RULEMAKING ISSUE

(Notation Vote)

September 13, 1994 SECY-94-239

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: PROPOSED AMENDMENTS TO 10 CFR PART 60 ON DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES--DESIGN BASIS EVENTS FOR THE GEOLOGIC REPOSITORY OPERATIONS AREA

PURPOSE:

To obtain Commission approval to publish proposed amendments to 10 CFR Part 60 for public comment and to grant in part, and deny in part, a U.S. Department of Energy (DOE) petition for rulemaking on the same subject.

SUMMARY:

The proposed rule would clarify Commission requirements for the protection of public health and safety from activities conducted at a geologic repository operations area before its permanent closure. In particular, the proposed rule would address the measures that are required to provide defense in depth against the consequences of "design basis events." Included are new and modified definitions, including the definition of structures, systems, and components "important to safety," 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. The specific proposed changes to Part 60 are presented in the supplementary information section of the proposed rule in Enclosure 1.

Contact: Richard Weller, NMSS
(301) 415-7287

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

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BACKGROUND:

On December 11, 1992, the staff provided a notation vote paper, SECY-92-408, to the Commission, concerning proposed amendments to Part 60, that would clarify the requirements necessary to protect public health and safety for a broad range of normal and accident conditions during the operational period of a geologic repository. As noted in SECY-92-408, the proposed amendments were intended to address regulatory uncertainties (i.e., those regulatory requirements that may be ambiguous, inadequate, or inconsistent with other Commission regulatory policy) identified by both the staff and DOE.

The staff, in conjunction with the Center for Nuclear Waste Regulatory Analyses, performed a comprehensive analysis of Part 60 for its clarity, adequacy, and sufficiency, and determined that the radiation protection criteria were deficient primarily in three areas. First, the definition of structures, systems, and components "important to safety" lacks clarity and sufficiency to adequately protect public health and safety. This important definition is the basis for specified design and quality assurance requirements for certain repository features. Second, there are uncertainties in the language of the performance objective for radiation protection that require clarification or interpretation. Lastly, there are differences between the regulatory criteria in 10 CFR Part 72 and Part 60, in areas wherein some similarities might be expected, especially in relation to the provisions for radiation protection from accident conditions or events. Unlike Part 60, Part 72 includes provisions for the establishment of a "controlled area" boundary, within which members of the public could be excluded, and dose criteria for individuals at or beyond that boundary during design basis accidents.

As previously indicated, DOE experienced similar difficulties in understanding Part 60 and filed a petition for rulemaking (PRM), under 10 CFR 2.802, on April 19, 1990 (PRM-60-3). DOE's petitioned rulemaking (Enclosure 2) requested the U.S. Nuclear Regulatory Commission to:

(1) Establish accident dose criteria of 0.05-Sv (5-rem) effective dose equivalent, or 0.5-Sv (50-rem) committed dose equivalent to any organ, for any individual located at the boundary of a newly defined "preclosure control area."

(2) Modify the definition of "important to safety," but retain the 5-mSv (0.5-rem) reference dose; however, unlike the present Part 60, which relates this value to the boundary of the unrestricted area, the dose limit would be applied at the boundary of the preclosure control area.

(3) Eliminate the phrase, "at all times," contained in the reference to 10 CFR Part 20, in 10 CFR 60.111(a), to clarify that Part 20 does not apply to accident conditions.

The DOE petition was published in the Federal Register on July 13, 1990, 55 FR 28771 (Enclosure 3). The Federal Register notice also described the NRC staff's independent regulatory initiative to address the deficiencies

identified in the rule, noting that the staff's approach to reduction of regulatory uncertainty was different from the petitioner's approach.

The comment period for the Federal Register notice expired on October 11, 1990. Comments (Enclosure 4) were received from: DOE; Edison Electric Institute and the Utility Nuclear Waste and Transportation Program (EEI/UWASTE); Intertech Consultants, on behalf of Lincoln County, Nevada, and the City of Caliente, Nevada; and a "Concerned U.S. Citizen."

In its letter of comment, dated November 26, 1990, DOE stated its intent to meet the guidance provided in NUREG-1318, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements," in its quality assurance program, which is subject to NRC review. In addition, protection of worker safety and health would also be ensured by the Department's compliance with Part 20. DOE urged NRC to proceed with the petition for rulemaking.

EEI/UWASTE supported the DOE petition. Lincoln County and the City of Caliente concurred in the need to reduce the programmatic uncertainty, particularly where it concerns public health and safety, but suggested that it would be prudent to delay initiation of the rulemaking until information from studies that NRC had initiated was available. The "Concerned U.S. Citizen" provided comments on a need for definition of "engineered safety feature" and on the use of separate dose limits for the preclosure control area and for the definition of "important to safety."

The NRC staff chose to continue with its regulatory initiative evaluation (consistent with the Lincoln County and City of Caliente suggestion) and informed DOE of this, and the petition status, in July 1991. On December 11, 1992, the staff issued SECY-92-408, which requested Commission approval to publish proposed amendments, to Part 60, regarding design basis events for the geologic repository operations area. SECY-92-408 also requested Commission approval to deny DOE's petition for rulemaking on the same subject.

In the staff requirements memorandum (SRM), dated February 3, 1994, the Commission disapproved publication of the proposed amendments to Part 60. The SRM directed the staff to undertake the following actions:

(1) Reconsider the definition of "important to safety," including other approaches for determining which structures, systems, and components are important to safety. Other approaches should include consideration of a dose-based standard, as well as the appropriateness of dose values from other Commission regulations (e.g., 10 CFR Parts 20 and 100 and proposed 10 CFR Part 76).

(2) Revise 10 CFR 60.111(a), "Protection against radiation exposures and releases of radioactive material," as indicated in the SRM, to address the uncertainties related to the phrase "at all times" in the language of the requirement.

(3) Retain the definition of "controlled-use area" and other proposals advanced in SECY-92-408.

(4) Reconsider the proposed denial of the DOE rulemaking petition.

(5) Seek and consider the views of the Advisory Committee on Nuclear Waste (ACNW) on any subsequent Commission papers on the design basis events rulemaking issue.

In response to the SRM, the staff has reconsidered its approach to the design basis events rulemaking and made substantive changes to elements of the proposals in SECY-92-408, consistent with Commission direction. This includes significant changes to the definition of "important to safety" and reconsideration of the prior proposal to deny the DOE petition. The staff now proposes that the Commission grant in part, and deny in part, the DOE petition. The proposed action on the petition is further discussed in Enclosure 5.

DISCUSSION:

The intent of this proposed rule is to clarify requirements, in Part 60, that are related to worker and public protection, for a broad range of conditions, during the operational period of a repository (i.e., before permanent closure). The proposed rule reflects the staff's independent regulatory initiative; consideration of the DOE petition, as well as public comments on the petition; the desire for consistency, where appropriate, with other NRC rules that regulate similar types of facilities or activities; the views of ACNW; and direction from the Commission, as provided in the SRM of February 3, 1994.

The major proposed changes to the rule necessitate the addition of several newly defined terms. This includes a proposed definition for the term "design basis events." "Design basis events" are defined as being of two categories: (1) 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 (2) 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. The definition serves to identify a set of events (Category 1) that must be taken into account in demonstrating compliance with the requirements of 10 CFR 60.111(a) that reference Part 20 and applicable U.S. Environmental Protection Agency regulations. It also identifies a set of events (Category 2) that must be taken into account in demonstrating compliance with the new preclosure controlled area reference-dose requirements of 10 CFR 60.136.

A primary issue of Commission concern, in the SRM, was the purely functional definition proposed in SECY-92-408 for "important to safety." To address this concern, the staff is now proposing a definition that not only has functional elements, but also dose criteria. The addition of dose criteria should lend specificity to the term and, thereby, aid in the identification of those

repository features that are "important to safety." As now proposed, structures, systems, and components "important to safety" are those features 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 10 CFR 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 of new 10 CFR 60.136 to any individual located on, or beyond, the nearest boundary of the newly defined preclosure controlled area.

Those repository features determined to be "important to safety" would be subject to specified design and quality assurance requirements. An essential feature of the definition as now proposed is that, unlike the current Part 60 definition, specified design and quality assurance measures would address the health and safety needs of both workers and members of the public. The definition is further structured to ensure internal consistency, in Part 60, with respect to the reference dose values specified to aid in the identification of structures, systems, and components "important to safety," and the corresponding dose values in other parts of the rule (specifically, 10 CFR 60.111(a) and new 10 CFR 60.136) that establish performance and design requirements for the geologic repository operations area. Lastly, the dose values incorporated by reference in the definition of "important to safety" are consistent with corresponding dose values in the rules for other Commission-regulated facilities. In this regard, the dose values in Part 20 are specified (by virtue of 10 CFR 60.111(a)) for those design basis events likely to occur regularly, moderately frequently, or one or more times before facility closure, and it has been the Commission's policy to apply Part 20 for these kinds of design basis events at other Commission-regulated facilities such as commercial nuclear power reactors and independent spent fuel storage installations. For credible, but unlikely, design basis events, the primary dose value incorporated by reference to new 10 CFR 60.136 is a total effective dose equivalent of 0.05 Sv (5 rem). Although the staff considered the appropriateness of dose values in other NRC rules (e.g., Part 20, Part 100, proposed Part 76) for this application, the 0.05-Sv (5-rem) value is basically adopted from Part 72, which applies to those facilities (monitored retrievable storage installations) most similar to the surface facilities of a repository. The staff notes that this value is also consistent with the acceptable dose values (0.06 Sv [6 rem] to the whole body) in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," for both fuel-handling accidents and spent-fuel cask-drop accidents. Moreover, the value is consistent with the preclosure controlled area boundary accident-dose value (0.05-Sv [5-rem] effective dose equivalent) proposed by DOE in its petition for rulemaking.

The term "design bases" appears in Part 60, but is not defined. As such, a definition is proposed here identical to that in Part 72.

The staff proposes to eliminate certain terms, in Part 60, that are undefined and may be subject to differing interpretations. These include the terms "normal operations," "anticipated operational occurrences," and "accidents," which would be supplanted by the new term "design basis events."

The phrase "at all times" would be deleted from the performance objective of 10 CFR 60.111(a), to clarify that this requirement does not apply to Category 2 design basis events. The supplementary information to the proposed rule would also note that this requirement does apply to all functions (e.g., radioactive waste receiving, handling, packaging, storage, and emplacement) expected to occur at a repository site, including retrieval, if that becomes necessary.

The staff proposes to change the title of 10 CFR 60.130 to the term "General considerations" and add clarifying language in the rule, to explain that 10 CFR 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 proposed definition of "important to safety," as well as to clarify the purpose of those criteria.

The proposed amendments include a newly defined "preclosure controlled area." This term is intended to delimit an area over which the licensee exercises control of activities to meet regulatory requirements. Control would include the power to exclude members of the public, if necessary. Along with the addition of this term, the existing term "controlled area," which applies solely to the period following repository closure, would be renamed to "postclosure controlled area," to avoid any confusion or misunderstanding about the use of the term "controlled area" in Parts 20 and 72. With this change in nomenclature, the term "controlled area" would also be changed to "postclosure controlled area," where it appears in the definitions for "accessible environment," "disturbed zone," and "site," and elsewhere in the rule.

Additional preclosure requirements are proposed to be added in a new 10 CFR 60.136, "Preclosure controlled area," which would provide for the establishment of a preclosure controlled area boundary for the geologic repository operations area, as well as reference dose values for members of the public at or beyond that boundary, for Category 2 design basis events. The requirements would stipulate that the geologic repository operations area must be designed so that, for Category 2 design basis events, no individual located on or beyond the nearest boundary of the preclosure controlled area will receive the more limiting of a total effective dose equivalent of 0.05 Sv (5 rem), or 0.5 Sv (50 rem) from the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue. The eye dose equivalent may not exceed 0.15 Sv (15 rem), and the shallow-dose equivalent to skin may not exceed 0.5 Sv (50 rem). The addition of these requirements to the rule provides for consistency with similar requirements in Part 72, although they are proposed here as design criteria, whereas in Part 72, they are included as "siting evaluation factors."

With the focus of the new 10 CFR 60.136 on protection of members of the public from credible, but unlikely, design basis events (i.e., Category 2 events), the staff has considered the need for corresponding requirements directed at radiological protection of onsite workers during these kinds of events. For several reasons, the staff has not yet determined that such requirements are

needed. First, it has not been the Commission's policy to establish, in the various rules for Commission-regulated facilities, design basis accident-dose criteria, for workers, that apply generally to the facility design. Second, for some design basis events, the facility design and quality assurance enhancements employed to satisfy the requirements for protection of members of the public (i.e., 10 CFR 60.136) will also provide a measure of protection for onsite workers. Lastly, and perhaps most importantly, onsite workers will be trained in emergency response and procedures and will have access to protective equipment and clothing. The staff presently believes that this training, coupled with the design, performance, and quality assurance requirements in the rule, will provide adequate levels of worker protection without the need for prescribed accident-dose design criteria. Part 20 should provide adequate worker protection standards.

Partial Grant/Partial Denial of DOE Petition:

As noted above, DOE submitted a petition for rulemaking that would establish specific dose criteria for design basis accidents, revise the definition of the term important to safety, and clarify the performance objective for the preclosure operations of the repository. The staff believes that the petition has merit and agrees with DOE's concept for specific dose criteria for design basis accidents. This concept is embodied in the proposed new 10 CFR 60.136. The staff also agrees that the definition of "important to safety" needs clarification, although not in the manner proposed by DOE. Finally, the staff is proposing that the Commission adopt DOE's request to delete the phrase "at all times" from the performance objective that applies to preclosure operations. The supplementary information to the proposed rule (Enclosure 1) also clarifies that this performance objective applies to all preclosure operations, including retrieval, should that become necessary.

Based on the above, the staff proposes that the Commission grant in part, and deny in part, the DOE petition for rulemaking. The Federal Register notice for this action is included as Enclosure 5.

A draft letter to the petitioner for this action is included as Enclosure 6.

Alternatives:

The "Regulatory Analysis," in Enclosure 7, considered four alternatives for resolving the regulatory uncertainties identified in Part 60. These alternatives included: (1) taking no action, (2) developing regulatory guidance, (3) adopting the DOE petition, and (4) rulemaking that combines elements of the DOE petition with the staff's regulatory initiative. The staff has rejected alternatives (1) and (2), as taking no action would leave the regulatory uncertainties in the rule and developing guidance would still leave the rule deficient in the requirements necessary to adequately protect public health and safety, recognizing that such guidance would not be binding on the license applicant. With regard to alternative (3), the DOE petition has merit, but there are some proposals with which the staff disagrees. As such, the staff does not recommend adopting the DOE petition in toto. As discussed previously, there are elements of the DOE petition that the staff

supports for resolving some of the uncertainties in the rule. However, there are other proposals, for rulemaking, that derive from the staff's regulatory initiative, that had a particular focus on achieving consistency among NRC regulations. As such, the staff recommends alternative (4), rulemaking that combines the best elements of the DOE petition with the complementary proposals from the staff's initiative. Although the "Regulatory Analysis" indicates that there may be some cost- and schedule-related impacts to DOE's program, as a result of the proposed rulemaking, there would be compensating benefits from resolution of the regulatory uncertainties and the provision of clearer, and more complete, regulatory requirements. NRC would benefit from the greater consistency among its regulations, and the public would benefit from the enhancements, in the proposed rule, that focus on protection of public health and safety.

