



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

OCT 27 1988

NOTE TO: All Interested Parties

FROM: Eileen T. Tana, Licensing Assistant
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Division of High-Level Waste Management, NMSS

SUBJECT: SECY-88-285, "REGULATORY STRATEGY AND SCHEDULES FOR THE HIGH-LEVEL
WASTE REPOSITORY PROGRAM"

Enclosed for your information is the subject paper to the Commission to inform them of the staff's strategy and schedule for the overall high-level waste repository program, with emphasis on the regulatory framework.

Sincerely,

Eileen T. Tana

Eileen T. Tana, Licensing Assistant
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Division of High-Level Waste Management
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Enclosure: SECY-88-285

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POLICY ISSUE
(Information)

SECY-88-285

October 5, 1988

For: The Commissioners

From: William C. Parler
General Counsel

Victor Stello, Jr.
Executive Director for Operations

Subject: REGULATORY STRATEGY AND SCHEDULES FOR THE HIGH-LEVEL WASTE
REPOSITORY PROGRAM

Purpose: To inform the Commission of the staff's strategy and
schedule for the overall high-level waste repository
program, with emphasis on the regulatory framework.

Summary: The Commission requested the staff to inform it about
the status of the regulatory framework for the high-
level waste (HLW) repository program, as well as about
the overall program strategy and schedule. The staff
has already written one Commission paper (SECY-88-227,
dated August 4, 1988) that covered the rulemaking actions
that the Executive Director for Operations (EDO) has
already approved and for which resources already have
been budgeted, as well as the subjects for potential
future rulemaking. This present paper expands on the
first paper by describing: (1) the existing regulatory
framework for licensing a repository; (2) the approaches
for identifying uncertainties in the framework; and
(3) the current strategy and schedules for further
refining the regulatory framework, to reduce uncertainties,
using a mix of rulemakings, Technical Positions, and
Regulatory Guides. No additional resources are needed in
FY89 for the potential new rulemakings. However, as the
staff gains experience in preparing rulemakings and
Technical Positions and as new candidates for both are
identified, changes in the program will be factored into
the annual update of the Five-Year Plan and Budget.

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Background:

By memorandum dated June 6, 1988, (M880512B) the Office of the Secretary identified several Commission requests, to the staff, for information dealing with the HLW repository program. In Item 2 of that memorandum, the Commission requested that the EDO and the Office of the General Counsel (OGC) prepare a joint paper carefully examining relevant regulations and guidance (e.g., staff Technical Positions, Regulatory Guides, rulemakings), to determine whether the proper mix of regulatory tools is in place for the U. S. Nuclear Regulatory Commission (NRC) to make a licensing determination for the HLW repository. Furthermore, in Item 3, the Commission requested a staff paper listing proposed rulemakings, Technical Positions, and standards, etc., that the staff may suggest within the next six months, to enhance the licensing of a HLW repository. Previously, a May 26, 1988 memorandum from Commissioner Rogers to Chairman Zech requested that an overall licensing program strategy and a detailed (level 1 or level 2) schedule be prepared.

In response to the above requests, the staff has already written one Commission paper (SECY-88-227, dated August 4, 1988) that covered the rulemaking actions that the EDO has already approved and for which resources already have been budgeted, as well as subjects for potential future rulemaking. This present paper expands on the first paper by describing: (1) the existing regulatory framework; (2) the staff's ongoing efforts to identify uncertainties in the existing regulatory framework; and (3) the current strategy and schedules for refining the regulatory framework, using a mix of rulemakings, Technical Positions, and Regulatory Guides. Although this paper focuses on the regulatory framework part of the program, a summary of the overall program and schedules is given in Enclosure 1. This summary explains all the major activities in the program and, most importantly, the interrelationships among developing the regulatory framework, developing the staff's independent review capability, and conducting prelicensing reviews and consultations with DOE.

In response to an earlier Commission request, a Commission paper was prepared (SECY-86-323, dated October 30, 1986) on approaches to licensing a geologic repository (Enclosure 2). Approaches were discussed for streamlining the hearing process, identifying and resolving licensing issues early, and improving the appeal process. Specific approaches such as the licensing support system (LSS), pre-licensing consultation, Technical Positions, and rulemakings were evaluated. The October 1986 paper is a foundation upon

which this current paper builds in refining the existing regulatory framework. Many of the ongoing and new activities described in this present paper implement some of the approaches originally discussed in the October 1986 paper.

