

*Rec'd with letter dated
3/15/95* [7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR PART 60

[Docket No. PRM-60-3]

DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES

AGENCY: U.S. Nuclear Regulatory Commission

ACTION: Partial Grant/Partial Denial of Petition for Rulemaking

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

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

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

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SUPPLEMENTARY INFORMATION:

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

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

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

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

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

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

Dated in Rockville, Maryland, this 15th day of March, 1995.

For the Nuclear Regulatory Commission



John C. Hoyle
Secretary of the Commission

NUCLEAR REGULATORY COMMISSION

10 CFR Part 60

RIN: 3150-AD51

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

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

DATE: Comments must be submitted on or before _____, 1995, [90 days from date of publication in the Federal Register]. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

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

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

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

SUPPLEMENTARY INFORMATION:

Background

Under the Nuclear Waste Policy Act of 1982, as amended, the U.S. Nuclear Regulatory Commission exercises licensing and related regulatory authority with respect to geologic repositories that are to be constructed and operated by the U.S. Department of Energy (DOE) for the disposal of high-level radioactive waste. The Commission's regulations pertaining to these geologic repositories appear at 10 CFR Part 60. In recent

years, NRC, in conjunction with its Federally-Funded Research and Development Center (the Center for Nuclear Waste Regulatory Analyses), completed a comprehensive review of the requirements of Part 60, regarding their clarity and sufficiency to protect public health and safety. NRC focused particular attention on any matters that may be ambiguous, insufficient for their intended purpose, or inconsistent with other expressions of its regulatory policy. The amendments presented in this proposed rule deal with a matter that was brought to light by this review and by a petition for rulemaking (PRM) filed by DOE (PRM-60-3).

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

desirable, it would be useful to review the pertinent provisions of existing Part 60. In this review and in subsequent discussions in this notice, unless the specific context suggests otherwise, the terms "provisions," "requirements," "standards," and "criteria" are generally used interchangeably; the term "limit" (as in "dose limit") is generally used to refer to a specific type of requirement or criterion; and the term "rule" is generally used to refer to the entire set of requirements or criteria (e.g., Part 60).

The Existing Rule

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

levels that are well within the bounds of risks accepted in other productive activities in society; and requirements for radiation safety programs and procedures and emergency plans. The Commission's radiation protection standards are codified in 10 CFR Part 20.

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

facilities most similar to a repository, during the repository's operational period. These concerns are discussed in turn.

"Important-to-Safety" Definition

The regulation states (10 CFR 60.2):

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

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

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

Performance Objective for Radiation Protection

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

Protection against radiation exposures and releases of radioactive material. The geologic repository operations

area shall be designed so that until permanent closure has been completed, radiation exposures and radiation levels, and releases of radioactive materials to unrestricted areas, will at all times be maintained within the limits specified in Part 20 of this chapter....

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

facilities regulated by the Commission under 10 CFR Parts 50 and 72, (i.e., at commercial power reactors and ISFSIs, respectively).

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

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

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

Category 1 events have typically been referred to in the rules and guidance documents (e.g., regulatory guides) for Commission-regulated facilities (nuclear power plants, MRS installations, geologic repositories) as those conditions resulting from "normal operation, including anticipated operational occurrences." Anticipated operational occurrences, including those of natural origin, are those conditions expected to occur one or more times during the lifetime of the facility.

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

necessary to protect public health and safety. Notwithstanding the general applicability of these regulations to all operational situations, it is not the Commission's intent that these requirements apply to Category 2 events as a design basis for the facility. Appropriate requirements other than the dose limits of Part 20 would be provided as the design basis for Category 2 events. Some of the confusion about this matter is no doubt linked to the terminology used in various Commission rules or guidance documents, where the terms "accidents" and "anticipated operational occurrences" may have been used interchangeably. It should be recognized that some "accidents" may, indeed, be "anticipated operational occurrences," if they are expected to occur one or more times during the lifetime of the facility. What is important, in this regard, is not the term applied to the event, but its expected frequency of occurrence, to determine both its category and whether Part 20 limits should apply as a design basis.

