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Dr. M. E. Wacks, Technical Program Chairman  
 Waste Management '91  
 College of Engineering and Mines  
 University of Arizona  
 Tucson, Arizona 85721

Dear Dr. Wacks:

Enclosed please find a summary of the paper I propose giving at the Waste Management '91 symposium. The paper is entitled "The NRC Regulatory and Safety Philosophy as Applies to the Design of a High-Level Waste Repository." It will discuss the general policy of the U.S. Nuclear Regulatory Commission (NRC) and describe how this will be applied to the repository. Also enclosed is the completed registration form.

If you have any questions or require additional information, please feel free to contact me at (301) 492-3403.

Sincerely,

## ORIGINAL SIGNED BY

Joseph J. Holonich, Section Leader  
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 Management  
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Enclosure: As stated

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## Summary of the Paper

"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

### Introduction

In licensing the high-level nuclear waste (HLW) repository, the U.S. Nuclear Regulatory Commission's (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 10 CFR Part 60 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 helping to ensure that DOE is proceeding in an acceptable manner and that when the application is received, the staff can expeditiously review it so as to 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 NRC's 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 eventual 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.

### 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 (10 CFR), which contains the regulations promulgated by the NRC. The requirements of 10 CFR are performance oriented as opposed to specification oriented. As a result, the requirements 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, Technical Positions (TPs) 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 License Application (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. 10 CFR 60.6 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) taking into account certain specified relevant factors. 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 regulations in 10 CFR from guidance documents is the degree of technical detail. The regulations in 10 CFR are very general. Regulatory Guides, TPs, 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, but compliance with them is not required. The approaches presented in these guidance documents are not the only alternatives that may be acceptable. Staff Positions contain the staff's interpretation of the regulations. They are issued as guidance to the NRC staff to use in its review of the DOE program. These positions are not intended as substitutes for the Commission's regulations and are not binding upon the other parties to any licensing proceeding.

An example of an existing review plan presently in use is the staff's quality assurance (QA) review plan, which implements the requirements of 10 CFR Part 50, Appendix B as appropriate. This plan provides guidance on what the staff will evaluate in its review of the DOE QA program plans.

#### 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 review of the LA by the NRC 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 through its inspection process, the staff will conduct the more detailed reviews to ensure that the detailed information supports the information provided in the LA. If problems are found in these inspections, the staff may expand its 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 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 I stated earlier, the NRC philosophy is 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. 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. However, even with the flexibility allowed DOE, the staff must still conduct its own QA audits to ensure that the DOE QA organizations are doing the necessary reviews and taking appropriate corrective actions. Problems identified on other inspections may indicate problems in QA programs. Therefore, as problems are reported from technical inspections, the NRC staff will evaluate them to determine if they are indicative of problems with the overall QA program.

#### NRC's General Safety Policy

As a final point, I believe it would be beneficial to discuss the general policy of the Commission as it relates to the design of nuclear facilities. Overall, 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 so that accidents can be arrested or accommodated safely while protecting the operating staff, the public, and the facility. In order to accomplish this, the designer needs to identify the credible accidents and provide design features in the facility that will either prevent or mitigate these accidents. This is why the Commission has not established a design basis accident dose limit for nuclear facilities. Rather, the Commission has promulgated requirements that establish design goals that would minimize the release of radiation following an accident. It should be noted that the Commission has established acceptable doses for normal operation. These are contained in 10 CFR Part 20 of the Commission's regulations.

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 extra margin is known as 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.

These are not acceptable doses members of the public can receive following an accident, but rather are the values used by the staff to determine the acceptability of 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, 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.

### 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.