COORDINATION:

The ACNW has been briefed on the proposed rule, and its suggestions (Enclosure 8) have been incorporated into the proposed rulemaking, with the exception of providing specific occupational worker exposure standards for category 2 events. The Office of Public Affairs and the Office of Congressional Affairs have been consulted regarding the public announcement (Enclosure 9) and the Congressional letters (Enclosure 10). Draft copies of the proposed rule (Enclosure 1) and partial grant/partial denial of petition for rulemaking (Enclosure 5) have been provided to the Office of Enforcement and the Office of the Inspector General. The Office of the General Counsel has no legal objection.

RECOMMENDATIONS:

That the Commission:

(1) Approve publication of the Notice of Proposed Rulemaking (Enclosure 1) for public comment.

(2) Certify that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities, to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b). This certification is included in the enclosed Federal Register notice.

(3) Approve the partial grant and partial denial of DOE's petition. (Enclosure 5).

(4) Note:

(a) That the proposed rule will be published in the Federal Register, allowing 90 days for public comment.

(b) That a public announcement will be issued.

(c) That the Subcommittee on Clean Air and Nuclear Regulation of the Senate Committee on Environment and Public Works, the Subcommittee on Energy and Mineral Resources of the House Committee on Natural Resources, and the Subcommittee on Energy and Power of the House Committee on Energy and Commerce, will be informed of this rulemaking action.

(d) That the proposed rule does not contain new or amended information collection requirements subject to the Paperwork Reduction Act.

(e) That the listing of proposed new section 60.136 among the sections for which there can be no criminal penalty under the Atomic Energy Act, is consistent with the listing of other sections of Part 60. However, staff and OGC will examine the issue of criminal penalties for DOE, apart from this rule, and inform the Commission if any further rule changes are necessary.

(f) That a copy of the proposed rule will be distributed to all interested persons.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. Proposed Rule
2. DOE Petition for Rulemaking
3. Notice of Receipt of Petition for Rulemaking from DOE (55 FR 28771)
4. Comments on FRN
5. Partial Grant/Partial Denial of Petition for Rulemaking
6. Draft Ltr. to Petitioner
7. Regulatory Analysis
8. ACNW Correspondence
9. Public Announcement
10. Draft Congressional Ltrs.

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Wednesday, September 28, 1994.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Wednesday, September 21, 1994, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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PROPOSED RULE

[7590-01-P]

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: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its policy on the protection of public health and safety from activities conducted at a geologic repository operations area (GROA) before permanent closure. In particular, the proposed rule would address 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.

DATE: Comments must be submitted on or before _____, 1994, [90 days from date of publication in the Federal Register]. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Attention: Docketing and Service Branch.

Hand-deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm Federal workdays.

Examine comments received at the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC.

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. The amendments presented in this proposed rule deal with a matter that was brought to light by this review and by a petition for rulemaking (PRM) filed by DOE (PRM-60-3).

The issue concerns the protection of public health and safety for a broad range of normal and accident conditions during the operational period of a geologic repository (i.e., before permanent closure). The Commission is concerned that the current requirements of Part 60 may be unclear and may be insufficient 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. The Commission also notes that certain elements of existing Part 60 differ from counterpart requirements in other NRC rules, and it believes that greater consistency in language would be beneficial. NRC is proposing rulemaking to address these identified concerns. To develop and explain the changes to the regulatory requirements that appear to be

desirable, it would be useful to review the pertinent provisions of existing Part 60.

The Existing Rule

The provisions of Part 60 generally reflect the defense-in-depth philosophy of the Commission that is commonly embodied in the requirements and practices for other types of Commission-regulated facilities, such as commercial nuclear power reactors and independent spent fuel storage installations (ISFSIs), with the overall intent to prevent or mitigate the occurrence of serious accidents and, thereby, to protect the public health and safety. Defense-in-depth is provided for, during the preclosure period, by conservatism, redundancy, and diversity in design; the application of a comprehensive quality assurance program, to facility design, construction, operation, and maintenance; the imposition of radiation protection standards, for both workers and members of the public, to limit the potential adverse consequences of licensed activities to levels that are well within the bounds of risks accepted in other productive activities in society; and requirements for radiation safety programs and procedures and emergency plans. The Commission's radiation protection standards are codified in 10 CFR Part 20.

Specifically, defense-in-depth is implemented in Part 60 by repository performance objectives and by detailed siting and design criteria. Further, the rule provides that those structures, systems, and components determined to be "important to safety" would be subject to additional design requirements and to quality assurance requirements, to add confidence that the repository and its subsystems will perform satisfactorily in service. However, examination of the specific provisions of the rule indicates that some elements may be deficient in terms of their clarity, sufficiency, or consistency with other NRC rules, resulting in concerns about the adequacy of defense-in-depth in Part 60. The most significant concerns relate to: (1) the definition of structures, systems, and components "important to safety" and the ability to identify such features; (2) uncertainties in the performance objective for radiation protection; and (3) the lack of consistency with 10 CFR Part 72 ("Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste") which applies to "monitored retrievable storage (MRS) installations," the facilities most similar to a repository, during the repository's operational period.

These concerns are discussed in turn.

"Important-to-Safety" Definition

The regulation states (10 CFR 60.2):

> "Important to safety," with reference to structures, systems, and components means those engineered structures, systems, and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure.

Note, first, that the definition refers to repository features "essential to the prevention or mitigation of an accident" (emphasis added) in the context of a dose limit (0.5 rem) "...equal to the annual dose to the whole body of an individual in an unrestricted area that would be permitted under 10 CFR Part 20 for normal operations...." (48 FR 28202; June 21, 1983, Final rule, "Disposal of High-Level Radioactive Wastes in Geologic Repositories"). However, the definition is unclear with respect to the range of "accidents" to be considered when it is applied to identify those structures, systems, and components important to safety. As such, the uncertainty in the definition raises questions about the adequacy of the technical criteria, in the rule, to protect the public health and safety for the full

range of conditions or events that may occur before closure, including those credible, but unlikely events with potentially serious consequences. Second, the focus of the definition is the protection of members of the public in unrestricted areas and, although supplemental design and quality assurance provisions for this purpose may also indirectly benefit onsite workers for some conditions or events, the definition does not explicitly address protection for the occupational workforce. Lastly, the value of 5 mSv (0.5 rem) as a dose limit in unrestricted areas for "accident" conditions is peculiar to Part 60, and lacks consistency with a corresponding limit in 10 CFR Part 72.

Performance Objective for Radiation Protection

As stated previously, the Commission's numerical radiation protection standards are codified in Part 20. These standards apply to operations at a geologic repository by virtue of 10 CFR 20.1002 as well as by 10 CFR 60.111(a), which provides, in part:

> 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 at all times be maintained within the limits specified in Part 20 of this chapter....

There are two conceptual difficulties with this language and both issues derive from the language in the rule that requires the limits of Part 20 to be met "at all times." The first issue relates to the uncertainty about the scope of activities intended in the requirement, specifically, whether Part 20 limits must be observed not only during planned operations, but also if the emplaced waste has to be retrieved in accordance with 10 CFR 60.111(b). The Commission previously addressed this issue in a prior proposed rulemaking, explaining that the phrase ("at all times") was included in the regulation so as "...to emphasize the need to design the geologic repository operations area so that any waste retrieval found to be necessary in the future could be carried out in conformance with the radiation protection requirements of 10 CFR Part 20" (51 FR 22288; June 19, 1986, proposed amendments to conform to U.S. Environmental Protection Agency (EPA) general environmental standards). The Commission adheres to this interpretation and believes that the application of Part 20 limits to possible retrieval activities is consistent with the policy followed in the application of Part 20 to corresponding activities (e.g., spent fuel handling) at other facilities regulated by the Commission under 10 CFR Parts 50 and 72, (i.e., at commercial power reactors and ISFSIs, respectively).

The second issue relates to uncertainty about the scope of conditions intended in § 60.111(a), specifically, whether Part 20 limits must be observed for the extreme conditions that may result from credible, but unlikely, scenarios or events. Here, the Commission recognizes the desirability of articulating its intentions more clearly. For this purpose, it is helpful to use a simple classification scheme for describing the broad range of conditions or events that effectively provide the design basis for the facility. These so-called "design basis events" are defined as being of two categories:

(1) 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

(2) 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.

Category 1 events have typically been referred to in the rules and guidance documents (e.g., regulatory guides) for Commission-regulated facilities (nuclear power plants, MRS installations, geologic repositories) as those conditions resulting from "normal operation, including anticipated

operational occurrences." Anticipated operational occurrences, including those of natural origin, are those conditions expected to occur one or more times during the lifetime of the facility.

In the administration of its regulatory program for facilities licensed under Parts 50 and 72, it has been the Commission's general practice, as well as its intent in Part 60, to apply the dose limits of Part 20 to Category 1 events. The Commission's intent, in this regard, is further clarified in the statement of considerations related to revision of its Part 20 standards (56 FR 23360; May 21, 1991, Final rule, "Standards for Protection Against Radiation"). Here, the Commission notes that the revision conforms its regulations to the "Presidential Radiation Protection Guidance to Federal Agencies for Occupational Exposure." The Commission further notes (56 FR 23365) that the dose standards in the Presidential guidance only apply to normal operating conditions. Although it is the Commission's intent that the regulations in Part 20 also be observed to the extent practicable during emergencies, the Commission also recognizes that, in an actual emergency, operations that do not conform to the regulations may be necessary to protect public health and safety. Notwithstanding the general applicability of these regulations to all operational situations, it is not the Commission's intent that these requirements apply to Category 2 events as a design basis for the facility. Appropriate requirements other than the limits of

Part 20 would be provided as the design basis for Category 2 events. Some of the confusion about this matter is no doubt linked to the terminology used in various Commission rules or guidance documents, where the terms "accidents" and "anticipated operational occurrences" may have been used interchangeably. It should be recognized that some "accidents" may, indeed, be "anticipated operational occurrences," if they are expected to occur one or more times during the lifetime of the facility. What is important, in this regard, is not the term applied to the event, but its expected frequency of occurrence, to determine both its category and whether Part 20 limits should apply as a design basis.

Although the foregoing discussion may help to clarify the Commission's intent regarding the applicability of Part 20 limits to Categories 1 and 2 design basis events, it leaves open the question about the adequacy, to protect public health and safety, of the Part 60 design criteria for Category 2 events. The Commission now proposes to address this matter by harmonizing the criteria of Part 60, as appropriate, with other parts of its regulations - particularly Part 72, which applies to facilities (MRS installations) with much in common with repositories, during their operational period. In this regard, the character and design of the features of an MRS installation would be expected to be very similar to the surface facilities of an operating repository. Further, the same kind of functional activities

would be performed at both types of facilities, namely, receiving, handling, packaging, storing, and retrieving high-level radioactive waste. As such, the Commission believes that greater consistency between Part 60 and Part 72 is both logical and desirable.

10 CFR Part 72

Part 72 also refers to structures, systems, and components important to safety. However, instead of defining this concept in specific quantitative terms, it provides the following (10 CFR 72.3):

> "Structures, systems, and components important to safety" mean those features of the ISFSI (independent spent fuel storage installation) or MRS (monitored retrievable storage installation) whose function is:
>
> (1) to maintain the conditions required to store spent fuel or high-level radioactive waste safely;
>
> (2) to prevent damage to the spent fuel or the high-level radioactive waste container during handling and storage; or

(3) to provide reasonable assurance that spent fuel or high-level radioactive waste can be received, handled, packaged, stored, and retrieved without undue risk to the health and safety of the public.

The Commission's concern in singling out this class of structures, systems, and components is to identify those features that are so important that it is prudent to warrant the application of special design and quality assurance criteria. The design elements that are then to be required are determined in the light of the design bases, a term that is defined as follows:

> "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. (10 CFR 72.3.)

Part 72 provides for a quality assurance program that encompasses a range of structures, systems, and components of somewhat indefinite scope. According to 10 CFR 72.140(b), the program "...must cover the activities identified in 10 CFR 72.24(n)," which in turn deals with "structures, systems, and components important to safety." The application of these provisions relates to the qualitative language of the definition of "...structures, systems, and components important to safety." In essence, an element is to be placed in this category if its function is to provide reasonable assurance that there is no undue risk to the health and safety of the public. Although the definition lacks specific numerical guidance as to what constitutes "undue risk," the Commission, nevertheless, regards this as a stringent test--one that contemplates that the numerical limits set out in Part 20 will generally be met for Category 1 design basis events, consistent with the general practice (as previously discussed) of the Commission in the application of these standards.

With respect to Category 2 design basis events, numerical guidance may be inferred from both the "Siting Evaluation Factors" (Subpart E) and "General Design Criteria" (Subpart F) of Part 72. As specified in 10 CFR 72.106, for each ISFSI or MRS facility, there must be a "controlled area" of such size that no individual located on or beyond its boundary will receive a dose greater than 0.05 Sv (5 rem) to the whole body, or to any organ, from any "design basis accident." Both external natural events and external man-induced events must be considered in defining the design bases that would result in the design basis accident. 10 CFR 72.126(d) specifies that analyses must be made to show that releases to the general environment from design basis accidents will be within the exposure limits of 10 CFR 72.106. These requirements suggest that the 0.05-Sv (5-rem) dose limit cited above could be used to aid in the identification of structures, systems, and components "important to safety." However, although the existing functional definition, in Part 72, for "important-to-safety" features, has sufficed for identifying those corresponding components or structures of an ISFSI, the Commission believes that the greater specificity (i.e., numerical guidance) provided by a quantitative definition similar in character to the existing Part 60 definition would be more suitable for the licensing of a more complex repository.

In the foregoing discussion, the Commission cited the requirements of 10 CFR 72.106, which include provisions for the

establishment of a "controlled area" boundary and dose criteria for limiting exposures to individuals at or beyond that boundary, during design basis accidents. The Commission notes that corresponding requirements are not provided in Part 60 which, in turn, raises questions about the adequacy of the criteria in Part 60 to ensure protection of public health and safety.

There is another matter the Commission wishes to address, in this action, that relates to another area of inconsistency between Part 72 and Part 60. Subpart F of Part 72 provides the "general design criteria" for an ISFSI or an MRS. These general design criteria establish the minimum requirements for the design, fabrication, construction, testing, maintenance, and performance, for the structures, systems, and components of the facility that are important to safety. In this regard, Subpart F of Part 72 is structured similarly to, and performs the same function as, Appendix A of 10 CFR Part 50 ("General Design Criteria for Nuclear Power Plants") in that both sets of criteria establish minimum requirements for structures, systems, and components "important to safety." The corresponding structure for the design criteria for the GROA in Part 60 is somewhat different from the corresponding structures in Parts 72 and 50.

