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FINAL REPLY:

Ivan Itkin
Department of Energy (DOE)

TO:

Chairman Meserve

FOR SIGNATURE OF :

** PRI **

CRC NO: 00-0304

Chairman

DESC:

Review of Draft Final Rule for Nuclear Waste
Repositories and Yucca Mountain Site Suitability
Guidelines

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AUTHOR: Ivan Itkin
AFFILIATION: DOE
ADDRESSEE: RICHARD MESERVE
SUBJECT: Concerns the revised draft final General Guidelines for Nuclear Waste Repositories and Yucca Mountain Site Suitability Guidelines.

ACTION: Signature of Chairman
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Department of Energy

Washington, DC 20585

May 4, 2000

Honorable Richard A. Meserve
Chairman
OCM/RAM
Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Chairman:

On November 30, 1999, the Department of Energy (DOE) issued a supplemental notice of proposed rulemaking to amend the General Guidelines for Nuclear Waste Repositories and to issue new proposed Yucca Mountain Site Suitability Guidelines. The notice opened a nearly 90-day public comment period, during which time the Department also held two public hearings in Nevada. The supplemental proposal, similar to the Department's 1996 proposal, provided for the Yucca Mountain site to be determined suitable by the Secretary of Energy under the guidelines, only if DOE demonstrates that the site is likely to meet applicable radiation protection standards.

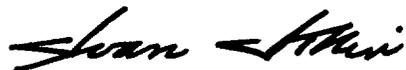
DOE is now planning to move forward with a notice of final rulemaking that addresses the comments and concerns raised by the public during the recently closed proposed rulemaking process. Consistent with the process followed with the issuance of the original guidelines in 1984, enclosed for the Commission's review and concurrence are the revised draft final General Guidelines for Nuclear Waste Repositories and Yucca Mountain Site Suitability Guidelines. In preparing the draft final rule, DOE has addressed the Commission Staff's comments received on the proposal.

I would appreciate the Commission's timely consideration of the draft final rule and its concurrence to allow the Department to utilize the final rule in the upcoming site recommendation process that is planned to begin this Fall. Copies of the public comments and hearings transcripts are also being forwarded to assist the Commission in its concurrence process.



Should any questions arise concerning our rulemaking, please contact Christopher Kouts of my staff (202-586-1253).

Sincerely,

A handwritten signature in black ink, appearing to read "Ivan Itkin". The signature is written in a cursive style with a prominent flourish at the end.

Ivan Itkin, Director
Office of Civilian Radioactive
Waste Management

Enclosure(s)

PRELIMINARY/PREDECISIONAL - DRAFT NOTICE OF FINAL RULEMAKING**[Billing Code 6450-01-P]****DEPARTMENT OF ENERGY****Office of Civilian Radioactive Waste Management****10 CFR Parts 960 and 963****RIN No. 1901-AA72****[Docket No. RW-RM-99-963]****General Guidelines for the Recommendation of Sites for Nuclear Waste Repositories;****Yucca Mountain Site Suitability Guidelines****AGENCY: Office of Civilian Radioactive Waste Management, Department of Energy
(DOE)****ACTION: Notice of Final Rulemaking****SUMMARY: DOE hereby amends the policies under the Nuclear Waste Policy Act of 1982 for evaluating the suitability of Yucca Mountain, Nevada, as a site for development of a nuclear waste repository. Today's revised rule focuses on the criteria and methodology to be used for**

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evaluating relevant geological and other related aspects of the Yucca Mountain site. Consistent with longstanding policy to conform DOE regulations regarding its nuclear waste repository program to comparable regulations of the Nuclear Regulatory Commission, DOE's criteria and methodology are based on the Nuclear Regulatory Commission's recently revised regulations for licensing a nuclear waste repository at Yucca Mountain.

FOR FURTHER INFORMATION CONTACT: Dr. William J. Boyle or Dr. Jane

Summerson, U.S. Department of Energy, Office of Civilian Radioactive Waste Management,

Yucca Mountain Site Characterization Office, P.O. Box 30307, North Las Vegas, Nevada 89036-0307.

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I. Introduction

Pursuant to the Nuclear Waste Policy Act of 1982, as amended, (NWPA), (42 U.S.C. 10101, *et seq.*), DOE today concludes a rulemaking which accomplishes two major purposes: (1) revision of 10 CFR part 960 ("General Guidelines for the Recommendation of Sites for Nuclear Waste Repositories"); and (2) promulgation of new part 963 ("Yucca Mountain Site Suitability Guidelines"). The NWPA provides for a multi-stage siting process including preliminary site screening, site characterization, DOE site recommendation to the President, and Presidential approval of a site for the location of nuclear waste repositories. As originally promulgated in 1984, part 960 governed DOE activities for comparing and selecting sites from preliminary site screening to site recommendation. As revised, part 960, is now limited to preliminary site screening to identify candidates for site characterization activities (i.e., physical site investigation activities). Consistent with 1987 amendments to the NWPA, part 963 deals with the criteria for determining the suitability of the potential site at Yucca Mountain, Nevada, based on site characterization activities, as part of the material that will be considered by the Secretary in any site recommendation to the President.

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DOE began this rulemaking by publishing a notice of proposed rulemaking on December 16, 1996 (61 FR 66158). That notice attracted critical comments from members of the public, State and local officials of Nevada, the U.S. Environmental Protection Agency (EPA), and the U.S. Nuclear Waste Technical Review Board (NWTRB). In substance, some comments criticized the omission from the proposed regulations of essential details of the criteria for determining site suitability. Other comments questioned the legal basis for the proposal, disputing DOE's interpretation of sections 112 and 113 of the NWPA. They also disputed the scientific and technical basis for the proposed regulations.

On November 30, 1999, DOE published a supplemental notice of proposed rulemaking that revised the terms of, and the legal and technical basis for, amending its site suitability criteria to tailor them, as required by law, to the conditions at Yucca Mountain (64 FR 67054). In explaining its reasons for reproposing, DOE acknowledged there was enough merit in the comments on its 1996 proposal to warrant issuance of a revised and more detailed proposal with an expanded explanation of the legal and technical basis for the proposal. DOE also relied on the implications of its December, 1998, "Viability Assessment of a Repository at Yucca Mountain" (DOE/RW-0508) (Viability Assessment) and of the U.S. Nuclear Regulatory Commission's (NRC's) 1999 notice of proposed regulatory amendments to limit its general licensing regulations in 10 CFR part 60 by excluding the Yucca Mountain site and to promulgate a new part 63 to establish licensing regulations exclusively for the Yucca Mountain site. On [insert date of publication of NRC final rule], the NRC published the final part 63 which does not differ from proposed part 63 in any way that materially affects this rulemaking.

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In the introductory section of the Supplementary Information portion of the November 30, 1999, supplemental notice of proposed rulemaking, DOE stated that it was seeking to improve its policies for determining site suitability based on site characterization activities by enhancing their transparency, validity, and verifiability. By enhancing transparency, DOE means providing informative and readable regulations, an explanation of the legal and technical basis for the regulatory amendments, and explanations of complex calculations and computer modeling that are suitable for non-technical audiences. By enhancing validity, DOE means providing an explanation of basis and purpose that clearly shows how the regulatory conclusions followed from DOE's legal and technical premises. By enhancing verifiability, DOE means being forthcoming about documented empirical results of experiments and computer analyses of relevant data sufficient to warrant conclusions that DOE may eventually draw from known facts in a supporting statement for a site recommendation to the President under section 114 of the NWPA.

In response to the supplemental notice of proposed rulemaking, DOE received a variety of written and oral comments from state and local officials of Nevada, other Federal agencies, industry sources, regulatory and oversight organizations, Native American organizations, and assorted private citizens and citizen groups. While supportive of much of the content of the proposed regulations, industry sources argued that the NWPA did not require this rulemaking and the opportunity it provided for state and local officials and other members of the public to have an impact on DOE's policymaking process. Although some Nevada local officials supported some features of the supplemental proposal, Nevada State and other local officials of

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Nevada continued to take issue with proposed regulatory provisions and the legal and technical bases for them. Especially useful were comments about appropriate arguments to help assess the validity of computer-generated performance assessment calculations, comments which provided the opportunity for DOE to underscore provisions in part 963 requiring multiple lines of argument in backup documentation (eventually to be made available for public comment) on subjects such as uncertainty, variability of parameter values, the technical basis for including or excluding certain features, events, and processes, and the capability of natural and engineered barriers to isolate radioactive waste.

DOE has provided responses below to the relevant major issues that emerged from the comments. These responses appear after sections that substantially repeat portions of the supplemental notice of proposed rulemaking stating the background, basis, and purpose of the supplemental proposal. (These sections are repeated to assist readers who otherwise would have to look back at a copy of the supplemental notice of proposed rulemaking.)

II. Background

This section provides an overview of the developments which have led DOE to propose to revise certain sections of the existing General Guidelines for the Recommendation of Sites for Nuclear Waste Repositories and to adopt a new rule governing the site suitability criteria for the Yucca Mountain site.

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A. *Enactment of the Nuclear Waste Policy Act of 1982*

1. Development of the Nuclear Waste Policy Act

The NWPA was enacted to provide for the siting, construction, and operation of repositories for which there is a reasonable assurance that the public and the environment will be adequately protected from the hazards posed by spent nuclear fuel and high-level radioactive waste (hereinafter referred to as “spent fuel” or “high-level waste” or both). The NWPA established the Federal responsibility and defined Federal policy for the disposal of spent fuel and high-level waste. Because this waste remains radioactive for many thousands of years, Congress recognized that disposal involved many complex and novel technical and societal issues. To develop an appropriate framework for the resolution of these issues, several years of intense legislative effort were required before a political consensus emerged to support enactment of the NWPA.

To meet the well-recognized reluctance of communities to host such facilities, the NWPA included a national site selection process that was designed to ensure fairness and objectivity in the identification of potential candidate sites for a repository. To ensure that the DOE would consider only candidate sites that had good potential for being licensed by the NRC, the NWPA required the DOE to obtain NRC concurrence on the DOE’s General Siting Guidelines. And to ensure that the regulatory requirements for a repository would be set independently of any responsibility assigned to the DOE to develop that repository, the EPA was authorized to

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promulgate generally applicable standards for the protection of the environment. The NRC was authorized to establish repository licensing requirements and criteria, although these requirements and criteria could not be inconsistent with any relevant public health standards promulgated by the EPA.

2. Overview of the Nuclear Waste Policy Act

As originally enacted in 1982, the NWPA set forth requirements for selecting sites for the disposal of spent fuel and high-level waste in a geological repository (42 U.S.C. 10101, *et seq.*). Several stages were established for the evaluation of potential sites, and these stages were defined in section 112, Recommendation of Candidate Sites for Site Characterization; section 113, Site Characterization; and section 114, Site Approval and Construction Authorization.

Section 112 of the NWPA addresses the initial stage of the site selection process, and includes four distinct steps: (1) DOE preliminary site screening (42 U.S.C. 10132(a)); (2) DOE nomination of at least five sites as suitable for characterization (42 U.S.C. 10132(b)(1)(A)); (3) DOE recommendation to the President of three of the five nominated sites as candidates for characterization (42 U.S.C. 10132(b)(1)(B)); and (4) Presidential approval of nominated sites for characterization (42 U.S.C. 10132(c)). Specifically, section 112(a) directs the DOE to issue General Guidelines for the recommendation of candidate sites for repositories, and to use the Guidelines in considering sites for site characterization. Section 112 directed DOE to consult with several federal agencies and obtain NRC concurrence on these Guidelines.

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Under section 112(a), DOE was required to specify in the Guidelines: (1) detailed geologic considerations that were to be the primary criteria for the selection of sites for characterization in various geologic media; (2) certain factors (e.g., hydrology, geophysics, seismic activity) that would either qualify or disqualify a site from characterization; and (3) population density and distribution factors that would disqualify any site for characterization (42 U.S.C. 10132(a)). Section 112(a) also required DOE to include certain factors related to the comparative advantages among candidate sites. DOE was directed to use the Guidelines to consider candidate sites for recommendation as candidates for characterization. Section 112(a) explicitly authorized DOE to modify the Guidelines consistent with the provisions of section 112(a).

Furthermore, section 112(a) directed DOE to develop certain qualifying or disqualifying factors for the preliminary site screening stage of the site selection process. Except for population density, the specific content of the qualifying or disqualifying factors was left to DOE's discretion. Because these factors are part of the Guidelines, their specific content could be modified in accordance with the authority in section 112(a).

Section 112(b) of the NWPA addressed DOE's recommendation to the President of sites for site characterization, that is, for intensive investigation of geologically related characteristics through surface and subsurface testing, among other investigative techniques. DOE was to nominate at least five sites as suitable for characterization. Each nominated site was to be accompanied by an environmental assessment. Of the five sites, DOE was to recommend three

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to the President for characterization. Section 112(c) of the NWPA addresses the President's review and approval of candidate sites for characterization.

Section 113 of the NWPA addresses site characterization, which involves activities that could proceed only after the section 112 actions had been completed. Section 113(a) authorizes DOE to conduct site characterization activities at the sites that had been approved by the President for characterization. Section 113(b) establishes the scope of DOE's site characterization activities, and directs the publication of a general plan for these activities (42 U.S.C. 10133(b)(1)(A)). DOE is to report semiannually on its ongoing and planned site characterization activities and the information derived therefrom (42 U.S.C. 10133(b)(3)). Section 113(b) also directs DOE to include in the site characterization plan, criteria to be used to determine the suitability of a site for the location of a repository, developed pursuant to section 112(a) (42 U.S.C. 10133(b)(1)(A)(iv)). Section 113(c) establishes limits on DOE's site characterization activities and provides direction on how DOE is to proceed if at any time it determines that a site would be unsuitable for development as a repository.

Section 114 addresses site approval and construction authorization, which can only proceed as the section 113 site characterization activities near completion. Four distinct steps are defined in this section: (1) DOE recommendation of a site to the President for approval to develop as a repository (42 U.S.C. 10134(a)); (2) recommendation of a site by the President to Congress (42 U.S.C. 10134(a)(2)); (3) Congressional designation of the site (42 U.S.C. 10134(b)); and (4) conduct of a licensing proceeding by the NRC (42 U.S.C. 10134(c)). Further, under section 115, after the President recommends a site to Congress, the Governor and the

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legislature of the host State may submit a notice of disapproval. If the State disapproves, Congress must enact a resolution of siting approval in order to designate the site (42 U.S.C. 10135(b)). If the Congressional designation takes effect, DOE must submit an application to the NRC for a construction authorization (42 U.S.C. 10134(b)).

Section 114(a) provides for DOE activities necessary to prepare a recommendation to the President for Presidential approval of a site for development as a repository. These activities include public hearings in the vicinity of the site to inform residents of the area and receive their comments, and the completion of site characterization. Upon completion of these hearings and site characterization, the Secretary may decide to recommend the site to the President. A comprehensive statement of the basis for this recommendation is to accompany the recommendation, and be made available to the public (42 U.S.C. 10134(a)(1)). Section 114(b) then authorizes DOE to apply to the NRC for construction authorization, if the President recommends a site to the Congress and that recommendation is permitted to take effect. Sections 114(c)-(e) direct the NRC and DOE on certain aspects of the construction authorization process. Section 114(f) requires that a final Environmental Impact Statement (EIS) accompany the Secretary's recommendation of a site to the President.

B. DOE Promulgation of General Guidelines at 10 CFR Part 960

1. Overview of the General Guidelines

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Section 112(a) of the NWPA directed DOE to issue General Guidelines for use in considering and recommending sites for site characterization, in consultation with certain Federal agencies and interested Governors, and with the concurrence of the NRC. These General Guidelines were to be comparative in nature, as DOE was required to consider various geologic media and such considerations as proximity to where spent fuel and high-level waste were stored. The General Guidelines were also to consider non-geologic factors, such as population density and distribution, that would not be examined in site characterization. No other requirements were imposed on the issuance of these Guidelines.

DOE promulgated the section 112(a) Guidelines by notice and comment rulemaking, in addition to the consultation and concurrence process specified in the NWPA. The DOE also conducted several public meetings on the Guidelines. These additional activities, although not required by the NWPA, enabled DOE to receive comments from interested members of the public. The General Guidelines were promulgated on December 6, 1984, and codified in the Code of Federal Regulations at 10 CFR part 960, General Guidelines for the Recommendation of Sites for the Nuclear Waste Repositories. 49 Fed. Reg. 47714.

2. Structure of the General Guidelines

The Guidelines promulgated by DOE defined the basic technical requirements that candidate sites must meet, and specified how DOE would implement its site-selection process. The Guidelines were structured according to three categories: implementation guidelines, preclosure guidelines and postclosure guidelines. The implementation guidelines addressed

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general application of all the Guidelines, and established the methodology for applying the Guidelines during the various stages of the siting process: site screening and nomination, recommendation for characterization, and recommendation for repository development. The preclosure guidelines governed the siting considerations that dealt with the operation of a geologic repository before it is closed. The postclosure guidelines governed the siting considerations that dealt with the long-term behavior of a geologic repository after waste emplacement and closure.

Both the preclosure and postclosure guidelines were organized under general categories of interest, for example, geohydrology and geochemistry. Each category was further divided into system guidelines and corresponding technical guidelines. The system guidelines addressed broad requirements for a geologic repository under preclosure and postclosure conditions; the corresponding technical guidelines specified conditions that would qualify or disqualify a site, and conditions that would be considered favorable or potentially adverse. 49 FR 47724. In effect, the technical guidelines and the associated qualifying and disqualifying conditions imposed specific "subsystem" performance requirements; each subsystem requirement would be used to evaluate the merits of a site, independent of the other requirements.

Section 112 of the NWPA described the minimum steps that DOE was to take during site screening and prior to site characterization. When promulgating the Guidelines in 1984, DOE determined that application of the Guidelines should extend beyond preliminary site screening to encompass site characterization activities and site recommendation to the President. Appendix III to the Guidelines explained how certain of the Guidelines would be applied at the principal

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decision points of the siting process: (1) identification of a site as being potentially acceptable under section 112(b); (2) nomination and recommendation of sites as suitable for characterization under sections 112(b) and (c); and (3) recommendation of a site for development as a repository (sections 113 and 114). 49 FR 47729-47730. With respect to the third decision point, which would be reached only after completion of site characterization activities and non-geologic data gathering activities, DOE did not promulgate separate guidelines. Instead, DOE indicated that the preclosure and postclosure guidelines would be applied to this decision, and appropriate findings issued, in the manner prescribed in Appendix III. Appendix III specified the types of findings that were to be issued from the application of the disqualifying and the qualifying conditions at each of the three decision points. The types of findings corresponded with the level of confidence required to make a finding; that is, a lower level finding required one degree of confidence in the finding, and a higher level finding required an increased level of confidence in the finding over the lower level. 49 FR 47728-47729. Appendix III included a table summarizing the level of the finding required at each of the three decision points.

Appendix III represents the analytical process DOE would follow to issue findings relative to the disqualifying and qualifying conditions of a site, and use in its decision-making on site selection. This analytical process dictates a higher-level of confidence in the findings of qualifying or disqualifying conditions at the last stage of the siting process, site selection for repository development, compared to the initial stage of the siting process, site nomination for site characterization. DOE anticipated that the higher-level of confidence in its technical findings would be obtained through the site characterization process undertaken at the later stages of the selection process.

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3. Bases for the Structure of the General Guidelines

The structure and development of the Guidelines were based on four primary sources of information and considerations: (1) the direction in the NWPA, as originally enacted; (2) the extant understanding of geologic disposal in the scientific and technical community; (3) applicable regulations proposed by the NRC and the EPA governing the disposal of spent nuclear fuel and high-level radioactive waste in geologic repositories; and (4) public comments.

DOE initiated the rulemaking process by assembling a task force of program experts. 49 FR 47718. The task force developed draft Guidelines based on criteria used earlier in the National Waste Terminal Storage Program, including program objectives, system performance criteria, and site performance criteria. At the time, the task force reviewed other criteria defined for geologic repositories by the National Academy of Sciences and the International Atomic Energy Agency.

The task force also sought consistency with NRC regulations and proposed EPA regulations related to geologic repositories. 49 FR 47718. NRC is the statutory agency responsible for licensing the construction and operation of a geologic repository; EPA is the statutory agency responsible for setting public health and safety standards for a geologic repository. Consistency of the DOE Guidelines with these regulatory standards was essential, since any potential site would be evaluated based on its ability to meet applicable regulatory requirements. 49 FR 47721.

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In sum, the structure and content of the Guidelines was based on the state of knowledge in the late-1970s and early-1980s in the regulatory community, as well as the national and international scientific community, regarding the development of geologic repositories.

DOE sought and received extensive public comments on a draft of the Guidelines before submitting them to the NRC for concurrence. On February 7, 1983, the proposed Guidelines were published in the *Federal Register* (48 FR 5670) for public review and comment. In addition, DOE published a separate notice soliciting comment from the Governors of the six States with potentially acceptable sites, and then met individually with officials from each of these States. DOE also held a series of regional public hearings. After considering the comments received, DOE drafted a set of alternate guidelines to address the comments. The alternate guidelines and public comments were made available in a second notice on June 7, 1983 (48 FR 26441), followed by a second public comment period. Further regional meetings and consultations with Federal agencies were held before DOE submitted the Guidelines to NRC for concurrence on November 22, 1983. 49 FR 47718-47719.

4. Consistency with NRC Technical and Procedural Conditions

Of particular importance to DOE's formulation of the Guidelines was consistency with NRC licensing regulations for the disposal of waste in a geologic repository. 49 FR 47718. In June 1983, NRC amended its licensing regulations at 10 CFR part 60 with respect to subpart E, technical criteria addressing siting, design and performance objectives of a geologic repository. 48 FR 28194. NRC concurred in the Guidelines subject to conditions that would satisfy the

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overall need to maintain consistency between NRC regulations and the DOE Guidelines. Among the NRC conditions were: (1) DOE clarifications and deletions of certain limiting terms such as “permanent” and “significant”; (2) DOE modifications for consistency with NRC criteria regarding anticipated processes and events, potentially adverse conditions, and the role of engineered barriers during the process for screening candidate sites for characterization; and (3) DOE revisions and additions to disqualifying conditions to ensure that unacceptable sites would be eliminated as early as practicable. 49 FR 47719-47722.

NRC concurrence conditions also addressed general, procedural aspects of how the DOE was to apply the Guidelines. For example, NRC concurrence was conditioned on a lack of conflict between NRC regulations at 10 CFR part 60 and the Guidelines, recognition by DOE that NRC regulations were controlling in the event of any differences, and a commitment that DOE would obtain NRC concurrence on any future revisions to the Guidelines. 49 FR 47719-47720. NRC also requested DOE to specify in greater detail how the Guidelines would be applied at each siting stage. This specificity was provided by the addition of Appendix III to the Guidelines. Appendix III indicated how the Guidelines would be applied at all of the site selection stages, including the recommendations to the President for site characterization and for the development of a site as a repository.

The NRC required additional changes after it met publicly with representatives of several interested states, Indian tribes, and DOE. After DOE committed to making those changes, the NRC voted to concur in the Guidelines. 49 FR 47720. Thus, the current Guidelines represent the substantial input provided by the NRC in 1984 through the statutory concurrence process.

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C. DOE Application of the Guidelines

Consistent with section 112(b) of the NWPA, DOE applied the Guidelines to: (1) nominate five sites as suitable for characterization; and (2) recommend to the President three of those five nominated sites for characterization as candidate sites for the first repository. On May 27, 1986, the President approved each of the sites that had been recommended for characterization. Yucca Mountain was one of the three sites that DOE recommended. The recommendation to the President was documented in a DOE report, *Recommendation by the Secretary of Energy for Site Characterization for the First Radioactive-Waste Repository* (May 1986; DOE/S-0048). In addition, a draft environmental assessment was prepared for each of the five sites and final environmental assessments were prepared for each of the three sites that were recommended.

This action concluded the process that had been established by the NWPA for identifying sites for characterization. The Guidelines' role of structuring DOE's process for identifying sites for characterization was completed in accordance with the Congressional directives to DOE. Under DOE's formulation of the Guidelines at that time, however, the Guidelines would remain relevant and applicable through the third principal siting decision point, the selection of a site to be recommended for the development of a repository.

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D. 1987 Amendments to NWPA

In 1987, Congress amended the NWPA to mandate Yucca Mountain as the sole site to be characterized (42 U.S.C. 10172 (Supp. V 1987)). The processes for site characterization under section 113 and site approval under section 114 were made applicable to only Yucca Mountain. Under sections 113(a) and (b), Yucca Mountain was designated as the site for which site characterization activities would take place, and a site characterization plan would be issued, respectively. Under section 113(c), Congress amended the statute to name Yucca Mountain as the site for which the restrictions on site characterization activities would be applicable. That is, DOE was directed to conduct only such activities at Yucca Mountain that are necessary to evaluate the suitability of the site for an application to the NRC for a construction authorization, and to comply with requirements under the National Environmental Policy Act (NEPA). Section 114 was amended to restrict DOE's analysis of alternative sites in any environmental impact statement (EIS) that may be prepared for the Yucca Mountain site under NEPA. Any such EIS would analyze the Yucca Mountain site, and no other sites, for potential development of a geologic repository. Further, section 160(b) directed DOE to "terminate all site specific activities (other than reclamation activities) at all candidate sites, other than the Yucca Mountain site." (42 U.S.C. 10172(a)(2)).