Some additional background is given below about the statutory framework for the HLW repository program. The Nuclear Waste Policy Act of 1982 (NWPA) establishes the statutory milestones and responsibilities, among other things, for the overall nuclear waste management program for which the repository program is one part. The U. S. Department of Energy's (DOE's) Mission Plan and Project Decision Schedule (PDS) periodically update the schedules for the milestones. The status of the actions that the NWPA requires NRC to take is tracked in an enclosure to the staff's Quarterly Progress Report on the Pre-licensing Phase of the DOE Civilian High-Level Radioactive Waste Management Program. The NWPA milestones and current schedules for both DOE and NRC actions are defined, for the staff's planning purposes, as level one milestones and are given in Enclosure 3. These level one milestones make up the basic statutory framework which NRC's program must meet.

Under the statutory framework established by the NWPA, the overall repository licensing process can be divided into five distinct phases (Enclosure 4). The first phase is the prelicense application phase. This phase precedes DOE's License Application submission and NRC's decision on docketing it. This phase consists of two parts, the pre-Site Characterization Plan (SCP) part, which involves informal reviews and consultations, and the post-SCP part, which primarily involves NRC's review of DOE's SCP and semi-annual progress reports. The first phase is referred to as "informal," because NRC has no licensing authority over DOE. The second phase, which begins after docketing of the License Application, involves the formal licensing activities related to the NRC decision on authorizing construction of the repository. The third phase results in the NRC decision on granting a license to receive waste. The fourth phase leads to the NRC decision on amending the license to allow permanent closure, and finally, the fifth phase ends in the NRC decision on terminating the license.

The staff is currently concentrating on the first and second phases of the licensing process. During the first phase, the Office of Nuclear Material Safety and Safeguards (NMSS), OGC, and the Office of Nuclear Regulatory Research (RES) staffs

will ensure that in the second phase the staffs will be able to conduct an effective review and that the construction authorization decision can be made within the NWPA-mandated three-year time period. To achieve this during the first phase, NMSS and RES in close consultation with OGC will: (1) refine the existing regulatory framework to support licensing; (2) ensure that DOE will submit a complete and high quality License Application that the staffs will find acceptable for conducting the licensing review and hearing process within the statutory time period; and (3) develop their technical capabilities to review DOE's License Application. During the first phase, both DOE and NRC will need to address many unique and complicated technical uncertainties related to the predictions of repository performance over 10,000 years, as required by the U. S. Environmental Protection Agency (EPA) Standard. Reducing these uncertainties will be an evolving and iterative process. Finally, during the first phase, the OGC staff will primarily focus on revising the procedural requirements for repository licensing in order to expedite the Hearing on the issuance of the Construction Authorization, in the second phase.

NRC's program during the first phase of the licensing process is subdivided into three levels of activities. The summary level of program activities is designated as level two. Current schedules for these are shown in Enclosure 5 and discussed in Enclosure 1. This discussion and the levels one and two scheduled activities demonstrate how NRC's program supports the statutory framework. A further level of schedule detail is designated as level three. The key rulemaking activities shown in Enclosure 6 are an example of the level three detail. A fourth level of detail, now being developed, will include the specific input and coordination activities with RES, OGC, the Advisory Committee on Nuclear Waste (ACNW), the Commission, DOE, and NRC contractors. Therefore, the specific integration of NRC's HLW repository program will be identified by these fourth-level activities and tracked by the High-Level Waste Management Division's (HLWM's) detailed operating plan.

Discussion:

I. The Existing Regulatory Framework

The existing regulatory framework consists of the following primary regulations:

- o 10 CFR Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories";

- ° 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings"; and
- ° 10 CFR Part 51, "Environmental Protection Regulation for Domestic Licensing and Regulatory Functions."

Additional regulations are incorporated by reference into the above primary regulations. With respect to 10 CFR Part 60, in February 1981, the Commission finalized "Licensing Procedures for HLW in Geologic Repositories," (46 FR 13980) and in June 1983, the Commission finalized "Technical Criteria for HLW in Geologic Repositories" (48 FR 28204).

In addition to the basic regulations, the existing regulatory framework also includes staff guidance to DOE in the form of Technical Positions and one Regulatory Guide on the format and content of DOE's SCP. Enclosure 7 lists the rulemakings, Technical Positions and Regulatory Guide, issued to date, applicable to the Yucca Mountain Site.

