Recommendations on Postclosure Aspects of Generic Standards for the Permanent Disposal of Spent Nuclear Fuel and High-Level and Transuranic Radioactive Wastes in the United States

DRAFT
FOR PUBLIC COMMENT

American Nuclear Society

Special Committee on Generic Standards for Disposal of High-Level Radioactive Waste

February 2023

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The American Nuclear Society's Special Committee on Generic Standards for Disposal of High-Level Radioactive Waste developed this draft report and recommendations for updated standards that will ensure adequate protection of future inhabitants from the potential hazards posed by material in a repository with the hope that it will be a catalyst for the development of updated geologic repository standards by the U.S. EPA.

This draft is released to the public to elicit feedback on its draft recommendations. Comments and suggestions are encouraged and should be submitted through the ANS Collaborate website at:

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American Nuclear Society

Special Committee on Generic Standards for Disposal of High-Level Radioactive Waste

February 2023

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PREFACE

WHAT ABOUT THE WASTE? “They don’t know what to do with the waste.” It’s a frequent criticism of nuclear energy—one that the nuclear industry has done a poor job of explaining.

In fact, the United States has a functioning system to safely manage nuclear waste from its nuclear power plants: low-level radioactive waste is compacted and shipped to regulated facilities for disposal. Highly radioactive waste materials, such as used nuclear fuel, are small in volume and exist in solid, stable forms. Used fuel is stored at reactor sites, first underwater in secure pools and then in robust, passively cooled dry storage systems.

The U.S. nuclear waste management system is missing one important piece, however: a long-term geologic repository. Like most other nations with nuclear plants, the U.S. has elected to dispose of its commercial used fuel directly in deep geologic formations, isolated from the environment. The site Congress has chosen for the U.S. repository, Yucca Mountain in Nevada, has been stalled by opposition from the state. Given the stalemate, policymakers are rethinking our nation’s approach, with consideration for consolidated interim storage and modified siting methods for waste facilities based on stakeholder consent. In addition, different and innovative technology approaches for management of used nuclear fuel and high-level radioactive waste are under development, such as advanced reprocessing methods for resource utilization and waste minimization, and borehole disposal of used fuel and other waste forms using well-established drilling techniques.

The future course in waste management is far from settled, but one fact is evident. There will be high-level radioactive waste that requires disposal, and that material will be emplaced in some sort of underground geologic repository or repositories. In fact, other countries are already proceeding down this path. Updated, transparent standards for long-term repository performance are needed to enable siting of future geologic disposal systems and engender public confidence in the safety of those facilities. The current U.S. geologic repository standards for all sites other than Yucca Mountain are codified in the Environmental Protection Agency (EPA) regulation 40 CFR Part 191, *Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes*, and that regulation has served adequately for the Waste Isolation Pilot Plant near Carlsbad, N.M. However, 40 CFR 191 is inconsistent with current international standards, lacks transparency, and is difficult to apply to certain disposal technologies. Accordingly, the American Nuclear Society Special Committee on Generic Standards for Disposal of High-Level Radioactive Waste has developed recommendations for updated standards that will ensure adequate protection of future inhabitants from the potential hazards posed by material emplaced in a geologic repository.

The country and the world need nuclear fission reactors as a clean, secure, reliable source of energy, both now and in the future. Those reactors have produced—and will continue to produce—relatively small volumes of waste that require geologic disposal. ANS has produced this report with the hope and expectation that it will prove to be a catalyst for the development of updated geologic repository standards by the EPA. That action will be a key building block for future progress on nuclear waste management, irrespective of what course of action policymakers ultimately choose to follow.

Portions of this report have appeared previously in draft form as conference papers presented at ANS's 2022 International High-Level Radioactive Waste Management Conference in Phoenix, Arizona [1], [2], [3].

Dr. Steven Arndt
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February 2023

EXECUTIVE SUMMARY

ES.1 Background

The Blue Ribbon Commission on America's Nuclear Future (BRC) recommended in 2012 that "the Environmental Protection Agency and the Nuclear Regulatory Commission should develop a generic disposal standard and supporting regulatory requirements early in the siting process" [4, p. ix]. The American Nuclear Society in its 2020 issue brief, "A Proposal for Progress on Nuclear Waste Management" [5, p. 2], endorsed the BRC's recommendation. To that end, ANS convened the Special Committee on Generic Standards for Disposal of High-Level Radioactive Waste (ANS Committee) to further consider the need for new standards and to develop recommendations on their content.

The ANS Committee agrees with past recommendations that new standards are needed for the following reasons:

- The current U.S. generic standards are more than 30 years old and are inconsistent with modern international approaches to such health and safety standards.

- The nexus between the release limits in the current U.S. generic standards and public health and safety is not readily apparent; as a result, the current standards are ill suited for instilling public confidence in effective regulatory oversight of a potential geologic repository.

- The current U.S. generic standards were developed with mined geologic repository disposal systems in mind, and it would be challenging to apply to apply them to other disposal technologies, such as boreholes.

The ANS Committee recognizes that constraints on nuclear waste management exist at multiple levels, including federal legislation (principally the Nuclear Waste Policy Act of 1982, as amended [NWPA]), regulatory requirements (both generic and site specific), and site selection guidelines developed in the past by the U.S. Department of Energy. Nonbinding recommendations regarding best practices may also be developed in the future by both regulators and the implementing organization. Most of these topics are outside the scope of the ANS Committee's consideration; the committee recognizes that much remains to be done in each of these areas but we have focused our recommendations on topics we believe are appropriately addressed in generic standards governing all potential disposal sites. We also note that there are statutory constraints placed on the EPA and the NRC by the terms of the NWPA and that future congressional action may be helpful to facilitate new rulemaking. With that in mind, the ANS Committee believes it would be useful to the radioactive waste disposal community to provide its recommendations and observations on the postclosure aspects of generic disposal standards that are protective of public health, safety, and the environment; consistent with international best practices; and implementable through established licensing processes.

The ANS Committee also wants to make it clear what these recommendations do not cover:

- **Future nuclear fuel cycle technologies** (e.g., advanced reactor designs, fuel forms, recycling). Irrespective of the fuel cycle, there will be long-lived radioisotopes that require isolation from humans.

- **Technologies for disposal** (e.g., mined repositories, boreholes). To the extent practical, standards should be technology independent and based on protecting public health and safety.

- **The merits of specific geologic media for disposal of radionuclides**. The United States has multiple types of stable geologic formations that would likely be suitable for the long-term isolation of radioactive waste; health and safety standards should be independent of the geologic media employed.

- **The merits, or lack thereof, of any proposed repository sites in the United States or abroad**.

- **The merits, or lack thereof, of any proposed siting process for a geologic repository** (e.g., consent-based siting). Effective regulatory oversight of geologic disposal, including transparent and protective public health and safety standards, is essential for building and maintaining public support for a repository program, irrespective of the siting process used.

ES.2 Recommendations

As described in more detail in sections III.1 and III.2 of this report, the recommendations of the ANS Committee can be broadly summarized as follows: Use the existing Yucca Mountain standards as a template for developing new standards, modified as necessary for general applicability. In general, the ANS Committee considers the Yucca Mountain standards to be representative of international best practices and implementable using established licensing processes.

Specific recommendations include the following:

- Retain the individual health consequence standard (e.g., individual dose rate or incremental individual health risk) as the primary quantitative metric.

- Retain the concepts of reasonable expectation and risk-informed decision-making as a recognition of the limitations of quantitative modeling of the far future.

- Retain the concept of basing the characteristics of the reasonably maximally exposed individual on current practice in the vicinity of the disposal site, and retain regulatory specificity regarding characteristics of and future changes to the biosphere and certain aspects of the geologic environment.

- Retain the requirements for the identification and screening of potentially relevant features, events, and processes.

- Retain the human intrusion requirement, but revise it to make it generally applicable to all potential sites and repository design concepts.

In addition to general modifications needed to make the Yucca Mountain standards generic, the ANS Committee recommends the following changes:

- Limit the regulatory time period for quantitative standards to 10,000 years.

- Replace the quantitative dose limits for the period beyond 10,000 years and before 1,000,000 years with a requirement to evaluate potentially relevant features, events, and processes to demonstrate that they are unlikely to result in substantially different behavior of the disposal system during that period.

- Adopt requirements for the multiple barriers, consistent with the approaches taken for generic repositories in 40 CFR 191.14(d) and implemented by the NRC for Yucca Mountain in 10 CFR Part 63, to ensure defense in depth.[1]

- Adopt requirements for retrievability of the wastes as prescribed by the NWPA §122, currently included in 40 CFR 191.14(f), and implemented by the NRC for Yucca Mountain in 10 CFR Part 63.

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[1]40 CFR Part 191, *Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes*; 10 CFR Part 63, *Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada.*

- Remove the concept of the “period of geologic stability” from generic disposal standards while retaining an upper bound on the regulatory period of 1,000,000 years.

- Adopt the definition of the controlled area provided in 40 CFR Part 191, with site-specific implementation to be determined by the implementor and the NRC.

- Make generic disposal standards applicable to deep borehole disposal concepts as well as mined repositories.

- Remove specificity regarding the establishment of the DOE as the implementing organization for disposal of spent nuclear fuel and high-level radioactive wastes.

In addition, the ANS Committee provides observations on other topics the committee believes could benefit from further consideration by the EPA and NRC:

- The approaches specified in existing regulations for determining health consequences from radiation exposures are in some instances out of date with respect to current international practice.

- The separate “Ground Water Protection Standards” (40 CFR 197.30 and 197.31) add no additional protection to the standards for human health, safety, or the environment, while introducing the potential for incentivizing the selection of sites with pristine groundwater.

- Regarding the specific limits applied to estimates of annual radiation doses to individuals, values in the range of 0.15–1 mSv (15–100 mrem) per year are appropriately conservative for a public health and safety standard.

Recommendations on Postclosure Aspects of Generic Standards for the Permanent Disposal of Spent Nuclear Fuel and High-Level and Transuranic Radioactive Wastes in the United States

CONTENT

I. INTRODUCTION

The Blue Ribbon Commission on America's Nuclear Future observed in 2012 that "America's nuclear waste management program is at an impasse" and recommended that as the first step toward developing a new, consent-based approach to siting storage or disposal facilities, "the Environmental Protection Agency and the Nuclear Regulatory Commission should develop a generic disposal standard and supporting regulatory requirements early in the siting process" [4, p. ix]. The American Nuclear Society endorsed the commission's recommendation in its 2020 issue brief, "A Proposal for Progress on Nuclear Waste Management" [5, p. 2]. The ANS Special Committee on Generic Standards for Disposal of High-Level Radioactive Waste (ANS Committee), which has authored this report, agrees with these observations and notes that they remain timely more than ten years after the Blue Ribbon Commission report was published. The primary reasons that new standards are needed are summarized below.

- The current U.S. generic standards are more than 30 years old and are inconsistent with modern international approaches to such health and safety standards.

- The nexus between the release limits in the current U.S. generic standards and public health and safety is not readily apparent; as a result, the current standards are ill-suited for instilling public confidence in effective regulatory oversight of a potential geologic repository.

- The current U.S. generic standards were developed with mined geologic repository disposal systems in mind, and would be challenging to apply to other disposal technologies such as boreholes.

The ANS Committee recognizes that constraints on nuclear waste management exist at multiple levels, including federal legislation (principally the Nuclear Waste Policy Act of 1982, as amended [NWPA]), regulatory requirements (both generic and site specific), and site selection guidelines developed in the past by the U.S. Department of Energy. Nonbinding recommendations regarding best practices may also be developed in the future by both regulators and the implementing organization. Most of these topics are outside the scope of the ANS Committee's consideration; the committee recognizes that much remains to be done in each of these areas but we have focused our recommendations on topics that we believe are appropriately addressed in generic standards governing all potential disposal sites. We also note that there are statutory constraints placed on the EPA and the NRC by the terms of the NWPA and that future congressional action may be helpful to facilitate new rulemaking. With that in mind, the ANS Committee believes it would be useful to the radioactive waste disposal community to provide its recommendations and observations on the postclosure aspects of generic disposal standards that are protective of public health, safety, and the environment; consistent with international best practices; and implementable through established licensing processes.

The ANS Committee also wants to make it clear what these recommendations do not cover:

- The committee makes no recommendations regarding future nuclear fuel cycles (e.g., advanced reactor designs, fuel forms, recycling). Irrespective of the fuel cycle, there will be long-lived radioisotopes that require isolation from humans.

- The committee makes no recommendations regarding technologies for disposal (e.g., mined repositories, boreholes). To the extent practical, standards should be technology independent and based on protecting public health and safety.

- The committee makes no recommendations on the merits of specific geologic media for disposal of radionuclides. The United States has multiple types of stable geologic formations that would likely be suitable for the long-term isolation of radioactive waste, but health and safety standards should be independent of the geologic media employed.

- The committee makes no recommendations on the merits, or lack thereof, of any proposed repository sites in the United States or abroad.

- The committee makes no recommendations on the merits, or lack thereof, of any proposed siting process for a geologic repository (e.g., consent-based siting). Effective regulatory oversight of geologic disposal, including transparent and protective public health and safety standards, is essential for building and maintaining public support for a repository program, irrespective of the siting process used.

II. BACKGROUND INFORMATION

The path by which the nation's nuclear waste disposal program reached the present impasse has been documented by others, including the Blue Ribbon Commission on America's Nuclear Future [4, pp. 9–26], and is familiar to most who have worked in the field. For those who may not be familiar with the history of the legislative and regulatory framework that provides the starting point for future rulemaking, the following sections provide a brief summary of national policy and the major aspects of the currently applicable regulatory standards. Appendix A of this report provides a more detailed discussion of the major statutes governing management and disposal of spent nuclear fuel (SNF), high-level radioactive waste (HLW), and transuranic (TRU) radioactive waste, and the history of the development of the specific radioactive waste disposal standards and regulations enacted by the EPA and the NRC.

II.1 National Policy Evolution

U.S. national policy regarding the management and disposal of radioactive materials has been defined by Congress through the NWPA of 1982, as amended—most significantly through the Nuclear Waste Policy Amendments Act of 1987. For the purposes of this discussion, key points of national policy that are defined by statute are as follows.

- **Permanent disposal of SNF and HLW, regardless of the civilian- or defense-related origin of the waste, is the responsibility of the DOE**. Specifically, the Atomic Energy Commission was given responsibility in the Atomic Energy Act of 1954 to "provide for safe storage, processing, transportation, and disposal of hazardous waste (including radioactive waste)" (§91(a)(3)) resulting from defense activities. That authority was transferred to the DOE by statute in the 1970s and was expanded by the NWPA to include the disposal of SNF and HLW of civilian origin. Costs for the storage and disposal of civilian-origin SNF and HLW remain the responsibility of the generators and owners of the wastes under the NWPA, however.

- **The EPA is the federal agency responsible for promulgating radiation protection standards for the permanent disposal of SNF and HLW**. Specifically, the NWPA requires that the EPA "shall, by rule, promulgate generally applicable standards for protection of the general environment from **offsite releases from radioactive material in repositories" (§121(a)).**

- **The NRC is the federal agency responsible for approving or disapproving licenses for repositories for SNF and HLW, unless such repositories are used exclusively for defense-origin wastes**. Specifically, the NWPA requires that the NRC shall "promulgate technical requirements and criteria that it will apply in approving or disapproving" license applications for repositories, consistent with EPA standards (§121(b)).

Therefore, based on existing legislation, we will refer to the regulatory body promulgating a protection standard for a *generic* site as the EPA and the regulatory body responsible for applying the EPA generic standard to specific sites and approving or disapproving site-specific licenses as the NRC.

