Appendix A: Development of Regulations for Geologic Disposal of High-Level Waste and Spent Nuclear Fuel

1.0 Introduction

NRC's generic regulations for high-level waste (HLW) disposal, which includes spent nuclear fuel were developed principally in the late 1970s and early 1980s. For example, the procedural requirements for licensing geologic HLW repositories under 10 CFR Part 60 were promulgated in 1981 (46 FR 13971; February 25, 1981), and technical criteria were promulgated in 1983 (48 FR 28194; June 21, 1983). At this time, the development of a performance assessment for evaluating geologic disposal was in its infancy and there were no quantitative evaluations available for understanding the performance of a potential repository site and design. Thus, NRC's generic regulations focused more on identifying a broad range of topics to address what might be relevant to a repository. The Commission also acknowledged at that time with respect to quantitative subsystem requirements (e.g., ground- travel time) that it was "appropriate to include reasonable generic requirements, that if satisfied, will ordinarily contribute to meeting the standards even though modifications may need to be made for some designs and locations" (48 FR 28196; June 21, 1983); and with respect to the level of detail for other prescriptive requirements of the design (e.g., shaft and borehole seals) that the emphasis should be placed on "the objectives that must be met and not become unduly concerned about the particular techniques that may be used in doing so" (48 FR 28198; June 21, 1983). After the promulgation of the technical criteria, the NRC staff spent the next decade and more conducting meetings to explain the requirements and to develop guidance for implementing a variety of requirements in its regulation (e.g., ground-water travel time, substantially complete containment, extreme erosion). During this same time period there was significant efforts at NRC and around the world to develop capabilities to conduct performance assessments for geologic disposal.

After the Yucca Mountain site was selected for further study as the HLW repository (Nuclear Waste Policy Amendments act of 1987), there were growing Congressional concerns that the U.S. Environmental Protection Agency (EPA) generic standards for HLW (40 CFR 191; 50 FR 38066; September 19, 1985) were not appropriately health based (see letter of J. Bennett Johnston to Robert W. Fri, May 20, 1993 provided in Appendix B "Congressional Mandate for This Report" of NAS Report). EPA's generic standards at 40 CFR 191 set an integrated release limit for specific radionuclides, such as carbon-14 (Table 1 in Appendix A in Final Standards [50 FR 38087; September 19, 1985) that raised questions about the relevance of this limit to health and safety. In particular, it was shown that release of carbon-14 to the atmosphere[1] could fail to meet the release limit but result in individual doses much less than a fraction of 0.01 mSv (1mrem) [Nygaard et al, 1993 and Von Konynenburg, 1991]. Thus, Congress took action to ensure the standards applicable to a repository at Yucca Mountain were appropriately health and safety based. In 1992, Congress directed EPA, at Section 801 of the Energy Policy Act of 1992, Public Law 102–486 (EnPA), to contract with the National Academy of Sciences (NAS) to

[1] Gaseous release of carbon-14 at a potential repository at Yucca Mountain would more likely be due to the location of the repository in the unsaturated zone. This would allow for air movement in rock pores and fractures, which are partially filled with water, more readily than if the repository were located in the saturated zone where the rock pores and fractures are filled with water.

advise EPA on the appropriate technical basis for public health and safety standards governing the Yucca Mountain repository. On August 1, 1995, the NAS Committee on Technical Bases for Yucca Mountain Standards issued its report, ''Technical Bases for Yucca Mountain Standards.'' "In its report, NAS recommended an approach and content that is significantly different from that adopted by EPA for its disposal standards at 40 CFR 191 (no longer applicable to sites characterized under Section 113(a) of NWPA), as well as from that adopted by NRC for its existing generic regulations at Part 60." [64 FR 8641; February 22, 1999 – from NRC's proposed regulations for Yucca Mountain at 10 CFR Part 63]

2.0 Risk-Informed, Performance-Based Regulations at Part 63

NRC re-examined its generic regulations at 10 CFR Part 60 based both on the EnPA and the NAS report on the Technical Basis for Yucca Mountain Standards. As discussed in the proposed Part 63 (64 FR 8640; February 22, 1999):

> "The Commission considered the most direct and time-efficient approach to the specification of concise, site specific criteria for Yucca Mountain that are consistent with current assumptions, with site-specific information and performance assessment experience, and with forthcoming EPA standards would be to develop site-specific regulations that apply solely to Yucca Mountain. In establishing these criteria, the Commission sought to establish a coherent body of risk-informed, performance-based criteria for Yucca Mountain compatible with the Commission's overall philosophy of risk-informed, performance-based regulation. "Stated succinctly, risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment (e.g., defense in depth), and performance history are used to (1) focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision-making." (64 FR 8643; February 22, 1999)

SECY 97-300 (December 24, 1997) and the proposed 10 CFR Part 63 (64 FR 8640; February 22, 1999) provide further elaboration on the development and approach for the rulemaking.

The following sections elaborate on selected aspects of NRC's regulations for disposal of high-level waste in 10 CFR Part 63 and speak to the concerns regarding EPA's generic standards for disposal of high-level waste.

2.1 Subsystem Requirements in Parts 60 and 63

Perhaps the most controversial aspect of NRC's generic regulations at 10 CFR Part 60 was the specification of quantitative subsystem requirements. The Commission elected to set specific quantitative limits for repository barriers to provide confidence in repository performance when, as noted above, performance assessment was at its infancy. These specific quantitative limits included – (1) the waste package is to last 300 to 1,000 years to ensure the waste is contained when it is hottest and releases would be most uncertain, (2) fractional releases from the waste package should be no more than10^{-5} per year to ensure after the waste package was breached the releases would be small, and (3) a minimum ground-water travel time to the accessible environment of 1,000 years to ensure any release would have time to decay and disperse prior to potential release to the environment accessible to humans (48 FR 28224; June 21, 1983 – 60.113 Performance of particular barriers after permanent closure). [Note: further discussion on the Commission's support at this time for the quantitative subsystem requirements is provided in NUREG-0804, pages 5-8 (NRC 1983)]