The design criteria for the GROA are provided in §§ 60.130 through 60.134 and include criteria for both preclosure considerations (i.e., criteria for features "important to

safety"), as well as postclosure interests (i.e., criteria for features "important to waste isolation"). However, only the criteria of § 60.131(b) are identified as "structures, systems, and components important to safety," and it is unclear if other criteria specified in §§ 60.131(a), 60.132, and 60.133, for operational considerations, are also "important to safety." In this regard, the Commission notes that there are some "important-to-safety" criteria in Part 72 that are not designated as such, in a corresponding manner, in Part 60. Although the Commission recognizes that this lack of consistency may be due, in part, to the dual interests, in Part 60, of preclosure safety and postclosure isolation, the Commission also believes that this structure may contribute to the difficulty in determining which features of the GROA are "important to safety" and subject to the quality assurance provisions of Subpart G.

The Petition for Rulemaking

On April 19, 1990, DOE filed a PRM with the Commission. It was assigned Docket No. PRM-60-3. A notice of receipt was published in the Federal Register on July 13, 1990 (55 FR 28771).

In its petition, DOE observed that 10 CFR 60.21(c)(3)(ii) requires that the safety analysis report for a repository include a description and analysis that considers "...the adequacy of structures, systems, and components provided for the prevention of accidents and mitigation of the consequences of accidents, including those caused by natural phenomena." Yet, Part 60 does not provide numerical dose criteria to use in identifying the need for engineered safety features and for determining their adequacy.

DOE noted how similar operations at a geologic repository were to those carried out at other licensed facilities, including, in particular, facility operations for independent storage of spent nuclear fuel. In common with these other facilities, the operations at a repository would involve receipt, handling, transfer, and storage of highly radioactive materials.

Under DOE's proposal, Part 60 would be amended to include accident dose criteria of 0.05-Sv (5-rem) effective dose equivalent or 0.5-Sv (50-rem) committed dose equivalent to any

organ. These criteria would apply to any individual at the boundary of a newly defined "preclosure control area." The definition of the term "important to safety" would be revised, but would retain the 5-mSv (0.5-rem) reference dose; however, unlike the present Part 60, which relates this value to the boundary of the unrestricted area, DOE's proposal would apply the dose limit at the boundary of the preclosure control area. The phrase, "at all times," would be deleted from 10 CFR 60.111(a), to clarify that Part 20 does not apply to accident conditions. Lastly, DOE proposed adding definitions of the terms "preclosure control area," "committed dose equivalent," "committed effective dose equivalent," and "effective dose equivalent," to support the application of the accident-dose criteria described above.

For a fuller discussion of the PRM, see the July 13, 1990, Federal Register notice.

Discussion

The Commission agrees with the petitioner that rulemaking is needed to address the uncertainties related to appropriate accident-dose criteria for those unlikely, but credible, conditions or events (i.e., Category 2 design basis events) that might occur. In this regard, the Commission agrees with the concept proposed by DOE, including the application of appropriate

accident-dose criteria at the boundary of a "preclosure control area."

Regarding the current definition of "important to safety," the Commission agrees with DOE that the term should be revised so as to clarify both its meaning and its intended scope. Although the revision proposed by DOE captures the Commission's intent, with respect to identifying those structures, systems, and components necessary to prevent or mitigate the consequences of credible, but unlikely accidents (i.e., Category 2 design basis events), it does not address the Commission's parallel interest in those repository features necessary to protect workers and members of the public from those events that occur regularly, moderately frequently, or one or more times during the lifetime of the GROA (i.e., Category 1 design basis events). The Commission proposes to address this matter by both expanding and modifying the current definition in Part 60.

With regard to DOE's remaining major item of concern in its petition, specifically the uncertainty in the language of 10 CFR 60.111(a), the Commission agrees with DOE's proposal to delete the ambiguous phrase "at all times" from the rule, to clarify that the objective does not apply to radiation exposures, levels, or releases from those credible, but unlikely conditions or events (i.e., Category 2 design basis events). Notwithstanding this change, it remains the Commission's intent

that this performance objective applies to all functional activities (e.g., radioactive waste receiving, handling, packaging, storage, and emplacement) expected to occur at a repository site, including retrieval, if that becomes necessary.

Finally, with respect to the new definitions that DOE proposed for 10 CFR 60.2, the Commission agrees that there is a need to define a boundary for a "preclosure control area." However, the terms "committed dose equivalent," "committed effective dose equivalent," and "effective dose equivalent" are all defined terms, in Part 20, and incorporated into Part 60 by virtue of 10 CFR 60.111(a). As such, these terms do not need to be defined in Part 60.

Based on the foregoing discussion of DOE's petition and the interest of greater consistency between Part 60 and Part 72, as previously discussed, the Commission proposes to amend Part 60 to ensure the adequacy of its requirements to protect the public health and safety. In this regard, generally applicable design basis dose criteria are proposed, in the rule, for protection of members of the public, during Category 1 and Category 2 design basis events, and for protection of the occupational workers, during Category 1 design basis events. The Commission notes that generally applicable dose criteria are not proposed for protection of occupational workers during Category 2 design basis

events, consistent with the policy in practice for facilities regulated by the Commission under Parts 50 and 72.

The Commission has determined that specific standards for the protection of occupational workers during category 2 events are not needed for Part 60. First, for some design basis events, the repository design and quality assurance enhancements employed to satisfy the proposed requirements, for protection of members of the public, during Category 2 events, will also provide a measure of protection for onsite workers. Second, onsite workers would have access to protective equipment (e.g., respirators) and clothing, should the need ever arise. Third, onsite workers would be trained in emergency response and procedures to deal with operational problems related to these kinds of events. Fourth, Part 20 should provide adequate worker protection standards.

The proposed amendments are discussed below.

Section-by-Section Analysis

Section 60.2. Definitions.

The proposed amendments involve eight 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 proposed because Part 60 already refers to a "controlled area" (within which waste isolation is to be ensured after 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 proposed 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" would be renamed "postclosure controlled area," to avoid any confusion or misunderstanding about this term, in relation to its use in Parts 20 and 72. No substantive change, however, is intended for the "postclosure controlled area," as this is a change in nomenclature, only. Consistent with this change in nomenclature,

the term "controlled area" would be changed to "postclosure controlled area," where it appears in the definitions for "accessible environment," "disturbed zone," and "site."

The term "important to safety" would be 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 proposes to retain the quantitative features of the existing definition, but specify different numerical criteria for each of the two categories (1 and 2) of design basis events. The structures, systems, and components "important to safety" would be 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 the nearest boundary of the preclosure controlled area.

Although the term "design bases" appears in existing Part 60, in 10 CFR 60.21(c)(2), it was not defined. As the discussion above 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 would be inserted, without change, into the list of defined terms in 10 CFR 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.

Section 60.8. Information collection requirements: OMB approval.

NRC is proposing to update 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 60.8 was to be corrected the first time other revisions were made.

Section 60.21. Content of application.

The petition for rulemaking suggested that provision for accident analysis might be accomplished by amendment of 10 CFR 60.111. The Commission proposes, instead, to provide for an accident analysis as part of the content of the application section (i.e., 10 CFR 60.21). The proposed language would require the application to address the potential dose, to an individual on or beyond 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 critical design basis events, singly, and demonstrate, by its analysis, that the doses on or beyond the preclosure controlled area boundary would be in accordance with the applicable standards. The proposed language serves the same purpose as the counterpart section of Part 72 (namely 10 CFR 72.24(m)).

The proposed rule also reflects the position, as discussed previously, that the applicant must demonstrate that the requirements of Part 20 will be met, assuming the occurrence of Category 1 design basis events. For this analysis, the applicant would consider Category 1 design basis events singly, or in appropriate combinations. The doses, exposures, or releases must be kept within Part 20 limits should less likely events (e.g., moderately frequent events) occur in combination with events that occur regularly.

The Commission also proposes to eliminate 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 would be supplanted by the new term "design basis events." Besides enhancing clarity of expression, the new language better reflects the regulatory framework articulated above. Lastly,

where the term "controlled area" appears in the language of this section, it would be changed to "postclosure controlled area."

Section 60.43. License specification.

The term "controlled area" would be changed to "postclosure controlled area."

Section 60.46. Particular activities requiring license amendment.

The term "controlled area" would be changed to "postclosure controlled area."

Section 60.51. License amendment for permanent closure.

The term "controlled area" would be changed to "postclosure controlled area."

Section 60.102. Concepts.

The term "controlled area" would be changed to "postclosure controlled area."

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

Consistent with the petitioner's proposal, the Commission would delete the phrase "at all times" from the performance objective of § 60.111(a). This change would clarify 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" would be changed to "postclosure controlled area."

Section 60.122. Siting criteria.

The term "controlled area" would be changed to "postclosure controlled area."

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

The Commission proposes to modify the title of this section to the term "General Considerations" and add 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" (10 CFR 60.2) as well as to clarify the purpose of these criteria. These changes will also provide consistency with the corresponding "minimum" design criteria, for an MRS, in 10 CFR 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 would delete the reference to "Structures, systems, and components important to safety" in the title of § 60.131(b), and re-letter or re-number the current criteria in §§ 60.131(b)(1) through 60.131(b)(10), as appropriate. This change would eliminate the confusion in the existing rule related to the identification of only the criteria in § 60.131(b) as "important to safety." It would also resolve 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 proposes to remedy 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, modification of paragraphs (b)(5)(i), (b)(7), and (b)(8) is being proposed for this section. The Commission would also revise the language in 10 CFR 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 10 CFR 60.111(a) and 10 CFR 60.136).

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)." As indicated previously, the design should ordinarily be sufficiently conservative so as 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," as proposed, will broaden the scope of this provision to reflect the Commission's intent more accurately.

Section 60.133. Additional design criteria for the underground facility.

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

Section 60.136. Preclosure controlled area.

The proposed rule would adopt the petitioner's concept of a preclosure control area under the name "preclosure controlled area." The term would delimit an area over which the licensee exercises control of activities to meet regulatory requirements. Control would include the power to exclude members of the public, if necessary. The zone, and related dose criteria, 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 reference dose on or beyond the preclosure controlled area boundary that is appropriate to ensure that the occurrence of any such events

presents 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 proposes to adopt the basic provisions of Part 72 - namely, a reference 0.05-Sv (5-rem) dose, 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. The reference 0.05-Sv (5-rem) dose in Part 72 was derived from the EPA protective action guides for emergency response planning to nuclear incidents and only accounted for the external exposure pathway.[1] However, current EPA guidance uses a TEDE approach in establishing bounding values (1 to 5 rem) for which protective actions would be taken to avoid undue exposures.[2] The Commission believes that 0.05-Sv (5-rem) TEDE, as described above, is an appropriate design basis for protection of public health and safety from Category 2 design basis events at a GROA.

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[1]EPA 520/1-75-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," September 1975.

[2]EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," May 1992. The referenced bounding doses (1 to 5 rem) reflect the sum of the effective dose equivalent resulting from exposure to external sources and the committed effective dose equivalent incurred from all significant intakes during the early phase of the incident.

Modification of the 0.05-Sv (5-rem) dose, to reflect the Part 20 system of dose limits, results in a family of reference doses: 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).[3] The eye and skin reference doses 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, and not cumulatively with other design basis events.

The only other noteworthy deviation from Part 72 (specifically 10 CFR 72.106) would be to refer to doses attributable to any "design basis event" instead of 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 a design basis accident is the consequence of some design basis event.

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

Section 60.183. Criminal penalties.

A conforming change has been 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.

Environmental Impact: Categorical exclusion

NRC has determined that this proposed 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 proposed regulation.

Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0127.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft 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, if adopted, 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

NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed 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. 553, NRC is proposing to adopt the following amendments to 10 CFR Part 60.

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

1. The authority citation for Part 60 continues 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).

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," renaming the defined term "Controlled area" to "Postclosure controlled area," 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) 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 (2) 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.

The events described in clause (1) of this definition are referred to as "Category 1" design basis events. The events described in clause (2) 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 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 the nearest 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 immediately 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.

* * * * *

Site means the location of the postclosure controlled area.

3. Section 60.8 is revised to read as follows:

§ 60.8 Information Collection Requirements: OMB 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 (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.). OMB 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 such 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 such information with respect to subsurface conditions outside the postclosure controlled area to the extent such 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 the 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 such provisions for worker protection as may be 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 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 the nearest 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 may not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin may 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.

17. In § 60.183, paragraph (b) is revised to read as follows:

§ 60.183 Criminal penalties.

* * * * *

(b) The regulations in Part 60 that are not issued under Sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 60.1, 60.2, 60.3, 60.5, 60.6, 60.7, 60.8, 60.15, 60.16, 60.17, 60.18, 60.21, 60.22, 60.23, 60.24, 60.31, 60.32, 60.33, 60.41, 60.42, 60.43, 60.44, 60.45, 60.46, 60.51, 60.52, 60.61, 60.62, 60.63, 60.64, 60.65, 60.101, 60.102, 60.111, 60.112, 60.113, 60.121, 60.122, 60.130, 60.131, 60.132, 60.133, 60.134, 60.135, 60.136, 60.137, 60.140, 60.141, 60.142, 60.143, 60.150, 60.151, 60.152, 60.162, 60.181, and 60.183.

Dated in Rockville, Maryland, this ___ day of _____, 1994.

For the Nuclear Regulatory Commission.

_____

Samuel J. Chilk,
Secretary of the Commission.

ENCLOSURE 2

DOE PETITION FOR RULEMAKING

Department of Energy
Washington, DC 20585

APR 1 9 1990

Secretary
U.S. Nuclear Regulatory Commission
Attention: Chief, Docketing and
Service Branch
Washington, D.C. 20555

Dear Sir:

The U.S. Department of Energy believes that to facilitate the development and licensing of a geologic repository for high-level radioactive waste it is necessary to amend 10 CFR Part 60 to include a specific dose criteria for design basis accidents. Consequently, we are hereby submitting the enclosed petition for rulemaking under the provisions of 10 CFR 2.802. The subject of this petition has been previously discussed with the Commission's Division of High-Level Waste Management staff and with the Advisory Committee on Nuclear Waste.

We would appreciate your consideration and acceptance of this petition. Any questions regarding the petition may be addressed to Mr. Ralph Stein of my staff on 586-6046.

Sincerely,

John W. Bartlett

John W. Bartlett, Director
Office of Civilian Radioactive
Waste Management

Enclosure:
Petition of the U.S. Department of Energy for a Rulemaking to Establish an Accident Dose Criteria for a High-Level Radioactive Waste Repository

cc:

R. Bernero, NRC
R. Browning, NRC
J. Youngblood, NRC
D. Moeller, ACNW
R. Loux, State of Nevada
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
S. Bradhurst, Nye County, NV

PETITION OF THE U.S. DEPARTMENT OF ENERGY FOR A RULEMAKING TO ESTABLISH ACCIDENT DOSE CRITERIA FOR A GEOLOGIC REPOSITORY FOR HIGH-LEVEL RADIOACTIVE WASTE

Docket No. _____

1.0 INTRODUCTION

Title 10 of the Code of Federal Regulations, Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories," does not contain specific accident dose criteria. The Department of Energy (DOE) considers such criteria to be necessary and is hereby petitioning the Nuclear Regulatory Commission (NRC) to amend 10 CFR Part 60 to include accident dose criteria of 5 rem effective dose equivalent with a limit of 50 rem on the committed dose equivalent to any organ. These criteria would apply to any individual at the boundary of a newly defined "preclosure control area" at any time until repository closure is completed.