II.2 Summary of Major Differences between Current U.S. Radioactive Waste Disposal Standards

Congressional actions over the last four decades have left the U.S. with two parallel sets of EPA and NRC regulatory standards for the permanent disposal of HLW and SNF (see Appendix A for a more detailed discussion). Both sets are consistent with the legal framework defined in the NWPA, and each set includes overall safety standards set by the EPA and implementing criteria defined by the NRC.

The first set of disposal regulations, the EPA's 40 CFR Part 191 and the NRC's 10 CFR Part 60, date from the middle 1980s, predating the congressional decision in 1987 to focus solely on the proposed Yucca Mountain Site.[1] While 40 CFR Part 191 is the standard under which the EPA has certified the Waste Isolation Pilot Plant (WIPP) in New Mexico for disposal of TRU waste, the NRC's 10 CFR Part 60 has not been implemented for any site. In the absence of new rulemaking, both regulations would still apply in principle to any disposal site other than WIPP and Yucca Mountain.

The second set of disposal regulations, EPA's 40 CFR Part 197 and NRC's 10 CFR Part 63, was written in the last 25 years specifically for the proposed Yucca Mountain repository.[2] Without new rulemaking, these regulations do not apply to any other disposal site.

Although both sets of regulations are protective of future human health and the environment, there are significant differences in how they ensure those goals (See Table 1). The older regulations, framed by the EPA in 40 CFR Part 191, defined the regulatory period as 10,000 years and set quantitative limits for scenarios involving all release pathways, including inadvertent human intrusion. Separate standards were established for (1) estimates of the probability that the total cumulative amount of radiation released during the entire period would exceed specified values (40 CFR 191.13, "Containment Requirements"), (2) the peak dose to an individual during 10,000 years of undisturbed performance (40 CFR 191.15, "Individual Protection Requirements"), and (3) radionuclide concentrations in groundwater (40 CFR 191 Subpart C, "Environmental Standards for Ground-Water Protection").

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[1]40 CFR Part 191, *Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes*; 10 CFR Part 60, *Disposal of High-Level Radioactive Wastes in Geologic Repositories.*

[2]40 CFR Part 197, *Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada*; 10 CFR Part 63, 10 CFR Part 63, *Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada.*

The decision to focus the Containment Requirements on the cumulative releases of radionuclides throughout the 10,000-year period rather than on radiation doses that might be incurred by any single individual in the future, was intended to emphasize long-term isolation of the wastes from the human environment without considering credit for other mechanisms that might reduce individual doses including dilution and dispersion. In part, the requirements were based on, and functioned as a surrogate for, the concept of a population dose standard, in which small doses to large numbers of people become equivalent to proportionally larger doses to fewer numbers of people. The decision to require a probabilistic uncertainty analysis (defined as "performance assessment" in 40 CFR 191.12 and further spelled out in the guidance provided in Appendix B of the 1985 version of 40 CFR Part 191) provided the regulatory basis for the quantitative computational analyses that became central to evaluating regulatory compliance for both the WIPP and Yucca Mountain. Capabilities and limitations of quantitative performance assessment modeling are discussed below in section III.2.1 of this report.

In practice, the Containment Requirements have proven to be the most restrictive aspect of 40 CFR Part 191 for the WIPP, primarily because consequences of inadvertent human intrusion by drilling were required to be included in the probabilistic compliance analysis of cumulative releases. For the WIPP—the only repository operating under 40 CFR Part 191—the approach to estimating the density of future drilling was specified by the EPA in the implementing criteria (40 CFR 194.33[3]) and was to be based on a survey of drilling practice within the region during the last century, with the specification that the observed rate would apply for the full 10,000-year regulatory period. As implemented, this requirement led to compliance being based on the consideration of multiple intrusion events during the regulatory period.

Two additional requirements of the older set of regulations that were modified significantly in the newer set also merit further discussion. First, 40 CFR Part 191 explicitly links the magnitude of the allowable release to the amount of waste initially emplaced in the repository: allowable releases are smaller for smaller repositories and larger for larger repositories. This specification was intended to avoid incentivizing the creation of multiple smaller repositories. Second, 10 CFR Part 60 specifies subsystem performance standards for waste package lifetime, the release rate from the engineered barriers, and groundwater travel time to the accessible environment that go beyond the system-level performance metrics contained in 40 CFR Part 191.

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[3] 40 CFR Part 194, *Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance With the 40 CFR Part 191 Disposal Regulations.*

The newer regulations, framed by the EPA in 40 CFR Part 197 in response to congressional direction to follow guidance from a committee convened by the National Academies of Sciences, Engineering, and Medicine (NASEM; see Appendix A in this report for further discussion), abandoned the cumulative release limits of the Containment Requirements and focus instead on probabilistic estimates of the long-term annual risk (expressed as dose) from a repository. Limits are set on the estimated mean peak dose received by a single “reasonably maximally exposed individual” in any one year during the next 1,000,000 years. (As discussed further in section III.2 and Appendix A, the period of 1,000,000 years was chosen to be consistent with the NASEM’s assertion that the period of geologic stability at Yucca Mountain is on the order of 1,000,000 years [6].)

Although the general approach to probabilistic uncertainty analyses remains the same, the specific metrics for comparison to the regulatory limits change from a complementary cumulative distribution function displaying the probability of cumulative release to a more intuitively recognizable display of estimated annual radiation dose incurred by a hypothetical future human near the site. To limit speculation about the ways in which uncertain future human behaviors might affect radiation doses, 40 CFR Part 197 provides site-specific direction regarding assumptions about the future biosphere and the characteristics of the “reasonably maximally exposed individual.” There is no provision for scaling the allowable release to the size of the repository; the peak dose limits apply regardless of the amount of waste emplaced at the site.

Human intrusion is required to be considered separately from overall performance in a stylized analysis. Releases directly to the land surface during drilling were excluded from consideration, in part because such releases “would be independent of whether the repository performs acceptably when breached by human intrusion” and would not provide a good test of the “resilience” of the disposal system.[4]

There are additional requirements for estimates of radionuclide concentrations in groundwater. In practice, the individual dose requirements have been shown to be more restrictive for Yucca Mountain.

Specific to the NRC licensing criteria for Yucca Mountain, subsystem performance requirements (i.e., quantitative limits during the first 1,000 years on waste package and engineered barrier systems performance and groundwater travel time to the site

[4]Environmental Protection Agency, “Public Health and Environmental Radiation Protection Standards for Yucca Mountain, NV,” 66 FR 32073–32135; 32104 (June 13, 2001).

boundary) specified in 10 CFR Part 60 are absent from 10 CFR Part 63. Quantitative aspects of compliance are based solely on the EPA's system-level requirements for estimates of mean annual dose to an individual both with and without human intrusion and groundwater concentrations of radionuclides.

The NRC explained its basis for this change in direction in detail in the preamble to the 1999 publication of the proposed 10 CFR Part 63.[5] In summary, the NRC found the following:

- The subsystem requirements of 10 CFR Part 60 were not clearly linked to the intent of the EPA's system-level standards.
- The subsystem requirements did not serve their original purpose of independently compensating for uncertainty regarding the system-level analyses because they relied on the same input information.
- The subsystem requirements had the potential to result in a considerable expenditure of resources without commensurate increases in public health and safety.
- Defense in depth could be better demonstrated within the context of the system-level analyses.

Table 1. Major differences between U.S. disposal standards.

Requirement	**40 CFR Part 191/10 CFR Part 60**	**40 CFR Part 197/10 CFR Part 63**
Generic or site specific	Generic	Site specific (Yucca Mountain only)
Regulatory period	10,000 years	1,000,000 years
Type of quantitative limits that have been shown in practice to be most restrictive	"Containment Requirements" (40 CFR 191.13): Estimated probability that cumulative releases of radionuclides during 10,000 years will exceed specified fractions of total inventory	"Individual-Protection Standard" (40 CFR 197.20): Estimated mean peak dose to an individual at any time during 1,000,000 years*
Primary quantitative metric required for comparison to the standard	Complementary cumulative distribution function displaying the probability that estimated cumulative releases during 10,000 years will exceed specified values**	Estimates of the mean annual dose incurred by a hypothetical future "reasonably maximally exposed individual" living near the site***

[5]Nuclear Regulatory Commission, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada; Proposed Rule," 64 FR 8640 (Feb. 22, 1999).

Table 1. cont.

Requirement	40 CFR Part 191/10 CFR Part 60	40 CFR Part 197/10 CFR Part 63
Consideration of the total inventory being disposed	Estimates of cumulative release are normalized to the total initial repository inventory to avoid incentivizing multiple small repositories	Estimates of mean annual dose are not normalized to the initial inventory; larger repositories should be expected to result in proportionally higher dose estimates, all other things being equal
Treatment of human intrusion	Consequences of human intrusion by drilling, including releases at the land surface during drilling, are included in probabilistic estimates of cumulative releases; at the WIPP these releases are shown to dominate estimates of long-term performance	Consequences of human intrusion are analyzed separately in a stylized scenario in which one intrusion is assumed to occur, and releases to the land surface during drilling are excluded from consideration
Subsystem performance standards	10 CFR Part 60 sets separate limits on waste package lifetime, release rate from the engineered barrier system, and groundwater travel time to the accessible environment	Subsystem performance standards are absent from 10 CFR Part 63, and quantitative aspects of compliance are based solely on the system-level limits established in 40 CFR Part 197; the repository must include multiple barriers (both natural and engineered) and the demonstration of compliance must describe the capability of those barriers to isolate waste

*Limits are specified to be 0.15 mSv (15 mrem) per year for 10,000 years and 1 mSv (100 mrem) per year between 10,000 and 1,000,000 years.
**Analyses must include consideration of all significant uncertainties, with regulatory specification of some aspects of the drilling intrusion scenario.
***Analyses must include consideration of all significant uncertainties with regulatory specification of characteristics of the “reasonably maximally exposed individual,” aspects of the biosphere, and some aspects of the drilling intrusion scenario.

III. ANS COMMITTEE RECOMMENDATIONS AND OBSERVATIONS FOR GENERIC DISPOSAL STANDARDS

The ANS Committee recommendations and observations that follow are based on two broad assumptions.

First, the ANS Committee assumes that the relevant legislative framework for regulation defined in the 1982 NWPA, as amended, remains unchanged. Specifically, the committee assumes that the EPA will be charged with promulgating environmental standards for disposal and that the NRC will be charged with approving or disapproving licenses for disposal facilities that are not restricted exclusively to defense-origin waste, using licensing requirements and criteria consistent with the EPA standards.

Second, the ANS Committee assumes that existing generic disposal standards will be updated or replaced. This assumption is consistent both with recommendations from the Blue Ribbon Commission on America's Nuclear Future [4]; the National Academies of Science, Engineering, and Medicine (NASEM) [7], and other review groups, as well as with past commitments from NRC staff (e.g., [8]). The committee strongly concurs with the conclusion that existing generic disposal standards should be replaced rather than simply revised. Revisions to 40 CFR Part 191 would needlessly complicate the EPA's ongoing certification under the existing generic standards of the WIPP. As written, 40 CFR Part 191 is highly protective of WIPP and, in the interest of regulatory stability and continuity, 40 CFR Part 191 should continue to be the governing regulation for WIPP. The committee recommends that the EPA promulgate a new regulation with public health and safety standards for all repositories other than WIPP (which would continue to be covered by 40 CFR Part 191) and Yucca Mountain (which would continue to be covered by 40 CFR Part 197). In conjunction with promulgation of the new standards, the scope of 40 CFR Part 191 would be narrowed so that it applies only to the WIPP.

III.1 ANS Committee Recommendations for Adopting 40 CFR Part 197 and 10 CFR Part 63 as a Starting Point for Developing Generic Standards

The ANS Committee concludes that the regulatory standards developed for Yucca Mountain provide an appropriate starting point for the development of generic standards. As discussed for specific examples in the following sections, there is much in both the EPA and NRC Yucca Mountain rules with which the committee agrees and which could be adapted with relatively little modification to be applicable to generic sites.

III.1.1 Retain the Individual Protection Standard as the Primary Quantitative Metric

The ANS Committee agrees with the approach taken for the Yucca Mountain Site by the EPA in 40 CFR Part 197 of adopting an Individual Protection Standard expressed in terms of dose as the primary quantitative metric to be used in licensing a repository. Specifically, the committee concludes that this approach, which provides a clear link to individual health consequence, is preferable to the approach taken in the Containment Requirements of 40 CFR Part 191, where limits are placed on the probability that cumulative releases to the accessible environment during the regulatory period will exceed specified amounts. The approach taken in the Individual Protection Standard of setting limits on estimated annual dose rather than on cumulative releases is consistent with international practice (see Appendix B) and provides greater clarity than the approach taken in 40 CFR Part 191 to quantify probabilistic releases. Both observations may help instill public confidence in the effectiveness of regulatory oversight.

The committee also concludes that basing compliance on estimated future doses to a single representative individual is preferable to setting limits on total doses to a population of individuals, either regional or global. Without going into further detail on this point, we note that the approach taken in the Individual Protection Standard of 40 CFR Part 197 was thoroughly evaluated by the EPA during the development of 40 CFR Part 197,[6] and that it is consistent with international practices (see Appendix B). Furthermore, it has withstood court challenges specific to its application for the Yucca Mountain Site.[7]

The NASEM recommended an individual protection standard for Yucca Mountain in the form of a risk limit [6], thinking that a risk limit would be preferable to a dose limit because the risk limit would be more durable—it would not need to change if the understanding of the dose response relationship (essentially, health effects per unit of radiation dose) were to evolve. In addition, the NASEM felt that a risk limit would best enable comparisons between the risks of radiation and other risks such as those from toxic chemicals. However, the NASEM acknowledged in its report that the two forms of an individual protection standard—dose and risk—are closely related. The ANS Committee believes that a dose standard is the preferable form because it enables straightforward comparison to other radiation protection regulations and it is more consistent with international practice.

III.1.2 Retain the Concepts of Reasonable Expectation and Risk-Informed Decision-Making

The ANS Committee agrees with the EPA's and NRC's recognition that "proof of the future performance of a disposal system is not to be had in the ordinary sense of the word" (40 CFR 191.13(b); restated by the NRC at 10 CFR 63.201(a)(2)). The EPA codified this observation for the Yucca Mountain Site in the definition of reasonable expectation in 40 CFR 197.14(a), stating that reasonable expectation "requires less than absolute proof because absolute proof is impossible to attain for disposal due to the uncertainty of projecting long-term performance."

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[6]See, e.g., EPA, 66 FR 32074 (2001).
[7]Nuclear Energy Institute, Inc. v. Environmental Protection Agency, No. 01-1258, 373 F.3d 1251 (D.C. Cir. 2004).

This straightforward observation provides the basis for the EPA's specifications for the treatment of uncertainty in the probabilistic performance assessment required to evaluate compliance with quantitative postclosure standards. The committee concurs fully with the EPA's definition of reasonable expectation in 40 CFR 197.14 and with the probabilistic approach to postclosure performance assessment it prescribes.

The Committee also concurs with the NRC's risk-informed and performance-based approach to regulatory decision-making as embodied for the Yucca Mountain Site in 10 CFR 63 [9].[8] This approach is consistent with the EPA's concept of reasonable expectation that underlies 40 CFR Part 197 and has been adopted more broadly by the NRC with the increasing incorporation of probabilistic risk assessment methods in the oversight of nuclear power plants.