In sum, Congress made clear its intent for DOE to focus its resources on investigating only Yucca Mountain as a potential site for a high-level radioactive waste repository.

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E. *Yucca Mountain Site Characterization Plan*

1. Statutory Requirements

Under sections 113 and 160 of the NWPA, as amended, DOE was authorized to conduct site characterization activities at the Yucca Mountain site. Prior to initiating site characterization under section 113, DOE was required to prepare a general plan for site characterization activities at the Yucca Mountain site. DOE was required to submit the plan to the NRC and the State of Nevada for their review and comment (42 U.S.C. 10133(b)(1)), as well as to members of the public in the vicinity of Yucca Mountain (42 U.S.C. 10133(b)(2)). Certain contents of the plan were mandated by section 113(b), including, among other things, a description of planned excavation and other testing activities, a description of the possible form or packaging of the high-level waste, and the criteria to be used to determine the suitability of the site for the location of a repository, developed pursuant to section 112(a). Section 113(b)(3) also required DOE to report every six months on the progress of site characterization activities at Yucca Mountain, and to provide the reports to the NRC, and the Governor and the legislature of the State of Nevada.

DOE prepared the site characterization plan in draft form in January 1988. In preparing the plan, DOE generally followed NRC guidance, as specified in the document, *Standard Format and Content of Site Characterization Plans for High Level Waste Geologic Repositories*, Regulatory Guide 4.17 (NRC 1987). After review and comment by NRC, the State of Nevada, and interested members of the public, DOE finalized the *Site Characterization Plan: Yucca*

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Mountain Site, Nevada Research and Development Area, Nevada (December 1988; DOE/RW-0198) (hereinafter also the SCP), in December 1988.

2. Structure of the Site Characterization Plan

“Site characterization” is defined in the NWPA to include research activities undertaken to establish the geologic condition of a site, for example, borings and surface excavations, and *in situ* testing necessary to evaluate the suitability of a candidate site for the location of a repository (42 U.S.C. 10101(21)). In the SCP, DOE described the purpose of its site characterization program at Yucca Mountain was to obtain the information necessary to determine whether or not the site is suitable for a repository, and could satisfy NRC licensing requirements (which must be consistent with EPA public health and safety standards). DOE also explained there that the information obtained from site characterization, such as the geologic, geoengineering, hydrologic, and climatological conditions at a site, would be used to develop and optimize repository design and to evaluate the performance of the site and the engineered barriers as an integrated system.

The purpose of the SCP was threefold: (1) to describe the site, and the preliminary designs for the repository and the waste packages in sufficient detail to form the basis for the site characterization program; (2) identify issues to be resolved during site characterization and present the strategy for resolving the issues; and (3) describe the plans for the work needed to obtain the information deemed necessary and to resolve outstanding issues. The SCP was

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organized along two lines: (1) an issues hierarchy, which embodies the DOE, NRC and EPA regulations governing the repository system; and (2) an issue-resolution strategy.

The issues hierarchy was a three-tiered framework laying out what must be known before the Yucca Mountain site could be selected and licensed. “Issues” were defined as questions related to performance of the repository that must be resolved to demonstrate compliance with applicable regulations of DOE, NRC and EPA. DOE identified four key issues to be addressed, based on regulatory requirements and the four system guidelines in part 960: 1) postclosure performance; 2) preclosure performance; 3) environment, socioeconomic, and transportation impacts of a repository; and 4) ease and cost of repository siting, construction, operation and closure. DOE also explained that only the first, second, and part of the fourth key issue would be addressed in the site characterization program, since resolution of these other key issues (that is, key issue 3 and part of key issue 4) were not dependent on information from site characterization activities. The issue-resolution strategy consisted of four parts: issue identification, performance allocation, data collection and analysis, and documentation of issue resolution. This framework was used to develop test programs and explain why the test programs were adequate and necessary. The object was to collect information to be used in a concluding set of analyses to resolve the issues, and to document resolution of the issues.

As required by section 113(b)(1)(A)(iv), the SCP included criteria to determine the suitability of the site for development of a repository. Those “criteria” were the provisions within the Guidelines pertinent to site characterization activities, namely, the postclosure guidelines, and the preclosure guidelines related to radiological safety and technical feasibility of

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repository siting, construction and operation, to be applied in the manner described in Appendix III. Appendix III set out the level of findings DOE must make relative to the system and technical requirements found in the postclosure guidelines (subpart C) and preclosure guidelines (subpart D) at the final decision point of recommending a site for development as a repository. DOE believed that the information gained through site characterization and the issue resolution process would form the basis for these findings.

DOE also explained in the SCP that not all of the Guidelines would be addressed as part of site characterization activities. The SCP would not address the environmental, socioeconomic and transportation guidelines, or certain guidelines related to ease and cost of repository siting, construction, operation, and closure, since DOE would not develop information related to those guidelines through site characterization activities. Those Guidelines would be addressed in other investigations and plans to be conducted concurrently with the site characterization program. Also, in light of the 1987 amendments to the NWSA permitting site characterization to proceed only at Yucca Mountain, DOE stated in the SCP that the comparative portions of the Guidelines would not be applied in the site suitability determination to be made under section 113(b).

In accordance with section 113(b)(3), approximately every six months DOE issues a report updating information on the conduct of site characterization activities at the Yucca Mountain site. Those reports briefly summarize the characterization activities undertaken at the site, the technical and scientific issues of key interest and their resolution, and issues that remain for further characterization and resolution. In addition, the semiannual reports provide references and a bibliography of other reports and documents containing more detailed information

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regarding site characterization activities. DOE provides the reports to the NRC, the Governor of Nevada, and the legislature of the State of Nevada.

The progress reports reflect DOE's ongoing interaction with the NRC. In July 1986, the NRC amended its regulations at 10 CFR Part 60 (51 FR 27158) to establish the method of interaction between DOE and the NRC on the development and implementation of the site characterization plan. NRC established a system for DOE to report on the results of site characterization, identify issues, plan for additional studies, eliminate planned studies no longer necessary, and identify decision points reached. In this manner, the NRC established a clear pathway to interact with DOE in the management and direction of the site characterization program.

Site characterization activities have continued up to and including the present, and are described in greater detail below in section II.G.

F. Energy Policy Act of 1992

In 1992, Congress enacted certain provisions in the Energy Policy Act of 1992 (Pub. L. No. 102-486) impacting the nation's nuclear waste repository program. In section 801(a) of the Energy Policy Act of 1992 (EPACT), Congress directed EPA to promulgate a new, health-based standard to ensure protection of the public health from high-level radioactive waste that may be disposed in a geologic repository located at Yucca Mountain. The new standards could depart from the generic EPA standards promulgated at 40 CFR part 191, and would be specific to Yucca

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Mountain. In section 801(b), Congress also directed the NRC, within one year of EPA adopting a new standard, to modify its technical requirements and criteria under section 121(b) of the NWPA (42 U.S.C. 10141(b)) (i.e., 10 CFR part 60), as necessary, to be consistent with the new EPA standards.

Before setting the new standard, however, EPA was required to contract with the National Academy of Sciences (NAS) to conduct a study to provide findings and recommendations on reasonable standards for protection of the public health and safety. Under section 801(a) of the EPACT, EPA was required to promulgate its new standards based on, and consistent with, the NAS findings and recommendations. Under the EPACT and accompanying congressional instruction, NAS's charge was to answer three specific questions embodied in section 801(a)(2), and to advise EPA on the technical basis for the health-based standards it was mandated to prepare. The three questions posed in section 801(a)(2) addressed: (1) whether or not a health-based standard based on doses to individual members of the public would provide a reasonable basis for protecting public health and safety; (2) whether or not it is reasonable to assume that a system for postclosure oversight of the repository, using active institutional controls, will prevent an unreasonable risk of breaching the repository's engineered or natural barriers, or of increasing the exposure of individual members of the public to radiation beyond allowable limits; and (3) whether or not it is possible to make scientifically supportable predictions of the probability that the repository's engineered or natural barriers will be breached as a result of human intrusion over a period of 10,000 years.

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In August 1995, NAS published the statutorily mandated report, entitled *Technical Bases for Yucca Mountain Standards*. In sum, NAS issued findings that: (1) a health standard for Yucca Mountain based on risk to individuals of adverse health effects from releases from the repository (rather than EPA's generic standards) which contain both individual dose and release limits) was an appropriate standard that would adequately protect the health and safety of the general public; (2) it is not reasonable to assume that a system for postclosure oversight can be developed, based on active institutional controls, which will itself prevent an unreasonable risk of breaching the repository's engineered barriers or of increasing the exposure of individual members of the public to radiation beyond allowable limits; and (3) it is not possible to make scientifically supportable predictions of the probability that a repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years.

Notwithstanding the latter two findings, the NAS recommended EPA include in its regulations a stylized human intrusion event. The NAS reasoned that such an analysis may provide useful insight into the degree to which the ability of a repository to protect the public health and safety would be degraded by an intrusion.

In reaching its findings and recommendations, the NAS consulted with numerous entities, including local, state and federal government agencies, private organizations, and scientists and engineers, both national and international, familiar with the technical issues under study, and held five open technical meetings to ensure a thorough review of the scientific literature on the subject. In the *Technical Bases for Yucca Mountain Standards*, the NAS provides a detailed explanation of the assumptions and analyses underlying the study, and the reasons for NAS's findings and recommendations. Among the more important of these is the NAS assumption,

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confirmed by its technical review, that it is possible to conduct scientifically justifiable analyses of repository behavior over thousands of years in order to assess whether or not a repository can comply with the applicable public health standard. In addition, based on its analyses, the NAS concluded that the proper way to evaluate the risks of adverse health effects, and to compare those risks to the proposed standard, is to assess the estimated potential future behavior of the entire repository system and its potential effect on humans. The procedure used to perform this analysis is called performance assessment (alternately called total system performance assessment).

In discussing the possible implications of its conclusions, the NAS noted that, if EPA issues standards based on individual risk (as recommended by the NAS), then the NRC would be required to revise its regulations embodied in 10 CFR part 60 to be consistent with EPA. This is because NRC's 10 CFR part 60 is directed in part to subsystem technical requirements, whereas the NAS concluded that it is the performance of the total system, rather than that of its individual elements in isolation, that is crucial in the context of a risk-based standard. Under a risk-based standard, imposing subsystem performance requirements might result in a deficient repository design even if each subsystem element meets or exceeds a certain performance standard. The NAS also observed that its recommendations, if adopted, implied the development by EPA of different regulatory and analytical approaches those employed in the past, and that the process of establishing the new standards would require significant time and opportunity for public comment and review. Nevertheless, NAS noted that these potential changes should not impede site characterization work by DOE at Yucca Mountain.

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At present, EPA is in the process of preparing new standards pursuant to EPACT and in light of the NAS findings and recommendations. Those new standards have been proposed in a rulemaking proceeding for public review and comment. Also consistent with EPACT, section 801(b), the NRC has proposed new regulations governing the technical requirements and criteria for licensing a potential geologic repository at the Yucca Mountain site based on the NAS findings and recommendations and in anticipation of new EPA standards. The EPA's and NRC's proposed regulations are discussed in greater detail below, in section II.J, and II. K, respectively.

G. Evolution of the Site Characterization Program

Since publication of the SCP in 1988, DOE's site characterization program at Yucca Mountain has made substantial progress in developing information and data about the site and resolving outstanding technical issues. Over time, the site characterization program has evolved and been driven by advances in science and technology, as well as legislative and managerial changes. The following summarizes the evolution and status of the site characterization program.

Technical Components of the Site Characterization Program. The three main technical components of the site characterization program are testing, design, and performance assessment. Testing encompasses the investigation of natural features and processes at the site through field testing, conducted above and below ground, and laboratory testing of rock and water samples. Design refers to work on development of the description of a repository and waste packages

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tailored to the site features, supported by laboratory testing of candidate materials for waste packages and design-related testing in the underground tunnels similar to those in which waste would be emplaced. Performance assessment refers to the quantitative estimates of the performance of the total repository system, over a range of possible conditions and for different repository configurations, by means of computer modeling techniques that are based on site and materials testing data and accepted principles of physics and chemistry.

Through the testing program, DOE has learned a great deal about the geologic conditions of the site. The single largest effort undertaken in this regard has been construction of the Exploratory Studies Facility (ESF). Construction of this facility began in 1992 and was completed in 1998. The ESF, a 4.9 mile long underground tunnel, has enabled DOE to conduct testing and exploration activities at the depth of the proposed repository. Utilization of this facility has formed the basis for increased knowledge and understanding of the mechanical and hydrologic characteristics of the geologic formation in which the repository would be constructed. Ongoing work at this facility will focus primarily on thermal and hydrologic testing in the cross drift to extend and, where necessary, modify this understanding of the properties of the host rock.

The design component of the site characterization program comprises those activities aimed at developing concepts for the engineered components of the geologic repository. Design activities use information about the site gained through the testing program, and information about the engineered barrier system gained through other scientific investigations, to generate and develop design concepts that can meet the requirements placed on the engineered

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components of the repository. Site characterization activities are structured to acquire data needed to support the design. For example, a number of the site characterization program tests focus on the hydrological, geomechanical and thermal properties of Yucca Mountain. These tests are significant because they provide the fundamental information needed to specify the approach to be used in developing the geologic repository thermal loading and underground support schemes. Also, under the design program, DOE examines various approaches to meeting engineered facility requirements, and conducts comparative evaluations of the costs and benefits of different approaches to developing design concepts. The performance assessment component of site characterization represents the analytical method (i.e., computer modeling) DOE uses to forecast the performance of the repository within the Yucca Mountain setting and assess that performance against regulatory standards. Put in simplified terms, performance assessment uses the information and data collected under the testing and design programs to feed computer models that describe how the site would behave in the presence of a repository and how the engineered system would behave within the environmental setting of the mountain. Each model, called a process model, is designed to describe the behavior of individual and coupled physical and chemical processes. A total system performance assessment (TSPA) links the results of individual process models to construct a computer model of the repository system and surrounding environment that are important to assessment of overall repository performance. With the TSPA model, DOE can estimate releases of radionuclides from a repository under a range of conditions, over thousands of years, and forecast the consequent probable doses to persons.

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Performance assessment (or TSPA), as described above, is an accepted method to assess the performance of a repository at Yucca Mountain. DOE's use of performance assessment models began even before issuance of the SCP in 1988. Since that time, however, significant advancements have been made in the technical capability, acceptance, and use of this analytical tool. In 1991, the Nuclear Energy Agency Radioactive Waste Management Committee and the International Atomic Energy Agency International Radioactive Waste Management Advisory Committee confirmed that TSPA provides an adequate means to evaluate long-term radiological impacts of a waste disposal system. On a national level, the NRC, the NAS and the Nuclear Waste Technical Review Board ("NWTRB") (a Congressionally mandated committee of experts chartered to evaluate the technical and scientific validity of activities undertaken by DOE to characterize Yucca Mountain to determine its suitability as a location for a repository) have acknowledged the value of this method for evaluating postclosure performance for a repository at Yucca Mountain.

A significant portion of the DOE site characterization program has been aimed at developing the scientific bases that serve as the foundation for the process models used in performance assessment. DOE developed performance assessment models and conducted benchmark performance assessments of the total repository system in 1991, 1993 and 1995. Between these benchmark assessments, DOE conducted many performance assessments to evaluate selected features of the site and the evolving design. DOE used these total system and subsystem performance assessments to evaluate design options and to determine further data needed from site investigations. The most recent TSPA was conducted in 1998, the results of which are contained in the Viability Assessment.

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Redirection of the Site Characterization Program. In 1994, DOE conducted extensive internal and external reviews of the program. As a result of those reviews, documented in the *Civilian Radioactive Waste Management Program Plan* (December 1994; DOE/RW-0458) (Program Plan), DOE identified cost-cutting measures to reduce the cost of completing site characterization. In response to Congressional concern with the 1994 Program Plan, DOE submitted a revised Program Plan to Congress that was designed to maintain scientific investigations at the site, and retain target dates for determining site suitability and recommendation for construction authorization. *Civilian Radioactive Waste Management Program Plan, Revision 1* (May 1996; DOE/RW-0458). As part of the revised strategy, DOE redirected project efforts to address the major unresolved technical questions and to complete an assessment of the viability of licensing and constructing a repository at Yucca Mountain. Congress indicated its approval of the revised Program Plan in the Conference Report on the Energy and Water Development Appropriations Act, 1997, H.R. Rep. No. 782, 104th Cong., 2d Sess. 82 (1996), by directing that the appropriated funds be used in accordance with the revised Program Plan issued by DOE in May 1996.

In the Fiscal Year 1997 Energy and Water Development Appropriations Act (Pub. L. No. 104-206), Congress directed DOE to provide the viability assessment of the Yucca Mountain site, referenced in DOE's revised Program Plan, to Congress and the President as a basis for making future decisions on program funding and direction. DOE issued the Viability Assessment in December 1998. Drawing on 15 years of scientific investigation and design work, the Viability Assessment summarizes a large technical basis of field investigations, laboratory tests, models, analyses and engineering. The Viability Assessment also identifies major

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uncertainties relevant to the technical defensibility of DOE's analyses and designs, the approach to managing these uncertainties, and the status of work relative to the target dates of 2001 for a determination on recommendation of Yucca Mountain and 2002 for submittal of a license application to NRC. The Viability Assessment also includes the most recent iteration of the TSPA, and the results of that process.

Coordination with NRC. DOE's implementation of its site characterization program and the issue resolution strategy embodied in the SCP has been conducted in close coordination with the NRC. In 1995, the NRC revised its prelicensing repository program as a result of changes in the DOE civilian radioactive waste management program, the findings of a NAS committee recommending changes to the public health standard for a potential Yucca Mountain repository, and budgetary constraints imposed by Congress. The NRC adjusted the scope of its program to focus only on those topics most critical to repository performance, termed "key technical issues." These issues were intended to be a vehicle to communicate to DOE those technical matters for which the NRC had remaining unanswered questions regarding the performance of the Yucca Mountain site, or the data needed to assess that performance. DOE's management of the site characterization program includes activities to obtain information to address the NRC key technical issues. DOE has structured the site characterization program such that one of its goals is for DOE and NRC to reach consensus that the remaining key technical issues have been addressed adequately, or that adequate plans are in place to address the issues.

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H. *The 1993-1995 Public Dialogue on the Guidelines*

In the SCP, issued in December 1988, DOE described how it would apply the Guidelines as part of the site characterization program to evaluate the suitability of the site. DOE indicated in the SCP that the Guidelines related to site characterization activities would be applied as the suitability criteria. DOE also indicated there that the comparative provisions of those requirements would not be applied in light of the 1987 amendments to the NWPA limiting site characterization activities to Yucca Mountain. Notwithstanding this explanation, a number of interested parties suggested it remained unclear how DOE would apply the Guidelines in the future. Because of this continuing stated uncertainty, the DOE instituted an ongoing dialogue with external parties on the Guidelines.

In October 1993, DOE briefed the representatives of the affected units of local government and the State of Nevada on its plans for activities related to site suitability evaluation. DOE followed this briefing with a Notice of Inquiry in the *Federal Register* (59 FR 19680), dated April 25, 1994, eliciting the views of the public on the appropriate role of the Guidelines. A public meeting was held on May 21, 1994 in Las Vegas, Nevada. The purposes of the meeting were to follow-up on a previous public meeting held in August 1993; to update the public on site characterization activities; and to provide an opportunity to discuss the development of a process to evaluate site suitability. DOE then published a second *Federal Register* notice (59 FR 39766) on August 4, 1994, announcing that it intended to use the Guidelines as currently written, subject to the programmatic reconfiguration directed in the 1987 NWPA amendments. Through that notice, DOE also announced the availability of a draft

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description of the proposed process and its intention to hold two additional public meetings to discuss the matter. Although several options were discussed, DOE discerned no clearly preferred option from this public comment process. In response to public comments at the meetings, DOE committed to provide background information and its rationale for maintaining the use of the Guidelines as originally promulgated, with modification to eliminate application of the comparative portions of the Guidelines. In September 1995, DOE published in the *Federal Register* the background information and its rationale, as committed to in previous public meetings. 60 FR 47737.

In the September 1995 public notice, DOE explained that amending the Guidelines, either to remove those portions that are primarily used for comparative purposes or to develop Guidelines tailored to evaluation of the suitability of the Yucca Mountain site, was not required at that time. DOE recognized then that the Guidelines might have to be amended at some future date to be consistent with any changes to EPA or NRC requirements. 60 FR 47740. Among the options considered in the 1993-1995 public dialogue was abandonment of the Guidelines and adoption of the NRC siting criteria in 10 CFR 60.122. DOE noted that the Guidelines were expressly derived from, and are tied to, the part 60 siting criteria. In addition, DOE noted that, should any differences between 10 CFR part 960 and 10 CFR part 60 be identified, 10 CFR part 60 would prevail in the licensing process. While recognizing that much of 10 CFR 960 subpart B, the implementation guidelines, was no longer applicable, DOE concluded that the Guidelines could be selectively interpreted to avoid the comparative aspects while applying the relevant provisions of subparts C and D, the postclosure and preclosure guidelines.

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I. *The 1996 Notice of Proposed Rulemaking*

For many of the reasons described earlier in this notice, including changes in congressional direction of the repository program and advancements in site characterization, on December 16, 1996, DOE published in the *Federal Register* a notice of proposed rulemaking for 10 CFR part 960. 61 FR 66158. In that notice, DOE proposed to clarify and focus the Guidelines and to add a new, site-specific subpart E to the Guidelines. Subpart E would apply only to the Yucca Mountain site, and would contain preclosure and postclosure system guidelines, each with a single qualifying condition. 61 FR 66163. In each of the periods, the qualifying condition would be that a repository at Yucca Mountain be capable of limiting radiological releases within applicable standards to be set by EPA and implemented by the NRC through the repository licensing process. DOE would demonstrate this capability through performance assessments. 61 FR 66164. These performance assessments would forecast the performance of a proposed geologic repository at Yucca Mountain and compare the results of the assessments to the applicable regulatory standards to determine whether or not the site would be suitable for development as a repository.

The 1996 proposal was consistent with the system-level evaluation originally envisioned for the conclusion of site characterization. DOE recognized in 1984 in the Guidelines that, only after the entire process of narrowing the number of potentially acceptable sites to one and after site characterization, would it be possible to conduct complete performance assessments. Such assessments require detailed information that can be obtained only during site characterization.

49 FR 47717. In addition, the 1996 proposal was consistent with DOE's longstanding position

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that the Guidelines must complement and not conflict with EPA and NRC regulations, since the ability to meet applicable public health and safety standards and develop information adequate to support a license application has always been central to the site suitability determination.

The 1996 proposal attracted a wide variety of comments from members of the public, the NRC, the EPA, and the Nuclear Waste Technical Review Board. The major issues that emerged from the public comment process were discussed in detail in the Supplementary Information to the supplemental notice of proposed rulemaking, issued on November 30, 1999 (discussed below at section L).

J. Proposed NRC Regulation, 10 CFR Part 63

1. Background

On February 22, 1999, the NRC published in the *Federal Register* a proposed new rule, 10 CFR part 63, containing licensing criteria for disposal of spent nuclear fuel and high-level radioactive waste in the proposed geologic repository at Yucca Mountain, along with proposed revisions to 10 CFR part 60 and other related regulations. 64 FR 8640. The proposed licensing criteria at part 63 would apply exclusively to Yucca Mountain; part 60 would be revised to make it applicable to any geologic repository other than one at Yucca Mountain. NRC's proposal seeks to establish a new system of risk-informed, performance-based regulation. Under this approach, risk insights, engineering analysis and judgment, and performance history are used to:

(1) focus attention on the most important activities; (2) establish objective criteria based upon

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risk insights for evaluating performance; (3) develop measurable or calculable parameters for monitoring system and licensee performance; (4) provide flexibility to determine how performance criteria are met; and (5) focus on results as the primary basis for regulatory decision-making. 64 FR 8643.

The NRC's rationale for proposing part 63 stems from the requirements of the EPACT. 64 FR 8641-8643. Section 801(b) of EPACT requires that, within one year after EPA promulgates its new standards for protection of public health and safety, the NRC must modify its technical requirements and criteria for repository licensing (i.e., part 60) to be consistent with the new EPA standards. In addition, the EPACT requires NRC to include in its modifications, consistent with the NAS findings and recommendations, certain assumptions that are specified in the EPACT with regard to the effectiveness of DOE's postclosure oversight of the repository.

