

NUCLEAR REGULATORY COMMISSION

10 CFR Part 60

RIN: 3150-AD51

Disposal of High-Level Radioactive Wastes
in Geologic Repositories; Design Basis Events

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations on the protection of public health and safety from activities conducted at a geologic repository operations area (GROA) before permanent closure. In particular, the final rule addresses the measures that are required to provide defense in depth against the consequences of "design basis events." These measures include prescribed design requirements, quality assurance requirements, and the establishment of a preclosure controlled area from which members of the public can be excluded.

EFFECTIVE DATE: _____, 1996 [30 days from date of publication in the Federal Register].

FOR FURTHER INFORMATION, CONTACT: Dr. Richard A. Weller,
Division of Waste Management, Office of Nuclear Material Safety

and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-7287.

SUPPLEMENTARY INFORMATION:

Background

Under the Nuclear Waste Policy Act of 1982, as amended, the U.S. Nuclear Regulatory Commission exercises licensing and related regulatory authority with respect to geologic repositories that are to be constructed and operated by the U.S. Department of Energy (DOE) for the disposal of high-level radioactive waste. The Commission's regulations pertaining to these geologic repositories appear at 10 CFR Part 60. In recent years, NRC, in conjunction with its Federally-Funded Research and Development Center, the Center for Nuclear Waste Regulatory Analyses, completed a comprehensive review of the requirements of Part 60 regarding their clarity and sufficiency to protect public health and safety. NRC focused particular attention on any matters that may be ambiguous, insufficient for their intended purpose, or inconsistent with other expressions of its regulatory policy. Independently, DOE conducted a similar review of Part 60.

The NRC review identified deficiencies regarding the clarity and sufficiency of the current Part 60 requirements to protect

public health and safety for the full range of credible conditions or events that may occur at an operating repository, including those low-probability events that have potentially serious consequences. NRC also noted that certain elements of existing Part 60 differ from counterpart requirements in other NRC rules where greater consistency in language would be beneficial. DOE's independent review of Part 60 requirements identified similar deficiencies in these requirements. To address these issues, DOE filed a petition for rulemaking (PRM), PRM-60-3, on April 19, 1990.

In response to the DOE petition and the results of the NRC review of Part 60, the Commission published a proposed rule for public comment in the Federal Register on March 22, 1995 (60 FR 15180) to clarify the requirements for protection of public health and safety related to activities conducted at a GROA before its permanent closure. In particular, the proposed rule provided new and modified definitions for certain terms (including the definition of "important to safety," with reference to structures, systems, and components), dose criteria for accident conditions, and requirements for the establishment of a preclosure controlled area from which members of the public can be excluded when necessary. In an accompanying notice (March 22, 1995; 60 FR 15190) the Commission also granted in part, and denied in part, the specific proposals in the DOE petition. For a fuller discussion of the PRM, the proposed rule,

and the partial grant/partial denial of the DOE petition, see the Federal Register notices cited above. As noted in the Federal Register notice for the proposed rule (60 FR 15180) and as intended in subsequent discussions in this notice, unless the specific context suggests otherwise, the terms "provisions," "requirements," "standards," and "criteria" are generally used interchangeably; the term "limit" (as in "dose limit") is generally used to refer to a specific type of requirement or criterion; and the term "rule" is generally used to refer to the entire set of requirements or criteria (e.g., Part 60). This final rule completes NRC action related to PRM-60-3.

Lastly, the Commission notes that, consistent with the mandates of the Energy Policy Act of 1992, the Environmental Protection Agency (EPA) is developing site-specific environmental radiation protection standards for a potential repository at Yucca Mountain, Nevada. In this regard, the Act specifies that, within one year after promulgation of the EPA standards, the Commission must promulgate a rule so that Commission regulations are consistent with the new EPA standards. Although the primary focus of the new EPA standards is on the postclosure period of repository performance, the staff will ensure that the current modifications to Part 60 proposed herein, which focus on the period of repository operations before permanent closure, are consistent with the new EPA standards. To the extent any inconsistencies between NRC and EPA requirements are identified,

they will be addressed in the planned future rulemaking by NRC to address new EPA standards.

Public Comments on the Proposed Rule

A period of 90 days was specified in the Federal Register for public comments on the proposed rule. The Commission specifically sought public comments on: (1) the appropriateness of the proposed 0.05 Sv (5 rem) dose limit in new 10 CFR 60.136 as the repository design basis for protection of public health and safety during accident conditions, and (2) the rationale supporting the proposed 0.05 Sv (5 rem) dose limit. Ten sets of comments were received on the proposed rule from the following organizations and individuals: (1) The Clean Water Fund of North Carolina (CWFNC); (2) Mr. Vernon J. Brechin; (3) DOE, Office of Civilian Radioactive Waste Management; (4) EPA, Office of Federal Activities; (5) Nye County, Nevada, Nuclear Waste Repository Project Office; (6) Virginia Power Company; (7) Nuclear Energy Institute (NEI); (8) Environmental Coalition on Nuclear Power (ECNP); (9) Wisconsin Electric Power Company; and (10) Mr. Marvin I. Lewis.

The principal issues raised in the comments are summarized below. (Comments that are duplicative, editorial, or beyond the scope of the rulemaking are not discussed herein but have been considered in the analysis of the public comments.) For the

reasons indicated, the Commission has decided to adopt the amendments substantially in the form proposed in the March 22, 1995, Federal Register notice (60 FR 15180) but with the changes noted that reflect the Commission's analysis of the public comments.

1. Controlled Area - Waste Isolation.

DOE noted that the supplementary information in the proposed rule referred to the "controlled area" as one "... (within which waste isolation is to be ensured after permanent closure)," DOE observed that this is inconsistent with the Part 60 definition of "controlled area," which does not refer to waste isolation. DOE recommended that the Commission delete the parenthetical phrase in the supplementary information.

The Commission agrees that the parenthetical phrase does not properly characterize the definition of "controlled area." However, rather than deleting the parenthetical phrase altogether, the Commission has modified the phrase to accurately reflect the definition of "controlled area" and its focus on postclosure activities.

2. Multiple Failure Scenarios.

DOE noted that the supplementary information under §60.136

seemed to indicate that multiple independent failure scenarios would be considered to be Category 2 design basis events and observed that, typically, nuclear safety analyses are not required to assume multiple failures of safety-related systems unless they are all credible consequences of the initiating event. DOE recommended that the Commission clarify how it intends to review the acceptability of repository systems, structures, and components in the context of the new rule.

The Commission agrees with this comment and has revised the supplementary information to clarify how it intends to review the analysis in the DOE license application to demonstrate compliance with the requirements of §60.136.

3. Probability Bounds for Design Basis Events.

In the Section-by-Section Analysis of §60.136 in the proposed rule, the Commission indicated that the lower bound for Category 2 design basis events is on the order of 1×10^{-9} per year (i.e., events with probabilities of occurrence less than 1×10^{-9} per year would generally be screened from further consideration due to their negligible contribution to overall risk). DOE and NEI objected that this lower bound is much too low and unjustified. DOE recommended a lower bound of 1×10^{-6} per year and NEI recommended a lower bound in the range of 1×10^{-6} per year to 1×10^{-7} per year. On the other hand, ECNP

recommended that the most improbable sequences and combinations of events and accidents (Category 2 and beyond) should be evaluated in repository accident analysis.

The Commission agrees with DOE and NEI that the lower probability bound discussed in the proposed rule for Category 2 design basis events is too low and is unjustified. The Commission considers that, on the basis of repository risk perspective, a lower probability bound of 1×10^{-6} per year is appropriate for these events. The Commission recognizes that the estimated consequences from Category 2 design basis events are somewhat limited and would not likely exceed several tenths of Sv (several tens of rem). At this consequence level, the estimated risk of cancer fatality from events with a probability lower than 1×10^{-6} per year is less than 1×10^{-8} per year. To put this risk in perspective, the International Commission on Radiological Protection¹ notes that a fatal cancer risk in the range of 1×10^{-6} to 1×10^{-5} per year from exposure to radiation would likely be acceptable to members of the public. As such, Category 2 design basis events which result in fatal cancer risks on the order of 1×10^{-8} per year or lower do not contribute significantly to individual risk. Accordingly, events with probabilities of occurrence lower than 1×10^{-6} per year can be screened from further consideration in repository risk analysis.

¹ Recommendations of the International Commission on Radiological Protection. ICRP Publication 26, January 1977.

The Commission has revised the Section-by-Section Analysis of §60.136 to reflect a lower bound for Category 2 design basis events on the order of 1×10^{-6} per year.

4. Definition of "Important to Safety" - Engineered Features.

DOE noted that the phrase "engineered structures, systems, and components," currently in the definition of "important to safety," was removed from the new definition and observed that it is clearly the intent of the regulation to apply the definition to engineered systems, not natural systems.

The Commission agrees with this comment and has revised the definition of "important to safety" to clarify this intent.

5. Applicability of Environmental Protection Agency Standards to the Management and Storage of High-Level Waste.

DOE stated that the proposed rule did not address all of the regulatory uncertainty associated with dose limits for design basis events because both the existing rule and the proposed rule appear to require compliance with both EPA radiation protection standards and Part 20 radiation standards and there is an inconsistency between these two standards. Virginia Power noted

that the definition of "important to safety" establishes the Part 20 limits that are referenced in 10 CFR 60.111(a) as the acceptance criteria for the Category 1 design basis events and concluded that this seems to be inappropriate. Virginia Power stated that Part 20 establishes occupational dose limits and radiation dose limits for members of the public, that these limits are expressed as annual limits, and that these limits are associated with normal licensed activities - not design basis events. Virginia Power considered that it is not appropriate to use Part 20 limits to evaluate specific events. Virginia Power further considered that acceptance criteria for design basis events are associated with the specific consequences of those events, as for example in §60.136 for the Category 2 design basis events, and that appropriate acceptance criteria will need to be developed if Category 1 design basis events are retained by the final rule.