III.1.3 Continue to Base the Characteristics of the Potentially Exposed Individuals on Current Practices

The ANS Committee agrees with the approach taken by the EPA for the Yucca Mountain Site in 40 CFR 197.21 regarding the characteristics of potentially exposed future individuals, specifically, that the "reasonably maximally exposed individual . . . [h]as a diet and living style representative of the people who now reside" in the vicinity of the repository. As described in greater detail in Appendix C, the committee concludes that this approach is both reasonable, in that it provides implementable specificity to a topic that would otherwise be subject to unbounded speculation, and conservative, because it focuses on that portion of the almost limitless range of future human conditions that would result in the greatest potential for exposure to radioactive releases from the repository. While this approach bases human characteristics and behaviors on current practices, it takes no credit for currently available technology to detect and mitigate radiological hazards in the environment.

The ANS Committee agrees in general with the approach taken in multiple places in 40 CFR Part 197 with regard to providing direction about how the current characteristics of the biosphere should be determined and what future changes to the biosphere and the geologic environment must be considered. Specificity on these points is essential to limiting boundless speculation, particularly regarding possible effects of future human actions on the disposal system.

[8]See also Nuclear Regulatory Commission, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," 60 FR 42622 (Aug. 16, 1995).

The ANS Committee notes that it is unavoidable that regulatory direction regarding some characteristics of the biosphere will need to be site specific. This was not a concern for the EPA in 40 CFR Part 197, which was in itself specific only to the Yucca Mountain Site. In generic standards, this can be addressed by removing requirements specific to the Yucca Mountain Site from the standard and directing the NRC to provide requirements for the selection of site-specific biosphere characteristics once a site has been selected. For example, the generic definition of the controlled area provided in 40 CFR Part 191 could be brought forward into a new standard to replace the Yucca Mountain–specific definition in 40 CFR Part 197. Not all such requirements can as readily be made fully generic; for example, regulatory direction contained in 40 CFR Part 197 for the Yucca Mountain Site includes the location of the reasonably maximally exposed individual, the specification of the representative volume of water to be considered in performance assessments, and methods to be used by the applicant in estimating concentrations of contaminants with the representative volume. Implementation of requirements for these aspects of the biosphere could be accomplished by the repository license applicant proposing appropriate values, consistent with NRC requirements and subject to approval by the NRC.

III.1.4 Retain the Requirements for the Identification and Screening of Potentially Relevant Features, Events, and Processes

The ANS Committee agrees that the general approach taken by the EPA in both 40 CFR Part 191 and 40 CFR Part 197 to the identification of potentially relevant features, events, and processes is sound and should be maintained. Similarly, we agree that the criteria provided for determining which of these features, events, and processes must be included in the quantitative performance assessment are appropriate. Specifically, past experience with both the WIPP and Yucca Mountain repository programs has demonstrated the value of allowing the applicant to omit features, events, processes from the quantitative performance assessment that are shown to be either very unlikely to occur[9] or to result in insignificant changes to the results of the performance assessment [10], [11], [12]. This approach, as presented for the Yucca Mountain Site in 40 CFR 197.36(a)(1), provides important limits to boundless speculation while maintaining a focus on the protection of public health, safety, and the environment, and is clearly consistent with the concept of risk-informed regulation.

[9]The EPA defines “very unlikely to occur” in 40 CFR Part 197 as “to have less than one chance in 100,000,000 per year of occurring.” The ANS Committee concurs with this definition and further recommends that the EPA provide an analogous definition of “unlikely to occur,” which is currently defined only by the NRC in 10 CFR Part 63.

For the purposes of developing generic standards, the ANS Committee recommends removing the Yucca Mountain–specific requirements in 40 CFR 197.36(c) for special consideration of individual events and processes.

III.1.5 Base the Human Intrusion Standard on Consideration of a Single Stylized Intrusion Event

The ANS Committee recognizes that the Human Intrusion Standard specified by the EPA for the Yucca Mountain in 40 CFR 197.25 and 40 CFR 197.26 is site specific and cannot be adopted as is for a generic site. We also conclude, however, that that approach specified by the EPA in 40 CFR Part 191 is inappropriate for a generally applicable standard. As seen in the compliance certification analyses done for the WIPP [10]), requiring inadvertent human intrusion to be included in probabilistic evaluations of the natural evolution of the site can create a situation where licensing decisions may be dominated by irreducible uncertainty regarding human actions in the far future, rather than on the merits of the site and repository design.

The committee concludes that the general approach specified in 40 CFR Part 197, requiring analysis of the consequences of a stylized human intrusion scenario consisting of subsurface groundwater releases from a single inadvertent and undetected drilling event that penetrates a single waste package, regardless of the probability of its occurrence, is preferable to the approach taken in 40 CFR Part 191. This approach will appropriately emphasize the merits of the site geology and repository design while removing speculation about future human actions.

The ANS Committee recommends specifying a separate standard for human intrusion using the approach taken for the Yucca Mountain Site in 40 CFR Part 197, modified to be generally applicable to generic sites. Specifically, human intrusion could be specified to be the result of exploratory drilling for natural resources of any type (rather than just groundwater, the only resource considered at Yucca Mountain), and the intrusion borehole should be assumed to provide connections to both overlying and underlying aquifers (rather than just the underlying aquifer specified for Yucca Mountain). We recommend that EPA retain the requirement in 40 CFR 197.26(c) that "drillers use common techniques and practices that are currently employed." To require otherwise would lead to unbounded speculation about future technologies.

The ANS Committee suggests that the time of the intrusion event could be specified to be either the "earliest time after disposal that the waste package would degrade sufficiently that a human intrusion . . . could occur without recognition by the drillers," as specified in 40 CFR 197.25(a) for the proposed Yucca Mountain repository, or 1,000 years after repository closure, whichever comes first. Specifying the time for the event would remove speculation about future drilling practices and would be consistent with the recognition that the standard relies on a stylized—rather than a realistic—event. An intrusion at 1,000 years provides time for the effects on the rest of the disposal system to be manifested in quantitative comparisons with the dose rate limit and represents a conservative estimate for the earliest time of undetected intrusion for many disposal system engineered barrier designs.

The committee agrees with the position taken by the EPA in promulgating 40 CFR Part 197 that including releases to the land surface during drilling would not provide useful information regarding the resilience of the disposal system following human intrusion,[10]. We also note that all proposed repositories with similar waste emplacement designs and configurations would show similar releases to the ground surface following intrusion, and including those release in the regulatory standard would not provide useful information for comparing multiple candidate sites or repository design concepts. Consistent with these observations, the committee recommends retaining the specification that analysis should be limited to releases through groundwater pathways.

The ANS Committee further notes that specifying a single intrusion regardless of the presence or absence of resources in the region may remove useful information about the site-specific potential for intrusion from the evaluation of the suitability of the site for a geologic repository. In a generic standard this approach could reduce the incentive to select sites with a negligible potential for future natural resource exploration and exploitation. We suggest that this incentive in the siting process could be restored by allowing an alternative approach. The applicant instead could forego the quantitative human intrusion analysis if a technical basis for the conclusion that inadvertent and undetected intrusion is very unlikely is presented, consistent with the configuration of the repository and the potential for the occurrence of exploitable natural resources at the site. Such a provision would provide an incentive to select sites in regions with little or no potential for resource development based on current understanding.

In addressing human intrusion, it is important to note that the threat posed to future humans is tempered by the capability of a future society to carry out the intrusion (which requires a certain level of technology) and the potential capability of an advanced future society to mitigate harm. The implications of the characteristics of a future society are discussed in more detail in Appendix C. While the ANS Committee considers it reasonable to include consideration of human intrusion in repository standards, that should not imply that human intrusion will actually occur or, even if it does, lead to harm caused to future inhabitants near the repository. Consistent with the

[10]EPA, 66 FR 32073 (2001).

recommendation below regarding the regulatory time period for quantitative standards, the ANS Committee recommends limiting the time period for quantitative consideration of the consequences of human intrusion to 10,000 years.

III.2 ANS Committee Recommendations for Changes from the Regulatory Approach Taken for Yucca Mountain

The recommendations of the previous section notwithstanding, there are several technical issues for which the ANS Committee believes generic standards could be significantly improved by modification of the approach taken for Yucca Mountain. These topics are discussed in more detail in the following sections.

III.2.1 Limit the Regulatory Time Period for Quantitative Standards

The committee recommends limiting the time period for quantitative standards to 10,000 years following disposal. The primary quantitative metric applied to postclosure performance of repositories is the estimated annual radiation dose to future humans; this dose depends in large part on the behavior of the exposed individuals. As discussed above, the committee agrees with the position taken by the EPA in text accompanying the initial promulgation of 40 CFR Part 197 that using the behavior of the individuals currently living in the region of the repository is a reasonable and conservative basis for limiting speculation about future behavior.[11] However, the projection becomes less valuable as input for decision-making when extended over time periods longer than recorded human civilization. Although computational models can be constructed that project behavior of natural and engineered systems for very long time periods, the capabilities of those models to cope with complex coupling of time-dependent boundary conditions remain problematic.

The ANS Committee concludes that the 10,000-year standard provided in 40 CFR Part 191 provides a more reasonable and defensible time period during which quantitative estimates of the protection to humans can be meaningfully assessed than does the 1,000,000-year period adopted for the Yucca Mountain Site in 40 CFR Part 197. Further, the committee believes that basing regulatory decisions on quantitative estimates of health risks to humans beyond 10,000 years introduces a false precision into a decision-making process that can be better informed by considering multiple lines of evidence, including alternative safety indicators. As discussed in section III.2, this recommendation is not intended to preclude the use of simplified, quantitative

[11]See, e.g., EPA, 66 FR 32074 (2001).

modeling over longer times by either the implementor or the regulator where appropriate; rather, it is intended to avoid creating unrealistic expectations about the interpretation of such model results by requiring their comparison to a quantitative dose standard.

It is important to understand the history associated with the EPA's establishment of a 1,000,000-year time period for quantitative standards for the Yucca Mountain regulation (40 CFR Part 197). In the first promulgation of these standards in 2001, the EPA retained the 10,000-year time period for quantitative demonstration of compliance. This was then challenged in the U.S. Court of Appeals, which agreed with the plaintiffs that the time period was not "based upon and consistent with" the recommendations of the NASEM, as required by the Energy Policy Act (EnPA) of 1992.[12] The court made no finding on an appropriate time frame for quantitative demonstration of compliance for geologic repositories in general, but it did conclude that the direction of the EnPA of 1992 had not been carried out for the Yucca Mountain regulation. In repromulgating the regulation, the EPA extended the time period to 1,000,000 years based on the Court of Appeals ruling that the NASEM found the period of geologic stability for Yucca Mountain to be on the order of 1,000,000 years. The EPA did provide for a higher regulatory limit on individual dose between 10,000 years and 1,000,000 years as an acknowledgement that projections in the longer time frame are inevitably more uncertain. The ANS Committee believes the use of the 1,000,000-year time period for the Yucca Mountain standards is predominantly an outcome of the process established by Congress for developing that regulation but that it does not constitute an inviolable precedent for all future geologic repository standards. (See Appendix A of this report for a more detailed history of the development of the Yucca Mountain regulation.)

As discussed further in Appendix B.5, there is widespread recognition in the international community that safety standards should recognize the uncertainties inherent in time-dependent factors, notably those associated with human behavior. For example, the International Atomic Energy Agency notes that over longer time periods, safety should be assessed through "simplified estimates and qualitative arguments rather than through the application of quantitative safety criteria" [13, sec. 6.49]. Similarly, the International Commission on Radiological Protection (ICRP) notes that "the scientific basis for assessments of detriment to health at very long times into the future therefore becomes uncertain, and the strict application of numerical criteria may be inappropriate" [14, p. 15], and that the results of any dose or risk assessments need to be interpreted in a qualitative way at long timescales [14, p. 41].

[12]Nuclear Energy Institute, Inc. v. Environmental Protection Agency (2004).

There is also precedent for the use of a 10,000-year time period for projecting performance of isolation of hazardous material in EPA regulations. Subpart C, "Petition Standards and Procedures," of 40 CFR Part 148 sets forth requirements that must be satisfied in a petition to allow the injection of a restricted hazardous waste into an injection well or wells.[13] In that instance, the EPA established a time period of 10,000 years for projections of retention of hazardous waste. Obviously, hazardous waste does not become harmless at year 10,001, but the EPA recognized the practical limitations associated with modeling geologic performance into the far future quantitatively for the purpose of direct comparison to a health limit. The ANS Committee also recognizes those limits on the utility of quantitative compliance requirements but believes it is important to assess geologic repository performance during time periods longer than 10,000 years.

III.2.2 Introduce a Separate Standard for Performance beyond 10,000 Years Based on Multiple Lines of Evidence

As an alternative to basing regulatory compliance on quantitative system-level dose assessments for 1,000,000 years, the ANS Committee recommends that the EPA require a demonstration that there is a reasonable expectation that the disposal system will continue to function as intended during years 10,000–1,000,000 following disposal. This could be accomplished in part by continuing to consider potentially relevant features, events, and processes over a 1,000,000-year time period. The applicant should identify and evaluate features, events, and processes, if any, that have the potential to initiate scenarios having significantly different (and detrimental) impacts on the safety functions of the disposal system after 10,000 years. Those evaluations—and the full range of evidence used to develop them—should be considered by the NRC during the licensing process. Rather than specifying quantitative limits that would in effect require a full quantitative dose assessment for 1,000,000 years, the burden would fall on the applicant to provide a sufficient analysis using qualitative or, where appropriate, quantitative methods to demonstrate that features, events, or processes that might operate differently after 10,000 years would not significantly degrade the overall performance of the repository. This is akin to using probabilistic risk analysis to identify "cliff-edge" effects in reactor safety analysis [15, sec. 8].

Examples of such processes that might need further analysis could include the impacts of future glacial cycles (which may be unlikely within 10,000 years), extrapolation of continued degradation of engineered barriers, changes in regional hydrology, and

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[13] 40 CFR Part 148, *Hazardous Waste Injection Restrictions.*

consequences of continued erosion at the site. Examples of methods and metrics used by the applicant in evaluating safety functions of the disposal system after 10,000 years could include qualitative observations based on current understanding (e.g., many geologic processes can reasonably be assumed to continue to function in the future as they do today). Process-specific observations and modeling (e.g., estimates of regional rates of uplift and erosion could be compared directly to the depth of the repository), and estimates of repository-derived radionuclide concentrations in groundwater could be compared to naturally occurring concentrations.

The proposed post-10,000-year standard would not preclude the use of long-term dose estimates in evaluating the impact of potential degradation of disposal system safety functions. Rather, the proposed standard would encourage consideration of multiple lines of evidence while avoiding the sole reliance on the precision of dose estimates over a period of time that far exceeds human history.

As proposed, the applicant would have the responsibility to identify the full set of potentially relevant post-10,000-year features, events, and process and determining their impact on the long-term safety of the repository. Determination of both the adequacy of the applicant's analysis and the relative significance of the impact would be the responsibility of the regulator.

III.2.3. Replace "Period of Geologic Stability" with "1,000,000 Years"

The ANS Committee recommends that the EPA remove the term "period of geologic stability" from the regulation and replace it with a generally applicable specification of 1,000,000 years. The "Period of geologic stability" was derived from the 1995 NAESM report *Technical Bases for Yucca Mountain Standards* [6] and is not generally applicable to generic sites. The term is defined in the Yucca Mountain standards synonymously with 1,000,000 years and would likely prove difficult to define using scientific criteria. Furthermore, it is an unsuitable concept for a generic standard, because some sites might reasonably be argued to be geologically stable for shorter or longer periods of time than others under consideration. Applying the term used in the regulatory standard literally to generic sites could have the unintended and counterintuitive effect of incentivizing sites with a potential for geologic instability, however that might be defined, at earlier times. One million years is more than two orders of magnitude longer than recorded human history, and the ANS Committee believes that it is a sufficient and conservative time period to consider the possible impacts of the behavior of geologic systems on human health.