NRC described its growing concerns with the quantitative subsystem requirements in Part 60 when it proposed site-specific regulations for Yucca Mountain:

> "Since their promulgation, the subsystem criteria in § 60.113, in particular, have not gained broad acceptance in the technical community. These criteria have been criticized as overly prescriptive, lacking in both a strong technical basis and a clear technical nexus to the overall performance objective (i.e., the EPA standards), and unclear in their wording." (64 FR 8649; February 22, 1999) [Note: Enclosure 3 in SECY 97-300 includes further discussion of concerns with the quantitative subsystem requirements in 10 CFR Part 60]

NRC described the evolution in performance assessment capabilities that had occurred since 1983 and were now available for quantitatively evaluating repository performance, including the repository's safety barriers:

> "During the more than 15 years since the initial technical criteria at 10 CFR Part 60 were promulgated, there has been considerable evolution in the capability of technical methods for assessing the performance of a geologic repository at Yucca Mountain ('TPA 3.1-Sensitivity and Uncertainty Analyses,' NUREG/CR–5549[2], in publication; 'Total System Performance Assessment—1995: An Evaluation of the Potential Yucca Mountain Repository,' DOE, 1995). These changes allow for the use of more effective and efficient methods of analysis for evaluating conditions at Yucca Mountain than do NRC's existing generic criteria. These new methods were not envisioned when the Part 60 criteria were established, and their implementation for Yucca Mountain will avoid the imposition of unnecessary, ambiguous, or potentially conflicting criteria that could result from the application of some of the Commission's generic requirements at 10 CFR Part 60." (64 FR 8640-1; February 22, 1999)

NRC also acknowledged support for performance-based regulations without the imposition of quantitative subsystem requirements:

> "In contrast to the state of performance assessment technology assumed at the time Part 60 criteria were put in place, the NAS Committee on Technical Bases for Yucca Mountain Standards found, in 1995, that the physical and geologic processes relevant to a Yucca Mountain repository: '* * * are sufficiently quantifiable and the related uncertainties sufficiently boundable that the performance [of a repository] can be assessed over timeframes during which the geological system is relatively stable or varies in a boundable manner.' As has been described earlier, it was a lack of confidence in this capability to quantify overall performance and adequately bound uncertainty that factored prominently in the Commission's decision to include

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[2] It was later decided to publish this document as a NUREG and not a NUREG/CR report, therefore, the report number was revised to NUREG-1668

> quantitative subsystem requirements in the Part 60 regulations. Also, as discussed earlier, NAS cautioned against implementation of multiple barriers through the use of subsystem performance requirements. In addition, the Commission's Advisory Committee on Nuclear Waste (ACNW) recently recommended that the Commission implement the concept of defense in depth by ensuring that the effectiveness of individual barriers be identified explicitly in the total system performance assessment (TSPA), but specifically did not endorse the establishment of rule-based subsystem requirements for Yucca Mountain. The ACNW noted that '* * * an overall performance-based regulation in the context of a risk-based standard is a superior tool for promoting safety relative to imposed subsystem requirements.' (see letters dated October 31, 1997 and March 6, 1998).'' (64 FR 8649; February 22, 1999)

Thus, the Commission reconsidered its approach for quantitative subsystem requirements:

> "Upon review of this regulatory history, the Commission is persuaded that much of the basis for NRC's initial development of the specific numerical values for the subsystem criteria was generic judgment with regard to what was (and was not) feasible with regard to the quantitative assessment of long-term repository performance. Because the stated goal was to compensate for uncertainty, there was never any attempt to derive the subsystem performance criteria from a specified dose or risk level or from some projected dose or risk reduction expected to be achieved by their application. Furthermore, after 15 years of experience in working with the requirements of Part 60, the Commission is concerned that, for the Yucca Mountain site, the application of the subsystem performance criteria at § 60.113 may impose significant additional expenditure of resources on the nation's HLW program, without producing any commensurate increase in the protection of public health and safety.
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> Specifically, when the Part 60 subsystem criteria were selected, they were intended to be separate, 'independent,' easily-determined measures of subsystem performance, determination of which would require only application of technology that was readily available. Extensive experience with site-specific performance assessment has shown them to be none of these. For example, because container performance, release rate, and ground-water travel time will be derived from the same general data and knowledge base as the TSPA, they are subject to many, if not all, of the same uncertainties. Furthermore, waste package performance and release rate are both a function of available water; therefore, it is arguable whether the existing (or any other) subsystem measures can provide truly independent assurance of total system performance.
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> Nevertheless, despite its reconsideration of the merits of establishing quantitative criteria for the performance of repository subsystems, the Commission continues to believe that multiple barriers, as required by NWPA, must each make a definite contribution to the isolation of waste at Yucca Mountain, so that the Commission may find, with reasonable assurance, that the repository system will be able to achieve the overall safety objective over timeframes of thousands of years. Geologic disposal of HLW is predicated on the expectation that a portion of the geologic setting will act as a barrier, both to water reaching the waste, and to dissolved radionuclides migrating away from the repository, and thus, contribute to the isolation of radioactive waste. Although there exists an extensive geologic record ranging from thousands to millions of years, this record is subject to interpretation and includes many uncertainties. These uncertainties can be quantified generally and are addressed by requiring the use of a multiple barrier approach; specifically, an engineered barrier system, consisting of one or more distinct

> engineered barriers, is required in addition to the natural barriers implicit in a geologic setting. Similarly, although the composition and configuration of engineered structures, as well as their capacity to function as barriers, can be defined with a degree of precision not possible for natural barriers, it is recognized that except for a few archaeologic analogues, there is no experience base for the performance of complex, engineered structures over periods longer than a few hundred years. It is expected that DOE will demonstrate that the natural barriers and the engineered barrier system will work in combination to enhance overall performance of the geologic repository." (64 FR 8649; February 22, 1999)

Thus, the Commission proposed a different approach for the multiple barrier requirements in 10 CFR Part 63, stating:

