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MEMORANDUM FOR: Robert M. Bernero, Director Office of Nuclear Material Safety and Safeguards

FROM: Robert E. Browning, Director Division of High-Level Waste Management Office of Nuclear Material Safety and Safeguards

SUBJECT: REQUEST FOR APPROVAL OF STAFF PAPER

In accordance with the Office of Nuclear Material Safety and Safeguards (NMSS) Policy and Procedures Letter 1-39, the Division of High-Level Waste Management (HLWM) is forwarding for your approval a staff paper to be presented at Waste Management '91. The paper is entitled "The NRC Regulatory and Safety Philosophy as Applied to the Design of a High-Level Waste Repository." Overall, the paper discusses the Commission's basic design approach for nuclear facilities including the defense-in-depth approach and multiple barrier concept, and then describes how these will be applied to the staff review of a high-level nuclear waste repository. Because the paper discusses policy considerations previously documented by the Commission, it requires approval by the Office or Deputy Office Director.

A final version of the paper needs to be provided to the conference by February 1, 1991. Therefore, any comments or suggestions you may have should be provided to HLWM by January 11, 1991. The paper will be presented by Mr. Joe Holonich of HLWM. It has been coordinated with and reviewed by the Office of the General Counsel.

Original Signed by Robert E. Browning

Robert E. Browning, Director Division of High-Level Waste Management Office of Nuclear Material Safety and Safeguards

Enclosure: As Stated

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"The NRC Regulatory and Safety Philosophy as Applied to the Design of a High-Level Waste Repository" by Joseph J. Holonich U.S. Nuclear Regulatory Commission

Abstract

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This paper provides insight to the U.S. Nuclear Regulatory Commission's (NRC's) overall regulatory and safety philosophy. Although this philosophy has been applied by the NRC in previous reactor and special nuclear material licenses, it has not been applied to a high-level nuclear waste (HLW) repository. In this paper, the basic NRC policy is discussed then extrapolated for application in the repository program.

Introduction

In licensing the HLW repository, the NRC's strategy involves an approach that is consistent with its general licensing philosophy; the safe operation of any nuclear facility is the responsibility of the licensee. The NRC's implementation of this philosophy in the HLW program has been to emphasize that it is the responsibility of the U.S. Department of Energy (DOE) to conduct the necessary site investigations, develop the repository design and demonstrate that the proposed repository meets all applicable requirements, and then to safely construct and operate the repository.

At present, the NRC staff is providing pre-licensing consultation with DOE on the proposed repository site. With these early consultations, the staff is providing DOE with guidance to help ensure that DOE is proceeding in an acceptable manner and to help DOE produce a high-quality License Application (LA). A high-quality LA is needed so that the staff can expeditiously review it and conform to the statutory, three-year licensing schedule. In licensing a repository, NRC must be satisfied that (1) the repository design is safe and consistent with its requirements, (2) the repository is constructed using sound practices, and (3) the repository is operated in a safe and reliable manner.

Although the NRC has and will maintain the same regulatory philosophy in reviewing the design of the HLW repository as it does in other licensing actions, many of the participants in the DOE program have not had previous involvement in the NRC licensing process. Therefore, these organizations and individuals may not appreciate how the NRC undertakes its mission and what approach it uses in conducting the necessary reviews and eventually inspections of the repository. And, they may not fully understand what the NRC expects of them as participants in the program. This paper will give some perspectives on how the NRC regulates, and what it expects of applicants and licensees.

ENCLOSURE

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Basic Design Philosophy

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Overall, the NRC has established a defense-in-depth design approach for nuclear facilities. Basically, this approach consists of three mutually reinforcing echelons of defense to prevent a serious accident from affecting the public. These three echelons are: (1) design for safety in normal operation, providing tolerance for system malfunction; (2) assume that incidents will occur and include safety systems in the facility to minimize damage and protect the public; and (3) provide provisions of additional safety systems to protect the public based on the evaluation of assumed, unlikely accidents.

In general, these three echelons are successive and mutually reinforcing, and are established to help the NRC ensure the safe design of nuclear facilities. The first level of the defense-in-depth concept requires that NRC licensed facilities be soundly and conservatively designed with a high degree of freedom from faults and errors. The selected design must be inherently stable and have a high tolerance for possible system malfunctions.