III.2.4 Adopt Requirements for Multiple Barriers Based on the Approach Taken by the EPA in 40 CFR Part 191

The ANS Committee agrees with the approach taken in 40 CFR 191.14(d) to require both engineered and natural barriers. This is also consistent with the NRC implementing regulations for the Yucca Mountain Site (see 10 CFR 63.102(h); 10 CFR 63.113(a); 10 CFR 63.115). We recommend that the EPA adopt this approach in its standards. Specifically, the committee concludes that the requirements in 10 CFR 63.115—to identify the barriers, describe their capabilities, and provide the technical basis for those capabilities consistent with the technical basis for the overall performance assessment—will result in a sound basis for the evaluation of the defense-in-depth provided by the repository. Further the committee concludes that this approach is preferable to the quantitative subsystem limits specified in 10 CFR Part 60 for the performance of selected components of the barrier system, because that approach carries the potential to encourage subsystem engineering solutions that may not correspond to improvements in overall disposal system performance.

This approach is consistent with the requirements of the NWPA "to provide for the use of a system of multiple barriers in the design of the repository" (§121(b)(1)(B)); NRC staff completed a thorough analysis of the requirements during the promulgation of 10 CFR Part 63 ().[14] Furthermore, this approach is consistent with international practice regarding the treatment of "safety functions" in repository performance (see Appendix B) and has withstood court challenges specific to its application for the Yucca Mountain Site.[15]

III.2.5 Adopt Requirements for Retrievability Consistent with NWPA §122

The ANS Committee agrees with the approach to regulating the retrievability of waste prescribed in the NWPA. Specifically, §122 states that "any repository constructed on a site approved under this subtitle shall be designed and constructed to permit the retrieval of any spent nuclear fuel placed in such repository, during an appropriate period of operation of the facility . . . ." In 40 CFR 191.14(f) the EPA states, "Disposal systems shall be selected so that removal of most of the wastes is not precluded for a reasonable period of time after disposal." Specific to the proposed Yucca Mountain repository, the NRC required in 10 CFR 63.111(e) that "the geologic repository operations area must be designed so that any or all of the emplaced waste could be

[14]See, e.g., Nuclear Regulatory Commission, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, NV; Final Rule," 66 FR 55732 (Dec. 3, 2001).
[15]Nuclear Energy Institute, Inc. v. Environmental Protection Agency (2004).

retrieved on a reasonable schedule starting at any time up to 50 years after waste emplacement operations are initiated, unless a different time period is approved or specified by the [NRC].” The committee recommends that the EPA adopt this approach in its generic standards while leaving details of the implementation (e.g., providing further guidance on what constitutes “an appropriate period of operation” or “a reasonable period of time after disposal”) to be determined by the NRC. As discussed in section III.2 6 below, deep borehole disposal concepts, with operational periods for disposal that are inherently far shorter than those needed for mined repositories, warrant different considerations for a “reasonable schedule” for retrievability, consistent with the NWPA.

The ANS Committee also notes that requirements and expectations regarding retrievability vary widely internationally and that the approach recommended here is consistent with those adopted in many other national programs (see Appendix B).

III.2.6 Adopt the Definition of the Controlled Area from 40 CFR Part 191

The 40 CFR Part 197 definition of the controlled area is specific to the Yucca Mountain Site and is clearly not appropriate for a generic repository. The ANS Committee recommends the use of the definition from 40 CFR Part 191: “no more than 100 square kilometers [extending] horizontally no more than five kilometers in any direction from the outer boundary of the original location of the radioactive wastes in a disposal system.” The controlled area for a specific site would be determined by the implementing organization based on the characteristics of that site, and it would be subject to approval of the NRC.

The controlled area concept is well understood for a mined geological repository like the WIPP or Yucca Mountain but has yet to be implemented for a borehole repository. The ANS Committee sees the concept as being fairly straightforward for a deep vertical borehole repository, including one with an array of boreholes (see sec. III.2.7). However, a horizontal borehole repository with boreholes projecting in multiple directions presents a potentially more complicated situation that would be addressed as described above.

III.2.7 Make Generic Standards Applicable to Deep Borehole Disposal Concepts

The ANS Committee recommends that the EPA make generic disposal standards applicable to deep borehole disposal concepts as well as the mined repositories that have been the only application of the existing regulations. In this regard, the committee agrees with intent of the EPA in their promulgation of 40 CFR Part 191 in 1985: “Although disposal of these materials in mined geologic repositories has received the most attention, the disposal standards apply to disposal by any means, except disposal directly into the oceans or ocean sediments.”[16] There have been significant advances in drilling technology since the initial promulgation of 40 CFR Part 191, including directional drilling techniques that allow for horizontal as well as vertical boreholes of sufficient length to function as repositories. All potential types of borehole disposal should be covered by a new generic repository standard.

The ANS Committee recognizes multiple ways in which borehole disposal systems could raise different regulatory issues than those posed by mined repositories. For example, the choice of whether to define the disposal system to be a single borehole or an array of multiple boreholes could impact many aspects of the compliance evaluation, ranging from the calculation of the estimated annual dose to definition of the controlled area and the location of the accessible environment boundary. Other issues could arise with the phased nature of borehole disposal: Would compliance assessments be required for each separate borehole as it is characterized and constructed? Would operational retrievability requirements be established borehole-by-borehole, allowing for the plugging of one borehole before going on to the next? The committee believes most such issues could be appropriately addressed in a straightforward manner by the NRC in site-specific implementing criteria for a repository after the basic disposal concept had been established. Three topics, however, appear to rise to the level of potentially requiring being addressed in the generic standards.

First, the committee recommends that the EPA define a borehole repository to be the full array of boreholes at a single site. This would allow applying quantitative limits to the full disposal inventory rather than applying them to single boreholes one at a time, and it would provide a logical basis for defining the boundaries of the accessible environment and the location of the reasonably maximally exposed individual using the same approach taken for mined repositories. The requirement should be written, however, to allow flexibility for the NRC in its specification of phased licensing operations as individual disposal boreholes are characterized, constructed, and sealed.

Second, the committee recommends that the EPA provide the opportunity for the NRC to address human intrusion, taking into account site-specific design and geometry considerations for deep borehole disposal systems.

[16]Environmental Protection Agency, “Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes; Final Rule,” 50 FR 38066 (Sep. 19, 1985).

Third, as noted above (sec. III.2.5), the committee recommends that the EPA allow specifically for consideration of a period of retrievability that is appropriately consistent with the operational periods likely for borehole disposal systems. This would be consistent with the requirements for retrievability provided by the NWPA §122.

III.2.8 Remove Specificity Regarding the Implementing Organization

The ANS Committee recommends that the new standards refer throughout to simply the "implementing organization" or the "implementor" rather than to the DOE. Existing language in 40 CFR Part 197 refers specifically to the DOE and its responsibilities. That is understandable, given that the NWPA specifies the DOE as the implementing agency for a repository at Yucca Mountain or other sites developed under the provisions of the act. However, the EPA's generic regulation should be general where possible and need not presuppose that the DOE will be the only implementing organization for all geologic repositories in the U.S. for all time. Flexibility may be useful should the current statutory framework for management of geologic disposal change.

III.3 Other Topics

In this section, the ANS Committee provides discussions of other topics that it believes may benefit from further consideration in the development of generic standards, regardless of whether changes result in the final rules.

III.3.1 Consider Updating Guidance and Requirements for Radiation Dose Assessments to Be Consistent with the Most Recent Recommendations of the ICRP

In some instances, the approaches specified in existing regulations for determining health consequences from radiation exposures are out of date with respect to current international practice. The most recent recommendations on dose conversion methodology from the ICRP are an appropriate starting point for the EPA to consider [14], [16], [17]. The committee notes that Appendix A of 40 CFR Part 197 used older ICRP dose conversion factors brought forward from 40 CFR Part 191 but left open the door for the DOE to use updated radiation weighting factors if allowed by the NRC. A future EPA disposal standard could be updated to bring itself into alignment with international practice. Given the multigenerational operational lifetime anticipated for many deep geologic repository concepts, continued updating of the dose conversion methodology by either the EPA or the NRC should be expected and welcomed.

III.3.2 Consider Removing the Ground Water Protection Standards

The ANS Committee recognizes that this topic was the subject of extensive comment and deliberation in the late 1990s during the drafting and promulgation of 40 CFR Part 197, and it may be unlikely that further recommendations at this point will be constructive. With that said, the committee concurs with the comments made by NRC staff in 1999 specific to the EPA's proposed Ground Water Protection Standards [18]. The committee's recommendation, consistent with NRC's required "all-pathways" safety assessment requirement, is to have in place overall quantitative standards for protection of human health; the imposition of additional groundwater protection standards based on treated drinking water systems, as is the case with current U.S. repository standards, is unnecessary and counterproductive. Specifically, we believe that the Ground Water Protection Standards as implemented in 40 CFR 197 add no additional protection to the standards for human health, safety, or the environment beyond that already provided by the Individual Protection Standard. The committee also shares the NRC's concern, expressed in 1999, that the allowable levels of radium, gross alpha activity, and combined beta and photon emitters specified in 40 CFR Part 197 were intended for application to treated sources of community drinking water (see 40 CFR 141.66) and are inappropriately and inconsistently applied to untreated groundwater in 40 CFR Part 197. If promulgated as part of a generic standard, applying drinking water standards to untreated groundwater has the potential to incentivize the selection of sites with otherwise pristine groundwater, because sites with higher background levels of radium or other sources of radioactivity would present greater challenges in meeting a standard that was never intended to be applied in this manner.

III.3.3 Establishing the Level of Protection

The ANS Committee makes no specific recommendation on the regulatory limit for annual dose to an individual living near a proposed repository. The individual protection dose limits in 40 CFR Part 191 and 40 CFR Part 197 are set at 0.15 mSv (15 mrem) per year for the first 10,000 years after repository closure. 40 CFR Part 197 applies a limit of 1 mSv (100 mrem) per year during 10,000–1,000,000 years after permanent closure. In this section, the committee offers some context for those, and other, values.

First, most other countries impose limits on projected dose as part of their repository standards. As discussed below in Appendix B, the levels of protection range from 0.1 to 1 mSv (10 to 100 mrem) per year. Both the IAEA and the ICRP recommend a dose limit for disposal facilities of 0.3 mSv (30 mrem) per year for members of the general public [19, sec. 2.15(b)], [17, p. 12]. From that perspective, the U.S. is toward the low (most restrictive) end of the spectrum for the first 10,000 years.

In addition, the average natural background dose for residents of the United States is approximately 3.1 mSv (310 mrem) per year [20]. The average total radiation dose to U.S. residents, including natural and man-made sources of radiation, is 6.2mSv (620 mrem) per year [18]. Background dose varies significantly due to numerous factors, including elevation, dwelling type, occupation, lifestyle, and medical treatment. According to a report prepared for the EPA, the average annual natural background dose varies between 1.31 mSv (131 mrem) in Florida and 9.63 mSv (963 mrem) in South Dakota [21]. The largest source of the variation is the amount of radon gas present. With respect to man-made sources, medical treatment is a significant variable; a single computed tomography scan can result in a dose of 1.5 mSv (150 mrem) [20]. Thus, doses in the range of 0.15–1 mSv per year, consistent with current geological repository standards, are significantly lower than current background radiation levels in the U.S. and lower than the variability of background radiation levels.

The NRC has established other regulatory limits for radiation dose to individual members of the public. For example, 10 CFR Part 20 sets a limit of 1 mSv (100 mrem) per year from the operation of a nuclear power plant. With respect to SNF management facilities, t10 CFR Part 72 sets a limit of 0.25 mSv (25 mrem) per year for radiation dose to the public from an independent spent fuel storage installation.[17] Both allowable annual doses are greater than the 10,000-year individual protection dose limits in 40 CFR Part 191 and 40 CFR Part 197.

The ANS Committee expects the EPA will establish an annual limit on projected individual dose due to a geologic repository in the range of 0.15–1 mSv (15–100 mrem) per year. A limit in that range is appropriately conservative for a public health and safety standard, with the lower end of the range being quite restrictive relative to many current U.S. and international practices.

IV. SUMMARY

The ANS Committee recommendations can be broadly summarized as follows: Use the existing Yucca Mountain standards as a template for developing new standards, modified as necessary for general applicability. In general, the Yucca Mountain standards are representative of international best practices and implementable using established licensing processes.

[17] 10 CFR Part 20, *Standards for Protection Against Radiation;* 10 CFR Part 72, *Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste.*

Specific recommendations include:

- Retain the individual health consequence standard (e.g., individual dose rate or incremental individual health risk) as the primary quantitative metric.
- Retain the concepts of reasonable expectation and risk-informed decision-making as a recognition of the limitations of quantitative modeling of the far future.
- Retain the concept of basing the characteristics of the reasonably maximally exposed individual on current practice in the vicinity of the disposal site, and retain regulatory specificity regarding characteristics of and future changes to the biosphere and certain aspects of the geologic environment.
- Retain the requirements for the identification and screening of potentially relevant features, events, and processes.
- Retain the human intrusion requirement, but revise it to make it generally applicable to all potential sites and repository design concepts.

In addition to general modifications needed to make the Yucca Mountain standards generic, we recommend the following changes:

- Limit the regulatory time period for quantitative standards to 10,000 years.
- Replace quantitative dose limits for the period beyond 10,000 years and before 1,000,000 years with a requirement to evaluate potentially relevant features, events, and processes to demonstrate that they are unlikely to result in substantially different behavior of the disposal system during that period.
- Adopt requirements for the multiple barriers, consistent with the approaches taken in 40 CFR 191.14(d) and implemented by the NRC for Yucca Mountain in 10 CFR Part 63, to ensure defense in depth.
- Adopt requirements for retrievability of the wastes as prescribed by the NWPA §122, currently included in 40 CFR 191.14(f) and implemented by the NRC for Yucca Mountain in 10 CFR Part 63.
- Remove the concept of “period of geologic stability” from generic disposal standards while retaining an upper bound on the regulatory period of 1,000,000 years.

- Make generic disposal standards applicable to deep borehole disposal concepts as well as mined repositories.
- Adopt the definition of the controlled area provided in 40 CFR Part 191, with site-specific implementation to be determined by the implementor and the NRC.
- Remove specificity regarding the establishment of the DOE as the implementing organization for disposal of SNF and HLW.

In addition, the ANS Committee provides observations on other topics it believes could benefit from further consideration by the EPA and NRC:

- The approaches specified in existing regulations for determining health consequences from radiation exposures are in some instances out of date with respect to current international practice.
- The separate "Ground Water Protection Standards" (40 CFR 197.30 and 197.31) add no additional protection to the standards for human health, safety, or the environment, while introducing the potential for incentivizing the selection of sites with pristine groundwater.
- Regarding the specific limits applied to estimates of annual radiation doses to individuals, values in the range of 0.15–1 mSv (15–100 mrem) per year are appropriately conservative for a public health and safety standard.

