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RULEMAKING ISSUE

(Notation Vote)

December 11, 1992

SECY-92-408

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 deny a Department of Energy (DOE) petition for rulemaking on the same subject.

Summary: The proposed rule would clarify Commission requirements on the protection of public health and safety from activities conducted at a geologic repository operations area prior to 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 prescribed design requirements, quality assurance requirements, and the establishment of a "controlled-use 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.

Background: In 1989, the Division of High-Level Waste Management, Office of Nuclear Material Safety and Safeguards was engaged in preparing a limited rulemaking activity to establish the concept of a controlled-use area in Part 60. The staff subsequently, in conjunction with the Center for Nuclear

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

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Waste Regulatory Analyses (CNWRA), engaged in a Systematic Regulatory Analysis (SRA) of the Commission's regulations on geologic repositories, in Part 60. As a part of this SRA effort, regulatory uncertainties (i.e., those regulatory requirements that may be ambiguous or inconsistent with other Commission regulatory policy) were identified. Therefore, before proceeding with the proposed limited rulemaking, the staff chose to use the results of the SRA to help identify the preclosure portions of Part 60 that needed to be changed along with the controlled-use area. In particular, differences between 10 CFR Part 20 and Part 60 and between 10 CFR Part 72 and Part 60 regulatory criteria were noted in relation to normal and accident radiation-exposure protection. The regulatory uncertainty previously identified by the staff was confirmed, in that Part 60 "...is not sufficiently specific to determine design basis dose criteria for normal and accident conditions, and needs further clarification or interpretation."¹

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

- 1) Establish a requirement for a "preclosure control area," similar to that in Part 72, in which public access can be controlled.
- 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) Modify the definition of "important to safety," to refer to the preclosure control area, rather than to the "restricted area," but still retaining a greater than 5 mSv (0.5 rem) whole body and organ accident reference dose, to identify structures, systems, and components important to safety.
- 4) Eliminate the phrase, "at all times," contained in the reference to Part 20 in 10 CFR 60.111(a), to clarify that Part 20 does not apply to accident conditions.

¹ CNWRA, "Identification and Evaluation of Regulatory and Institutional Uncertainties in 10 CFR Part 60," CNWRA 90-003, San Antonio, TX, February 1990.

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 establish additional preclosure regulatory requirements for high-level waste (HLW) geologic repositories.

The NRC initiative would: (1) perform a functional analysis of a HLW repository, using a systematic approach; (2) identify functions necessary to protect public and worker safety; (3) develop repository operational criteria; (4) compare these criteria with Part 60 to identify potential uncertainties; and (5) use the results of these studies and comparisons as a basis for consideration of potential rulemaking.²

The Federal Register notice also noted that the DOE approach differed markedly from that contemplated by the Nuclear Regulatory Commission. The DOE proposed rule would continue to identify structures, systems, and components important to safety, relative to a reference boundary dose. However, under DOE's approach (as well as under the existing rule) it would be possible to have no structures, systems, or 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 could result in inferior structures, systems, and components in the geologic repository operations area. Although this approach might be adequate for protection of the public, it could ignore the safety of workers. NRC envisioned that 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. Accordingly, design and quality assurance requirements for structures, systems, and components important to safety should be retained to ensure the continued protection of repository workers.

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.

² U.S. Nuclear Regulatory Commission, "Repository Operational Criteria Analysis," NUREG/CR-5804, August 1992.

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 features" and on the use of separate dose limits for the preclosure control area and the definition of "important to safety." The comments are further discussed in the petition denial (Enclosure 6).

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. To date, there has been no formal disposition of the DOE petition. The staff intent is to deny the petition when this proposed rule is published for public comment.

Discussion:

The intent of this proposed rule is to clarify requirements in Part 60 that are related to worker and public protection and eliminate inconsistencies with other NRC rules that regulate similar types of facilities.

The definition of "important to safety" is changed to a functional definition, similar to the definition in Part 72, rather than the present dose-related definition. Structures, systems, and components will now be "important to safety" and subject to quality assurance and special design requirements, if they have or affect the function of: (1) maintaining the conditions to store HLW safely; (2) preventing or mitigating damage to HLW or HLW containers; or (3) providing reasonable assurance that HLW can be received, handled, packaged, stored, and retrieved without undue risk to the health and safety of the public.

In this definition, the identification of structures, systems, and components important to safety would not be linked to restricted-area size or controlled-area boundary location.

The proposed definition of "design bases" is identical to that in Part 72.

A definition of "Design Basis Events" has also been added. "Design Basis Events" are defined as being of two categories: 1) those events that are reasonably likely to occur before permanent closure, and 2) other natural and human-induced events that are considered unlikely, but sufficiently credible to warrant consideration, that are postulated because their consequences may result in maximum potential impacts on the environs of the geologic repository operations area. The first category of events, those events that are anticipated to occur during the operating life of the facility (i.e., before permanent closure) must meet the requirements of 10 CFR 60.111(a), which reference Part 20 and applicable Environmental Protection Agency regulations. For the second, unlikely but credible, category of events, the siting, design, and operations must satisfy the new controlled-use-area boundary reference-dose requirement of 10 CFR 60.136. This represents a clearer expression of the staff's views on the application of Part 20 to "accidents" than has been made in the past, and its adoption should significantly clarify the Commission's regulatory requirements.

Certain terms pertaining to the functions of structures, systems, and components important to safety that may be subject to differing interpretations -- specifically, the terms "normal conditions," "anticipated operational occurrences," and "accidents," are proposed to be eliminated. The new language replaces these terms with the phrase "design basis events."

The supplementary information to the proposed rule also discusses classes of design events, consistent with Part 72 regulatory guidance, that need to be considered in system and installation design. These are: 1) Design Event I - that set of events that are expected to occur regularly or frequently in the course of normal operations; 2) Design Event II - that set of events that can be expected to occur with moderate frequency, or on the order of once during a calendar year; 3) Design Event III - that set of infrequent events that could reasonably be expected to occur during the lifetime of the facility; and 4) Design Event IV - the

credible, but unlikely, events that are postulated because their consequences may result in the maximum potential impact on the immediate environs of the geologic repository operations area. Design event Classes I through III are included in the first category of design basis events, noted above, and Class IV would correspond to the second category.

A preclosure requirement is added, in 10 CFR 60.136, that a controlled-use area, similar to the controlled area of Part 72, be established, within which public access can be controlled. The geologic repository operations area must be designed so that, for any design basis event, no individual located on or beyond the boundary of the controlled-use area will receive the more limiting of a total effective dose equivalent (TEDE) of 0.05 Sv (5 rem), or the sum of the deep-dose equivalent, and the committed dose equivalent, of 0.5 Sv (50 rem), 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). This controlled-use-area-boundary reference dose is similar to the Part 72 controlled-area 5 rem total, or boundary organ reference dose, but modified to be consistent with the May 1992, revised Part 20 standards for protection against radiation. This controlled-use area requirement is included as a design criterion in a manner consistent with the regulatory approach in the proposed revisions to 10 CFR Part 50 and 10 CFR Part 100 (SECY-92-215, June 12, 1992).

The 0.05 Sv (5 rem) reference dose addresses the calculated risk (the expectation value) of a fatal cancer. A consideration of both the annual frequency of occurrence of any Design Event IV (on the order of 1×10^{-3} per year or less) and the maximum expected reference dose on or beyond the boundary of the controlled-use area of 0.05 Sv (5 rem) TEDE, in conjunction with the risk of a fatal cancer per rem, results in a calculated risk for a fatal cancer that is a small fraction of that permitted by the Commission's regulations for routine operations at a nuclear facility (see Enclosure 5). The total annual risk experienced by members of the public, including the risk due to accidental releases, would be a small increment to the risk associated with the Commission's Part 20 routine release limit of 1 mSv (0.1 rem) per year.

The supplementary information to the proposed rule clarifies that the phrase "at all times," in reference to Part 20 in §60.111(a), is intended to mean that Part 20 also applies during waste retrieval, if such retrieval is required. It

does not imply that Part 20 is applicable to those unlikely events that are defined above as Category 2 design basis events.