This petition addresses all the requirements of 10 CFR 2.802(c). The proposed amendments to the current rule, 10 CFR Part 60, are included in Section 2, the grounds for and DOE's interest in the action requested are described in Section 3, and a discussion of the specific issues involved, supporting arguments, relevant information, and the reasons why the current rule is deficient are provided in Section 4.

2.0 PROPOSED AMENDMENTS TO 10 CFR PART 60

This section provides a general description of the proposed amendments, followed by specific additions and modifications to the current rule to accomplish the amendments.

2.1 General Description of Proposed Amendments to 10 CFR 60

Amendments are proposed for both 10 CFR 60, Subpart A (General Provisions, Definitions) and Subpart E (Technical Criteria, Performance Objectives).

In Subpart A, definitions are proposed to be added to 10 CFR 60.2 for "preclosure control area", "committed dose equivalent", "committed effective dose equivalent" and "effective dose equivalent". The current version of 10 CFR Part 60 does not contain these definitions, and they are needed to support the application of accident dose criteria.

Also, a revised definition is proposed for the current definition of "important to safety" provided in 10 CFR 60.2. The current definition requires revision as a result of adding the new "preclosure control area" term, addition of new radiation dose terms, and to clarify that the mitigation of the radiological consequences of accidents is not required if doses resulting from these accidents are below the accident dose criteria.

In Subpart E, quantitative accident dose criteria are proposed for addition to 10 CFR 60.111 as a new performance objective under "Performance of the Geologic Repository Operations Area Through Permanent Closure". This includes the requirement that the calculation be applied at the nearest boundary of a newly defined preclosure control area.

Given the proposed new performance objective, it is proposed that the phrase "at all times" be deleted from the performance objective in 10 CFR 60.111(a), to clarify that the objective does not apply to exposures from accidents.

2.2 Specific Proposed Amendments to 10 CFR 60 Subpart A - General Provisions, Definitions

In 10 CFR 60.2, the following new definitions should be inserted:

"Preclosure control area," means the area immediately surrounding the repository facilities for which the licensee exercises authority over its use during the period up to completion of permanent closure. This 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.

"Committed dose equivalent," means the dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50 year period following the intake.

"Committed effective dose equivalent," means the sum of the products of the weighing factors applicable to each of the body organs or tissues which are irradiated and the committed dose equivalent.

"Effective dose equivalent," means the sum of the products of the dose equivalent to the organ or tissue and the weighing factors applicable to each of the body organs or tissues which are irradiated.

In 10 CFR 60.2 the current definition of "important to safety" should be replaced with the following:

"Important to safety," with reference to structures, systems, and components, means those engineered structures, systems, and components the failure of which could result in a release of radioactive material that produces an effective dose equivalent of 0.5 rem or greater to an individual located at or beyond the nearest boundary of the preclosure control area for an accident that could occur at any time until the completion of permanent closure. All engineered safety features shall be included within the meaning of the term "important to safety."

2.3 Specific Proposed Amendments to 10 CFR 60 Subpart E - Technical Criteria, Performance Objectives

In 10 CFR 60.111, delete "at all times" from (a), Protection against radiation exposures and releases of radioactive materials, (2) move (b), Retrievability of waste, to (c), and (3) insert a new (b):

Accident analyses. The geologic repository operations area shall be designed such that any individual member of the public located at or beyond the nearest boundary of the preclosure control area shall not receive a radiation dose from direct exposure and inhalation greater than 5 rem effective dose equivalent or 50 rem committed dose equivalent to any organ from any accidents considered in the design of the repository that could occur at any time until the completion of permanent closure.

3.0 PETITIONER'S GROUNDS FOR AND INTEREST IN THE PETITION

This section describes the DOE's grounds for and interest in the action requested.

The Department of Energy will be the licensee for a geologic repository developed pursuant to the Nuclear Waste Policy Act, as amended. As such, it will be subject to the requirements in 10 CFR Part 60. Section 60.21(c)(3)(ii) requires that the Safety Analysis Report for a repository include a description and analysis that considers "the adequacy of structures, systems, and components provided for the prevention of accidents and mitigation of the consequences of accidents, including those caused by natural phenomena." However, 10 CFR Part 60 does not provide numerical dose criteria to use in identifying the need for engineered safety features and for determining their adequacy. Although the rulemaking record for 10 CFR Part 60[1]

[1] U.S. Nuclear Regulatory Commission, 1983. Staff Analysis of Public Comments on Proposed Rule 10 CFR Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories," NUREG-0804.

shows that some comments suggested such criteria[2], no such criteria were included in the final rule.

During the advanced conceptual design of the repository, DOE will explore design alternatives, ultimately arriving at firmly fixed and refined design criteria and concepts, with further detail to be provided in later design efforts. The absence of accident dose criteria creates uncertainty about how the adequacy of structures, systems, and components will be determined by the regulators at the licensing phase, and could result in major redirection of design efforts.

The regulatory uncertainties introduced by the absence of accident dose criteria in 10 CFR Part 60 are sufficient to warrant rulemaking, particularly when viewed in light of the NRC's commitment to provide sufficient guidance to protect public health and safety. Therefore, explicit accident dose criteria need to be included in the regulations.

Based on the reasons set out below, the DOE requests the NRC to amend 10 CFR Part 60 to include accident dose criteria of 5 rem effective dose equivalent, with a limit of 50 rem on the committed dose equivalent to any organ. Such criteria are generally consistent with NRC accident dose criteria for similar operations at other nuclear facilities and would provide adequate protection of public health and safety.

4.0 SUPPORTING INFORMATION

This section provides a discussion of the specific issue involved in the petition, supporting arguments, and other relevant information, and the reasons why the current rule is considered deficient. The specific issue is whether there is a need to amend 10 CFR Part 60 to include quantitative accident dose criteria and pertinent definitions to facilitate application of the criteria. The current rule is considered deficient simply because it does not specify quantitative criteria. The arguments supporting this position are based on the evaluation of current regulations for similar operations and are not based on an independent assessment of the accident risks associated with those operations or the consequences for potential accidents. Additional information is provided to support the contention that the proposed criteria are consistent with accepted radiological protection criteria. Also, other relevant information is provided to explain the need for the definition of a preclosure control area, and revision to the current definition of "important to safety".

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[2] U.S. Nuclear Regulatory Commission, 1983. Staff Analysis of Public Comments on Proposed Rule 10 CFR Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories," NUREG-0804, Comment Numbers 326-327.

The current rule is considered deficient in that it does not contain the numerical dose criteria needed to determine design adequacy.

As indicated above in Section 3, 10 CFR 60.21(c)(3)(ii) requires an analysis that considers adequacy with respect to potential repository accidents considered. However, the current rule does not contain the numerical dose criteria to be used in determining such adequacy. The absence of quantitative accident dose criteria in 10 CFR Part 60 creates programmatic uncertainties associated with the design of the geologic repository operations area and the procurement of long lead-time items based on that design. This uncertainty could result in major redirection of design efforts and possibly affect the schedule for development of a geologic repository.

There exists a considerable body of knowledge and experience in the type of handling operations that will occur at a repository.

Activities at a geologic repository will be similar to activities that occur at other nuclear facilities, including several facilities licensed by the NRC, and others operated by DOE. These activities will include the receipt, handling, transfer, and storage of highly radioactive materials, principally spent nuclear fuel assemblies and canisters of vitrified high-level radioactive waste. Similar or identical operations with highly radioactive materials are, or have been performed routinely at facilities for independent storage of spent nuclear fuel, such as General Electric's Morris Operations, at commercial nuclear power plants, such as Virginia Power Company's Surry nuclear power plant and others, at commercial fuel cycle facilities, such as Nuclear Fuel Services (NFS) West Valley Reprocessing Plant, and at DOE facilities, such as Savannah River Plant (SRP), Hanford, Engine Maintenance and Disassembly Facility (EMAD), and Idaho National Engineering Laboratory (INEL).

Specific operational similarities include (1) cask handling and cask unloading, (2) spent fuel loading into casks and containers, (3) spent fuel storage, and (4) spent fuel transfers within facilities. Cask handling and unloading operations have been performed at commercial reactors and at such facilities as Morris, NFS, SRP, Hanford, and INEL. At a repository, it is anticipated that spent fuel assemblies will be removed from shipping casks and loaded into disposal containers under dry conditions. This has been done at EMAD. At Morris, spent fuel assemblies are removed from shipping casks and loaded into fuel storage baskets, which are then transferred to the storage basins. With the exception of the operations being conducted underwater, this fuel storage basket loading operation is similar to the fuel container loading operation expected to occur at a repository. The same is also true for the loading of spent fuel

assemblies into shipping casks at commercial nuclear power plants. Dry storage, such as would occur at the repository, has been performed at Surry, INEL and Carolina Power and Light's (CP&L) H. B. Robinson nuclear power plant. Similar spent fuel transfer operations have occurred at other nuclear facilities including fuel storage basket transfers at Morris and cask transfers to concrete storage pads at Surry. Thus, there exists a considerable body of knowledge and experience in the type of handling operations that will occur at a repository.

The repository accident dose criteria proposed by DOE are within the range of accident dose criteria established by the NRC for similar activities.

In view of the similarity between repository operations and operations at other nuclear facilities, it is reasonable that the accident dose criteria for the repository be generally consistent with existing dose criteria for these operations. The dose criteria proposed by DOE are consistent with the 5 rem criteria established by the NRC for accidents at facilities for independent storage of spent nuclear fuel and high-level radioactive waste[3] and even more conservative than the 6.25 rem criteria for nuclear power plant fuel handling accidents, including accidents involving drops of heavy loads on fuel assemblies or safety-related systems, components, or equipment[4]. For the repository, postulated accident scenarios similarly include crane failures and other waste handling accidents that may result in damage to the waste canister such that there is a breach of a confinement barrier[5].

5-rem effective dose equivalent accident dose criteria is supported by accepted radiological protection criteria.

Some of the postulated accident scenarios noted above may result in atmospheric release of radioactive particulates containing, among others, isotopes of cesium, strontium, plutonium, americium, and curium. The dominant exposure pathway for these radionuclides is atmospheric transport followed by inhalation. The potential doses from inhalation would be greatest in internal organs, with doses to the bone surface being the major concern

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[3] Code of Federal Regulations, Title 10, Part 72: Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste, Section 72.106(b), August 1988.

[4] U.S. Nuclear Regulatory Commission, 1981. Section 15.7.4 of the Standard Review Plan, "Radiological Consequences of Fuel Handling Accidents at Nuclear Power Plants," NUREG-0800; U.S. Nuclear Regulatory Commission, 1980. "Control of Heavy Loads at Nuclear Power Plants," NUREG-0612.

[5] Nevada Nuclear Waste Storage Investigations Project Site Characterization Plan Conceptual Design Report, Vol. 4, Appendix F, SAND84-2641.

(i.e., bone is the critical organ) and uptake in the liver and retention in the lung being of lesser importance[6]. To account for the exposure of multiple organs, DOE proposes that the 5 rem accident dose criteria be expressed in the form of effective dose equivalent, as defined by the International Commission on Radiological Protection (ICRP)[7] and the National Council on Radiation Protection and Measurements (NCRP)[8], and be applied to the sum of the effective dose equivalent from external exposure and the committed effective dose equivalent from intake of radionuclides.

In addition, to avoid nonstochastic effects, DOE is proposing that the accident dose criteria include a limit of 50 rem on the committed dose equivalent to any organ.

For dosimetric purposes DOE recommends that the dose criteria be applied to a member of the public who is generally representative of the exposed population (i.e., reference man)[9], as is done with other NRC accident dose criteria.[10]

The exposure pathways to which the accident dose criteria would apply should be limited to direct irradiation and inhalation. Ingestion of contaminated foodstuffs should not be included because the primary determinant of exposure from this pathway is the effectiveness of public health measures taken after the accident (i.e., interdiction of land and foodstuffs) rather than the severity of the accident itself. Criteria for such measures typically fall within the scope of emergency response considerations.

The risk from 5 rem effective dose equivalent is very small. Based on risk coefficients recommended by the ICRP[11] and NCRP[12], a

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[6] Nevada Nuclear Waste Storage Investigations Project, Site Characterization Plan Conceptual Design Report, Vol. 4, Appendix F, SAND84-2641.

[7] International Commission on Radiological Protection, A Compilation of the Major Concepts and Quantities in Use by ICRP, ICRP Publication 42, Ann. ICRP, 14(4): 1-18 (1984).

[8] National Council on Radiation Protection and Measurements, Recommendations on Limits for Exposure to Ionizing Radiation, NCRP Report No. 91, Bethesda, Md., 1987.

[9] International Commission on Radiological Protection, Anatomical, Physiological and Metabolic Characteristics, ICRP Publication 23, Pergamon Press (1975).

[10] U.S. Nuclear Regulatory Commission, Regulatory Guide 3.34, Revision 1, "Assumption Used for Evaluating the Potential Radiological Consequences of Accidental Nuclear Criticality in a Uranium Fuel Fabrication Plant, U.S. Nuclear Regulatory Commission (July, 1979).

[11] International Commission on Radiological Protection, Recommendations of the International Commission on Radiological Protection, ICRP Publication 26, Ann. ICRP, 1(3): 1-53 (1977).

5 rem effective dose equivalent corresponds to an annual probability of 2×10^{-3} of fatality from radiogenic cancer or of a serious hereditary disease (within the first two generations) over a 50 year period following exposure of an individual. (This is the risk to an individual member of the public averaged over both sexes and all ages; the annual risk to any specific individual would depend on age at exposure and time after exposure, and other factors).

Recent reports (i.e., UNSCEAR-88[13] and BEIR-V[14]) indicate that the risk from exposure to low linear energy transfer (LET) radiation (e.g., gamma and beta rays) may be higher than thought previously. Based on those reports, the annual risk from an acute whole body dose of 5 rem of low LET radiation could be 8×10^{-3}. The risk would likely be lower if the doses were delivered at a low dose rate. The risk would still be very low, being only about 2% of the current baseline risk of death due to cancer in the United States.

The ICRP recommends that "...a risk in the range of 10^{-6} to 10^{-5} per year would likely be acceptable to any individual member of the public"[15]. The proposed accident dose criteria are not inconsistent with this range since the low probabilities of repository accidents which could lead to atmospheric radioactive releases would further reduce the overall calculated risk.[16]

For radionuclides of primary concern in potential repository accidents, most of the dose commitment to critical organs would be from high LET alpha particles rather than from low LET radiation[17]. For these radionuclides, the dose is likely to be controlled by the 50 rem cap on the dose to the bone surface rather than by the 5 rem effective dose equivalent limit. For

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[12] National Council on Radiation Protection and Measurements, Recommendations on Limits for Exposure to Ionizing Radiation, NCRP Report No. 91, Bethesda, Md., 1987.

[13] United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), Sources, Effects and Risks of Ionizing Radiation, Report to the General Assembly, with Annexes, New York, United Nations. (1988).

[14] National Research Council, Committee on the Biological Effects of Ionizing Radiation (BEIR-V), Health Effects of Exposure to Low Levels of Ionizing Radiation, Washington, D.C., National Academy Press (1990).