V. REFERENCES

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APPENDIX A - U.S. LEGISLATIVE AND REGULATORY HISTORY GOVERNING PERMANENT DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTE AND SPENT NUCLEAR FUEL

A.1 Legislative History

Key aspects of the statutory framework governing regulations for the disposal of spent nuclear fuel (SNF) and high-level radioactive waste (HLW) come from a relatively small body of federal legislation. The Atomic Energy Acts (AEAs) of 1946 and 1954 created the basis for federal authority; the federal Energy Reorganization Acts of 1974 and 1977 created the Department of Energy and the Nuclear Regulatory Commission, two of the three primary agencies responsible for implementing national policy (the third, the Environmental Protection Agency, was created by executive order in 1970); and the Nuclear Waste Policy Act (NWPA) of 1982 defined the national policy for nuclear waste management and disposal. Subsequent modifications to policy and statute in the Nuclear Waste Policy Amendments Act of 1987 (NWPAA; included in the Omnibus Budget Reconciliation Act of 1987), the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA) of 1992, and the Energy Policy Act (EnPA) of 1992 have impacted the course of the national program and have provided the EPA and NRC with specific direction regarding the development of their standards and regulations. A Joint Resolution of Congress in 2002 approving the Yucca Mountain Site for development did not constrain the development of the EPA standards and NRC regulations but did confirm the intent of Congress to focus solely on the Yucca Mountain Site, consistent with the requirements of the NWPAA of 1987.[1]

The Atomic Energy Act of 1946 sets national nuclear policy. The AEA of 1946 is silent on the subject of radioactive waste management and disposal, but it created a basis for civilian nuclear energy activities and established the Atomic Energy Commission (AEC) authority to oversee nuclear research and the control of nuclear materials in the private and public sectors. Specifically, the AEA stated as a national policy goal that “the development and utilization of atomic energy shall, so far as

[1]Atomic Energy Act of 1946, Pub. L. No. 585, 79th Cong. (1946); Atomic Energy Act of 1954, Pub. L. No. 83-703, 68 Stat. 919 (1954); Energy Reorganization Act of 1974, Pub. L. No. 93-438, H.R. 11510, 93rd Cong. (1974); Energy Reorganization Act of 1977, Pub. L. No. 95-91 Stat. 565, 95th Cong. (1977); Nuclear Waste Policy Act of 1982, Pub. L. No. 97-425, 96 Stat. 2201, 97th Cong. (1982); the Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, H.R. 3545, 100th Cong. (1987); Waste Isolation Pilot Plant Land Withdrawal Act, Pub. L. No. 102-579, 106 Stat. 4777, 102nd Cong. (1992); Energy Policy Act of 1992, Pub. L. No. 102-486, H.R. 776, 102nd Cong. (1992); Joint Resolution Approving the Site at Yucca Mountain, Nevada, Pub. L. No. 107-200, 116 Stat. 735, 107th Cong. (2002).

practicable, be directed toward improving public welfare, increasing the standard of living, strengthening free competition in private enterprise, and promoting world peace" (§1(a)). The AEC was the agency tasked with implementing programs to achieve this goal, in addition to its defense-related responsibilities.

The Atomic Energy Act of 1954 expands federal responsibility to include defense-origin wastes. The AEA of 1954 provided significantly more authority and specificity to the roles and responsibilities of the AEC, including, as noted above, the first statutory obligation for the management of radioactive wastes. The AEC's responsibility was limited at this point to wastes generated by defense-related activities. This responsibility has shifted to the DOE but remains in effect.

The Energy Reorganization Act of 1974 and the Department of Energy Organization Act of 1977 create the NRC and the DOE and define their scopes. Congress dismantled the AEC in 1974, separating its regulatory responsibilities from those related to nuclear defense and energy programs. The NRC was established as an independent regulator of commercial nuclear activities, and the Energy Research and Development Administration (ERDA) was established to oversee both the AEC's nuclear defense and energy programs and a wide range of federal nonnuclear energy research and development activities. Congress reorganized the ERDA into the DOE in 1977, specifically ensuring that responsibilities for nuclear activities originally assigned to the AEC were transferred to the DOE.

The Nuclear Waste Policy Act of 1982 defines national policy. The NWPA provides a comprehensive framework for federal storage and permanent disposal of SNF and HLW of civilian (i.e., commercial) origin, with provisions for the inclusion of defense-origin wastes in the federally managed civilian disposal program. For the purposes of this discussion, the most important aspect of the NWPA is the clear definition of roles and responsibilities for the EPA and the NRC in developing standards and regulations for permanent disposal. The NWPA also provides specific direction to the NRC regarding the content of its implementing regulations with respect to the requirement of a system of multiple barriers in the design of the repository and restrictions on the retrievability of the wastes from the repository (§121(b)(1)(B); §122).

The Nuclear Waste Policy Amendments Act of 1987 redirects national policy. The NWPAA provided a major redirection of the national program by selecting Yucca Mountain as the only site to be evaluated by the DOE under the "first repository" provisions of the NWPA for potential submittal of a license application to the NRC, terminating the NWPA-prescribed site-selection process before it was complete. The NWPAA had no direct impact on the EPA and NRC regulatory frameworks for the repository, but the combination of the redirection of the national program and court actions vacating the EPA's generally applicable standard led to the creation of a new set of EPA and NRC regulations specific to Yucca Mountain (as discussed above in sec. II.1.2).

The WIPP Land Withdrawal Act and the Energy Policy Act of 1992 provide regulatory direction to EPA and NRC. In 1992, Congress provided clarity regarding changes in the roles and responsibilities of the EPA and the NRC resulting from the 1987 legislation focusing solely on the Yucca Mountain Site for disposal of SNF and HLW. The EnPA of 1992 directed the EPA and the NRC to prepare new standards and regulations specific to the Yucca Mountain Site, and WIPP LWA clarified that the generally applicable EPA standards used for the WIPP would not apply to the Yucca Mountain Site. As discussed in more detail above (sec. II.1.2), the EnPA of 1992 provided specific direction to the EPA and NRC regarding the content of the new standards and regulations for Yucca Mountain, and both acts provided a timeline for the completion of rulemaking activities.

2002 Joint Resolution of Congress approving the Yucca Mountain Site. In July 2002, Congress passed a joint resolution "approving the site at Yucca Mountain, Nevada, for the development of a repository for the disposal of high-level radioactive waste and spent nuclear fuel, pursuant to the Nuclear Waste Policy Act of 1982." Consistent with the requirements of the NWPA, as amended (§116(b)), this law was passed to override the governor of Nevada's disapproval earlier year of the President George W. Bush's recommendation of the site to Congress. Passage of the joint resolution required the DOE to proceed with submitting an application for construction authorization at the site to the NRC within 90 days (NWPA §114(b)). The 2002 joint resolution placed no constraints on the content of the EPA standards or the NRC regulations for Yucca Mountain, nor did it place any constraints on the outcome of the licensing process.

Current status of federal legislation relevant to EPA and NRC rulemaking for generic disposal standards. In the absence of new legislation, the NWPA, as amended by the NWPAA and as supplemented by the WIPP LWA and the EnPA of 1992, remains the governing statute that EPA and NRC must follow in developing new, generally applicable standards and regulations for the disposal of SNF and HLW.

A.2 Regulatory History

As noted above, the NWPA tasked the EPA with creating the regulatory standards and tasked the NRC with establishing and enforcing licensing criteria consistent with those standards. The following sections and Table A.1 summarize the history of the actions taken by the EPA and NRC to fulfill these obligations.

Promulgation of initial EPA and NRC regulations as required by the NWPA. Both the EPA and the NRC regulations were to have been promulgated by January 1984, one year after the enactment of the NWPA in January 1983. The NRC had already issued its first iteration of 10 CFR Part 60, *Disposal of High-Level Radioactive Wastes in Geologic Repositories*, in February 1981 and worked quickly once the NWPA was enacted to have licensing criteria in place in 10 CFR Part 60 by June 1983. Because final EPA standards were not yet available, the 1983 criteria simply noted that, with respect to quantitative long-term performance, releases of radioactive materials must remain within "such generally applicable standards for radioactivity as may have been established by the Environmental Protection Agency." The EPA standards, *Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes*, were promulgated in September 1985, providing the U.S. with a complete regulatory framework for geologic disposal, as envisioned by the NWPA.[2]

The 1987 court-ordered remand of the EPA standard. The regulatory framework for geologic disposal did not remain intact for long. In response to lawsuits brought by the Natural Resources Defense Council and other parties, the U.S. Court of Appeals for the First Circuit found in July 1987 that aspects of 40 CFR Part 191 were inconsistent with the requirements of the Safe Drinking Water Act, and the court vacated those portions of the rule and remanded it to the EPA for further consideration.[3] The court also noted that the EPA had not provided an adequate explanation for selecting the 1,000-year design criterion for the Individual Protection Requirement and that the Ground-water Protection Requirements were promulgated without proper notice and comment. The court rejected other challenges to the rule, but the remand had the effect of leaving the nation without SNF and HLW disposal standards until revisions could be promulgated.

Congressional direction in 1992. Following the remand of 40 CFR Part 191 in 1987, the U.S. disposal program proceeded with evaluation and development of the candidate repository sites at Yucca Mountain in Nevada (for HLW and SNF) and at the WIPP in southeastern New Mexico (for defense-related transuranic [TRU] waste) under the

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[2] Nuclear Regulatory Commission, "Part 60—Disposal of High Level Radioactive Wastes in Geologic Repositories," 46 FR 13980 (Feb. 25, 1981); NRC, "Part 60 . . . Subpart E—Technical Criteria," 48 FR 28222 (June 21, 1983); 10 CFR 60.111, in NRC, "Part 60 . . . Subpart E ," 48 FR 28223; Environmental Protection Agency, "Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes; Final Rule," 50 FR 38066 (Sep. 19, 1985).
[3]Natural Resources Defense Council, Inc., et al. v. U.S. Environmental Protection Agency, et al., 824 F.2d 1258 (1st Cir. 1987).

assumption that the EPA would repromulgate final disposal standards in a timely manner. Ambiguity about the regulatory framework for both Yucca Mountain and the WIPP remained until October 1992, when Congress enacted two laws. The WIPP LWA (P.L. 102-579), in addition to transferring formal ownership of the site from the U.S. Bureau of Land Management to the DOE, reinstated those portions of 40 CFR Part 191 that were not affected by the 1987 court decision and directed the EPA to repromulgate the final rule addressing the court's concerns within six months. The act also established the EPA's role as the certifying agency for WIPP, directed the EPA to promulgate certification criteria specific to WIPP, and stipulated that the reinstated requirements of 40 CFR Part 191 would not apply to any site required to be characterized under the NWPA (i.e., Yucca Mountain). The EnPA of 1992 (P.L. 102-486) included provisions directing the EPA to promulgate "generally applicable standards for the Yucca Mountain Site . . . based upon and consistent with the findings and recommendations of the National Academy of Sciences" (§801). The National Academy of Sciences was, in turn, directed by the EnPA of 1982 to conduct a study and provide findings and recommendations to the EPA by December 31, 1993, regarding three aspects of a disposal standard: (1) whether a dose-based standard would be protective, (2) whether active institutional controls at the site can prevent unreasonable risks of exposures to individual members of the public after the repository has been closed, and (3) "whether it is possible to make scientifically supportable predictions of the probability . . . of human intrusion" over a period of 10,000 years. The National Academy of Sciences' recommendations and the EPA's rulemaking were specified to apply to only the Yucca Mountain Site. The EnPA of 1992 further directed the NRC to update its licensing requirements and criteria for Yucca Mountain to be consistent with the new EPA standards.

EPA and NRC rulemaking in response to congressional direction of 1992. Consistent with the requirements of the WIPP LWA, the EPA issued a revised version of 40 CFR Part 191 in December 1993 (eight months after the date specified in the LWA) and provided WIPP-specific certification criteria in 40 CFR Part 194 in February 1996 (27 months after the date specified in the LWA.[4]

Consistent with the requirements of the EnPA of 1992, the National Academies of Science, Engineering, and Medicine (NASEM) convened a committee of experts to provide the EPA with findings and recommendations regarding a regulatory standard for the proposed Yucca Mountain Site. Those recommendations were published in 1995

[4] Environmental Protection Agency, "Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes; Final Rule," 58 FR 66398 (Dec. 20, 1993); EPA, :Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations," 61 FR 5224 (Feb. 9, 1996).

[1] and provided input both the EPA and the NRC used in subsequent rulemaking. The EPA promulgated a final version of 40 CFR Part 197, *Public Health and Environmental Radiation Protection Standards for Yucca Mountain, NV*, in June 2001, four years and 10 months after the date specified in the EnPA of 1992 relative to the publication of the NASEM committee report. The NRC followed the EPA release of 40 CFR 197 with the promulgation of 10 CFR Part 63, *Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain*, NV, in November 2001.[5]

2004 Court decision vacates portions of 40 CFR Part 197 and 10 CFR Part 63. In July 2004, the U.S. Circuit Court of Appeals for the District of Columbia found, in adjudicating a case brought by the State of Nevada and others against the EPA, that the 10,000-year compliance period specified in 40 CFR 197 and repeated in 10 CFR 63 was not "based upon and consistent with" the recommendations of the NASEM, as required by the EnPA of 1992.[6] The NASEM committee had concluded that the timescale of long-term stability at Yucca Mountain was on the order of 1,000,000 years and recommended that "compliance assessment be conducted for the time when the greatest risk occurs, within the limits imposed by the long-term stability of the geologic environment" [1, p. 5]. All other aspects of the legal challenges brought against the EPA and NRC rules for Yucca Mountain were found to be without merit and were dismissed. The court's action effectively vacated both the EPA and NRC rules for Yucca Mountain and returned them to the agencies for revision. No date was set for repromulgation of the rules.

2008 and 2009 promulgation of final regulatory standards for Yucca Mountain. The EPA addressed the DC Circuit Court of Appeals decision in a final version of 40 CFR Part 197 promulgated in October 2008 extended the regulatory period to 1,000,000 years. With the NRC's subsequent promulgation in March 2009 of a final version of 10 CFR Part 63, the U.S. repository program had a final set of regulatory standards for permanent disposal, approximately 25 years after the date envisioned in the NWPA.[7] The State of Nevada filed suits in the D.C. Circuit Court of

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[5]Environmental Protection Agency, "Public Health and Environmental Radiation Protection Standards for Yucca Mountain, NV," 66 FR 32073–32135; 32074 (June 13, 2001); Nuclear Regulatory Commission, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, NV; Final Rule," 66 FR 55732 (Dec. 3, 2001).

[6] Nuclear Energy Institute, Inc. v. Environmental Protection Agency, No. 01-1258, 373 F.3d 1251 (D.C. Cir. 2004).

[7]Environmental Protection Agency, "Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada; Final Rule," 73 FR 61256 (Oct. 15, 2008); Nuclear Regulatory Commission, "Implementation of a Dose Standard After 10,000 Years; Final Rule," 74 FR 10811 (Mar. 13, 2009).

Appeals against both the EPA and the NRC,[8] challenging the final rules; the court held those suits in abeyance in 2010 pending congressional resolution of uncertainty regarding the Yucca Mountain licensing process. As of this writing, both suits remain in abeyance, and the regulatory standards in 40 CFR Part 197 and 10 CFR Part 63 remain in effect for Yucca Mountain.

Current status of regulatory standards for disposal of SNF, HLW, and TRU waste. In the absence of additional rulemaking by the EPA, disposal of SNF, HLW, or TRU waste at any site other than Yucca Mountain would be regulated under 40 CFR Part 191. Consistent with requirements of NWPA §212 and §213 and in the absence of additional rulemaking by the NRC, repositories that are not used exclusively for the disposal of wastes resulting from atomic energy defense activities would also be regulated by the NRC under 10 CFR Part 60.

[8]State of Nevada v. U.S. Environmental Protection Agency, No. 08-1327 (D.C. Cir. 2008); State of Nevada v. U.S. Environmental Protection Agency et al., No. 08-1345 (D.C. Cir. 2008); State of Nevada v. U.S. Nuclear Regulatory Commission, No. 09-1133 (D.C. Cir. 2009).

Table A.1.
Summary history of U.S. regulatory standards for permanent disposal of HLW, TRU waste, and SNF.