NRC established the second echelon on the assumption that failures or operating errors will occur during the lifetime of the facility. To address these potential failures, the NRC's position is to require safety systems to prevent or mitigate the consequences from such failures. Implementation of this objective is achieved through a number of different means some of which include conservative designs, adequate safety margins, and redundancy in design.

The third echelon of defense complements the first two by requiring features that provide additional margins to protect the public against unlikely accidents. The objective of this echelon is demonstrated by incorporating design features that provide an additional margin of safety to protect against design basis accidents. Design basis accidents are accidents that can be postulated to occur, but are unlikely. The effectiveness of these design features is then determined by assuming the design basis accident, and evaluating the facility's response to see if the consequences of such accidents are minimized.

Considered in the defense-in-depth approach is the use of multiple barriers to attempt to prevent the release of radiation to the environment. The multiplebarrier approach is a cornerstone of NRC's safety philosophy. It has been implemented in the licensing of all nuclear facilities. An example of the multiple barrier concept for reactors involves the design of a stable fuel form, the use of fuel cladding, a reactor coolant system, and a containment building. By using multiple barriers, the NRC has established the use of redundancy before radiation can be released to the environment.

As I will discuss later in this paper, the basic concepts embodied in the defense-in-depth approach and the use of multiple barriers also applies to the licensing of the HLW repository.

NRC Licensing Documents

For the NRC review of the HLW repository, there are a number of principal sources of licensing requirements or documents. First and most important are the statutory requirements, most notably the Atomic Energy Act and the Nuclear Waste Policy Act. Second there is the Code of Federal Regulations, Title 10, Chapter I (10CFR), which contains the regulations promulgated by the NRC. The requirements

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of 10 CFR are broad and general, providing relatively little guidance as to how the prescribed assurance of safety is to be achieved. Therefore, in order to provide guidance on how the staff conducts its review, the NRC staff will issue a number of different guidance documents. All of these documents provide guidance to DOE although only two types, Staff Technical Positions (STPs) and Regulatory Guides, are specifically issued as guidance to the Department. The other two guidance documents are the License Application Review Plan (LARP) and Staff Positions. Both of these provide guidance to the NRC staff in its review of the DOE application. However, DOE should understand and use these documents in preparing the LA since both of these will be used by the staff to judge the adequacy of the LA.

One of the two characteristics which differentiate guidance documents and 10 CFR is the extent to which compliance with their terms is required. Compliance with 10 CFR is mandatory. If 10 CFR cannot be met the only alternative is an exemption. Generally, before the NRC will issue an exemption, an applicant must demonstrate that the 10 CFR requirement would not serve, or is not necessary to achieve the underlying purpose of the rule that is involved. In addition, the regulation requires that exemptions "not endanger life or property or the common defense and security, and are otherwise in the interest of the public."

It should be noted however that the requirements of 10 CFR Part 60, the part pertaining to a geologic repository, offer a large degree of flexibility. For example, 10 CFR 60.113(b) allows DOE the option to propose, and the Commission to approve, some standard other than the nominal ones specified in 10 CFR 60.113(a), the subsystem performance objectives. In the application of 10 CFR 60.113(b), there are a number of factors that must be considered by the Commission before it approves or specifies other values for the subsystem performance objectives of 10 CFR 60.113(a). In determining if other values for the subsystem performance objectives of 10 CFR 60.113(a) could be approved or specified, the Commission will use the particular factors set out in 10 CFR 60.113(b) along with other relevant factors on a case-by-case basis. This flexibility of proposing alternatives to 10 CFR 60.113(a) is different from being granted an exemption from the regulations under 10 CFR 60.6.

The second characteristic that differentiates the NRC regulations in 10 CFR from guidance documents is the degree of technical detail. As noted earlier, the regulations in 10 CFR are very general. Regulatory Guides, STPs, and the LARP are much more detailed and offer specifics as to what can be done to meet the regulations. They present acceptance criteria and methods that the staff would find acceptable for demonstrating compliance with the regulations. However, compliance with them is not required. The approaches presented in these guidance documents are not the only alternatives that may be acceptable. DOE may propose other alternatives as long as it can acceptably demonstrate that the regulation is met.