Although the foregoing discussion may help to clarify the Commission's intent regarding the applicability of Part 20 limits to Categories 1 and 2 design basis events, it leaves open the question about the adequacy, to protect public health and safety, of the requirements of Part 60 for Category 2 events. The Commission now proposes to address this matter by harmonizing the requirements of Part 60, as appropriate, with other parts of its regulations - particularly Part 72, which applies to facilities

(MRS installations) with much in common with repositories, during their operational period. In this regard, the character and design of the features of an MRS installation would be expected to be very similar to the surface facilities of an operating repository. Further, the same kind of functional activities would be performed at both types of facilities, namely, receiving, handling, packaging, storing, and retrieving high-level radioactive waste. As such, the Commission believes that greater consistency between Part 60 and Part 72 is both logical and desirable.

10 CFR Part 72

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

"Structures, systems, and components important to safety" mean those features of the ISFSI (independent spent fuel storage installation) or MRS (monitored retrievable storage installation) whose function is:

(1) to maintain the conditions required to store spent fuel or high-level radioactive waste safely;

(2) to prevent damage to the spent fuel or the high-level radioactive waste container during handling and storage; or

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

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

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

system, or component must meet its functional goals. The values for controlling parameters for external events include: (1) estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved and (2) estimates of severe external man-induced events to be used for deriving design bases that will be based on analysis of human activity in the region taking into account the site characteristics and the risks associated with the event. (10 CFR 72.3.)

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

numerical limits set out in Part 20 will generally be met for Category 1 design basis events, consistent with the general practice (as previously discussed) of the Commission in the application of these standards.

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

character to the existing Part 60 definition would be more suitable for the licensing of a more complex repository.

In the foregoing discussion, the Commission cited the requirements of 10 CFR 72.106, which include provisions for the establishment of a "controlled area" boundary and dose criteria for limiting exposures to individuals at or beyond that boundary, during design basis accidents. The Commission notes that corresponding requirements are not provided in Part 60 which, in turn, raises questions about the adequacy of the criteria in Part 60 to ensure protection of public health and safety.

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

for the design criteria for the GROA in Part 60 is somewhat different from the corresponding structures in Parts 72 and 50.

The design criteria for the GROA are provided in §§ 60.130 through 60.134 and include criteria for both preclosure considerations (i.e., criteria for features "important to safety"), as well as postclosure interests (i.e., criteria for features "important to waste isolation"). However, only the criteria of § 60.131(b) are identified as "structures, systems, and components important to safety," and it is unclear if other criteria specified in §§ 60.131(a), 60.132, and 60.133, for operational considerations, are also "important to safety." In this regard, the Commission notes that there are some "important-to-safety" criteria in Part 72 that are not designated as such, in a corresponding manner, in Part 60. Although the Commission recognizes that this lack of consistency may be due, in part, to the dual interests, in Part 60, of preclosure safety and postclosure isolation, the Commission also believes that this structure may contribute to the difficulty in determining which features of the GROA are "important to safety" and subject to the quality assurance provisions of Subpart G.

The Petition for Rulemaking

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

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

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

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

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

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

Discussion

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

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

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

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

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

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

Based on the foregoing discussion of DOE's petition and the interest of greater consistency between Part 60 and Part 72, as previously discussed, the Commission proposes to amend Part 60 to ensure the adequacy of its requirements to protect the public health and safety. In this regard, dose limits are proposed, in the rule, for protection of members of the public, during Category 1 and Category 2 design basis events, and for protection of workers, during Category 1 design basis events. The Commission notes that dose limits are not proposed for protection of workers during Category 2 design basis events, consistent with the policy in practice for facilities regulated by the Commission under Parts 50 and 72.

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

There is one other matter the Commission would like to note in relation to this action. During the course of consideration of the DOE PRM and development of the amendments as proposed herein, the Commission identified an additional regulatory uncertainty with respect to Part 60 requirements. Specifically, while Part 60 includes a definition for structures, systems, and components "important to safety," there is no corresponding definition in the rule for structures, systems, and components "important to waste isolation." These definitions are important as they are the predicates for required design and quality assurance requirements in the rule. However, the focus of the amendments proposed in this action is strictly in relation to the adequacy of Part 60 requirements to protect public health and

safety during the operational period of the repository. Recognizing that the lack of a definition for "important to waste isolation" relates solely to the period of isolation following permanent repository closure, the Commission plans to address this matter separately in a subsequent rulemaking action.

The proposed amendments are discussed below.

Section-by-Section Analysis

Section 60.2. Definitions.

The proposed amendments involve eight definitions needed in Part 60.