DOE Petition
Denial:

As noted above, DOE submitted a petition for rulemaking that would establish specific dose criteria for design basis accidents. The NRC-proposed rule addresses the issues raised by DOE, in a manner different from the one proposed by DOE in its petition. NRC's approach is consistent with other Commission regulations for similar facilities, for example, 10 CFR Part 72, for independent storage of spent nuclear fuel and high-level radioactive waste. The NRC proposed rule would provide a preclusion controlled-use area and a preclusion controlled-use-area-boundary reference dose consistent with the revised Part 20 standards. The supplementary information to the proposed rule clarifies that the term "at all times," the intent of which was unclear to DOE, refers to the waste retrieval period, if retrieval becomes necessary. It is made clear that the term does not apply to Category 2 design basis events. Also, the NRC proposed rule differs markedly from the DOE petition in the definition of "important to safety." The staff considers the definition proposed in this rulemaking necessary to ensure an adequate level of worker and public radiological protection.

Based on the above discussions, the DOE petition for rulemaking would be denied subject to the Commission's approval of the proposed rule. The Federal Register notice of denial is included as Enclosure 6.

A draft letter of denial to the petitioner is included as Enclosure 7.

Alternatives:

The "Regulatory Analysis," Enclosure 8, considered three alternatives to the proposed rule. These alternatives included: (1) taking no action; (2) developing regulatory guidance, and (3) adopting the DOE petition. Rulemaking, however, best serves to achieve consistency among NRC regulations and resolve the regulatory uncertainties that have been identified by NRC and DOE. Rulemaking provides DOE with clear regulatory requirements for system design and evaluation.

DOE has indicated, in its response to the Federal Register notice of receipt of its petition, the intent to 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." Furthermore, the proposed changes to Part 60 conform to NRC regulations for similar HLW handling facilities (i.e., Part 72) which are being applied in the design of the associated Monitored Retrievable Storage facility. Although some impact to DOE's program may occur as a result of the proposed rulemaking, the impacts would be compensated by the benefits of resolving identified uncertainties and having consistency among NRC regulations.

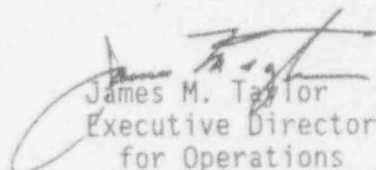
Coordination:

The Advisory Committee on Nuclear Waste has been briefed on the proposed rule, and its suggestions (Enclosure 9) have been incorporated into the proposed rulemaking. The Office of Public Affairs and the Office of Congressional Affairs have been consulted regarding the public announcement (Enclosure 10) and the Congressional letters (Enclosure 11). Draft copies of the proposed rule and petition denial 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 the Notice of Proposed Rulemaking (Enclosure 1) publication 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 Denial of DOE's petition. (Enclosure 6).
- (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 Nuclear Regulation of the Senate Committee on Environment and Public Works, the Subcommittee on Energy and the Environment of the House Committee on Interior and Insular Affairs, 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 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 a Petition
for Rulemaking from DOE
(55 FR 28771)
4. Comments on FRN
5. Risk Comparison
6. FRN of Petition Denial
7. Draft Ltr. to Petitioner
8. Regulatory Analysis
9. ACNW Correspondence
10. Public Announcement
11. Draft Congressional Ltrs.

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Monday, December 28, 1992.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Friday, December 18, 1992, 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.

DISTRIBUTION:

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ENCLOSURE 1

FEDERAL REGISTER NOTICE OF
PROPOSED RULEMAKING

NUCLEAR REGULATORY COMMISSION

10 CFR Part 60

RTN 3150-AD51

Design Basis Events for the Geologic Repository Operations Area

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The proposed rule would clarify the Commission's policy on the protection of public health and safety from activities conducted at a geologic repository operations area 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 controlled-use area from which members of the public can be excluded. The proposed rule is necessary to provide clear regulatory requirements to ensure radiological protection for the public health and safety.

DATES: Comments must be submitted on or before [Insert date 90 days from date of publication in the FEDERAL REGISTER.]

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

FOR FURTHER INFORMATION CONTACT: Dr. Mysore S. Nataraja,
Division of High-Level Waste Management, Office of Nuclear
Material Safety and Safeguards, U.S. Nuclear Regulatory
Commission, Washington, DC 20555, telephone 301-504-3459.

SUPPLEMENTARY INFORMATION:

Under the Nuclear Waste Policy Act of 1982, as amended, the 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 such geologic repositories appear at 10 CFR Part 60. NRC has lately been engaged, with the assistance of its Federally-Funded Research and Development Center (the Center for Nuclear Waste Regulatory Analyses), in a review of the requirements of Part 60. NRC has focused particular attention on any matters that may be ambiguous 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 filed by DOE (PRM-60-3).

The issue concerns the protection of public health and safety in an accident event or other unlikely conditions during the operational period of a geologic repository (i.e., before permanent closure). Some change in the regulation may be

necessary, but determining just what change is appropriate dictates a consideration of fundamental principles.

The Commission's principal statutory mandate is set out in the Atomic Energy Act of 1954, as amended, which, among other things, authorizes the issuance of rules deemed "...necessary or desirable ... to protect health or to minimize danger to life or property." Acting pursuant to this authority, the Commission follows a defense-in-depth philosophy that is intended to ensure successive and mutually reinforcing echelons of defense that act to prevent or mitigate the occurrence of serious accidents and to protect the public health and safety. In addition, the Commission has established certain numerical limits on radiation doses, exposures, concentrations, etc., that are designed to limit potential adverse consequences of licensed activities - both for workers and for members of the general public - to levels that are well within the bounds of risks accepted in other productive activities in society.

The first echelon of protection in the defense-in-depth philosophy deals with accident prevention. It requires that facilities be of sound and conservative designs and be constructed, operated, and maintained in accordance with stringent quality standards so that malfunctions that could lead to a major accident will be highly improbable. The second echelon relies on conservative, redundant, and diverse detection

and actuation equipment in protection systems. This echelon is intended to compensate for failures or operating errors that may occur over the lifetime of the facility. In a sense, it provides backup to the structures, systems, and components of the first echelon. The regulatory language that serves the foregoing purposes typically calls for the identification of structures, systems, and components "important to safety" and requires that those elements be designed to carry out their safety functions assuming occurrence of "design basis events." The third and final echelon of defense requires the inclusion of supplementary features that provide an additional margin of safety to protect the public health and safety by limiting potential radiation exposures if other measures should fail. The design of these features is based primarily on the calculated consequences of postulated accidents at a specified location, such as the boundary of an "exclusion area."

The numerical radiation protection standards are codified in 10 CFR Part 20. These standards apply to operations at a geologic repository, by virtue of 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. In the first place, the relationship of Part 20 to accident conditions is not clearly defined. The second issue derives from the phrase in the language just quoted that requires the limits to be observed "at all times." (This could be read to mean that the design for a geologic repository must be sufficiently robust that the numerical limits set out in Part 20 would not be exceeded even in the event of the extreme credible set of conditions; or, alternatively, it could be construed to mean that 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).)

Although it is prudent to leave to individual cases as they may arise the precise application of the requirements of 10 CFR Part 20, the Commission recognizes the desirability of articulating its intentions in general terms. For this purpose, it finds the classification scheme referenced in Regulatory Guide 3.48, Revision 1, dated August 1989, "Standard Format and Content for the Safety Analysis Report for an Independent Spent Fuel

Storage Installation (Dry Storage)," to be quite helpful.¹ The classification scheme set out in that document lists, and gives examples for, four classes of "design events." Design Event I "...consists of that set of events that are expected to occur regularly or frequently in the course of normal operation." Design Event II "... consists of that set of events that, although not occurring regularly, can be expected to occur with moderate frequency or on the order of once during a calendar year" of operation. Design Event III "... consists of that set of infrequent events that could reasonably be expected to occur during the lifetime" of the facility. Design Event IV "... consists of the [unlikely] events that are postulated because their consequences may result in the maximum potential impact on the immediate environs. Their consideration establishes a conservative design basis for certain systems with important confinement features."

¹ Regulatory guides are issued to describe, and make available to the public, methods acceptable, to the NRC staff, of implementing specific parts of the Commission's regulations; to delineate techniques used by the staff in evaluating specific problems or postulated accidents; or to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with them is not required. The Commission's reference to Regulatory Guide 3.48 is not intended to, and will not, affect these limitations on its use. It is cited here solely for the purpose of elucidating the Commission's reasoning with respect to the present rulemaking activity. The classification scheme that is referenced in the cited regulatory guide appears in "Design Criteria for an Independent Spent Fuel Storage Installation (Dry Storage Type)," American National Standard ANSI/ANS-57.9-1984.