> "Drawing from this experience, the Commission is now proposing to require that DOE evaluate the behavior of barriers important to waste isolation in the context of the performance of the geologic repository. The Commission does not intend to specify numerical goals for the performance of individual barriers. Such an approach will require DOE to provide an analysis that: (1) identifies those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation; (2) describes the capability of these barriers to isolate waste, taking into account uncertainties in characterizing and modeling the barriers; and (3) provides the technical basis for the description of the capability of these barriers. In implementing this approach, the Commission proposes to incorporate flexibility into its regulations by requiring DOE to demonstrate that the geologic repository comprises multiple barriers but not prescribe which barriers are important to waste isolation or the methods to describe their capability to isolate waste." (64 FR 8649-50; February 22, 1999)

NRC finalized its approach for multiple barriers in 10 CFR Part 63 on November 2, 2001 (66 FR 55732) requiring that (1) the geologic repository must include multiple barriers, consisting of both natural barriers and an engineered barrier system (§ 63.113(a)) and the Department of Energy (DOE) must (a) Identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation, (b) Describe the capability of barriers, identified as important to waste isolation, to isolate waste, taking into account uncertainties in characterizing and modeling the behavior of the barriers, and (c) Provide the technical basis for the description of the capability of barriers, identified as important to waste isolation, to isolate waste (the technical basis for each barrier's capability shall be based on and consistent with the technical basis for the performance assessment) (§ 63.115).

The change from quantitative subsystem requirements in 10 CFR Part 60 to the approach in 10 CFR Part 63 that provides the flexibility for DOE to identify the barriers it would rely on and provide the technical support for each barrier's performance was challenged (among other things such as the 10,000 year compliance period in the EPA Standard) in court. On July 9, 2004, the U.S. Court of Appeals for the District of Columbia Circuit s (373 F.3d 1251, 1297), ruled that:

> "In light of NRC's detailed analysis supporting its decision to evaluate the performance of the Yucca Mountain repository based on the barrier system's overall performance, we believe that it adequately explained its change in course. See, e.g., Motor Vehicle Mfrs. Ass'n, 463 U.S. at 57. Accordingly, we conclude that NRC acted neither arbitrarily nor

> capriciously in rejecting part 60's subsystem performance approach in favor of the overall performance approach." (page 71)

Abandoning quantitative subsystem requirements in favor of reliance on performance assessment results and all its supporting data and analyses was, in the staff's view, the most significant technical change in NRC's regulatory approach for HLW post-closure safety. This approach in Part 63 provides the foundation for a risk-informed review. As will be described in the technical review section (see Section 4), the technical review of post-closure began with an examination of DOE's identification and discussion of each barriers significance as means to ensure the review was commensurate with each barrier's significance to safety. The staff's Yucca Mountain Review Plan (YMRP) explained how the information DOE provides in its license application on the multiple barriers would be used to risk inform the post-closure review. In particular as stated in the YMRP (Section 2.2 Repository Safety after Permanent Closure; page 2.2-1):

> "Section 2.2.1 requires the staff to apply risk information throughout the review of the performance assessment. First, the staff reviews the barriers important to waste isolation in Section 2.2.1.1. The U.S. Department of Energy must identify the important barriers (engineered and natural) of the performance assessment, describe each barrier's capability, and provide the technical basis for that capability. This risk information describes the U.S. Department of Energy understanding of each barrier's capability to prevent or substantially delay the movement of water or radioactive materials. Staff review of the U.S. Department of Energy performance assessment—first the barrier analysis and later the rest of the performance assessment—considers risk insights from previous performance assessments conducted for the Yucca Mountain site, detailed process modeling efforts, laboratory and field experiments, and natural analog studies. The result of the initial multiple barrier review is a staff understanding of each barrier's importance to waste isolation, which will influence the emphasis placed on the reviews conducted in Sections 2.2.1.2, 'Scenario Analysis and Event Probability' and 2.2.1.3, 'Model Abstraction.' The emphasis placed on particular parts of the staff review will change based on changes to the risk insights or in response to preliminary review results."

2.2 Reasonably, Maximally, Exposed Individual (RMEI)

The NAS Committee for Yucca Mountain Standards identified potential issues associated with estimating doses to individuals far into the future and recommended that the characteristics of the exposure scenario for estimating the post-closure dose estimate (e.g., reference biosphere) should be specified in regulation to limit unreasonable speculation of human behaviors in the distant future (see Part III: Exposure Scenarios in Performance Assessment in the NAS Report on Yucca Mountain Standards).

NRC and EPA in final regulations and standards specified attributes to be used for exposure scenarios in the post-closure period. NRC's Statements of Consideration in its final regulations (66 FR 55732; November 2, 2001) and EPA's preamble in its final standards (66 FR 32074; June 13, 2001) provide a more comprehensive discussion of the technical basis – the discussion here is intended to provide perspective on key aspects of the exposure scenario to be used in the post-closure performance assessment. Some of the important characteristics of the exposure scenarios, as specified in 10 CFR Part 63, are summarized below:

§ 63.102(i) – Reference Biosphere and Reasonably Maximally Exposed Individual is a hypothetical person living in a community with characteristics of the Town of Amargosa Valley based on current human behavior and biospheric conditions in the region.

§ 63.305 Required characteristics of the reference biosphere: consistent with present knowledge of the conditions in the region; do not project changes in society and biosphere (except climate change) – assume factors remain constant as they are at the time of submission of the application; DOE must vary factors related to related to geology, hydrology, and climate based upon cautious but reasonable assumptions consistent with present knowledge; and biosphere pathways must be consistent with arid or semi-arid conditions.

§ 63.312 Required characteristics of the reasonably maximally exposed individual (RMEI): live in the accessible environment (location outside the controlled area, which is approximately 20 kilometers downgradient from Yucca Mountain – DOE controls the area inside this distance) above the highest concentration of radionuclides in the plume of contamination; has a diet and living style representative of the people who now reside in the Town of Amargosa Valley (use mean values based upon surveys of people residing in the Town of Amargosa Valley); use average water concentration based on an annual water demand of 3,000 acre-feet; drinks 2 liters a day from well drilled into the plume of contamination; and is an adult with metabolic and physiological considerations consistent with present knowledge of adults.