The Commission agrees with DOE that both the dose limits and the methodology for calculating doses to members of the public in the EPA standards differ from the dose limits and methodology for calculating doses to members of the public in Part 20, Subpart D. Notwithstanding the differences between these standards, the staff does not consider that there is any regulatory uncertainty regarding applicable dose limits for Category 1 design basis events. In DOE's demonstration of compliance, either the EPA standards or the Part 20 standards may be more limiting or

controlling than the other, but that does not relieve DOE of the requirement to comply with both standards. As such, the Commission has made no changes to the proposed rule to address DOE's concerns about the differences between Part 20 and the EPA standards.

The Commission disagrees with Virginia Power that Part 20 limits are inappropriate. The Commission's numerical radiation protection standards are codified in Part 20 and apply to operations at a geologic repository by virtue of 10 CFR 20.1002 and §60.111(a). However, it is not the Commission's intent that it is necessary to use the annual limits in Part 20 to evaluate specific Category 1 design basis events on an individual basis. Instead the Commission intends that the sum of the annual doses, exposures, and releases from all Category 1 design basis events shall not exceed the limits specified in Part 20 and in the EPA standards.

6. Preclosure Controlled Area.

DOE expressed a concern that the use of the word "immediately" in the definition of "preclosure controlled area" could lead to an implication that the boundary must be next to the GROA. DOE also expressed a concern that the use of the word "nearest" in §60.136(b) (i.e., "...no individual located on or beyond the nearest boundary of the preclosure controlled

area...") is confusing.

The Commission agrees with these comments and has:
(1) deleted the word "immediately" in the definition of "preclosure controlled area" in 10 CFR 60.2, (2) changed the phrase "nearest boundary" to "any point on the boundary" in the definition of "important to safety" in §60.2 and in the design requirements of the geological repository operations area in §60.136(b).

7. Definition of Site.

DOE recommended that the definition of "site" should include "preclosure" and "postclosure controlled areas."

The Commission agrees with this comment and has modified the definition of "site" to reflect its meaning during the period before permanent repository closure (i.e., the operational period), as well as the period following permanent closure.

8. Effluent Control.

DOE stated that, with the deletion of the term "during normal operations," the application of the Part 20 effluent limits invoked by §60.111(a) is not clear. DOE recommended that 10 CFR 60.132(c)(1) be revised to clarify that the latter section

is applicable only to Category 1 design basis events.

The Commission agrees with this comment and has revised §60.132(c)(1) to clarify that this section is applicable only to Category 1 design basis events.

9. Criticality Control.

DOE noted that the Commission intended to clarify the requirements pertaining to criticality control, currently in 10 CFR 60.131(b)(7), but that some confusion concerning those requirements remains. DOE pointed out that the proposed criticality control requirements in §60.131(h) refer to "isolation of radioactive waste," a phrase with postclosure connotations, while noting that systems "must be designed for criticality safety assuming occurrence of design basis events," a phrase which has preclosure implications. Furthermore, DOE argued that the last sentence in §60.131(h) could be interpreted as requiring a deterministic demonstration of criticality safety over the entire period of regulatory concern. However, given the time frames involved, DOE considered probabilistic analyses to be an essential part of demonstrating long-term criticality safety.

The Commission considers that the applicability of the criticality control requirements proposed in §60.131(h) is clear with respect to preclosure considerations but agrees with DOE

that uncertainty remains with respect to the applicability of the criticality control requirements to the postclosure period. However, the Commission intends to address this remaining uncertainty in a future rulemaking to make the NRC requirements consistent with the revised EPA standards that are currently under development, as mandated by the Energy Policy Act of 1992. Accordingly, in this final rule, §60.131(h) is promulgated, as proposed in the proposed rule.

10. The Use of the terms "Important to Safety," "Accidents," "Normal Conditions," "Anticipated Operational Occurrences," and "Design Basis Events" in Part 60.

CWFNC stated that there was not any ambiguity in the current use of the terms "important to safety" and "accidents" in Part 60. ECNP stated that the terms "normal conditions," "anticipated operational occurrences," and "accidents" are not equivalent to nor adequately described by the term "design basis events."

The Commission disagrees with CWFNC that there is no ambiguity in the current use of the terms "important to safety" or "accidents" in Part 60. The latter term is undefined in Part 60, and there is uncertainty about its meaning with respect to the range of events the term encompasses. The full range of

Category 1 design basis events would not generally be considered as "accidents," especially those events occurring regularly or moderately frequently. However, certain lower frequency Category 1 events, which occur one or more times during the operating lifetime of a facility and are otherwise known as "anticipated operational occurrences," have at times been identified as "accidents." But "anticipated operational occurrences" are conditions of normal operation which are not to be confused with the unlikely, but credible and potentially significant, Category 2 design basis events. As such, the current definition of "important to safety" is unclear with respect to its intended applicability to the design of structures, systems, or components for normal operations, including anticipated operational occurrences. Further, with the focus on protection of members of the public in unrestricted areas, the current definition of "important to safety" does not explicitly address protection for the occupational work force. The uncertainty is not related to interpreting the meaning of "unrestricted area" but, rather, is related to the narrow focus of public exposure in unrestricted areas. Lastly, the value of 0.005 Sv (0.5 rem) as a dose limit in unrestricted areas for "accident" conditions lacks consistency with a corresponding limit in Part 72 and with dose values established as guidance for selected accidents (fuel handling and cask drop events) at Part 50 facilities (commercial power reactors).

Notwithstanding the comments offered by ECNP, the Commission considers that the definition of "design basis events" in the proposed rule does adequately define that term and that the supplementary information in the proposed rule does adequately describe the relationship between the terms "normal conditions," "anticipated operational occurrences," "accidents," and "design basis events." In this regard, it was the Commission's intent to supplant undefined terms in the rule (i.e., "normal conditions," "anticipated operational occurrences," and "accidents") with a defined term (i.e., "design basis events").

For the above reasons, the Commission has not revised the definitions in the proposed rule for "design basis events." As discussed in items 4 and 6 above, editorial changes have been made to the definition of "important to safety," but these changes are unrelated to the arguments advanced by CWFNC or ECNP.

11. Radiation Protection Standards.

CWFNC stated that a 0.005 Sv (0.5 rem) limit would not be overly protective of public health and safety and there is no reason to seek a weaker standard. CWFNC suggested modifying Part 20 to clarify any ambiguities in radiation protection standards for repositories. ECNP offered a number of comments related to radiation protection standards:

- The Commission should require DOE to provide design basis

accident analyses for more than undefined "critical design basis events, singly" and should require demonstration that doses would be kept far below the maximum permissible dose limits, with an as low as is reasonably achievable requirement at least comparable with that for operating reactors.

- The Part 60 limits must be much more stringent than for operating nuclear facilities.
- The limit of radiation exposure should be no higher than the most restrictive exposure limit that EPA imposes for any licensee or other source of regulated nuclear activity.
- A 0.005 Sv (0.5 rem) limit should be impermissible for an individual dose from a waste site.
- The most stringent level of worker protection, better than Part 20, should be required.
- Part 20 standards are not restrictive enough for the purpose of public health protection with respect to the storage and disposal of radioactive waste.
- The definitional alteration of the term "important to safety" is not adequate to assure health protection for the public because the proposed Categories 1 and 2 numerical limits for radiation exposures are based on standards that have failed to take into account the noncancer but adverse health effects of chronic low-dose radiation exposures that have been reported in the literature since development of NRC's Part 20 revision.

- Extremely conservative radiation protection standards should be utilized in repository design and performance criteria, and a zero release facility design goal should be required for all radioactive waste management.
- An acceptable rationale for the 0.05 Sv (5 rem) dose limit proposed in the proposed rule is totally absent.

The Commission acknowledges that the 0.005 Sv (0.5 rem) dose limit in the definition of "important to safety" in the existing rule could be construed to be an implicit basis for designing structures, systems, and components to prevent or mitigate the consequences of accidents at the boundary of the unrestricted area. On the other hand, the 0.005 Sv (0.5 rem) dose limit could also be interpreted more narrowly, to identify only those structures, systems, and components that are subject to additional design requirements and a quality assurance program to ensure performance of intended functions. See §60.131(b) and §60.151. In short, the 0.005 Sv (0.5 rem) dose limit in the definition of "important to safety" in the existing rule is, in the Commission's view, subject to conflicting interpretations.

As previously discussed, the Commission's comprehensive review of Part 60 identified deficiencies in both the clarity and sufficiency of requirements to protect workers and public health and safety. Among the identified deficiencies is the regulatory uncertainty created by possible conflicting interpretations that

could be given to the 0.005 Sv (0.5 rem) dose limit in the "important to safety" definition described above and by the absence of an explicit design basis dose limit in Subpart E of the existing rule. An objective of this rulemaking is, therefore, to resolve the uncertainty in Part 60, as well as remedy the incomplete definition of "important to safety" that fails to address protection of both workers and members of the public during Category 1 design basis events (i.e., "normal conditions," including "anticipated operational occurrences"). The Commission has addressed these deficiencies with the addition of new §60.136, which now provides explicit design basis accident dose criteria for repository structures, systems, and components, and modification of the definition of "important to safety" to include the broader interests of both worker and public health and safety for the full range of conditions or events that may occur before repository closure. The Commission believes that these amendments, as well as the others as described herein, clarify and enhance the provisions in the rule to protect worker and public health and safety.