II. Strategy to Identify Uncertainties within the Existing Regulatory Framework

The staffs' identification of uncertainties within the existing regulatory framework has been and will be a continuous process to refine the regulatory requirements and improve the effectiveness of the licensing process for use by NRC reviewers, adjudicatory boards, and DOE. For example, a rulemaking completed in 1985 was conducted to resolve regulatory uncertainties of a technical nature about disposal in the unsaturated zone, after DOE began considering a repository in the unsaturated zone at the Yucca Mountain site in Nevada. Similarly, the passage of NWPA created institutional uncertainties of a procedural nature about site characterization and State/Tribal participation. These uncertainties were resolved by a 1986 rulemaking. In addition, the Commission recently issued a proposed rule amending 10 CFR Part 51, to establish the Commission's NEPA review procedures for repository licensing in accordance with the NWPA.

As a follow-up to the October 1986 Commission Paper on approaches to licensing, the NMSS, OGC and RES staffs have been identifying the most significant regulatory, technical, and institutional uncertainties related to 10 CFR Part 60, to determine what refinements to the regulatory framework might be needed. Regulatory uncertainties exist where the

meaning of a requirement or definition in 10 CFR Part 60 is subject to more than one interpretation (e.g., definition of disturbed zone) or where what must be proven in general terms to demonstrate compliance with a requirement (i.e., elements of proof) is not completely defined in the requirement itself. Technical uncertainties are related to how compliance with a requirement should be demonstrated (i.e., an acceptable method or sufficient information). Institutional uncertainties pertain to conflicting or unclear roles, actions or schedules, between NRC and other participating agencies, that could adversely affect licensing (e.g., NRC's adoption of DOE's Environmental Impact Statement (EIS) and NRC's role in reviewing compliance with mine safety regulations or other regulations referenced in 10 CFR Part 60). These also include procedural reforms relating to repository licensing.

The staff has identified and will continue to identify uncertainties based on: (1) the experience with applying the regulation to prelicensing technical reviews of the DOE program; (2) the results of NMSS and RES contractor studies; and (3) the identification of uncertainties by DOE, the State of Nevada, and other parties. For example, the staff's review of the consultation draft SCP resulted in a concern with DOE's interpretation of "substantially complete containment" in 10 CFR Part 60. As a result, the staff has commented to DOE and is considering a rulemaking to clarify these terms. Another example relates to the recent concern about the lack of compatibility between the methods used in on-site spent fuel storage at reactor sites and DOE's transportation and disposal systems. As a followup to this concern, the staff will review, from a systems engineering standpoint, the need for a rulemaking which would standardize container requirements for reactor storage, transportation, and disposal in a repository, so as to minimize the handling and repackaging of waste.

The staff is also using two other approaches to identify uncertainties and evaluate the regulatory framework. The first is a coordinated effort, among the CNWRA, NMSS, and OGC staffs, to systematically analyze the regulations related to NRC's NWPAs responsibilities, including those related to the repository. This approach will be a more systematic and complete analysis of the regulations to identify regulatory, technical, and institutional uncertainties. It will also recommend mechanisms to reduce the uncertainties found. The first portion of this analysis is focused on siting-related uncertainties and is currently scheduled to be completed in late December 1988. The full-

scale analysis is scheduled to be completed by September 1989. The staff's consideration of the resulting recommendations may result in a future adjustment to the current plans, described below, to improve the regulatory framework. New or modified research needs and priorities may also result.

A second approach to identifying regulatory and technical uncertainties involves the staff developing capability to use computer models and perform analyses related to determining compliance with the performance objectives of 10 CFR Part 60, including the EPA standard (i.e., performance assessments). Recently, a coordinated effort has been started between NMSS and RES to develop the staffs' modeling capability (initially based on a transfer of contractor-developed capability). The ultimate objective of this effort is to ensure that the NRC staff will be able to review the demonstration of repository compliance with 10 CFR Part 60 that DOE must provide in its License Application. However, in developing this capability, a short-term benefit will also be gained, which will allow the staff to perform independent, site-specific performance assessments throughout the prelicense application phase as DOE collects data. These assessments are expected to be an important additional way to identify both regulatory and technical uncertainties and to assess their significance. Thus, they can identify areas where new or modified rules, guidance, or research may be needed. They will also be used to prepare or revise the staffs' review plans and focus staff reviews of DOE's site characterization program on significant areas of technical uncertainty and site features of concern. Ultimately, these assessments will be repeated in the licensing review process to determine whether the site is acceptable.

The staff will assess the results of the ongoing efforts described above and, as needed, will revise the plans to improve the regulatory framework. This will be done as part of the Five-Year Plan and Budget planning process. In addition, any significant changes to the plan that are necessary during the year will be brought to the Commission's attention in Item 7 (early resolution of issues through a program of Licensing Topical Reports and other mechanisms) of the Quarterly Progress Reports to the Commission on the Pre-licensing Phase of the DOE's Civilian High-level Radioactive Waste Management Program.