The term "preclosure controlled area" is new. It is essentially the same as the term "preclosure control area" proposed by DOE in its petition (PRM-60-3) and corresponds closely to the term "controlled area," as defined in 10 CFR 72.3. The term "preclosure controlled area" is proposed because Part 60 already refers to a "controlled area" (within which waste isolation is to be ensured after permanent closure). The function of the new term is to delimit an area over which the licensee exercises control of activities to meet regulatory requirements. Control includes the power to exclude members of the public, if necessary. Because Part 60 (unlike Part 72)

involves ongoing underground operations and timeframes of concern over centuries and millennia, language in the proposed definition is included that, consistent with its function, limits the area to the surface and limits the duration to the period up to, and including, permanent closure.

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

The term "important to safety" would be amended to address the issues previously discussed. The existing provision is unclear and fails to ensure proper levels of protection of public and worker health and safety for the broad range of conditions or events that might occur at a repository site. This is an important term, because it is the predicate for required design features, as well as required quality assurance measures that provide defense-in-depth. The Commission proposes to retain the quantitative features of the existing definition, but specify different numerical limits for each of the two categories (1 and

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

Although the term "design bases" appears in existing Part 60, in 10 CFR 60.21(c)(2), it was not defined. As the discussion above makes clear, "design bases" should be understood in relation to that range of events, including external natural or man-induced events, that is taken into account in the design, and, in particular, in relation to conditions that could result in radiological consequences beyond specified limits. The definition in Part 72 would be inserted, without change, into the list of defined terms in 10 CFR 60.2.

The inclusion of a definition of "design basis events" serves two purposes. First, it identifies a set of events (referred to elsewhere as Category 1 design basis events) that must be taken into account in demonstrating compliance with the requirement to show, with reasonable assurance, that the provisions of Part 20 will be met. (This set of events is described as "...those natural and human-induced events that are

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

Section 60.8. Information collection requirements:

OMB approval.

NRC is proposing to update 10 CFR 60.8, "Information Collection Requirements: OMB Approval," to reflect the fact that subsequent to the original issuance of Part 60, NRC requested, and obtained Office of Management and Budget (OMB) approval for

the Part 60 "Information Collection Requirements." Section 60.8 was to be corrected the first time other revisions were made.

Section 60.21. Content of application.

The petition for rulemaking suggested that provision for accident analysis might be accomplished by amendment of 10 CFR 60.111. The Commission proposes, instead, to provide for an accident analysis as part of the content of the application section (i.e., 10 CFR 60.21). The proposed language would require the application to address the potential dose, to an individual on or beyond the preclosure controlled area boundary, that is attributable to Category 2 design basis events. The procedure that is envisaged is that the applicant would address the critical design basis events, singly, and demonstrate, by its analysis, that the doses on or beyond the preclosure controlled area boundary would be in accordance with the applicable requirements. The proposed language serves the same purpose as the counterpart section of Part 72 (namely 10 CFR 72.24(m)).

The proposed rule also reflects the position, as discussed previously, that the applicant must demonstrate that the requirements of Part 20 will be met, assuming the occurrence of Category 1 design basis events. For this analysis, the applicant would consider Category 1 design basis events singly, or in appropriate combinations. The doses, exposures, or releases must

be kept within Part 20 limits should less likely events (e.g., moderately frequent events) occur in combination with events that occur regularly.

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

Section 60.43. License specification.

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

Section 60.46. Particular activities requiring license amendment.

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

Section 60.51. License amendment for permanent closure.

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

Section 60.102. Concepts.

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

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

Consistent with the petitioner's proposal, the Commission would delete the phrase "at all times" from the performance objective of § 60.111(a). This change would clarify that this requirement does not apply to radiation exposures, levels, and releases from Category 2 design basis events.

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

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

Section 60.122. Siting criteria.

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

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

The Commission proposes to modify the title of this section to the term "General Considerations" and add clarifying language, to the existing discussion, to indicate that §§ 60.131 through 60.134 specify the minimum criteria for the design of those structures, systems, and components important to safety, or important to waste isolation. These changes are necessary to provide consistency with the modified definition of "important to safety" (10 CFR 60.2) as well as to clarify the purpose of these criteria. These changes will also provide consistency with the corresponding "minimum" design criteria, for an MRS, in 10 CFR Part 72.