NRC’s regulations at Subparts K and L implement the relevant portions of the EPA Standards for Yucca Mountain (40 CFR Part 197) such as §§ 63.305 and 63.312.

2.3 Human Intrusion

Concern for human intrusion into a repository was one of the concerns cited in the Energy Policy Act of 1992 (EnPa). Congress included specific direction to the EPA to contract with the National Academy of Sciences to assist in developing the technical basis for Yucca Mountain standards. In Section 801 of the Energy Policy Act of 1992 (P.L. 102-486), Congress directed:

> “(2) Study by National Academy of Sciences. Within 90 days after the date of the enactment of this Act, the Administrator shall contract with the National Academy of Sciences to conduct a study to provide, by not later than December 31, 1993, findings and recommendations on reasonable standards for protection of the public health and safety, including
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> (A) whether a health-based standard based upon doses to individual members of the public from releases to the accessible environment (as that term is defined in the regulations contained in subpart B of part 191 of title 40, Code of Federal Regulations, as in effect on November 18, 1985) will provide a reasonable standard for protection of the health and safety of the general public;
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> (B) whether it is reasonable to assume that a system for post-closure oversight of the repository can be developed, based upon active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered or geologic barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits; and

(C) whether it is possible to make scientifically supportable predictions of the probability that the repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years.

(3) Applicability. The provisions of this section shall apply to the Yucca Mountain site, rather than any other authority of the Administrator to set generally applicable standards for radiation protection.

(b) Nuclear Regulatory Commission Requirements and Criteria.
(1) Modifications. Not later than 1 year after the Administrator promulgates standards under subsection (a), the Nuclear Regulatory Commission shall, by rule, modify its technical requirements and criteria under section 121(b) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10141(b)), as necessary, to be consistent with the Administrator's standards promulgated under subsection (a)."

Thus, the National Academy of Sciences (NAS) report on the Technical Basis for Yucca Mountain Standards provides considerable thought and discussion on appropriate approaches for addressing technically supportable scenarios for human intrusion (see Part III Exposure Scenarios in Performance Assessment and Chapter 4 Human Intrusion and Institutional Controls in the NAS report). As stated in the NAS Report:

"there is no scientific basis for assuming the long-term effectiveness of active institutional controls to protect against human intrusion. Although it may be reasonable to assume that a system of post-closure oversight can be developed and relied on for some initial period of time, there is no defensible basis for assuming that such a system can be relied on for times far into the future." (page 106)

"Just as there is no basis for assuming the effectiveness of either active or passive institutional controls to reduce the risk of human intrusion, we also conclude that there is no scientific basis for estimating the probability of intrusion at far-future times." (page 107)

"For these reasons, to address the human intrusion issue on an adequate basis, we recommend that the repository developer should be required to provide a reasonable system of active and passive controls to reduce the risk of intrusion in the near term and that EPA should specify in its standard a typical intrusion scenario to be analyzed for its consequences on the performance of the repository. Such an analysis will provide useful quantitative information that can be meaningful in the licensing process, as described later in this chapter. Because the assumed intrusion scenario is arbitrary and the probability of its occurrence cannot be assessed, the result of the analysis should not be integrated into an assessment of repository performance based on risk, but rather should be considered separately. The purpose of this consequence analysis is to evaluate the resilience of the repository to intrusion." (pages 108 and 109)

Thus, the NAS stated:

"we conclude that it is not possible to assess the probability of human intrusion into a repository over the long-term, and we do not believe that it is scientifically justified to incorporate alternative scenarios of human intrusion into a risk-based compliance assessment. We do, however, conclude that it is possible to carry out calculations of the consequences for particular types of intrusion events. The key performance issue is whether repository performance would be substantially degraded as a consequence of an inadvertent intrusion for which the intruder does not recognize that a hazardous situation has been created. This consequence assessment is to be done separately from the calculation of compliance with the risk limit from other events and processes, and is to exclude exposures to drillers or to members of the public due to cuttings. We recommend that EPA should require that the conditional risk as a result of the assumed intrusion scenario be no greater than the risk limits adopted for the undisturbed repository case." (page 121)

Additionally, the NAS provided perspective on the type of intrusion event that might be considered, stating "[F]or simplicity, we considered a stylized intrusion scenario consisting of one borehole of a specified diameter drilled from the surface through a canister of waste to the underlying aquifer. One can always conceive of worse cases, such as multiple boreholes with each penetrating a canister, but this single-borehole scenario seems to us to hold the promise" (page 111).

Both EPA and NRC developed standards and regulations consistent with the NAS recommendations. Key aspects of the human intrusion evaluation prescribed in Part 63 are:

§ 63.321 Individual Protection Standard for Human Intrusion (74 FR 10811; March 13, 2009 – note this portion of the regulation was revised after Part 63 was finalized in 2001 to implement a dose limit after 10,000 years – see Section 2.4 for further information on the dose limit after 10,000 years)

- DOE determines the earliest time the waste package would degrade sufficiently that a human intrusion could occur without recognition by the drillers
- Depending on the timing of the intrusion it must meet either the dose limit for the initial 10,000 years or the dose limit for the period after 10,000 years

§ 63.322 Human Intrusion Scenario (66 FR 55814, November 2, 2001)

The DOE must make the following assumptions in the analysis of human intrusion:
(a) There is a single human intrusion as a result of exploratory drilling for ground water;
(b) The intruders drill a borehole directly through a degraded waste package into the uppermost aquifer underlying the Yucca Mountain repository;
(c) The drillers use the common techniques and practices that are currently employed in exploratory drilling for ground water in the region surrounding Yucca Mountain;
(d) Careful sealing of the borehole does not occur, instead natural degradation processes gradually modify the borehole;
(e) No particulate waste material falls into the borehole;
(f) The exposure scenario includes only those radionuclides transported to the saturated zone by water (e.g., water enters the waste package, releases radionuclides, and transports radionuclides by way of the borehole to the saturated zone); and
(g) No releases are included which are caused by unlikely natural processes and events.