III. Reducing Uncertainties and Refining the Regulatory Framework

The plans for both ongoing work and new work to revise the existing regulatory framework are described below. The staff's objectives are to reduce regulatory uncertainties, reduce institutional uncertainties involving NRC's licensing role and procedures, and provide DOE with guidance in areas of high technical uncertainty.

As previously mentioned, the staff has categorized uncertainties as regulatory, technical, and institutional. Therefore, the discussion below will address each of the three categories of uncertainty by identifying the mechanisms and the specific activities NMSS, OGC, and RES staffs will use for reducing these uncertainties.

A. Reducing Regulatory Uncertainty

It is clear that reducing regulatory uncertainties identified by NRC, DOE and others is NRC's responsibility. The staff will use rulemakings, Technical Positions, and at least one Regulatory Guide to reduce major regulatory uncertainties. Rulemakings will be considered where authoritative and binding clarification or elaboration is needed on the meaning of requirements or definitions in the 10 CFR Part 60. Rulemakings might also be used to address what must be proven to demonstrate compliance with a requirement (i.e., elements of proof) for selected requirements. In either case, however, rulemakings would be pursued only where practicable. For example, reducing regulatory uncertainty may depend on site-specific information to provide a firmer basis for determining what additional requirements may be necessary to protect health and safety. Therefore, attempting to reduce such an uncertainty in the abstract might not be worth the additional effort of rulemaking.

A major benefit to rulemaking is that uncertainties can be formally resolved and then, according to 10 CFR Section 2.758, the Commission's rules generally cannot be challenged in a licensing proceeding. Therefore, rulemaking can provide more assurance that uncertainties have been reduced and will not be contested in the Hearing. However, rulemaking is, of course, subject to litigation. This potential risk, along with the resources commitment necessary to conduct a rulemaking, will be considered before recommending topics to the EDO for rulemaking.

As previously noted in SECY-88-227, the staff has tentatively identified nine new topics (listed in Enclosure 8) where regulatory uncertainties could be reduced by means of rulemaking. In FY89 the staff will first develop preliminary positions for these topics and then decide which of them to recommend to the EDO for approval to initiate the formal two-year rulemaking process. Those not so recommended may be issued as Technical Positions. These rulemakings are currently scheduled (see Enclosure 6) to be completed by FY92, which is when DOE is currently planning to begin developing its License Application. One of the candidate rulemaking topics is a result of previous Commission action. In the development of 10 CFR Part 60, the staff identified the need for regulations dealing with emergency planning criteria. Another rulemaking on conforming Part 60 to the EPA standard issued in June 1986 is being held in abeyance, pending the completion of a court-ordered EPA review of these standards. Finally, it is important to note here that the potential rulemaking on establishing criteria for containment of greater-than-Class-C low-level waste is dependent on the proposed amendment to 10 CFR Part 61 regarding disposal facilities to be used for such waste.

In addition to rulemakings, the staff will prepare a Regulatory Guide for the format and content of the License Application. Regulatory Guides have consistently been the mechanism used by other NRC programs to give format and content guidance to applicants. Guidance will be given on the specific content of the License Application. The staff might also include the essential elements of proof (i.e., what must be proven to demonstrate compliance with the requirements of 10 CFR Part 60). This Regulatory Guide will also give guidance on the format and organizational structure of the License Application and, therefore, will be a framework for the staff's License Application Review Plan.

B. Reducing Technical Uncertainties

The staff considers it to be DOE's responsibility to reduce technical uncertainties (e.g., develop acceptable test and analysis methods) through site characterization activities and precicensing consultations with NRC, the State of Nevada, and other parties. However, the staff intends to prepare Technical Positions in areas of high uncertainty where standard testing or analysis methods are either not available or existing methods are controversial. The staff

considers it more appropriate for NRC as a regulatory agency to develop Technical Positions which give criteria for acceptable methods than to prescribe specific acceptable methods developed by the staff. Criteria would also provide a basis for the staff's review of DOE's methods. Technical Positions will be developed through a process of involving all interested parties, including targeted technical groups, so that their questions and concerns can be addressed in an open and documented manner.

Technical Positions will allow testing and analysis methods to evolve that are appropriate for the Yucca Mountain Site. Presently, the staff considers that reducing technical uncertainties by rulemaking is not appropriate since reduction may depend on collection of site-specific data or development of site-specific methods requiring further understanding of the site. In addition, for some cases, rulemaking may be unreasonable for methods where technology is still evolving. Therefore, as mentioned above, it is DOE's responsibility to reduce technical uncertainties. The staff, however, will continue to consider the appropriateness and timeliness of using rulemakings for resolving technical uncertainties that require authoritative and binding clarification or elaboration.