The NAS issued its findings and recommendations in the report, *Technical Bases for Yucca Mountain Standards*, August 1995. The NAS findings and recommendations reported there, along with consultation NRC has had with EPA, provide the basis for NRC's proposed modifications. 64 FR 8641, 8643. The NAS recommended approach to setting a public health and safety standard has a different objective from the NRC approach reflected in the existing part 60 requirements and criteria. 64 FR 8643. Accordingly, the modifications proposed by the NRC, based on the NAS report, and the subsequently proposed EPA rule marked a change in methodology and licensing philosophy.

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2. Structure of Proposed Part 63

Preclosure Requirements. Proposed part 63 would require DOE to demonstrate compliance with the applicable preclosure regulatory standards by the use of an integrated safety analysis. 64 FR 8652. An integrated safety analysis is a systematic examination of the geologic repository operations area's hazards and their potential for initiating events (for example, accidents), the potential consequences of the events, and the site, structures, systems, components, equipment and activities of personnel. The analysis would be conducted to ensure that all relevant hazards that could result in unacceptable consequences have been adequately evaluated and appropriate protective measures have been identified. "Integrated" means joint consideration of safety measures that otherwise might conflict, including such measures as fire protection, radiation safety, criticality safety, and chemical safety. The results of the analysis would be used to support a finding of compliance with a performance objective for the preclosure period of limiting radiation exposures and releases within a dose limit of 25 millirem (mrem) to any member of the public beyond the site boundary.

Postclosure Requirements. While certain parts of proposed part 63 are similar to part 60, in particular with respect to many procedural and administrative regulations, the substance of the regulations governing postclosure performance objectives is fundamentally different. The part 60 technical criteria for postclosure rely on several quantitative, *subsystem* performance objectives. In 1983-4, NRC believed this approach was best suited to meet its statutory requirement under section 121(b)(1)(B) of the NWPA to prescribe criteria that would involve use of a system of multiple barriers in the design of the repository. 64 FR 8648. At the time part 60

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was written, NRC's technical opinion was that compliance with this requirement could be best demonstrated by specifying subsystem technical requirements, thereby assuring multiple, independent and redundant systems and barriers. Given advancements in technical understanding and analytical capability, and information acquired through site-characterization at Yucca Mountain, the NRC no longer believes this approach is an optimal and reliable approach to assure compliance with public health and safety standards. 64 FR 8648-8649.

Part 63 does not contain subsystem performance requirements, or analogs for those requirements, as found in part 60. The part 63 requirements are based on only one quantitative standard -- demonstrating compliance with an individual dose limit. The part 63 technical criteria are compatible with the NRC's philosophy of risk-informed, performance-based regulation. This approach is consistent with NAS recommendations that would require compliance with a health-based standard established in consideration of risk to a hypothetical critical group as the only quantitative standard for postclosure repository performance. 64 FR 8643. The *NRC concept of critical group* means the hypothetical group of individuals reasonably expected to receive the greatest exposure to radioactive materials potentially released from a geologic repository at Yucca Mountain. The EPA proposes in its rule (described in section II. K) the use of a *reasonably maximally exposed individual* (RMEI). The RMEI is a hypothetical individual having certain characteristics that include where the RMEI lives, what the RMEI's diet would consist of and the amount of water consumed by the RMEI on daily basis. For the purposes of this proposed rule, the term receptor is used in lieu of either the EPA or NRC concept. A receptor is intended to represent a member of the public, either an individual or group, that could be exposed to releases of radiation from a repository at Yucca Mountain.

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When the suitability determination is made, DOE would implement the regulatory concept applicable at that time.

This approach is also consistent with NRC's obligation to ensure a multiple barrier system by requiring DOE to demonstrate that the natural barriers and the engineered barriers will work in combination to enhance overall performance of the repository.

Part 63 would require DOE to demonstrate compliance with the applicable postclosure regulatory standard by the use of performance assessment. 64 FR 8650. Performance assessment is a systematic analysis that identifies the features, events, and processes that might affect performance of the geologic repository, examines their effects on performance, and estimates the resulting expected annual dose. Demonstrating compliance with the postclosure performance of 10 CFR part 63 would require a performance assessment to quantitatively estimate the expected annual dose, over the compliance period, to the average member of the critical group. The critical group would be a hypothetical group of individuals reasonably expected to receive the greatest exposure to radioactive materials released from the geologic repository. Consistent with the EPACT and the 1995 NAS report, the NRC proposed that the results of the performance assessment be the sole quantitative measure used to demonstrate compliance with the individual dose limit. 64 FR 8650.

Because of the importance of the performance assessment, part 63 is structured to establish certain minimum requirements governing the content and validation methods for the performance assessment. 64 FR 8650-8651. For example, DOE would be required to include in

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the performance assessment data related to the geology, hydrology and geochemistry of Yucca Mountain, as well as data related to the design of the engineered barrier system; to account for uncertainties and variabilities in the data used to model performance of the repository; to provide the technical basis for either inclusion or exclusion of specific features, events, and processes of the geologic setting; and to provide the technical basis for the models used in the overall performance assessment by providing, for example, comparisons of the output of detailed process-level models and empirical observations. In addition, part 63 would prescribe the characteristics of the reference biosphere and receptor to be used in the performance assessment. DOE also would be required to conduct a separate performance assessment based on a limited human intrusion scenario prescribed by the NRC.

K. Proposed EPA Regulation, 40 CFR Part 197

1. Background

On August 27, 1999, the EPA published in the *Federal Register* a proposed new rule, 40 CFR part 197, to establish public health and safety standards governing the storage and disposal of spent nuclear fuel and high level waste in a potential repository at Yucca Mountain, Nevada. 64 FR 46975. EPA is promulgating this rulemaking pursuant to section 801(a) of the EPACT. As explained earlier in this preamble (section I.F.), in section 801(a)(1) of the EPACT Congress directed EPA to promulgate a health-based standard for the protection of the public from releases from radioactive materials stored or disposed of in a repository at the Yucca Mountain site. Also

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under EPACT, Congress directed that the EPA standard was to be the only standard applicable to the Yucca Mountain site, and that the EPA standard must be based upon and consistent with NAS' findings and recommendations.

As directed by Congress in the EPACT, it is EPA's role to establish the public health and safety standard, and NRC's role to implement that standard in any licensing process NRC may conduct for a repository at Yucca Mountain. It is anticipated that NRC would conform its proposed licensing regulation at 10 CFR part 63 to the final EPA radiation protection standards, as necessary and appropriate.

2. Structure of Proposed part 197

The proposed EPA rule is structured in two parts. Part A of the rule would establish the environmental standards for storage of spent nuclear fuel and high level waste at Yucca Mountain; part B would establish the environmental standards for disposal of spent nuclear fuel and high level waste at Yucca Mountain. The following is an overview of the main components of EPA's proposed rule; in many areas of the rule EPA has proposed alternative language and requirements for public review and consideration. For simplicity, not all of those alternative considerations will be presented here.

For storage of spent nuclear fuel and high level waste, EPA proposes a standard limiting the annual committed effective dose equivalent (CEDE) to no more than 15 millirems to any

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member of the public in the general environment. This limit would apply to releases from the combination of management and storage of spent nuclear fuel and high level waste that is within the Yucca Mountain repository (below ground) and outside the Yucca Mountain repository but within the Yucca Mountain site (aboveground). EPA proposes this standard to be consistent with the risk level set in its generic standards for management and storage of spent nuclear fuel, high level waste, and transuranic waste, codified at subpart A of 40 CFR 191 and with its interpretation of section 801 of EPACT requiring it to set site-specific standards for storage of waste at Yucca Mountain. In EPA's view, storage of waste, whether inside the Yucca Mountain repository or outside the Yucca Mountain repository but within the Yucca Mountain site, presents the same technical situation and is analogous to the storage of radioactive waste at other facilities covered by 40 CFR part 191. Accordingly, EPA proposes the storage standard for Yucca Mountain be essentially the same as the standard applicable to other facilities subject to subpart A of 40 CFR part 191.

For disposal of spent nuclear fuel and high level waste, EPA proposes essentially three standards -- an individual protection standard, a human intrusion standard, and a ground water standard -- that DOE would need to demonstrate to the satisfaction of the NRC to ensure protection of public health and safety. Under the individual protection standard, DOE would be required to demonstrate that there is a reasonable expectation that for 10,000 years following disposal the reasonably maximally exposed individual (RMEI) receives no more than an annual committed effective dose equivalent (CEDE) of 15 millirems (mrem) from releases from the undisturbed Yucca Mountain disposal system. All potential pathways must be included in this analysis. In proposing this individual protection standard, EPA concluded that radiation release

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limits, such as those embodied in 40 CFR part 191, were not necessary in order to protect members of the general public from releases from a repository at Yucca Mountain.

For the proposed human intrusion standard, EPA proposes two alternative rules, one of which would impose a CEDE limit of 15 mrem to a RMEI based on an assumed human intrusion event, while the alternative rule would impose the dose limit if complete waste package penetration can be shown to occur before 10,000 years after disposal. EPA also proposes a rule outlining the elements of the human intrusion scenario to be used in the analysis.

Under the proposed ground water protection standard, EPA would require DOE to provide in its license application a reasonable expectation that for 10,000 years of undisturbed performance after disposal, releases of radionuclides from radioactive material in the Yucca Mountain disposal system will not cause the level of radioactivity in the representative volume of ground water at the point of compliance to exceed certain limits (e.g., combined beta and photon emitting radionuclides cannot exceed a limit of 4 millirems per year to the whole body or any organ). EPA presents for public review and comment several alternatives for the selection of the representative volume of water and for the location of the point of compliance.

EPA's proposed approach to setting public health and safety standards for a repository at Yucca Mountain follows the NAS recommendations and findings, and the regulatory approach proposed by the NRC in its proposed licensing regulations. Although EPA has proposed some requirements in its rulemaking that differ from certain NAS findings and recommendations and NRC's proposed licensing regulations, (for example, EPA proposes use of a dose standard

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instead of a risk standard, and use of the RMEI concept instead of critical group), EPA's proposed rule is consistent with the primary NAS findings and recommendations that a public health standard based on risk or dose to an individual member of the public can be protective of general public health and safety, and that the Yucca Mountain-related physical and geologic processes are sufficiently quantifiable and the related uncertainties sufficiently boundable that the performance can be assessed over certain time frames.

In the case of the individual protection standard, EPA would expressly require DOE to use performance assessment to calculate the dose limits established in its proposed radiation protection standards for disposal. Although EPA generally would not prescribe requirements on how the performance assessments would be conducted, it would impose certain limitations. For example, proposed section 197.40 would limit consideration by DOE in its performance assessments of events that are estimated to have less than one chance in 10,000 of occurring within 10,000 years of disposal. In addition, EPA, similar to the NRC, acknowledges certain inherent limitations in DOE's ability to demonstrate compliance with the public health and safety standard through use of performance assessment, but nevertheless mandates the use of that method of assessment. EPA's rule recognizes, through the concept of reasonable expectation, that, among other things, there are inherent uncertainties in making long-term projections of the performance of the Yucca Mountain disposal system, that performance assessments and analyses should be focused upon the full range of defensible and reasonable parameter distributions, and that assessments should not exclude important parameters simply because they are difficult to precisely quantify to a high degree of confidence.

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L. *The 1999 Notice of Proposed Rulemaking*

On November 30, 1999, DOE published a revised notice of proposed rulemaking (64 FR 67054) in order to revise its December 16, 1996, proposal (61 FR 66158) to amend 10 CFR part 960, the "General Guidelines for the Recommendation of Sites for Nuclear Waste Repositories" and to issue proposed Yucca Mountain Site Suitability Guidelines under a new part 963.

In its December 16, 1996, proposal, DOE published proposed regulatory amendments to the Guidelines to reflect the prevailing scientific view on how to evaluate the suitability of the Yucca Mountain site for the development of a nuclear waste repository. Because the preliminary site screening stage was complete and Congress has required DOE to focus on Yucca Mountain, Nevada, DOE's proposed regulatory amendments dealt with provisions of the Guidelines applicable to the site recommendation stage. In its November 30, 1999, revised proposal, DOE revised the terms of its proposal for three reasons.

First, during the comment period on the December 16, 1996, proposal, DOE received comments from members of the public, State and local officials of Nevada, the EPA, and the NWTRB, that in substance criticized the omission from the proposed regulatory amendments of the essential details of the criteria and methodology for evaluating the suitability of the Yucca Mountain site for the location of a nuclear waste repository. Some of the comments made pointed recommendations for Guidelines at a more definitive level of specificity than the proposed regulatory text provided. Also, there were comments critical of the legal basis for DOE's proposal and its consistency with what those commenters viewed as DOE's past position

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on the meaning of sections 112(a) and 113(b) of the Act. As explained in detail later in this notice, DOE concluded that there was enough merit in these comments to warrant revision of the proposed regulatory amendments and expansion of the explanation of the factual and legal bases for them.

Second, in December, 1998, DOE issued, pursuant to Congressional direction, the Viability Assessment. This document, which is available through the Internet on the web site (www.ymp.gov) or in hard copy upon request (see above, Further Information) sets forth the bases for the site suitability criteria DOE is proposing to use and the methodology for applying the criteria to a design for a proposed repository at the Yucca Mountain site. DOE can now assist commenters in responding to DOE's proposal with appropriate descriptions of, and references to, key portions of the Viability Assessment in the Supplementary Information.

Third, after the close of the comment period, the NRC, consistent with Congressional direction to the EPA to develop a site-specific radiation protection standard for the Yucca Mountain site, proposed to issue site-specific licensing requirements for that site in a new 10 CFR part 63 and to eliminate the site from coverage under 10 CFR part 60. Thereafter, EPA issued the Congressionally-mandated proposal for site-specific public health and safety standards for a repository at Yucca Mountain, to be codified at 40 CFR part 197. Section 113(c) of the NWPA provides that a determination of site suitability for development as a repository is largely an estimate that an application to the NRC for a construction authorization would be successful (42 U.S.C. 10133(c)). Thus, the details of the EPA and NRC proposals, which were not available when DOE formulated its December 16, 1996, proposal, affect the continuing

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usefulness of existing 10 CFR part 960, the text of DOE's proposed regulatory amendments, and the bases for those amendments in performing the analysis required by section 113. For reasons explained in detail in its 1999 revised proposal, DOE presented the view that the proposed part 63, if finalized without significant change, would make it illogical to apply the existing provisions of 10 CFR part 960, which are explicitly linked to provisions of the NRC's part 60. Moreover, the details of the NRC's proposal suggested the need for making conforming changes to the December 16, 1996, proposal to set forth the requirements for carrying out a total system performance assessment as the method for applying the site suitability criteria to the data developed during site characterization of the Yucca Mountain site.

Consistent with EPA's proposal for site-specific public health standards and NRC's proposal to limit part 60 and to establish a new part 63 for the Yucca Mountain site, DOE proposed regulations to: (1) limit 10 CFR part 960 to preliminary site screening for repositories located elsewhere than Yucca Mountain; and (2) establish a new part 963 to contain the site suitability criteria and the methods for considering the potential of the Yucca Mountain site for a nuclear waste repository under those criteria. The proposed suitability criteria and methods were to provide a link between the geologic considerations identified in section 112(a) of the NWSA as primary criteria for siting a repository, and the current scientific understanding of site characteristics and related processes that are important to assessing the performance and safety of a potential geologic repository at the Yucca Mountain site. Although closely linked to the NRC's proposed part 63 licensing criteria and requirements, as is necessary and appropriate, DOE's proposed regulations in part 963 were not the equivalent of a determination that the site necessarily will meet all requirements to obtain a license from the NRC, or to be recommended

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by the Secretary for development as a geologic repository. Rather, DOE issued the proposed rule to better define its policies and criteria for determining the suitability of the Yucca Mountain site only in terms of, and based on, the information and data developed through the program of site characterization activities DOE has conducted over the years at Yucca Mountain under section 113(b) of the NWPA.

In issuing the revised notice, DOE sought to improve its policies for determining site suitability by enhancing their *transparency, validity, and verifiability*. In terms of enhancing *transparency*, DOE aimed at regulations that are easier to read and understand. In terms of enhancing *validity*, DOE aimed at an explanation of the legal and scientific basis for the regulations that shows how DOE's policies logically follow from scientifically supportable and legally sound premises. In terms of enhancing *verifiability*, DOE aimed at showing that the scientific conclusions underlying its policies are based on documented empirical results of experiments, and computer analyses of relevant data sufficient to warrant the conclusions DOE may eventually draw from known facts in a supporting statement for site recommendation to the President.

DOE followed the consultation procedures set forth in section 112(a) of the NWPA for promulgation of the Guidelines in seeking review and comment on this revised proposal.

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III. Basis for Final Rule

A. *Legal Authority and Necessity to Amend the Guidelines and Criteria*

1. Overview

Section 112(a) of the NWPA explicitly establishes DOE authority to "issue general guidelines for the recommendation of sites for repositories" and to "use [the] guidelines established under this subsection in considering candidate sites for recommendation under subsection (b)." Subsection (b) of section 112 provides for a process, to be conducted following promulgation of the Guidelines that would result in: (1) the nomination of 5 potential sites for characterization; and (2) the selection of 3 of those 5 sites for recommendation to the President as suitable for site characterization activities. Section 112(a) also includes explicit authority to revise the Guidelines, from time to time, consistent with the provisions of 112(a).

Shortly after the enactment of the NWPA, DOE promulgated the Guidelines (codified at 10 CFR part 960) to implement section 112. The approach taken at that time was to structure the Guidelines to provide a framework not only for the section 112 decisions (for which it was statutorily required) but also for subsequent steps in the site selection process. Consistent with this view, the Guidelines as originally promulgated also addressed actions to be taken under sections 113 and 114. The rationale permitting that approach was the provision in section 113(b) that DOE include in its site characterization plan "criteria to be used to determine the suitability of [a] site for the location of a repository, developed pursuant to section 112(a)." 49 FR 47730.

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DOE reasoned that, since the site characterization plan was to be an element supporting any Secretarial recommendation of one site for development under section 114, the Guidelines were “intended to be used in deciding which among the characterized sites is to be recommended to the President, the Congress, and finally to the NRC for appropriate approvals.” 49 FR 47730. That approach was understandable in 1984 when DOE anticipated the need to evaluate by comparison multiple characterized sites, a comparison similar to the choosing of sites for characterization for which the Guidelines were required by section 112(a) of the NWPA. After the 1987 amendments to the NWPA designated Yucca Mountain as the only site to be characterized, DOE chose to apply some, but not all, of the Guideline provisions in the Site Characterization Plan prepared under section 113(b) of the NWPA as criteria to determine site suitability. DOE/RW-0199 (1988). In 1995, DOE reconsidered the Guidelines in the context of evaluating the suitability of the Yucca Mountain site under the Site Characterization Plan. DOE decided then that “[b]ecause DOE need apply only the relevant provisions” of the Guidelines, amending or supplanting them with “Guidelines specifically tailored” to evaluating the suitability of the Yucca Mountain site was “not required at this time.” 60 FR 47737, 47740 (1995).

As discussed in greater detail below, DOE now has determined that a new approach is called for in light of the cumulative effect of the intervening legislative, regulatory, and technical developments that have occurred since 1984. DOE now proposes to develop criteria, using section 112(a) in the development of the criteria, but not adopting the particular section 112(a) Guidelines as those criteria, to form the basis for a determination of the suitability of the Yucca Mountain site for the location of a repository. The rationale for this approach stems from the basic analysis recommended by the National Academy of Sciences, which differed from that

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embedded in the 1984 Guidelines, and the advent of new regulations proposed by the NRC that, under the NWPA's structure, must define the areas and methodology of DOE's inquiries into Yucca Mountain's suitability.

Accordingly, DOE today issues final revisions to the existing Guidelines at 10 CFR part 960 to limit their application to only the initial site selection process set forth in section 112. DOE may make additional revisions to the Guidelines if, in the future, circumstances were to change and DOE were to reinstate a preliminary site screening process under section 112. Further, DOE today promulgates a new rule, consistent with section 113(b)(1)(A)(iv), to establish criteria to be used to determine the suitability of Yucca Mountain for the location of a geologic repository. The criteria identified in this new rule are based on the geologic factors and considerations referenced in section 112(a), as they relate to DOE's current scientific understanding and methodology for assessing the suitability of the Yucca Mountain site as a location for a repository.

2. Section 112

DOE's approach in today's final rule is grounded on the text of section 112(a) and the basic structure of the NWPA, as originally enacted and as amended. As originally enacted, the NWPA set up a sequential process for selecting, comparing, and evaluating potential sites for the development of a geologic repository for high-level waste. The 1987 amendments eliminated any continued comparison of sites; only Yucca Mountain is authorized for site characterization activities leading to possible recommendation as a repository site. Beyond the first step in the

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process, recommendation of multiple sites for site characterization (section 112), there is no explicit direction in the Act (in its original enactment or amendment) whether or how to utilize the Section 112(a) Guidelines in the succeeding site selection processes (sections 113 and 114). Instead, section 112(a) specifies the intended use of the Guidelines: “[t]he Secretary shall use guidelines established under this subsection in considering sites to be recommended for site characterization under section 112(b).” Likewise, the environmental assessment of the various sites nominated for characterization pursuant to section 112 is to include “evaluation” of each nominated site under each Guideline not requiring characterization for its application and all the Guidelines pertinent to whether or not a site is “suitable for site characterization” (42 U.S.C. 10132(b)(1)(D)(I)&(ii)). Nowhere in its text does section 112 require any additional use of the Guidelines.

In sum, the text of section 112 and its relation to other provisions in the NWPA indicate that the Guidelines are to govern the process of selecting and comparing among potential sites to determine which sites are appropriate to proceed to the next, more detailed evaluation stage, site characterization. In contrast, nothing in the text of section 112 specifies that the Guidelines are also to govern the process for determining site suitability and site recommendation under sections 113 and 114.

3. Section 113

Section 113 of the NWPA requires DOE to prepare a site characterization plan for a candidate site selected under section 112 for site characterization activities. A required element

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of a site characterization plan is “*criteria* to be used to determine the suitability of such candidate site for the location of a repository, *developed pursuant to section 112(a)*” (42 U.S.C.

10133(b)(1)(A)(iv) (emphasis added)). The NWPA does not define the term “criteria.” The NWPA does, however, define the term “site characterization” as activities “undertaken to establish the geologic condition” of a candidate site (42 U.S.C. 10101(21)(B)). This definition indicates that the required scope of the general site characterization plan and therefore of the section 113(b) “criteria” is limited to geologic and related considerations. This reading of section 113(b) is reinforced by the provisions of section 112(a) in which the only usage of the term “criteria” in that section are the “primary criteria” that are explicitly equated to “geological considerations.”

Section 113(b) requires that the “criteria” to be included in the Site Characterization Plan be “developed pursuant to section 112(a)” of the NWPA. Because section 112(a) of the NWPA is devoted to the “Guidelines” for selecting candidate sites while section 113(b) is devoted to the “criteria” under which selected candidate sites subsequently are to be characterized, it is necessary to consider how the Guidelines are required to relate to the criteria by section 113's requirement that the criteria be “developed pursuant to section 112(a).”

It is unlikely that the Congress intended to require the “criteria” to be the Guidelines themselves. It would have been simple enough for Congress to have legislated that policy in section 113(b) by a straightforward requirement that the Site Characterization Plan specify that the “Guidelines developed pursuant to section 112(a)” would be used “to determine the suitability of each candidate site” (Compare 42 U.S.C. 10133(b)(1)(A)(iv)). Had Congress

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intended this policy result it is unlikely that it would have chosen such an elliptical and opaque way of expressing it as the actual statutory text that does not use the term “Guidelines” at all. And a construction of section 113(b) requiring the suitability “criteria” to be the same as the section 112 Guidelines would risk tension with section 113(c)’s restriction that limits DOE to conducting “only” characterization activities “necessary to provide the data required” to prepare an NRC license application. The NRC, of course, is not required to base its licensing standards on the Guidelines adopted by DOE under section 112(a) of the NWPA (although it was required to concur in them), nor does section 112 afford the NRC the ability to compel DOE to reformulate the Guidelines should the NRC determine to amend or supplant its licensing standards.

Section 112(a) contains specific procedural mandates required to be employed by DOE in issuing or revising the Guidelines. Before DOE may promulgate the Guidelines, DOE must consult with several specified federal agencies and with “interested Governors” (42 U.S.C. 10132(a)). In addition, the NRC must “concur[]” in the issuance of the Guidelines. *Id.* These distinctive procedural requirements obviously are tailored to the particular circumstances of site decision-making under the NWPA and therefore specify procedural requirements that would not otherwise obtain under the rulemaking provisions of the Administrative Procedure Act or the rulemaking provisions of the Department of Energy Organization Act that were in force when the NWPA was adopted.

The requirement of section 113(b) that the SCP’s “criteria” for characterizing sites be “developed pursuant to section 112(a)” therefore is best understood as mandating observance of

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the special procedural requirements of section 112(a) in formulating or altering the section 113(b) “criteria.” This understanding of the statutory text seems the most faithful to its explicit terms and the larger statutory context in which it occurs. Moreover, it seems the only understanding of section 113(b) that is consistent with the 1987 changes to the NWPA (which mandated exclusive characterization work for the Yucca Mountain site without amending section 113(b) despite amending the statute elsewhere to remove the element of comparing sites, to which the Guidelines of section 112(a) were devoted). This understanding of the requirements of section 113(b) also comports with DOE’s prior understanding, as was described in the 1995 notice, that not all the original Guideline elements need be applied in site characterization under section 113 of the NWPA.