2.4 Regulations for the Period after 10,000 Years

After publication of final EPA standards (66 FR 32074; June 13, 2001) and NRC regulations (66 FR 55732; November 2, 2001) lawsuits were filed on a variety of aspects, including NRC's removal of quantitative sub-system requirements. The U.S. Court of Appeals for the District of Columbia Circuit upheld both EPA's standards and NRC's regulations on all but one of the issues raised by the petitioners – the court disagreed with EPA's decision to adopt a 10,000-year period for compliance with the standards and NRC's adoption of that 10,000-year compliance period in NRC's implementing regulations (No. 01-1258) [July 9, 2004]. The court concluded, in part:

> V. Conclusion
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> "In sum, we vacate 40 C.F.R. part 197 to the extent that it incorporates a 10,000-year compliance period because, contrary to EnPA section 801(a), that compliance period is not ''based upon and consistent with'' the recommendations of the National Academy of Sciences. The remaining challenges to the EPA rule are without merit. We vacate the NRC rule insofar as it incorporates EPA's 10,000-year compliance period. In all other respects, we deny Nevada's petition for review challenging the NRC rule."

Following this decision, EPA and NRC evaluated revisions to the standards and regulations to accommodate implementation of an unprecedented time period of 1-million years for evaluating the post-closure safety of Yucca Mountain as recommended by the NAS. In short, the NAS in its report on the Technical Basis for Yucca Mountain Standards recommended that "compliance assessment be conducted for the time when the greatest risk occurs, within the limits imposed by long-term stability of the geologic environment" (page 7), and that the time scale of the long-term stability of the fundamental geologic regime at Yucca Mountain[3] is a time scale that is on the order of 1-million years (page 6).

The EPA and NRC recognized that such an unprecedented time frame as 1-million years needed to carefully consider how to reasonably implement such a long compliance period. EPA in its final standards for the period after 10,000 years (73 FR 61256; October 15, 2008) choose to (a) set an annual dose limit of 100 mrem for the period after 10,000 years up to 1-million years (this applied for overall compliance as well as the human intrusion evaluation), (b) those events that are considered significant in the initial 10,000 year period are to be used for the period after 10,000 years, (c) the same features, events, and processes used in the 10,000 year are to be used in the performance assessment for the period after 10,000 years the following exceptions – (i) seismic analysis, subject to probability limits in the standard, may be limited to damage to the repository drifts, failure of the waste package and changes to the elevation of the water table under Yucca Mountain (unless NRC chooses not to require consideration of the water table rise in the performance assessment), (ii) the igneous analysis may be limited to the effects of a volcanic event directly intersecting the repository and damage to the waste packages resulting in direct release of radionuclides to the biosphere, atmosphere, or groundwater, (iii) DOE must assess the effects of climate change limited to the effects of increased water flow through the repository and the resulting transport and release of

[3] It should be noted that the NAS specifically identified the period of geologic stability was the driver for a 1-miilion year compliance period. It has been suggested that if similar logic were to be applied at a different site where the period of geologic stability was determined to be significantly longer (e.g., 10-million years) it could imply the need for a compliance period of 10 million years at such a site.

radionuclides to the accessible environment – this analysis may commence at 10,000 years after disposal and extend through the period of geologic stability or 1-million years (NRC shall specify in regulation the values to be used to represent climate change such as temperature, precipitation, or infiltration rate of water, and (iv) DOE must assess the effects of general corrosion on engineered barriers and DOE may use a constant representative corrosion rate throughout the period of geologic stability (1 million years) or a distribution of corrosion rates correlated to other repository parameters. Thus, EPA provided a variety of specific limitations that were to be used in estimation doses after 10,000 years out to 1 million years.

NRC implemented the specific limits in the EPA standard for the period after 10,000 years in its regulations at § 63.342, Limits on Performance Assessments, and implemented the dose limits for the period after 10,000 years at § 63.311 (individual protection standard) and § 63.321 (human intrusion) [74 FR 10811; March 13, 2009]. Of the four exceptions for treatment of features, events, and processes for the period after 10,000 years, only the NRC treatment for the exception for climate change is elaborated further below.

As specified in EPA's standard the NRC specified the values used to represent climate change in the period after 10,000 years – NRC choose to specify that (i) climate change analysis may be limited to the effects of increased water flow through the repository and the resulting transport and release of radionuclides to the accessible environment, (ii) the nature and degree of climate change may be represented by constant-in-time climate conditions and use the spatial average of the deep percolation rate within the area bounded by the repository footprint, and the constant-in-time deep percolation rates to be used to represent climate change shall be based on a lognormal distribution with an arithmetic mean of 41 mm/year (1.6 inches/year) and a standard deviation of 33 mm/year (1.3 inches/year), and (iii) the lognormal distribution is to be truncated so that the deep percolation rates vary between 10 and 100 mm/year (0.39 and 3.9 inches/year) (63.342(c)(2)).

The NRC provided a number of references and discussion in the proposed rule (70 FR 53313; September 8, 2005) and the final rule (74 FR 10811; March 13, 2009) to support NRC's approach and values for the deep percolation rate for representing climate change after 10,000 years.

The information supporting the approach for specification of the deep percolation provided in the Statements of Consideration for the NRC's proposed and final rules provided a comprehensive technical basis. In particular, some of the key aspects supporting the NRC approach included:

1) Consistency with NAS Yucca Mountain Standards report

The Commission noted the NAS Committee views regarding future climate changes when it finalized its regulations for the period after 10,000 years.