The staff also considers that the prelicense application review and consultation process will complement Technical Positions in giving DOE guidance on reducing technical uncertainties before DOE submits the License Application. In its review of DOE's Topical Reports and Issue Resolution Reports, the staff will identify objections, that if not resolved by DOE, would result in the staff not accepting the License Application. Objections will be identified for areas where DOE's reduction of technical uncertainties is unacceptable to the staff. Any unresolved objections would also be factored into NRC's Preliminary Site Characterization Sufficiency Comments (required by Section 114(a)(3) of NHPA) that will be submitted as part of the President's Site Recommendation to Congress.

There are several benefits from DOE's resolving NRC objections. One benefit is to have a complete and high-quality License Application which will reduce the number of technical uncertainties and focus the remaining uncertainties that would be adjudicated in the Hearing. The extent to which objections to DOE's reduction of technical uncertainties do not become licensing issues in the Hearing will be an important factor in meeting the three-year licensing requirement. Even if resolved

objections are raised in the Hearing, the Hearing Licensing Board will be able to deal with them more directly and quickly because of the documentation that will exist. The staff's open item tracking system will provide access to this documentation by identifying all the documents related to the identification and resolution of objections (and other concerns) with DOE's reduction of technical uncertainties. Documents would include DOE's resolution, and NRC's comments and acceptance, along with comments from other parties. Resolving objections will also streamline the staff's review of the License Application regarding sufficiency of information and acceptable methods since, ideally, these will have already been reviewed and DOE's resolution of NRC objections accepted by the staff. This would allow the staff to concentrate its review on DOE's compliance demonstrations and the results compared to the regulatory requirements.

At this time, the staff has identified 22 topics for which work is ongoing or will begin on developing Technical Positions (see Enclosure 8). Work will begin in FY89 on topics that are considered to be most important to DOE's surface-based testing and exploratory shaft construction testing. Work will begin later, in FY89 and FY90, on other topics important to longer-term DOE work, such as repository design and in-situ testing that will start in FY91 after the two exploratory shafts are connected. As site characterization proceeds, additional topics will probably be identified.

C. Reducing Institutional Uncertainties

The staff will reduce institutional uncertainties using a variety of mechanisms, depending on the nature of the uncertainty. Possibilities include rulemakings, memoranda of understandings, and comments and consultations on DOE's PDS.

Four rulemakings to resolve institutional uncertainties in 10 CFR Parts 2, 51, and 60 are listed in Enclosure 8 and their schedules shown in Enclosure 5. Two of these rulemakings are going on now and will resolve uncertainties of a procedural nature. The first rulemaking, for which a proposed rule has been recently issued, deals with amending 10 CFR Part 51 to implement the NWPA provisions that require NRC to adopt DOE's Environmental Impact Statement (EIS) to the extent practicable. This rulemaking will complete all rulemakings required for conformance to NWPA and the Nuclear Waste Policy Amendments Act (NWPAA).

The second ongoing rulemaking is the negotiated rulemaking on the LSS. The draft proposed rule was recently forwarded to the Commission (SECY 88-249). In general this draft proposed rule revises 10 CFR Part 2 to establish the basic procedures and schedules for the HLW licensing proceeding, including procedures for the use of the LSS in the HLW proceeding. Specifically, the draft proposed rule establishes requirements for: submission and entry of material to the LSS; access to the LSS; a Pre-License Application Licensing Board to resolve disputes during the period before DOE submits the License Application for the repository; LSS administration; the electronic transmission of formal papers during the licensing hearing; discovery; intervention and participation in the Hearing; appeals; and the Commission's immediate effectiveness review of the initial Licensing Board decision on the repository. OGC believes that the LSS rulemaking will establish the fundamental procedural framework necessary for the effective conduct of the licensing proceeding. As such it addresses the critical issues related to streamlining the hearing and appeal process identified in SECY 86-232 (Enclosure 2).

A potential future rulemaking of a procedural nature deals with revising the existing content requirements in 10 CFR Part 60 for the License Application and establishing criteria for acceptance of the License Application. The purpose of such a rulemaking would be to have DOE either (1) resolve, before submittal of the License Application, NRC's objections raised during the prelicense application reviews concerning sufficiency of information and acceptable compliance demonstration methods, or (2) explain in the License Application why resolution was not achieved, and the significance to licensing.

Finally, the staff's upcoming review of the PDS and the systematic analysis of the regulations are two activities that may yield additional institutional uncertainties.