There can be little argument that, under normal conditions, including those recurring events that can be expected to require an interruption of operations from time to time during the lifetime of the facility, the provisions of Part 20 that protect the worker and the general public must be observed. Thus, the applicant for a license is expected to describe its proposed activities in a way that shows that they can be carried out safely (in accordance with Part 20) in a facility of its proposed design, at the proposed location, under those classes of conditions. Similarly, the review of the NRC staff will address these same considerations. The more difficult question involves the extent to which the design, along with the radiation-protection procedures that can be employed, must be sufficient to maintain radiation exposures and releases within Part 20 limits under more unlikely scenarios. For materials licensees, at least, the practice has been quite conservative - and properly so - with an expectation that both the workers and the general public should be protected from exposure to levels greater than those established in Part 20, even in the case of infrequent eventualities. If a condition can be expected to be reasonably likely to occur at some time during the lifetime of a licensed facility (i.e., a Design Event III), measures should be in place to meet the regulation's benchmarks if this condition does, in fact, occur. This is needed to provide an adequate level of protection. The Commission cannot conclude, however, that this standard must be met under all credible conditions, no matter how

speculative and unlikely. Under those circumstances, which can be characterized as Design Event IV in nature, the Commission's strategy is to require supplementary features that can provide additional margins of safety to protect the public health and safety from the consequences of a serious accident.

It appears that the existing provisions of Part 60 have not applied these concepts in a rigorous fashion and that this has been a source of uncertainty to all parties concerned. The Commission now proposes to address the matter by harmonizing Part 60 with other parts of its regulations, particularly 10 CFR Part 72 (pertaining to the regulation of independent spent fuel storage installations and monitored retrievable storage installations). The principles that are stated here represent a clearer expression of Commission's views on the application of Part 20 to "accidents" than we have had occasion to make in the past, and their adoption should significantly clarify the regulatory requirements.

The Existing Rule

We turn now to an examination of existing Part 60, focusing as above on both the defense-in-depth philosophy and the expression of numerical radiation protection standards.

There are, in fact, several elements of the present regulation that address the Commission's concern that there be defense in depth that is sufficient to cope with the full range of credible events at a high-level waste repository, including low-probability situations that have potentially serious consequences. These elements include:

- (1) A definition of certain structures, systems, and components as being "important to safety" (10 CFR 60.2);
- (2) A set of provisions that, in effect, requires that structures, systems, and components important to safety be designed so as to prevent or mitigate the consequences of accidents (10 CFR 60.131(b)); and
- (3) The application of an appropriate quality assurance program to such structures, systems, and components (10 CFR 60.151).

For purposes of this rulemaking, and without prejudice to future reexamination, the Commission is satisfied that both the design criteria and quality assurance program provisions are fundamentally sound. The definition of structures, systems, and components "important to safety," however, is neither consistent with other parts of NRC regulations nor sufficient to ensure proper levels of protection of public health and safety.

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.

The range of "accidents" to be addressed might be subject to debate. However, it is reasonable to construe the term to take into account natural phenomena as well as failures of engineered structures or operational errors and to consider the full range of credible events. The weakness of the language, however, is that it links the class of structures, systems, and components important to safety to the size of the unrestricted area. By extending the boundary of the unrestricted area far enough from the geologic repository operations area, one could, in principle, remove all structures, systems, and components from the design and quality assurance requirements of the rule.

The principal objection to this scheme is that it entirely overlooks the need to protect onsite personnel, in accident events, in a manner consistent with our defense-in-depth

philosophy. In addition, the value of 5 mSv (0.5 rem) concerning releases to (and radiation doses in) unrestricted areas under accident conditions is peculiar to Part 60 and lacks any documented principled basis.

For numerical radiation standards, the previous discussion has already alluded to the provisions of 10 CFR 60.111(a), which requires maintenance of Part 20 exposure limits "at all times" during the period of repository operations. The Commission has explained, on another occasion, that the phrase 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, 22296; June 19, 1986, proposed amendments to conform to Environmental Protection Agency general environmental standards.) The Commission adheres to this construction, which is consistent with its policy for other activities within its jurisdiction. Achievement of Part 20 limits is called for here, as well as in other regulatory contexts, over a broad range of events, but not necessarily in the improbable yet credible situations.

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 72.142(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 difficulty in applying 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. The Commission regards this as a stringent test -- one that contemplates that the numerical limits set out in 10 CFR Part 20 will generally be met (i.e., for Design Events I, II, and III, using the terminology presented above) and that the consequences of the low-probability credible scenarios (Design Event IV) will also be guarded against by conservative design and prudent quality assurance.

This framework permits the applicant and the staff to identify a discrete set of structures, systems, and components that are "important to safety." This requires, in the first instance, the development of "design bases," as defined

previously. Given these design bases, it becomes possible to determine which of the structures, systems, and components must perform particular safety functions to provide reasonable assurance that the storage and handling of radioactive waste present no "undue risk to the health and safety of the public" as explained in the prior paragraph.

Part 72 contains yet another provision to provide protection to public health and safety, even under unlikely conditions. As specified in 10 CFR 72.106, for each ISFSI or MRS site, there must be a zone (described in Part 72 as 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. The concept of such a "controlled area," or exclusion zone, is consistent with the policy of striving to conduct operations so that, under all likely conditions, both occupational and public exposure levels will conform to Part 20, yet recognizing that, in the extraordinary case (as determined by identifying design basis accidents), other measures should be employed to ensure that adverse consequences are kept to acceptable levels.

The Petition for Rulemaking

On April 19, 1990, DOE filed a petition for rulemaking 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, there would continue to be a restricted area that would be subject to normal access controls

and radiological monitoring. In addition, however, Part 60 would be amended to require the establishment of a "preclosure control area"; and the numerical accident-dose criteria that DOE called for would be applied at the boundary of that area. The definition of the term "important to safety" would retain the 5 mSv (0.5 rem) reference dose; but unlike the present Part 60, which relates this value to the boundary of the restricted area,

DOE's proposal would apply it at the boundary of the preclosure control area. The petition also proposed that performance objectives would be revised to incorporate an explicit accident dose limit at that boundary of 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) committed dose equivalent. 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.

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

Discussion

The Commission regards the present language of the rule to be fundamentally sound in that it addresses the protection of public health and safety under conditions that can be expected to occur during the period of operations at the geologic repository operations area (i.e., Design Events I, II, and III). This

position reflects two principles that have been discussed previously: (1) that there must be reasonable assurance of maintaining doses, exposures, and concentrations, within Part 20 limits, under all such conditions; and (2) that the phrase "at all times," in 10 CFR 60.111, relates to phases of the period of operations (e.g., a retrieval phase (if necessary) as well as an emplacement phase) and does not encompass "times" when the unlikely (yet credible) conditions might occur.

The Commission agrees with the petitioner that the rule should be modified to address the remaining class of significant conditions, namely, those that are unlikely, yet credible (Design Event IV). However, as indicated in the following excerpt from the Commission's notice of receipt of the petition (55 FR 28773) there are difficulties with the proposed amendments (these difficulties are also present in the existing rule):

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 [one] 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 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 would be derived from a consideration of the functional requirements of the repository system. In addition, criteria for a preclosure controlled area that take into account postulated accident conditions 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.

A consideration of the functional requirements of the repository system indicates, in the first place, that a broad range of activities at the geologic repository operations area

presents sufficient public health and safety implications as to warrant the application of measures characterized as the defense-in-depth philosophy. All operations involving the receipt, handling, packaging, storage, and retrieval of high-level radioactive waste (collectively, "waste operations") are presumptively of this character.

Waste operations must be carried out in a manner that not only satisfies Part 20 requirements, but also presents no undue risk to the health and safety of the public under any of the credible conditions that may arise. The regulation should, therefore, provide in some manner for an assessment of, and response to, those conditions. Drawing in large part from the precedent of Part 72, this can be accomplished by (1) defining a class of "design basis events," (2) requiring the applicant to analyze the radiological consequences of such design basis events, and (3) providing defense-in-depth measures, as necessary to protect health and safety, if design basis events should occur. The proposed amendments, as discussed below, are designed to serve this purpose.

Section-by-Section Analysis

Section 60.2 Definitions.

The proposed amendments involve four definitions needed in Part 60.