It was not the intent of this rulemaking to modify, in any way, the Commission's numerical radiation protection standards. As discussed earlier, these standards are codified in Part 20 and apply to operations at a geologic repository by virtue of §20.1002, as well as §60.111(a). The Commission believes that these standards continue to be appropriate for its licensees and

provide adequate protection of worker and public health and safety at a repository. As such, comments by CWFNC and ECNP about possible modifications to the Commission's radiation protection standards as they would apply to an operating repository are beyond the scope of this rulemaking.

The Commission agrees with ECNP that the term "critical design basis events" is undefined and, in the Section-by-Section Analysis of §60.21 of this final rule, has changed "critical design basis events" to "Category 2 design basis events." With regard to the scope of design basis accidents that should be considered in the license application, the Commission previously addressed this issue in the discussion of probability bounds for Category 2 design basis events and determined that events with probabilities of occurrence lower than 1×10^{-6} per year could be screened from further consideration due to their negligible contribution to individual risk.

Regarding the rationale for the 0.05 Sv (5 rem) dose limit in §60.136, the Commission continues to believe that the potential risks to members of the public from an operating repository are very small. In light of this limited risk, the 0.05 Sv (5 rem) dose limit provides an adequate margin of safety and an appropriate basis for the design of repository structures, systems, and components to prevent or mitigate the consequences of low probability, but credible events. The Commission's

reasoning behind the 0.05 Sv (5 rem) dose limit can be found in the Section-by-Section Analysis of §60.136 that appears later in this notice.

12. Exclusion of the Public from Preclosure Controlled Area.

Vernon J. Brechin objected to the use of the word "can" versus "will" in the description of preclosure controlled area.

The Commission disagrees with this comment. It is not the Commission's intention to generally exclude members of the public from the preclosure controlled area (which would be the "controlled area" as defined in 10 CFR 20.1003). However, access to the preclosure controlled area can be limited by the licensee for any reason (not necessarily one related to radiation protection). Within the preclosure controlled area will be a "restricted area" (as defined in §60.2 and §20.1003). Access to a restricted area must be controlled for purposes of radiation protection. Members of the public in the preclosure controlled area will be subject to the dose limits for members of the public in 10 CFR 20.1301. However, an individual who receives occupational dose in the preclosure controlled area will be

subject to the occupational dose limits of Part 20, Subpart C. All doses in a restricted area are occupational doses. The size of the preclosure controlled area is not specified by the regulations because it will be dependent upon the particular activities conducted during the operational period.

13. Definition of Design Basis Events.

Virginia Power and NEI recommended that the definition of "design basis events" should make clear that the normal operations associated with receiving, handling, packaging, storing, emplacing, and retrieving high-level waste are not design basis events.

The Commission disagrees with this comment. It is the Commission's intent that events occurring regularly or frequently during the course of normal operations are considered as Category 1 design basis events. Category 1 design basis events effectively embody repository activities and conditions previously identified in Part 60 as "normal operations, including anticipated operational occurrences." In this regard, the Commission intends the Part 20 dose limits to be applicable to the conduct of repository activities, such as receiving,

handling, packaging, storing, placing, and retrieving high-level waste.

14. Definition of "Important to Safety" - Function.

Virginia Power noted that in the proposed rule, the definition of "important to safety" refers to "... (1) to provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of [10 CFR] 60.111(a) for Category 1 design basis events; or...." Virginia Power recommended that this part of the definition should be revised to make it clear that the focus of important to safety is design basis events and not the normal operations that are described by the definition in the proposed rule.

The Commission disagrees with this comment. As explained in Item 13, the Commission intends that events occurring regularly or frequently during the course of normal operations are considered as Category 1 design basis events.

15. Definition of "Important to Safety" - Quality Assurance Issues.

Virginia Power and NEI stated that the definition of "important to safety" proposed in the proposed rule would apply

full Quality Assurance (QA) requirements to almost every system and component of the repository, and that the latter definition does not establish a graded QA system to properly distinguish systems that are "important to safety" and ensure that the full QA program is only applied to those systems.

The Commission disagrees with this comment. When identifying items "important to safety," if it is determined that a particular structure, system, or component is essential to maintaining doses below Part 20 limits during normal operations (or during any Category 1 design basis event), then that structure, system, or component must be designated as "important to safety." The list of structures, systems, and components "important to safety," as well as the list of engineered barriers "important to waste isolation," are collectively referred to as the "Q-list" and are subject to the QA provisions of Part 60, Subpart G. The Commission supports a graded approach to meeting the QA provisions of Part 60. Such an approach is consistent with the NRC staff's "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to QA Requirements (NUREG-1318)." The guidance given in that technical position (TP) is still applicable under the rule's changes. The TP describes a graded application of QA measures consistent with that applied to other facilities (e.g., nuclear power reactors) licensed by the Commission. In this regard, the application of QA program requirements to repository structures, systems, and

components would generally be commensurate with their importance to safety.

16. Design Bases - Similarities between GROA Facility and other Facilities Licensed by NRC.

ECNP stated that it is wrong to liken design basis for a waste repository (or long-term storage) facility to design basis for an operating nuclear reactor or other contemporary nuclear facility because of the longevity of the hazard and uncertainties of future monitoring and control.

The Commission disagrees with this comment. The design bases provided in the rule are for operations at the GROA and not for postclosure performance. Because operations at the repository are expected to be similar to operations at other facilities licensed by the Commission (e.g., 10 CFR Part 72 facilities), the Commission believes that it is appropriate that their design bases be comparable.

17. The Phrase "At All Times".

ECNP recommended that the phrase "at all times" should be retained throughout Part 60.

The Commission disagrees with this comment. The phrase "at

all times" was originally included in the regulation to emphasize the need to design the GROA such that retrieval activities, if found necessary, would be conducted in accordance with Part 20. The Commission continues to interpret the regulation in this manner but has removed the phrase "at all times" from §60.111 in the rule to clarify that the limits of Part 20 apply to Category 1 design basis events and that the separate design bases of §60.136 apply for Category 2 design basis events. Further, the Commission recognizes that conformance to the regulations should not hinder any actions that are necessary to protect public health and safety, such as lifesaving or maintaining confinement of radioactive materials (May 21, 1991; 56 FR 23365). The phrase "at all times" is ambiguous in this respect and was therefore removed.

18. AS HIGH AS REASONABLY ACHIEVABLE (AHARA) Design Standard for the GROA.

ECNP recommended that NRC adopt an AHARA standard with respect to criteria for the design of the GROA. ECNP states that the purpose of such a standard would be to provide an extra measure of conservatism in the design. ECNP further states that, for an operating nuclear facility, regulatory changes over time that mandate tighter standards and reduced emissions can be

accommodated by means of backfitting, but this is not so readily accomplished at a disposal facility.

The Commission disagrees with this comment and considers that the requirements of Part 60, as amended in this rulemaking, are sufficient to ensure public health and safety. The Commission also considers that backfitting, if necessary, can be accomplished at a disposal facility.

Section-by-Section Analysis

Section 60.2. Definitions.

The amendments involve 10 definitions needed in Part 60.

The term "preclosure controlled area" is new. It is essentially the same as the term "preclosure control area" proposed by DOE in its petition (PRM-60-3) and corresponds closely to the term "controlled area," as defined in 10 CFR 72.3. The term "preclosure controlled area" is adopted because Part 60 already refers to a "controlled area" (which area has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure). The function of the new term is to delimit an area over which the licensee exercises control of activities to meet regulatory requirements. Control includes the power to exclude

members of the public, if necessary. Because Part 60 (unlike Part 72) involves ongoing underground operations and timeframes of concern over centuries and millennia, language in the definition is included that, consistent with its function, limits the area to the surface and limits the duration to the period up to, and including, permanent closure.

The existing term "controlled area" is renamed "postclosure controlled area," to avoid any confusion or misunderstanding about this term in relation to its use in Parts 20 and 72. However, no substantive change is intended for the "postclosure controlled area" because this is a change in nomenclature only. Consistent with this nomenclature change, the term "controlled area" is changed to "postclosure controlled area," where it appears in the definitions for "accessible environment," "disturbed zone," and "site."

The term "important to safety" is amended to address the issues previously discussed. The existing provision is unclear and fails to ensure proper levels of protection of public and worker health and safety for the broad range of conditions or events that might occur at a repository site. This is an important term because it is the predicate for required design features as well as required quality assurance measures that provide defense-in-depth. The Commission is retaining the quantitative features of the existing definition but is

specifying different numerical limits for each of the two categories (1 and 2) of design basis events. The structures, systems, and components "important to safety" are those necessary: (1) to provide reasonable assurance that the requirements of §60.111(a) would be observed for Category 1 design basis events; or (2) to prevent or mitigate Category 2 design basis events that could result in doses equal to, or greater than, the values specified in [new] §60.136 to any individual located on or beyond any point on the boundary of the preclosure controlled area.