III. Effects on the Five-Year Plan and Budget

The activities described above for improving the regulatory framework affect the NMSS FY89-93 Five-Year Plan and FY91 Budget only in the areas of rulemakings and Technical Positions. Other activities and associated resources are not affected. The plans described above show an increase in potential rulemakings (from two to nine) and a decrease in Technical Positions (down from 29 to 22). The NMSS resources needed for the additional rulemaking have become

available from both the decrease in the number of Technical Positions and a delay in starting some Technical Positions from FY89 to FY90. Therefore, NMSS does not need additional resources at this time.

The RES resources needed for the additional rulemakings identified in this paper will be made available by delaying completion of regulatory efforts such as achieving comparability with EPA regulations to implement the Uranium Mill Tailings Recovery and Conservation Act (UMTRCA) and the development of lower priority Regulatory Guides. Therefore, RES does not need additional resources in FY89. Furthermore, NMSS and RES have not identified the need to initiate additional research other than what is ongoing and currently projected in the Five-Year Plan to develop rulemakings. Finally, no additional resources are needed in FY89 for OGC.

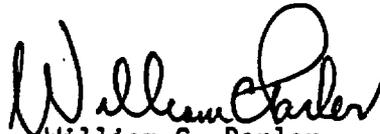
It should be emphasized that the resource estimates are best estimates at this time and may change as the staff gains experience in preparing rulemakings and Technical Positions and as new candidates for both are identified. Such changes in resource estimates will be factored into the annual update of the Five-Year Plan and Budget.

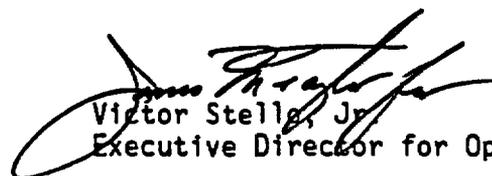
Conclusions:

Based on the discussion above, the staff has the following major conclusions:

1. A regulatory framework for licensing a repository is currently in place.
2. As a result of its ongoing program to identify uncertainties and refine the existing regulatory framework, the staff has the following coordinated set of activities scheduled:
 - a) Nine potential new rulemakings and one Regulatory Guide are currently planned to reduce regulatory uncertainties. The topics being considered for rulemaking will be evaluated to determine if rulemaking is needed and practicable. If not, Technical Positions will be prepared.
 - b) Four ongoing and potential rulemakings are planned to resolve institutional uncertainties involving NRC's licensing role as well as procedures and schedules for the licensing proceeding.

- c) Twenty-two Technical Positions are planned which will give guidance for DOE's reduction of major technical uncertainties.
4. The prelicense application review and consultation process will complement Technical Positions in guiding DOE's reduction of technical uncertainties before submittal of the License Application. This process could also help streamline the detailed review of the License Application by the staff.
5. No additional resources are needed in FY89 for the potential new rulemakings.
6. Finally, it should be emphasized that the resource estimates are best estimates at this time and may change as the staff gains experience in preparing rulemakings and Technical Positions and as new candidates for both are identified. Changes in the program will be reflected in the Quarterly Progress Reports to the Commission and factored into the annual update of the Five-Year Plan and Budget.


William C. Parler
General Counsel


Victor Stelle, Jr.
Executive Director for Operations

Enclosures:

1. Summary of High-level Waste Repository Licensing Program Activities
2. Commission Paper on Approaches to Licensing a Geologic Repository (SECY-85-323)
3. Timeline of Level One NRC and DOE NWPA Major Repository Milestones
4. Phases of the Repository Licensing Process
5. Timeline of Level Two Summary Schedule of NRC Repository Program Activities
6. Timeline of Level Three schedules for NRC Rulemaking Activities
7. List of Issued Rulemakings, Technical Positions, and Regulatory Guides Applicable to the Yucca Mountain Site
8. List of Ongoing and Planned Potential Rulemakings, Technical Positions, and Regulatory Guides

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ENCLOSURE 1

SUMMARY OF HIGH-LEVEL WASTE REPOSITORY LICENSING PROGRAM ACTIVITIES

1. INTRODUCTION

The U.S. Nuclear Regulatory Commission's (NRC's) high-level waste repository licensing program is both proactive and reactive. Proactive activities include such events as NRC initiating the actions of preparing Technical Positions or rulemaking which are timely enough to support the U.S. Department of Energy's (DOE's) key programmatic milestones, but do not depend on a DOE action such as issuance of the Site Characterization Plan (SCP). In contrast, reactive activities involve an NRC action in response to a DOE action. These include reviewing DOE programmatic reports (e.g., SCP, Mission Plan, and Project Decision Schedule (PDS)) and auditing the DOE program. Both proactive and reactive work forms the basic program; however, in the event of delay in reactive work (e.g., delay in issuance of the SCP) resources will be balanced by adjusting the priorities and schedules of proactive activities.