> "The NAS committee (1995) was familiar with the science behind predicting future climate changes and stated, in its recommendations on Yucca Mountain standards, that a future ice age in the next few hundred years is 'unlikely but not impossible,' and in the next 10,000 years is 'probable but not assured.' However, over a 1-million-year time frame, the climate is much more likely to pass through several glacial-interglacial cycles (i.e., ice ages). The NAS indicated there is a reasonable data base from which to infer

past changes and noted that '[a]lthough the range of climatic conditions has been wide, paleoclimate research shows that the bounding conditions, the envelope encompassing the total climatic range have been fairly stable' and that '[b]ased on this record, it seems plausible that the climate will fluctuate between glacial and interglacial stages during the period suggested for the performance assessment calculations.' Further, in its 1995 findings, the NAS stated that 'enough of the important aspects [of climate change] can be known within reasonable limits of uncertainty, and these properties and processes are sufficiently understood and stable over the long time scales of interest to make calculations possible and meaningful, we believe that there is a substantial scientific basis for making such calculations, taking uncertainty and natural variability into account.'" (74 FR 10818-19; March 13, 2009)

2) Consideration for climate change over very long time periods

"According to climatologists, the so-called intermediate and monsoon climate states, which occur between the warmer 'interglacial' and the cooler 'full glacial' climate states, are both wetter than the present climate state. Climatologists estimate a mean annual precipitation, during these climate states, at about twice that of present mean annual precipitation at Yucca Mountain. Over the past million years, these two wetter climate states were the predominate climate states (Civilian Radioactive Waste Management System, Management and Operating Contractor, ''Future Climate Analysis—10,000 years to 1,000,000 Years After Present,'' MOD–01–001 Rev. 00, 2002). To the extent that climate is controlled by changes in solar radiation arising from variations in the Earth's orbit [op. cit.], it is reasonable to assume that climate patterns during the next 1 million years would follow a similar cycle. Deep percolation rates depend on both precipitation and temperature and their associated effects on evaporation and plant transpiration. Today, the mean precipitation, measured at Yucca Mountain, is 125 millimeters/year (mm/ year) (4.9 inches/year) (Thompson, R. S., K. H. Anderson, and P. J. Bartlein, 'Quantitative Paleoclimatic Reconstructions from Late Pleistocene Plant Macrofossils of the Yucca Mountain Region,' U.S. Geological Survey Open-File Report 99–338, U.S. Geological Survey, Denver, CO, 1999). About 4 percent of that water reaches the repository horizon. This corresponds to an estimated deep percolation rate of 5 mm/year (0.20 inches/year) when averaged over the repository footprint (Zhu, C., J. R. Winterle, and E. I. Love, 'Late Pleistocene and Holocene Groundwater Recharge from the Chloride Mass Balance Method and Chlorine-36 Data,' Water Resources Research, Vol 39, No. 7, page 1182, 2003). Examination of locations in the United States, analogous to Yucca Mountain in some future intermediate and monsoon climates, suggests potential precipitation rates of between 266 and 321 mm/year [10.5 and 12.6 inches/year] (Thompson, R. S., K. H. Anderson, and P. J. Bartlein, 'Quantitative Paleoclimatic Reconstructions from Late Pleistocene Plant Macrofossils of the Yucca Mountain Region,' U.S. Geological Survey Open-File Report 99–338, U.S. Geological Survey, Denver, CO, 1999)." (70 FR 53316; September 8, 2005)

3) Consideration of the effects of anthropogenic climate change

"NRC considered the effects of anthropogenic influences on climate change. Based on that evaluation, the NRC believes the range of values specified for deep percolation rates adopted in the final rule captures the range of temporal variability, uncertainty, and magnitude of deep percolation expected as a consequence of future climate change.

The magnitude and timing of the anthropogenic effects are likely to be more pronounced during the first 10,000 years. The final regulation addresses only the 10,000 to 1 million year time period, during which any anthropogenic effects are anticipated to diminish. Anthropogenic effects, as represented in Global Circulation Models (GCMs), might persist for a 100,000 year time periods, but they do not fluctuate periodically and they decrease with time after an initial peak. Therefore, NRC believes that these effects can be captured by the long-term average infiltration [sic deep percolation] values adopted in the final regulation because the range of values for the sampled population bounds these effects in an appropriately conservative manner.

Atmospheric reorganization and increased frequency and magnitude of extreme events might result from natural or anthropogenic climate change. However, extreme 10-to 20-year events effectively become long-term averages that are incorporated into the range specified for deep percolation in the final regulation, when simulating a time period of 1 million years." (74 FR 10819; March 13, 2009)

4) Consideration of extreme events from climate change

"Atmospheric reorganization and increased frequency and magnitude of extreme events might result from natural or anthropogenic climate change. However, extreme 10-to 20-year events effectively become long-term averages that are incorporated into the range specified for deep percolation in the final regulation, when simulating a time period of 1 million years." (74 FR 10819; March 13, 2009)

5) Consideration of repository depth to dampen effects of short-term events

"The Paintbrush non-welded tuff unit (PTn unit) overlying the potential repository dampens the effects of transient phenomena associated with shorter time frames (Manepally, C., et al., 'The Nature of Flow in the Faulted and Fractured Paintbrush Nonwelded Hydrogeologic Unit,' San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, April 2007) in the system's response to external hydrologic events. The NAS also recognized that long-term net infiltration averages can bound and describe Yucca Mountain hydrology adequately, stating that 'the subsurface location of the repository would provide a temporal filter for climate change effects on hydrologic processes' One commenter on NRC's rule also acknowledged this, quoting Cohen, 'no evidence shows that high-frequency fluctuations (a few years or shorter) penetrate to the depth of the potential repository' (Cohen, S., 'Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments,' S. Cohen & Associates, prepared for U.S. Environmental Protection Agency, August 8, 2005). Flow simulations have shown that the non-welded PTn rock unit effectively damps out decadal flow transients." (see 74 FR 10819; March 13, 2009)

6) Consideration of detailed climate analyses

"NRC has conducted detailed climate analyses considered time-varying values of historic, inferred prehistoric, and potential future precipitation rates to support the range of long-term-average future deep percolation rates adopted in the final regulations. These time-varying precipitation rates were also used to estimate the range and bounds of 1-million-year-average annual precipitation. Having considered the comments and conducted further analyses, the Commission believes the time-varying precipitation rates used to estimate future mean annual deep percolation rates are appropriate.