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

Consistent with the modifications to § 60.130, as described above, the Commission would delete the reference to "Structures, systems, and components important to safety," in the title of

§ 60.131(b), and re-letter or re-number the current criteria in §§ 60.131(b)(1) through 60.131(b)(10), as appropriate. This change would eliminate the confusion in the existing rule related to the identification of only the criteria in § 60.131(b) as "important to safety." It would also resolve the present incongruity with § 60.131(b)(7), "Criticality control," regarding the reference to waste "isolation" (a postclosure term) in the requirement.

The current rule employs the term "normal and accident conditions," or similar expression, in several places. However, the conditions that must be addressed under this language are not well-defined. The Commission proposes to remedy this situation by replacing current terminology with references to "design basis events," thereby ensuring that the design appropriately takes into account the consequences of all design basis events (i.e., as discussed in this document, Category 1 and 2 design basis events). Accordingly, modification of paragraphs (b)(5)(i), (b)(7), and (b)(8) is being proposed for this section. The Commission would also revise the language in 10 CFR 60.131(b)(1), which refers to "anticipated" natural phenomena and environmental conditions, so as to encompass all design basis events. The "necessary safety functions" that must be accommodated in the design, pursuant to that paragraph, include whatever is necessary to meet the quantitative limits set

out in the Commission's rules (i.e., in 10 CFR 60.111(a) and 10 CFR 60.136).

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

Section 60.132(c)(1) requires that the surface facilities must be "...designed to control the release of radioactive materials in effluents during normal operations so as to meet the performance objectives of § 60.111(a)." As indicated previously, the design should ordinarily be sufficiently conservative so as to provide reasonable assurance of meeting Part 20 not only during normal operations, but even for events that are likely to occur moderately frequently or one or more times before permanent closure of the geologic repository (i.e., all Category 1 design basis events). Deleting the phrase "during normal operations," as proposed, will broaden the scope of this provision to reflect the Commission's intent more accurately.

Section 60.133. Additional design criteria for the underground facility.

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

Section 60.136. Preclosure controlled area.

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

accounts for exposures via the ingestion and inhalation dose pathways.

Modification of the 0.05-Sv (5-rem) dose limit, to reflect the Part 20 system of dose limits, results in a family of dose limits: a TEDE of 0.05 Sv (5 rem); or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem); an eye dose equivalent of 0.15 Sv (15 rem); and a shallow dose equivalent, to skin, of 0.5 Sv (50 rem).¹ The eye and skin dose limits are adequate to ensure that no observable effects (e.g., induction of cataracts in the lens of the eye) will occur as a result of any accidental radiation exposure. In implementing this provision, dose calculations should be made solely with reference to the consequence of the specific Category 2 design basis event, and not cumulatively with other design basis events. To clarify this matter further, the analysis of a specific Category 2 design basis event would require an analysis of an event sequence or scenario which includes an initiating event (e.g., an earthquake) and the associated combinations of repository system or component failures that can potentially lead to exposure of the public to radiation. An example sequence is a postulated earthquake (the initiating event) which results in the failure of a crane lifting

¹Radiation exposure terminology is as used in Part 20 (56 FR 23360; May 21, 1991).

a spent fuel waste package inside a waste handling building, the drop and breach of the waste package, damage to the spent fuel and partitioning of a fraction of the radionuclide inventory to the building atmosphere, failure of the building filtration system, and public exposure to the released radioactive material.

The only other noteworthy deviation from Part 72 (specifically 10 CFR 72.106) would be to refer to doses attributable to any "design basis event" instead of any "design basis accident." The term "design basis event" is used because it is a defined term in Part 60. The change in terminology is not intended to be one of substance as a design basis accident is the consequence of some design basis event.

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

nuclear power plants.² Moreover, the proposed dose limit is consistent with the accident-dose value (0.05 Sv [5 rem] effective dose equivalent) proposed by DOE in its PRM.

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

Based on estimates provided by the National Council on Radiation Protection and Measurements (NCRP)³ the lifetime risk to individuals in the general population is 0.05 fatal cancers per Seivert (Sv) of exposure. Therefore, the lifetime risk of fatal cancer from an assumed 0.05 Sv (5 rem) exposure resulting from a postulated Category 2 design basis event is 0.0025 (i.e., 2.5×10^{-3}) per individual exposed. While this assessment

² NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," June 1987.

³ National Council on Radiation Protection and Measurements, "Risk Estimates for Radiation Protection," NCRP Report No. 115, December 31, 1993.

provides perspective on the risk associated with a hypothetical exposure of a 0.05 Sv (5 rem) dose, it does not provide perspective on the estimated actual risk associated with the spectrum of possible Category 2 design basis events at a repository during its operational lifetime (estimated to be about 100 years).