The term "controlled-use area" is new. It corresponds closely to the term "controlled area," as defined in 10 CFR 72.3. Its function is to delimit an area from which members of the public can be excluded, if necessary, should an unlikely design basis event occur. The reason it is called "controlled-use" instead of "controlled" is that Part 60 already refers to a "controlled area" (within which waste isolation is to be ensured after permanent closure). Because Part 60 (unlike Part 72) involves ongoing underground operations and time frames 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 term "important to safety" would be amended to reflect the considerations previously discussed. The existing provision lacks a firm regulatory basis, can be rendered ineffective by extending the boundary of the unrestricted area, and fails to address the importance of protecting workers as well as members of the general public. This is an important term, because it is the predicate for some required design features as well as required quality assurance measures. These design and quality assurance measures, for structures, systems, and components

important to safety, provide protection for members of the general public and workers. The Commission proposes to modify the definition to conform, in all material respects, to the language that already appears in 10 CFR 72.3. Several minor deviations can be explained readily. First, since for purposes of Part 60 the term "HLW" [high-level radioactive waste] is defined to include irradiated reactor fuel, Part 72's mention of spent fuel is omitted when the context permits. Second, the definition is not linked to "structures, systems, and components," because the phrase is also employed in reference to "impacts" (in 10 CFR 60.17(a)(2)(iv)), "equipment" (in 10 CFR 60.44(a)(2)), and "systems and components" (in 10 CFR 60.160). Third, for purposes of clarification, "handling and storage" is changed to "handling or storage" in paragraph (2). (Paragraph (3), which refers to receipt, handling, packaging, storage, and retrieval of high-level radioactive waste, should be construed to apply to all operational activities at a geologic repository operations area, including shielding, emplacement, onsite movement, etc.)

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 are taken into account in the design, and, in particular, in relation to conditions that could result

in radiological consequences beyond those allowed by Part 20. 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 Design Events I, II, and III) that must be taken into account in demonstrating compliance with the provisions of Part 20. (This set of events is described as "those events that can reasonably be expected to occur prior to permanent closure.") Second, it identifies an additional set of events ("such other natural and man-induced events that are considered unlikely, but are sufficiently credible to warrant consideration, that are postulated because their consequences may result in maximum potential impacts on the environs of the geologic repository operations area") that must be taken into account in applying the Commission's defense-in-depth philosophy. 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 is the subject 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 the 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 controlled-use area boundary, that is attributable to the full range of design basis events. The procedure that is envisaged is that the applicant would address the critical design basis events singly, or in appropriate combination, and demonstrate by its analysis that the doses on or beyond the controlled-use 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 reflects the position, outlined above, that the applicant should demonstrate that the requirements of Part 20 will be met, assuming the occurrence of any event or appropriate combination of events, that are likely to occur "prior to permanent closure" (a phrase that is used interchangeably with "until permanent closure has been completed"). The doses, exposures or releases must be kept within Part 20 limits even if less likely events should occur (for example, Design Events II or III in combination with Design Event I).

The Commission also proposes to eliminate certain terms pertaining to the functions of structures, systems, and components important to safety that may be subject to differing interpretations -- specifically, the terms "normal conditions," "anticipated operational occurrences," and "accidents." Besides enhancing clarity of expression, the new language better reflects the regulatory framework articulated above.

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

This section is important in accomplishing the Commission's defense-in-depth objectives. The way this is achieved is by requiring that certain structures, systems, and components must be designed to meet exacting specifications -- namely, that they be able to achieve prescribed performance levels under a defined range of conditions. The rule currently employs the term "normal and accident conditions", or similar expression, in several places. However, the conditions that must be addressed under this language are poorly defined. The Commission proposes to remedy this situation by replacing current terminology with references to "design basis events," thereby assuring that the design appropriately takes into account the consequences of all design basis events (i.e., as discussed in this document, Design Events I, II, III, and IV). Accordingly, modification of paragraphs (b)(5)(i), (b)(7), and (b)(8) is being proposed for this section.

In 10 CFR 60.131, (b)(1), which refers to "anticipated" conditions, as well as natural phenomena and environmental conditions, would be revised 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 Section 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 in the event of off-normal conditions (Design Events II and III) that are reasonably likely to occur before permanent closure of the geologic repository. Deleting the phrase "during normal operations," as proposed, will broaden the scope of this provision to reflect more accurately the Commission's intent.

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 Controlled-use area.

The proposed rule would adopt the petitioner's concept of a preclosure control area, under the name "controlled-use area." The function of this area is to define a zone from which members of the public can be excluded under the unusual conditions that have here been characterized as Design Event IV - credible yet not likely to occur during the period of operations. The issue that is presented concerns the reference dose on or beyond the controlled-use area boundary that is appropriate to assure that the occurrence of any such events presents no unreasonable risk to the health and safety of the public. (Releases resulting from events classified as Design Events I, II, and III would not be permitted to cause doses exceeding the limits of Part 20.) The Commission proposes to adapt the basic provisions of Part 72 - namely, a reference 0.05 Sv (5 rem) dose on or beyond the controlled-use area boundary - as modified to reflect the recently amended Part 20.

To accomplish this, there would be reference doses: 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); an eye dose equivalent of 0.15 Sv (15 rem); and

a shallow dose equivalent to skin of 0.5 Sv (50 rem).² The eye and skin 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. The 0.05 Sv (5 rem) reference dose addresses the calculated risk (the expectation value) of a fatal cancer. A consideration of the annual frequency of occurrence of any Design Event IV (on the order of 1×10^{-3} per year or less), the maximum expected reference dose on or beyond the boundary of the controlled-use area of 0.05 Sv (5 rem) TEDE, and the risk of a fatal cancer per rem, results in a calculated risk for a fatal cancer that is a small fraction of that permitted by the Commission's regulations for routine operations at a nuclear facility. The total annual risk experienced by members of the public, including the risk due to accidental releases, would be a small increment to the risk associated with the Commission's Part 20 routine release limit of 1 mSv (0.1 rem) per year. Considering the low probability of occurrence of any Design Event IV, the Commission views these limits as providing an adequate level of protection. In implementing this provision, dose calculations should be made solely with reference to the consequence of the specific Design Event IV, and not cumulatively with other design events.

² Radiation exposure terminology is as used in 10 CFR Part 20 (56 FR 23360; May 21, 1991).

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 accident" is avoided because it lacks a definition. A design basis accident is merely the consequence of some design basis event, and so the change in terminology is not intended to be one of substance.

Section 60.183 Criminal Penalties.

A conforming change has been made to this section, to include section 60.136 (pertaining to the controlled-use 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

The information collection requirements contained in this proposed rule of limited applicability affect fewer than 10 respondents. Therefore, Office of Management and Budget clearance is not required pursuant 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. M. Nataraja, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of High-Level Waste Management, Washington, DC 20555, Telephone 301-504-3459.

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 penalty, 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 in definitions of "Controlled-use area," "Design bases" and "Design basis events" and by revising the definition of "Important to safety," to read as follows:

§ 60.2 Definitions.

* * * * *

Controlled-use 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.

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 events that are reasonably likely to occur prior to permanent closure, and

(2) Other natural and man-induced events that are considered unlikely, but are sufficiently credible to warrant consideration, that are postulated to occur prior to permanent closure because their consequences may result in maximum potential impacts on the environs of the geologic repository operations area.

* * * * *

Important to safety means having or affecting the function of:

- (1) Maintaining the conditions required to store HLW safely,
- (2) Preventing or mitigating damage to HLW, or HLW containers, during handling or storage, or
- (3) Providing reasonable assurance that HLW can be received, handled, packaged, stored, and retrieved without undue risk to the health and safety of the public.

* * * * *

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, paragraph (c)(3) is revised to read as follows:

§ 60.21 Content of application.

* * * * *

(c) * * *

(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 design basis events that are reasonably likely to occur before permanent closure; and

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

* * * * *

5. In § 60.131, paragraphs (b)(1), (b)(5)(i), (b)(7), and (b)(8) are revised to read as follows:

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

* * * * *

(b) Structures, systems, and components important to safety.

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

* * * * *

(5) Utility services. (i) Each utility service system that is important to safety must be designed so that essential safety functions can be performed, assuming occurrence of the design basis events.

* * * * *

(7) Criticality control. All systems for processing, transporting, handling, storage, retrieval, emplacement, and isolation of radioactive waste must be designed to ensure that a nuclear criticality accident 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.

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

* * * * *

6. 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 must be designed to control the release of radioactive materials in effluents so as to meet the performance objectives of § 60.111(a).

* * * * *

7. In § 60.133, the introductory text 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 must be designed to:

* * * * *

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

* * * * *

8. A new § 60.136, with accompanying caption, is added to read as follows:

CONTROLLED-USE AREA

§ 60.136 Controlled-use area.