[15] International Commission on Radiological Protection, Recommendations of the International Commission on Radiological Protection, ICRP Publication 26, Ann. ICRP, 1(3): 1-53 (1977).

[16] Nevada Nuclear Waste Storage Investigation Project, Site Characterization Plan Conceptual Design Report, Vol. 4, Appendix F SAND84-2641.

[17] Nevada Nuclear Waste Storage Investigations Project, Site Characterization Plan Conceptual Design Report, Vol. 4, Appendix F, SAND84-2641.

example, if the doses to various organs resulting from inhalation of a radionuclide mixture characteristic of 10 year old spent fuel were normalized to 5 rem effective dose equivalent, the corresponding dose to the bone surface would be about 72 rem. Since this would exceed the 50 rem organ dose limit, the latter would be controlling.

Based on risk coefficients for high LET radiation developed by the National Academy of Sciences (BEIR-IV)[18], a committed dose equivalent of 50 rem to the bone surface from alpha particles is estimated to result in an annual risk of fatality from bone cancer of about 2×10^{-3}. This risk is also consistent with that suggested by the NCRP and the ICRP as acceptable criteria for establishing radiological protection criteria for the public.[19,20]

It should also be noted that the application of ICRP recommendations regarding acceptability of risk to accident situations is conservative because the recommendations are intended to limit risk from exposures that are expected to occur,[21] whereas exposure from accidents is highly unlikely.

<u>The accident dose criteria should be applied at the boundary of a newly defined preclosure control area.</u>

The regulations for nuclear facilities typically require that there be an area established over which control can be exercised in case of an accident (see 10 CFR 72.106(a)). These regulations usually define a different area to which access is controlled during normal operations to provide for radiation protection measures on a routine basis[22]. In case of a radiological accident, the area within which public access is to be controlled is desired to be large, since the distance provides added

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[18] National Research Council, Committee on Biological Effects of Ionizing Radiation (BEIR-IV), Health Risks of Radon and Other Internally Deposited Alpha-Emitters, Washington D.C., National Academy Press (1988).

[19] National Council on Radiation Protection and Measurements, Recommendations on Limits for Exposure To Ionizing Radiation, NCRP Report No. 91, Bethesda, Md., (1987).

[20] International Commission on Radiological Protection Recommendations of the International Commission on Radiological Protection ICRP Publication 26, Ann. ICRP 1(3): 1-53 (1977).

[21] International Commission on Radiological Protection, Recommendation of the International Commission on Radiological Protection, ICRP Publication 26, Ann. ICRP, 1 (3): 1-53 (1977).

[22] 10 CFR 20 defines a restricted area for this purpose.

protection independent of design features[23]. In contrast, for practical purposes pertaining to ensuring proper controlled access and radiation monitoring, the area controlled during normal operations is usually maintained as small as practicable. However, the restricted area defined in 10 CFR 60.2 is used for both of these purposes[24], which has led the DOE to size a restricted area based on accident considerations. Such an area is unnecessarily large for application of normal access controls and radiological monitoring. To enable DOE to reduce the size of this area to a more appropriate size, it is necessary to establish separate boundaries for the two controlled zones (i.e., accident and routine access control). By making this distinction, the DOE will be in a better position to apply the controls needed to ensure a proper and practical level of radiation protection for routine operations.

The need for separate boundaries was recognized by the NRC when 10 CFR Part 72 was promulgated. In discussing the newly defined "controlled area" for application of the accident dose limit, the NRC stated that "while the terminology used in 10 CFR Part 20, specifically, 'restricted' and 'unrestricted' areas, applies to all nuclear facilities, it is limited to radiation protection concerns associated with normal operations and the means used by the licensee to control the access to areas of potential radiation exposure . . .the term 'unrestricted' used in 10 CFR Part 20 is too narrow in meaning for applications to areas beyond the boundaries of the licensee's property"[25].

For other nuclear facilities, the area within the boundary where the accident dose limit is applied is typically on land controlled by the licensee such that the licensee has authority to exclude or remove personnel and property from the area. This area is called the "exclusion area" at reactor sites (see 10 CFR 100.11) and the "controlled area" at facilities for independent storage of spent nuclear fuel and high-level radioactive waste (see 10 CFR 72 106(a)). For a repository, DOE is proposing to define the location for application of the accident dose criteria and the "important to safety" threshold as the "preclosure control area" boundary. Figure 1 illustrates the differences between the boundaries which would be proposed and the current

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[23] For nuclear reactors the licensee is required by 10 CFR 100.11 to provide an "exclusion area" which is large enough to limit doses from any credible accident to a specified value. Facilities licensed under 10 CFR Part 72 are required to establish a "controlled area" large enough to limit doses from a design basis accident to a specified value. A minimum size for the controlled area is specified.

[24] 10 CFR 60.2 specifies that the 0.5 rem threshold for identifying structures, systems, and components important to safety should be applied at or beyond the nearest boundary of the restricted area. 10 CFR 60.111 applies the requirements of 10 CFR 20 which defines restricted and unrestricted areas for normal operations use.

[25] 45 Federal Register 74696 (1980) (codified at 10 CFR Part 72).

boundaries defined in 10 CFR Part 60. It should be noted that the boundary of the preclosure control area does not necessarily have to coincide with the boundary of the postclosure controlled area defined in 10 CFR 60.2. The shapes of the controlled area and the boundary for accident dose calculation are based on different considerations. For the controlled area, the geohydrologic conditions (e.g. direction of groundwater flow) are important. For the preclosure control area, the meteorological conditions (e.g. predominant wind direction) and population distribution are important.

Establishment of accident dose criteria would not change the intent of the 0.5-rem "important to safety" threshold for classification.

The 0.5 rem threshold in 10 CFR 60.2 for classifying items important to safety is intended to assure the reliability of structures, systems, or components whose failure could result in significant exposures to the public. The desired reliability is obtained by applying the design criteria in 10 CFR 60.131(b) and the quality assurance (QA) requirements in 10 CFR Part 60, Subpart G.

For an accident whose projected consequences exceed 0.5 rem but do not exceed the 5 rem effective (or 50 rem committed) dose equivalent accident dose criteria, the structure, system, or component the failure of which would result in the accident would be designed according to 10 CFR 60.131(b) and subject to Subpart G requirements. Mitigation would not be required within this dose range. However, if analyses indicate that the accident dose criteria would be exceeded, the structure, system, or component in question would not only be designed according to 10 CFR 60.131(b) and would be subject to Subpart G requirements, but also, engineered safety features would be applied to mitigate the accident consequences to below the accident dose criteria. The engineered safety features applied would also be classified as "important to safety."

As indicated above, the establishment of accident dose criteria would not change the intent of the "important to safety" classification. However, the current definition of "important to safety" needs to be modified to be consistent with other changes described in this petition. The current definition could be interpreted to mean that an accident resulting in a radiation dose of 0.5 rem or greater must be mitigated: "those engineered structures, systems, and components essential to the prevention or mitigation of an accident..." (10 CFR 60.2, emphasis added). The threshold for determining the need for mitigation through the use of engineered safety features is the accident dose criteria, not the "important to safety" threshold.

Additional modification of the current definition of "important to safety" is needed to make it consistent with the proposed accident dose criteria by incorporating the effective dose equivalent concept and the new preclosure control area boundary.

5.0 CONCLUSION

Accident dose criteria are needed to establish objective requirements for determining whether 10 CFR 60.21 has been met i.e., to determine the need for and the adequacy of structures, systems, and components provided to prevent or mitigate accidents. The current version of 10 CFR Part 60 does not contain specific accident dose criteria. The absence of such critera unnecessarily creates programmatic uncertainty associated with the design of the geologic repository operations area and the procurement of long lead-time items based on that design. This uncertainty can best be eliminated through rulemaking by amending 10 CFR Part 60 to include specific accident dose criteria, and pertinent definitions to facilitate application of the criteria.

Based on the information presented above, DOE petitions the Commission to amend 10 CFR Part 60 to include accident dose criteria of 5 rem effective dose equivalent, with a limit of 50 rem on the committed dose equivalent to any organ. Such criteria are generally consistent with the Commission's dose criteria for similar accidents at other nuclear facilities and would provide adequate protection of public health and safety.

Respectfully Submitted,

John W. Bartlett

John W. Bartlett, Director
Office of Civilian Radioactive
Waste Management

DATED: April 19, 1990

UNDER CURRENT 10 CFR 60

PROPOSED REVISIONS IN DOE PETITION FOR RULEMAKING

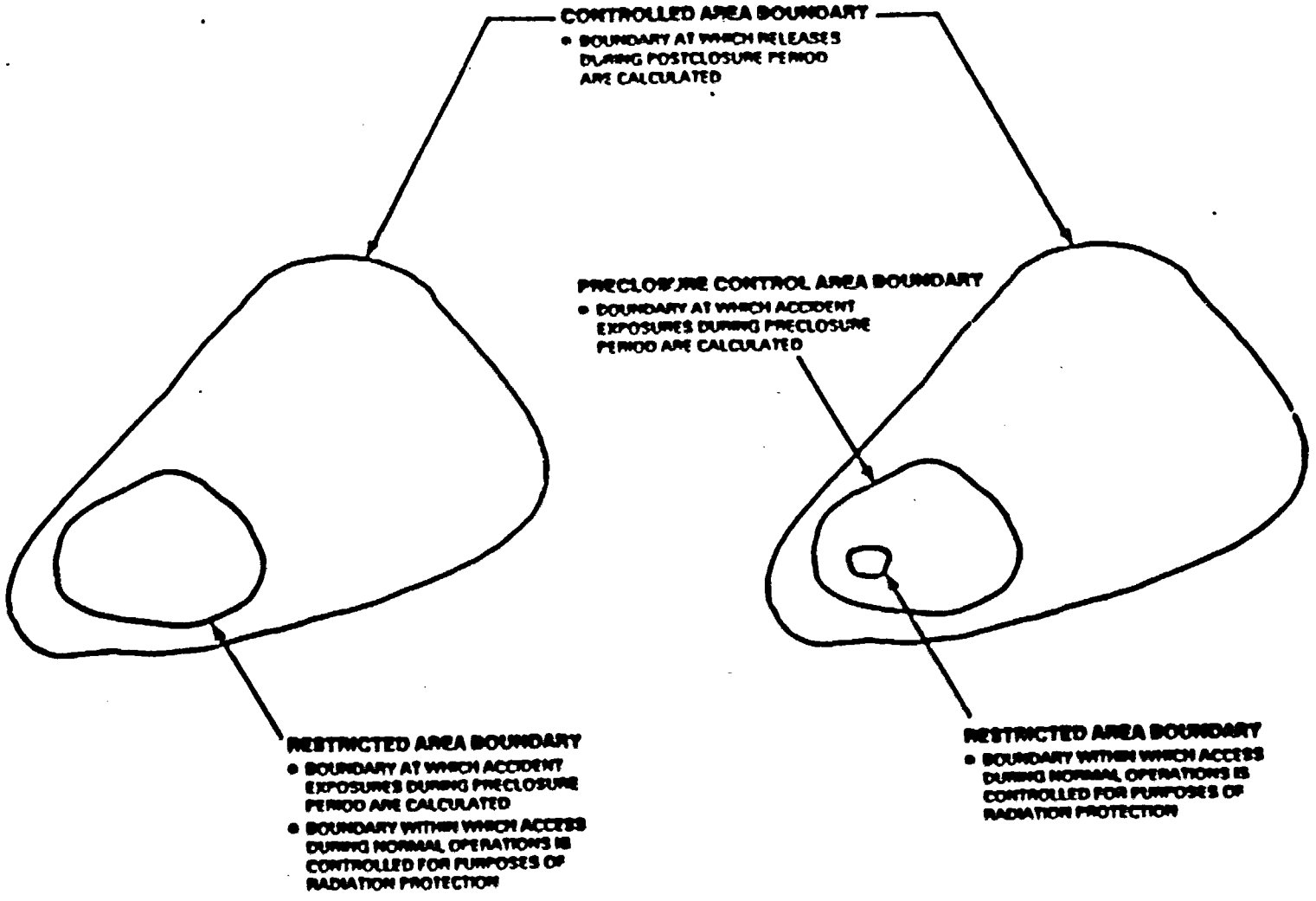

Figure 1. Comparison of Current and Proposed Boundaries

ENCLOSURE 3

NOTICE OF RECEIPT OF A PETITION

FOR RULEMAKING

Hearing Clerk, room 2171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments as provided by the Poultry Products Inspection Act should be directed to Dr. Karen Wesson, at (202) 447-3840.

FOR FURTHER INFORMATION CONTACT: Dr. Karen Wesson, Acting Director, Processed Products Inspection Division, Science and Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447-3840.

SUPPLEMENTARY INFORMATION: In response to the increased consumer demand for fresh convenience foods, the meat and poultry industry has begun producing an increasing variety of ready-to-eat, uncured, perishable products packaged in sealed containers bearing a "Perishable, Keep Refrigerated," or similar label statement. These products are processed and packaged so as to destroy or retard the growth of spoilage-type microorganisms in order to extend product refrigerated shelf life. In many cases, product shelf life claims are significantly longer than similar products familiar to consumers. Moreover, these products normally are marketed as "ready-to-eat," meaning consumers are likely to apply little or no additional heat to the product before consumption.

Many regulatory and public health officials believe that such products, when improperly processed or handled, pose certain unique risks to consumers which, coupled with the increasing prevalence of these products, may warrant additional regulatory action by FSIS.

On May 14, 1990, FSIS published an advance notice of proposed rulemaking (55 FR 19868) requesting comments, information, scientific data, and recommendations on whether it should propose new regulations governing ready-to-eat, uncured, perishable meat and poultry products which are packaged in a variety of sealed containers bearing a "Perishable, Keep Refrigerated," or similar label statement.

Interested persons were given until July 13, 1990, to comment in response to this advance notice of proposed rulemaking. FSIS has received requests to extend the comment period to allow additional time for data and information to be gathered and submitted. FSIS is interested in receiving this information and is, therefore, extending the comment period for an additional 90 days.

Done at Washington, DC, on July 6, 1990.
Lester M. Crawford,
Administrator, Food Safety and Inspection Service.
[FR Doc. 90-16221 Filed 7-12-90; 8:45 am]
BILLING CODE 3410-DM-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 60

[Docket No. PRM-60-3]

Department of Energy; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing for public comment a notice of receipt of a petition for rulemaking which was filed by the U.S. Department of Energy (DOE). The petitioner requests that the NRC amend its regulations pertaining to the disposal of high-level radioactive wastes in geologic repositories to include a specific dose criterion for design basis accidents. The petitioner believes this would facilitate the development and licensing of a geologic repository for high-level radioactive waste.

DATES: Submit comments by October 11, 1990. Comments received after this date will be considered if it is practical to do so but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

For a copy of the petition, write the Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street NW., (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7758 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

Background

On April 18, 1990, the U.S. Department of Energy (DOE) filed a petition for rulemaking with the Commission. Pursuant to 10 CFR 2.802, this petition was docketed by the Commission on April 26, 1990, and has been assigned Docket No. PRM-60-3.