B. Events Necessitating Amendment of the Guidelines and Criteria

1. Congressional Redirection of the Program

Since the NWPA was enacted in 1982 and the Guidelines promulgated in 1984, Congress has made major changes to the framework for developing a geologic repository. Those changes are described below and, in part, form the basis for the revisions to 10 CFR part 960 and the promulgation of a new 10 CFR part 963 as presented in this notice.

1987 Amendments to the NWPA. Congress amended the NWPA in 1987 to select Yucca Mountain as the only site to be characterized. In support of that decision, Congress directed DOE to terminate site-specific activities at the two other sites that had been recommended for

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site characterization in 1986 (42 U.S.C. 10172). Further, Congress restricted DOE's characterization activities at Yucca Mountain to only those the Secretary considers necessary to provide the data required for evaluation of the suitability of the site for NRC construction authorization (i.e., license application), and for compliance with the National Environmental Policy Act of 1969. A provision was added to the NWPA to provide for termination of site characterization activities at Yucca Mountain if at any time the Secretary determines that Yucca Mountain is unsuitable for development as a repository.

Although the 1987 amendments to the Act were decisive in focusing the repository program and DOE's efforts on one specific site, for many years DOE maintained that these changes were not so significant as to warrant amendment of the Guidelines. Instead, DOE believed the Guidelines, for the most part, could be applied to Yucca Mountain for purposes of determining the suitability of the site (because Yucca Mountain already had been found suitable for characterization under other provisions of the Guidelines) in support of a possible site recommendation by the Secretary. The only changes to the Guidelines necessitated by the 1987 amendments were to eliminate consideration of those parts of the Guidelines related to comparative analysis. Similarly, the NRC had not made significant modifications to its technical requirements and criteria in 10 CFR part 60 as a result of the 1987 amendments to the Act.

1992 Energy Policy Act. In the 1992 Energy Policy Act, Congress reinforced its intent that Yucca Mountain was the exclusive focus of the nation's repository program, not only for DOE, but also for the other federal agencies, EPA and NRC, with authority and responsibility over the repository program. Section 801 of the EPACT directed the EPA to promulgate, by

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rule, new public health and safety standards for the protection of the public from releases from radioactive materials stored or disposed of in a repository at the Yucca Mountain site. Unlike the previous standard, which was generic to geologic repositories and included limits on radioactive releases to the environment, the new standards were required to prescribe maximum annual radioactive dose limits to individual members of the public based on releases to the accessible environment from materials stored or disposed of at Yucca Mountain. To aid EPA in this process, Congress directed a National Academy of Sciences (NAS) study to provide findings and recommendations on reasonable standards for protection of the public health and safety. EPA was required to base its new rule on the findings and recommendations of the NAS. For Yucca Mountain, these standards would replace the generally applicable standards for the protection of the general environment that the EPA had promulgated at 40 CFR part 191 under the authority of section 121 of the NWPA.

The EPACT also directed the NRC to modify its technical requirements and criteria, as necessary, to be consistent with the EPA's new standards. In addition, NRC was directed to ensure that, consistent with the NAS findings and recommendations, its requirements and criteria for postclosure oversight of a Yucca Mountain repository would be sufficient to prevent any activities at the site posing an unreasonable risk of breaching the engineered and natural barriers of the site, and to prevent any increase in exposure of individual members of the public beyond allowable limits.

These changes were significant because they set the stage for future regulatory changes governing the standards a Yucca Mountain repository must meet to ensure public health and

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safety, and to obtain a license for construction. The ability to meet regulatory standards has always been a dominant factor in the site selection process. This requirement is reflected in the structure of the Guidelines, is reinforced by the 1987 amendments to the Act, and is a prime focus of DOE's site characterization program. Thus, the Congressional mandate in the EPACT directing new and revised regulations governing geologic disposal at Yucca Mountain necessarily impacts DOE's formulation of the criteria that will be used to determine the suitability of Yucca Mountain as a site for development of a repository. Until recently, however, the full extent and nature of those impacts have not been defined. The NRC's recent proposal to amend 10 CFR part 60, its technical requirements and criteria for licensing a repository, to add a new part 63 specific to Yucca Mountain, provides DOE with an outline of anticipated regulatory changes, and signals for DOE how and why it must conform its Guidelines and criteria for determining the suitability of the Yucca Mountain site for the location of a repository.

Fiscal Years 1996 and 1997 Appropriations Acts and the Viability Assessment. Finally, in response to budgetary concerns, the Conference Report on the Energy and Water Development Appropriations Act, 1996 (Pub. L. No. 104-46) (H.R. Rep. No. 293, 104th Cong., 1st Sess. 68 (1995)) directed the DOE to focus on only those activities necessary to assess the performance of a repository at the Yucca Mountain site and to collect the scientific information needed to determine the site's suitability. DOE responded by revising its Program Plan for 1996 in which it indicated that, among other changes, DOE would complete a viability assessment of the Yucca Mountain site in 1998, and would develop a proposal to amend the Guidelines and develop new regulations specific to the Yucca Mountain site. Congress indicated its approval of the changes by directing that appropriated funds be used in accordance with the revised program plan.

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Congress reinforced this direction in the Fiscal Year 1997 Energy and Water Appropriations Act, where it mandated that DOE provide to the Congress and the President a viability assessment of the Yucca Mountain site in 1998.

These changes in budget for DOE's civilian radioactive waste management program indicate congressional intent for DOE to focus site characterization activities on assessing the viability and suitability of Yucca Mountain, and to complete those activities in the near term. In light of this congressional direction, it is reasonable for DOE to amend the Guidelines in a manner that acknowledges Yucca Mountain as the only site at which site characterization has occurred and for which DOE would need to conduct a suitability evaluation under section 113(b).

2. Consistency Between DOE and NRC Regulations

Procedural Consistency. The DOE's site characterization suitability criteria must be consistent with the NRC's licensing criteria if the DOE is to present a potentially successful license application to the NRC. Such consistency originally was attained in the Guidelines through the NRC's concurrence process, as required by section 112(a) of the NWPA. DOE will preserve this consistency in these final suitability criteria by ensuring that they reflect the changes to the licensing criteria that recently have been proposed by the NRC in a new rule to be codified at 10 CFR part 63, and by soliciting NRC concurrence on DOE's final amendments to the guidelines and the promulgation of a new regulation at 10 CFR part 963.

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Substantive Consistency. NRC's proposed new rule establishing the technical requirements and criteria for repository licensing at Yucca Mountain, proposed 10 CFR part 63, is different from its existing general rule on repository licensing, 10 CFR part 60. DOE now has little choice but to propose site suitability criteria that are consistent with the NRC's proposed licensing requirements. The suitability of a site for the location of a repository is a function of the DOE's ability to demonstrate the site can meet applicable regulatory requirements. DOE has conducted the site characterization program at Yucca Mountain with the statutory objective (42 U.S.C. 10133(c)) of demonstrating its ability to obtain construction authorization from the NRC (i.e., to meet NRC licensing requirements and EPA health and safety standards, as implemented by NRC through the license). DOE could not scientifically and technically support a suitability determination, and, hence, a license application, without conforming its criteria for suitability to the proposed NRC technical requirements and criteria for a repository license. Such conforming criteria are finalized in this notice.

The NRC proposed rule part 63 is a departure from the philosophy and technical requirements of 10 CFR part 60. The new rule would be based on the 1995 NAS report recommending a risk-limit standard for a repository at Yucca Mountain. The NRC timed publication of its proposal now to ensure NRC has sufficient time, once EPA issues its new standard, to put the new licensing standards in effect. The proposed rule embodies a new approach of risk-informed, performance-based regulation, and is specific to Yucca Mountain. The old rule relied on subsystem performance objectives and a release limit standard. Under the proposed rule, the performance of a Yucca Mountain repository would be evaluated against a health-based standard in consideration of risk to a hypothetical critical group and this standard

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would be the only quantitative standard for the postclosure performance of the repository. The new rule would require DOE to demonstrate compliance with postclosure technical criteria through performance assessments, and preclosure criteria through an integrated safety analysis. The new approach embodied in the proposed rule would eliminate current part 60 design and siting criteria, as well as quantitative subsystem requirements, but would add specific requirements for the content of performance assessments to ensure their sufficiency and adequacy. In other words, a proposed Yucca Mountain repository would be evaluated as an entire system, not by assessing its individual parts in isolation, in order to determine whether or not it meets applicable standards to protect public health and safety.

Once the proposal is finalized, the current structure of DOE's technical guidelines, which is premised on a demonstration of system and subsystem technical requirements, will no longer be consistent with, and in some cases may conflict with, the NRC technical requirements to support a license application. For example, several of DOE's technical guidelines require compliance with the siting and design requirements set forth in 10 CFR parts 60.113, 60.122 and 60.133. Those requirements would not exist in proposed part 63 and would not be applicable to Yucca Mountain under proposed amendments to part 60. Those requirements are subsystem performance requirements that are inconsistent with the NRC's new approach of evaluating the technical merits of a potential site based on the performance of the repository system as an integrated whole, and not on the performance of each part independent of the other parts.

A good example of this is the geohydrology guideline at 960.4-2-1. Under this guideline, DOE set qualifying and disqualifying conditions for the geohydrology of a site. The qualifying

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condition for geohydrology requires a site be capable of compliance with radionuclide release limits set by EPA in 40 CFR part 191, and by NRC in 10 CFR part 60.112, as well as compliance with DOE subsystem performance requirements that mirror NRC requirements in 60.113. At present, there is no applicable release limit set by EPA under 40 CFR part 191, and the NRC's proposed amendments to 10 CFR part 60 would nullify the applicability of 60.113 to Yucca Mountain and create a new part 63 for which there is no analogous release limit or subsystem performance objective for geohydrology. Accordingly, it would be illogical for DOE to reach a finding relative to this qualifying condition, as required by Appendix III, based on regulatory requirements that no longer would be applicable to the Yucca Mountain site and would not support a determination of site suitability for the Yucca Mountain site.

The DOE Guideline 960.4-2-1 also contains a disqualifying condition. Under this condition, DOE would disqualify a site if the pre-waste emplacement ground water travel time from the disturbed zone to the accessible environment is expected to be less than 1,000 years along any pathway of likely and significant radionuclide travel. Under the analogous NRC provision, 60.113, there is a performance objective directing that the pre-waste emplacement ground water travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment must be at least 1,000 years or such other travel time as approved by the NRC. Under NRC's proposed revisions to its regulations, this subsystem performance requirement would no longer apply to a repository at Yucca Mountain under part 60, and it would not exist, nor would there be any requirement similar to it, under new part 63. Accordingly, it would be illogical for DOE to reach a finding relative to this disqualifying condition, as required by Appendix III, based on regulatory requirements that no longer would be

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applicable to the Yucca Mountain site and would not support a determination of site suitability for the Yucca Mountain site.

Below is a table further illustrating the inconsistencies between the current Guidelines and the proposed part 63. Table 1 provides a cross walk between the technical guidelines to be applied as the criteria under section 113(b), their analog in existing part 60, and their analog, if any, in proposed part 63.

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Table 1

Section	Guideline	Condition	10 CFR 60	New 10 CFR 63
4-1(a)	System	Qualifying	60.112	63.113
4-2-1(a)	Geohydrology	Qualifying	60.112/113	63.113/None
4-2-1(d)	“ ”	Disqualifying	60.113(a)(2)	None
4-2-2(a)	Geochemistry	Qualifying	60.112/113	63.113/None
4-2-3(a)	Rock Characteristics	Qualifying	60.112/113	63.113/None
4-2-4(a)	Climatic Changes	Qualifying	60.112	None
4-2-5(a)	Erosion	Qualifying	60.112	None
4-2-5(d)	“ ”	Disqualifying	60.122(b)(5)	None
4-2-6(a)	Dissolution	Qualifying	60.112	None
4-2-6(d)	“ ”	Disqualifying	60.112	None
4-2-7(a)	Tectonics	Qualifying	60.112	None
4-2-7(d)	“ ”	Disqualifying	60.112	None
4-2-8(a)	Natural Resources	Qualifying	60.122(c)(1)	None
4-2-8(d)(1)	“ ”	Disqualifying	60.122(c)(1)	None
4-2-8(d)(2)	“ ”	Disqualifying	60.122(c)(1)	None
4-2-9 (a)	Site Ownership and Control	Qualifying	60.121	63.121
5-1(a)(1)	System	Qualifying	60.111	63.111
5-1(a)(3)	System	Qualifying	None	None
5-2-1(a)	Population Density and Distribution	Qualifying	60.111	63.111
5-2-1(a)(1)	“ ”	Disqualifying	60.122(6)	None
5-2-1(a)(2)	“ ”	Disqualifying	60.122(6)	None
5-2-1(a)(3)	“ ”	Disqualifying	None	None
5-2-2(a)	Site Ownership and Control	Qualifying	60.121	63.121
5-2-3(a)	Meteorology	Qualifying	60.111	63.111
5-2-4(a)	Offsite Installations and Operations	Qualifying	None	None
5-2-4(d)	“ ”	Disqualifying	None	None
5-2-8(a)	Surface Characteristics	Qualifying	60.122(c)(1)	None
5-2-9(a)	Rock Characteristics	Qualifying	60.133(a)(1)	None
5-2-9(d)	“ ”	Disqualifying	None	None
5-2-10(a)	Hydrology	Qualifying	60.111	None
5-2-10(d)	“ ”	Disqualifying	None	None
5-2-11(a)	Tectonics	Qualifying	60.122(b)(1)	None
5-2-11(d)	“ ”	Disqualifying	None	None

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As demonstrated in the above table, in most cases there is no analog between the DOE Guidelines and NRC's proposed part 63. In addition, the Guidelines could not continue to reference and rely on revised part 60, since NRC's proposed revisions to part 60 would make them inapplicable to a repository at Yucca Mountain. Under the circumstances, it would be irrational and difficult, if not impossible, for DOE to apply the Guidelines in their current form.

Under these changed circumstances, DOE must act to propose amendments to its outdated Guidelines and conform its site suitability criteria to the NRC proposed rule for licensing a Yucca Mountain repository.

3. Improvements in Analytical Methods

DOE's final changes will also serve to conform the rules for assessing the suitability of a site with the current scientific and technical methods developed and utilized by DOE in its site characterization program. The final changes in the regulatory scheme reflect the advances in the scientific and technological understanding of the processes relevant to assessing the long-term performance of a geologic repository. The regulatory revisions issued by EPA, NRC and DOE, mark a change from generic regulations based on limited information about geologic disposal developed early in the Nation's quest for sites for geologic disposal, to regulations promulgated specifically for the Yucca Mountain site that reflect over 20 years of data collection and intensive site characterization activities at the Yucca Mountain site. It would be irrational for DOE to ignore these changes, and continue to rely on technical requirements that are not aligned with, and are not supported by, the prevailing scientific knowledge and understanding.

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As recognized by the NRC in its proposed part 63, during the more than 15 years since the NRC promulgated its initial technical criteria at 10 CFR part 60 (and DOE promulgated matching technical requirements in 10 CFR part 960), there has been considerable evolution in the capability of technical methods for assessing the performance of a geologic repository at Yucca Mountain. 64 FR 8640-8641. These advances result from both improved computer capability and better analytical methods. Indeed, these changes for the first time enable the vast quantities of data that have been collected through site characterization to all be used in models that more accurately model site performance. NRC stated that these new methods were not envisioned when the part 60 criteria were established, and that their implementation allows for the use of more effective and efficient methods of analysis for evaluating conditions at Yucca Mountain than do the existing NRC generic criteria in part 60. 64 FR 8641. Moreover, NRC believes that implementation of these new analytical methods for evaluating Yucca Mountain will avoid the imposition of unnecessary, ambiguous, or potentially conflicting criteria that could result from the application of some of the generic requirements of 10 CFR part 60. 64 FR 8641.

The evolution in performance assessment methodology formed the basis for DOE's 1996 proposal to amend the Guidelines. In that proposal, DOE explained that only by assessing how specific design concepts will work within the natural system at Yucca Mountain and comparing the results of these assessments to the applicable regulatory standards, can DOE reach a meaningful conclusion regarding the site's suitability for development as a repository. The proposed amendments to the Guidelines would have required a comprehensive evaluation focused on whether or not a geologic repository at Yucca Mountain would adequately protect the public and the environment from the hazards posed by high-level radioactive waste and spent

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nuclear fuel (61 FR 66160). DOE explained that recent results in four major areas have advanced the ability to evaluate the Yucca Mountain site, and geologic disposal, to the point that a system approach is now appropriate. These four areas are: (1) analysis and integration of data collected from surface-based testing and regional studies; (2) examination of the potential repository horizon made possible by the excavation of the Exploratory Studies Facility; (3) the site-specific conceptual design of the engineered facilities; and (4) performance assessment analyses (61 FR 66161).

As with the NRC, DOE recognizes that this improved understanding now allows the reconsideration of General Guidelines that may be unnecessary or ambiguous, or that may present conflicting requirements for Yucca Mountain. Based on the DOE's accumulated knowledge, and significantly enhanced understanding, DOE has determined that a system performance approach provides the most meaningful method for evaluating whether or not the Yucca Mountain site is suitable for development as a repository. In today's final rule, DOE expands on its 1996 and 1999 proposals to modify the Guidelines and incorporates performance assessment as the appropriate approach to assess the forecasted performance of a repository, and to serve as the basis for site characterization suitability criteria. This final rule provides greater detail, comprehension and transparency of information describing the performance assessment methodology, and how it serves as a foundation for site characterization suitability criteria.

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IV. Response to Public Comments on the 1999 Proposal

DOE published the supplemental notice of proposed rulemaking on November 30, 1999 in the *Federal Register* (64 FR 67054), and posted it on the Internet that same day. The public comment period on the supplemental notice extended from the date of publication until February 28, 2000. Two public hearings were held on the supplemental notice; two sessions in Pahrump, Nevada and two sessions in Las Vegas, Nevada.

DOE received numerous comments on the supplemental notice, both oral and written, from members of the public, state and local officials, Native Americans, regulatory and oversight organizations, and representatives of various non-governmental organizations, and the nuclear power industry. Opinions about the supplemental notice were divided. Some comments were critical of DOE's conduct of this rulemaking. In particular, several commenters expressed a desire for greater dialogue on the rulemaking, additional time to review the proposed rulemaking, and frustration regarding the overlapping public comment periods on this rulemaking and DOE's draft Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, Nevada (hereafter "Yucca Mountain EIS"). DOE acknowledges the comments, questions, and concerns raised by members of the public during this rulemaking, and has considered them in preparing this notice of final rulemaking. However, DOE believes that the comment period on this rulemaking, lasting 89 days, and the comprehensive background and description of the proposed rulemaking contained in the supplemental notice, provided the public with sufficient time and information to review the supplemental notice and provide meaningful comments. In addition,

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the public hearings on this rulemaking, although they coincided with some other public hearings on the Yucca Mountain EIS outside the State of Nevada, did not deprive the public of a full and fair opportunity to comment on both proceedings. The public comment period on the Yucca Mountain EIS was initiated in July of 1999, lasted for 199 days, and included 21 public hearings, 10 of which were held within Nevada.

Several comments received by DOE did not directly address this notice of proposed rulemaking, but dealt with other aspects of DOE's civilian radioactive waste program. For example, several commenters expressed dissatisfaction with U.S. policy to dispose of spent fuel and high-level waste in a geologic repository, raised claims of limited federal authority over Yucca Mountain, criticized the nation's dependence on nuclear power, and raised concerns about the transportation of high-level waste and spent nuclear fuel to a repository. Many of these comments were similar to those raised during the public comment period on the 1996 proposal to amend the guidelines. As explained in response to public comments on the 1996 proposal, many of these comments are outside the scope of this rulemaking. While DOE acknowledges the differing public opinion on these matters of public policy, any response to those comments here would be inappropriate. Accordingly, presented below is DOE's response to the major issues emerging from the public comments and questions directly related to the supplemental notice.

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A. The statutory basis and regulatory need for part 963.

Several commenters, including representatives of the State of Nevada, asserted that DOE's legal rationale for revising the guidelines was flawed and in violation of the NWPA, and that there is no statutory or legal basis for the proposed amendments. In support of this position, many commenters noted, among other things; that section 112(a) of the NWPA directs DOE to promulgate guidelines for the recommendation of sites for a repository, not merely for site characterization; that the substantive requirements of section 112(a), such as the use of qualifying and disqualifying factors and consideration of transportation impacts, must be part of any site suitability criteria proposed by DOE; that Congress' failure to direct DOE to revise its guidelines in the 1987 Amendments Act and the 1992 Energy Policy Act is an indication that Congress did not believe the guidelines required modification; and that the intent of section 112(a) was to require DOE to evaluate sites based on geology (e.g., natural barriers), and not engineered barriers (e.g., waste package design). Several commenters also noted that it was premature to revise the guidelines since the EPA and NRC have not yet finalized their regulations regarding a repository at Yucca Mountain and that, in any event, there is no requirement that the guidelines closely conform to the EPA and NRC regulations.

DOE also received comments in support of the statutory and regulatory need for the revisions to part 960 and the establishment of Yucca Mountain specific suitability criteria. Those comments noted that the proposed revisions to the guidelines are legally appropriate and timely under the NWPA; that there is no statutory connection between the section 112(a) guideline requirements and the section 113(b) suitability criteria; that there is no need to establish site

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suitability criteria in a rulemaking proceeding; and that DOE appropriately is updating its site suitability criteria to comport with current scientific understanding and regulatory revisions proposed by the EPA and NRC.

As explained in detail in the Supplementary Information under the section entitled, "Legal Authority and Necessity to Amend the Guidelines and Criteria," DOE believes that there is a sound statutory and regulatory basis upon which to revise part 960 and promulgate part 963. DOE believes that this rulemaking effectively harmonizes the statutory language and purposes of relevant sections of the NWPA and the 1992 Energy Policy Act with the current state of scientific and technical understanding of how best to evaluate the performance of a geologic repository, and the anticipated regulatory framework governing the public health and safety and licensing of a repository at Yucca Mountain. While DOE does not believe there was any misrepresentation of the statutory language of section 112(a) of the NWPA, as some commenters asserted, minor modifications have been made in the background section of this Supplemental Information to avoid any confusion.

As previously stated, the approach DOE elected to take in 1984 to implement section 112(a) and formulate the 960 guidelines was understandable at that time, when DOE anticipated the need to evaluate, by comparison, multiple characterized sites under section 113 leading to the selection of one site under section 114, and the NRC licensing regulations were premised on a demonstration of both system and subsystem performance requirements. In the supplemental notice of proposed rulemaking and in this notice, DOE discussed in detail the numerous intervening events, of a regulatory, technical and legislative nature, that necessitated DOE's

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revision to the 960 guidelines and the proposal to add a new part 963 to establish the site suitability criteria and methodology to be used in assessing the suitability of the Yucca Mountain site.

Several commenters correctly note that Congress has not changed the language of the NWPA in section 112(a), despite opportunities for such change in the 1987 Amendments and the 1992 Energy Policy Act. Congressional silence on this point is not dispositive, however. As previously noted, there is no explicit language or direction in section 112 that requires or directs DOE to use the 112(a) guidelines as the criteria to assess the suitability of a characterized site under section 113(b). Therefore, the failure of Congress to revise section 112 has no particular bearing here. Other commenters argued that it seems specious to argue that Congress meant the 112(a) guidelines, including the requirement of qualifying and disqualifying factors, to be abandoned once a site was designated for site characterization, and that any suitability guidelines must include qualifying and disqualifying factors.

In this final rule, DOE is not abandoning the concept embodied in section 112(a) that a site should be evaluated based on such criteria as the geology, hydrology and geophysics of the site. Nor is DOE inappropriately accounting for engineered barriers in setting site suitability criteria under the NWPA. Table 2 of this Supplementary Information provides a crosswalk between the section 112(a) geologic considerations and the criteria for evaluating site suitability in part 963. In addition, section 113 directs DOE to engage in activities related to developing waste form and packaging designs and describing the relationship between the waste form and the geologic medium. Thus, those barriers are also appropriately included in the criteria for

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assessing the suitability of a repository at Yucca Mountain. As is necessary, DOE has articulated the site suitability criteria in a manner that is consistent with the technical and analytical approach in the proposed EPA and NRC regulations for a geologic repository at Yucca Mountain.

Moreover, as explained above, DOE interprets the language in section 113(b)(1)(A)(iv), referring to section 112(a) to mean that only the procedural requirements of section 112(a) should be followed in setting the criteria for site suitability under section 113(b). The inclusion of qualifying and disqualifying factors is in the nature of a substantive requirement of the guidelines promulgated under section 112(a); it is not a statutory requirement for the establishment of suitability criteria under section 113(b)(1)(A)(iv). In addition, DOE does not believe that it is reasonable or necessary to retain explicit qualifying and disqualifying conditions in the present site suitability guidelines. Such conditions do not comport with either the proposed regulatory framework established for a repository at Yucca Mountain, nor the current state of scientific and technical understanding of how best to evaluate the performance of a repository. Accordingly, DOE has established site suitability guidelines that are reasonable and fully consistent with the mandates of the NWPA.