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

(b) The geologic repository operations area must be designed so that, for design basis events, no individual located on or beyond the boundary of the controlled-use 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 controlled-use area must be at least 100 meters.

(c) The controlled-use 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.

9. In § 60.183, paragraph (b) is amended by adding § 60.136 so that paragraph (b) reads as follows:

§ 60.183 Criminal Penalties

* * * * *

(b) The regulations in Part 60 that are not issued under Sections 161b, 161i, or 161c 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, 670.143, 60.150,
60.151, 60.152, 60.162, 60.181, and 60.183.

Dated in Rockville, Maryland, this ____ day of _____,
1992.

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 19 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, 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 60¹

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 criteria², 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".

² U.S. Nuclear Regulatory Commission, 1963. Staff Analysis of Public Comments on Proposed Rule 10 CFR Part 60. "Disposal of High-Level Radioactive Wastes in Geologic Repositories," NUREG-DB04, Comment 7, pp. 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 waste³ 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 equipment⁴. 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 barrier⁵.

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

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-D612.

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 importance⁶. 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 ICRP¹¹ and NCRP¹², a

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^{-5} 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-88¹³ and BEIR-V¹⁴) 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^{-5} . 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 radiation¹⁷. 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

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.

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

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 basis²². 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

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 features²³. 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 purposes²⁴, 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

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 D.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.

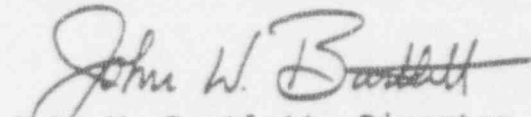
Additional modification of the current definition of "important to safety" is needed to make it consistent with the proposed accident dose criteria by incorporating the effective dose equivalent concept and the new preclosure control area boundary.

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 criteria 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, Director
Office of Civilian Radioactive
Waste Management

DATED: April 19, 1990

UNDER CURRENT 16 CFR 69

PROPOSED REVISIONS IN DOE PETITION FOR RULEMAKING

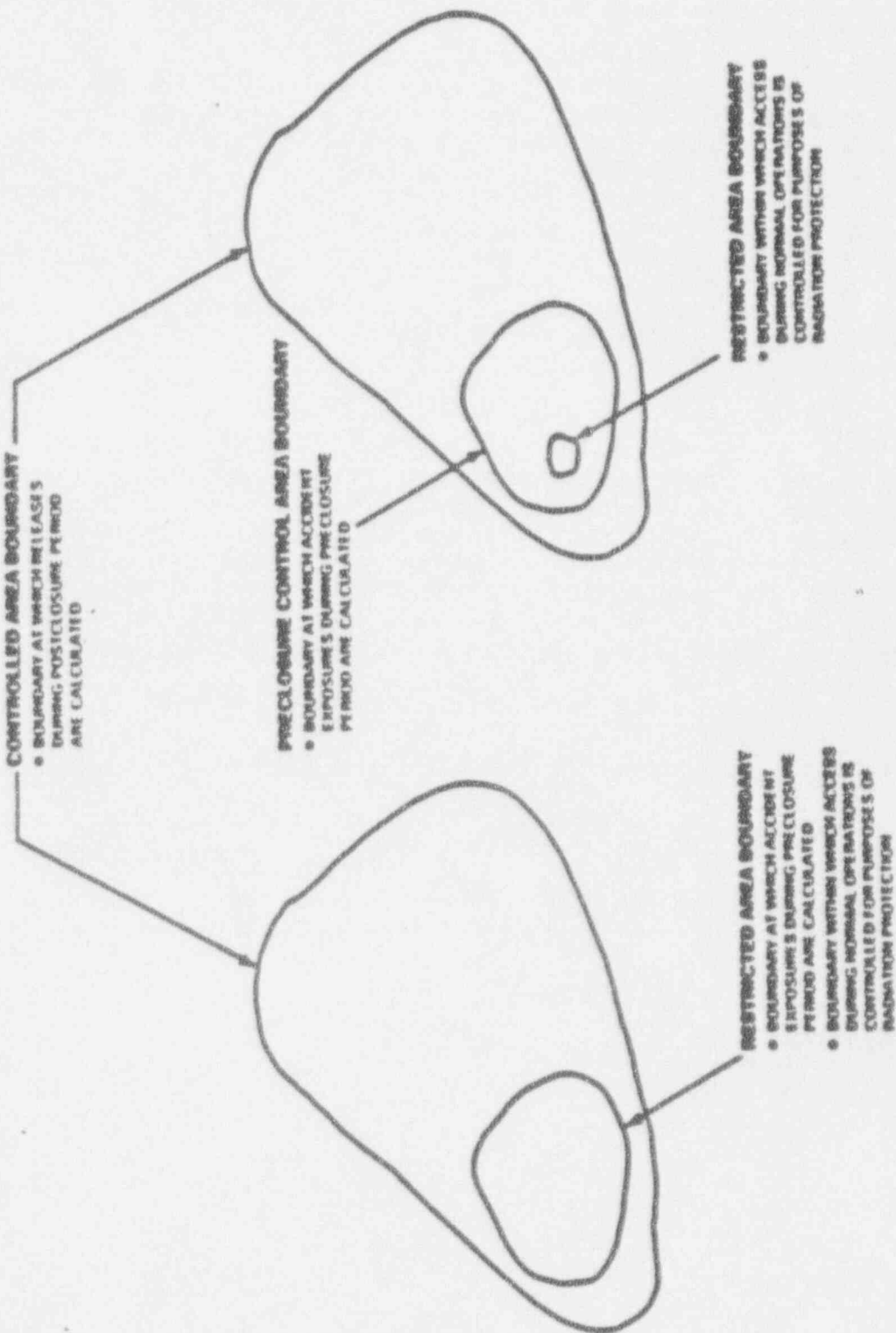


Figure 1. Comparison of Current and Proposed Boundaries

ENCLOSURE 3

NOTICE OF RECEIPT OF A PETITION

FOR RULEMAKING

Hearing Clerk, room 3171, 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 (56 FR 19828) 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 9, 1990.
Lester M. Crawford,
Administrator, Food Safety and Inspection Service.
[FR Doc. 90-18323 Filed 7-12-90; 8:45 am]
BILLING CODE 3410-06-6

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.

DATE: 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.

ADDRESS: 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. Lessar, 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 19, 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)(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. 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 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."

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. It 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 6.25 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-0956, 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 (RLN 3150-ADS1). 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. Chalk,
Secretary of the Commission.
[FR Doc. 90-16417 Filed 7-12-90; 8:45 am]
BILLING CODE 7899-91-98

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 100-658, 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 requirement 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



REGISTRATION NUMBER
(55 FR 28771)

Department of Energy
Washington, DC 20585

RECEIVED
NRC

NOV 29 1990

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, Director
Office of Civilian Radioactive
Waste Management

Enclosure:

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

9012110110 901126
PDR PRM
60-3 PDR

cc w/enclosure:

- R. Bernero, NRC
- R. Browning, NRC
- J. Youngblood, NRC
- D. Moeller, ACHW
- 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 "...plying 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"

Intertech Consultants

PLANNING - ECONOMICS - PROGRAM MANAGEMENT

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

2

DOCKETED
USNRC

90 OCT 15 AIO: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.

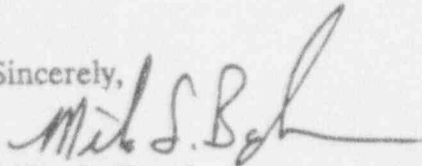
Lincoln County and the City of Caliente would suggest that further consideration be given by DOE and NRC to both the definition of preclosure control area and the exposure pathways under which the effective dose is assumed to be administered. Concerning the former, protection of facility workers should 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 guarantee 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

Page 2
Secretary of the Commission
October 9, 1990

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
Gerri Ann Stanton, Lincoln County

DOCKET NUMBER

PETITION RULE PRM 60-3

DOCKETED
USNRC

(55FR 28771)

2

'90 OCT 12 A10:51

DEPARTMENT OF ENERGY
DOCKETING AND SERVICE
BRANCH

LORING E. MILLS
Vice President, Nuclear Activities



EDISON ELECTRIC
INSTITUTE

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 preclosure 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.

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Secretary of the Commission

October 11, 1990

Page 2

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.

Secretary of the Commission

October 11, 1990

Page 3

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.

EEL/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, EEL/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." EEL/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

Secretary of the Commission

October 11, 1990

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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.