Perspective on actual risk must include consideration of the frequencies (i.e., probabilities) of occurrence of these events, as well as their consequences, as "risk" is defined as the probability of an event times its consequences. With respect to the range of probabilities of Category 2 design basis events, the upper bound is roughly 1×10^{-2} per year (i.e., event scenarios with probabilities of occurrence greater than 1×10^{-2} per year would generally be considered to be Category 1 events) and the lower bound is considered to be on the order of 1×10^{-9} per year (i.e., event scenarios with probabilities of occurrence less than 1×10^{-9} per year would generally be screened from further consideration due to their negligible contribution to overall risk). Accordingly, assuming event consequences equivalent to the proposed 0.05 Sv (5 rem) dose limit for Part 60, the hypothetical upper bound on individual risk is 2.5×10^{-5} fatal cancers per year. To put this risk in perspective, the International Commission on Radiological Protection⁴ notes that,

⁴ Recommendations of the International Commission on Radiological Protection. ICRP Publication 26, January 1977.

based on a review of information related to risks regularly accepted in everyday life for stochastic phenomena, a fatal cancer risk in the range of 1×10^{-6} to 1×10^{-5} per year from exposure to radiation would likely be acceptable to individual members of the public. Thus, while the risk associated with repository event consequences at the proposed dose limit and bounding probability of occurrence exceeds this range by a small factor, and is at a level that the Commission considers safe for occupational exposures, the Commission believes this result significantly overestimates the actual risk of an operating repository.

Perspective on actual repository risk can be obtained by developing an understanding of the spectrum of potential Category 2 design basis events and estimating the consequences of these events as well as their probabilities of occurrence. In this regard, the Commission recognizes that there is no high-level waste repository operating experience and that only conceptual designs have been developed for these facilities. Nonetheless, some perspective can be gained from the preliminary risk assessment by DOE⁵ of a conceptual design for a repository

⁵ U.S. Department of Energy, "Site Characterization Plan, Yucca Mountain Site, Nevada Research and Development Area, Nevada," DOE/RW-0199, December 1988.

at Yucca Mountain, Nevada, as well as from consideration of risk assessments of selected U.S. nuclear power plants.⁶

Consistent with risk assessments for nuclear power plants, the spectrum of possible repository design basis events includes both internally and externally initiated events. Internally initiated events would include waste transporter collisions, crane failures or other types of fuel assembly, waste package or cask drop events, building or facility exhaust filter fires, and exhaust filter bypass or failure. Externally initiated events would include those resulting from earthquakes, tornados, and flooding. Regardless of the type or nature of the initiating event, the Commission believes that, for several reasons, both the variety of credible event sequences and the resulting potential consequences to members of the public will be somewhat limited at repository facilities. First, in comparison with a nuclear power plant, an operating repository is a relatively simple facility in which the primary activities are in relation to waste receipt, handling, storage, and emplacement. A repository does not require the variety and complexity of systems necessary to support an operating nuclear power plant. Further, the conditions are not present at a repository to generate a radioactive source term of a magnitude that, however unlikely, is potentially capable at a nuclear power plant

⁶ NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," December 1990.

(e.g., from a postulated loss of coolant event). As such, the estimated consequences resulting from limited source term generation at a repository would be correspondingly limited. This conclusion is consistent with the results of the aforementioned preliminary risk assessment by DOE of a conceptual repository design at Yucca Mountain, Nevada. In that assessment, the DOE considered 149 scenarios for a variety of internally and externally initiated events. Of the 149 scenarios, only 7 resulted in offsite doses in excess of 0.005 Sv (0.5 rem) to the critical organs of a maximally exposed individual and also had associated probabilities of occurrence greater than 1×10^{-9} per year. The highest estimated offsite dose from the DOE risk assessment was 0.021 Sv (2.1 rem) with an associated probability of occurrence of 5×10^{-7} per year.

The dose estimates of the DOE risk assessment are only reflective of a conceptual design for a repository at Yucca Mountain, Nevada. Nonetheless, the Commission believes they provide perspective on the magnitude of the estimated consequences to members of the public from postulated Category 2 design basis events and that variations in repository design or site selection would not likely vary these estimates by more than order of magnitude. The results of the DOE risk assessment also provide some perspective on the estimated probabilities of occurrence of the postulated repository design basis events and, as such, perspective on actual risk from an operating repository.

