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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.

Licensing Documents

For the NRC review of the high-level waste 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, Part 60 (10 CFR Part 60), which contains the regulations promulgated by the NRC. The requirements of 10 CFR Part 60 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 compliance with the regulations can be demonstrated, the NRC will issue a number of different guidance documents. All of these documents provide guidance to DOE although only two types, Staff Technical Positions and Regulatory Guides, are specifically issued as guidance to the Department. The other two guidance documents are the review plans 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 License Application since both of these will be used by the staff to judge its adequacy.

One of the two characteristics which differentiate guidance documents and 10 CFR Part 60 is the extent to which compliance with their terms is required. Compliance with 10 CFR Part 60 is mandatory. If 10 CFR Part 60 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 Part 60 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 Part 60 from guidance documents is the degree of technical detail. As noted earlier, the regulations in 10 CFR Part 60 are very general. Regulatory Guides, Staff Technical Positions, and the License Application Review Plan 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. Staff Positions contain the staff's interpretation of the regulations. They do not provide 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, Staff Positions are available to any interested member of the public.

NRC Review

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 NRC staff will conduct a complete review of the broad level of information in the License Application. Then the staff will conduct more detailed reviews on an audit basis to ensure that the specific work supports the information provided in the License Application. If problems are found in the more detailed reviews, the staff may expand its detailed evaluation to other areas or 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 License Application.

There are two reasons the NRC staff has confidence in this approach. First, in its review, the NRC staff will identify important areas concerning the public health and safety. In these areas, the staff will then conduct a detailed review of all aspects of DOE's programs. By doing this, the NRC staff is able to review the complete DOE program under its jurisdiction, but also focus on areas that require more detailed reviews.

The second reason the NRC staff has confidence in this approach is that it places a large amount of emphasis on the quality assurance (QA) 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 still plans to conduct its own QA audits to gain additional confidence that the DOE QA 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.

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

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. These evaluations were conducted using the QA review plan, and were performed to determine if the QA program plans were acceptable. In addition to reviewing the written QA plans, the NRC staff must also have confidence that the overall program is being implemented in an acceptable manner. 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 effective 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, it has requested that DOE provide a letter documenting its finding of acceptability for the overall program. To date, NRC has agreed with DOE's findings that two contractor programs were acceptable with no exceptions, and four were acceptable with some exceptions.

The NRC staff approach of observing DOE audits rather than conducting independent audits requires DOE to first pass judgement on the acceptability of any QA programs it wants NRC to accept. This is one example of how the staff is ensuring that DOE retains responsibility

for ensuring that the repository program is being conducted in an acceptable manner. Once DOE has accepted the QA programs, if it agrees, the staff will concur with the DOE finding.

NRC's General Safety Philosophy

As a final point, I will discuss the NRC's general safety policy and its application to the repository program. 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 occurrence from affecting the public. These three echelons are: (1) design for safety in normal conditions, providing tolerance for uncertainty in features; (2) assume that incidents will occur and include safety features in the facility to minimize damage and protect the public; and (3) provide additional safety features to protect the public based on the evaluation of events that are not expected but whose likelihood of occurrence is credible.

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 allow for uncertainties in features.

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

The third echelon of defense complements the first two by requiring features that provide additional margins to protect the public against unlikely but credible events. The objective of this echelon is demonstrated by incorporating features that provide an additional margin of safety to protect against these events. The effectiveness of these features is then determined by assuming the event, and evaluating the facility's response to see if the consequences of such events are acceptable.

Considered in the defense-in-depth approach is the use of multiple barriers to minimize the potential release of radioactive material to the environment. The multiple-barrier 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 (the reactor pressure vessel and associated coolant loops), and a containment building. By using multiple barriers, the NRC has established the use of a number of containments that must be breached before radioactive material can be released to the environment.

Preclosure Repository Application

So far, my discussion has centered on the basic philosophy of the NRC, and an example of its implementation in the reactor arena. Now, I would like to discuss how this philosophy is applied to a high-level waste repository. Unlike a reactor plant, the repository has two distinct phases. These phases are preclosure, which covers the operation of the repository through permanent closure, and postclosure, which is the period following permanent closure. The Commission's defense-in-depth approach is applied to both of these phases.

For the preclosure period, application of the Commission's defense-in-depth approach requires that DOE first 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 system malfunction. Second, the designer needs to identify those incidents that are expected to occur over the operating life of the repository, and provide design features beyond those needed for normal operation of the facility that will either prevent or mitigate these incidents. These incidents 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 incidents can be prevented or mitigated.

In addition to providing design features to prevent or mitigate incidents, the Commission has also required additional features to provide assurance that the public is protected from events that are not expected but credible. This is the third echelon of protection provided in the defense-in-depth approach. For the preclosure period, it provides for additional features to protect the public. An example of this extra margin is the exclusion area for nuclear power plants or the controlled area for independent spent fuel storage facilities, such as a monitored retrievable storage facility, licensed under 10 CFR Part 72. 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 is addressing the need and appropriateness of such a requirement both on its own initiative and in response to a pending petition for rulemaking from DOE. In addition, the NRC has established the use of

emergency planning zones as yet another feature that offers protection.