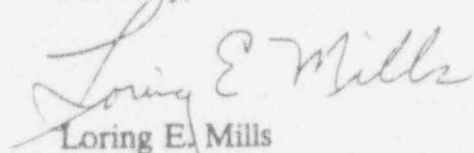
Secretary of the Commission

October 11, 1990

Page 5

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,

A handwritten signature in cursive script that reads "Loring E. Mills". The signature is written in dark ink and is positioned above the printed name.

Loring E. Mills

LEM/cht

DOCKET NUMBER

PETITION RULE PRM 60-3

(55 FR 28971)

DOCKETED
USNRC

1

90 OCT 10 P3:31

October 1, 1990

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

OFFICE OF SECRETARY
DOCKETING & 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 that are between the two values (i.e., between 0.5 rem and 5 rem).

Concerned U.S. Citizen

ENCLOSURE 5

RISK COMPARISON

COMPARATIVE RISK

The amendments proposed for 10 CFR Part 60, "Design Basis Events for the Geologic Repository Operations Area," would allow a person located at the boundary of the controlled-use area to receive a maximum accident radiation dose of 0.05 Sv (5 rem). This dose limit would be allowed only for those accidents that are unlikely to occur during the 100-year lifetime of a repository -- that is, those accidents with frequencies that might reasonably be expected to be in the range of 10^{-3} /year or less. The fatal cancer risk for such accidents would be given by the following expression:

$$\begin{aligned} \text{Risk} &= (10^{-3}/\text{yr}) (0.05 \text{ Sv}) (5 \times 10^{-2} \text{ risk/Sv}) \\ &= 2.5 \times 10^{-6}/\text{yr} \end{aligned}$$

For comparison, the limit in 10 CFR 20.1301 for members of the public is 1 mSv/year. The fatal cancer risk associated with such a dose would be:

$$\begin{aligned} \text{Risk} &= (1 \text{ mSv/yr}) (5 \times 10^{-2} \text{ risk/Sv}) \\ &= 5 \times 10^{-5}/\text{yr}. \end{aligned}$$

Thus, the amendments proposed here would impose a risk to members of the public that is only a fraction of the level of risk currently permitted by Part 20. (The fatal cancer dose conversion factor, 5×10^{-2} risk/Sv (5×10^{-4} risk/rem), is taken from the supplementary information for the revised 10 CFR Part 20, 56 FR 23363, and is consistent with recent findings of the National Academy of Sciences (BEIR V), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and the International Commission on Radiological Protection (ICRP publication 60).)

ENCLOSURE 6

FEDERAL REGISTER NOTICE OF

PETITION DENIAL

NUCLEAR REGULATORY COMMISSION

10 CFR PART 60

[Docket No. PRM-60-3]

U. S. Department of Energy, Denial of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is denying a petition for rulemaking (PRM-60-3) submitted by the U. S. Department of Energy (DOE) which requested an amendment to the regulation that deals with the disposal of high-level radioactive waste (HLW) in geologic repositories. The petition requested the NRC to revise its regulations to include specific dose criteria for design basis accidents. NRC is publishing a notice of proposed rulemaking in the Federal Register that addresses the regulatory issue raised by the petitioner. However, the NRC-proposed rule addresses the issues in a manner different from the one proposed by DOE in its petition. Because the approach requested by DOE is inconsistent with other NRC regulations and does not provide the worker and general public health and safety protection considered necessary by NRC, the petition is denied.

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. M. Nataraja, Office of Nuclear Material Safety and Safeguards, U. S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 504-3459.

SUPPLEMENTARY INFORMATION:

The Petition

DOE submitted a petition for rulemaking on April 19, 1990. On July 13, 1990, (55 FR 28771) the 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 require the establishment of a "preclosure control area" and to prescribe certain numerical accident-dose criteria to be applied at the boundary of that 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. Finally, 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. (For a fuller description of the petition for rulemaking, see the Federal Register notice cited above.)

Basis for Request

The issue raised by the petitioner concerns the adequacy of the existing rule with respect to design criteria to be applied for design basis accidents. DOE considers the current rule deficient in that it does not contain numerical dose criteria to determine design adequacy under such conditions.

"...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."

Public Comment on the Petition

In publishing the DOE petition in the Federal Register, NRC included a discussion of its ongoing independent regulatory initiative to establish additional preclosure regulatory requirements for HLW geologic repositories. NRC noted that under DOE's approach (as well as in the existing Part 60), it would be possible to have no structures, systems, or 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 and could result in inferior structures, systems, and components in the geologic operations area. NRC indicated that additional measures would be needed to assure the protection of workers.

Comments were solicited with respect to NRC's initiative as well as the DOE 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.

DOE, by letter of November 26, 1990, reiterated its concern with the absence of quantitative accident dose criteria in Part 60. It disagreed with NRC's interpretation of DOE's approach because it intends 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 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.

EEI/UWASTE supported the DOE petition. It stated that 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 which, if unresolved, could result in significant delays in the NRC Staff's evaluation of DOE's license application and in the licensing process. EEI/UWASTE did not share NRC's concern that the preclosure control area boundary could be located so as to compromise the safety of the general public or repository workers since the accident dose criteria

would be only one component of a detailed regulatory regime that would include, for example, regulations governing acceptable occupational doses. EEI/UWASTE considered NRC's concern with the inconsistency of Part 60 with 10 CFR Part 72 unfounded since the licensing requirements would apply to different types of facilities designed for different purposes. It was suggested that if there was any inconsistency, that Part 72 be made consistent with Part 60, rather than vice-versa. The Commission was strongly urged to act favorably on 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. They suggested, however, that it would be prudent to delay initiation of the rulemaking proceeding until information from the series of studies NRC had initiated was available and that further consideration be given to both the definition of preclosure control area and the exposure pathways (specifically ingestion) under which effective dose is assumed to be administered. They recognized the need to treat the protection of facility workers and the off-site public as matters of equal importance.

The Concerned U. S. Citizen stated that "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 [preclosure control

area accident dose limit and limit for identifying items important to safety] should be the same." It was also suggested that "engineered safety features" in DOE's definition of important to safety was redundant and unnecessary or needed to be defined.

Staff Action on the Petition

By letter of July 23, 1991, NRC informed DOE that it was conducting necessary technical work to support the development of its position regarding specific dose criteria, and its response to DOE's petition.

Discussion

The Commission agrees that Part 60 should be revised to more clearly set out the Commission's requirements. The Commission has, therefore, proposed modifications to the rule to more clearly define performance and design requirements related to accident conditions. The proposed rule provides definitions of "design bases," "design basis events," and a revised definition of "important to safety." The revised definition identifies structures, systems, and components "important to safety" from consideration of their repository system functional requirements rather than the specified dose limit proposed by DOE. This definition better accommodates the protection of worker health

and safety as a regulatory requirement and is consistent with other NRC regulations, in particular Part 72. Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste," has been satisfactorily applied in the licensing of spent fuel storage facilities. The operations at these facilities are sufficiently similar to those required for the handling and storage of spent fuel and HLW at a geologic repository to warrant the establishment of analogous regulatory requirements.

The DOE-proposed addition to the "important to safety" definition, "All engineered safety features shall be included within the meaning of the term 'important to safety,'" was not adopted. The term "engineered safety features" in the DOE petition is undefined and ambiguous, as noted by one of the commenters. In place of the DOE wording, the definition being proposed by the Commission spells out the specific functions (receipt, handling, packaging, storage, and retrieval) which will be deemed to be significant from the standpoint of safety and hence classified as "important to safety." All structures, systems, and components falling within the definition must be subject to appropriate design and quality assurance measures to prevent or mitigate accidents, and not limited - as DOE would suggest - to accidents having the potential for exceeding the prescribed dose limits at a preclosure-control-area boundary.

Responding to the proposal of the petitioner, while at the same time making the terminology consistent with that of other NRC regulations, the proposed rule includes a requirement for the establishment of a controlled-use area, and a controlled-use-area-boundary reference dose. No individual located on or beyond the boundary of the controlled-use area is to 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). Consistent with the Part 72 regulatory approach, and as recommended by Lincoln County and the City of Caliente, ingestion dose would be included in these calculations.

The reader is referred to the proposed rule, published for public comment in the Federal Register, for a detailed discussion of the proposed amendments and rationale for NRC's approach.