Although the term "design bases" appears in existing Part 60, in §60.21(c)(2), it was not defined. As the previous discussion makes clear, "design bases" should be understood in relation to that range of events, including external natural or man-induced events, that is taken into account in the design, and, in particular, in relation to conditions that could result in radiological consequences beyond specified limits. The definition in Part 72 is inserted, without change, into the list of defined terms in §60.2.

The inclusion of a definition of "design basis events" serves two purposes. First, it identifies a set of events (referred to elsewhere as Category 1 design basis events) that must be taken into account in demonstrating compliance with the requirement to show, with reasonable assurance, that the

provisions of Part 20 will be met. (This set of events is described as "...those natural and human-induced events that are reasonably likely to occur regularly, moderately frequently, or one or more times before permanent closure of the geologic repository operations area.") Second, it identifies an additional set of events (previously referred to as Category 2 design basis events) that must be taken into account in applying the Commission's defense-in-depth philosophy. (This set of events is described as those "...other natural and human-induced events that are considered unlikely, but sufficiently credible to warrant consideration, taking into account the potential for significant radiological impacts on public health and safety.") The Commission recognizes that the criterion of "sufficiently credible to warrant consideration" is inexact, leaving its application to a consideration of the particular site and design that are the subjects of a license application. Generally, the Commission would expect that such design basis events would include as broad a range of external phenomena as would be taken into account in defining the design basis for other regulated facilities, including nuclear reactors. The Commission would also expect that the analysis of a specific design basis event would require an analysis which includes an initiating event (e.g., an earthquake) and the associated combinations of repository system or component failures that can potentially lead to exposure of the public to radiation.

The definitions of "restricted area" and "unrestricted area" are amended to conform with the definitions in Part 20. The current definitions in Part 60 do not precisely conform to the current Part 20 because no change was made to these Part 60 definitions when Part 20 was revised.

The amendments of §60.2 adopted in this final rule differ from the amendments of §60.2 proposed in the proposed rule (March 22, 1995; 60 FR 15180) in the following respects: (1) the revised definitions of "restricted area" and "unrestricted area" were not proposed in the proposed rule; (2) in the definition of "important to safety," the phrases "features of the repository" and "nearest boundary" in the proposed rule were changed to "engineered features of the repository" and "any point on the boundary," respectively; (3) in the definition of "preclosure controlled area", the phrase "immediately surrounding the geologic repository operations area" in the proposed rule was changed to "surrounding the GROA"; and (4) in the definition of "site", the phrase "location of the postclosure controlled area" was changed to "location of the preclosure controlled area, or of the postclosure controlled area, or both." The rationale for the revised definitions of "restricted area" and "unrestricted area" is provided in the preceding paragraph. The rationale for the other changes is discussed under "Response to Public Comments on the Proposed Rule."

Section 60.8. Information collection requirements:

OMB approval.

NRC is updating 10 CFR 60.8, "Information Collection Requirements: OMB Approval," to reflect the fact that subsequent to the original issuance of Part 60, NRC requested, and obtained Office of Management and Budget (OMB) approval for the Part 60 "Information Collection Requirements." Section 60.3 was to be corrected the first time other revisions were made.

The amendment of §60.8 adopted in this final rule differs from the amendment of §60.8 in the proposed rule (60 FR 15180) in that the term "Paperwork Reduction Act of 1980," in the proposed rule, has been changed to the term "Paperwork Reduction Act of 1995" in the final rule.

Section 60.21. Content of application.

The DOE petition suggested that provision for accident analysis might be accomplished by amendment of §60.111. The Commission, instead, is requiring an accident analysis as part of the content of the application section (i.e., §60.21). The language requires that the application address the potential dose, to any individual located on or beyond any point on the preclosure controlled area boundary, that is attributable to Category 2 design basis events. The procedure that is envisaged

is that the applicant would address the Category 2 design basis events, singly, and demonstrate, by its analysis, that the doses to any individual located on or beyond any point on the preclosure controlled area boundary would be in accordance with the applicable requirements. The language serves the same purpose as the counterpart section of Part 72 (namely, 10 CFR 72.24[m]).

The final rule also reflects the position that the applicant must demonstrate that the requirements of Part 20 and the EPA standards will be met, assuming the occurrence of Category 1 design basis events. For this analysis, the applicant would calculate the sum of the doses, exposures, and releases from all Category 1 design basis events to ensure that these results do not exceed the limits specified in Part 20 and in the EPA standards.

The Commission also is eliminating certain terms in Part 60 that are undefined and may be subject to differing interpretations -- specifically, the terms "normal conditions," "anticipated operational occurrences," and "accidents." These terms are supplanted by the new term "design basis events." Besides enhancing clarity of expression, the new language better reflects the articulated regulatory framework. Lastly, where the term "controlled area" appears in the language of this section, it is changed to "postclosure controlled area."

Section 60.43. License specification.

The term "controlled area" is changed to "postclosure controlled area."

Section 60.46. Particular activities requiring license amendment.

The term "controlled area" is changed to "postclosure controlled area."

Section 60.51. License amendment for permanent closure.

The term "controlled area" is changed to "postclosure controlled area."

Section 60.102. Concepts.

The term "controlled area" is changed to "postclosure controlled area."

Section 60.111. Performance of the geologic repository operations area through permanent closure.

The Commission is deleting the phrase "at all times" from

the performance objective of §60.111(a). This change clarifies that this requirement does not apply to radiation exposures, levels, and releases from Category 2 design basis events.

Section 60.121. Requirements for ownership and control of interests in land.

The term "controlled area" is changed to "postclosure controlled area."

Section 60.122. Siting criteria.

The term "controlled area" is changed to "postclosure controlled area."

Section 60.130. Scope of design criteria for the geologic repository operations area.

The Commission is modifying the title of this section to the term "General Considerations" and is adding clarifying language, to the existing discussion, to indicate that §§60.131 through 60.134 specify the minimum criteria for the design of those structures, systems, and components important to safety, or important to waste isolation. These changes are necessary to provide consistency with the modified definition of "important to safety" (§60.2), as well as to clarify the purpose of these

criteria. These changes also provide consistency with the corresponding "minimum" design criteria, for an MRS, in Part 72.

Section 60.131. General design criteria for the geologic repository operations area.

Consistent with the modifications to §60.130, as described above, the Commission is deleting the reference to "Structures, systems, and components important to safety," in the title of §60.131(b), and re-numbering the current criteria in §§60.131(b)(1) through 60.131(b)(10), as appropriate. This change eliminates the confusion in the existing rule related to the identification of only the criteria in §60.131(b) as "important to safety." It also resolves the present incongruity with §60.131(b)(7), "criticality control," regarding the reference to waste "isolation" (a postclosure term) in the requirement.

The current rule employs the term "normal and accident conditions," or similar expression, in several places. However, the conditions that must be addressed under this language are not well-defined. The Commission is remedying this situation by replacing current terminology with references to "design basis events," thereby ensuring that the design appropriately takes into account the consequences of all design basis events (i.e., as discussed in this document, Category 1 and 2 design

basis events). Accordingly, paragraphs (b)(5)(i), (b)(7), and (b)(8) are modified for this section. The Commission also is revising the language in §60.131(b)(1), which refers to "anticipated" natural phenomena and environmental conditions, so as to encompass all design basis events. The "necessary safety functions" that must be accommodated in the design, pursuant to that paragraph, include whatever is necessary to meet the quantitative limits set out in the Commission's rules (i.e., in §60.111(a) and §60.136).

As discussed under "Public Comments on the Proposed Rule," the Commission considers the applicability of the criticality control requirements in §60.131(h) to be clear with respect to preclosure considerations. The Commission also believes that uncertainty remains with respect to the applicability of the criticality control requirements to the postclosure period. The Commission intends to address the remaining uncertainty in a future rulemaking to make the NRC requirements consistent with the revised EPA standards that are currently under development, as mandated by the Energy Policy Act of 1992.

Section 60.132. Additional design criteria for surface facilities in the geologic repository operations area.

Section 60.132(c)(1) requires that the surface facilities must be "...designed to control the release of radioactive

materials in effluents during normal operations so as to meet the performance objectives of §60.111(a)." The design should ordinarily be sufficient to provide reasonable assurance of meeting Part 20 not only during normal operations, but even for events that are likely to occur moderately frequently or one or more times before permanent closure of the geologic repository (i.e., all Category 1 design basis events). Deleting the phrase "during normal operations," broadens the scope of this provision to reflect the Commission's intent more accurately.

The amendment of §60.132 adopted in this final rule differs from the amendment of §60.132 in the proposed rule in that the phrase "in effluents" in the proposed rule was changed to "in effluents during Category 1 design basis events" in the final rule. The rationale for this change was discussed in the "Response to Public Comments on the Proposed Rule."

Section 60.133. Additional design criteria for the underground facility.

As in the case of the changes to 10 CFR 60.131, a reference to design basis events is substituted for the less precise "normal operations and ...accident conditions."

Section 60.136. Preclosure controlled area.

The final rule adopts the petitioner's concept of a preclosure control area under the name "preclosure controlled area." The term delimits an area over which the licensee exercises control of activities to meet regulatory requirements. Control would include the ability to exclude members of the public, if necessary. The zone, and related dose limits, would also be used to analyze and identify structures, systems, and components that are important to safety under unusual conditions that have heretofore been characterized as Category 2 design basis events - credible, yet not likely to occur during the period of operations. The issue that is presented concerns the dose limits to ensure that the consequences of any events which occur present no unreasonable risk to the health and safety of the public. (Releases resulting from Category 1 design basis events would not be permitted to cause doses exceeding the limits of Part 20.) The Commission adopts the basic provisions of Part 72 - namely, a 0.05 Sv (5 rem) dose limit, on or beyond the preclosure controlled area boundary - as modified to reflect the Part 20 system of dose limits (see §20.1201[a]). In addition to providing for separate dose limits for individual organs and tissue, the lens of the eye, and the skin, the use of "total effective dose equivalent" (TEDE) in Part 20 explicitly accounts for exposures via the ingestion and inhalation dose pathways.