The petition pertains to the requirements that would apply to DOE as the licensee for a geologic repository for high-level radioactive waste developed pursuant to the Nuclear Waste Policy Act, as amended, 42 U.S.C. 10101 et seq. As a licensee, DOE would be subject to the licensing requirements contained in 10 CFR part 60. In its petition, DOE observes that § 60.21(c)(1)(ii) requires that the Safety Analysis Report for a repository include a description and analysis that considers "the adequacy of structures, systems, and components provided for the prevention of accidents and mitigation of the consequences of accidents, including those caused by natural phenomena," yet part 60 does not provide numerical dose criteria to use in identifying the need for engineered safety features and for determining their adequacy. The petitioner believes that specific accident dose criteria are necessary to reduce the uncertainties in the current regulation and to provide specific guidance for the protection of public health and safety.

The Suggested Amendments

The petitioner requests that the NRC amend 10 CFR part 60 to include quantitative accident dose criteria of 5 rem effective dose equivalent, with a limit of 50 rem on the committed dose equivalent to any organ. To accomplish the desired amendment, the petitioner suggests that definitions be added for "preclosure control area," "committed dose equivalent," "committed effective dose equivalent," and "effective dose equivalent." The petitioner believes these definitions are needed to support the application of accident dose criteria.

The petitioner also believes there is a need to include a revision to the current definition of "important to safety." The specific amendments suggested by the petitioner are as follows:

1. In § 60.2, the definition of "important to safety" is revised and definitions of "committed dose equivalent," "committed effective dose equivalent," "effective dose equivalent," and "preclosure control area" are added to read as follows:

Section 60.2 Definitions.

• • • • •

Committed dose equivalent, means the dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent, means the sum of the products of the weighing factors applicable to each of the body organs or tissues which are irradiated and the committed dose equivalent.

• • • • •

Effective dose equivalent, means the sum of the products of the dose equivalent to the organ or tissue and the weighing factors applicable to each of the body organs or tissues which are irradiated.

• • • • •

Important to safety, with references to structures, systems, and components, means those engineered structures, systems, and components the failure of which could result in a release of radioactive material that produces and effective dose equivalent of 0.5 rem or greater to an individual located at or beyond the nearest boundary of the preclosure control area for an accident that could occur at any time until the completion of permanent closure. All engineered safety features shall be included within the meaning of the term "important to safety."

• • • • •

Preclosure control area, means the area immediately surrounding the repository facilities for which the licensee exercises authority over its use during the period up to completion of permanent closure. This 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.

• • • • •

2. In § 60.111, paragraph (a) is amended by removing "at all times." paragraph (b) is redesignated as paragraph (c), and a new paragraph (b) is added to read as follows:

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

• • • • •

(b) Accident analysis. The geologic repository operations area shall be designed such that any individual member of the public located at or beyond the nearest boundary of the preclosure control area shall not receive a radiation dose from direct exposure and inhalation greater than 5 rem effective dose equivalent or 50 rem committed dose equivalent to any organ from any accidents considered in the design of the repository that could occur at any time until the completion of permanent closure.

• • • • •

Supporting Information

The purpose of this proposed amendment is to establish quantitative accident dose criteria and to provide pertinent definitions to facilitate application of these criteria.

The petitioner considers the current rule deficient in that it does not contain the numerical dose criteria needed to determine design adequacy. The petitioner believes that the absence of quantitative accident dose criteria creates programmatic uncertainties associated with the design of the geologic repository operations area and the procurement of long lead-time items based on that design and that uncertainty could result in major redirection of design efforts and possibly affect the schedule for development of a geologic repository.

The petitioner points out that considerable knowledge and experience in the type of handling operations that will occur at a repository exists. In particular, activities at a geological repository would be similar to activities that occur at other nuclear facilities, including several facilities licensed by the NRC and others operated by DOE. These activities will include the receipt, handling, transfer, and storage of highly radioactive materials, principally spent nuclear fuel assemblies and canisters of vitrified high-level radioactive waste. Similar or identical operations with highly radioactive materials are, or have been, performed routinely at facilities for independent storage of spent nuclear fuel.

The petitioner maintains that its proposed repository dose criteria are within the range of accident dose criteria established by the NRC for similar activities. He claims that proposed dose criteria would be consistent with the 5 rem criteria established by the NRC for accidents at facilities for independent storage of spent nuclear fuel and high-level radioactive waste (10 CFR part 72) and even more conservative than the 0.25 rem criteria for nuclear power plant fuel handling accidents, including accidents involving drops of heavy loads on fuel handling accidents, including accidents involving drops of heavy loads on fuel assemblies or safety-related systems, components, or equipment. (For further information, DOE refers to NUREG-0800, Standard Review Plan, and NUREG-0612, Control of Heavy Loads at Nuclear Power Plants). Postulated accident scenarios include crane failures and other waste handling accidents that may result in damage to the waste canister such that there is a breach of confinement barrier.

The petitioner considers the 5 rem effective dose equivalent accident dose criteria to be supported by accepted radiological protection criteria. DOE proposes that the 5 rem accident dose criteria be expressed in the form of effective dose equivalent, as defined by the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRPM), and be applied to the sum of the effective dose equivalent from external exposure and the committed effective dose equivalent from intake of radionuclides. To avoid nonstochastic effects, DOE is proposing that the accident dose criteria include a limit of 50 rem on the committed dose equivalent to any organ. For dosimetric purposes, DOE recommends that the dose criteria be applied to a member of the public who is generally representative of the exposed population (i.e., reference man), as is done with other NRC accident criteria. The exposure pathways to which the accident dose criteria would apply should be limited to direct irradiation and inhalation.

In the petitioner's view, the accident dose criteria should be applied at the boundary of a newly defined preclosure control area. The restricted area defined in 10 CFR 60.2 is used for both the area to be controlled in case of a radiological accident and the area controlled under normal operations. The petitioner believes that this area is unnecessarily large for application of normal access controls and radiological monitoring. To reduce the size of this area to size that the petitioner deems more appropriate, it would be necessary to establish separate boundaries for the two controlled zones (i.e., accident and routine access control). For a repository, DOE proposes to define the location for application of the accident dose criteria and the "important to safety" threshold as the "preclosure control area" boundary.

The petitioner believes that establishment of accident dose criteria would not change the intent of the 0.5-rem "important to safety" threshold for classification. However, in its view, the current definition of "important to safety" would need to be modified to be consistent with other changes it has suggested. The current definition could be interpreted to mean that an accident resulting in a radiation dose of 0.5 rem

or greater must be mitigated: "those engineered structures, systems, and components essential to the prevention or mitigation of an accident * * *" (10 CFR 60.2, emphasis added). The threshold for determining the need for mitigation through the use of engineered safety features is the accident dose criterion, not the "important to safety" threshold. The petitioner suggests modification of the current definition "important to safety" to make it consistent with the proposed accident dose criterion by incorporating the effective dose equivalent concept and the new preclosure control area boundary.

Related NRC Regulatory Initiative

In the NRC Regulatory Agenda (NUREG-0936, Vol. 8, No. 4, published January 1990) and in the Unified Agenda of Federal Regulations (55 FR 17174; April 23, 1990), the NRC has announced a contemplated rulemaking action that would establish additional preclosure regulatory requirements for high-level waste geologic repositories (RIN 3150-AD51). The subject matter of the DOE petition relates closely with the actions under consideration by the NRC as part of this rulemaking effort.

The NRC approach to this related regulatory initiative includes plans to:

1. Perform a functional analysis of a geologic repository using a systematic approach. This functional analysis would include an evaluation of the preclosure operations phase of a repository.

2. Identify in this analysis the functions necessary to protect the health and safety of the workers and the public during normal conditions and abnormal conditions (e.g. design bases accidents/events).

3. Develop repository operational criteria for each function necessary to protect the health and safety of the workers and public.

4. Compare these repository operational criteria to the current criteria in 10 CFR part 60 to help identify any potential regulatory uncertainties.

5. Use the results of the functional analysis and comparison studies as a basis for consideration of any potential rulemaking.

The NRC is in the process of obtaining studies that would address potential regulatory uncertainties in this area. The results of these studies would be made available as NUREG reports. These studies would provide technical support for any regulatory action that may be needed. The NRC estimates that these reports would be available after November 1991.

Although DOE's petition does address areas of concern similar to those addressed in the NRC regulatory initiative described above, the petitioner's approach to establishing design criteria for structures, systems, and components important to safety differs markedly from the contemplated by the NRC. In applying the approach of the petitioner, it would be possible to have no structures, systems, and components important to safety if the nearest boundary of the preclosure control area were sufficiently distant. This could encourage extending the boundary of the preclosure control area in order to justify less effective safety design and quality assurance measures and result in inferior structures, systems, and components in the geologic repository operations area. While this approach might be adequate for protection of the general public, it would ignore the safety of the workers.

In contrast, in applying the approach proposed by the NRC staff, the scope of, and the design criteria for, structures, systems, and components important to safety would be derived from a consideration of the functional requirements of the repository system. In addition, criteria for a preclosure controlled area that takes into account postulated accident conditions that may be developed as a matter apart from the question of structures, systems, and components important to safety. The corresponding provisions in 10 CFR Part 72 may be considered as possible models for regulatory language in this context.

Comments are solicited with respect to the NRC's regulatory initiative as well as the DOE petition.

Dated in Rockville, Maryland, this 9th day of July, 1990.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 90-16417 Filed 7-12-90; 8:45 am]

BILLING CODE 7590-01-M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

Small Business Size Standards; Waiver of the Nonmanufacturer Rule; Aluminum

AGENCY: Small Business Administration.

ACTION: Notice of intent to waive the nonmanufacturer rule for aluminum sheet and plate products.

SUMMARY: This notice advises the public that the Small Business Administration (SBA) is considering waivers of the "nonmanufacturer rule" for aluminum sheet and plate products. The basis for a waiver would be that no small business manufacturer or producer is supplying these products to the Federal government. The effect of a waiver would be to allow an otherwise qualified regular dealer to supply products produced by any domestic manufacturer on a Federal contract set aside for small business or awarded through the 8(a) program relating to these products. The public is requested to comment on the validity of this proposed action.

DATES: Comments must be submitted on or before August 13, 1990.

ADDRESSES: Address comments to: Robert J. Moffitt, Chairman, Size Policy Board, U.S. Small Business Administration, 1441 L Street NW., room 600, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Robert N. Ray, Economist, Size Standards Staff, Tel: (202) 653-6373.

SUPPLEMENTARY INFORMATION: Public Law 100-656, enacted on November 15, 1988, incorporated into the Small Business Act the previously existing regulation that recipients of Federal contracts set aside for small business or 8(a) contracts must provide the product of a small business manufacturer or processor, if the recipient is other than the actual manufacturer or processor. This requirements is commonly referred to as the "nonmanufacturer rule." The SBA regulations imposing this requirement are found at 13 CFR 121.906(b) and 121.1106(b). Section 303(h) of the law provides for waiver of this requirement by SBA for any "class of products" for which there are no small business manufacturers or processors in the Federal market.

This notice proposes to waive the nonmanufacturer rule for producers of aluminum sheet and plate products. The issue of a lack of small business producers of these products was recently brought to the attention of SBA by a wholesale firm in the 8(a) program. In response to this concern, SBA initiated a review of small business manufacturers of aluminum sheet and plate products to the Federal Government.

To be considered in the Federal market, a small manufacturer or producer must have been awarded a contract by the Federal government within the last three years. A class of products is considered to be a particular Product and Service Code (PSC) under the Federal Procurement Data System, or an SBA recognized product line within a PSC. In this case the relevant classes of

ENCLOSURE 4

COMMENTS ON FEDERAL

REGISTER NOTICE

Department of Energy
Washington, DC 20585

NOV 26 1990

Secretary
U.S. Nuclear Regulatory Commission
Attention: Chief, Docketing and
Service Branch
Washington D.C. 20555

Dear Sir:

This letter and its enclosure constitute the Department of Energy's (DOE) comments on the Federal Register Notice published on July 13, 1990. The notice (55 FR 28771-28773) publishes for public comment receipt of a petition for rulemaking filed by DOE requesting that the U.S. Nuclear Regulatory Commission (NRC) amend its regulations pertaining to the disposal of high-level radioactive wastes in geologic repositories to include a specific dose criterion for design basis accidents.

DOE has reviewed NRC's related regulatory initiative. We urge you to proceed with the DOE's petition for rulemaking now and have specific comments in response to your notice of receipt of petition for rulemaking, as provided in the enclosure.

We appreciate the opportunity to comment on your Federal Register Notice. We were granted an extension by Michael T. Lesar, Chief, Rules Review Section, Regulatory Publications Branch, Division of Freedom Information and Publications Services, Office of Administration, NRC, until December 1, 1990. If you have any questions, please contact Dwight Shelor of my staff at (202) 586-6046.

Sincerely,

John W. Bartlett

John W. Bartlett, Director
Office of Civilian Radioactive
Waste Management

Enclosure:
Department of Energy Comments on Notice of Receipt of Petition for Rulemaking (55 FR 28771-28773)

cc w/enclosure:
R. Bernero, NRC
R. Browning, NRC
J. Youngblood, NRC
D. Moeller, ACNW
R. Loux, State of Nevada
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
S. Bradhurst, Nye County, NV

Department of Energy Comments on Notice of
Receipt of Petition for Rulemaking (55 FR 28771-28773)
Docket No. PRM-60-3

General Comment

The NRC acknowledges that the petition addresses areas of concern similar to those that would be addressed in an NRC contemplated rulemaking action to establish additional preclosure regulatory requirements for HLW geologic repositories. The NRC's approach involves performing a functional analysis, followed by development of operational criteria and comparison studies, and using the results of that effort as a basis for consideration of any potential rulemaking. The NRC estimates that the reports of the above effort would be available after November 1991. Accordingly, any potential rulemaking action would not be initiated until after November 1991 and issuance of any final rule could well be 2 or 3 years away from that date. The absence of quantitative accident dose criteria in 10 CFR Part 60 creates programmatic uncertainties associated with the design of the geologic repository operations area and the procurement of long lead-time items based on that design. This concern prompted DOE to take the initiative to submit the subject petition for rulemaking to establish accident dose criteria. DOE strongly urges NRC to undertake an accelerated schedule with regard to resolution of this issue.

Specific Comments

NRC states that "In applying the approach of the petitioner, it would be possible to have no structures, systems, and components important to safety if the nearest boundary of the preclosure control area were sufficiently distant. This could encourage extending the boundary of the preclosure control area in order to justify less effective safety design and quality assurance measures and result in inferior structures, systems, and components in the geologic repository operations area. While (DOE's) approach might be adequate for protection of the general public, it would ignore the safety of the workers."

We disagree with NRC's interpretation of DOE's approach in its petition. DOE is aware of its responsibility of ensuring public and worker safety. The guidance provided in section 4.1(b) of NUREG-1318,* "Criteria for Non-Q-list Items" states that DOE should implement a program addressing "items and activities, such as those associated with meeting the design criteria contained in 10 CFR 60.131(a) for protection of worker health and safety". DOE intends to meet the guidance provided in NUREG-1318 in its quality assurance program, which is subject to review by NRC. In addition, protection of worker safety and health would also be assured by the Department's compliance with 10 CFR Part 20.