The fourth and final type of guidance is a Staff Position (SP). SPs contain the staff's interpretation of the regulations. They do not provided detailed guidance on how the regulations can be met. Rather, they are issued as guidance to the NRC staff to use in its review of the DOE program, and offer the staff's interpretation of a specific requirement in 10 CFR Part 60. These positions are not intended as substitutes for the Commission's regulations and are not binding upon the other parties to any licensing proceeding. Like all NRC guidance documents, SPs are available to any interested member of the public.

An example of an existing review plan presently in use is the staff's quality assurance (QA) review plan. This plan provides guidance on the requirements of 10 CFR 60.152 which require compliance with 10 CFR Part 50, Appendix B as applicable. By providing the detailed acceptance criteria in the review plan, the staff is providing information to DOE on what portions of 10 CFR Part 50, Appendix B are considered applicable to the HLW program. Overall, the QA review plan provides information on what the staff will evaluate in its review of the DOE QA program plans.

NRC Review

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In conducting its review, the NRC staff will use each of the regulatory documents described above to determine if the repository design meets the applicable regulations. The review of the LA by the NRC staff and subsequent inspections are done on an audit basis. In other words, the NRC staff will review the information in the higher-level LA. Then the staff will conduct more detailed reviews to ensure that the specific work supports the information provided in the LA. If problems are found in the more detailed reviews, the staff may expand its evaluation to other areas or do more work or request DOE to do more work within that area to determine the extent of the problem. Additionally, the staff will conduct inspections of ongoing construction and operations activities to ensure that they are carried out in a manner consistent with the information provided in the LA.

The reason the NRC staff has confidence in its audit approach is that it places a large amount of emphasis on the quality assurance programs of DOE and its contractors. As with all of its regulations, the NRC QA requirements are broad and allow for a great deal of flexibility in the development of QA programs by DOE and its contractors. This is consistent with the NRC philosophy that it is the responsibility of the applicant or licensee to safely construct and operate its facility. Therefore, it is important that DOE have a sound QA program in place to allow for the proper amount of checks to be done to ensure that all licensing work is quality assured. Even if DOE develops and implements an acceptable QA program, the staff must still conduct its own QA audits to gain additional confidence that the DOE organizations are doing the necessary reviews and taking appropriate corrective actions. Problems identified in other reviews may indicate problems in QA programs. Therefore, as problems are reported from technical reviews and inspections, the NRC staff will evaluate them to determine if they are indicative of problems with the overall QA program.

In its present role of providing pre-licensing consultations, the NRC staff has conducted an evaluation of the DOE and DOE contractor QA program plans (QAPPs). These evaluation were conducted using the QA review plan discussed earlier, and were performed to determine if the QAPPs were acceptable. In addition to reviewing the QAPPs, the NRC staff must also have confidence that the overall program is being acceptability implemented. To this end, the NRC staff is evaluating the implementation of the QA programs by observing the audits of the programs by DOE. These NRC observation audits give the staff an opportunity to judge how effectively the QA programs are being implemented and how well DOE is auditing the programs. Before the NRC staff will find any of the QA programs acceptable, DOE will provide a letter documenting its finding of acceptability for the contractor's program. To date, NRC has agreed with DOE's findings that two contractor programs were acceptable, and four were acceptable subject to some additional actions to be resolved in the near future.

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The NRC staff approach of observing DOE audits rather than conducting independent audits ensures DOE will first pass judgement on the acceptability of any QA programs it wants NRC to accept. This is one example of how the staff is encouraging DOE to take responsibility for ensuring that the repository program is being conducted in an acceptable. Once DOE has accepted the QA programs, if it agrees, the staff will concur with the DOE finding.

NRC's General Safety Policy

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As a final point, I will discuss how the general policy of the Commission relates to the design of the HLW repository. Previously, I mentioned that the Commission's position has been that facilities should be designed to operate as intended with a high degree of reliability and that accidents will be prevented by design features. If accidents occur, the design should include various protective devices and systems, including multiple barriers, so that accidents can be arrested or accommodated safely while protecting the operating staff, the public, and the facility. This safety philosophy is implemented by using a defense-indepth approach, which establishes three successive and mutually reinforcing echelons of protection. Application of this philosophy to the HLW repository is generally the same as it is to any other nuclear facility licensed by the Commission.