Modification of the 0.05 Sv (5 rem) dose limit, to reflect the Part 20 system of dose limits, results in a family of dose

limits: a TEDE of 0.05 Sv (5 rem); or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem); an eye dose equivalent of 0.15 Sv (15 rem); and a shallow dose equivalent, to skin, of 0.5 Sv (50 rem).² The eye and skin dose limits are adequate to ensure that no observable effects (e.g., induction of cataracts in the lens of the eye) will occur as a result of any accidental radiation exposure. In implementing this provision, dose calculations should be made solely with reference to the consequence of the specific Category 2 design basis event, not cumulatively with other design basis events. To clarify this matter further, the analysis of a specific Category 2 design basis event would require an analysis which includes an initiating event (e.g., an earthquake) and the associated combinations of repository system or component failures that can potentially lead to exposure of the public to radiation. An example design basis event is a postulated earthquake (the initiating event) which results in: (1) the failure of a crane lifting a spent fuel waste package inside a waste handling building, (2) damage to the building ventilation filtration system, (3) the drop and breach of the waste package, (4) damage to the spent fuel, (5) partitioning of a fraction of the radionuclide inventory to the building atmosphere, (6) release of some radioactive material through the damaged

²Radiation exposure terminology is as used in Part 20 (56 FR 23360; May 21, 1991).

ventilation filtration system, and (7) public exposure to the released radioactive material. It should be noted that it is not necessary to assume multiple failures of safety-related systems unless these multiple failures are credible consequences of the initiating event. An analysis of a specific event for a real repository would be dependent on the particular features of the facility design and related operating procedures. In general, credit for the proper functioning of repository structures, systems, and components in an analysis would be commensurate with the merits of the design. In the example cited above, a waste package designated "important to safety" would not necessarily be assumed to breach in a drop event if the maximum hypothetical drop falls within the design parameters of the waste package to withstand such an event. Similarly, repository ventilation filtration systems would be analyzed for their capability to withstand natural phenomena (e.g., earthquakes) and detect, isolate, or filter radioactive material in ventilation flow.

The only other noteworthy deviation from Part 72 is to refer in §60.136 to doses attributable to any "Category 2 design basis event" whereas the corresponding section (i.e., 10 CFR 72.106) in Part 72 refers to doses attributable to any "design basis accident." The term "design basis event" is used because it is a defined term in Part 60. The change in terminology is not intended to be one of substance as Category 2 design basis events would generally be considered as accidents.

The 0.05 Sv (5 rem) dose limit is being adopted by the Commission as the appropriate design basis for protection of public health and safety from Category 2 design basis events at a GROA and will harmonize Part 60 with Part 72. In this regard, the Commission notes that Part 72 applies to those facilities (MRS installations) most similar to the surface facilities of a repository and for which the kinds of design basis events are also expected to be similar. Further, the dose limit is consistent with dose values (0.06 Sv [6 rem] to the whole body) established as guidance for both fuel-handling accidents and spent-fuel cask-drop accidents at nuclear power plants.³ Moreover, the dose limit is consistent with the accident-dose value (0.05 Sv [5 rem] effective dose equivalent) proposed by DOE in its PRM.

However, while consistency between the proposed 0.05 Sv (5 rem) dose limit for Part 60 and other Commission rules or guidance documents is important, consistency alone does not necessarily ensure that there would be no unreasonable risk to the health and safety of the public associated with the proposed limit. As such, a perspective is provided on the risks associated with an operational repository and the appropriateness of the proposed 0.05 Sv (5 rem) dose limit as the design basis for protection of public health and safety from Category 2 design

³ NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," June 1987.

basis events.

Based on estimates provided by the National Council on Radiation Protection and Measurements⁴, the lifetime risk to individuals in the general population is 0.05 fatal cancers per Sv of exposure. Therefore, the lifetime risk of fatal cancer from an assumed 0.05 Sv (5 rem) exposure resulting from a postulated Category 2 design basis event is 0.0025 (i.e., 2.5×10^{-3}) per individual exposed. While this assessment provides perspective on the risk associated with a hypothetical exposure of a 0.05 Sv (5 rem) dose, it does not provide perspective on the estimated actual risk associated with the spectrum of possible Category 2 design basis events at a repository during its operational lifetime (estimated to be about 100 years).

Perspective on actual risk must include consideration of the frequencies (i.e., probabilities) of occurrence of these events, as well as their consequences, as "risk" is defined as "the probability of an event times its consequences." With respect to the range of probabilities of Category 2 design basis events, the upper bound is roughly 1×10^{-2} per year (i.e., events with probabilities of occurrence greater than 1×10^{-2} per year would generally be considered to be Category 1 events). Accordingly, assuming event consequences equivalent to the 0.05 Sv (5 rem)

⁴ National Council on Radiation Protection and Measurements, "Risk Estimates for Radiation Protection," NCRP Report No. 115, December 31, 1993.

dose limit for Part 60, the hypothetical upper bound on individual risk is 2.5×10^{-5} fatal cancers per year. To put this risk in perspective, the International Commission on Radiological Protection⁵ notes that, based on a review of information related to risks regularly accepted in everyday life for stochastic phenomena, a fatal cancer risk in the range of 1×10^{-6} to 1×10^{-5} per year from exposure to radiation would likely be acceptable to individual members of the public. Thus, while the risk associated with the consequences of a repository event at the dose limit and upper bound probability of occurrence exceeds this range by a small factor, and is at a level that the Commission considers safe for occupational exposures, the Commission believes this result significantly overestimates the actual risk of an operating repository. Similarly, the Commission considers that the lower bound of Category 2 design basis events is on the order of 1×10^{-6} per year (i.e., events with probabilities of occurrence less than 1×10^{-6} per year would generally be screened from further consideration due to their negligible contribution to overall risk). In the proposed rule (March 22, 1995; 60 FR 15180), the Commission had considered a probability of occurrence of 1×10^{-9} per year as an appropriate lower bound. However, upon further analysis as discussed below, the Commission considers that a lower bound of 1×10^{-9} per year is too low and unjustified, and that a lower

⁵ Recommendations of the International Commission on Radiological Protection. ICRP Publication 26, January 1977.

bound of 1×10^{-6} per year is appropriate. Screening out events with probabilities of less than 1×10^{-6} is expected to provide conservative estimates of risk. A higher screening criterion could probably be justified given the magnitude of the consequences and risks from this facility, but this criterion is not expected to cause an excessive analytical burden for demonstrating compliance with §60.136, consistent with the Commission's guidance on the application of probability risk assessment methods in licensing. It is important to note that the arguments advanced for this screening criterion apply solely to the period of repository operations before permanent closure.

Assuming bounding repository event consequences of roughly 0.2 Sv (20 rem), a lifetime risk to individuals in the general population of 0.05 fatal cancers per Sv of exposure, and a lower bound of 1×10^{-6} per year for the probability of occurrence of Category 2 design basis events, the estimated risk of cancer fatality from these low probability events would be 1×10^{-6} per year. Events which result in risks at or below this level do not contribute significantly to repository risk to an individual and, as such, can be neglected in the overall risk assessment.

Perspective on actual repository risk can be obtained by developing an understanding of the spectrum of potential

Category 2 design basis events and estimating the consequences of these sequences, as well as their probabilities of occurrence. In this regard, the Commission recognizes that there is no high-level waste repository operating experience, and that only conceptual designs have been developed for these facilities. Nonetheless, some perspective can be gained from the preliminary risk assessment by DOE⁶ of a conceptual design for a repository at Yucca Mountain, Nevada, as well as from consideration of risk assessments of selected U.S. nuclear power plants.⁷

Consistent with risk assessments for nuclear power plants, the spectrum of possible repository design basis events includes both internally and externally initiated events. Internally initiated events would include waste transporter collisions, crane failures or other types of fuel assembly, waste package or cask drop events, building or facility exhaust filter fires, and exhaust filter bypass or failure. Externally initiated events would include those resulting from earthquakes, tornados, and flooding. Regardless of the type or nature of the initiating event, the Commission believes that, for several reasons, both the variety of credible events and the resulting potential consequences to members of the public will be somewhat limited at

⁶ U.S. Department of Energy, "Site Characterization Plan, Yucca Mountain Site, Nevada Research and Development Area, Nevada," DOE/RW-0199, December 1988.

⁷ NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," December 1990.

repository facilities. First, in comparison with a nuclear power plant, an operating repository is a relatively simple facility in which the primary activities are waste receipt, handling, storage, and emplacement. A repository does not require the variety and complexity of active systems necessary to support an operating nuclear power plant. Further, the conditions are not present at a repository to generate a radioactive source term of a magnitude that, however unlikely, is potentially capable at a nuclear power plant (e.g., from a postulated loss of coolant event). As such, the estimated consequences resulting from limited source term generation at a repository would be correspondingly limited. This conclusion is consistent with the results of the aforementioned preliminary risk assessment by DOE of a conceptual repository design at Yucca Mountain, Nevada. In that assessment, DOE considered 149 events for a variety of internally and externally initiated events. Of the 149 events, only 7 resulted in offsite doses in excess of 0.005 Sv (0.5 rem) to the critical organs of a maximally exposed individual and also had associated probabilities of occurrence greater than 1×10^{-6} per year. The highest estimated offsite dose from the DOE risk assessment was 0.021 Sv (2.1 rem) with an associated probability of occurrence of 5×10^{-7} per year.