In response to other comments regarding the allegedly premature nature of this rulemaking, DOE believes that the rulemaking is timely and not premature. Although the NRC and EPA regulations were in proposed and not final form at the issuance of the proposed rulemaking on part 963, DOE deemed it necessary and appropriate to initiate the process for promulgating this rule in advance of the finalization of the EPA and NRC regulations. It was

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necessary to initiate the rulemaking process in order to allow sufficient time to obtain public review and comment, and NRC concurrence on the rule, prior to the time of a possible DOE site recommendation currently planned for mid-2001. In addition, it was appropriate to initiate the process, since the EPA and NRC proposed regulations provided sufficient substance to enable DOE to formulate its proposed rulemaking and solicit public comment on that rulemaking. By initiating the process in this manner, DOE did not intend, nor did it preclude, the option that DOE might reopen the comment period for this rulemaking as necessary to accommodate changes from the proposed to final rules of the EPA and NRC.

Furthermore, DOE fully explained in the supplemental notice and this notice the reasons why it is necessary and reasonable for DOE to conform its suitability criteria and methodology with the NRC licensing criteria and EPA standard, in accordance with the NWPA. As illustrated in Table 1 of this notice, DOE does not believe that the 960 guidelines are substantively consistent with the newly developed EPA and NRC rules, thereby necessitating the amendments promulgated today.

B. The proposed rules use (or allow the use of) engineered barriers to compensate for the inadequacies of the site.

Several commenters stated that the proposed rule inappropriately allows the use of engineered barriers to compensate for inadequacies in the performance of the natural system. Certain of these commenters suggested that the NWPA, in particular section 112(a), prohibits reliance on the performance of engineered barriers in developing a repository system, reasoning

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that the performance of the repository must rely solely on the performance of the natural barriers.

As explained above, DOE does not believe that the provisions of the NWPA limit or prohibit DOE's investigation and use of engineered barriers to assess the suitability of siting a geologic repository at Yucca Mountain. Section 113(b)(1)(B) of the NWPA directs DOE to describe the waste packages and waste forms to be used and their relation to the geology of the site; section 113(c) restricts DOE activities conducted under section 113 to those necessary to provide data required for a repository construction authorization application to the NRC. In turn, section 121(b)(1)(B) requires the NRC, in setting licensing criteria for a repository, to provide for the use of a system of multiple barriers in the design of the repository. In this context, multiple barriers means engineered and natural barriers. Thus, DOE believes that the NWPA, as originally enacted and as amended, contemplates that any site undergoing characterization for possible development as a repository would include investigation of, and reliance on, multiple barriers -- natural and engineered barriers.

Indeed, the NRC's original repository licensing requirements, 10 CFR part 60, made clear that the use of both natural and engineered barriers would be required for repository licensing. Nevertheless, the NRC was also concerned, at the time of the promulgation of part 960 in 1984, that DOE not use engineering barriers to compensate for deficiencies in any comparison of candidate sites. The NRC, through its concurrence process on the original part 960 guidelines, required DOE to make clear that engineered barriers would not constitute a compensating measure for deficiencies in the geologic media during site screening. This was accommodated by provisions at 10 CFR 960.3-1-5 that address comparisons of the sites in the basis for site

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evaluations. That provision states that comparisons of sites shall be structured so that engineered barriers are not relied upon to compensate for deficiencies in the geologic media. Furthermore, it states that engineered barriers shall not be used to compensate for an inadequate site; mask the innate deficiencies of a site; disguise the strengths and weaknesses of a site and the overall system; and mask differences between sites *when they are compared*. (emphasis added). In its final decision to concur in 10 CFR 960, the NRC noted that the revisions made to 960.3-1-5 showed that DOE would not select sites where engineered barriers must be used to compensate for deficiencies in the geologic media (49 FR 28136).

At present, DOE is not in a situation of comparing multiple sites for possible development as a repository. Part 963 applies only to a determination of the suitability of the Yucca Mountain site for possible development as a repository. Importantly, absent in NRC's current requirements for licensing, 10 CFR part 63, and in NRC's concurrence on this rule, are any requirements that DOE demonstrate repository performance based solely on natural barriers.

The NRC expects that, in any licensing proceeding for a repository at Yucca Mountain, DOE will demonstrate that the natural barriers and the engineered barrier system will work in combination to enhance the overall performance of the geologic repository. NRC regulations require an engineered barrier system in addition to the natural barriers provided by the geologic setting, and that natural barriers and the engineered barrier system work in combination to enhance the resiliency of the geologic repository and increase confidence that the postclosure performance objective at 10 CFR 63.113(b) will be achieved.

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NRC's expectation is shared by the EPA, and other oversight entities. In 40 CFR part 197, EPA defines the Yucca Mountain disposal system as the combination of underground engineered and natural barriers at the Yucca Mountain site that prevents or substantially reduces releases from the disposed radioactive material, and emphasizes the importance of engineered barriers as a method, within human control, to delay the release of radionuclides from the repository. Oversight entities, such as the NWTRB and the Advisory Committee on Nuclear Waste, have been consistent in their recommendations to pursue robust, long lived waste packages to protect the health and safety of the public.

In consideration of this information, DOE incorporated in its proposal specific criteria to address the performance of the engineered components of the repository system. The Department believes that the criteria are consistent with the Congressional intent in the NWPA, and the regulatory expectations of the EPA and the NRC, that there be performance contributions from both the natural and engineered barriers. DOE does not believe that reliance on such barriers would mask or compensate for inadequacies in the natural system, but rather, such barriers enhance and prolong the ability of the natural system to contain, and mitigate the rate of release of, individual radionuclides.

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C. The rules should not be changed to fit the site.

1. The site would be disqualified under existing guidelines.

Several commenters stated their belief that Yucca Mountain would be disqualified under the existing guidelines and, on that basis, DOE is attempting to change the rules to fit the site. This same comment was made in response to DOE's 1996 proposal to amend part 960. The primary reason for this comment, then as now, is the argument that the site cannot meet the disqualifying condition in 960.4-2-1(d) pertaining to groundwater travel time. Many commenters also questioned what condition would disqualify the site under part 963, and how far contaminated groundwater may travel under part 963.

As stated in the preamble to the supplemental notice of proposed rulemaking (64 FR 67071), DOE's reasons for amending the guidelines are not based on a belief or finding that the Yucca Mountain site would be disqualified if the 960 guidelines were applied without amendment. With respect to groundwater travel time, the Department continues to evaluate groundwater movement and other hydrological properties of the site to assess the performance of a repository at Yucca Mountain. Based on the results of the 1998 Viability Assessment and ongoing evaluations, the Department believes there is no basis at this time to find that disqualifying conditions, as identified in 10 CFR part 960, exist at Yucca Mountain.

With regard to the question of what condition would disqualify the Yucca Mountain site, part 963 requires the Secretary of Energy to evaluate the suitability of the site based on the

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likelihood that a repository at the site could meet the applicable radiation protection standard. Accordingly, if the Secretary determines this requirement has not been met, the site may not be determined suitable by the Secretary and thus “disqualified” for consideration for further development. With regard to the question of how groundwater travel time will be assessed under part 963, groundwater flow and transport will be analyzed as suitability criteria, section 963.17(a)(7), unsaturated zone flow and transport, and section 963.17(a)(8), saturated zone flow and transport. Accordingly, groundwater flow and transport will continue to be studied for its role in repository performance and the ability of the site to meet applicable radiation protection standards.

2. DOE is changing the rules in the middle of the game.

Several commenters claimed that DOE is inappropriately establishing suitability guidelines as a result of ongoing site characterization work, instead of setting the guidelines in advance of that work. In that regard, one commenter questioned whether the guidelines would affect the design of the repository. Stated otherwise, DOE understands the concern to be that it is perceived as setting guidelines to meet a specific repository design or other site characteristic, rather than setting guidelines based on predetermined criteria for repository design or other site characteristics.

In all, these comments present an alternative opinion on how best to evaluate site suitability, and express a speculative belief that DOE’s approach in this rulemaking -- amending site suitability criteria to conform to current regulatory and scientific understanding -- engenders

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widespread public distrust of the process. While DOE acknowledges that there may be differing views on the best approach to evaluating site suitability, DOE believes the approach embodied in part 963 is the better, more reasonable approach and is fully consistent with the law, the science, and the goal of maximum protection of public health and safety. DOE's intent is to establish suitability guidelines in conformance with the direction of Congress, the regulatory framework for construction and operation of a geologic repository at Yucca Mountain, and prevailing national and international opinion on the best scientific methods to evaluate and assess repository performance. To do otherwise would be unreasonable.

That these site suitability guidelines are being issued now, instead of earlier in the site characterization process, is not to the public's disadvantage, since they reflect the most recent developments in regulatory requirements and standards and technical understanding. For example, the guidelines are structured to evaluate repository performance against a set of criteria potentially important to waste isolation. The repository design, although not directly affected by the guidelines, will be structured to take advantage of the features of the natural and engineered barriers that are important to waste isolation.

Moreover, DOE's current approach is consistent with earlier opinions expressed by the National Academy of Sciences, Board on Radioactive Waste Management (Board). In its report, *Rethinking High-Level Radioactive Waste Disposal* (1990), the Board addressed this issue and discussed the relative merits of an approach that presets technical criteria for evaluation of a repository site versus an approach that remains flexible and responsive to data and information as it is developed. In that report, the Board criticized the U.S. high-level waste program for its

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approach, at that time, of defining in advance the technical requirements for every part of the multi-barrier system, and in its emphasis on the geologic component of the barrier. The Board opined that the better approach, consistent with geologic and mining practice, is to remain flexible instead of setting rigid predefined goals. The Board observed that, instead of trying to anticipate all the complexities of a natural geologic environment, the better approach would be to define the goal broadly in ultimate performance terms, rather than anticipatory requirements, so that increased knowledge can be incorporated in the design at a specific site.

D. The part 963 guidelines would (a) mask the degree of safety, which can lower or eliminate public confidence, and (b) lower, or eliminate the degree of safety.

(a) Some commenters believed that the proposed revisions, that is, the use of a total system performance assessment instead of individual, subsystem requirements, mask the degree of safety of the site. These commenters felt that the TSPA method, with its heavy reliance on computer modeling, is too uncertain and subject to mishandling to form the basis for assessing the safety of the site and ensuring public confidence in the resulting assessment. Other commenters expressed the view that use of the TSPA method is appropriate. One commenter, Nye County, Nevada, commented that the criteria provide for greater transparency and verifiability than DOE's initial proposed amendments to part 960 in 1996, and that the TSPA approach is preferred to DOE's previous consideration of site-specific revisions to the 960 guidelines.

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As explained in other sections of this notice, the prevailing view in the relevant scientific community supports use of the TSPA method to assess and evaluate expected performance of a geologic repository over thousands of years. This is the evaluation method required by the NRC and the EPA in assessing repository performance for licensing purposes. It would be unreasonable for DOE to establish criteria to determine the suitability of the Yucca Mountain site that are not based on the prevailing scientific and regulatory view of performance assessment.

Over the past several years, DOE and other entities involved in oversight and regulation of high level waste programs have undertaken significant efforts to make the results of total system performance assessment calculations more transparent to non-technical audiences. This is in response to the type of concerns expressed by the commenters here, that the complex calculations are difficult to visualize and verify, and, hence, may mask the degree of safety provided. While DOE acknowledges the difficulty in comprehending TSPA for the lay person, DOE has attempted, through this rulemaking and in other public forums, to enhance transparency in presenting the results of TSPA and associated complex technical calculations and modeling. For example, in the Viability Assessment, DOE provided a detailed explanation of the TSPA method and the computer models and technical data and information supporting those modes. This explanation has been augmented by presentations and other briefings provided by DOE to oversight agencies and other members of the public.

One of DOE's primary considerations in drafting and finalizing this rulemaking was to make the TSPA process and method more transparent and verifiable. As explained in the Viability Assessment, transparency is manifested through the ease of a reader in understanding

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the process by which a study was carried out, which assumptions are driving the results, how they were arrived at, and the rigor of the analyses leading to the results. Transparency is achieved when a reader has a clear picture of what was done in the analyses, what the outcome was, and why. For a reader to have confidence, the presentation must clearly illustrate: (1) the conceptual basis for the individual components in the quantitative analyses, that is, how the system is intended to work; (2) how the individual components are combined into an assessment of system behavior; and (3) the scientific understanding used to develop the quantitative analysis tools that describe the system's expected evolution.

Part 963, at section 963.16(b)(1), (5), (6), (7), and (9), requires specific consideration of these types of details for determining the suitability of the site. Additionally, confidence in the results of the performance assessment calculations can be enhanced if the presentation illustrates: (1) the system's expected evolution, as defined by the spatial and temporal response of the system to waste emplacement; and (2) the uncertainty in the system's expected evolution and the significance of that uncertainty to the system performance goals. Part 963 requires DOE to give specific consideration to these details for determining the suitability under 963.16(b)(2), (3), (8), (9), (10), and (12).

Further, section 963.17 requires DOE to evaluate suitability through criteria that reflect both the processes and the models that are important to the total system performance. Those criteria are expressly identifiable and traceable components of the TSPA, thereby increasing transparency and traceability of the results. In addition, DOE intends to make available to the public the documentation underlying any TSPA analyses and results. With this material, the

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public will have an opportunity to review the technical information and data underlying the analyses supporting the postclosure performance assessment.

(b) Some commenters expressed the view that the use of TSPA, and the lack of qualifying or disqualifying subsystem requirements, would lower or eliminate the degree of safety.

Part 963 is structured to align DOE's site suitability determination with the EPA public health and safety standard, as implemented by the NRC regulations, and to base a suitability determination on the likelihood that the site could meet applicable radiation protection standards. Through Congressional direction, EPA modified the basis for a public health and safety standard from a release based standard to a health effects standard. In turn, Congress directed the NRC to conform its licensing regulations to the EPA standard and implement that standard. Both regulators predicate a demonstration that the standard can be met on the use of performance assessment.

DOE is in agreement with Congress, EPA and NRC that a dose based standard, that explicitly limits the risk of adverse health effects and considers health effects to the potentially affected public, is an appropriate basis upon which to assess public health and safety. Further, DOE believes that the risk or dose approach provides additional and better protection to the health and safety of the public in the vicinity of Yucca Mountain than a release based approach which is reflected in the 960 guidelines. The part 963 guidelines require DOE to explicitly consider health effects to the public in the vicinity of the Yucca Mountain site. Under the part

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960 guidelines, the DOE would only have been required to calculate releases from the repository, not the potential health effects. Hence, the part 963 guidelines enhance the degree of safety provided to the public in the vicinity of the Yucca Mountain site, rather than lowering it or eliminating it.

E. The appropriateness of the proposed criteria.

One commenter questioned the post closure criteria proposed by DOE stating that the criteria were simply a list of physical characteristics with no bases for discrimination, that would be necessary for a suitability determination, while other commenters supported the Department's proposal indicating that the proposed post closure criteria were appropriate for decisionmaking.

In the supplemental notice of proposed rulemaking, the Department provided its rationale for the selection of the broader definition of criteria as “characterizing traits” rather than the more narrow definition as benchmarks or pass-fail standards. The rationale included, among other reasons, the fact that section 112(a) of the NWPA uses the term “primary criteria” synonymously with the term “detailed geologic considerations,” a term that does not necessarily imply any benchmark.

In DOE's view, the lack of a benchmark or quantitative standard does not mean the suitability criteria are not true criteria for assessing site suitability. Indeed, the NRC also expressed concern that DOE, in analogizing its suitability criteria to the NRC's Quality Assurance (QA) criteria, found in Appendix B of 10 CFR part 50, may have mischaracterized the

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importance and nature of the NRC requirements by noting that they are not expressed as quantitative, pass-fail standards. Contrary to NRC's misperception, DOE does not believe that NRC's QA criteria are not true regulatory requirements, nor is there a belief that these criteria are any less important or less mandatory for their lack of quantitative, pass-fail references. Similarly, DOE views its site suitability criteria in part 963 in the same way NRC views its QA criteria. That is, those criteria are factors or characterizing traits relevant to assessing the performance of a geologic repository that must be present and evaluated for adequacy to support DOE's preclosure and postclosure suitability determinations. NRC's Appendix B QA criteria, and the suitability criteria of sections 963.14 and 963.17, are the same in that they are required factors or characterizing traits, but they do not contain quantitative, pass-fail, benchmark standards.

To avoid confusion and respond to the NRC comment, DOE has changed the discussion in the Supplementary Information describing the suitability criteria to read as follows: "For example, in 10 CFR part 50, the NRC sets forth quality assurance "criteria" that are factors that must be present for anyone's QA program to be judged adequate. However, although these QA criteria are required factors, they are not, nor do they contain, quantitative, pass-fail, benchmark standards."

F. DOE should consider preclosure issues, including environmental, socioeconomic, and transportation issues.

Several commenters objected to DOE's exclusion in part 963 of certain 960 preclosure guidelines such as environmental quality, socioeconomic and transportation, on the basis that

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section 112(a) of the NWPA requires consideration of those factors, along with qualifying or disqualifying conditions for those factors. Additionally, several commenters questioned where such topics would be addressed, and expressed their belief that the draft Yucca Mountain EIS did not fully or adequately address those topics.

As previously explained, DOE does not agree that the site suitability criteria established under section 113(b) must be the same as the guidelines promulgated under section 112(a). Part 963 establishes the criteria and methodology for determining the suitability of the site under section 113(b)(1)(A)(iv) as part of DOE's site characterization activities and site characterization plan. Since 1988 and the publication of the Site Characterization Plan, DOE has indicated that information relative to socioeconomics, transportation and environmental quality guidelines referred to in part 960 would be obtained through means other than site characterization activities. Accordingly, DOE does not agree that socioeconomics, transportation and environmental quality must be included in part 963 as criteria to determine the suitability of the site under section 113(b).

DOE agrees that socioeconomics, environmental quality and transportation should be considered in any determination by the Secretary to recommend the Yucca Mountain site for development. As stated in the rule and in this notice, those factors and other relevant information will be addressed by DOE in documents subject to public review, such as the Yucca Mountain EIS, that will be considered in any Secretarial site recommendation under section 114 of the NWPA. While some commenters may be critical of the adequacy of the Yucca Mountain EIS analysis, or the extent of coverage, DOE believes that the majority of the 960 guidelines on

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socioeconomics, transportation and environmental quality are addressed in the Yucca Mountain EIS. DOE is in the process of evaluating public comments on the draft Yucca Mountain EIS, including those comments submitted under this rulemaking. Upon completion of the EIS, DOE believes that coverage of these factors will be fully adequate for consideration in any Secretarial site recommendation.

G. DOE should define the margin by which it will meet the radiation protection standard, or the way in which it will meet the standard.

At least one commenter suggested that DOE should be more definitive or restrictive for the determinations to be made in section 963.12, preclosure suitability, and section 963.15, postclosure suitability. Specifically, it was suggested that DOE be more definitive or clarify what is meant by the phrase "likely to meet" in those sections, such as specifying the mean result of the TSPA calculation as the basis for a determination of postclosure suitability.

DOE does not believe it is useful to be more definitive or restrictive regarding the phrase "likely to meet." By this phrase DOE is indicating, as it must, that site suitability is largely a DOE estimate of the ability to obtain a license from the NRC for repository construction. This determination is not the equivalent of a license application by DOE, nor is it the equivalent of an NRC determination that a license application will be successful. Under the circumstances, DOE believes this phrase accurately captures the level of information and confidence required by the Secretary to make a suitability determination. With regard to the comment that DOE should use only the mean result of the TSPA to judge the likelihood of meeting the standard, DOE believes

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more than the mean result would be appropriate in estimating the ability to licensing regulations. Under NRC regulations, 10 CFR subpart 63.101, DOE must demonstrate, at the time of licensing, reasonable assurance that the radiation protection standard can be met. This requirement necessitates DOE develop and provide more than just the mean result in demonstrating compliance with the standard. Therefore, the use of "results" is appropriate in sections 963.12 and 963.15, instead of something more singular, such as a mean or expected result only.

In addition, some commenters noted that the rule should require performance in excess of the standard; stated otherwise, that DOE should specify a margin or level of confidence regarding performance results. This same comment was made in response to the 1996 proposed rulemaking. DOE has reconsidered this comment here, but nevertheless maintains the same response as provided in response to comments on the 1996 proposal. That is, DOE does not believe it is appropriate or most effective to specify or quantify a level of confidence or margin of safety as part of the rule. The public, as well as the Secretary of Energy, will have access to data and information underlying the TSPA analyses and supporting analyses. This information will include the probabilistic distribution of values around the expected value, in order to assess the level of confidence in the performance calculation.

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- H. Whether DOE should revoke the guidelines in 10 CFR part 960 in making the site suitability determination for the Yucca Mountain site or continue to use them in addition to part 963.**

DOE proposed amendments to modify part 960 so that it would apply only to competitive site selection for the purpose of nominating sites for site characterization activities. Opinion about this part of the November 30, 1999, proposal was divided. Some commenters argued for complete revocation of part 960 because it embodies a methodology for site comparisons that is: (1) obsolete; (2) inconsistent with internationally accepted practice; and (3) inconsistent with currently proposed NRC and EPA rules for the Yucca Mountain site. Other commenters disagreed, arguing that the sub-system approach in part 960 can and should be applied in addition to the rules for total system performance assessments in part 963. They viewed the provisions of part 960 as a viable and better method than proposed part 963 for assessing the suitability of the Yucca Mountain site for the location of a nuclear waste repository.

With regard to the comments favoring complete revocation of part 960, DOE does not think that reaching final conclusions on their viability for competitive selection of sites for site characterization is appropriate for two reasons. First, the 1987 amendments to the Nuclear Waste Policy Act of 1982 require DOE to focus its efforts exclusively on evaluation of Yucca Mountain. Second, if there is ever a need to return to competitive selection of sites for site characterization, that would be the time to replace part 960 with a methodology that reflects scientific advances since part 960 became effective in 1984.

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With regard to commenters who favored application of the subsystem requirements of part 960 in addition to part 963, DOE thinks that this approach is scientifically unsound and impossible to carry out. As explained at length above, the subsystem methodology of part 960 is scientifically unsound because it largely ignores the crucial interactions of various features, events, and processes that should be determinative. In DOE's view, reliance on the methodology of part 960 would result in conclusions that are too likely to be erroneous. Even if the subsystem methodology of part 960 were a scientifically sound basis for evaluating site suitability, DOE will not be able to apply it because of the NRC's revisions to its licensing regulations. In the notice of supplemental proposed rulemaking, DOE included a table, reproduced above, which sets forth the cross references in part 960 to the NRC's part 60 and demonstrates the lack of any substitutable cross reference to the NRC's part 63. The table was accompanied by a narrative exploring the groundwater guidelines in particular to show the impossibility of applying it after the NRC substituted part 63 for part 60. None of the commenters disputed this table, and in DOE's view, it shows continued use of part 960 in the evaluation of the Yucca Mountain site is not a viable option.

I. Response to NRC Comments

a. Coordination with NRC

NRC made the comment that proposed part 963 did not address the potential matter of a conflict between the proposed DOE regulation and the applicable NRC regulations. NRC

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recommended that DOE explain how it would address this matter in this statement of consideration.

NRC correctly notes that proposed part 963 does not contain a provision expressly requiring NRC regulations to take precedence in the event of a conflict or inconsistency between the DOE regulations and NRC regulations. DOE does not believe such a provision is necessary, given the nature and structure of part 963. Moreover, DOE believes this provision could create confusion in the implementation of the DOE regulation, since it suggests that in certain circumstances not presently identified DOE would need to substitute an NRC regulation for its own.

DOE recognizes that its site suitability guidelines must provide an estimate of the ability of the Yucca Mountain site to meet licensing requirements, pursuant to section 113(c) of the NWPA, but that the license application process, over which NRC has jurisdiction, is distinct and separate from DOE's estimate of site suitability. Accordingly, part 963, which is specific to the Yucca Mountain site, is carefully crafted to conform to pertinent parts of the NRC's part 63, the NRC's licensing requirements specific to the Yucca Mountain site, that serve DOE's need for assessing the suitability of the site as a basis for a possible site recommendation. Under this structure, the necessary consistency between the DOE and NRC regulations is obtained during the drafting of the DOE regulation. Any conflicts between the DOE and NRC regulations have been resolved through the NRC concurrence process on the regulation.

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b. Quality Assurance

The NRC also commented that DOE should recognize in the preamble to part 963 the importance and role of quality assurance in DOE site characterization activities, and the expected pedigree of the technical information and data underlying the suitability determination.