2. PROACTIVE ACTIVITIES

The proactive part of the program involves an ongoing effort of: (1) identifying uncertainties in the regulatory framework; (2) developing regulatory requirements and guidance to resolve uncertainties; (3) developing the staff's independent site characterization and license application review capability; and (4) evaluating progress toward meeting the Nuclear Waste Policy Act (NWPA) and Nuclear Waste Policy Amendments Act (NWPAA) requirements. The ongoing effort of identifying uncertainties in the regulatory framework will be complemented by two new activities. The first effort is an ongoing systematic review of all the relevant regulations in order to identify the regulatory, technical, and institutional uncertainties that need to be addressed during the pre-licensing period, so that licensing can be conducted within the three-year time period mandated by the NWPA. Regulatory uncertainties exist where the meaning of certain existing regulatory requirements are subject to more than one interpretation or where what must be proven in general terms to demonstrate compliance with a requirement (i.e., element of proof) is not completely defined in the requirement itself. Technical uncertainties are related to how compliance with a requirement should be demonstrated. Institutional uncertainties pertain to conflicting or unclear roles, actions, or schedules between NRC and other participating agencies (e.g., NRC's adoption of DOE's Environmental Impact Statement (EIS)). These also include procedural reforms relating to repository licensing. The second new effort involves the Office of Nuclear Materials Safety and Safeguards (NMSS) and the Office of Nuclear Regulatory Research (RES) developing and using performance assessment models

with Yucca Mountain site data. While the direct purpose of this effort is to develop the staff's technical assessment capability, it will have the additional benefit of identifying areas of regulatory and technical uncertainty.

2.1 Programmatic and Regulatory Requirements and Technical Guidance

Rulemakings will focus on resolving regulatory and some institutional uncertainties related to significant ambiguities in the meaning of a requirement or definition in 10 CFR Part 60 and those regulations incorporated by reference in 10 CFR Part 60. Rulemakings, in some cases, may also include defining the elements of proof for certain requirements where these are unclear and where resolution by rulemaking is important enough to make the investment of time and resources worthwhile. The License Application Format and Content Regulatory Guide will provide a format and organizational structure, for the information to be included in the License Application, that will facilitate the staff's review. Therefore, the outline of the Guide will provide a framework for the License Application Review Plan. This Guide might also contain the essential elements of proof (i.e., what DOE must prove to demonstrate compliance with the regulation). Technical Positions will focus primarily on technical uncertainties related to acceptable methods for how compliance should be demonstrated for selected areas that are both controversial and critical to repository performance. These Technical Positions will consist of the criteria that will be guidance to DOE and that the staff will use to review the methods DOE develops to resolve the technical uncertainties. Both the Technical Position mechanism and the use of criteria (rather than prescribe specific methods) allow DOE flexibility in its application of state-of-the-art technology to demonstrate compliance. Technical Positions will become major components of the License Application Review Plan. To the extent practicable, the staff will resolve significant regulatory uncertainties with final rulemakings and Technical Positions before 1992, which is generally when DOE will begin preparing its License Application. Draft Technical Positions and proposed rulemakings, however, will provide DOE and other parties an early opportunity to understand and comment on the staff's evolving position. Finally, the process of developing the above mentioned rulemakings and guidance involves all interested parties, including targeted technical groups, so that their questions and concerns can be addressed in an open and documented manner before licensing.

2.2 Technical Assessment Capability

In addition to developing guidance for DOE, the proactive activities result in developing the staff's independent review capability in the form of review plans, assessment methods (including models and codes), and the capability to

apply these tools to review DOE's program. The SCP Review Plan, the Study Plan Review Plan, and the Quality Assurance (QA) Review Plan guide the staff's review of both the technical and QA plans for DOE's overall prelicensing and site characterization program. The License Application Review Plan will guide the staff's review of the data collection activities, data, and assessments resulting from the DOE site characterization program; preliminary site characterization sufficiency; and ultimately the License Application itself. This plan will integrate and focus all the staff's proactive work by referencing staff Technical Positions and assessment methods and combining these with the review criteria and procedures the staff will use to conduct its independent review of DOE's License Application. The Performance Assessment Review Strategy will be prepared as an initial phase in developing the License Application Review Plan. This strategy will determine how thorough and independent the staff's reviews of DOE's compliance demonstration modeling should be. Such guidance will be a basis for further developing the License Application Review Plan and will also be a justification for which areas and what types of assessment capabilities should be developed by the staff. Those methods developed will be referenced in the License Application Review Plan. NMSS and RES have recently completed a memorandum of understanding to assure a coordinated effort in developing and implementing a staff modeling capability consistent with the Performance Assessment Review Strategy.