Year	Law, regulation, or event relevant to HLW, TRU, and SNF disposal regulations	Actions for the EPA and the NRC	Date actions completed
1982	NWPA of 1982	Act of Congress establishes roles and responsibilities for the EPA and the NRC	Enacted Jan. 7, 1983
1983	10 CFR Part 60	The NWPA requires the NRC to promulgate criteria for licensing “not later than January 1, 1984.”	June 21, 1983
1985	EPA 40 CFR Part 191	The NWPA requires the EPA to promulgate a general standard for disposal within one year, by January 7, 1984	Sept. 19, 1985
1987	Federal court decision	First Circuit Court of Appeals remand of 40 CFR Part 191, no date set for repromulgation	July 17, 1987
1992	WIPP LWA	Act of Congress directs EPA repromulgation of 40 CFR Part 191 by Apr. 30, 1993, and promulgation of EPA certification criteria by Oct. 30, 1994	Oct. 30, 1992
1992	EnPA of 1992	Act of Congress requires National Academy of Sciences standards report for Yucca Mountain by Dec. 31, 1993; EPA standards one year later, and NRC criteria one year after EPA standards	Oct. 24, 1992
1993	40 CFR Part 191 revision	As directed by Congress in the WIPP LWA	Dec. 20, 1993
1995	NASEM Yucca Mountain standards report	The EnPA of 1992 sets due date of Dec. 31, 1993, for the NASEM report to the EPA	Aug. 1, 1995
1996	40 CFR Part 194 (WIPP certification criteria)	As directed by Congress in the WIPP LWA	Feb. 9, 1996
2001	40 CFR Part 197	The EnPA of 1992 sets due date of Dec. 31, 1994	June 13, 2001
2001	10 CFR Part 63	The EnPA of 1992 sets date one year after EPA standards	Nov. 2, 2001
2004	Federal court decision	Court of Appeals for the District of Columbia vacates portions of 40 CFR Part 197, no date set for repromulgation	July 9, 2004
2008	40 CFR Part 197	Final promulgation	Oct. 15, 2008
2009	10 CFR Part 63	Final promulgation	Mar. 13, 2009

A.3 Reference

[1] National Research Council, *Technical Bases for Yucca Mountain Standards*, National Academies Press, Washington, D.C. (1995); doi.org/10.17226/4943.

APPENDIX B - INTERNATIONAL CONSIDERATIONS

Many countries in addition to the United States are confronted with developing and applying safety standards and licensing regulations for safe, final disposal of high-level radioactive waste (HLW)[1] in deep geological repositories. Indeed, there have been successful initial steps in licensing geological repositories, such as those in Finland and Sweden.

Appendix B identifies and reviews common principles and policies from independent international agencies that the ANS Committee considered in making its recommendations and which might help inform future updates and revisions to Environmental Protection Agency and Nuclear Regulatory Commission generic standards and guidelines. Leading sources and compilations regarding international HLW disposal programs, postclosure safety regulations, and consensus approaches to assessing long-term safety are cited. Topical headers presented here are, where possible, aligned to topics discussed in section III of this report.

B.1 International Agencies

International programs pursuing final geological disposal of HLW are linked to and guided by their national radiological safety regulators. Because of different enabling legislation, societal and cultural perspectives, and past regulatory precedents, diverse international approaches have been implemented in establishing regulatory agencies.[2] This has led to promulgation of international safety regulations that are broadly similar yet distinct in detail. As the International Atomic Energy Agency [1, sec. 4.8] acknowledges, "National regulations often establish standards and criteria relating to specific indicators (for example, dose or risk indicators), expressed as targets, constraints, or limits. Such indicators may differ from State to State."

In response to this diversity in regulations, the IAEA has become a primary source for summary compilations regarding national implementer and regulatory programs[2].[3]

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[1]HLW and spent nuclear fuel (SNF) are different waste forms but may be disposed of in the same geologic repository. For the purpose of this discussion, HLW is taken to include SNF.

[2]A key difference relative to the U.S. is that most nations have a single entity responsible for setting safety standards and licensing, rather than the separated EPA and NRC roles.

[3] This IAEA project is the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, which has published individual country reports since 2003 and is currently updated through the seventh review. meeting of 2022. A searchable database of convention documents can be found at iaea.org/topics/nuclear-safety-conventions/joint-convention-safety-spent-fuel-management-and-safety-radioactive-waste/documents.

The agency also prepares consensus technical reports regarding topics of mutual interest among nations, for example, approaches to postclosure regulations and safety assessment approaches, as published in “The Safety Case and Safety Assessment for the Disposal of Radioactive Waste,” [1], a report that will be extensively cited here. While national differences in specific regulations and terminology are recognized and respected in IAEA reports, there is an attempt made by the agency to identify broad principles and policies on which there is consensus.

The OECD Nuclear Energy Agency (NEA) is another collective review organization in which international repository programs, including the U.S., participate [3], [4].

The U.S. Nuclear Waste Technical Review Board (NWTRB) has published a useful synopsis of postclosure health and safety requirement for HLW disposal based on 13 of the IAEA’s country reports [5]. Table B.1 (adapted from the NWTRB report) shows, for example, some key postclosure health and safety requirements of 13 nations. Numerous other tables in the original report detail further requirements (e.g., retrievability) of these same countries.

Other sources also provide international perspectives on safety standards and their implementation. As a specific example, the Finnish radiological safety regulator STUK published a thorough account of its regulations and bases for decisions regarding Posiva’s postclosure safety case [6]. STUK’s review supported subsequent acceptance of Posiva’s construction license application by the Finnish government. A parallel perspective on that licensing process from the implementor side, which focuses on the need for early, clear, fixed, quantitative compliance requirements, has also been published [7]. On a more general basis, Chapman and McCombie [8] reviewed the development and basis of safety regulations as of that date, with a strong focus on guiding principles and “lessons learned” for the development of newer regulations.

TABLE B.1
Summary of some key postclosure health and safety requirements for 13 countries.

Country	Dose Constraint	Risk Limit*	Compliance Period
United States	Yucca Mountain: 0.15 millisievert (mSv)/year 1.0 mSv/year	Not specified Not specified	Less than 10,000 years Greater than 10,000 years but less than 1,000,000 years
Belgium	No decision has been made	No decision has been made	No decision has been made
Canada	An upper dose limit of 1.0 mSv/year established; implementer is required to provide a rationale for the dose constraint, which is a fraction of the dose limit	Not specified	Not specified
China	No decision has been made	No decision has been made	At least 10,000 years
Finland	Less than 0.1 mSv/year, for normal events; Release limits for various radionuclides established;	Not specified	First several thousand years
	Impacts should be comparable to those arising from natural radioactive materials but should remain insignificantly low	Not specified	Beyond first several thousand years
France	0.25 mSv/year for normal scenarios	Not specified	10,000 years
Germany	0.01 mSv/year for probable developments; 0.1 mSv/year for less probable developments	Not specified	1,000,000 years
Japan	No decision has been made	No decision has been made	No decision has been made
Republic of Korea	10 mSv/year for a single scenario, including low-probability natural phenomena and human intrusion	10-6/year for a scenario, which includes natural phenomena and human intrusion	At least 10,000 years
Spain	No decision has been made.	No decision has been made	No decision has been made

Table B.1 cont.

Country	Dose Constraint	Risk Limit*	Compliance Period
Sweden	Not specified	Less than 10-6/year for a representative individual in the group exposed to the greatest risk	Minimum of 100,000 years and can extend up to 1,000,000 years.
Switzerland	0.1 mSv/year for expected scenarios	10-5/year for expected scenarios	1,000,000 years
United Kingdom	0.5 mSv/year for the operational period.	Guidance calls for less than 10-6/year for those at greatest risk	Not specified

Source: Adapted from [5], Table 6 (p. 9).
*The risk limit for a given consequence (e.g., dose constraint) is measured in terms of the probability per year, e.g., 1 in 1,000,000 (or, 10^{-6}/year).

Applications for initial construction of underground facilities at specific sites for disposal of spent fuel have been accepted by regulatory authorities and national governments in Sweden and Finland; the Finnish site has been approved and repository construction has begun. France and Switzerland are in the processes of evaluating potential sites. All four of these countries have been conducting detailed design and safety assessments since the 1980s and 1990s. Accordingly, subsequent subsections will focus on postclosure aspects of these nations.

B.2 Safety Case

The concept of a "safety case" as applied to regulation of radioactive waste disposal mainly originated in the United Kingdom in the 1990s [9]. It draws a parallel between what should be considered in regulating safe, final disposal and what strategies, actions, evidence, and argumentations are involved in preparing a legal case. The concept was further refined by review groups [2], [4], although unfortunately slightly different definitions emerged from these separate agencies.

Today, the safety case methodology has been widely applied to radioactive waste disposal programs on low- and intermediate-level waste, borehole disposal of sealed sources and, most relevant to the U.S. situation, HLW disposal. The two recent, successful regulatory licensing of national programs for the disposal of SNF—Finland [10], [11] and Sweden [12]—each adopted and applied a safety case approach.

A guide was prepared by the IAEA to provide guidance and recommendations on meeting the safety requirements in respect of the safety case and supporting safety assessment for the disposal of radioactive waste. It defines a safety case thus:

> The safety case is the collection of scientific, technical, administrative, and managerial arguments and evidence in support of the safety of a disposal facility, covering the suitability of the site and the design, construction and operation of the facility, the assessment of radiation risks, and assurance of the adequacy and quality of all of the safety related work associated with the disposal facility.
>
> The safety case and supporting safety assessment provide the basis for demonstration of safety and for licensing. They will evolve with the development of the disposal facility and will assist and guide decisions on siting, design, and operations. The safety case will also be the main basis on which dialogue with interested parties will be conducted. [1, sec. 1.3]

Note that “safety case” and “safety assessment” are identified and defined as distinct concepts.

The IAEA has also offered further guidance:

> 5.13. The safety case for the period after closure should be based on quantitative analyses and should be further supported by qualitative arguments. It may include the presentation of multiple lines of reasoning based, for example, on studies of natural analogues and palaeohydrogeological studies. A major part of the safety case is concerned with demonstrating that consideration has been given to all the important uncertainties.
>
> 5.14. The regulatory body should stipulate or provide guidance concerning timescales for safety assessments. Comparison of calculated doses or risks to dose limits or risk limits specified in regulatory requirements may be required for at least several thousand years and may be extended to timescales beyond this, for example, to estimate peak dose. However, it is recognized that for timescales beyond several thousand years, uncertainty concerning future conditions of the geosphere and biosphere is such that reference calculations based on appropriate simplifying assumptions may be sufficient, with account taken of scenarios for evolution of the natural characteristics of the disposal system and “stylized” approaches (i.e. under certain prescribed conditions) to human behaviour and characteristics, for example, using reference biospheres.

> 5.17 For very long timescales for which dose estimates can be very uncertain, complementary arguments may be useful to illustrate safety, for example, safety indicators, such as concentrations and fluxes of radionuclides of natural origin. [13]

With respect to defining the role of complementary considerations, Posiva Oy states the following:

> Complementary considerations are evaluations, evidence and qualitative supporting arguments that lie outside the scope of the other reports of the quantitative safety assessment. These arguments include, for example:
>
> 1. Support from natural systems for both key process understanding and total system performance;
> 2. Comparison of the methodology and results of safety cases made for other repository projects to ensure comprehensiveness, consistency and reasonableness of the present assessment;
> 3. Simplified bounding analyses of extreme, unrealistic cases for scenarios not considered in the quantitative safety assessment;
> 4. Use of safety indicators other than dose to avoid having to take account of uncertainties in future human lifestyles (e.g. food production and consumption);
> 5. Use of complementary indicators that avoid having to account for biosphere evolution and geological processes on very long timescales;
> 6. Consideration of the calculation results from a wider perspective to consider significance of their assessed impact on human health and the environment compared with other risks. [14, pp.14–16]
>
> . . . .
>
> . . . complementary arguments can also be made to address other aspects of safety, especially continuing isolation, even at times beyond when quantitative safety assessments can be supported. [14, p. 17]

When such guidance and recommendations are merged, there is a clear requirement for quantitative analyses to demonstrate compliance with dose/risk standards for an initial period of several to many thousands of years. Qualitative complementary considerations and evidence can and should support such compliance analyses.

At longer timescales, however, increasing uncertainties regarding future conditions of the geosphere and biosphere argue for simpler, stylized assessments. Such stylized safety assessments necessarily rely more on complementary evidence (e.g., natural analogs), bounding assumptions, and multiple lines of reasoning. Supplemental safety indicators, in parallel with speculative dose calculations to future humans with unknown characteristics and behavior, might be considered. One example of an alternative safety indicator is comparison of future radionuclide releases from the repository to the geosphere (so-called geosphere-biosphere interface) with known concentrations or fluxes of naturally occurring radionuclides crossing the same barrier [15]. This could allow the significance of the repository releases to be assessed within the context of the natural background radiation of the environment without needing to consider exposure of a hypothetical future human population.

U.S. safety regulations and licensing guidelines by the EPA and the NRC were promulgated prior to the advent and widespread use of the safety case methodology; hence, U.S. regulations do not explicitly use the safety case terminology. In 2003, the National Academies of Sciences, Engineering, and Medicine examined this situation:

> When comparing these [U.S. regulations] with the characteristics of the safety case, the technical content appears to be equivalent. The primary differences are that the safety case presents key safety arguments understandably by a wider audience and it is updated more often. [16]

The IAEA clarified that "As a minimum, the safety assessment is to be updated in the periodic safety review carried out at predefined intervals in accordance with regulatory requirements" [1, sec. 3.11], acknowledging the following as further confirmation:

> The concept of developing a safety case for disposal facilities . . . is used in many States. The terminology used is different, though, in some States. For example, in the United States of America the term "total system performance analysis" is used (together with the regulations relevant to the specific disposal method), covering all aspects of the safety case as described in this Safety Guide. [sec. 1.2]

B.3 Dose/Risk Criteria

Consistent with our recommendation above (sec. III.1.1), the IAEA endorses use of dose and risk criteria in safety requirements [1].

Table B.1 further confirms specific dose and risk requirements that have been established by 13 leading international disposal programs. Dose criteria range from 0.1 to 1 mSv per year (10–100 mrem per year), and it is noteworthy that some national programs identify different dose values for different time periods or for consideration between expected and less probable scenarios for the disposal system far into the future.

In addition, Finland's safety regulations adopt the view that potential far-future releases should more appropriately be compared to natural radiological fluxes in the environment rather than to hypothetical doses to people at such remote time periods.

The International Commission on Radiological Protection is an independent, international, nongovernmental organization with the mission to protect people, animals, and the environment from the harmful effects of ionizing radiation. Early safety standards for geological disposal of radioactive waste from the 1980s used ICRP dosimetry values based on 1950s data. These data, however, have been significantly revised based on the best-available scientific evidence that has been peer-reviewed by the ICRP. International safety standards for geological disposal, other than those in the U.S., are now, appropriately and uniformly, based on modern ICRP's dose-conversion factors [17], [18].