The lowest and highest values of the 1-million-year-average future annual precipitation in any climate sequence used to estimate the 1-million-yearaverage future deep percolation rate are 211 and 471 mm/year (8.3 and 18.5 in./year) at a 1,524 meter (5,000 foot) reference elevation. NRC used two approaches, which are described by Stothoff and Walter, 'Long-Term Average Infiltration at Yucca Mountain, Nevada: Million-Year Estimates,' San Antonio, TX: Center for Nuclear Waste Regulatory Analyses (2007), to estimate time-varying sequences of mean annual precipitation that vary over glacial cycles. Both approaches estimate precipitation for glacial stages, with the sequence of glacial stages determined using well-known orbital dynamics relationships. The first approach is based on the climate reconstruction by Sharpe, 'Future Climate Analysis: 10,000 Years to 1,000,000 Years After Present,' Reno, NV: Desert Research Institute (2003), with present-day and monsoon climatic conditions adjusted to reflect historical precipitation measurements in the vicinity of Yucca Mountain based on meteorological data in Bechtel SAIC Company (BSC), 'Simulation of Net Infiltration for Present-Day and Potential Future Climates,' Las Vegas, NV: Bechtel SAIC Company, LLC (2004). The 1-million-year-average mean annual precipitation rate from the first approach ranges from 213 to 389 mm/year (8.4 to 15.3 in./year), and with a mean of 315 mm/year (12.4 in./year) and a standard deviation of 52 mm/year (2.0 in./year). The second approach is based on estimated sequences of future continental ice volumes, which respond to insolation variation caused by orbital dynamics, with changes in precipitation related to changes in atmospheric patterns occurring from changes in continental ice volume. The 1-million-year-average mean annual precipitation for the second approach ranges from 211 to 471 mm/year (8.3 to 18.5 in./year), and with a mean of 322 mm/year (12.7 in./year) and a standard deviation of 47 mm/year (1.8 in./year).

Both approaches described by Stothoff and Walter, 'Long-Term Average Infiltration at Yucca Mountain, Nevada: Million-Year Estimates,' San Antonio, TX: Center for Nuclear Waste Regulatory Analyses (2007) subdivide the 1-million-year period into a sequence of interglacial and glacial stages that vary in duration from 500 to 40,000 years. For each stage, a range of mean annual precipitation is estimated that includes uncertainty. The smallest and largest values of estimated mean annual precipitation considered in any stage are 162 and 581 mm/year (6.4 and 22.9 in./year)."

(74 FR 10820-1; March 13, 2009)

It is noted that the reference identified above as Stothoff and Walter (2007) was later published as Stothoff, S.A., and G.R. Walter. 2013. “Average Infiltration at Yucca Mountain Over the Next Million Years.” Water Resources Research. Vol. 49, No. 11. pp 7,528–7,545, doi:10.1002/2013WR014122

7) Consideration of uncertainty

“The stylized climate scenario and deep percolation rate in the final rule do not depend only on information provided by the USGS. The NRC has developed its own model and has performed independent field observations and measurements to support this final rule. In addition, the NRC has evaluated other regional information to corroborate its estimates of percolation under different climate regimes (Stothoff and Musgrove, ‘Literature Review and Analysis: Climate and Infiltration,’ San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, 2006).

To address uncertainty in estimates of net infiltration (and hence, deep percolation) during future climates, NRC developed its own independent climate and net infiltration models. Some DOE information that NRC judged to be reasonable from a scientific perspective was used in the model inputs. Further, NRC understands that DOE has reaffirmed the quality of data used in response to the USGS e-mail issue investigations. For important model inputs, NRC independently collected data to gain confidence in the model results.

Three of the most important model inputs are precipitation, soil thickness, and incident solar energy. For precipitation, NRC analyzed local and regional data patterns and developed a future climate model based on ice core volumes (Stothoff and Walter, ‘Long-Term Average Infiltration at Yucca Mountain, Nevada: Million-Year Estimates,’ San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, 2007). NRC climate model results were compared with indirect observations such as lake records and glacier advances in the Sierra Mountains. For soil thickness, NRC made its own measurements at the ridges and hillslopes of Yucca Mountain (Fedors, ‘Soil Depths Measured at Yucca Mountain During Site Visits in 1998,’ Interoffice Note to J. Guttmann, Washington, DC: Nuclear Regulatory Commission, January 9, 2007). NRC used the measurements of soil depth to gain confidence in its own model for soil thickness across the Yucca Mountain area. For the incident solar energy, which is important for evapotranspiration in this semi-arid climate, NRC independently developed its own water-energy flow model from the general literature (Stothoff, ‘BREATH Version 1.1—Coupled Flow and Energy Transport in Porous Media: Simulator Description and User Guide,’ Washington, DC: Nuclear Regulatory Commission, 1995).

Previously, NRC had developed a bulk bedrock permeability model (Waiting, et al. ‘Technical Assessment of Structural Deformation and Seismicity at Yucca Mountain, Nevada,’ San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, 2001) and performed independent soil permeability measurements, which provided a basis to evaluate the reasonableness of related DOE data ‘Infiltration Tabulator for Yucca Mountain: Bases and Confirmation,’ San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, August, 2008; and Fedors (‘Soil Hydraulic Properties Measured

During Site Visits to Yucca Mountain, Nevada,’ Interoffice Note to E. Peters, Washington, DC: Nuclear Regulatory Commission, August, 2008).

NRC’s model for estimating net infiltration is independent of the DOE model and uses a different conceptualization. The NRC model is a physically-based numerical heat and mass transfer model, which solves the Richards equation for water flow, with hourly climatic inputs to determine net infiltration for a range of climates and hydraulic property sets. Results from the heat and mass transfer model are used to develop an abstraction that is applied to Geographical Information System (GIS) based inputs covering the Yucca Mountain area.” (74 FR 10823; March 13, 2009)

Since the publication of the FRN, NRC’s independent models for estimating net infiltration have been published in the two following articles:

Stothoff, S. A. 2013. “Uncertainty and Variability – Infiltration at Yucca Mountain. Part 1: Numerical Model Development.” Water Resources Research. Vol. 49, No.6.pp 3,787–3,803, doi: 10.1002/wrcr.20252; and

Stothoff, S. A. 2013. “Uncertainty and Variability – Infiltration at Yucca Mountain. Part 2: Model Results and Corroboration.” Water Resources Research, 49(6), 3804–3824, doi:10.1002/wrcr.20262.