As the NRC acknowledges in its comments, the Department expects to use essentially the same data for both its site suitability determination and any potential license application, even though the site suitability determination is not the equivalent of a determination that the site will meet all the requirements needed to obtain a construction authorization under NRC regulations. DOE acknowledges that the site suitability determination must be based on credible and verifiable data and information, and that assurance of the quality of that data and information is a factor in that determination. Therefore, due consideration will be given by the Department to any outstanding quality assurance issues that may affect the pedigree of technical information underlying the part 963 suitability determination.

c. Definition of Cladding

In response to a comment from the NRC that the proposed definition of cladding found at 10 CFR subpart 963.2 conveyed an inaccurate notion that all cladding is corrosion resistant, the Department has modified the proposed definition as follows: cladding is the metallic outer sheath of a fuel rod element; it is generally made of a corrosion resistant zirconium alloy or stainless steel, and is intended to isolate the fuel from the external environment. Also, the Department

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has clarified the use of the term cladding in section VI(B)(h)(2) of this Supplemental Information, and in the rule at section 963.17(a)(5)(i).

J. Response to Nuclear Waste Technical Review Board

The NWTRB provided comments on the 963 rulemaking, noting several considerations for DOE to address in its suitability guidelines. The NWTRB endorsed the use of performance assessment in support of a site suitability determination, but also noted that additional lines of argument and evidence should be used. In particular, the NWTRB supported use of other lines of evidence such as safety margins, defense-in-depth, performance confirmation, consideration of disruptive process and events, and reference to insights from natural and man-made analogs noting that such topics were addressed in revision 3 of the report, “*Repository Safety Strategy: Plan to Prepare the Postclosure Safety Case to Support Yucca Mountain site Recommendation and Licensing Considerations*” (“Repository Safety Strategy”) (TRW-WIS-RL-000001, January 2000). The NWTRB emphasized that understanding uncertainties in the performance assessment analysis is a critical component to attain technical credibility and sound decisionmaking. In that regard, the NWTRB recommended that DOE include in its representation of performance uncertainty: a) a description of critical assumptions; b) an explanation of why particular parameter ranges were chosen; c) a discussion of possible data limitations; d) an explanation of the basis and justification for using expert judgements, e) an assessment of confidence in the conceptual models used; and f) identification and quantification of uncertainties associated with the performance estimates.

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DOE agrees with much of the NWTRB's comments and recommendations. In fact, part 963, in its proposed and final form, already includes much of the information and analysis the NWTRB recommends and that was identified in revision 3 of the Repository Safety Strategy. Under section 963.16(b), DOE will conduct a TSPA in a manner to satisfy twelve enumerated conditions. Those conditions correspond to a large degree with the specific recommendations of the NWTRB repeated above, and provide the additional lines of evidence and argument beyond the performance assessment calculations. DOE structured this section of the rule to correspond to NRC's licensing regulation, proposed section 63.114. To clarify this point, DOE added language to the description of this rule, in section VI of this Supplementary Information, to better articulate how the additional lines of evidence and recommendations will be accounted for in the suitability determination. Presented below is additional explanation of how the NWTRB's comments are addressed in part 963.

The additional lines of evidence and argument recommended by the NWTRB are included in the requirements of section 963.16(b), except for performance confirmation. DOE believes that performance confirmation is important, and will develop a performance confirmation plan in conjunction with the licensing process. DOE will provide in the underlying documentation of the TSPA calculation, performed in accordance with section 963.16(b), the "margin" by which the expected performance of the repository exceeds the applicable radiation protection standards. Although DOE does not agree that it is necessary to quantify or specify the margin of safety as part of the rule, information and data about the margin will be available to decision-makers for review and consideration in reaching a suitability determination. Under sections 963.16(b)(8), (9), and (10), DOE will identify and evaluate multiple and independent

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barriers to waste isolation, thereby providing information on defense-in-depth. Disruptive processes and events are analyzed and included in the TSPA under sections 963.16(b)(4) and (5), and are express criteria of suitability in section 963.17(b). Insights from natural and man-made analogs are also analyzed and included in the TSPA under section 963.16(b)(7), which requires DOE to provide the technical basis for the TSPA models, including comparisons made with empirical observations, such as natural analogs.

The NWTRB recommendations, described above, are also included in part 963. NWTRB recommendation (a), describe critical assumptions, is included in the requirements of section 963.16(b)(2), accounting for uncertainties and variabilities in parameter values; section 963.16(b)(3), consideration of alternative models of features and processes and evaluation of the effects of the alternative models; and section 963.16(b)(12), conduct of appropriate sensitivity analyses. In addition, the analyses and documentation underlying the TSPA will contain an explanation of assumptions in conformance with quality assurance requirements.

NWTRB recommendation (b), explain why particular parameter ranges are chosen, is included in the requirements of section 963.16(b)(2), an accounting of uncertainties and variabilities in parameter values and identification of the technical basis for parameter ranges, probability distributions, and bounding values.

NWTRB recommendation (c), include a discussion of possible data limitations, is included in the requirements of section 963.16(b) that require an explanation of the technical bases of the data and models (e.g., sections 963.16(b)(2), (3), (5), (6), (7), and (10)). For

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example, section 963.16(b)(6) requires DOE to provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers.

Compliance with this regulation will entail a discussion of possible data limitations.

NWTRB recommendation (d), provide an explanation of the basis and justification for using expert judgment, is included in the requirements of section 963.16(b) that require an explanation of technical bases (e.g., sections 963.16(b)(2), (5), (6), (7), and (10)). In those explanations, DOE will explain where expert judgment has been used.

NWTRB recommendation (e), provide an assessment of confidence in the conceptual models used, is included in the requirements of sections 963.16(b)(3) and (5). In those sections of the rule, DOE will consider alternative models of features and processes and their effects on performance, and provide the technical basis for either inclusion or exclusion of specific features, events and processes (FEPs) of the geologic setting. In essence, these analyses will help DOE and others to assess the validity of the conceptual models and estimates of the significance of those models to repository performance.

NWTRB recommendation (f), identify and quantify the uncertainties associated with the performance estimates, is included in the requirements of sections 963.16(b)(2), (3), (5), (6), (7), (9) and (10). Through all of these requirements, DOE will identify and quantify uncertainties associated with the performance estimates.

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V. Description of Proposal - 10 CFR Part 960

A. Subpart A General Provisions

This section of the Guidelines contains the statement of applicability and definitions. The final revisions to section 960.1, Applicability, limit the application of the Guidelines to evaluations of the suitability of sites for site characterization under section 112(b) of the NWPA. The revisions eliminate the applicability of the Guidelines to determinations of suitability of a site at the site characterization stage under section 113, or the site recommendation stage under section 114. These revisions clarify the applicability of the Guidelines to the preliminary site screening stage, which entails a comparative analysis process, and thereby better align the application of the Guidelines with the structure of the NWPA, as originally enacted and as amended in 1987. The final revisions to the third and fourth sentences update the reference to other regulatory requirements of the NRC and EPA, in light of the current status of applicable NRC and EPA regulations relative to high-level waste geologic repositories. The fifth through seventh sentences remain unchanged.

The final revisions to the definitions section make the terms consistent with the NWPA and with the other revisions to the Guidelines limiting applicability of subparts B, C, and D of the Guidelines to determinations of site suitability for site characterization under section 112 of the NWPA.

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B. Subpart B - Implementation Guidelines

The final revisions to the implementation guidelines would limit the procedures and basis for application of the postclosure and preclosure guidelines of subparts C and D, respectively, to evaluations of the suitability of sites for site characterization.

Section 960.3, implementation guidelines, would be revised to eliminate the sentences in that section setting forth the procedures and basis for application of subparts C and D in evaluations and determinations of the suitability of a site under section 113 and section 114 of the NWPA. These revisions would remove section 960.3-1-4-4, Site Recommendation for Repository Development, in its entirety. That section pertains to the procedure and evidence required to make a site recommendation decision under section 113 and 114. Those decisions would not be governed by the Guidelines, and therefore reference to them would be removed. Section 960.3-1-5, Basis for Site Evaluation, would be revised to eliminate all references to Appendix III and the application of the requirements of that section in making suitability determinations at the site characterization or site recommendation stages. Only the last sentence of section 960.3-2, Siting Process, would be revised. This revision would limit the applicability of the siting process to the recommendation of sites for site characterization. Section 960.3-2-4, Recommendation of Sites For the Development of Repositories, would be removed in its entirety. That section pertains to the comparison of characterized sites, leading to a recommendation by the Secretary to the President of a site for development as a repository. The final revisions eliminate that decision process from evaluation under the Guidelines, and the section in its entirety are removed.

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C. Appendix III

The final revisions to Appendix III remove and eliminate the applicability of this Appendix to decisions for repository site selection and siting decisions. The qualifying and disqualifying conditions of the technical guidelines in subparts C and D now apply only to the decision point for selecting sites for site characterization. All references to the site selection and site recommendation decisions under sections 113 and 114 are removed, including the tabular column in Appendix III referencing the repository site selection siting decision.

With respect to the Guidelines listed in Appendix III that apply to environmental quality, socioeconomics and transportation considerations, DOE considered whether to continue to require their applicability to a Yucca Mountain site recommendation under section 114 of the NWPA. DOE decided not to do so because the issues addressed by these Guidelines will be substantially covered in the environmental impact statement for the Yucca Mountain site, and section 114(a)(1)(D) requires that the final environmental impact statement be part of the comprehensive statement of the basis for a site recommendation to the President (42 U.S.C. 10134(a)(1)(D)). Opportunities for public comment on the analysis of environmental quality, socioeconomics and transportation issues have been provided as part of the public review and comment process on the draft environmental impact statement. In sum, DOE believes that the environmental quality, socioeconomics and transportation guideline requirements are substantially and unnecessarily duplicative of requirements under the procedures for developing an environmental impact statement and for formulating and informing a site recommendation under section 114.

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VI. Description of Final Rule - 10 CFR Part 963

The purpose of this part of the Supplementary Information is to explain the meaning and basis for those provisions of the final part 963 that are not self-explanatory. The following is a section by section analysis of the final rule, and the accompanying explanation.

A. Subpart A - General Provisions

Subpart A comprises two parts, the statement of Purpose, section 963.1, and Definitions, section 963.2.

(a) *Purpose - section 963.1.* The purpose of the final rule is as stated in this section: to establish the methods and criteria for determining the suitability of the Yucca Mountain site for the location of a geologic repository in completing DOE's site characterization program activities to be conducted under section 113(b) of the NWPA. The suitability evaluation methods to be used by DOE are consistent with the methods proposed by the NRC for assessing the potential of a geologic repository at the Yucca Mountain site to meet licensing criteria and requirements. The suitability criteria relate to the geologic considerations identified in section 112(a) as they reflect current scientific understanding and regulatory expectations (both NRC and EPA) regarding the performance and safety of a geologic repository during the preclosure and postclosure periods of operation. Because the suitability criteria are part of the site characterization program, these criteria relate to site characterization activities. Site characterization activities relate to scientific and technical investigations of the site to determine its natural properties and features, for

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example, studying the geohydrology and geochemistry of the site, as distinct from consideration of other features, such as cost, socioeconomics and transportation of waste to the repository. An explanation of how the suitability criteria were derived is provided below.

The final rule does not address the site recommendation process in its entirety. Other information required under section 114 of the NWPA that must be considered and submitted to the President and made available to the public if the site is recommended for development as a geologic repository is not addressed by the final rule. Regarding any repository site recommendation the Secretary of Energy shall make available to the public, and submit to the President, a comprehensive statement of the basis of such recommendation, including the following: (a) a description of the proposed repository, including preliminary engineering specifications for the facility; (b) a description of the waste form or packaging proposed for use at such repository, and an explanation of the relationship between the waste form or packaging and the geologic medium of the site; (c) a discussion of data, obtained in site characterization activities, relating to the safety of such site; (d) a final environmental impact statement prepared for the Yucca Mountain site; (e) the preliminary comments of the NRC concerning the extent to which the at-depth site characterization analysis and the waste form proposal for such site seem to be sufficient for inclusion in any application to be submitted by the Secretary for licensing of such site as a repository; (f) the views and comments of the Governor and legislature of any State, or the governing body of any affected Indian tribe, as determined by the Secretary, together with the response of the Secretary to such views; (g) such other information as the Secretary considers appropriate; and (h) any impact report submitted under section 116(c)(2)(B) of the NWPA (42 U.S.C. 10136(c)(2)(B)) by the State of Nevada.

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(b) *Definitions – section 963.2.* The final rule includes definitions of certain words and terms. The definitions clarify DOE's intent and meaning in the context of this rule. The definitions are also intended to make the terms consistent with proposed NRC regulation governing the construction and licensing of a repository at the Yucca Mountain site. Several of the terms are important to understanding the suitability evaluation process, and are addressed here.

Criteria are those characterizing traits that are relevant to assessing the performance of a geologic repository at the Yucca Mountain site. The criteria relate to the geologic considerations identified in section 112(a) of the NWPA that are relevant to the assessment of the performance of a geologic repository at the Yucca Mountain site. The *geologic repository* includes the natural barriers of the geologic setting and the engineered barriers of the repository design. The suitability *criteria* of the final rule are specific characterizing traits of the Yucca Mountain site that, through the site characterization process, DOE has identified as important indicators of the performance of the total repository system (that is, the integrated natural and engineered barrier systems).

Consistent with varying definitions in standard dictionaries, DOE considered narrowly defining the term “criteria” as benchmark, pass-fail standards rather than more broadly as “characterizing traits.” DOE decided not to adopt the more narrow definition for four reasons. First, in section 112(a) of the NWPA, the term “primary criteria” is used synonymously with the term “detailed geologic considerations,” a term that does not necessarily imply any benchmark.

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Second, as used in context in section 113 of the NWPA, the term “criteria” appears to refer to the considerations for evaluating whether or not a repository in a particular geologic medium is likely to meet applicable NRC standards, thus indicating that the site suitability criteria and the NRC standards are not one and the same. Third, section 121 of the NWPA (which addresses NRC’s regulatory responsibilities) distinguishes between “criteria” and “standards,” a distinction which implies that “criteria” are not necessarily benchmark standards themselves. Finally, although some are inclined to define the term “criteria” narrowly, that inclination is not universal. For example, in 10 CFR part 50, the NRC sets forth quality assurance “criteria” that are factors that must be present for a QA program to be judged adequate. However, although these QA criteria are required factors, they are not, nor do they contain benchmark, pass-fail standards.

The performance of the total system is evaluated using a computer modeling tool called *total system performance assessment*. *Total system performance assessment* identifies the features, events and processes that might affect the performance of a repository, as well as the probabilities and significance of occurrence. *Total system performance assessment* examines the effects of those features, events and processes on that performance by estimating the expected annual dose to the receptor as a result of releases from the repository.

For the preclosure period, suitability would be evaluated through a *preclosure safety evaluation* method. The *preclosure safety evaluation* would consider site characteristics and preliminary engineering specifications to assess the adequacy of the repository facilities to

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perform their intended functions and to mitigate the effects of *design basis events*, or credible accidents that could affect the ability of the geologic repository to operate safely. *Design basis events* are categorized in two ways: 1) those events, both natural and human-induced, that are expected to occur one or more times before permanent closure; or 2) those events, both natural and human-induced, that have at least one chance in 10,000 of occurring before permanent closure. The *preclosure safety evaluation* would assess the ability of the geologic repository to meet the applicable radiation protection standard for the preclosure period under both categories of design basis events.

DOE's evaluation of the suitability of a geologic repository at the Yucca Mountain site would be based on consideration of a preliminary *design* for the *geologic repository*. The *design* is the description of the potential geologic repository, which includes multiple barriers to the release and transport of radionuclides. These multiple barriers consist of both the natural barriers and an engineered barrier system. The *geologic repository* includes not only the facilities and areas where radioactive wastes are handled, but also that portion of the geologic setting that provides *isolation* of the radioactive wastes. As used in the final rule, and in NRC's proposed part 63, *isolation* means inhibiting the movement of radioactive material from the repository to the location where the receptor resides, so that radiation exposures will be less than the radiation dose limits prescribed in NRC's proposed regulation.

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B. Subpart B - Site Suitability Determination, Methods and Criteria

(a) *Scope - section 963.10.* The scope of subpart B includes, for both the preclosure and postclosure periods, the basis for DOE's suitability determination for the Yucca Mountain site. There are separate sections of the final rule for the preclosure and postclosure time periods. The scope of these sections also includes the site suitability criteria to be applied in accordance with section 113(b) of the NWPA, the methods for applying the criteria and evaluating suitability, and the basis for the resulting suitability determination.

The final rule is divided into two sections corresponding to the preclosure and postclosure periods, and within each period, three subsections. The subsections present for each period: (1) the suitability determination; (2) the suitability evaluation method; and (3) the criteria to be used for the evaluation. The purpose of separating the preclosure and the postclosure periods is to make clear the differences in determining the suitability of a geologic repository during these two periods. This separation is consistent with the current structure of the Guidelines, and the structure of the current and proposed new NRC licensing regulations, which have separate performance objectives for the preclosure and the postclosure periods. The preclosure method and criteria govern the suitability considerations that deal with the operation of the repository before it is closed, while waste is being received, stored and emplaced, and allow for the possibility of retrieval. These are the considerations important in protecting the public and repository workers from exposures to radiation during repository operations, especially if an accident should occur. The postclosure method and criteria govern the suitability considerations

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that deal with the long-term behavior of the repository. The behavior of interest here is after waste emplacement and repository closure.

(b) *Suitability determination - section 963.11.* This section describes how DOE will determine the suitability of the site based on the information and data developed through the program of site characterization activities at Yucca Mountain. DOE may find the Yucca Mountain site suitable for the location of a repository based on its determinations relative to the preclosure and postclosure suitability evaluations under sections 963.12 and 963.15. Those determinations, in turn, entail assessment of preclosure and postclosure suitability using the designated evaluation method and criteria for each time period. The overall suitability determination, if affirmative, will be one part of the Secretary's decision, under section 114, whether or not to recommend the Yucca Mountain site to the President for development of a repository.

(c) *Preclosure suitability determination - section 963.12.* The suitability evaluation of the Yucca Mountain site will consider the safety of the geologic repository during the operational or preclosure time period. The preclosure criteria to evaluate the suitability of a geologic repository operations area at Yucca Mountain will be considerations that are important to determining safety during construction and active operation and to demonstrating compliance with the applicable radiation protection standard.

(d) *Preclosure suitability evaluation method - section 963.13.* The preclosure suitability criteria will be applied through a preclosure safety evaluation method. The preclosure safety

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evaluation would support the recommendation to approve the Yucca Mountain site for submittal of a license application. The NRC provides a framework indicating how to conduct this type of evaluation in proposed 10 CFR part 63.112. DOE designed the preclosure safety evaluation method in this final rule based on this NRC framework and a DOE assessment of what information would be necessary and sufficient to determine, at the site suitability stage, whether or not a proposed geologic repository at Yucca Mountain is likely to meet the applicable radiation protection standards for the preclosure period.

The preclosure safety evaluation method, using preliminary engineering specifications, will assess the adequacy of the repository facilities to perform their intended functions and prevent or mitigate the effects of postulated design basis events that are deemed sufficiently credible to warrant consideration. The preclosure safety evaluation will consider: a preliminary description of the site characteristics, the surface facilities, and the underground facilities; a preliminary description of the expected design bases for the operating facilities and a preliminary description of any associated limits on operation; a preliminary description of potential hazards (for example, seismic activity, flooding and severe winds), event sequences, and their consequences; and, a preliminary description of the structures, systems, components, equipment, and operator actions intended to mitigate or prevent accidents. The purpose of the preclosure safety evaluation is to ensure that relevant hazards that could result in unacceptable consequences have been adequately evaluated and appropriate protective measures have been identified such that the geologic repository operations area will comply with the preclosure requirements for protection against radiation exposures and releases of radioactive material.

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The preclosure safety evaluation will emphasize performance requirements, analytical bases and technical justifications, and evaluations that show how safety functions will be accomplished. The adequacy of the facility design will be evaluated by consideration of postulated design basis events viewed as sufficiently credible that the facility should be designed to prevent or mitigate their effects. Design basis events are those natural and human-induced events that are either expected to occur before closure, or have one chance in 10,000 of occurring before permanent closure. DOE will evaluate the probability of the event and the associated consequences. For events of high frequency, the consequences should be low. For less probable accidents that are potentially more severe, the allowable consequences are higher. In either case, the suitability determination will be supported by a design that DOE considers likely to meet the applicable radiation protection standard.

(e) *Preclosure suitability criteria - section 963.14.* DOE will evaluate the suitability of the Yucca Mountain site during the preclosure period using the following criteria: (a) ability to contain and limit releases of radioactive materials; (b) ability to implement control and emergency systems to limit exposures to radiation; (c) ability to maintain a system and components that perform their intended safety functions; and (d) ability to preserve the option to retrieve wastes during the preclosure period. These criteria are considerations important to determining the performance of a potential repository at Yucca Mountain. For example, in applying the first criterion, DOE will ensure repository facilities are designed to keep the radioactive materials confined in order to limit releases of radioactive material. The second and third criteria address DOE's ability to ensure that emergency controls and procedures are developed to limit releases should an accident occur, and that the system and its components will perform their safety

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function as intended. The fourth criterion is also important to the safe functioning of a repository; that is, ensuring the capability to retrieve or recover the wastes from the repository should conditions warrant.

These criteria also relate to certain geologic considerations in section 112(a) of the NWPA. The geologic considerations identified in section 112(a) that are relevant to the preclosure period are hydrology, geophysics, seismic activity, atomic energy defense activities, proximity to water supplies and proximity to populations. These considerations are relevant to the evaluation of preclosure suitability because they bear on the evaluation of repository system safety during the preclosure period. The hydrology and geophysics of the site are important to preclosure safety because they are indicators of possible initiating events for accidents. Seismic activity is also important in this regard, as it is an indication of the potential for earthquake activity to disrupt normal functioning of a repository surface facility. The location of atomic energy defense activities in relation to the Yucca Mountain site is important to preclosure safety and would be considered to the extent they exist and may impact operations of the repository facility. Proximity to water supplies and proximity to populations are important to preclosure safety because they relate to potential locations where people could eventually be exposed to radionuclides either through airborne transport or through a water pathway.

(f) *Postclosure suitability determination - section 963.15.* The postclosure suitability evaluation of the Yucca Mountain site will consider the safety of the geologic repository during the time after operations cease, the postclosure period. DOE will determine the suitability of the Yucca Mountain site for the postclosure period by examining the results of a TSPA conducted

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under section 963.16. If the results indicate a repository at Yucca Mountain is likely to meet the applicable radiation protection standard, then DOE may determine, on the basis of site characterization activities, that the site is suitable for the postclosure period.

(g) *Postclosure suitability evaluation method – section 963.16.* DOE will evaluate the suitability of a potential repository at the Yucca Mountain site using the TSPA method (described in greater detail below). Using the TSPA method, DOE will estimate quantitatively the expected annual dose, over the compliance period, to the receptor. With this estimate, DOE will evaluate the performance of the repository and its ability to limit radiological exposures within the applicable radiation protection standard.

(1) *Section 963.16(a).* Section 963.16(a) describes how DOE will conduct separate performance assessments in order to evaluate the postclosure performance of a geologic repository at Yucca Mountain. One TSPA will be conducted in accordance with the method described in 963.16(b) and using all of the criteria identified in section 963.17, except the criterion assuming a human intrusion into the repository. A second TSPA will be conducted in accordance with the method described in 963.16(b) (except not all engineered and natural barriers will be considered), and using all of the criteria in section 963.17, including the criterion assuming a stylized human intrusion into the repository, as defined by NRC regulations. The results of each performance assessment will be examined by DOE to determine the suitability of the site for the postclosure period.

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The conduct of separate assessments is consistent with EPA's proposed 40 CFR part 197 and NRC's proposed regulations at 10 CFR part 63. The proposed regulations, in turn, are based on NAS recommendations in the report, *Technical Bases for Yucca Mountain Standards*, on how best to assess the performance and resilience of a potential repository. Because the manner and likelihood of human intrusion occurring many hundreds or thousands of years into the future cannot be estimated reliably by examining either the historic or geologic record, the NAS recommended an approach that will assess how resilient the geologic repository would be against a postulated intrusion. The consequences of the assumed human intrusion event will be addressed in a "stylized" manner, that is, by assuming a particular human intrusion event occurs in a certain way, at a specified time. Proposed EPA and NRC regulations define different stylized human intrusion events to be examined by DOE. At the time of the suitability determination, DOE will conduct the human intrusion analysis within the framework of the applicable regulatory concept, and use the results of the performance assessment to evaluate the suitability of the site for the postclosure period.

(2) *Section 963.16(b)*. Section 963.16(b) provides an outline of the contents and manner in which DOE will conduct its performance assessments. As described previously in this notice, and briefly summarized here, performance assessment in this context is a method of forecasting how a system or parts of a system designed to contain radioactive waste will behave over time. Its goal is to aid in determining whether or not the system can meet established performance requirements. A TSPA is a type of performance assessment analysis in which the components of a system are integrated or linked into a single analysis.