In general, the Commission would expect the potential higher consequence events to have correspondingly lower probabilities of occurrence. This expectation is consistent with the results of the DOE risk assessment as the estimated probabilities of occurrence for the 7 scenarios which resulted in offsite doses in excess of 0.005 Sv (0.5 rem) vary from 1×10^{-9} to 5×10^{-6} per year. The corollary to the above is the expectation that higher frequency events would have correspondingly lower offsite consequences and perspective on actual risk from an operating repository necessitates consideration of these events as well as lower frequency events. Review of the DOE risk assessment indicates that some higher frequency, but lower consequence, events are just as important to actual risk as the lower frequency, but higher consequence, events. With respect to actual risk from the broad spectrum of all events considered in the DOE risk assessment, the estimated actual risk of an operating repository is roughly two to three orders of magnitude lower than the range of fatal cancer risks that would likely be acceptable to members of the public (i.e., a fatal cancer risk of 1×10^{-6} to 1×10^{-5} per year as noted in ICRP Publication 26).

With respect to the appropriateness of the proposed 0.05 Sv (5 rem) dose limit for Part 60 as the design basis for protection

of public health and safety from Category 2 design basis events, the DOE risk assessment indicates the potential for events with offsite consequences on the order of several hundredths to several tenths of Sv (several rem to several tens of rem), depending on design and siting factors. The event consequences in this range, coupled with the estimated event probabilities of occurrence, result in estimated risks that would likely be acceptable to members of the public. However, given the lack of repository design, siting and operating experience and the supporting data base for probabilistic risk assessment, the Commission believes there is considerable uncertainty in the estimates of both the consequences and the probabilities of occurrence of postulated Category 2 design basis events. As such, the Commission believes that establishing a dose limit in Part 60 to the proposed 0.05 Sv (5 rem) value would provide an adequate margin of safety and an appropriate design basis for protection of members of the public from unlikely, but credible events. Further, the Commission believes that a singular dose limit is appropriate for the broad range of possible event frequencies, given the limited potential for offsite consequences at repository facilities and the significant uncertainties in repository risk assessment. Stated differently, the level of sophistication in repository risk assessment does not presently exist to warrant a more complex set of requirements in Part 60 for protection of public health and safety from postulated Category 2 design basis events. Notwithstanding these views and

the Commission's parallel interest in harmonizing Part 60 and Part 72, the Commission specifically seeks public comment on (1) the appropriateness of the proposed 0.05 Sv (5 rem) dose limit in Section 60.136 as the design basis for protection of public health and safety, and (2) the rationale, as discussed herein, supporting the proposed 0.05 Sv (5 rem) dose limit.

Section 60.183. Criminal penalties.

A conforming change has been made to this section, to include § 60.136 (pertaining to the preclosure controlled area) among the regulations that are not issued under Sections 161b, 161i, or 161o of the Atomic Energy Act, for purposes of section 223 of the Act.

Environmental Impact: Categorical Exclusion

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

Paperwork Reduction Act Statement

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

Regulatory Analysis

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

Regulatory Flexibility Certification

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

Backfit Analysis

NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed rule, because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 60

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, the Nuclear Waste Policy Act of 1982, as amended, and 5 U.S.C. 553, NRC is proposing to adopt the following amendments to 10 CFR Part 60.

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

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

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

2. Section 60.2 is amended by adding definitions of "Design bases," "Design basis events," and "Preclosure controlled area," revising the definitions of "Accessible environment," "Disturbed zone," "Important to safety," and "Site," renaming the defined term "Controlled area" to "Postclosure controlled area," and alphabetizing the definitions to read as follows:

§ 60.2. Definitions.

* * * * *

Accessible environment means: (1) the atmosphere, (2) the land surface, (3) surface water, (4) oceans, and (5) the portion

of the lithosphere that is outside the postclosure controlled area.

* * * * *

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

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

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

Design basis events means: (1) those natural and human-induced events that are reasonably likely to occur regularly, moderately frequently, or one or more times before permanent closure of the geologic repository operations area; and (2) other natural and man-induced events that are considered unlikely, but sufficiently credible to warrant consideration, taking into account the potential for significant radiological impacts on public health and safety.

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

* * * * *

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

* * * * *

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

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

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

* * * * *

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

* * * * *

Preclosure controlled area means that surface area immediately surrounding the geologic repository operations area for which the licensee exercises authority over its use, in accordance with the provisions of this part, until permanent closure has been completed.