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

DOE notes that the provisions currently contained in 10 CFR Part 60 could lead to the type of scenario that is depicted in the above NRC comment. For example, nothing in the current definition of "important to safety" contained in 10 CFR Part 60, precludes one from choosing a sufficiently distant boundary for the "restricted area" so as to result in the same scenario postulated in the NRC comment.

DOE's purpose for proposing a preclosure control area boundary, at which accident dose criteria would be applied, is to rectify an inconsistency that exists in 10 CFR Part 60 compared to other NRC regulations governing nuclear facilities (e.g., 10 CFR Part 72). Other nuclear facilities, such as reactors and independent spent fuel storage installations, typically use two separate area boundaries: 1) an area over which control can be exercised in case of an accident, and 2) a different but much smaller area for access control and routine radiation monitoring for normal operations. Examples are: "Controlled Area", defined in 10 CFR Part 72 for application of accident dose criteria; and "Restricted Area", defined in 10 CFR Part 20 for application of dose criteria during normal operations. 10 CFR Part 60 is inconsistent with such long established practice by requiring that both the accident dose criteria and the routine access controls be applied at the "restricted area" boundary. At the same time, the definition of "restricted area" in 10 CFR Part 60 remains identical to that of 10 CFR Part 20. As illustrated in the diagram accompanying its petition, DOE seeks to rectify such inconsistency by proposing an area boundary called "preclosure control area" where accident dose criterion will be applied. The term "preclosure control area" (which could be larger than the restricted area, but smaller than the controlled area) would be similar to the term "controlled area" as defined in 10 CFR Part 72. The definition of the term "restricted area" remains unchanged and will be used for normal operations considerations, as intended in 10 CFR Part 20.

The approach suggested by NRC, in its July 13, 1990 Federal Register Notice, to determine structures, systems and components important to safety, departs from the objective dose based criterion that NRC adopted, in response to public comments, when 10 CFR Part 60 was promulgated. In addition, a similar dose based criterion approach is used for safety related electrical equipment in 10 CFR Part 50.49. Instead, the suggested approach appears to use as a basis, some arbitrary, highly subjective functional criteria that are yet to be developed. DOE is concerned that NRC intends to abandon the approach to safety classification that it adopted in 10 CFR Part 60 and NUREG-1318, and is not aware of any developments that would justify such action since Part 60 was promulgated. If the NRC intends to pursue a functional analysis approach, it raises a question concerning the status of guidance provided in NUREG-1318, which defines items important to safety on a dose based criterion.

Editorial Comments

1. Page 28772 "Important to Safety"	(a) Line 1: Change "references" to "reference" (b) Line 6: Change "and" to "an"
2. Page 28772 "Preclosure Control Area"	Line 4: Change "Licenses" to "licensee"
3. Page 28772 "Supporting Information"	Paragraph 4, line 5: Change words "In claims" to "The petitioner claims"
4. Page 28772 "Supporting Information"	Paragraph 6, line 12: Add "a" between the words "to" and "size"

DOCKET NUMBER
PROPOSED RULE PRM 60-3
(55 FR 28771)

(3)

Intertech Consultants

PLANNING - ECONOMICS - PROGRAM MANAGEMENT

DOCKETED
USNRC

'90 OCT 15 A10:42

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

October 9, 1990

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attention: Docketing and Service Branch

RE: Comments To Petition For Rulemaking - Docket No. PRM-60-3

Dear Sir:

On behalf of Lincoln County, Nevada and the City of Caliente, Nevada, the following comments to a Petition for Rulemaking submitted by the U.S. Department of Energy (Docket No. PRM-60-3) are provided for your consideration. By its petition, DOE seeks to have 10 CFR Part 60 amended to include a specific dose criteria for design basis accidents. DOE asserts that inclusion of such criteria are essential if existing uncertainties regarding the determination of repository adequacy in protecting public health and safety are to be reduced or eliminated.

The County and City would concur in the need to reduce programmatic uncertainty, particularly where it concerns public health and safety. DOE's justification for the proposed rulemaking is largely grounded in a desire to reduce procedural uncertainty. It is suggested here that beyond uncertainty associated with process, the lack of specific dose criterion may imply significant perceived uncertainty about the degree of public health and safety protection afforded by repository structures, systems, and components. The public may therefor be unable to effectively judge the adequacy of such facility attributes. Perceived facility risks may consequently be heightened and public acceptability of the facility further diminished.

Despite the apparent need to establish specific dose criterion, the immediacy of the need has not been established by DOE. Given that NRC has undertaken a series of studies which may serve to further inform the basis for dose criterion, it would appear prudent to delay initiation of the rulemaking proceedings until such information is available.

Lincoln County and the City of Caliente would suggest that further consideration be given by DOE and NRC to both the definition of preclosure control area and the exposure pathways under which the effective dose is assumed to be administered. Concerning the former, protection of facility workers should be of equal importance to protection of off-site publics. With regard to exposure pathways, the exclusion of ingestion is not sufficiently justified in the petition. Because of the inability of the licensure proceedings to gaurantee that emergency management procedures will be effectively designed and/or implemented, the existence of grower-consumed agricultural products being grown within Lincoln County areas immediately downwind of the repository site should be explicitly

25 Clark Road • Fiskdale Massachusetts 01518 • (508) 347-5040 • FAX (508) 347-5445

considered.

DOE's finding that the estimated risk of a committed dose equivalent of 50 rem falls within the range of acceptable risk level as defined by the NCRP and ICRP, should be qualified as being near the upper-bound of acceptability. Further, although exposures from accidents may be highly unlikely, such low-probability/high-consequence accidents are precisely those for which the public has been shown to be most concerned.

Sincerely,

Mike L. Baughman
Principal

cc: Judy Foremaster, City of Caliente
Geri Ann Stanton, Lincoln County

701 Pennsylvania Avenue, N.W.
Washington D.C. 20004-2696
Telephone 202-508-5750

(2)

EDISON ELECTRIC INSTITUTE

Lorne E. Mills
Vice President, Nuclear Activities

October 11, 1990

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Docketing and Service Branch

Re: Department of Energy; Receipt of Petition for Rulemaking; Docket No. PRM-60-3; 55 Fed. Reg. 28771 (July 13, 1990).

Dear Sir:

This letter is the Edison Electric Institute's and the Utility Nuclear Waste and Transportation Program's (EEI/UWASTE) response to the petition for rulemaking filed by the U.S. Department of Energy (DOE) with the U.S. Nuclear Regulatory Commission (Commission) seeking amendments to 10 C.F.R. Part 60, the regulatory provisions governing the design and licensing of a geologic repository for the disposal of high-level radioactive wastes under the Nuclear Waste Policy Act of 1982 (NWPA), as amended. The DOE's petition requests that the Commission amend 10 C.F.R. Part 60 to incorporate therein specific quantitative accident dose criteria for repository pre-closure activities and to make certain other conforming changes. As requested by the Commission in the Federal Register notice, we also address the Commission's contemplated rulemaking action to establish additional preclosure regulatory requirements for the repository.

Edison Electric Institute is the association of the Nation's investor-owned electric utilities. Its members generate approximately 75% of all the electricity in the nation. EEI/UWASTE is a group of 50 electric utilities with nuclear energy programs that takes actions necessary to ensure that safe, environmentally sound, publicly acceptable, and cost-effective radioactive waste management and disposal and nuclear material transportation systems are maintained and developed in a timely manner.

Based on a thorough review of DOE's rulemaking petition, as well as industry experience with the Commission's regulatory regime, EEI/UWASTE supports DOE's request that the Commission adopt criteria, to be incorporated in 10 C.F.R. Part 60, that would specify the maximum dose that an individual "off-site" of the repository could receive in the event of an accident before permanent closure. The Commission's decision not to promulgate specific quantitative accident dose criteria when it adopted Part 60 has injected a significant element of regulatory uncertainty into its repository licensing standards. This uncertainty, if unresolved, could result in significant delays in the NRC Staff's evaluation of the DOE's license application and in the licensing process due to the need both to determine the appropriate accident dose criteria and to determine whether the repository design satisfies those criteria. ..

Moreover, absent clearly defined accident dose criteria, the DOE will essentially be developing a repository system without knowing one of the criteria that must be satisfied to obtain a license, a situation that could require a major redirection of design efforts at a very late stage in the design process. As explained in DOE's petition, the Commission has considerable information and knowledge concerning the types of operations that will occur at the repository based on the experience gained from decades of similar operations at other licensed facilities. NRC, therefore, has a solid basis for establishing acceptable accident dose criteria at this time. Accordingly, given the significant benefits that could be gained from an early definition of acceptable accident dose criteria (both to DOE's efforts and the Commission's regulatory review), and the potential costs to the repository program if quantitative accident dose criteria are not adopted well in advance of DOE's submittal of a license application, EEI/UWASTE strongly urges the Commission to act favorably on DOE's petition.

The specific accident dose criteria proposed by DOE in its petition -- 5 rem effective dose equivalent, applied at a preclosure control area boundary (with a limit of 50 rem on the committed dose equivalent to any organ) -- represent reasonable, conservative and appropriate accident dose criteria that will assure adequate protection of public health and safety. As DOE points out in its petition, these proposed accident dose criteria are consistent with the dose criteria established by the Commission for accidents at other licensed facilities, including those applicable to nuclear power reactors (10 CFR Part 100), independent spent fuel storage installations and monitored retrievable storage facilities (10 CFR Part 72). Moreover, as DOE also explains in its petition, these values are well within the acceptable risk level recommended by the most recent reports addressing acceptable radiological risk to members of the public.

DOE's use of effective dose equivalent to measure the radiation dose experienced by a member of the public is consistent with the dose measurement approach adopted by the International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements. It is also the approach recently adopted by the Commission in its proposal to amend 10 CFR Part 20. The definitions adopted in conjunction with any amendments to Part 60 in response to the DOE's petition should be consistent with any definitions adopted for purposes of Part 20 or other provision of the Commission's regulations.

EEI/UWASTE also supports the additional changes to Part 60 proposed by DOE as consistent with its proposed accident dose criteria. The definition of a separate preclosure control area boundary, at which the accident dose criteria would be applied and is larger than the boundaries of the area required to be controlled during normal operations, makes practical sense and is consistent with Commission regulations governing other licensed facilities. [See 10 C.F.R. §100.11 and §72.106(a).] Similarly, EEI/UWASTE agrees with DOE concerning the appropriate relationship between the accident dose criteria and the "important to safety" threshold for the application of engineered safety features to mitigate accident consequences. Specifically, the current definition of "important to safety" for purposes of Part 60 should be modified to make clear that mitigation of the radiological consequences of accidents through engineered safety features would not be required unless the projected consequences of the accident would exceed the accident dose criteria. This modification is necessary to make the general design criteria for the repository consistent with the quantitative accident dose criteria adopted by the Commission. Moreover, because the accident dose criteria represent the acceptable level of risk to the public resulting from a repository accident, modification of the "important to safety" definition as proposed by DOE will ensure adequate protection of public health and safety.

The Federal Register notice expresses a concern that under DOE's proposal, the preclosure control area boundary could be located so as to compromise the safety of the general public or repository workers. The alleged compromise would occur, because NRC fears that all structures, systems or components would be sufficiently distant from the boundary that they will not be classified as "important to safety." EEI/UWASTE does not share this concern. The accident dose criteria would be only one component of a detailed regulatory regime that would also include, for example, regulations governing acceptable occupational doses. DOE's proposal to define a separate preclosure control area boundary is based on practical considerations and

experience with other licensed facilities, not an attempt to circumvent the Commission's regulatory requirements. Other regulations, such as 10 CFR Part 20, would continue to apply.

To the extent that the Commission's concern over DOE's proposed redefinition of systems, structures and components important to safety for purposes of part 60 stems from the inconsistency of that proposed definition with the definitional section of Part 72, EEI/UWASTE believes that such concern is unfounded. Part 60 and Part 72 contain the licensing requirements for different types of facilities designed for different purposes. It is therefore appropriate for the regulations adopted in each of those subparts to reflect the unique operational considerations and risks posed by the particular facility to be licensed thereunder. Adoption of DOE's proposed modification of the Part 60 definition therefore would not create the definitional inconsistency with Part 72, but rather would revise the definitional section of Part 60 to reflect appropriately the adoption of quantified accident dose criteria and the risks posed by a high-level radioactive waste repository. If there is any inconsistency, perhaps the better approach would be to make Part 72 consistent with Part 60, rather than vice-versa.

At the conclusion of the notice, the Commission notes that it is contemplating a rulemaking that would change the fundamental approach adopted in Part 60. From the limited information available concerning the Commission's plans, it appears that this rulemaking initiative would be far broader in scope than DOE's proposal to modify Part 60 through the adoption of quantified accident dose criteria. However, the Commission will not be in a position to make a decision on whether to proceed with this rulemaking until November 1991, at the earliest, when the technical studies addressing this new regulatory approach are scheduled for completion. Given these scheduling considerations, and the significant uncertainty as to whether the Commission's contemplated rulemaking action will in fact be initiated, EEI/UWASTE believes that the Commission should proceed to address the merits of DOE's petition in a timely manner, rather than delay action thereon pending a decision on a broader restructuring of Part 60. As noted above, favorable Commission action on DOE's petition would facilitate DOE's repository development efforts by adding a necessary measure of certainty to the licensing regime. Moreover, the adoption of specific accident dose criteria at this time would not foreclose further modifications to Part 60 at a later date.

Accordingly, for the foregoing reasons, EEI/UWASTE supports the DOE's proposal that the Commission revise Part 60 through the adoption of quantified accident dose criteria and make certain conforming changes to the definitional portion of Part 60. EEI/UWASTE requests that the Commission consider DOE's proposal on its merits at the close of the comment period, and not defer action on DOE's petition pending a decision on the Commission's contemplated rulemaking initiative to restructure Part 60.

Sincerely,

Loring E. Mills

Loring E. Mills

LEM/cht

October 1, 1990

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attention: Docketing and Service Branch

The following are comments on Docket No. PRM-60-3, Petition of the U.S. Department of Energy for a Rulemaking to Establish Accident Dose Criteria for a Geologic Repository for High-Level Radioactive Waste (10 CFR 60), as requested in the Federal Register, Volume 55, No. 135:

1. The proposed revision to the definition of "important to safety" uses the term "engineered safety feature", which needs to be defined. Engineered safety features do not appear to be any different than items important to safety; if there is no difference, the terms are redundant and the term "engineered safety feature" is unnecessary.

2. The proposed additional requirements for accident analyses (new section 10 CFR 60.111b) include an accidental dose limit that is different than the limit for identifying items important to safety. Items important to safety should include all structures, systems, and components that are needed to reduce accidental doses below the accident dose limit; therefore, these numerical limits should be the same. If the dose value used to identify items important to safety is less than the dose value used to limit accident analyses (as currently proposed), then the regulations will be unclear about how to apply design and quality assurance requirements to items whose failure could result in accidental doses than are between the two values (i.e., between 0.5 rem and 5 rem).