It is important to state 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 NRC believes is necessary to protect the public, including workers. This approach will also be applied in the licensing of the repository.

Although not explicitly discussed here, the NRC will also require the use of multiple barriers in the design and operation of the repository. However, until the repository design becomes more detailed, the types of multiple barriers that will be needed cannot be determined.

Postclosure Repository Application

As with the preclosure period, the NRC has established the use of a defense-in-depth approach for the postclosure period of the repository. This approach also includes the use of multiple barriers and is similar to the approach used for nuclear reactors mentioned earlier. If you recall, I stated that 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 approach for the high-level waste repository is to have a waste form that provides a controlled release of radionuclides, a waste package to contain the waste, an underground facility to afford additional protection, and finally a geologic environment that limits radionuclide transport. To implement the multiple-barrier approach, the NRC has established a set of subsystem performance objectives in 10 CFR 60.113(a), which establish performance objectives for the waste package, the engineered barrier system, and the geologic environment.

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 NRC has established a release rate limit that is intended to require the engineered barrier system to control the release of radionuclides after the initial containment period. Finally, the NRC has established a 1,000-year groundwater travel time requirement as an indicator of the site's ability to isolate the wastes from the environment. Thus, each of the subsystem performance objectives listed in 10 CFR 60.113(a) is intended to

measure the effectiveness of some component of the repository's multiple barriers.

By establishing the subsystem performance objectives, the NRC has identified performance requirements for the multiple barriers that will help fulfill the main function of the repository, waste isolation. Because the NRC cannot predict every possible combination of circumstances that could affect the repository, the use of multiple barriers will help to limit the release and transport of radionuclides. The two major engineered barriers, the waste package and engineered barrier system are intended to limit the release of radioactive material. During the containment period when the radiation and thermal levels are high, the NRC has placed emphasis on the waste package's ability to contain the wastes. Following that period, the engineered barrier system is intended to limit the release of radioactive material while the geologic setting works to control the release of radioactive material to the accessible environment. Having three barriers will ensure that uncertainties in the performance of any one barrier will be compensated for by the ability of the remaining barriers to perform their function.

In evaluating the effectiveness of the multiple barriers, the NRC will use the defense-in-depth approach. During the postclosure period, there will be events that will affect the long-term performance of the repository. For these events, there are three categories that can be considered. These include events that are expected, events that are not expected but are credible, and events that are not likely enough to consider. Application of the defense-in-depth approach for the repository would require DOE to evaluate the effects of expected events and the events that are not expected, but are credible. The third category of events will not be required in the licensing design basis of the repository.
For the expected events, DOE will have to evaluate the repository's performance for events that are expected to occur from within the repository system as well as those that are expected to act upon the repository system from the outside. Events that are expected to occur from within the repository are those that can cause deterioration of the engineered system. Examples of these include corrosion and radiolysis. Events that act upon the repository from the outside and are expected to occur are those that would be identified as anticipated processes and events. Occurrence of these events are expected to result in some upset condition at the repository.

Analyses conducted for these events would be consistent with the first and second echelons of the Commission's policy - namely, design for safety in normal conditions, providing for uncertainty in features, and include safety features in the facility to minimize damage and protect the public from incidents likely to occur. The regulatory requirement that applies the Commission policy can be found in the subsystem performance objectives of 10 CFR 60.113(a). In that

subsection of 10 CFR Part 60, the Commission requires that DOE demonstrate that the the waste package and engineered barrier system perform their intended functions for the expected events. Therefore, DOE must demonstrate that those barriers are designed such that safety can be achieved in normal conditions and from events likely to occur.

The third echelon in the defense-in-depth approach is fulfilled in considering the U.S. Environmental Protection Agency (EPA) standard, or the overall system performance objective of 10 CFR 60.112. In order for DOE to comply with 10 CFR 60.112, it must not only demonstrate that the EPA standard is met for the expected events, but it must also show that it is met for unanticipated events. This is done by first identifying those events that are not expected to occur at the repository but are sufficiently likely to warrant consideration. Having identified these events, DOE must include them as part of its design basis for the repository, and then conduct an evaluation of the facility's response assuming occurrence of those events. Through this evaluation, DOE must demonstrate that the additional features included to accommodate both categories of events minimize the consequences of such events. This is done by showing that the EPA standard is met.

It should be noted that the subsystem performance objectives of 10 CFR 60.113(a) complement the EPA standard in offering a means of accounting for uncertainties in assessing the waste isolation capability of the repository for expected events. As stated earlier, compliance with the EPA standard covers both categories of licensing events. Hence, consideration of the anticipated events is done under 10 CFR 60.112 and 60.113(a). However, because the subsystem performance objectives are only evaluated for the anticipated events, a demonstration of compliance with the EPA standard must be made in order to also include the unanticipated events.

Conclusion

This paper has 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, it is hoped that insight has been provided to all of the participants involved in the high-level waste program.