Reason for Denial

The issue raised by the petitioner is being fully addressed in a notice of proposed rulemaking being published concurrently in the Federal Register. The NRC-proposed rule addresses the issues in a manner different from the one proposed by DOE in its

petition. NRC's approach is necessary to ensure adequate protection for workers and the general public and consistency with other Commission regulations for similar facilities. As the amendment suggested by the petitioner is inconsistent with NRC's proposed regulatory approach, the petition for rulemaking is denied.

Dated at Rockville, Maryland this ____ day of _____, 1992

For the Nuclear Regulatory Commission

Samuel J. Chilk,

Secretary of the Commission.

11/18/92

DBEDENY.EDO

ENCLOSURE 7

DRAFT LETTER TO PETITIONER



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

RAFT

Dr. John W. Bartlett, Director
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Dear Dr. Bartlett:

Enclosed are advance copies of Federal Register notices for: 1) a denial 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.

The NRC-proposed rule addresses the issues raised by DOE, in a manner different from the one proposed by DOE in its petition. NRC's approach is consistent with other Commission regulations for similar facilities, for example, 10 CFR Part 72, for independent storage of spent nuclear fuel and high-level radioactive waste. For this reason, and others, as stated in the Federal Register notices, the DOE petition for rulemaking is denied.

Sincerely,

Samuel J. Chilk
Secretary of the Commission

Enclosures:

1. Federal Register notice on Denial of DOE Rulemaking Petition
2. Proposed Amendments to 10 CFR Part 60

(See attached list for cc's)

LETTER TO DR. JOHN W. BARTLETT FROM SAMUEL J. CHILK, SUBJECT:
10 CFR 2.801 AND 10 CFR PART 60, 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. Vaughan II, Esmeralda County, NV
C. Shank, Churchill County, NV

ENCLOSURE 8

REGULATORY ANALYSIS

REGULATORY ANALYSIS

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

September 1992

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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.¹ Several regulatory uncertainties (i.e., ambiguous or inconsistent expressions of regulatory requirements or policy) were identified. In particular, uncertainties were identified in that:

- 1) the relationship of 10 CFR Part 60 to accident conditions in Part 60 is not clearly defined, and
- 2) the definition of "important to safety" is not consistent with other Nuclear Regulatory Commission regulations and does not ensure an adequate level of protection of public health and safety.

The U. S. Department of Energy (DOE), the potential applicant for a repository license under Part 60, independently noted the first of these uncertainties. The DOE contends that 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, if not resolved by rulemaking, could require future redirection of design efforts that result in major cost increases and program delays. The DOE submitted a petition for NRC rulemaking on April 19, 1990 and receipt was noticed in the Federal Register, on July 13, 1990, 55 FR 28771.

DOE's rulemaking petition would:

- 1) 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.
- 2) Establish a requirement for a "pre-closure controlled area," similar to that in 10 CFR Part 72, in which public access is controlled.
- 3) Establish a pre-closure, controlled-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.

¹ CNWRA, "Identification and Evaluation of Regulatory and Institutional Uncertainties," CNWRA 90-003, March 1990.

4) Modify the definition of "important to safety," to refer to the pre-closure controlled area, rather than the "restricted area," but still retaining 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.'"

In noting the DOE petition in the Federal Register, the Commission also discussed its ongoing independent regulatory initiative to establish additional pre-closure regulatory requirements for high-level radioactive waste (HLW) geologic repositories and noted that the DOE approach differed markedly from that contemplated by NRC.

The DOE proposed definition of "important to safety" identifies those structures, systems and components essential to the prevention or mitigation of an accident based on a boundary radiation dose limit. With this definition, it would be potentially possible to extend the boundary to meet the dose criteria such that no structures, systems, and components would be identified as important to safety. This could provide public protection but would ignore the safety of workers in that certain safety and quality assurance requirements, related to structures, systems, and components important to safety, could be bypassed. Further, this definition is inconsistent with NRC's 10 CFR Part 72 regulation. NRC's approach to the resolution of this regulatory uncertainty (the second regulatory uncertainty noted above) is to define structures, systems, and components "important to safety" from consideration of the functional requirements of the repository system consistent with the language of Part 72.

2. OBJECTIVE

The objective of the proposed rulemaking is to eliminate those regulatory uncertainties of concern to DOE, to provide consistency among NRC regulations, and thereby to provide an adequate level of public, including worker, safety and protection.

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 during the lifetime of the licensed facility. A requirement would be established for a "controlled-use area" and controlled-use boundary reference dose limit, similar to that proposed by DOE, but modified to be compatible with the terminology of Part 60 and the recently revised radiation protection requirements of Part 20.

"Important to safety," in 10 CFR 60.2, would be changed to a functional definition rather than a dose-related definition so as to conform, in all material respects, to the language that already exist in 10 CFR Part 72. Those structures, systems, and components determined to be "important to safety" are required to maintain safety functions under design basis events and to meet quality assurance requirements that provide worker, as well as the general public, protection.

A definition of "design bases, and "design basis events" is proposed, and design basis events would be used in lieu of the terms "normal" and "accident" conditions.

3. ALTERNATIVES

Alternatives considered with regard to removing the identified regulatory uncertainties consisted of: 1) take no action on present rule; 2) provide regulatory guidance; 3) adopt the petitioned rule; and 4) proceed with the NRC rulemaking initiative.

3.1 No Action

No action to amend 10 CFR Part 60 would have the least near-term impact on NRC resources and other scheduled 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 in order 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.

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 concern to be addressed is the inadequacy - as opposed to the ambiguity - of the existing rule. Since the uncertainty involved concerns 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 is similar in many respects to the NRC proposed rulemaking. However, this petitioned rule would not resolve the deficiency in the definition of "important to safety," nor the inconsistency in NRC regulations. Safety functions and quality assurance requirements for structures, systems and, components important to safety could be bypassed such that worker safety might be compromised. The DOE rulemaking petition is inconsistent with NRC's philosophy for protection of health and safety and is, therefore, not a recommended alternative.

3.4 Rulemaking - Recommended Action

The proposed rulemaking 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. The rulemaking action, which includes publication in the Federal Register and a public comment period, is the most appropriate option to resolve uncertainties related to a health and safety interpretation of Part 60.

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.

4.0 CONSEQUENCES OF RECOMMENDED ALTERNATIVE

4.1 Impact on Public

The proposed rulemaking action will reduce regulatory uncertainty and will enhance worker and public safety. Also, 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 reduced 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. However, public input to the licensing process would not be reduced by this action; rather, it would enable public input at an early date.

4.2 Impact on DOE

The proposed rulemaking provides design bases criteria that effectively resolve DOE's concerns related to normal and accident conditions. The rule also establishes a requirement for a controlled-use area boundary and boundary reference dose limit, as proposed by DOE. However, the proposed rulemaking changes the definition of "important to safety" in 10 CFR 60.2 to a functional rather than dose related definition. Such a change in definition 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 special design and quality assurance requirements, this could, potentially, have an impact on DOE's program schedule and cost. The proposed rule change is not, however, unexpected, and implementation should be facilitated by present DOE procedures.

DOE was alerted to NRC's concerns and likely action in the Federal Register notice publication of its rulemaking petition. DOE's comments to the Federal Register notice stated its intent to meet NRC quality assurance guidance provided in NUREG-1318,² 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." Further, DOE's Yucca Mountain Project Administrative Procedure, AP-6.17Q, March 19, 1990, specifically implements the requirements of NUREG-1318. In addition, the proposed changes to Part 60 conform to NRC regulations for similar HLW handling facilities (i.e., Part 72) which are being applied in the design of the associated Monitored Retrievable Storage facility.

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

² 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.

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-mandated 3-year schedule.

4.4 Impact on Other Requirements

The proposed regulation will provide consistency among NRC regulations, thus removing a potential source of uncertainty. NRC regulatory guidance documents, specifically NUREG-1318, 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.

5.0 DECISION RATIONALE

The staff has evaluated regulatory uncertainties related to 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 evaluation of design basis events as may lead to accident conditions. "Important to safety" would be defined consistent with other NRC regulations in a manner that would ensure an adequate level of public health and safety.

The rulemaking would be the final action on this subject.

6.0 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 development phase and there should not be significant impacts on physical equipment.) Since DOE has indicated 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 can not be given at this time, it is reasonable to assume that implementation of the proposed rule could be accomplished in one or two 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 function, rather than in relation to dose, might be accomplished consistent with a scheduled quality assurance program review.