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The TSPA addresses both the engineered and natural system components. The engineered system is to some extent controllable, but the natural system generally is not. The responses of the total system extend over periods beyond those for which data have been or can be obtained. The relationship of the components of a TSPA is often described as a pyramid. The lowest level of the pyramid represents the complete suite of process and design data and information (that is, field and laboratory studies that are the first step in understanding the system). The next higher level indicates how the data feed into conceptual models that portray the operation of the individual system components. The next higher level represents the synthesis of information from the lower levels of the pyramid into computer models. The term *abstraction* often is used to indicate the extraction of essential information from large quantities of data. The TSPA models are usually referred to as abstracted models. At this point, the subsystem behavior may be described by linking models together into representations; this is the point at which performance assessment modeling is usually thought to begin. This is also the basis for the identification of the Yucca Mountain specific suitability criteria contained in the final rule.

The upper level is the final level of distillation of information into the most significant aspects to represent the total system. At this point, the models are linked together. These are the models used to forecast system performance and estimate the likelihood that the performance will comply with regulations and ensure long-term safety.

As information flows up the pyramid, it generally is distilled into progressively more simplified or essential forms, or becomes more abstracted. However, abstraction is not synonymous with simplification. If a particular component model cannot be simplified without

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losing essential aspects of the model, then the model becomes part of the TSPA calculation tool. Thus, an abstracted model in a TSPA may take the form of something as simple as a table of values that were calculated using a complex computer model, or the abstraction may take the form of a fully three dimensional computer simulation.

The TSPA method described in section 963.16(b) is a systematic analysis that identifies the features, events, and processes (i.e., specific conditions or attributes of the geologic setting, degradation, deterioration, or alteration processes of engineered barriers, and interactions between the natural and engineered barriers) that might affect performance of the geologic repository; examines their effects on performance; and estimates the expected annual dose. The features, events, and processes considered in the TSPA will represent a wide range of effects on geologic repository performance. According to proposed EPA and NRC regulations, those features, events, and processes expected to affect compliance significantly or be potentially adverse to performance are included, while events of very low probability (less than one chance in 10,000 of occurring within 10,000 years of disposal) can be excluded from the analysis. The expected annual dose to the group receptor is estimated using the selected features, events, and processes, and incorporating the probability that the estimated dose will occur.

The TSPA that will be used to assess the postclosure performance of the Yucca Mountain repository will be conducted in the manner described in section 963.16(b). It will synthesize data and information into a set of models that simulate the behavior of the individual system components. DOE will abstract essential information from its initial models and refine them into linked models, including computer models, that represent important aspects of system

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performance. DOE will use these models to forecast system behavior and the likelihood of system compliance with the applicable radiation protection standard.

The TSPA method described in section 963.16(b) contains twelve enumerated conditions to be satisfied in conducting the TSPA for the postclosure suitability determination. Those conditions will provide DOE with multiple lines of argument and evidence in support of the resultant TSPA calculation. For example, as part of the TSPA calculation, DOE will consider disruptive processes and events, identify and evaluate multiple barriers to waste isolation, produce information relative to the margin by which the site will meet the applicable radiation protection standard, and include analysis of insights from man-made analogs. Development of this information will build confidence in the TSPA result and aid decision-makers in reaching a suitability determination. Through documentation of the technical basis for much of the analysis, DOE will identify and quantify uncertainties associated with the performance estimates, explain and describe the critical assumptions used and possible data limitations, and identify the areas where expert judgment and natural analogs were used in the analyses.

The TSPA calculations will be used to address conditions in the natural and engineered components of a repository at Yucca Mountain over the time that the standards apply. The TSPA calculations will also be used to consider disruptive events that are improbable, but that are important to understanding the repository behavior in the future. A requirement for TSPA will be identification of those natural features of the geologic setting and the design features of the engineered barrier system that are considered barriers important to waste isolation. TSPA will be used to assess the capability of the barriers, identified as important to waste isolation, to isolate

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waste, taking into account uncertainties in characterizing and modeling the barriers. By conducting these analyses and documenting the technical basis for them, DOE will account for multiple and independent barriers to waste isolation. Sensitivity studies and the regulatory definition of very-low probability events will provide the technical basis for inclusion or exclusion of specific features, events, and processes of the geologic setting in the TSPA.

Specific features, events, and processes of the geologic setting will be evaluated through sensitivity analyses to determine if the magnitude and time of the resulting expected annual dose would be significantly changed by their omission. Sensitivity analysis is a technique that is used to examine how a system responds if one of its components is changed. Systems are said to be sensitive to such a component if the results of the calculation are changed significantly in response to changes in that component's values. The sensitivity calculations will also provide the technical basis for either inclusion or exclusion of degradation or alteration processes of engineered barriers in the TSPA. Degradation or alteration processes will be evaluated further if the magnitude and timing of the resulting expected annual dose would be significantly changed by their omission.

Using the TSPA results, DOE can examine the sensitivity of one or more components of the calculations in the assessment. DOE can examine the response of the geologic repository system with regard to sensitivities of the system to the suitability criteria, in order to evaluate whether or not the geologic repository meets the applicable radiation protection standard.

As part of the TSPA, DOE will account for uncertainties and variabilities in both calculations and data, and provide the technical bases for parameter ranges, probability

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distributions, and bounding values. This accounting will enable DOE to identify critical assumptions, address uncertainties in those assumptions, and understand possible data limitations. The reason for this accounting is that it is recognized, by the NRC and others, that there are inherent uncertainties in the understanding of the evolution of the geologic setting, biosphere, and engineered barrier system. DOE will demonstrate compliance and the performance of the potential repository using sophisticated, complex predictive models that are supported by data from field and laboratory tests, site-specific monitoring, and natural analog studies that may be supplemented with expert judgment.

Another aspect of DOE's conduct of the TSPA is the analysis of alternative models of features and processes. Under 963.16(b)(3), DOE will consider alternative models of features and processes that are consistent with available data and current scientific understanding, and evaluate the effects that alternative models would have on the estimated performance of the geologic repository. These analyses will help DOE and others to assess the validity of the conceptual models and estimates of the significance of those models to repository performance. In this regard, if other interested persons suggest and present to DOE alternative models that are consistent with available data and current scientific understanding, DOE will evaluate those other models. In implementing this requirement, however, DOE does not believe it would be scientifically or technically useful, and may be administratively burdensome, to require that, in every case, DOE provide the bases for not using an alternative model suggested by another party. However, DOE may decide, on a case-by-case basis, to document consideration of alternative models that were suggested by other interested persons, but not used because, among other things, the model is not consistent with available data and current scientific understanding.

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(h) *Postclosure suitability criteria - section 963.17.* The postclosure criteria to evaluate the suitability of a geologic repository at Yucca Mountain will be considerations that reflect both the processes and the models used to simulate those processes that are important to the total system performance of the geologic repository. These criteria are characterizing traits that are relevant and important in the processes to be modeled in the TSPA that evaluates the suitability of the Yucca Mountain site for the postclosure period. These criteria also are related to the section 112(a) geologic considerations identified in the NWPA. Following is a description of how the section 112(a) geologic considerations relate to the postclosure suitability criteria, as well as a discussion of the criteria as they relate to the processes and computer models to be used in evaluating the performance of a geologic repository in the postclosure period.

(1) *Section 112(a) geologic considerations.* The geologic considerations identified in section 112(a) of the NWPA that are relevant to the postclosure performance of a repository at Yucca Mountain are: location of valuable natural resources, hydrology, geophysics, seismic activity, proximity to water supplies, and proximity to populations. These considerations are relevant to postclosure performance because they impact components and processes of the repository system related to potential transport of radionuclides via ground water to members of the public.

The location of valuable natural resources is a relevant geologic condition for postclosure performance because the presence of these resources in the geologic setting of Yucca Mountain could lead to exploratory drilling or excavation and a consequent breach of the repository's safety barriers. Hydrology- and geophysics- related conditions are relevant because they describe some

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of the geologic features of the site that are related to safety and the physical characteristics that are related to potential transport of radionuclides to the biosphere. Seismic activity is relevant to postclosure performance because it is related to the potential for changes in geologic structures that could lead to enhanced transport of radionuclides. Proximity to water supplies and populations are relevant to postclosure performance because they are related to potential locations where people could eventually be exposed to radionuclides in their water.

Table 2 provides a cross-references between the section 112(a) factors related to geologic considerations, and the postclosure suitability criteria. As previously stated, the postclosure suitability criteria largely represent the process model components of the total system performance assessment that DOE will use to evaluate the performance of the repository during the postclosure period. DOE has identified these processes as pertinent to assessing the performance of a repository at Yucca Mountain through information and data developed under its site characterization program. These processes also are related to, and impacted by, the geologic considerations found in section 112(a) of the NWPA.

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Table 2

	NWPA §112(a) Factors	Suitability Criteria
Postclosure	<i>(a) Processes pertinent to total system performance</i>	
	Hydrology, geophysics, seismic activity	(1) Site characteristics
	Hydrology, geophysics, seismic activity	(2) Unsaturated-zone flow characteristics
	Hydrology, geophysics, seismic activity	(3) Near-field environment characteristics
	Hydrology, geophysics, seismic activity	(4) Engineered barrier system degradation characteristics
	Hydrology, geophysics, seismic activity	(5) Waste form degradation characteristics
	Hydrology, geophysics, seismic activity	(6) Engineered barrier system degradation, flow, and transport characteristics
	Hydrology, geophysics, seismic activity	(7) Unsaturated-zone flow and transport characteristics
	Hydrology, geophysics, seismic activity	(8) Saturated-zone flow and transport characteristics
	Hydrology, proximity to water supplies, proximity to populations	(9) Biosphere characteristics
	<i>(b) Disruptive processes and events</i>	
Hydrology, geophysics	(1) Volcanism	
Seismic activity, geophysics	(2) Seismic events	

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Hydrology, geophysics, seismic activity	(3) Nuclear criticality
Location of valuable natural resources, proximity to populations	(4) Inadvertent human intrusion

(2) *Suitability criteria.* DOE has developed its site characterization program to address those processes of the repository system that are pertinent to understanding how a repository at Yucca Mountain would comply with applicable radiation protection standards. The program also has been developed to better understand these processes, and resolve or put in place methods to resolve issues related to those processes. DOE has described these processes, and the methods to resolve issues related to the processes, in the SCP, in semi-annual progress reports on site characterization program activities, in several TSPAs conducted over the years, and most recently in the Viability Assessment. These processes are simulated through performance assessment models; those models are integrated and refined to a point resulting in a representation of the performance of the system in total.

Put in simple terms, the processes that are pertinent to understanding the performance of a repository at Yucca Mountain, and that form the basis for the numerical models in the TSPA and the suitability criteria in section 963.17, are those physical processes of water falling on Yucca Mountain as rain and snow, moving into the mountain, down through the unsaturated zone to the potential repository level, from the repository level to the saturated zone, and from there to the outside environment. At the repository level, the water would be affected by the physical

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processes associated with the repository and with the waste packages and the waste forms.

Eventually, the water could move out of the repository horizon and further downward through the unsaturated zone. Subsequently, it could move into the saturated zone where it could be transported to a point where humans could be exposed to any radionuclides carried in the water. Disruptive events could potentially affect these processes and, therefore, need to be considered. This set of physical processes is simulated in the numerical modeling method of the TSPA that will be used to assess quantitatively the radionuclide releases to the public and, consequently, the safety and suitability of the Yucca mountain site.

The suitability criteria presented in this final rule are derived from these pertinent physical processes. These criteria represent the characteristic traits pertinent to assessing the performance of a geologic repository at the Yucca Mountain site. They also reflect and represent in a larger sense the geologic considerations identified in section 112(a) of the NWPA such as hydrology, geophysics, seismic activity, and proximity to water supplies and populations.

The sequence in which the suitability criteria are presented in the final rule generally corresponds to the process of water flow presented above. In general, the criteria can be thought of as building blocks; each criterion in the sequence is evaluated on its own, with the results of that evaluation incorporated into the evaluation of the succeeding criteria, and so on until the final analysis. As the site characterization program evolves, DOE may refine these process models to better reflect and assess the processes pertinent to performance of a geologic repository at the Yucca Mountain site. It is possible that the processes, as well as the design selected, could dictate other ways to arrange the information included under the individual criteria. While the individual

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components of the process models may vary according to improvements in data and information, DOE's resultant suitability determination would be based on an evaluation of each of the postclosure suitability criteria.

The criteria are separated into two categories. The first category, presented in section 963.17(a), represent those criteria important to the total system performance assessment without accounting for disruptive processes and events that could impact that performance. The second category, presented in section 963.17(b), are those criteria representing disruptive processes and events that could adversely affect the characteristics of the repository system, and consequently release radionuclides to the human environment. Each criterion in the first category is linked to a specific TSPA model component that will be used to evaluate the performance of that criterion. Each criterion in the second category is generally treated as an effect imposed on the system at a time that reflects the probability of occurrence of the disruptive event.

Under section 963.17(a), the first and a fundamental criterion that will be modeled to assess performance of a repository at the Yucca Mountain site is the representation of pertinent site characteristics. The criterion of *site characteristics* includes: (a) the geologic properties of the site - for example, stratigraphy, rock type and physical properties, and structural characteristics; (b) the hydrologic properties of the site - for example, porosity, permeability, moisture content, saturation, and potentiometric characteristics; (c) the geophysical properties of the site - for example, thermal properties, densities, velocities and water contents, as measured or deduced from geophysical logs, and (d) the geochemical properties of the site - for example, precipitation, dissolution characteristics, and sorption properties of mineral and rock surfaces. Together, as

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reflected in the performance assessment, these characteristics enable a representative simulation of the behavior of a geologic repository at the Yucca Mountain site.

The second criterion, *unsaturated zone flow characteristics*, relates to the processes affecting the limitations and amount of water entering the unsaturated zone above the repository and contacting wastes in the repository. *Unsaturated zone flow characteristics* include: (a) climate - for example, precipitation and postulated future climatic conditions; (b) infiltration - for example, precipitation entering the mountain in excess of water returned to the atmosphere by evaporation and plant transpiration; (c) unsaturated-zone flux - for example, water movement through the pore spaces, or flowing along fractures or through perched water zones above the repository; and (d) seepage - for example, water dripping into the underground repository openings from the surrounding rock. Together, the first and second criteria define the temporal and spatial distribution of water flow through the unsaturated zone above the water table at Yucca Mountain, and the temporal and spatial distribution of water seepages into the underground openings of the repository.

The third criterion, *near field environment characteristics*, also relates to processes important to limiting the amount of water that could contact wastes. This criterion includes: (a) thermal hydrology - for example, effects of heat from the waste on water flow through the site, and the temperature and humidity at the engineered barriers; and, (b) near-field geochemical environment - for example, the chemical reactions and products resulting from water contacting the waste and the engineered barriers materials. The thermal regime generated by the decay of the radioactive wastes can mobilize water over the first hundreds to thousands of years. For these

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reasons, the amount of water flowing in the rock and seeping into drifts is expected to vary with time.

The fourth criterion, *engineered barrier system degradation characteristics*, relates to the processes important to long waste package lifetimes. This criterion includes: (a) engineered barrier system component performance - for example, drip shields, backfill, coatings, or chemical modifications; and (b) waste package degradation - for example, the corrosion of the waste package materials within the near-field repository environment. This criterion and the first criterion, *site characteristics*, define the spatial and temporal distribution of the time periods when waste packages are expected to breach. The thermal, hydrologic, and geochemical processes acting on the waste package surface are the most important environmental factors affecting the waste package lifetime. In addition, the degradation characteristics of the waste package materials significantly impact the timing of waste package breaches.

The fifth criterion, *waste form degradation characteristics*, addresses the initial aspects of low rate of release of radionuclides. This criterion includes: (a) cladding degradation - for example, corrosion or break-down of the cladding on the spent fuel pellets; and, (b) waste form dissolution - for example, the ability of individual radionuclides to dissolve in water that penetrates breached waste packages. This criterion is important to understanding how and in what manner the waste forms could break down, permitting the release of radionuclides to the immediately surrounding environment.

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The sixth criterion, *engineered barrier system degradation, flow, and transport characteristics*, addresses the processes important to the manner in which radionuclides can begin to move outward once the engineered barrier system has been degraded. This criterion includes :

(a) colloid formation and stability - for example, the formation of colloidal particles and the ability of radionuclides to adhere to these particles as they may be washed through the remaining barriers; and (b) engineered barrier transport - for example, the movement of radionuclides dissolved in water or adhering to colloidal particles to be transported through the remaining engineered barriers and in the underlying unsaturated zone. This criterion and the first criterion, *site characteristics*, lead to a determination of the spatial and temporal distribution of the mass of radioactive wastes released from the waste packages. Each characteristic depends on the thermal, hydrologic, and geochemical conditions inside the waste package, which change with time.

The next two criteria -- *unsaturated zone flow and transport characteristics (criterion seven)*, and *saturated zone flow and transport characteristics (criterion eight)* -- relate to processes important to radionuclide concentration reduction during transport. To assess the movement of radionuclides away from the degraded engineered barrier system, the first important process to understand is the unsaturated zone flow characteristics in combination with the unsaturated zone transport characteristics. The *unsaturated zone flow and transport characteristics* criterion includes: (a) unsaturated-zone transport - for example, the movement of water with dissolved radionuclides or colloidal particles through the unsaturated zone underlying the repository, including retardation mechanisms such as sorption on rock or mineral surfaces; and (b) thermal hydrology - for example, effects of heat from the waste on water flow through the site. The next criterion, *saturated zone flow and transport characteristics*, addresses similar

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radionuclide transport processes, only in the saturated zone. This criterion includes: (a) saturated zone transport - for example, the movement of water with dissolved radionuclides or colloidal particles through the saturated zone underlying and beyond the repository, including retardation mechanisms such as sorption on rock or mineral surfaces; and (b) dilution - for example, diffusion of radionuclides into pore spaces, dispersion of radionuclides along flow paths, and mixing with non-contaminated ground water.

The ninth criterion, *biosphere characteristics*, addresses the characteristics that describe the lifestyle and habits of individuals who potentially could be exposed to radioactive material at a future time. Because of the difficulty in predicting the lifestyles and habits of future generations, such assessments are to be based on representative current conditions. Both the EPA and the NRC have proposed rules that would require DOE to apply current conditions in assessments of the reference biosphere. This criterion includes: (a) a reference biosphere and receptor defined, for example, by considering pathways, location and behavior representative of current conditions; and (b) biosphere transport and uptake - for example, the consumption of ground or surface waters through direct extraction or agriculture, including mixing with non-contaminated waters and exposure to contaminated agricultural products.

Together, the criteria of *unsaturated zone flow and transport characteristics*, *saturated zone flow and transport characteristics*, and *biosphere characteristics*, address the spatial and temporal variations of radionuclide concentrations in ground water. The ground water concentration ultimately yields the mass of radionuclides that may be ingested or inhaled by individuals exposed to that ground water, which in turn leads to a level of radiological dose or

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risk associated with that potential exposure. The concentration depends on both the mass release rate of the radionuclides as well as the volumetric flux of water along the different pathways in the different components.

Section 963.17(b) presents four final criteria (separately enumerated from section 963.17(a)) under the category of disruptive processes and events. These criteria relate to disruptive processes and events that could potentially release radionuclides directly to the human environment, or otherwise adversely affect the characteristics of the system. The criteria pertinent to assessing repository performance relative to this attribute include: (1) *volcanism* - for example, the probability and potential consequences of a volcanic eruption intersecting the repository; (2) *seismic events* - for example, the probability and potential consequences of an earthquake on the underground facilities or hydrologic system; and (3) *nuclear criticality* - for example, the probability and potential consequences of a self-sustaining nuclear reaction as a result of chemical or physical processes affecting the waste either in or after release from breached waste packages.

The last of the four disruptive processes and events criteria, *inadvertent human intrusion*, is a special criterion to be applied and assessed in its own performance assessment. Although characterization of the Yucca Mountain site and region indicates that it is not a likely choice for future exploration for natural resources, the NRC has identified the examination of a human intrusion scenario through drilling as a requirement for a TSPA in its proposed part 63. Accordingly, *inadvertent human intrusion* - for example, consequences to repository system performance following a stylized human intrusion scenario, is included in the criteria for disruptive processes and events, although it will be treated in a separate performance assessment.

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In making its suitability determination, DOE would apply the regulatory concept for human intrusion applicable at that time.

VII. Regulatory Review

A. Review for Compliance with the National Environmental Policy Act (NEPA)

One commenter questioned whether or not this rulemaking would require compliance with NEPA. The issuance of these amendments to the Guidelines is a preliminary decision-making activity pursuant to subsections 112 (d) and 113(d) of the Act and therefore does not require the preparation of an environmental impact statement pursuant to subsection 102(2)(C) of the NEPA or any other environmental review under subsection 102(2)(E) or (F) of the NEPA.

B. *Review under the Regulatory Flexibility Act*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) was enacted by Congress to ensure that a substantial number of small entities do not unnecessarily face significant negative economic impact as a result of Government regulations. The DOE certifies that the rule amending the Guidelines will not have a significant impact on a substantial number of small entities. The final rule will not regulate or otherwise economically burden anyone outside of the DOE. It merely articulates considerations for the Secretary of Energy to use in determining whether or not the Yucca Mountain site is suitable for development as a repository. Moreover, in response to the revised notice of proposed rulemaking, a few entities who commented were small entities, and

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none of them identified economic burdens that the regulations would impose. Accordingly, no regulatory flexibility analysis is required under the Regulatory Flexibility Act.

C. Review under the Paperwork Reduction Act

The DOE has determined that this final rule contains no new or amended record keeping, reporting, or application requirements, or any other type of information collection requirements subject to the Paperwork Reduction Act (Pub. L. No. 96-511).

D. Review under Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104-4) generally requires Federal agencies to closely examine the impacts of regulatory actions on State, local, and tribal governments. Subsection 101(5) of Title I of that law defines a Federal intergovernmental mandate to include any regulation that would impose an enforceable duty upon State, local, or tribal governments, except, among other things, a condition of Federal assistance or a duty arising from participating in a voluntary federal program. Title II of that law requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and tribal governments, in the aggregate, or to the private sector, other than to the extent such actions merely incorporate requirements specifically set forth in a statute. Section 202 of that title requires a Federal agency to perform a detailed assessment of the anticipated costs and benefits of any rule that includes a Federal mandate which may result in costs to State, local, or tribal governments, or to the private sector, of \$100 million or more. Section 204 of that title requires each agency that proposes a rule

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containing a significant Federal intergovernmental mandate to develop an effective process for obtaining meaningful and timely input from elected officers of State, local, and tribal governments.

This final rule is not likely to result in any Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$100 million or more in any one year. Further, the Guidelines in 10 CFR part 960, the final amendments to part 960 and the final part 963 largely incorporate requirements specifically provided in Sections 112 and 113 of the Act. Moreover, Sections 112, 113 and 114 of the Act provide for meaningful and timely input from elected officials of State, local and tribal governments. Accordingly, no assessment or analysis is required under the Unfunded Mandates Reform Act of 1995.

E. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Public Law 105-277) requires Federal agencies to issue a Family Policymaking Assessment for any final rule or policy that may affect family well-being. Today's final rulemaking would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

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F. *Review under Executive Order 12866*

Section 1 of Executive Order 12866 (“Regulatory Planning and Review”), 58 FR 51735, establishes a philosophy and principles for Federal agencies to follow in promulgating regulations. Section 1(b)(9) of that Order provides: “Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, agencies shall seek to harmonize Federal regulatory actions with regulated State, local and tribal regulatory and other governmental functions.”

Section 6 of Executive Order 12866 provides for a review by the Office of Information and Regulatory Affairs (OIRA) of a “significant regulatory action,” which is defined to include an action that may have an effect on the economy of \$100 million or more, or adversely affect, in a material way, the economy, competition, jobs, productivity, the environment, public health or safety, or State, local, or tribal governments. The Department has concluded that this final rule is a significant regulatory action that requires a review by the OIRA. DOE submitted this rule for OIRA clearance, and OIRA has completed its review.

One commenter suggested that, under Executive Order 12866, DOE should assess the effects of this rulemaking on State, local, and tribal governments including reasonable efforts to

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minimize any burdens that uniquely or significantly affect such governmental entities. The commenter argued that ongoing characterization and development of the Yucca Mountain site affected the economy, jobs, the environment, and public health and safety. While certain determinations in DOE's nuclear waste repository program may have such effects that can be analyzed, the decision to promulgate today's rule is not one of them. It will not regulate anyone other than DOE officials. It will affect preliminary decision-making in a way that does not have specific identifiable economic, environmental, or health effects.

G. Review under Executive Order 12875

Executive Order 12875 (Enhancing Intergovernmental Partnership), provides for reduction or mitigation, to the extent allowed by law, of the burden on State, local and tribal governments of unfunded Federal mandates not required by statute. The analysis under the Unfunded Mandates Reform Act of 1995, above, satisfies the requirements of Executive Order 12875. Accordingly, no further analysis is required under Executive Order 12875.