Concerned U.S. Citizen

ENCLOSURE 5

PARTIAL GRANT/PARTIAL DENIAL OF PETITION
FOR RULEMAKING

NUCLEAR REGULATORY COMMISSION

10 CFR PART 60

[Docket No. PRM-60-3]

DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES

AGENCY: U.S. Nuclear Regulatory Commission

ACTION: Partial Grant/Partial Denial of Petition for Rulemaking

SUMMARY: In a petition for rulemaking (PRM-60-3) submitted by the U.S. Department of Energy (DOE), the U.S. Nuclear Regulatory Commission was requested to establish specific dose criteria for design basis accidents at a high-level radioactive waste repository. NRC hereby grants in part, and denies in part, the specific proposals of the petitioner.

ADDRESSES: Copies of the petition for rulemaking, the public comments received, and NRC's letter to the petitioner are available for public inspection or copying, for a fee, in the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Dr. Richard Weller, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-7287.

SUPPLEMENTARY INFORMATION:

DOE submitted a petition for rulemaking on April 19, 1990. On July 13, 1990, (55 FR 28771) NRC published a notice of receipt of the petition for rulemaking. The comment period expired on October 11, 1990. The petition requested that the Commission amend 10 CFR Part 60 to prescribe certain numerical accident-dose criteria to be applied at the boundary of a "preclosure control area."

Under DOE's proposal, the definition of "important to safety," in 10 CFR 60.2, would be changed to apply a reference dose limit at the preclosure-control-area boundary, instead of the present unrestricted-area boundary; further, the definition would be amended to add a statement "All engineered safety features shall be included within the meaning of the term 'important to safety.'" The petition also proposed that performance objectives of 10 CFR 60.111 would be revised to incorporate an explicit accident dose limit, at the preclosure control area boundary, of 0.05-Sv (5-rem) effective dose equivalent, or 0.5-Sv (50-rem) committed dose equivalent. DOE indicated its intention that this limit would apply to direct irradiation and inhalation pathways, alone, and not to ingestion of contaminated foodstuffs. The phrase "at all times" would be deleted from 10 CFR 60.111(a), to clarify that the performance objective for the period of operations does not apply to exposure from accidents. Finally, the petition proposed adding new definitions, to 10 CFR 60.2, for the terms "preclosure control area," "committed dose equivalent," "committed effective dose equivalent," and "effective dose equivalent," to support the application of the accident dose criteria described above.

For a fuller statement of the petition for rulemaking, see the Federal Register notice cited above.

In response to NRC's publication of notice of receipt of the petition, comments were received from: DOE; Edison Electric Institute and the Utility Nuclear Waste and Transportation Program (EEI/UWASTE); Intertech Consultants, on behalf of Lincoln County, Nevada, and the City of Caliente, Nevada; and an anonymous "Concerned U.S. Citizen." The Commission, having now considered the petition and comments, grants the petition in part and denies the petition in part, and to that end, the Commission is publishing, concurrently with this notice, a notice of proposed rulemaking.

Under the proposed rule, accident-dose criteria would be applied at the boundary of a newly defined "preclosure controlled area," as recommended by DOE. Further, in response to the petition, the term "important to safety" would be redefined, though not in the form suggested by DOE. The Commission is also proposing to adopt the petitioner's request that the phrase "at all times" be deleted from the performance objective that applies to preclosure operations. In all other respects, the petition is denied.

The reasons for the action, insofar as it both grants and denies parts of the petition, are set out at length in the statement of considerations accompanying the proposed rule.

Dated in Rockville, Maryland, this _____ day of _____, 1994.

For the Nuclear Regulatory Commission.

_____

Samuel J. Chilk,
Secretary of the Commission.

ENCLOSURE 6

DRAFT LETTER TO PETITIONER

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

Daniel A. Dreyfus, Director
Office of Civilian Radioactive
Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Dear Mr. Dreyfus:

Enclosed are advance copies of Federal Register notices for: 1) a partial grant of a petition for rulemaking (PRM), PRM-60-3, submitted on April 19, 1990, by the Department of Energy (DOE), that requested the Nuclear Regulatory Commission to establish accident dose criteria for a geologic repository for high-level radioactive waste (Enclosure 1); and 2) proposed amendments to 10 CFR Part 60, "Disposal of High-Level Radioactive Waste in Geologic Repositories," regarding "Design Basis Events for the Geologic Repository Operations Area," for public comment (Enclosure 2). These Federal Register notices will be published within a few days.

As stated in the Federal Register notices, the Commission believes that the DOE petition has merit in particular respects and, as such, has incorporated certain elements of DOE's petition into the proposed amendments to 10 CFR Part 60. The Commission does not agree with the other elements of DOE's petition. Thus, for reasons as described in the Federal Register notices, the Commission has granted in part, and denied in part, the DOE petition for rulemaking.

Sincerely,

Samuel J. Chilk
Secretary of the Commission

Enclosures:
(1) FRN on Partial Grant/Partial Denial of DOE Rulemaking Petition
(2) Proposed Amendments to 10 CFR Part 60

cc: See attached list

Letter to Daniel A. Dreyfus
Subject: 10 CFR 2.801 and 10 CFR Part 60

cc List Dated _____

cc: R. Loux, State of Nevada
T. J. Hickey, Nevada Legislative Committee
C. Gertz, DOE/NV
M. Murphy, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO
P. Niedzielski-Eichner, Nye County, NV
B. Mettam, Inyo County, CA
V. Poe, Mineral County, NV
F. Sperry, White Pine County, NV
R. Williams, Lander County, NV
P. Goicoechea, Eureka County, NV
L. Vaughn II, Esmerald County, NV
C. Shank, Churchill County, NV

ENCLOSURE 7

REGULATORY ANALYSIS

REGULATORY ANALYSIS

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

AUGUST 1994

1. STATEMENT OF PROBLEM

The Commission, with the assistance of its Federally-funded research and development center (the Center for Nuclear Waste Regulatory Analyses [CNWRA]), 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. Receipt of the petition was noticed in the Federal Register on July 13, 1990 (55 FR 28771).

DOE's rulemaking petition would:

1) Modify the definition of "important to safety," to refer to the "preclosure control area," rather than the "unrestricted area," but still retain a greater than 5-mSv (0.5-rem) whole body and organ accident reference dose, to identify structures, systems, and components important to safety. The recommended definition would also state that "All engineering safety

features shall be included within the meaning of the term 'important to safety.'"

2) Establish a "preclosure control area" boundary accident dose criterion of 0.05-Sv (5-rem) effective dose equivalent, with a limit of 0.5-Sv (50-rem) committed dose equivalent to any organ.

3) Eliminate the phrase "at all times," in the 10 CFR 60.111(a) reference to 10 CFR Part 20, to clarify that Part 20 does not apply to accident conditions.

4) Add new definitions to 10 CFR Part 60.2, for the terms "preclosure control area," "committed dose equivalent," "committed effective dose equivalent," and "effective dose equivalent," to support the application of the foregoing proposed changes.

2. OBJECTIVE

The objective of the proposed rulemaking is to eliminate the regulatory uncertainties identified by the Commission and DOE and, thereby, provide for the protection of public, including worker, health and safety.

The proposed Part 60 rulemaking, "Design Basis Events for the Geologic Repository Operations Area," would clarify 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 would be 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 would be 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" would be 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" would be subject to specified design and quality assurance requirements to protect public health and safety.

New definitions are proposed for the terms, "preclosure controlled area," "design bases," and "design basis events." The existing term, "controlled area," would be renamed to "postclosure controlled area." The term "controlled area" would also be 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, 3) adopting the DOE petition, and 4) rulemaking that combines elements of the DOE petition with the Commission'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. DOE's Rulemaking Petition

The DOE rulemaking petition has merit, in particular respects, and the Commission agrees with a number of elements that DOE has proposed. 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 the Commission does not agree. Thus, the DOE petition would resolve some regulatory uncertainties, but not others. Although this would result in less potential for cost and schedule impacts than the "no action" or "regulatory guidance" alternatives, the Commission does not recommend adopting the DOE petition in toto as the preferred alternative.

3.4 Rulemaking - Combined Elements of DOE Petition and Commission Initiative

The Commission 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, as previously discussed, there are elements of the DOE petition that the Commission proposes to adopt. There are other elements of the petition that would not resolve all of the Commission's concerns with the existing rule. For these elements, the Commission proposes to adopt the approach to uncertainty resolution from its own initiative. The proposed rulemaking, which combines the preferred elements of the DOE petition with the complementary portions of the Commission'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 proposed 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 proposed rulemaking provides design bases criteria that effectively resolve the Commission'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

proposed 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 quality assurance 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 proposed rule change is not, however, unexpected, and implementation should be facilitated by present DOE plans and procedures for developing the repository. Moreover, the Commission 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 proposed rule. The proposed rulemaking would, however, provide clear direction to DOE and reduce the potential for future extensive NRC staff involvement to resolve design deficiencies affecting licensing. The proposed rulemaking would also make the HLW repository licensing process more efficient, through elimination of regulatory uncertainties that could be the

basis for legal contentions. NRC resources would, 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 proposed regulation will provide greater consistency among NRC regulations, thus removing a potential source of uncertainty. NRC regulatory guidance documents, specifically NUREG-1318,[1] 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.

5. DECISION RATIONALE

The staff 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, with public input, have the authority of law to establish criteria for protection of public health and safety.

The rulemaking would be the final action on this subject.

[1]U.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.

6. IMPLEMENTATION

Implementation of the proposed rulemaking will require NRC to revise its regulations, regulatory guidance, and procedures (particularly quality assurance audit procedures). These are not considered difficult tasks and would 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 would have major effects on priorities for related activities. Rather, it is expected that the requirements of the proposed regulation would 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 quality assurance program review.

ENCLOSURE 8

ACNW CORRESPONDENCE

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON NUCLEAR WASTE
WASHINGTON, D.C. 20555

July 13, 1994

The Honorable Ivan Selin
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Selin:

SUBJECT: DRAFT NOTICE OF PROPOSED RULEMAKING ON DESIGN BASIS EVENTS FOR THE GEOLOGIC REPOSITORY OPERATIONS AREA

In accord with the staff requirements memorandum (SRM) of February 3, 1994, the ACNW reviewed the subject document and heard presentations by the NRC staff on this topic at its 65th meeting on June 29-30, 1994. The Committee concludes that the draft notice of proposed rulemaking for revisions to 10 CFR Part 60 is satisfactory, and the Committee is in general agreement with the text, the numerical standards, and the definitions. However, the Committee has the following concerns with specific statements and with the compatibility of the definitions with current risk and safety assessment methods. The Committee has discussed these concerns with appropriate staff managers during its 65th meeting:

1. The Committee believes that reference to "maximum potential impacts" in the design basis event definition is not appropriate. The use of "maximum potential impacts" implies upper allowable or existing limits that do not exist and introduces conceptual difficulties akin to those encountered in the past regarding maximum credible accidents in the reactor field. The Committee suggests the staff use a phrase such as "serious impacts" to describe the consequences of events for which design is to be a mitigating factor.

2. The Committee strongly recommends that the Office of Nuclear Regulatory Research carefully review the statements in the rulemaking, and particularly the definitions. We especially believe that a review of the definitions by the PRA staff would provide additional assurance that the rule is compatible with the increasing use of risk-based arguments employed to make more useful the qualifiers such as "unlikely," "moderately," "frequently," and "credible."

3. The Committee notes that while facility design is used to limit the dose to the public from a design basis event, no such provision is invoked for worker protection for a Category 2 design basis event. It appears that the NRC staff intends

to use administrative provisions to mitigate the consequences to workers of design basis events. The Committee is concerned that this appears to allow open-ended risk for workers that nevertheless could, in part, be mitigated by additional facility design considerations. The Committee recommends that NRC staff examine regulatory procedures that could increase worker protection.

Sincerely,

Martin J. Steindler
Chairman

Reference:
Memorandum dated February 3, 1994, to James M. Taylor, EDO, from Samuel J. Chilk, SECY, Subject: SECY-92-408 - Proposed Amendments, to 10 CFR Part 60, on Disposal of High-Level Radioactive Wastes in Geologic Repositories - Design Basis Events for the Geologic Repository Operations Area

ENCLOSURE 9

PUBLIC ANNOUNCEMENT

NRC PROPOSES AMENDMENTS TO REGULATIONS GOVERNING
HIGH-LEVEL RADIOACTIVE WASTE REPOSITORY

The Nuclear Regulatory Commission is proposing to amend its regulations governing the construction, operation and closure of a deep-underground, geologic repository for the disposal of high-level radioactive wastes which predominantly consist of used nuclear fuel.

At the same time, the Commission is granting in part, and denying in part, a petition for rulemaking submitted by the Department of Energy which requested the Commission to address many of the same issues being addressed in this proposed rulemaking.

The purpose of the proposed amendments is to clarify existing requirements that govern the protection of workers and the public from radiation for a broad range of normal and accident conditions before permanent closure of the repository. The proposed amendments would also provide greater consistency with other NRC regulations governing similar types of facilities such as independent spent fuel storage installations.

As proposed, the amendments would, among other things:
-- modify the definition for those structures, systems, and components that are "important to safety;"

-- add requirements for the establishment of a preclosure controlled area from which members of the public could be excluded if necessary;

-- provide radiation dose criteria for protection of the public during accident conditions; and

-- clarify the radiation protection requirements for workers and members of the public during normal or, otherwise, anticipated conditions.

Written public comments on the proposed amendments to Part 60 of the Commission's regulations should be received by (date). They should be addressed to the Secretary of the Commission, Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

ENCLOSURE 10

DRAFT CONGRESSIONAL LETTERS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

The Honorable Richard H. Lehman, Chairman
Subcommittee on Energy and Mineral Resources
Committee on Natural Resources
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed is a copy of a proposed rule, which would amend 10 CFR Part 60, that is to be published in the Federal Register, for public comment, and a notice of partial grant of a U.S. Department of Energy (DOE) petition for rulemaking, on the same subject.

The U.S. Nuclear Regulatory Commission is proposing to amend Part 60, its regulation governing the disposal of high-level radioactive waste in geologic repositories. The proposed rule would clarify the preclosure performance requirements for considering "design basis events," to meet standards for protection against radiation. The proposed rule would redefine the term "important to safety," to retain the quantitative features of the existing definition, but specify different numerical criteria for each of two categories of design basis events. Part 60 would be further amended to include requirements for a "preclosure controlled area" and preclosure controlled area boundary reference doses, similar to regulatory requirements contained in 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste." These proposed amendments are necessary to provide clarity and consistency in the Commission's regulations and, thereby, ensure the adequacy of these requirements to protect public health and safety.

The proposed rule will resolve issues raised by DOE in a rulemaking petition, PRM-60-3. The petition has merit in particular respects and the Commission has incorporated several of the petitioner's suggestions in the proposed rule. Accordingly, the petition is partially granted and the remainder of the petition is being denied.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Proposed Amendment to 10 CFR Part 60
2. Partial Grant of DOE Petition for Rulemaking

cc: The Honorable Barbara Vucanovich

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

The Honorable Joseph I. Lieberman, Chairman
Subcommittee on Clean Air and Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Proposed Amendment to 10 CFR Part 60
2. Partial Grant of DOE Petition for Rulemaking

cc: The Honorable Alan K. Simpson

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

The Honorable Philip Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Proposed Amendment to 10 CFR Part 60
2. Partial Grant of DOE Petition for Rulemaking

cc: The Honorable Michael Bilirakis