)
Becquerel	1 nuclear disintegration per second. See Curie. (10 CFR Part 20)
Curie	3.7×10^{10} disintegrations per second = 3.7×10^{10} becquerels = 2.22×10^{12} disintegrations per minute. See becquerel. (10 CFR Part 20)
Byproduct Material	(i) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear

material; and (ii) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition. (10 CFR Part 20)

Collective Dose	The sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation. (10 CFR Part 20)
Committed Dose Equivalent ($H_{T,50}$)	The dose equivalent to organs or tissues of reference (T) which will be received from an intake of radioactive material by an individual during the 50-year period following the intake. (10 CFR Part 20)
Committed Effective Dose Equivalent (HE,50)	The sum of the products of the weighing factors applicable to each of the body organs or tissues which are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma w_T H_{T,50}$). (10 CFR Part 20)
Controlled Area	A surface location, to be marked by suitable monuments, extending horizontally no more than 10 km in any direction from the outer boundary of the underground facility, and the underlying subsurface, which area has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure. (10 CFR Part 60)
Critical Group	A group of individuals who are homogeneous with respect to dose received from a single source and who constitute the most exposed group. The dose constraint should be applied to the mean dose in the critical group. (ICRP 60, ¶ 186)
Deep-Dose Equivalent (H_d)	Applies to external whole-body exposure. This is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2). (10 CFR Part 20)
Derived Standard	A limit which is calculated from a health-based or technology-based standard and expressed in different terms such as activity or concentration. Examples of derived standards are the annual limits of intake for radionuclides, expressed in activity (Bq y^{-1} or Ci y^{-1}).
Disposal	The isolation of radioactive wastes from the accessible environment. (10 CFR Part 60)

Dose Equivalent (H_T)	The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv). (10 CFR Part 20)
Dose to the Public	The dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee, or to another source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose, or dose received from natural background, as a patient from medical practices, or from voluntary participation in medical research programs. (10 CFR Part 20)
Dose or Radiation Dose	A generic term which means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. The exact meaning must be determined from the context. (10 CFR Part 20)
Effective Dose Equivalent (H_E)	The sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighing factors (w_T) applicable to each of the body organs or tissues which are irradiated ($H_E = \Sigma w_T H_T$). (10 CFR Part 20)
Engineered Barrier System	The waste packages and the underground facility. (10 CFR Part 60)
External Dose	That portion of the dose equivalent received from radiation sources outside of the body. (10 CFR Part 20)
Generally Applicable Environmental Radiation Standards	Standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, which impose 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. (10 CFR Part 20)
Geologic Repository	A system which is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media. (10 CFR Part 60)
Gray (Gy)	The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram (100 rads). (10 CFR Part 20)
Health-Based Standard	A standard based primarily on judgements about acceptable risks to the public. (Kocher, 1993)

High-Level Radioactive Waste (HLW)	(i) Irradiated reactor fuel, (ii) 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 (iii) solids into which such liquid wastes have been converted. (10 CFR Part 60)
Inadvertent Intruder	A person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which the person might be unknowingly exposed to radiation from the waste. (10 CFR Part 61)
Institution	A public or private organization, establishment, agency, society, or other entity engaged in or directed to a particular objective. (Note: adapted from the draft NRC document on institutional control provided by Jim Firth of the NRC on October 5, 1993.)
Institutional Controls	Actions taken by an "institution" for management and control of a waste disposal site after closure. It includes activities such as: physical security; surveillance; environmental monitoring; access control; site utilization; maintenance operations; site marking and preservation of records; government land ownership; and other activities as determined by the responsible regulatory authority. Certain of these activities are related to protection against human intrusion and habitation of the site while others are directed at maintenance and monitoring. (Note: adapted from the draft NRC document on institutional control provided by Jim Firth of the NRC on October 5, 1993.)
Internal Dose	That portion of the dose equivalent received from radioactive material inside the body. (10 CFR Part 20)
Intruder Barrier	A sufficient depth of cover over the waste which inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in this part, or engineered structures which provide equivalent protection to the inadvertent intruder. (10 CFR Part 61)
Limits or Dose Limits	The permissible upper bounds of radiation doses. (10 CFR Part 20)
Member of the Public	An individual in either a controlled or unrestricted area except for individuals who are exposed occupationally. (10 CFR Part 20)
Minor	An individual less than 18 years of age. (10 CFR Part 20)

Passive Institutional Control	Man-made controls, such as a fencing or restrictive land covenants, which do not require or directly involve deliberate human action after they have been put in place. Such controls do not rely on continuing human activity to ensure effectiveness in restricting access or maintaining site integrity. Passive controls are undertaken primarily to provide control over access and future use of the waste disposal site. It is expected that certain passive institutional controls such as restrictive land covenants, will survive long after active institutional controls have been terminated. The distinction between active and passive controls is not entirely clear in practice, however, because passive controls such as fencing require periodic maintenance and effectiveness of restrictive land covenants relies on maintaining institutions which record and control land use. (Note: adapted from the draft NRC document on institutional control provided by Jim Firth of the NRC on October 5, 1993.)
Quality Factor (Q)	The modifying factor which is used to derive dose equivalent from absorbed dose. (10 CFR Part 20)
Rad	The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray). (10 CFR Part 20)
Rem	The special unit of dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sieverts). (10 CFR Part 20)
Risk	Used in the context of radiation protection, the product of the probability of a particular radiation dose occurring to an individual times the probability that the dose will cause a deleterious effect. If several different doses are possible, then the risk is the sum of the products of each possible dose times the probability of occurrence of each possible dose times the probability of each dose causing a deleterious effect.
Risk-Based Standard	A standard which incorporates the probability of a deleterious health effect occurring for a given dose and the probability that the given dose itself will occur.
Sievert	The SI unit of dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems). (10 CFR Part 20)
Technology-Based Standard	A standard based primarily on judgements about system performance which is reasonably achievable using currently available technology (Kocher, 1993).

Total Effective Dose Equivalent (TEDE)	The sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). (10 CFR Part 20)
Weighting factor (w_T)	For an organ or tissue, (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. (10 CFR Part 20)
Whole Body	For purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee. (10 CFR Part 20)