* * * * *

Site means the location of the postclosure controlled area.

3. Section 60.8 is revised to read as follows:

§ 60.8 Information Collection Requirements: OMB Approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements of general applicability contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0127.

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

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

§ 60.21. Content of application.

* * * * *

(c) * * *

(1) * * *

(i) The description of the site shall also include the following information regarding subsurface conditions. This description shall, in all cases, include such information with respect to the postclosure controlled area. In addition, where

subsurface conditions outside the postclosure controlled area may affect isolation within the postclosure controlled area, the description shall include such information with respect to subsurface conditions outside the postclosure controlled area to the extent such information is relevant and material. The detailed information referred to in this paragraph shall include:

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

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

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

(D) the hydrogeologic properties and conditions;

(E) the geochemical properties; and

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

(ii) * * *

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

* * * * *

(3) A description and analysis of the design and performance requirements for structures, systems, and components of the geologic repository that are important to safety. The analysis must include a demonstration that -- (i) the requirements of § 60.111(a) will be met, assuming occurrence of Category 1 design basis events; and (ii) the requirements of § 60.136 will be met, assuming occurrence of Category 2 design basis events.

* * * * *

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

* * * * *

§ 60.43 [Amended].

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

* * * * *

§ 60.46 [Amended].

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

* * * * *

§ 60.51 [Amended]

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

* * * * *

§ 60.102 [Amended].

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

* * * * *

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

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

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

* * * * *

§ 60.121 [Amended].

* * * * *

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

* * * * *

§ 60.122 [Amended].

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

* * * * *

12. Section 60.130 is revised to read as follows:

§ 60.130 General considerations.

Pursuant to the provisions of § 60.21(c)(2)(i), an application to receive, possess, store, and dispose of high-level radioactive waste in the geologic repository operations area must include the principal design criteria for a proposed facility. The principal design criteria establish the necessary design, fabrication, construction, testing, maintenance, and performance requirements for structures, systems, and components important to safety and/or important to waste isolation. Sections 60.131 through 60.134 specify minimum requirements for the principal design criteria for the geologic repository operations area. These design criteria are not intended to be exhaustive, however. Omissions in §§ 60.131 through 60.134 do not relieve DOE from any obligation to provide such features in a specific facility needed to achieve the performance objectives.

* * * * *

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

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

* * * * *

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

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

(d) Protection against fires and explosions. (1) The structures, systems, and components important to safety shall be designed to perform their safety functions during and after credible fires or explosions in the geologic repository operations area.

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

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

(4) The geologic repository operations area shall be designed to include means to protect systems, structures, and

components important to safety against the adverse effects of either the operation or failure of the fire suppression systems.

(e) Emergency capability.

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

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

(f) Utility services.

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

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

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

(g) Inspection, testing, and maintenance. The structures, systems, and components important to safety shall be designed to permit periodic inspection, testing, and maintenance, as necessary, to ensure their continued functioning and readiness.

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

(i) Instrumentation and control systems. The design shall include provisions for instrumentation and control systems to

monitor and control the behavior of systems important to safety, assuming occurrence of design basis events.

(j) Compliance with mining regulations. To the extent that DOE is not subject to the Federal Mine Safety and Health Act of 1977, as to the construction and operation of the geologic repository operations area, the design of the geologic repository operations area shall nevertheless include such provisions for worker protection as may be necessary to provide reasonable assurance that all structures, systems, and components important to safety can perform their intended functions. Any deviation from relevant design requirements in 30 CFR, Chapter I, Subchapters D, E, and N will give rise to a rebuttable presumption that this requirement has not been met.

(k) Shaft conveyances used in radioactive waste handling.

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

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

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

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

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

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

(c) Radiation control and monitoring.

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

* * * * *

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

§ 60.133 Additional design criteria for the underground facility.

* * * * *

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

* * * * *

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

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

Preclosure Controlled Area

§ 60.136 Preclosure controlled area.

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

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

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

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

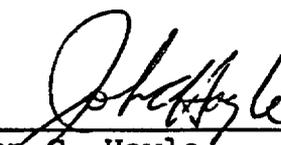
§ 60.183 Criminal penalties.

* * * * *

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

Dated in Rockville, Maryland, this 15th day of March, 1995.

For the Nuclear Regulatory Commission.



John C. Hoyle
Secretary of the Commission