H. Review under Executive Order 12898

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations) requires Federal agencies to achieve environmental justice by identifying and addressing, as appropriate, disproportionately high and adverse human health and environmental effects of its programs, policies, and activities on minority and low-

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income populations. One commenter on the proposed rule said that DOE should fully apply this Executive Order to this rulemaking, but did not provide any supporting reasons. In DOE's view, the requirements of Executive Order 12898 are not implicated by this rulemaking. This rulemaking has direct effects or regulates only DOE, and therefore will not have disproportionate and adverse human health effects on minority and low-income populations.

I. Review under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any Guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. The DOE has completed the required review and

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determined that, to the extent permitted by law, the final rule meets the relevant standards of Executive Order 12988.

J. Review under Executive Order 13084

Under Executive Order 13084, "Consultation and Coordination with Indian Tribal Governments," DOE may not issue a discretionary rule that significantly or uniquely affects Indian tribal governments and imposes substantial direct compliance costs. This final rulemaking would not have such effects. Accordingly, Executive Order 13084 does not apply to this rulemaking.

K. Review Under Executive Order 13132

The President has replaced Executive Order 12612 with Executive Order 13132. The new Executive Order creates special requirements for preemption and inter-governmental consultation with regard to rules that have federalism implications. According to the new Executive Order, a policy has federalism implications if it has "substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

One of the county governments in Nevada asserted that DOE should be demonstrating consideration of the effects of the rule on State and local governments, the relationship between the Federal government and the States, or the distribution of power and responsibility among various

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levels of government. The comment was conclusory and did not identify any “substantial direct” effects that would warrant consideration under the executive order. For a variety of reasons, DOE is of the view that the special requirements of the Executive Order 13132 do not apply to this rule. First, the rule does not preempt State law. Second, the rule applies directly only to DOE and deals with a preliminary stage in a decision-making process about the Yucca Mountain site that calls for additional inter-governmental consultation and public hearings. Third, the rule does not regulate or alter the relationship between the United States and State, local, and tribal governments because the terms of that relationship are set forth in the NWPA. Fourth, the rule has no impact on the distribution of power and responsibilities among various levels of government.

List of Subjects in 10 CFR Parts 960 and 963

Criteria, Environmental protection, Geologic repositories, Nuclear energy, Nuclear materials, Radiation protection, Suitability, Waste disposal.

Issued in Washington, D.C., on

Ivan Itkin, Director

Office of Civilian Radioactive Waste Management

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For the reasons stated in the preamble, DOE hereby amends part 960, and adds a new part 963 to, Chapter II of Title 10 of the Code of Federal Regulations as follows:

PART 960 - GENERAL GUIDELINES FOR THE RECOMMENDATION OF SITES FOR A NUCLEAR WASTE REPOSITORY

1. The authority for 10 CFR part 960 is revised to read as follows: 42 U.S.C. 2011, et seq., 42 U.S.C. 7101, et seq., 42 U.S.C. 10101. et seq.

2. The part heading for Part 960 is revised to read: **GENERAL GUIDELINES FOR THE PRELIMINARY SCREENING OF POTENTIAL SITES FOR A NUCLEAR WASTE REPOSITORY.**

§ 960.1 [AMENDED]

3. **Section 960.1** is amended by removing the phrase “for the development of repositories” from the first sentence and removing the phrase “and any preliminary suitability determinations required by Section 114(f)” from the second sentence.

4. **Section 960.2** is amended by revising the definitions of “Act,” “Application” and “Determination” to read as follows:

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§ 960.2 Definitions

* * * * *

Act means the Nuclear Waste Policy Act of 1982, as amended.

* * * * *

Application means the act of making a finding of compliance or noncompliance with the qualifying or disqualifying conditions specified in the Guidelines of subparts C and D.

* * * * *

Determination means a decision by the Secretary that a site is suitable for site characterization for the selection of a repository, consistent with applications of the Guidelines of subparts C and D in accordance with the provisions set forth in subpart B.

* * * * *

§ 960.3 [AMENDED]

5. **Section 960.3** is amended by removing the phrase “for the development of repositories” from the first sentence.

§ 960.3-1-4-4 [REMOVED]

6. **Section 960.3-1-4-4** is removed.

7. **Section 960.3-1-5** is revised to read as follows:

§ 960.3-1-5 Basis for site evaluations.

(a) Evaluations of individual sites and comparisons between and among sites shall be based on the postclosure and preclosure guidelines specified in subparts C and D of this part, respectively. Except for screening for potentially acceptable sites as specified in Sec. 960.3-2-1,

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such evaluations shall place primary significance on the postclosure guidelines and secondary significance on the preclosure guidelines, with each set of guidelines considered collectively for such purposes. Both the postclosure and the preclosure guidelines consist of a system guideline or guidelines and corresponding groups of technical guidelines.

(b) The postclosure guidelines of subpart C of this part contain eight technical guidelines in one group. The preclosure guidelines of subpart D of this part contain eleven technical guidelines separated into three groups that represent, in decreasing order of importance, preclosure radiological safety; environment, socioeconomics, and transportation; and ease and cost of siting, construction, operation, and closure.

(c) The relative significance of any technical guideline to its corresponding system guideline is site specific. Therefore, for each technical guideline, an evaluation of compliance with the qualifying condition shall be made in the context of the collection of system elements and the evidence related to that guideline, considering on balance the favorable conditions and the potentially adverse conditions identified at a site. Similarly, for each system guideline, such evaluation shall be made in the context of the group of technical guidelines and the evidence related to that system guideline.

(d) For purposes of recommending sites for development as repositories, such evidence shall include analyses of expected repository performance to assess the likelihood of demonstrating compliance with 40 CFR part 191 and 10 CFR part 60, in accordance with Sec. 960.4-1. A site shall be disqualified at any time during the siting process if the evidence supports a finding by the DOE that a disqualifying condition exists or the qualifying condition of any system or technical guideline cannot be met.

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(e) Comparisons between and among sites shall be based on the system guidelines, to the extent practicable and in accordance with the levels of relative significance specified above for the postclosure and the preclosure guidelines. Such comparisons are intended to allow comparative evaluations of sites in terms of the capabilities of the natural barriers for waste isolation and to identify innate deficiencies that could jeopardize compliance with such requirements. If the evidence for the sites is not adequate to substantiate such comparisons, then the comparisons shall be based on the groups of technical guidelines under the postclosure and the preclosure guidelines, considering the levels of relative significance appropriate to the postclosure and the preclosure guidelines and the order of importance appropriate to the subordinate groups within the preclosure guidelines. Comparative site evaluations shall place primary importance on the natural barriers of the site. In such evaluations for the postclosure guidelines of subpart C of this part, engineered barriers shall be considered only to the extent necessary to obtain realistic source terms for comparative site evaluations based on the sensitivity of the natural barriers to such realistic engineered barriers. For a better understanding of the potential effects of engineered barriers on the overall performance of the repository system, these comparative evaluations shall consider a range of levels in the performance of the engineered barriers. That range of performance levels shall vary by at least a factor of 10 above and below the engineered-barrier performance requirements set forth in 10 CFR 60.113, and the range considered shall be identical for all sites compared. The comparisons shall assume equivalent engineered barrier performance for all sites compared and shall be structured so that engineered barriers are not relied upon to compensate for deficiencies in the geologic media. Furthermore, engineered barriers shall not be used to compensate for an inadequate site; mask the innate deficiencies of a site; disguise the strengths and weaknesses of a site and the overall system; and mask differences between sites when they are compared. Releases

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of different radionuclides shall be combined by the methods specified in appendix A of 40 CFR part 191.

(f) The comparisons specified above shall consist of two comparative evaluations that predict radionuclide releases for 100,000 years after repository closure and shall be conducted as follows. First, the sites shall be compared by means of evaluations that emphasize the performance of the natural barriers at the site. Second, the sites shall be compared by means of evaluations that emphasize the performance of the total repository system. These second evaluations shall consider the expected performance of the repository system; be based on the expected performance of waste packages and waste forms, in compliance with the requirements of 10 CFR 60.113, and on the expected hydrological and geochemical conditions at each site; and take credit for the expected performance of all other engineered components of the repository system. The comparison of isolation capability shall be one of the significant considerations in the recommendation of sites for the development of repositories. The first of the two comparative evaluations specified in the preceding paragraph shall take precedence unless the second comparative evaluation would lead to substantially different recommendations. In the latter case, the two comparative evaluations shall receive comparable consideration. Sites with predicted isolation capabilities that differ by less than a factor of 10, with similar uncertainties, may be assumed to provide equivalent isolation.

8. In section 960.3-2, the last sentence is revised to read as follows:

§ 960.3-2 Siting process

* * * The recommendation of sites as candidate sites for characterization shall be accomplished in accordance with the requirements specified in § 960.3-2-3.

§ 960.3-2-4 [REMOVED]

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9. Section 960.3-2-4 is removed.

Appendix III to Part 960 [AMENDED]

10. Appendix III to Part 960 is amended as follows:

In paragraph 1, introductory text, first sentence, revise the phrase “the principal” to read “certain”

In paragraph 1, remove the definition (decision point) for “Repository Site Selection.”

In paragraph 2, remove the definition for the numeral “4” and paragraphs “a” and “b” which follow.

In the table, Findings Resulting From the Application of the Qualifying and Disqualifying Conditions of the Technical Guidelines at Major Siting Decisions, remove the column heading and corresponding entries for “Repository Site Selection” under the heading “Siting Decision.”

4. New part 963 is added to read as follows:

PART 963 - YUCCA MOUNTAIN SITE SUITABILITY GUIDELINES

Subpart A - General Provisions

963.1 Purpose.

963.2 Definitions.

Subpart B - Site Suitability Determination, Methods and Criteria

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- 963.10 Scope.
- 963.11 Suitability determination.
- 963.12 Preclosure suitability determination.
- 963.13 Preclosure suitability evaluation method.
- 963.14 Preclosure suitability criteria.
- 963.15 Postclosure suitability determination.
- 963.16 Postclosure suitability evaluation method.
- 963.17 Postclosure suitability criteria.

Authority: 42 U.S.C. 2011 et seq.; 42 U.S.C. 7101 et seq.; 42 U.S.C. 10101, et seq.

Subpart A - General Provisions

§ 963.1 Purpose.

(a) The purpose of this part is to establish DOE methods and criteria for determining the suitability of the Yucca Mountain site for the location of a geologic repository. DOE will use these methods and criteria in analyzing the data from the site characterization activities required under section 113 of the Nuclear Waste Policy Act.

(b) This part does not address other information that must be considered and submitted to the President, and made available to the public, by the Secretary under section 114 of the Nuclear Waste Policy Act if the Yucca Mountain site is recommended for development as a geologic repository.

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§ 963.2 Definitions.

For purposes of this Part:

Barrier means any material, structure or process that prevents or substantially delays the movement of water or radionuclides.

Cladding is the metallic outer sheath of a fuel rod element; it is generally made of a corrosion resistant zirconium alloy or stainless steel, and is intended to isolate the fuel from the external environment.

Closure means the final closing of the remaining open operational areas of the underground facility and boreholes after termination of waste emplacement, culminating in the sealing of shafts and ramps, except those openings that may be designed for ventilation or monitoring.

Colloid means any fine-grained material in suspension, or any such material that can be easily suspended.

Criteria means the characterizing traits relevant to assessing the performance of a geologic repository, as defined by this section, at the Yucca Mountain site.

Design means a description of the engineered structures, systems, components and equipment of a geologic repository at Yucca Mountain that includes the engineered barrier system.

Design basis event means

- (1) those natural and human-induced events that are expected to occur one or more times before permanent closure; or
- (2) other natural and human-induced events that have at least one chance in 10,000 of occurring before permanent closure.

DOE means the U.S. Department of Energy, or its duly authorized representatives.

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Engineered barrier system means the waste packages and the underground facilities.

Expected means assumed to be probable on the basis of existing evidence and in the absence of significant evidence to the contrary.

Geologic repository means a system that is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media including the engineered barrier system and the portion of the geologic setting that provides isolation of the radioactive waste.

Geologic setting means geologic, hydrologic, and geochemical system of the region in which a geologic repository operations area at Yucca Mountain is or may be located.

Infiltration means the flow of a fluid into a solid substance through pores or small openings; specifically, the movement of water into soil and fractured or porous rock.

Near-field means the region where the adjacent natural geohydrologic system has been significantly impacted by the excavation of the repository and the emplacement of the waste.

NRC means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

Perched water means ground water of limited lateral extent separated from an underlying body of ground water by an unsaturated zone.

Preclosure or preclosure period means the period of time before and during closure of the geologic repository.

Preclosure safety evaluation means a preliminary assessment of the adequacy of repository support facilities to prevent or mitigate the effects of postulated design basis events (including fire, radiation, criticality, and chemical hazards), and the site, structures, systems, components, equipment, and operator actions that would be relied on for safety.

Postclosure means the period of time after the closure of the geologic repository.

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Radioactive waste means high-level radioactive waste and other radioactive materials, including spent nuclear fuel, that are received for emplacement in the geologic repository.

Reference biosphere means the description of the environment, inhabited by the receptor, comprising the set of specific biotic and abiotic characteristics of the environment, including, but not limited to, climate, topography, soils, flora, fauna, and human activities.

Repository support facilities means all permanent facilities constructed in support of site characterization activities and repository construction, operation, and closure activities, including surface structures, utility lines, roads, railroads, and similar facilities, but excluding the underground facility.

Seepage means the inflow of ground water moving in fractures or pore spaces of permeable rock to an open space in the rock such as an excavated drift.

Sensitivity study mean an analytic or numerical technique for examining the effects on outcomes, such as radionuclide releases, of varying specified parameters, such as the infiltration rate due to precipitation, when a model run is performed.

Site characterization means activities, whether in the laboratory or in the field, undertaken to establish the geologic conditions and the ranges of the parameters of a candidate site relevant to the location of a repository, including borings, surface excavations, excavations of exploratory shafts, limited subsurface lateral excavations and borings, and in situ testing needed to evaluate the suitability of a candidate site for the location of a repository, but not including preliminary borings and geophysical testing needed to assess whether site characterization should be undertaken.

Surface facilities means repository support facilities within the restricted area located on or above the ground surface.

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System performance means the complete behavior of a geologic repository system at Yucca Mountain in response to the conditions, processes, and events that may affect it.

Total system performance assessment means a probabilistic analysis that is used to:

- (1) identify the features, events and processes that might affect the performance of the geologic repository;
- (2) examine the effects of such features, events, and processes on the performance of the geologic repository; and
- (3) estimate the expected annual dose to the receptor as a result of releases from the geologic repository.

Underground facility means the underground structure, backfill materials, if any, and openings that penetrate the underground structure (e.g., ramps, shafts and boreholes, including their seals).

Waste is synonymous with "radioactive waste."

Waste form means the radioactive waste materials and any encapsulating or stabilizing matrix.

Waste package means the waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

Yucca Mountain site means the candidate site in the State of Nevada recommended by the Secretary to the President under section 112(b)(1)(B) of the Nuclear Waste Policy Act of 1982 (NWPA) [42 U.S.C. 1032(b)(1)(B)] on May 27, 1986.

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Subpart B - Site Suitability Determination, Methods, and Criteria

§ 963.10 Scope.

(a) The scope of this subpart includes the following for both the preclosure and postclosure periods:

(1) The bases for the suitability determination for the Yucca Mountain site as a location for a geologic repository;

(2) The suitability evaluation methods for applying the site suitability criteria to a geologic repository at the Yucca Mountain site; and

(3) The site suitability criteria that DOE will apply in accordance with section 113(b)(1)(A)(iv) of the NWPA.

(b) DOE will seek NRC concurrence on any future revisions to this subpart.

§ 963.11 Suitability determination.

DOE will evaluate whether the Yucca Mountain site is suitable for the location of a geologic repository on the basis of the preclosure and postclosure determinations described in sections 963.12 and 963.15. If DOE's evaluation of the Yucca Mountain site for the location of a geologic repository under sections 963.12 and 963.15 shows that the geologic repository is likely to meet the applicable radiation protection standards for the preclosure and postclosure periods, then DOE may determine that the site is a suitable location for the development of such a repository.

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§ 963.12 Preclosure suitability determination.

DOE will apply the method and criteria described in sections 963.13 and 963.14 to evaluate the suitability of the Yucca Mountain site for the preclosure period. If DOE finds that the results of the preclosure safety evaluation conducted under section 963.13 show that the Yucca Mountain site is likely to meet the applicable radiation protection standard, DOE may determine the site suitable for the preclosure period.

§ 963.13 Preclosure suitability evaluation method.

(a) DOE will evaluate preclosure suitability using a preclosure safety evaluation method. DOE will evaluate the performance of the geologic repository at the Yucca Mountain site using the method described in paragraph (b) of this section and the criteria in section 963.14. DOE will consider the performance of the system in terms of the criteria to evaluate whether the geologic repository is likely to comply with the applicable radiation protection standard.

(b) The preclosure safety evaluation method, using preliminary engineering specifications, will assess the adequacy of the repository facilities to perform their intended functions and prevent or mitigate the effects of postulated design basis events that are deemed sufficiently credible to warrant consideration. The preclosure safety evaluation will consider:

(1) A preliminary description of the site characteristics, the surface facilities and the underground operating facilities;

(2) A preliminary description of the design bases for the operating facilities and a preliminary description of any associated limits on operation;

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(3) A preliminary description of potential hazards, event sequences, and their consequences; and

(4) A preliminary description of the structures, systems, components, equipment, and operator actions intended to mitigate or prevent accidents.

§ 963.14 Preclosure suitability criteria.

DOE will evaluate preclosure suitability using the following criteria:

(a) ability to contain radioactive material and to limit releases of radioactive materials;

(b) ability to implement control and emergency systems to limit exposure to radiation;

(c) ability to maintain a system and components that perform their intended safety functions; and

(d) ability to preserve the option to retrieve wastes during the preclosure period.

§ 963.15 Postclosure suitability determination.

DOE will apply the method and criteria described in sections 963.16 and 963.17 to evaluate the suitability of the Yucca Mountain site for the postclosure period. If DOE finds that the results of the total system performance assessments conducted under section 963.16 show that the Yucca Mountain site is likely to meet the applicable radiation protection standard, DOE may determine the site suitable for the postclosure period.

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§ 963.16 Postclosure suitability evaluation method.

(a) DOE will evaluate postclosure suitability using the total system performance assessment method. DOE will conduct a total system performance assessment to evaluate the ability of the geologic repository to meet the applicable radiation protection standard under the following circumstances:

(1) DOE will conduct a total system performance assessment to evaluate the ability of the geologic repository to limit radiological exposures in the case where there is no human intrusion into the repository. DOE will model the performance of the geologic repository at the Yucca Mountain site using the method described in paragraph (b) of this section and the criteria in section 963.17, excluding the criterion in paragraph (b)(4) of section 963.17. DOE will consider the performance of the system in terms of the criteria to evaluate whether the geologic repository is likely to comply with the applicable radiation protection standard.

(2) Consistent with applicable NRC regulations regarding a stylized human intrusion case, DOE will conduct a total system performance assessment to evaluate the ability of the geologic repository to limit radiological exposures in a stylized limited human intrusion case. DOE will model the performance of the geologic repository at the Yucca Mountain site using the method described in paragraph (b) of this section and the criteria in section 963.17. DOE will consider the performance of the system in terms of the criteria to evaluate whether the geologic repository is likely to comply with the applicable radiation protection standard. The human intrusion evaluation under this paragraph will be separate from the evaluation conducted under paragraph (a)(1) of this section.

(b) In conducting a total system performance assessment under this section, DOE will:

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- (1) Include data related to the suitability criteria in section 963.17;
- (2) Account for uncertainties and variabilities in parameter values and provide the technical basis for parameter ranges, probability distributions, and bounding values;
- (3) Consider alternative models of features and processes that are consistent with available data and current scientific understanding, and evaluate the effects that alternative models would have on the estimated performance of the geologic repository;
- (4) Consider only events that have at least one chance in 10,000 of occurring over 10,000 years;
- (5) Provide the technical basis for either inclusion or exclusion of specific features, events, and processes of the geologic setting, including appropriate details as to magnitude and timing regarding any exclusions that would significantly change the expected annual dose;
- (6) Provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers, including those processes that would adversely affect natural barriers, (such as degradation of concrete liners affecting the pH of ground water or precipitation of minerals due to heat changing hydrologic processes), including appropriate details as to magnitude and timing regarding any exclusions that would significantly change the expected annual dose;
- (7) Provide the technical basis for models used in the total systems performance assessment such as comparisons made with outputs of detailed process-level models and/or empirical observations (for example, laboratory testing, field investigations, and natural analogs);
- (8) Identify natural features of the geologic setting and design features of the engineered barrier system important to isolating radioactive waste;

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(9) Describe the capability of the natural and engineered barriers important to isolating radioactive waste, taking into account uncertainties in characterizing and modeling such barriers;

(10) Provide the technical basis for the description of the capability of the natural and engineered barriers important to isolating radioactive waste;

(11) Use the reference biosphere and group receptor assumptions specified in applicable NRC regulations; and

(12) Conduct appropriate sensitivity studies.

§ 963.17 Postclosure suitability criteria.

(a) DOE will evaluate the postclosure suitability of a geologic repository at the Yucca Mountain site through suitability criteria that reflect both the processes and the models used to simulate those processes, that are important to the total system performance of the geologic repository. The applicable criteria are:

(1) Site characteristics, which include:

(i) Geologic properties of the site - for example, stratigraphy, rock type and physical properties, and structural characteristics;

(ii) Hydrologic properties of the site - for example, porosity, permeability, moisture content, saturation, and potentiometric characteristics;

(iii) Geophysical properties of the site - for example, densities, velocities and water contents, as measured or deduced from geophysical logs; and

(iv) Geochemical properties of the site - for example, precipitation, dissolution characteristics, and sorption properties of mineral and rock surfaces

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(2) Unsaturated zone flow characteristics, which include:

(i) Climate - for example, precipitation and postulated future climatic conditions

(ii) Infiltration - for example, precipitation entering the mountain in excess of water returned to the atmosphere by evaporation and plant transpiration;

(iii) Unsaturated zone flux - for example, water movement through the pore spaces, or flowing along fractures or through perched water zones above the repository;

(iv) Seepage- for example, water dripping into the underground repository openings from the surrounding rock;

(3) Near field environment characteristics, which include:

(i) Thermal hydrology - for example, effects of heat from the waste on water flow through the site, and the temperature and humidity at the engineered barriers.

(ii) Near field geochemical environment - for example, the chemical reactions and products resulting from water contacting the waste and the engineered barrier materials;

(4) Engineered barrier system degradation characteristics, which include:

(i) Engineered barrier system component performance - for example, drip shields, backfill, coatings, or chemical modifications, and

(ii) Waste package degradation - for example, the corrosion of the waste package materials within the near-field environment;

(5) Waste form degradation characteristics, which include:

(i) Cladding degradation - for example, corrosion or break-down of the cladding on the spent fuel pellets;

(ii) Waste form dissolution - for example, the ability of individual radionuclides to dissolve in water penetrating breached waste packages;

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(6) Engineered barrier system degradation, flow, and transport characteristics, which include:

(i) Colloid formation and stability - for example, the formation of colloidal particles and the ability of radionuclides to adhere to these particles as they may be washed through the remaining barriers; and

(ii) Engineered barrier transport - for example, the movement of radionuclides dissolved in water or adhering to colloidal particles to be transported through the remaining engineered barriers and in the underlying unsaturated zone;

(7) Unsaturated zone flow and transport characteristics, which include:

(i) Unsaturated zone transport - for example, the movement of water with dissolved radionuclides or colloidal particles through the unsaturated zone underlying the repository, including retardation mechanisms such as sorption on rock or mineral surfaces;

(ii) Thermal hydrology - for example, effects of heat from the waste on water flow through the site;

(8) Saturated zone flow and transport characteristics, which include:

(i) Saturated zone transport - for example, the movement of water with dissolved radionuclides or colloidal particles through the saturated zone underlying and beyond the repository, including retardation mechanisms such as sorption on rock or mineral surfaces; and

(ii) Dilution - for example, diffusion of radionuclides into pore spaces, dispersion of radionuclides along flow paths, and mixing with non-contaminated ground water;

(9) Biosphere characteristics, which include:

(i) Reference biosphere and receptor- for example, biosphere water pathways, location and behavior of receptor; and

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(ii) Biosphere transport and uptake - for example, the consumption of ground or surface waters through direct extraction or agriculture, including mixing with non-contaminated waters and exposure to contaminated agricultural products.

(b) DOE will evaluate the postclosure suitability of a geologic repository at the Yucca Mountain site using criteria that consider disruptive processes and events important to the total system performance of the geologic repository. The applicable criteria related to disruptive processes and events include:

(1) Volcanism - for example, the probability and potential consequences of a volcanic eruption intersecting the repository;

(2) Seismic events - for example, the probability and potential consequences of an earthquake on the underground facilities or hydrologic system;

(3) Nuclear criticality - for example, the probability and potential consequences of a self-sustaining nuclear reaction as a result of chemical or physical processes affecting the waste either in or after release from breached waste packages;

(4) Inadvertent human intrusion - for example, consequences to repository system performance following a stylized human intrusion scenario.