In particular, the NRC incorporated estimates of the model inputs and their uncertainties into an algorithm for stochastic representation of net infiltration at Yucca Mountain (Stothoff, ‘‘Infiltration Tabulator for Yucca Mountain: Bases and Confirmation,’’ San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, August, 2008). The NRC algorithm was derived from simulations performed using NRC’s physically based BREATH code. Both the algorithm and BREATH code were developed independently of DOE and USGS models,

8) Resilience of approach to potential changes in understanding

“The NRC recognizes that scientific progress is expected to continue the understanding of potential future climate. However, the intention of the rule is to specify a reasonable basis for evaluating safety using current knowledge. Given the current approach for estimating deep percolation, it would take a major shift in scientific understanding for the deep percolation rates to change significantly. For example, if future scientific advances suggest there is a period when there would be no rainfall in the Yucca Mountain area for a period of 100,000 years, this would result in a ten percent change in the long-term average over the 1-million-year period. Such changes are not expected to significantly change dose estimates. However, if future scientific advances show the regulation is no longer sufficiently protective of public health and safety and the environment, NRC would not hesitate to propose appropriate changes to the regulations.

Further, if any person believes that the specification for climate change no longer provides a reasonable basis for demonstrating compliance based on new scientific evidence, they can petition NRC to amend the rules. In addition, NRC’s procedural rules enable any party to an adjudicatory proceeding to petition that application of a rule be waived in circumstances when the rule would not serve the purposes for which it was adopted.” (74 FR 10823-4; March 13, 2009)

9) Compliance with OMB Information Quality Act (IQA)

> "NRC considers its calculations and technical bases supporting the deep percolation estimates to be consistent with the IQA and the associated OMB guidelines concerning peer review. The OMB peer review guidance applies to 'influential scientific information' that will have a clear and substantial impact on important public policies or the private sector (70 FR 2667; January 14, 2005). The distribution and range for deep percolation rates have a limited effect on repository performance and expected dose given the nature of the geologic environment and anticipated performance of engineered barriers. Specifying deep percolation assumptions in NRC regulations limits unbounded speculation concerning a narrow and discrete aspect of the overall performance assessment. Doing so does not determine either how DOE will apply that range of rates over the entire repository horizon or DOE's related analysis of the consequences for repository performance, much less constrain an NRC conclusion with respect to the acceptability of a potential application. Consequently, NRC does not consider its specification of the deep percolation rates or the data supporting it to be influential scientific information within the meaning of the OMB guidance.
>
> As discussed in relation to Climate Change issues in this document, NRC's estimates of deep percolation are appropriate and well supported. Based on public comment, the NRC has revised its specification for deep percolation values and provided additional clarification for the basis of the range of values. Further, these values are independent of any work or information provided by EPA or its contractors. With respect to the basis for the deep percolation rates, the NRC is not, as asserted by the State of Nevada, 'overwhelmingly relying on EPA information, including EPA's contractor documents' in its calculations and judgments when the responsibility rests with NRC." (74 FR 10824; March 13, 2009)

National and international research in climate change continues today as is reflected in climate assessment updates every few years by International Panel on Climate Change (IPCC) and the U.S. Global Change Research Plan (USGCRP). These climate assessments synthesize research advancements into regional and national climate assessments. In particular, the USGCRP's 3rd (2014) and 4th (2018) National Climate Assessments continue to project warmer and drier conditions due to anthropogenic climate change for the desert southwest.

Finally, it is important to note that there is a pending legal challenge to the final standards and regulations for the period after 10,000 years; this case is, however, being held in abeyance, subject to periodic status reports. The case may resume should Yucca Mountain program activities resume.

2.5 Specific Changes Affecting Performance Assessment

NRC specified two aspects of performance assessment (use of modern dosimetry and identifying the technical basis to be used for the performance assessment after 10,000 years) in its final regulation for the period after 10,000 years (74 FR 10811; March 13, 2009).

At § 63.102 (Concepts), NRC clarified how current dosimetry could be applied in estimating doses for determining compliance with dose limits. Specifically,

> "When external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The radiation and organ or tissue weighting factors in Appendix A of 40 CFR part 197 are to be used to calculate TEDE. After the effective date of this regulation, the Commission may allow DOE to use updated factors, which have been issued by consensus scientific organizations and incorporated by EPA into Federal radiation guidance. Additionally, as scientific models and methodologies for estimating doses are updated, DOE may use the most current and appropriate (e.g., those accepted by the International Commission on Radiological Protection) scientific models and methodologies to calculate the TEDE. The weighting factors used in the calculation of TEDE must be consistent with the methodology used to perform the calculation."
> (10 CFR 63.102(o))

The NRC specified at § 63.114(a) the types of information that were to be used to support the performance assessment to demonstrate compliance with the standard for the initial 10,000 years; and § 63.114(b) specified that the performance assessment methods used to satisfy the requirements of § 63.114 (a) are considered sufficient for the performance assessment for the period of time after 10,000 years and through the period of geologic stability. Thus, data and information used for the initial 10,000 years was considered appropriate for the period after 10,000 years, and thereby, appropriately limiting the information that would be needed over the unprecedented period of 1,000,000 years. NRC stated:

> "The changes to § 63.114 impose no additional limits on the performance assessment for the period after 10,000 years. The changes ensure consistency between NRC's regulations and EPA's final standards. In particular, EPA's final standards specify that FEPs used for the first 10,000 years should be used for estimating performance after 10,000 years. Thus, § 63.114(b) specifies that the same performance assessment methods used for the first 10,000 years are to be used for the period after 10,000 years. For example, parameter ranges used in the performance assessment for the first 10,000 years would be used in the performance assessment for the period after 10,000 years. Additional technical basis for selection of FEPs, beyond that developed for the performance assessment for the first 10,000 years, is not required. Thus, the changes at § 63.114 ensure the performance assessment methods, such as the support and treatment of FEPs will be the same for the periods before and after 10,000 years, subject to the limits on performance assessments at § 63.342." (see 74 FR 10817; March 13, 2009)

3.0 References

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