The dose estimates of the DOE risk assessment are only reflective of a conceptual design for a repository at Yucca Mountain, Nevada. Nonetheless, the Commission believes they

provide perspective on the magnitude of the estimated consequences to members of the public from postulated Category 2 design basis events, and that variations in repository design or site selection would not likely vary these estimates by more than an order of magnitude. The results of the DOE risk assessment also provide some perspective on the estimated probabilities of occurrence of the postulated repository design basis events and, as such, perspective on actual risk from an operating repository.

In general, the Commission would expect the potential higher consequence events to have correspondingly lower probabilities of occurrence. This expectation is consistent with the results of the DOE risk assessment as the estimated probabilities of occurrence for the seven events which resulted in offsite doses in excess of 0.005 Sv (0.5 rem) vary from 1×10^{-9} to 5×10^{-6} per year. The corollary to this is the expectation that higher frequency events would have correspondingly lower offsite consequences, and perspective on actual risk from an operating repository necessitates consideration of these events, as well as lower frequency events. Review of the DOE risk assessment indicates that some higher frequency, but lower consequence, events are just as important to actual risk as the lower frequency, but higher consequence, events. With respect to actual risk from the broad spectrum of all events considered in the DOE risk assessment, the estimated actual risk of an operating repository is roughly two to three orders of magnitude

lower than the range of fatal cancer risks that would likely be acceptable to members of the public (i.e., a fatal cancer risk of 1×10^{-6} to 1×10^{-5} per year as noted in ICRP Publication 26).

With respect to the appropriateness of the proposed 0.05 Sv (5 rem) dose limit for Part 60 as the design basis for protection of public health and safety from Category 2 design basis events, the DOE risk assessment indicates the potential for events with offsite consequences on the order of several hundredths to several tenths of Sv (several rem to several tens of rem), depending on design and siting factors. The event consequences in this range, coupled with the estimated event probabilities of occurrence, result in estimated risks that would likely be acceptable to members of the public. However, given the lack of repository design, siting and operating experience and the supporting data base for probabilistic risk assessment, the Commission believes there is considerable uncertainty in the estimates of both the consequences and the probabilities of occurrence of postulated Category 2 design basis events. As such, the Commission believes that establishing a dose limit in Part 60 to the 0.05 Sv (5 rem) value would provide an adequate margin of safety and an appropriate design basis for protection of members of the public from unlikely, but credible events. Further, the Commission believes that a single dose limit is appropriate for the broad range of possible event frequencies, given the limited potential for offsite consequences at

repository facilities.

Lastly, the amendments of §60.136 adopted in this final rule differ slightly from the amendments of §60.136 proposed in the proposed rule (60 FR 15180) in that the phrase "on or beyond the nearest boundary" in the proposed rule was changed to "on or beyond any point on the boundary" in the final rule and the phrase "may not exceed" in the proposed rule was changed to "shall not exceed" in the final rule. The rationale for the latter change is to improve clarity and the rationale for the former change was discussed earlier in the "Response to Public Comments on the Proposed Rule."

Section 60.183. Criminal penalties.

In the proposed rule, a conforming change was made to this section to include §60.136 (pertaining to the preclosure controlled area) among the regulations that are not issued under Sections 161b, 161i, or 161o of the Atomic Energy Act, for purposes of Section 223 of the Act. On reconsideration, the Commission has decided not to revise this section (i.e., criminal penalties are authorized for violations of §60.136).

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement

Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

Environmental Impact: Categorical Exclusion

The NRC has determined that this regulation is the type of action described in 10 CFR 51.22 (c)(2), pertaining to the promulgation of technical requirements and criteria that the Commission will apply in approving or disapproving applications under Part 60. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). Existing requirements were approved by OMB, approval number 3150-0127.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this final rule. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC. Single copies of the analysis may be obtained from Dr. Richard A. Weller, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of Waste Management, Washington, DC 20555, Telephone (301) 415-7287.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. The only entity subject to regulation under this rule is DOE.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule and, therefore, that a backfit analysis is not required for this final rule, because these amendments do not involve any provisions that would impose

backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 60

Criminal penalties, High-level waste, Nuclear power plants and reactors, Nuclear materials, Reporting and record-keeping requirements, and Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to Part 60.

PART 60 - DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES
IN GEOLOGIC REPOSITORIES

1. The authority citation for Part 60 is amended to read as follows:

Authority: Secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 929, 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2071, 2073, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95-601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 114, 121, Pub. L. 97-425, 96 Stat. 2213g, 2228, as amended (42 U.S.C. 10134, 10141), and Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851).

2. Section 60.2 is amended by adding definitions of "Design bases," "Design basis events," and "Preclosure controlled area," revising the definitions of "Accessible environment," "Disturbed zone," "Important to safety," and "Site," revising the name of the defined term "Controlled area" to "Postclosure controlled area" and presenting this renamed term without change for the convenience of the user, and alphabetizing the definitions to read as follows:

§60.2. Definitions.

* * * * *

Accessible environment means:

- (1) The atmosphere;
- (2) The land surface;
- (3) Surface water;
- (4) Oceans; and
- (5) The portion of the lithosphere that is outside the postclosure controlled area.

* * * * *

Design bases means that information that identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under which a structure, system, or component must meet its functional goals. The values for controlling parameters for external events include:

- (1) Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved; and

(2) Estimates of severe external man-induced events, to be used for deriving design bases, that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event.

Design basis events means:

(1)(i) Those natural and human-induced events that are reasonably likely to occur regularly, moderately frequently, or one or more times before permanent closure of the geologic repository operations area; and

(ii) Other natural and man-induced events that are considered unlikely, but sufficiently credible to warrant consideration, taking into account the potential for significant radiological impacts on public health and safety.

(2) The events described in paragraph (1)(i) of this definition are referred to as "Category 1" design basis events. The events described in paragraph (1)(ii) of this definition are referred to as "Category 2" design basis events.

* * * * *

Disturbed zone means that portion of the postclosure controlled area, the physical or chemical properties of which have changed as a result of underground facility construction or as a result of heat generated by the emplaced radioactive wastes, such that the resultant change of properties may have a significant effect on the performance of the geologic repository.

* * * * *

Important to safety, with reference to structures, systems, and components, means those engineered features of the repository whose function is:

(1) To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of §60.111(a) for Category 1 design basis events; or

(2) To prevent or mitigate Category 2 design basis events that could result in doses equal to or greater than the values specified in §60.136 to any individual located on or beyond any point on the boundary of the preclosure controlled area.

* * * * *

Postclosure controlled area means a surface location, to be marked by suitable monuments, extending horizontally no more than 10 kilometers in any direction from the outer boundary of the underground facility, and the underlying subsurface, which area has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure.

Preclosure controlled area means that surface area surrounding the geologic repository operations area for which the licensee exercises authority over its use, in accordance with the

provisions of this part, until permanent closure has been completed.

* * * * *

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set aside as a restricted area.

* * * * *

Site means the location of the preclosure controlled area, or of the postclosure controlled area, or both.

* * * * *

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

* * * * *

3. Section 60.8 is revised to read as follows:

§60.8 Information Collection Requirements: Approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements of general applicability contained in this part to the Office of Management and Budget for approval as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). The Office of Management and Budget

has approved the information collection requirements contained in this part under control number 3150-0127.

(b) The approved information collection requirements contained in this part appear in §§60.62, 60.63, and 60.65.

4. In §60.21, paragraphs (c)(1)(i), (c)(1)(ii)(B), (c)(3), and (c)(8) are revised to read as follows:

§60.21. Content of application.

* * * * *

(c) * * *

(1) * * *

(i) The description of the site shall also include the following information regarding subsurface conditions. This description shall, in all cases, include this information with respect to the postclosure controlled area. In addition, where subsurface conditions outside the postclosure controlled area may affect isolation within the postclosure controlled area, the description shall include information with respect to subsurface conditions outside the postclosure controlled area to the extent the information is relevant and material. The detailed information referred to in this paragraph shall include:

(A) The orientation, distribution, aperture in-filling and origin of fractures, discontinuities, and heterogeneities;

(B) The presence and characteristics of other potential pathways such as solution features, breccia pipes, or other potentially permeable features;

(C) The geomechanical properties and conditions, including pore pressure and ambient stress conditions;

(D) The hydrogeologic properties and conditions;

(E) The geochemical properties; and

(F) The anticipated response of the geomechanical, hydrogeologic, and geochemical systems to the maximum design thermal loading, given the pattern of fractures and other discontinuities and the heat transfer properties of the rock mass and groundwater.

(ii) * * *

(B) Analyses to determine the degree to which each of the favorable and potentially adverse conditions, if present, has been characterized, and the extent to which it contributes to or detracts from isolation. For the purpose of determining the presence of the potentially adverse conditions, investigations shall extend from the surface to a depth sufficient to determine critical pathways for radionuclide migration from the underground facility to the accessible environment. Potentially adverse

conditions shall be investigated outside of the postclosure controlled area if they affect isolation within the postclosure controlled area.