The final proactive activity is the quarterly evaluation of progress on NRC statutory actions required by NWPA and NWPA and DOE actions that the staff considers critical for a successful prelicensing program. This evaluation is documented in the Quarterly Progress Reports to the Commission on the Pre-Licensing Phase of the DOE's Civilian High-Level Radioactive Waste Management Program and sent to DOE. This evaluation complements the numerous more specific reviews and consultations by taking a broad view of progress and identifying fundamental concerns, based on a synthesis of specific concerns.

3. REACTIVE ACTIVITIES

The reactive part of the program consists primarily of the QA activities and prelicensing and site characterization technical reviews and consultations following the review plans that the NRC staff prepares for the proactive part of the program. This work depends on a specific DOE action such as the issuance of the SCP or the scheduling of a DOE audit. These reactive activities are for a selected sample of DOE's program, including followup on previously identified concerns with DOE's program and how DOE is resolving them. These activities will focus on areas of significant technical uncertainty. They will give DOE programmatic guidance for the specific parts

of the program reviewed, and will be used to resolve problems with the effectiveness of DOE's implementation of the overall issue resolution process given in the SCP.

3.1 QA Program Activities

The QA activities consist of reviewing DOE's and DOE's contractor QA plans and evaluating their implementation. Both NRC audits and NRC observations of DOE audits, using both QA and technical staff, will check implementation. The objective of these reviews and audits is to identify and resolve staff concerns so that NRC can accept DOE's program before significant data collection activities are performed during site characterization. The QA activities complement the selective nature of technical reviews described below by independently assuring that DOE is effectively implementing a qualified QA program to assure the quality of its work from the start of its program and to assure that DOE is also verifying that its program is being implemented properly.

3.2 Prelicensing and Site Characterization Reviews

NRC's prelicensing and site characterization reviews follow DOE's sequence and schedule of activities. Therefore, in the early stages of the program, the emphasis is on reviewing plans such as the SCP (required by NWPA and NRC regulation) and the more detailed study plans and procedures which implement the SCP. The SCP review will focus on the top-level strategies, assumptions, and content of DOE's program, as described in DOE's issue resolution strategies and each of the program and investigation plans. NRC will review all study plans to determine if DOE's study plan process is effective and if there are any objections to starting work (i.e., potential adverse effects on either waste isolation or other site characterization activities). However, detailed reviews will be conducted for only a sample (about 20 percent) of the approximately 100 study plans. This sample is less than half of the study plans where key concerns already have been identified, for studies related to potential adverse conditions at the site, areas of significant uncertainty, and for certain nonstandard or controversial test methods. These detailed reviews will also be used to determine the proper implementation of the SCP at the detailed level.

As site characterization proceeds the SCP will be updated semiannually by DOE and reviewed semiannually by NRC, until DOE submits its License Application. NRC's review of these SCP semiannual progress reports will focus on: (1) evaluating DOE's resolution of previously identified NRC concerns (open items) and (2) identifying new concerns with new information about the site and designs, new plans, or changes to the original plans and schedules.

Also during site characterization, NRC will conduct on-site reviews of selected DOE testing activities and the data that are collected by them. These activities are another way to check the proper implementation of the SCP by DOE. In addition, NRC will review selected DOE study reports and position papers which document the detailed results of DOE's work. NRC will review DOE's topical reports and issue resolution reports which summarize, integrate, and evaluate the site characterization work for individual licensing topics and DOE issues related to demonstrating compliance with NRC's regulation. As such, these reports will become inputs to the License Application, and therefore, the staff's review of these will identify concerns that DOE needs to resolve before submittal of the License Application. Similar concerns might also result from the staff's review of site characterization sufficiency, as required by NHPA, before DOE's site recommendation to the President and Congress.

All concerns identified in the staff reviews and DOE's progress toward resolving them and their root causes will be tracked by the staff as open items. The tracking system, presently being implemented, will focus the staff prelicensing review activities on identifying and resolving concerns with how DOE is resolving technical uncertainties. The tracking system will also provide a document trail, to use in licensing, of all the NRC and DOE actions related to resolving specific concerns.

Lastly, on-site representation at the Yucca Mountain site will continue to facilitate direct information exchange with DOE as well as the State of Nevada, and will provide both QA and technical oversight of data, documents, and site characterization activities.