REGULATORY ANALYSIS

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

MARCH 19, 1996

1. STATEMENT OF PROBLEM

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

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

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

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

2. OBJECTIVE

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

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

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

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

3. ALTERNATIVES

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

3.1 No Action

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

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

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

This alternative is not recommended.

3.2 Regulatory Guidance

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

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

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

3.3 Rulemaking - Combined Elements of DOE Petition and NRC Initiative

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

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

4. CONSEQUENCES OF RECOMMENDED ALTERNATIVE

4.1 Impact on Public

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

4.2 Impact on DOE

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

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

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

4.3 Impact on NRC

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

4.4 Impact on Other Requirements

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

4.5 Constraints

There are no known constraints to implementing the recommended action.

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[8]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.

5. DECISION RATIONALE

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

The rulemaking is the final action on this subject.

6. IMPLEMENTATION

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

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

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