First, DOE must design the repository using sound and conservative engineering practices. The facility must be designed to accommodate normal operating conditions as well as anticipated operational occurrences without the possibility of system malfunction. Second, the designer needs to identify the credible accidents and provide design features beyond those needed for normal operation of the facility that will either prevent or mitigate these accidents. These credible accidents are based on assumptions that failures or operating errors will occur during the service lifetime of the facility. In general, DOE should provide additional design or operating features beyond those needed for normal operation to enhance the reliability of the facility such that the consequences from these credible accidents can be prevented or mitigated. It is not good enough to demonstrate that with just normal operating design features the consequences of these accidents do not exceed specific radiation dose limits. Rather, the Commission has promulgated requirements that establish design goals, including additional design features, that would minimize the release of radiation following an accident.

In addition to providing design features to prevent or mitigate accidents, the Commission has also established additional features to provide assurance that the public is protected even in the event of an occurrence of unlikely and unforeseen circumstances. This is the third echelon of protection provided in the defensein-depth approach. It provides for additional margins to protect the public against unlikely accidents. An example of this extra margin is the exclusion area for nuclear power plants or the controlled area for facilities licensed under 10 CFR Part 72. Additional protection is afforded the public by requiring the facility operator to establish a boundary around the facility, the extent of the controlled area being determined in the light of certain reference values. For nuclear power plants, 10 CFR 100.11(a) contains reference values of 25 rem to the whole body or 300 rem to the thyroid. 10 CFR 72.104 has set 5 rem as the value for facilities licensed under that part. 6

It should be emphasized that these are not acceptable design specifications for doses members of the public can receive following an accident, but rather are the values used by the staff to determine the acceptability of the boundary for the controlled areas. Although 10 CFR Part 60 does not presently have a controlled area requirement like the one in 10 CFR Part 72 that is, one that pertains to the operating lifetime of the facility, the NRC staff will address the need and appropriateness of such a requirement both on its own initiative and in response to a pending petition for rulemaking from DOE. It is important to reiterate here that the dose provided in 10 CFR 72.104 is used to determine if the controlled-use area boundary is acceptable. It is not used to evaluate the acceptability of the facility design. Other design specific requirements have been established to determine the acceptability of the design. These design requirements establish the level of safety the Commission believes is necessary to protect the public. This approach will also be applied in the licensing of the repository.

As a final point, I would like to address the Commission's multiple barrier concept as applied to the repository. This application is similar to the approach used for nuclear reactors mentioned earlier. It should be noted that the multiple barrier concept for a reactor is during its operating life, while the multiple barrier concept for a repository is applied following its closure. However, the intent of the concept is the same for both.

In particular, nuclear power plants are designed to have a stable fuel form, cladding around the individual fuel elements, a reactor coolant system to contain any leaks from the fuel cladding, and a containment vessel to contain leaks from the reactor coolant system. Overall, the Commission approach for the HLW repository is to have a stable waste form, a waste package to contain the waste, an underground facility to afford additional protection, and finally a stable geologic environment. To implement the multiple barrier approach, the Commission has established a set of subsystem performance objectives in 10 CFR 60.113(a). These objectives establish performance objectives for the waste package, the engineered barrier system, and the geologic environment. These subsystem performance objectives complement the overall U.S. Environmental Protection Agency standard, which will be included in 10 CFR 60.112. It is not the intent of this paper to address how 10 CFR 60.112 and 60.113 are related.

Specifics of the subsystem performance objectives include the establishment of technical criteria that require that the waste package be designed to contain the waste for 300 to 1,000 years following emplacement. This is the first barrier in the multiple barrier approach. Next, the Commission has established a release rate limit that is intended to require the engineered barrier system to control the release of radionuclides during a 10,000 year period. Finally, the Commission established a 1,000-year groundwater travel time requirement as a measurement of the site's capacity to provide isolation of the wastes from the environment. Thus, each of the subsystem performance objectives listed in 10 CFR 60.113(a) is intended to the measure the effectiveness of some component of the Commission's multiple barriers. As the staff begins to develop specific methods for implementing this rule, it may find that changes need to be proposed. If this is the case, the staff will propose any necessary changes to the Commission.

Conclusion

In this paper I have attempted to discuss several aspects of the NRC's licensing philosophy and process. By discussing and explaining the general approach the NRC takes in implementing its statutory responsibilities, I hope that I have provided insight to all of the participants involved in the HLW program.