* * * * *

(3) A description and analysis of the design and performance requirements for structures, systems, and components of the geologic repository that are important to safety. The analysis must include a demonstration that --

(i) The requirements of §60.111(a) will be met, assuming occurrence of Category 1 design basis events; and

(ii) The requirements of §60.136 will be met, assuming occurrence of Category 2 design basis events.

* * * * *

(8) A description of the controls that the applicant will apply to restrict access and to regulate land use at the site and adjacent areas, including a conceptual design of monuments which would be used to identify the postclosure controlled area after permanent closure.

* * * * *

§60.43 [Amended]

5. In §60.43(b)(5), the term "controlled area" is revised to read "postclosure controlled area."

§60.46 [Amended]

6. In §60.46(a)(3), the term "controlled area" is revised to read "postclosure controlled area."

§60.51 [Amended]

7. In §60.51(a)(2)(i) and (a)(2)(ii), the term "controlled area" is revised to read "postclosure controlled area."

§60.102 [Amended]

8. In §60.102(c), the term "controlled area" is revised to read "postclosure controlled area."

9. In §60.111, paragraph (a) is revised to read as follows:

§60.111. Performance of the geologic repository operations area through permanent closure.

(a) Protection against radiation exposures and releases of radioactive material. The geologic repository operations area shall be designed so that until permanent closure has been completed, radiation exposures and radiation levels, and releases of radioactive materials to unrestricted areas, will be maintained within the limits specified in Part 20 of this chapter and such generally applicable environmental standards for radioactivity as may have been established by Environmental

Protection Agency.

* * * * *

§60.121 [Amended]

10. In §60.121(a) and (b), the term "controlled area" is revised to read "postclosure controlled area."

§60.122 [Amended]

11. In §60.122(b)(6) and (c), the term "controlled area" is revised to read "postclosure controlled area."

* * * * *

12. Section 60.130 is revised to read as follows:

§60.130 General considerations.

Pursuant to the provisions of §60.21(c)(2)(i), an application to receive, possess, store, and dispose of high-level radioactive waste in the geologic repository operations area must include the principal design criteria for a proposed facility. The principal design criteria establish the necessary design, fabrication, construction, testing, maintenance, and performance requirements for structures, systems, and components important to safety and/or important to waste isolation. Sections 60.131 through 60.134 specify minimum requirements for the principal design criteria for the geologic repository operations area.

These design criteria are not intended to be exhaustive. However, omissions in §§60.131 through 60.134 do not relieve DOE from any obligation to provide such features in a specific facility needed to achieve the performance objectives.

13. In §60.131, paragraph (b) is revised, and paragraphs (c) through (k) are added to read as follows:

§60.131. General design criteria for the geologic repository operations area.

* * * * *

(b) Protection against design basis events. The structures, systems, and components important to safety shall be designed so that they will perform their necessary safety functions, assuming occurrence of design basis events.

(c) Protection against dynamic effects of equipment failure and similar events. The structures, systems, and components important to safety shall be designed to withstand dynamic effects such as missile impacts, that could result from equipment failure, and similar events and conditions that could lead to loss of their safety functions.

(d) Protection against fires and explosions.

(1) The structures, systems, and components important to

safety shall be designed to perform their safety functions during and after credible fires or explosions in the geologic repository operations area.

(2) To the extent practicable, the geologic repository operations area shall be designed to incorporate the use of noncombustible and heat resistant materials.

(3) The geologic repository operations area shall be designed to include explosion and fire detection alarm systems and appropriate suppression systems with sufficient capacity and capability to reduce the adverse effects of fires and explosions on structures, systems, and components important to safety.

(4) The geologic repository operations area shall be designed to include means to protect systems, structures, and components important to safety against the adverse effects of either the operation or failure of the fire suppression systems.

(e) Emergency capability.

(1) The structures, systems, and components important to safety shall be designed to maintain control of radioactive waste and radioactive effluents, and permit prompt termination of operations and evacuation of personnel during an emergency.

(2) The geologic repository operations area shall be designed to include onsite facilities and services that ensure a safe and timely response to emergency conditions and that facilitate the use of available offsite services (such as fire, police, medical, and ambulance service) that may aid in recovery from emergencies.

(f) Utility services.

(1) Each utility service system that is important to safety shall be designed so that essential safety functions can be performed, assuming occurrence of the design basis events.

(2) The utility services important to safety shall include redundant systems to the extent necessary to maintain, with adequate capacity, the ability to perform their safety functions.

(3) Provisions shall be made so that, if there is a loss of the primary electric power source or circuit, reliable and timely emergency power can be provided to instruments, utility service systems, and operating systems, including alarm systems, important to safety.

(g) Inspection, testing, and maintenance. The structures, systems, and components important to safety shall be designed to permit periodic inspection, testing, and maintenance, as

necessary, to ensure their continued functioning and readiness.

(h) Criticality control. All systems for processing, transporting, handling, storage, retrieval, emplacement, and isolation of radioactive waste shall be designed to ensure that nuclear criticality is not possible unless at least two unlikely, independent, and concurrent or sequential changes have occurred in the conditions essential to nuclear criticality safety. Each system must be designed for criticality safety assuming occurrence of design basis events. The calculated effective multiplication factor (k_{eff}) must be sufficiently below unity to show at least a 5 percent margin, after allowance for the bias in the method of calculation and the uncertainty in the experiments used to validate the method of calculation.

(i) Instrumentation and control systems. The design shall include provisions for instrumentation and control systems to monitor and control the behavior of systems important to safety, assuming occurrence of design basis events.

(j) Compliance with mining regulations. To the extent that DOE is not subject to the Federal Mine Safety and Health Act of 1977, as to the construction and operation of the geologic repository operations area, the design of the geologic repository operations area shall nevertheless include provisions for worker protection necessary to provide reasonable assurance that all

structures, systems, and components important to safety can perform their intended functions. Any deviation from relevant design requirements in 30 CFR, Chapter I, Subchapters D, E, and N will give rise to a rebuttable presumption that this requirement has not been met.

(k) Shaft conveyances used in radioactive waste handling.

(1) Hoists important to safety shall be designed to preclude cage free fall.

(2) Hoists important to safety shall be designed with a reliable cage location system.

(3) Loading and unloading systems for hoists important to safety shall be designed with a reliable system of interlocks that will fail safely upon malfunction.

(4) Hoists important to safety shall be designed to include two independent indicators to indicate when waste packages are in place and ready for transfer.

14. In §60.132, paragraph (c)(1) is revised to read as follows:

§60.132. Additional design criteria for surface facilities in

the geologic repository operations area.

* * * * *

(c) Radiation control and monitoring - (1) Effluent control.

The surface facilities shall be designed to control the release of radioactive materials in effluents during Category 1 design basis events so as to meet the performance objectives of §60.111(a).

* * * * *

15. In §60.133, the introductory texts of paragraph (g) and paragraph (g)(2) are revised to read as follows:

§60.133 Additional design criteria for the underground facility.

* * * * *

(g) Underground facility ventilation. The ventilation system shall be designed to:

* * * * *

(2) Assure the ability to perform essential safety functions assuming occurrence of design basis events.

* * * * *

16. A new undesignated center heading and §60.136 are added to read as follows:

Preclosure Controlled Area

§60.136 Preclosure controlled area.

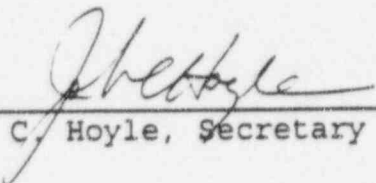
(a) A preclosure controlled area must be established for the geologic repository operations area.

(b) The geologic repository operations area shall be designed so that, for Category 2 design basis events, no individual located on or beyond any point on the boundary of the preclosure controlled area will receive the more limiting of a total effective dose equivalent of 0.05 Sv (5 rem), or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The eye dose equivalent shall not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin shall not exceed 0.5 Sv (50 rem). The minimum distance from the surface facilities in the geologic repository operations area to the boundary of the preclosure controlled area must be at least 100 meters.

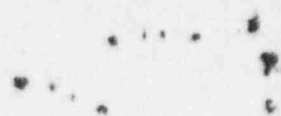
(c) The preclosure controlled area may be traversed by a highway, railroad, or waterway, so long as appropriate and effective arrangements are made to control traffic and to protect public health and safety.

Dated in Rockville, Maryland, this 25th day of November, 1996.

For the Nuclear Regulatory Commission.



John C. Hoyle, Secretary of the Commission.



REGULATORY ANALYSIS

REGULATORY ANALYSIS

FINAL REGULATIONS CONCERNING
DESIGN BASIS EVENTS FOR THE GEOLOGIC
REPOSITORY OPERATIONS AREA

MARCH 19, 1996

1. STATEMENT OF PROBLEM

The Nuclear Regulatory Commission, with the assistance of its Federally-funded research and development center (the Center for Nuclear Waste Regulatory Analyses), has conducted a systematic regulatory analysis of the Agency's regulation, 10 CFR Part 60, "Disposal of High-Level Radioactive Waste in Geologic Repositories," to identify potential regulatory or institutional uncertainties. Several regulatory uncertainties (i.e., ambiguous, insufficient, or inconsistent expressions of regulatory requirements or policy) were identified that raise questions about the adequacy of the rule to protect public health and safety. These uncertainties are in relation to the definition of the term, "important to safety," the performance objective for radiation protection, and the lack of design basis accident-dose criteria in the rule.