ENCLOSURE 9

ACNW CORRESPONDENCE



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

June 2, 1992

Mr. James M. Taylor
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Taylor:

SUBJECT: RULEMAKING ON DESIGN BASIS EVENTS FOR GEOLOGIC REPOSITORY
OPERATIONS AREA

During its 43rd meeting, May 28-29, 1992, the Advisory Committee on Nuclear Waste met with members of the Office of Nuclear Material Safety and Safeguards (NMSS) staff to review the proposed rulemaking on "Disposal of High-Level Radioactive Wastes in Geologic Repositories--Design Basis Events for the Geologic Repository Operations Area."

On the basis of our discussions with the staff, and our detailed reading of the supporting documents, we believe that the NMSS staff has prepared this proposed rule in a competent manner. Our principal comments follow:

1. The staff has indicated that the four classes of design basis events will be described in the "Statement of Considerations" that will accompany the rule. We suggest that further consideration be given to incorporating this descriptive information into the rule itself.
2. One of the bases for establishing the 50-mSv (5-rem) dose limit at the boundary of the "controlled-use area" is to ensure protection of the onsite workers at the repository. This goal should be clearly enunciated in the proposed rule.

Some time ago, we were told that similar rulemaking would be undertaken to resolve a number of key issues related to the licensing of a high-level radioactive waste repository. We recommend that the use of the rulemaking process be pursued to resolve these other key issues in a timely manner.

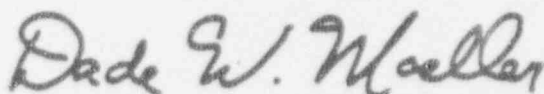
Mr. James M. Taylor

2

June 2, 1992

Detailed comments regarding this subject can be found in the transcript of our meeting. We endorse publication of this proposed rule for comment, taking into account our recommendations.

Sincerely,

A handwritten signature in cursive script that reads "Dade W. Moeller".

Dade W. Moeller
Chairman

Reference:

Memorandum dated April 29, 1992 from B. J. Youngblood, Nuclear Material Safety and Safeguards, transmitting Draft Proposed Rulemaking, "Disposal of High-Level Radioactive Waste in Geologic Repositories--Design Basis Events for the Geologic Repository Operations Area"



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

August 24, 1992

MEMORANDUM FOR: Dade W. Moeller, Chairman
Advisory Committee on Nuclear Waste

FROM: James M. Taylor
Executive Director
for Operations

SUBJECT: RULEMAKING ON DESIGN BASIS EVENTS FOR GEOLOGIC
REPOSITORY OPERATIONS AREA

I am responding to your letter of June 2, 1992, concerning the proposed rulemaking on "Disposal of High-Level Radioactive Waste in Geologic Repositories-- Design Basis Events for the Geologic Repository Operations Area." Your letter made two principal recommendations: 1) that the four design basis event classes be described in the rule itself, and 2) that the goal of worker protection be clearly enunciated in the proposed rule.

Addressing the Committee's first concern, including the description of the four classes of design events in the rule, itself, would require a departure from the language employed in other parts of the Commission's regulations. In 10 CFR Part 72, for example, the rule refers to the design bases, but the event classes that should be considered are addressed in a regulatory guide, rather than in the rule itself. The staff plans, however, to include, within the rule, itself, two principal categories of events: 1) those events that can reasonably be expected to occur before permanent closure (Classes I through III), under which the requirements of 10 CFR Part 20 must be met; and 2) such other postulated unlikely, but credible, natural or man-induced events (Class IV), under which the controlled-use-area reference-dose requirements must be met. In response to your second recommendation, the staff will modify the rule or supplementary information, as appropriate, to enunciate more clearly the goal of worker protection. This would be accomplished in the context of the revised definition of "important to safety," rather than in the discussion of the "controlled-use area."

The Committee has correctly noted a previous commitment to use rulemaking to resolve a number of key issues related to the licensing of a high-level radioactive waste repository. Identification of topics for rulemakings is being accomplished through the Division of High-Level Waste Management's Systematic Regulatory Analysis (SRA) process. To date, the SRA has identified two areas for rulemaking. The first is the Design Basis Events Rule, and the second is the relationship between the 10 CFR 60.122 adverse conditions, and

the performance objectives of 10 CFR 60.112 and 60.113. The staff is also proceeding with evaluations of other identified regulatory issues, to determine those most appropriate for rulemaking action.

Original Signed By:
James M. Taylor

James M. Taylor
Executive Director
for Operations

cc: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque
SECY
OGC

Concurred by E. Kraus 8/06/92 via fax

OFC	: HLPD	: HLPD	: HLG	: HLWM	: HLWR	: PMA
NAME	: PAltomare	: JHolovich	: RBal	: JLinahan	: JYoungblood	: AEiss
DATE	: 08/12/92	: 08/12/92	: 08/12/92	: 08/17/92	: 08/17/92	: 08/17/92
OFC	: OGC	: IMNS	: NMSS	: NMSS	: EDO	: EDO
NAME	: STreby	: R Cunningham	: GAlotto	: RBernero	: HThompson	: JTaylor
DATE	: 08/13/92	: 08/12/92	: 08/12/92	: 08/15/92	: 08/15/92	: 08/15/92

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EBeckjord, RES CKammerer, SP
AEiss, PMDA NMSS D/O r/f
TMurley, NRR JScinto, OGC
DMorris, EDO AJordan, AEOD
BLynn, HLWM

ENCLOSURE 10
PUBLIC ANNOUNCEMENT

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

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

At the same time, the Commission is denying a petition for rulemaking submitted by the Department of Energy which specified somewhat different approaches to address many of the same issues addressed by the proposed amendments.

The purpose of the proposed amendments is to clarify existing requirements that govern the protection of workers and the public from radiation under normal and accident conditions in a manner consistent with other NRC regulations which govern similar types of facilities.

As proposed, the amendments would:

- 1) Change the definition of "important to safety" from the existing radiation dose-related definition to a functional definition which would make structures, systems and components "important to safety" subject to quality assurance and special design requirements if they have or affect the function of: (a) maintaining the conditions to store high-level radioactive waste safely; (b) preventing or mitigating damage to high level waste or high-level radioactive waste containers; or (c) providing

reasonable assurance that high-level waste can be received, handled, packaged, stored, and retrieved without undue risk to the health and safety of the public.

2) Add the definition of the term "design bases." This would be identical to the definition for the same term contained in the NRC's regulations which govern the construction and operation of monitored retrievable storage facilities for spent fuel.

3) Add a definition of "design basis events" that specifies two categories of events--those events that are reasonably likely to occur before permanent closure of a repository and, second, other natural and man-induced events that are considered unlikely but sufficiently credible to warrant consideration and are postulated because their consequences could result in maximum potential impacts on the environs of the geologic repository operations area.

4) Replace the terms "normal operations", "anticipated operations occurrences" and "accidents" with the term "design basis events".

5) Establish a requirement for a controlled-use area, similar to the requirement in the regulations governing a monitored retrievable storage facility, in which public access can be controlled. The size of the controlled-use area would be determined by calculations which would assure that the radiation doses to persons located on or beyond its boundaries would not exceed specified doses.

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 11
DRAFT CONGRESSIONAL LETTERS



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

DRAFT

The Honorable Bob Graham, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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

The Nuclear Regulatory Commission is proposing to amend 10 CFR Part 60, its regulation governing the disposal of high-level radioactive waste in geologic repositories. The proposed rule would clarify the regulatory requirements for considering "design basis events," to meet standards for protection against radiation. Part 60 would be amended to include a "controlled-use area" and a controlled-use-area-boundary reference dose, similar to regulatory requirements presently contained in 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste." Part 60 would further be amended to define "important to safety" in a manner consistent with Part 72. These proposed amendments are necessary to provide clarity and consistency in the Commission's regulations.

The proposed rule will resolve issues raised by DOE in a rulemaking petition, PRM-60-3, in a manner compatible with the Commission's regulations for protection of public health and safety. Accordingly, DOE's petition is denied.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:

1. Proposed Amendment to 10 CFR Part 60
2. Denial of DOE Petition for Rulemaking

cc: The Honorable Alan K. Simpson



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

DRAFT

The Honorable Philip Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 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. Denial of DOE Petition for Rulemaking

cc: The Honorable Carlos J. Moorhead



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

DRAFT

The Honorable Peter H. Kostmayer, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington D.C. 20515

Dear Mr. Chairman:

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

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:

1. Proposed Amendment to 10 CFR Part 60
2. Denial of DOE Petition for Rulemaking

cc: The Honorable John J. Rhoades