The ICRP also has considered this issue of long timescale for safety assessments:

> In the distant future, the geological disposal facility might give rise to some releases to the accessible environment, and the safety case has to demonstrate that such releases, should they occur, will be within radiological protection criteria specified as part of the regulatory requirements. In application of the optimisation principle, the reference radiological impact criterion for the design of a waste disposal facility recommended by ICRP is an annual dose constraint for the population of 0.3 mSv per year [19], without any weighting of doses in the distant future. For doses in the future and for less likely events resulting in exposures, both categorised as potential exposures, the Commission continues to recommend a risk constraint for the population of 1E-5 per year when applying an aggregated approach combining probability of the exposure scenario and the associated dose. However, *Publication 103* [*The 2007 Recommendations of the International Commission on Radiological Protection*] also warns that effective dose loses its direct connection to health detriment for doses in the future after a time span of a few generations, given the evolution of society, human habits, and characteristics. Furthermore, in the distant future, the geosphere, the engineered system and, even more so, the biosphere will evolve in a less predictable way. The scientific basis for assessments of detriment to health at very long times into the future therefore becomes uncertain, and the strict application of numerical criteria may be inappropriate. In the very long term, dose and risk criteria should be used for the comparison of options rather than a means of assessing health detriment. [20, p. 14]

B.4 Risk-Informed, Reasonable Assurance, and Reasonable Expectation

The concept of "risk informed" that characterizes current U.S. safety regulations can be found in international safety case reports:

> The results of the safety assessment shall be used to specify the programme for maintenance, surveillance and inspection; to specify the procedures to be put in place for all operational activities significant to safety and for responding to anticipated operational occurrences and accidents; to specify the necessary competences for the staff involved in the facility or activity and to make decisions in an integrated, risk informed approach. [1, sec. 3.17]
>
> Within the step by step approach, the scientific understanding of the disposal system and the design of the disposal facility should be progressively advanced, and the safety case should become more focused on key areas of concern. It should not only be scientific understanding that is advanced, but also an understanding of the important contributors to risk. [1, sec. 4.13]
>
> The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise. [1, n.p.]

With respect to reasonable assurance and risk reduction, the IAEA states the following:

> There is reasonable assurance that the doses and/or risks resulting from the expected evolution of the disposal system will not exceed the constraints, over time frames for which the uncertainties are not so large as to prevent meaningful interpretation of the results. The likelihood of events that might disturb the performance of the disposal facility so as to give rise to higher doses or risks has been reduced as far as is reasonably possible by siting and design. [1, sec. 4.67]

Regarding the EPA and NRC acknowledgment that "proof of future performance of a disposal system is not to be had in the ordinary sense of the word" (discussed above in sec. III.1.2), the IAEA also affirms that

> It is recognized that radiation dose to individuals in the future, including those that may occur after institutional management of a waste disposal facility has ceased, can only be estimated. Nevertheless, estimates of possible doses and risks

for long time can be made and used as indicators for comparison with the safety criteria. [1, sec 3.10n7]

B.5 Regulatory Time Period for Quantitative Standards

Figure B.1 presents a schematic, summary representation for timescales related to key time-dependent factors affecting safety assessments, developed by an international group of repository programs for the OECD NEA [3].

Four basic "elements" considered within a repository safety assessment are identified by the OECD NEA group. These are the engineered barrier system (EBS) and surrounding host rock, the hydrogeological system, surface processes, and radiological exposure modes.[4] Laterally, potential changes to these repository elements are represented as arrows indicating the approximate range in time over which changes might occur for a specific site. In a qualitative manner, potential changes (representing uncertainties in this element) arising at earlier times are shown on the right side of the figure, and those changes/increasing uncertainties arising at later times are shown on the left.

Of particular relevance to establishing a timescale for regulatory requirements, estimated time ranges for confidence (predictability[5]) in each of the four elements are presented by the OECD NEA as vertical bars [3]. The fading of the bars is meant to suggest limits to predictability, attributable to likelihood of the identified changes. Of particular note is the extremely short time interval (decades) for which radiological exposure models, dependent on changing human and environmental factors, can be applied with confidence.

[4] Of course, different types of sites and repository concepts will affect estimated long-term performance.

[5] This term of 'predictability' misunderstands that the purpose of safety assessments is *not* to provide precise predictions of future behavior, but rather to provide broad estimates of future safety.

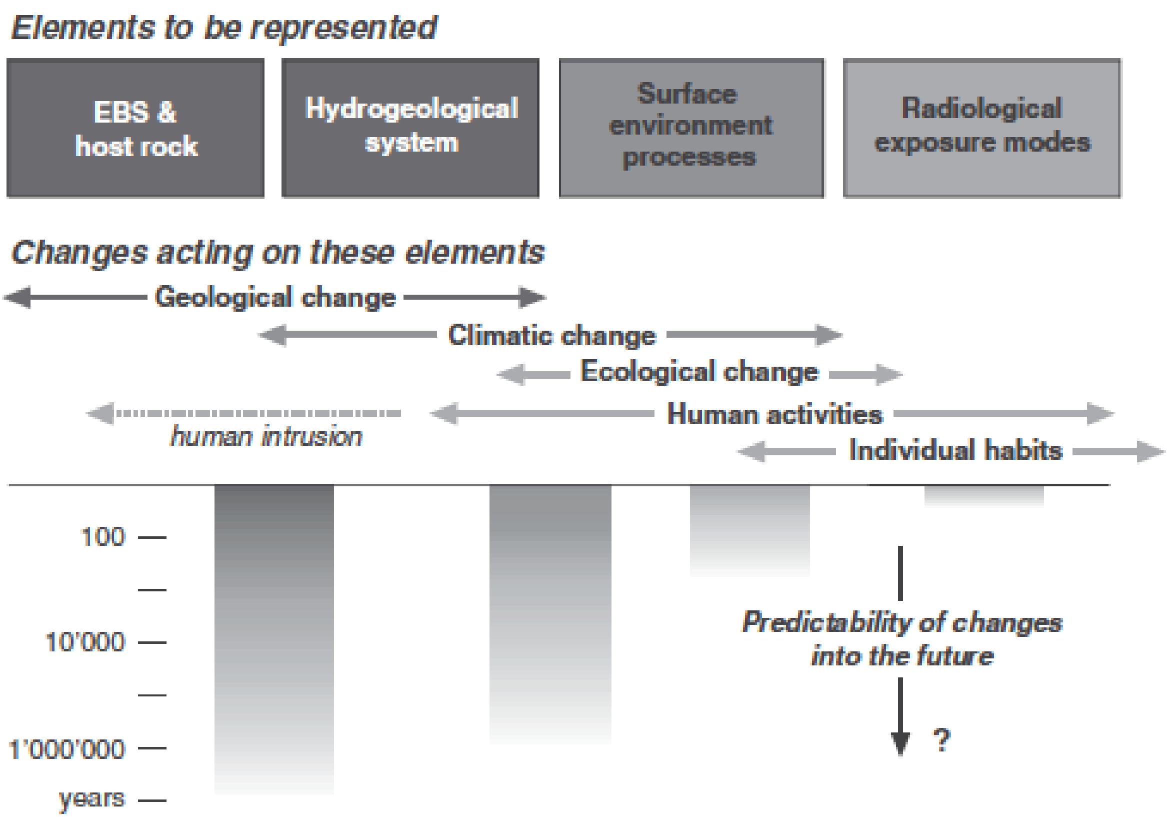

Fig. B.1. Time-dependent factors affecting safety assessment modeling. (Source: [3, p. 28, Fig. 2.3]).

Thus, there is a clear distinction in confidence between potential rapid change in future human behavior and the present-day environment, versus the much higher confidence in the estimated future behavior of a geological site. Indeed, reliance of isolation and long-term, passive safety imposed by the geological site is a fundamental argument for permanent, deep geological disposal.

Regarding time periods for quantitative and qualitative assessments, the IAEA states the following:

> In view of the complexity and variability of [many uncertain] factors, it is not possible to establish a universal timescale over which meaningful quantitative results from modeling can be obtained . . . . For deeper facilities, such as geological disposal facilities for high-level waste, modelling for periods of tens of thousands of years and beyond may still result in meaningful estimates of upper bounds of possible radiation doses. [1, sec. 6.45]
>
> . . . .

> The safety case should also address the evolution of the disposal facility and its potential impacts for times beyond the end of the safety assessment calculations, if at that point in time non-negligible hazards are still expected to exist. This should be done by means of simplified estimates and qualitative arguments rather than through the application of quantitative safety criteria. For example, for deep geological disposal facilities, this may be done by using arguments about the geological stability of the site. [1, sec. 6.49]

The ICRP stresses that

> The process of evaluating the potential exposure from emplaced waste includes understanding the potential mechanisms of radionuclide release from the engineered facility, including modelling transport through the geosphere to the biosphere, and the resultant release into an appropriate environmental compartment that could give rise to exposures to humans and the environment. Depending on the level of knowledge, probabilities may be estimated for these release scenarios. However, at the long time scales considered in geological disposal, evolution of the biosphere and, possibly, the geosphere and the engineered system will increase the uncertainty of these probabilities. Hence, the results of any dose or risk assessments need to be interpreted in a qualitative way at long timescales. [19, p. 41]

Thus, the consensus from international organizations is that safety standards and licensing regulations need to recognize the inherent uncertainties and changes in time-dependent factors, notably human behavior, affecting repository safety assessment. Accordingly, two basic timeframes can be envisioned for postclosure regulatory safety assessments:

- Quantitative, risk-informed assessment over a time period from permanent closure to a future time for which assuming future human activities and associated biosphere can be reasonably linked to a present-day conditions (perhaps on the order of several thousand years up to 10,000 years).

- Analyses in which concerns regarding possible scenario-initiating events are evaluated more qualitatively and comparatively within a risk-considered framework in which safety relies more on the stability/resilience of the geological site and physical-chemical constraints (e.g., radioelement solubilities) imposed by the site.

B.6 Human Intrusion

The “concentrate-and-contain” principle that underlies disposal of radioactive waste in deep geological repository systems is internationally recognized and accepted as the most appropriate means of safely isolating such wastes from the biosphere [16]. The potential for future intrusion and disturbance of such a concentrated repository, however, is an unavoidable consequence of this guiding principle.

It has been long accepted by the international waste management community [18] that regulatory requirements should not seek to protect future societies from intentional intrusion; rather, they should focus on measures to minimize the probability (thus, consequences) of speculative, inadvertent human intrusion.

Different approaches to setting standards for the possibility of future inadvertent intrusion into a geological repository have been cogently reviewed [18], [8], [21], [22]. Two leading approaches have been implemented and successfully conducted in several countries.

In the first approach, during siting the implementor would be tasked to demonstrate in selecting a site that appropriate consideration has been made to minimize intrusion probability. This would be achieved by evaluating and giving preference to a site with negligible exploitable resources. There would be no requirement to conduct quantitative analyses of a hypothetical intrusion, or to consider human intrusion in the final licensing of such a selected site. According to the IAEA:

> Consideration has to be given to locating the facility away from significant known mineral resources, geothermal water, and other valuable subsurface resources. This is to reduce the risk of human intrusion into the site and to reduce the potential for use of the surrounding area to be in conflict with the facility. [22, sec. 3.20]

For example, the successful license applications for both the Finnish and the Swedish repositories initially addressed human intrusion requirements by locating their respective repositories at great depth at sites where the host rock can be assumed to be of no economic interest to future generations, so that the risk of human intrusion was minimized. Furthermore, the role of surface plugs and borehole seals in their KBS-3 design concept is to close off any connection to the surface and to limit the likelihood of inadvertent human intrusion in the repository.

An alternate approach, typically required in addition to the siting approach, is to conduct a stylized analysis, as described by the ICRP:

> Because the occurrence of human intrusion cannot be totally ruled out, the consequences of one or more typical plausible stylized intrusion scenarios should be considered by the decision maker to evaluate the resilience of the repository to potential intrusion . . . . Since no scientific basis exists for predicting the nature or probability of future human actions, it is not appropriate to include the probabilities of such events in a quantitative performance assessment that is to be compared with dose or risk constraints. [21, p. 18]

The IAEA addresses this same alternative approach:

> It is not possible to predict the behaviour of people in the future with any certainty, and its representation in assessment models is necessarily stylized . . . .
>
> The possibility exists that in the future, an activity or activities undertaken by people could cause some type of intrusion into a disposal facility for radioactive waste. It is not possible to say definitively what form such an intrusion will take or what the likelihood of the intrusion event will be, owing to the unpredictability of the behaviour of people in the future. Nevertheless, the impact of certain generic intrusion events, such as construction work, mining, or drilling, can be evaluated as reference scenarios. [22, sec. A.5, A.6]

The Swedish license application, for example, included analysis of human intrusion scenarios resulting in a degradation of system performance. Under Swedish regulations, such stylized scenarios were to be considered as “less probable” and the analyses not included in the risk summation [12]. In a similar manner, Finnish safety regulations required analysis of unintentional disturbance of or intrusion into the repository by humans subsequent to repository closure [11]. Uncertainties in the evolution of human society and of the state-of-the-art in science and technology were noted. Estimates of consequences of human intrusion scenarios were based on “stylized assumptions” that were acknowledged as unable to be fully substantiated or evaluated in respect to conservatism of radiological consequence estimates. Such illustrative analyses were therefore treated as a class of speculative scenarios, separate from repository assessment scenarios.

B.7 Multiple Barriers/Multiple Safety Functions/Features, Events, and Processes

Internationally, past formulation of a "multiple barriers" requirement to assure long-term isolation and safety of disposed radioactive waste has been updated by the "multiple safety functions" approach. This safety function approach has been adopted and applied by regulatory agencies and disposal programs leading to successful review and approval of construction license applications for disposal of spent fuel [12]. A safety function is a feature of the disposal system that provides a specific function that is relevant to the performance (or safety) of the system. The set of these safety functions presents a high-level summary of the strategy by which the performance of the disposal system is assured.

With respect to safety functions, the IAEA recommends the following:

> The host environment shall be selected, the engineered barrier of the disposal facility shall be designed . . . to ensure that safety is provided by means of *multiple safety functions* [emphasis added]. Containment and isolation of the waste shall be provided by means of a number of physical barriers of the disposal system. The performance of these physical barriers shall be achieved by means of diverse physical and chemical processes . . . . The capability of the individual barriers . . . shall be demonstrated. The overall performance of the disposal system shall not be unduly dependent on a single safety function. [22, p. 24]

The connection between multiple barriers and multiple safety functions is evident. A main reason for evolving to multiple safety functions is that this methodology has been found to provide a technical, transparent approach to development of scenarios between the applicant and regulators, as well as enhance overall communication of safety with stakeholders during licensing [11], [12]. It also focuses attention on a system of multiple barriers and processes that act in concert to provide confidence in long-term safety.

The safety function approach also links to the previous use of features, events, and processes (FEPs) to identify conditions that may occur in the future, and that may affect the ability of the disposal system to perform successfully. While FEP analyses have been widely conducted by HLW repository programs, they have also been identified to have a number of drawbacks [23]. In particular, as a bottom-up approach, a FEP-based approach seeks to identify all conditions of concern without necessarily focusing on key safety-significant/risk-informed issues.

There has been more emphasis in the performance assessment literature and construction license applications on the use of the top-down safety-functions approach as an augmentation to FEP analyses [23]. In particular, the safety-functions approach has proved effective in attaining regulatory closure on so-called What if? scenarios and contentions in the context of regulations [11], [12].

B.8 Retrievability

The NWTRB [24] summarizes requirements/current views for 13 countries regarding retrievability of HLW.

The technical feasibility of waste package retrieval has already been demonstrated for certain disposal concepts, such as the so-called KBS-3 concept planned in Sweden and Finland, basically using similar methods as employed for emplacement of the waste packages [25]. In addition, it has been pointed out that retrieval of wastes in a deep mined repository is always technically possible [26], albeit at costs that depend on factors such as design, age of the deeply emplaced waste packages, radiation shielding of packages, and so forth. The IAEA stresses the following:

> Retrievability should not be made an excuse for an indefinite delay in making decisions concerning the development of the disposal facility and is not a substitute for a well designed and well sited disposal facility for which the basis for closure of the facility at the end of its lifetime can be justified. [1, sec. 6.76]
>
> Where retrievability is mentioned in national regulatory guidelines, there is usually an overriding requirement that any measures to enhance retrievability should not compromise the passive long term safety of a disposal facility. [1, sec. 6.78]

TABLE B.2.
Requirements on retrievability of waste.