The U.S. Department of Energy (DOE), the potential applicant for a repository license under Part 60, independently identified similar problems with the rule and submitted a petition for NRC rulemaking on April 19, 1990.

In response to the DOE petition and the results of the NRC review of Part 60, NRC published a proposed rule for public comment in the Federal Register on March 22, 1995 (60 FR 15180) to clarify the requirements for protection of public health and safety related to activities conducted at a geologic repository operations area before its permanent closure. In particular, the proposed rule provided new and modified definitions for certain terms (including the definition of "important to safety", with reference to structures, systems, and components), dose criteria for accident conditions,

and requirements for the establishment of a preclosure controlled area from which members of the public can be excluded when necessary. In an accompanying notice (60 FR 15190), NRC also granted in part, and denied in part, the specific proposals in the DOE petition.

2. OBJECTIVE

The objective of the final rule is to eliminate the regulatory uncertainties identified NRC and DOE and, thereby, provide for the protection of public, including worker, health and safety.

The final Part 60 rulemaking, "Design Basis Events for the Geologic Repository Operations Area," clarifies that Part 20 applies to those design basis events that are reasonably likely to occur regularly, moderately frequently, or one or more times before permanent closure of the repository. A requirement is established for a "preclosure controlled area" boundary, as well as reference dose values for members of the public at or beyond that boundary during those unlikely, but credible, design basis events, taking into account the potential for significant radiological impacts on public health and safety. The definition of "important to safety" in 10 CFR Part 60.2 is revised to retain the quantitative features of the existing definition but specify different numerical criteria for each of two categories of design basis events. The structures, systems, and components "important to safety" are those necessary: 1) to satisfy specified numerical criteria for those events likely to occur regularly, moderately frequently, or one or more times before permanent closure; or 2) to prevent or mitigate those credible, but unlikely, events

that could result in doses greater than specified values to any individual located on or beyond the nearest boundary of the preclosure controlled area. Those structures, systems, and components that are determined to be "important to safety" are subject to specified design and quality assurance (QA) requirements to protect public health and safety.

New definitions are provided for the terms, "preclosure controlled area," "design bases," "design basis events," "restricted area," and "unrestricted area." The existing term "controlled area" is renamed to "postclosure controlled area." The term "controlled area" is changed to "postclosure controlled area," where it appears in the definitions for "accessible environment," "disturbed zone," "site," and elsewhere in the rule.

3. ALTERNATIVES

Alternatives considered with regard to removing the identified regulatory uncertainties consisted of: 1) taking no action on the present rule, 2) developing regulatory guidance, and 3) rulemaking that combines elements of the DOE petition with NRC's initiative.

3.1 No Action

No action to amend Part 60 would have the least near-term impact on NRC resources and other scheduled high-level waste (HLW) repository program activities. However, the uncertainties in Part 60 interpretation and inconsistencies among regulations would remain, and DOE would have to make a

number of assumptions to design and construct the surface and underground repository facilities. There would be an increased litigation risk, and the licensing board might be confronted with the same ambiguities in interpretation of Part 60 that presently exist. Questions would remain about the adequacy of the requirements in Part 60 to protect public health and safety. Significant NRC resources would likely be needed to address these issues.

No action by NRC could result in significant expenditures of DOE staff and monetary resources at a later date. Requirements for redesign might also require that the schedule for completion of the HLW repository be extended.

This alternative is not recommended.

3.2 Regulatory Guidance

Regulatory interpretations and guidance on acceptable methods to implement regulations can be provided through technical positions, staff positions, or regulatory guides. Unlike rulemaking, such guidance is not subject to administrative procedures, is not binding on the license applicant, and can be challenged at a hearing convened to review an application for an NRC license.

Although regulatory guidance and interpretation may clarify NRC's position, compliance by the applicant is not legally required and does not eliminate the potential for contention in a license hearing. Moreover, guidance appears inadequate, in this instance, because the concerns to be addressed include the

inadequacies, as well as the ambiguities, in the existing rule. Since the uncertainties involved concern public health and safety and may result in significant retrofit cost and schedule delays, this is not a recommended alternative.

3.3 Rulemaking - Combined Elements of DOE Petition and NRC Initiative

NRC believes that rulemaking, which includes publication in the Federal Register and a public comment period, is the most appropriate option to resolve the concerns related to the adequacy of Part 60 to protect public health and safety. In this regard, there are elements of the DOE petition that NRC proposes to adopt. These include DOE's proposed concept for design basis accident-dose criteria at a "preclosure control area" boundary and the proposal to clarify the performance objective in 10 CFR 60.111(a). However, there are other elements of the petition, especially DOE's proposed definition of the term "important to safety" with which NRC does not agree. Thus, the DOE petition would resolve some regulatory uncertainties, but not others. There are other elements of the petition that would not resolve all of NRC's concerns with the existing rule. For these elements, NRC is adopting the approach to uncertainty resolution from its own initiative. The rulemaking, which combines the preferred elements of the DOE petition with the complementary portions of NRC's initiative, will provide DOE with the regulatory criteria to confidently proceed with the design of the HLW geologic repository and provide necessary worker and public health and safety protection. It will have the least litigative risk and potential for schedule delays and increased costs at the time of licensing.

Rulemaking is a dispositive means of resolving an uncertainty that could have a significant effect on a national program and is the recommended course of action.

4. CONSEQUENCES OF RECOMMENDED ALTERNATIVE

4.1 Impact on Public

The rulemaking action will reduce regulatory uncertainty and, most importantly, will enhance worker and public safety. Also, it will contribute to efficient design and timely licensing by clarifying regulatory ambiguities. The HLW repository is financed through a surcharge to nuclear electric utility ratepayers. Since a large portion of the public bears the costs of licensing and construction of the repository, efficient design and timely licensing of the HLW repository would benefit the public by reducing development cost as well as minimizing dependence on costly storage of HLW. A reduction in regulatory uncertainty at this time--in the pre-licensing phase of HLW repository development--would allow the DOE development program to proceed in an orderly and more efficient way. It would also facilitate the licensing hearing in that all participants could focus on important health and safety issues rather than the interpretation of the rule. Public input to the regulatory process would not be reduced by this action; rather, it would enable public input at an early date through rulemaking.

4.2 Impact on DOE

The rulemaking provides design bases criteria that effectively resolve NRC's and DOE's concerns related to normal and accident conditions. The rule also establishes a requirement for preclosure controlled area boundary reference dose criteria, consistent with the concept proposed by DOE to prevent or mitigate the consequences of accidents. Lastly, the rulemaking modifies the definition of the term "important to safety" to retain its dose-based features but more clearly define its scope and intent. This change could affect the process and, therefore, the number of structures, systems, and components identified as important to safety. Since such structures, systems, and components are subject to specified design and QA requirements, this could potentially have an impact on DOE's program schedule and cost. The implementation of the accident dose criteria could also impact the program schedule and cost.

The rule change is not, however, unexpected, and implementation should be facilitated by present DOE plans and procedures for developing the repository. Moreover, NRC is proposing to adopt much of DOE's petition and this will tend to alleviate the impacts on DOE plans and procedures.

Noting the above, although some impact to DOE's program may occur, it would be compensated for by the benefits of resolving identified uncertainties and having greater consistency among NRC regulations.

4.3 Impact on NRC

In the near term, NRC will be required to expend resources to complete and implement the rule. The rulemaking will, however, provide clear direction to DOE and reduce the potential for future extensive NRC staff involvement to resolve design deficiencies affecting licensing. The rulemaking will also make the HLW repository licensing process more efficient through elimination of regulatory uncertainties that could be the basis for legal contentions. NRC resources will, therefore, be conserved in the long term, and there would be greater assurance of completing the licensing hearing within the Nuclear Waste Policy Act's mandated 3-year schedule.

4.4 Impact on Other Requirements

The regulation will provide greater consistency among NRC regulations, thus removing a potential source of uncertainty. NRC regulatory guidance documents, specifically NUREG-1318,⁸ will have to be updated to include the new definition of "important to safety."

4.5 Constraints

There are no known constraints to implementing the recommended action.

⁸U.S. Nuclear Regulatory Commission, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements," NUREG-1318, April 1988.

5. DECISION RATIONALE

NRC has evaluated regulatory uncertainties related to preclosure performance requirements, accident dose criteria, and the definition of "important to safety." Removing the uncertainties by amending Part 60 is determined to be the most appropriate action. This will have the authority of law to establish criteria for protection of public health and safety.

The rulemaking is the final action on this subject.

6. IMPLEMENTATION

Implementation of the rulemaking will require NRC to revise its regulations, regulatory guidance, and procedures (particularly QA audit procedures). These are not considered difficult tasks and will not have significant impacts on operations. DOE will need to revise its administrative procedures and program documentation. (The repository is in the developmental phase and there should not be significant impacts on physical equipment.) As DOE has indicated, in comments on the Federal Register notice of its rulemaking petition, that it is following the guidance of NUREG-1318, this is not expected to represent a major implementation effort. Although an exact schedule and implementation period cannot be given at this time, it is reasonable to assume that implementation of the proposed rule could be accomplished in 1 or 2 years.

It is not anticipated that the implementation of the rulemaking will have major effects on priorities for related activities. Rather, it is expected that the requirements of the proposed regulation will be implemented in the normal course of program activities. For example, identification of

structures, systems, and components important to safety, in relation to dose, might be accomplished consistent with a scheduled QA program review.