Country	Requirements
United States	Within 50 years from the start of waste emplacement unless a different period set by the NRC
Belgium	No decision has been made
Canada	Adaptive Phased Management includes potential for retrievability of the used fuel for an extended period, until such time as a future society makes a determination on the final closure and the appropriate form and duration of postclosure monitoring. (Note: This requirement has not yet been incorporated into regulations.)
China	No decision has been made
Finland	Posiva included a plan and cost estimate for retrieving the waste in its construction license application

Table B.2 cont.

Country	Requirements
France	The repository must be designed so that it is “reversible” for at least 100 years. Reversibility is a management concept that requires technical retrievability.
Germany	Retrievability of HLW and SNF need not be provided in the disposal concept. However, ionizing radiation shielding has to be guaranteed so that waste will be manageable for a period of 500 years after repository closure.
Japan	No decision has been made.
South Korea	No decision has been made but, in the conceptual-level Korea Reference Disposal System, waste packages had to be retrievable for an indeterminate period.
Spain	No decision has been made.
Sweden	No retrievability requirement is imposed.
Switzerland	The retrievability of HLW has to be considered when designing the repository. The technical feasibility of retrieving the waste has to be demonstrated in experiments on a 1:1 scale before the repository starts operation.
United Kingdom	No decision has been made.

***Source:* Information derived from [24].**
[*]This requirement has not yet been incorporated into regulations.

Plans, disposal designs,[6] and requirements regarding retrievability, however, are often a key issue with respect to stakeholder concerns [8]. In this regard, there are disposal concepts that permit immediate, safe, inspectable storage of dual-purpose disposal containers in open, excavated caverns, equivalent to dry cask storage at the surface. This concept permits a decision to be made at a later time, to either backfill the cavern for final disposal, or to easily retrieve the waste back to the surface [27].

B.9 Summary of International Considerations

National standards and requirements for geologic disposal differ from one another, reflecting different enabling legislation, societal and cultural perspectives, and past regulatory precedents. Nevertheless, for many key elements of national standards there has been a broad convergence over the years, reflecting the development of technically sound and practical approaches that are informed by scientific work and stakeholder interactions. This convergence is reflected in reports and recommendations from the IAEA and other international organizations. Revisions and updates to U.S. regulations

[6]For example, at-depth cavern-retrievable (CARE) disposal concepts involving delayed backfilling have been specifically designed to promote and assure ease of long-term retrievability, enhancing programmatic flexibility with respect to addressing stakeholder concerns and final management decisions.

should be informed by the current state of knowledge and best practices reflected in national and international standards.

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APPENDIX C - CHARACTERISTICS OF FUTURE HUMAN SOCIETY ASSUMED IN GEOLOGIC REPOSITORY STANDARDS

C.1 Introduction

Assumptions about the uncertain characteristics of far-future human societies will be necessary for assessments of compliance and should be well understood up-front during the development of geologic repository standards. Rather than attempting to address the infinite number of potential types of future society, the ANS Committee considered three potential future societies, described below. This evaluation informed the ultimate recommendations on appropriate assumptions for characteristics of future societies for demonstrations of compliance with repository environmental standards.

C.2 Background

It is generally accepted that the current generation has a responsibility to deal with its own waste products in a manner that will protect not only themselves but future generations. Accordingly, postclosure geologic repository standards are developed with the intent of protecting people who will not exist until many years in the future.

The primary hazard a repository poses to future inhabitants is the release of long-lived radionuclides into the biosphere where exposure of humans to radiation could increase the risk of premature death due to cancer. Of interest in calculating dose rates to future humans living in the vicinity of the repository are the “vectors” for radionuclide transfer within the biosphere. The major transfer vectors are radionuclide transfer via ingestion (e.g., drinking water, production and consumption of crops and livestock using contaminated groundwater, and edible aquatic species living in contaminated waters); inhalation of airborne radionuclides; and external exposure from radionuclides present in the soil. Based on performance assessments performed on many different repositories, the dominant vector is almost always contaminated groundwater. Radionuclide exposure via these and other transfer vectors will occur only if the society does not have an ability to detect harmful constituents in the water and avoid its use.

Public health and safety regulations typically assume that current human and societal behaviors relevant to radionuclide transfer vectors persist for the duration of the regulation, except that no credit is given for detecting and avoiding radiation. Standards are chosen to be sufficiently protective of humans based on those behaviors. That approach makes sense when addressing enterprises relatively short in duration (e.g., nuclear power plants, which are licensed to operate for 40 years, albeit with the possibility—or even expectation—of one or more 20-year license renewals). That may not be so reasonable for regulations requiring dose assessments for longer timespans, such as low-level waste repositories (effectively regulated for 1,000 years under 10 CFR Part 61), underground injection wells (effectively regulated for 10,000 years under 40 CFR Part 148), or high-level waste repositories (effectively regulated for 10,000 years under 40 CFR Part 191 or for 1,000,000 years at Yucca Mountain, under 40 CFR Part 197).

C.3 Future Human Characteristics

The theory of evolution holds that species, including humans, evolve over time, so that their biophysical characteristics change. Current thinking is that *Homo sapiens* (modern humans) evolved in Africa during a time of dramatic climate change approximately 300,000 years ago [1]. While human society has changed markedly since then, the physiological characteristics of *Homo sapiens* have not. However, the possibility that the intrinsic characteristics of humans could change again in a significant manner cannot be completely discounted. If repository performance were to be assessed only in the present or the immediate future, the probability of human evolution can be assumed to be vanishingly low.

From the standpoint of geologic repository public health and safety standards, an evolution in human biophysical characteristics would be important only if it affected the potential for harm to humans from exposure to radiation originating in material emplaced in a repository. For example, if future humans evolved to be more resistive to DNA damage from ionizing radiation, the hazard posed by repository material would be reduced and the level of protection could potentially be relaxed. It is not possible to know if any human evolution will take place in the time frame of interest, or, if it does, what type of changes would result. Therefore, from a practical perspective, it should be assumed that future humans will be as susceptible to harm from radiation as current humans.

C.4 Future Human Society

While the human species is relatively stable, human societies are not. The characteristics of societies that affect use of water and other resources in the biosphere have varied dramatically over the past several millennia. Even today, there are many different types of societies across the globe. The technological level of the given society will affect the likelihood those inhabitants would, among other radionuclide transfer vectors, use contaminated water supplies on a large scale. In addition, the technological level of future societies will impact the ability to detect radionuclides in water, soil, air, and food products and mitigate the effects of cancer.

For almost the whole time *Homo sapiens* has been present on the planet, people lived in small hunter-gatherer tribes with a very low level of technology, which affected the types of potential radionuclide transfer to humans. For example, lack of agriculture would mean that irrigation of crops and animal husbandry using contaminated water resources would not occur. Consumption of local wildlife and plants would require consideration of how radionuclides would transfer into those species via other pathways. Historically, life spans were very short, compared with today's. Diseases that primarily afflict older humans (e.g., heart disease and cancer) were largely irrelevant due to the fact that people usually died of other causes before such diseases could arise. Over the past 10,000, years technology has improved as humans developed agriculture and animal husbandry practices. People began to use a wider range of water supplies. In the developed world, the average life span has lengthened to generally exceed 70 years, which results in longer exposures to radionuclides entering the biosphere. If technology continues to advance at the current rate, human societies of the future could soon be unrecognizable to us. Of course, there is no guarantee that the human race will continue to advance and thrive. Factors such as warfare, disease, and ecological change could reverse the current course and send humans back to technological levels characteristic of earlier times—or even extinction.

Paraphrasing a Danish proverb, Dr. Niels Bohr once observed "Prediction is very difficult, especially if it's about the future." Fortunately, in order to develop a public health and safety regulation that will be reasonably protective of future humans living near a geologic repository, it is not necessary to know everything about those people. The necessary knowledge about a future society that would impact doses received by repository neighbors is limited, and there are some reasonable suppositions that can be made relative to those future conditions. These include radionuclide transfer vectors for which transfer data exist or can be collected. Rather than trying to imagine every possible future society, we can bin potential future human societies into three rough groups based on technological capability: low, similar to current, and advanced. The low-technology possibility, referred to herein as the "Flintstones" group,[7] is consistent with human behavior from the hunter-gatherer era, prior to the development of agriculture and animal husbandry. The more current technology possibility, referred to as the "Waltons" group,[8] is largely consistent with the world of the past few hundred years through the present, with widespread use of agriculture and animal husbandry

[7]The name of this group is based on "The Flintstones" animated television comedy by Hanna-Barbera Productions, which centered on a Stone Age family and originally aired on ABC from 1960 to 1966.

[8]The name of this group is based on "The Waltons," a historical drama television series about a rural family, set roughly during the Great Depression and World War II (1933–1946). The show originally aired on CBS from 1972 to 1981.

and a higher probability of long life spans, but with no ability to detect or mitigate radionuclides in the biosphere. The advanced-technology possibility of the future, referred to as the "Jetsons" group,[9] would reasonably be characterized by the ability to detect and mitigate the presence of radionuclides in the biosphere, availability of medical treatment to address mortality from most diseases (including many or most cancers), and presumably a longer life span.

C.4.1 Flintstones Society

In a Flintstones-like hunter-gatherer society, certain primary exposure pathways that would affect more technologically advanced societies do not apply, such as those related to agriculture, animal domestication, and use of wells to retrieve groundwater. Instead, consideration would be given to, for example, how the wildlife and plants a member of a Flintstones society consumes might ingest or uptake radionuclides from contaminated surface water and soil.

However, given the host of other factors limiting a Flintstones human lifespan (e.g., obtaining sufficient food, disease, and dangers from predators and other humans), the incremental morbidity due to potential exposure to radionuclides emanating from a geologic repository would almost certainly be relatively small.

C.4.2 Waltons Society

Unlike members of the Flintstones society, a person in the Waltons society would be capable of accessing radionuclides from a repository via irrigation or by drinking water from groundwater wells. These more advanced activities would put him or her at a higher risk from ionizing radiation. The greater number of radionuclide transfer pathways in this society would be exacerbated by the Waltons human's inability to detect radionuclides, recognize the hazard posed, and avoid it. Thus, for the effects of radionuclide release from repository and transfer to the biosphere to pose an acute hazard, the Waltons member would need to be in a technological "sweet spot": having the technology and energy resources to access contaminated water resources but lacking the technology and/or awareness to check for and avoid radiological hazards.

In addition, the relatively longer life span of a Waltons society human would mean a potentially longer radionuclide exposure during his or her lifetime. Hence, the

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[9]The name of this group is based on "The Jetsons" animated comedy by Hanna-Barbera Productions, a futuristic space-age counterpart to "The Flintstones," which originally aired on ABC from 1962 to 1963.

incremental morbidity caused by radionuclides entering the biosphere from the repository would be higher than that for a person in the Flintstones society.

Thinking about this in historical terms, Waltons living immediately before and after the beginning of the 20th century would be most at risk.

C.4.3 Jetsons Society

A Jetson should not come to harm due to radionuclides from material emplaced in a geologic repository for disposal. While a member of this society would certainly have the capability to access potentially contaminated groundwater, he or she would clearly have the ability and knowledge to detect and mitigate radionuclide releases and thereby prevent latent cancer deaths due to exposure to ionizing radiation from high-level radioactive waste. In fact, a Jetsons society human may well have advanced to a level of medical technology in which cancer is simply another curable affliction.

C.5 Human Intrusion

The discussion to this point has focused on "undisturbed" repository performance in which the long-term degradation of repository system barriers by natural processes leads to migration of radionuclides to the biosphere. The other scenario of concern in repository regulation is human intrusion, which refers to advertent actions by future humans (e.g., drilling or mining) that disturb the repository itself and lead to transportation of radionuclides to the accessible environment. Repository regulations typically require consideration of the potential effects of human intrusion on repository performance.[10] With that being said, from an international perspective, regulations focus predominately on undisturbed performance and address scenarios involving human intrusion in a more qualitative manner. Nevertheless, the characteristics of future human societies impact the probability and consequences of human intrusion and deserve discussion in that context.

For the Flintstones scenario, human intrusion is clearly not possible. That society would lack the technological capability to drill deep enough to the material emplaced in a deep geologic repository. A Jetsons society human would certainly have the capability to access a repository well below the earth's surface; however, such a person would also

[10]From a regulatory perspective, it is important to note the significant practical limits on consideration of potential hazards posed by human intrusion into a repository. Regulators typically focus on the health effects to future humans due to the subsequent natural evolution of the repository system and radionuclide migration from the disturbed repository, and not on the immediate health effects to the intruders themselves.

possess imaging and detection techniques that would make him or her aware of the potential hazard so he or she could avoid it or manage it.

The concern for human intrusion centers on the Waltons society; in this scenario, a person could possess in some instances the capability to drill down to and disturb repository material but not have the wherewithal to detect and avoid or mitigate the hazard. This understanding informs the recommendation of the ANS Committee to address human intrusion through a single, site-specific intrusion analysis rather than attempting to incorporate human intrusion in a comprehensive performance evaluation (see sec. III.1.7). Such an approach is consistent with the recommendations of the National Academy of Sciences, Engineering, and Medicine Committee on Technical Bases for Yucca Mountain Standards [2] and the approach taken by the EPA for human intrusion in its Yucca Mountain standards, found in 40 CFR Part 197.

C.6 Summary

We do not—and cannot—know whether humans will have fundamentally evolved many thousands of years from now in ways that would alter the effects of radionuclide exposure on the human body, nor can we know what kinds of human behavior will occur that would affect exposures from ingestion, inhalation, or other pathways. To avoid endless speculation, it is necessary for the regulator to specify in general terms future human biophysics and behavior for the purpose of conducting repository performance estimates.

As discussed above, it is appropriate to assume biophysical characteristics of future humans that are akin to present day *Homo sapiens*. Concerns about both undisturbed repository performance as well as a human intrusion scenario should be most acute for Waltons-type societies (the technological level of the United States in the decades surrounding the turn of the 20th century). Such a society would have a wide range of radionuclide transfer vectors within the biosphere, such as use of multiple water resources for agriculture, animal husbandry, and the like. It is assumed that a Waltons society member would lack the capability to detect radionuclides in the biosphere. A regulatory performance standard that is sufficiently protective for a Waltons society human would lead to health effects estimates that almost certainly bound those for societies at a lower (Flintstones) and higher (Jetsons) technology levels.

The ANS Committee recommends, therefore, that for the purpose of estimating health effects caused by radionuclides escaping the repository and entering the biosphere to humans living in the far future, the regulator provide guidance to limit speculation on future human biophysical characteristics and behavior as follows:

- No evolution of the human species would occur that would significantly alter the effects of internal or external radiation exposure on human health.
- Human behavior is characteristic of a Waltons society that makes significant use of water and land resources, but is not able to detect radionuclides in the biosphere. The specific behaviors making use of water and land resources as well as the nature of a human intrusion would need to be consistent with the site-specific characteristics of the local biosphere.

The committee notes that these recommendations are broadly consistent with the approach taken by EPA in its Yucca Mountain standards (see sec. III.1.2 of this report; 40 CFR Part 197).

C.7 References

[1] "What does it mean to be human?" Smithsonian Museum of Natural History website, updated January 22, 2021; humanorigins.si.edu/evidence/human-fossils/species/homo-sapiens.

[2] National Research Council, *Technical Bases for Yucca Mountain Standards,* National Academies Press, Washington, D.C. (1995); doi.org/10.17226/4943.