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MEMORANDUM FOR: Stuart A. Treby  
Assistant General Counsel for  
Rulemaking and Fuel Cycle  
Office of the General Counsel

Ronald L. Ballard, Chief  
Geoscience & Systems Performance Branch  
Division of High-Level Waste Management

Joseph O. Bunting, Chief  
Engineering Branch  
Division of High-Level Waste Management

FROM: John J. Linehan, Director  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste Management

SUBJECT: PARTICIPATION IN REGULATORY AND INSTITUTIONAL UNCERTAINTY  
REDUCTION TASK TEAM

Enclosed is a task plan for a team approach to addressing and resolving where possible the regulatory and institutional uncertainties identified in the Center for Nuclear Waste Regulatory Analyses (CNWRA) report, CNWRA 90-003. A draft of this task plan was provided to J. Wolf, J. Bunting, and R. Ballard for review and I feel we have resolved all significant comments. I would be most appreciative if you would provide the necessary support for this activity and appoint a member of your staff to serve on the task team. Resources for this effort were specifically called out in the recent revision of the FY91 DHLWM budget. In order to initiate this activity as soon as possible, it would be most helpful if you could identify to me before August 31, 1990, the member of your staff that will be appointed.

If you have any questions concerning the proposed task team please do not hesitate to contact me or Philip Altomare of my staff. Thank you for your assistance.

*JS/*

John Linehan, Director  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste Management

Enclosures: As stated

cc: S. Mearse, CAB      A. Whiting, CNWRA  
    J. Funches, PMDA    W. Patrick, CNWRA  
    S. Fortuna, PMDA    J. Wolf, OGC

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## PROPOSED TASK APPROACH FOR REGULATORY AND INSTITUTIONAL UNCERTAINTY REDUCTION

### A. BACKGROUND

The Center for Nuclear Waste Regulatory Analyses (CNWRA), under contract to the Nuclear Regulatory Commission (NRC), is conducting a Systematic Regulatory Analysis (SRA) of the regulations related to the licensing of a High Level Radioactive Waste Repository. This work is being performed under the NRC Waste Systems Engineering and Integration (WSE&I) Program Element in accordance with established CNWRA Technical Operating Procedures, TOP-001-02, "Program Architecture Relational Database Content and Development Instructions." As a part of the SRA effort, an analysis has been completed to identify regulatory and institutional uncertainties in NRC regulation 10 CFR Part 60, "Disposal of High Level Waste in Geologic Repositories." This analysis was performed in two parts: the first covering only Subparts B and E of 10 CFR Part 60 and completed in May 1989 as report CNWRA 89-003; the second part, which included review and revision of the first report, was completed in February 28, 1990 as report CNWRA 90-003, "Identification and Evaluation of Regulatory and Institutional Uncertainties in 10 CFR Part 60." The latter report presents the complete set of CNWRA identified regulatory and institutional uncertainties (43 uncertainties) with their rationale. The CNWRA is also conducting a functional analysis of the high-level waste repository to identify uncertainties of "omission," i.e., regulatory requirements that perhaps should have been but were not covered in 10 CFR part 60. The NRC staff provided comments on the CNWRA draft reports for consideration, however, the reports were intended to be, and are, the CNWRA's independent assessment.

The CNWRA 90-003 report does not, and was not intended to, specify approaches for the uncertainty reduction. It remains, therefore, for the NRC staff to: 1) assess whether the uncertainty provided intended regulatory flexibility; 2) assess whether the uncertainty is of such significance as to require resolution or reduction; 3) determine what uncertainty reduction approach will be applied; and, 4) to implement the uncertainty reduction.

Many of the uncertainties identified, while requiring clarification or change in the rule text to avoid confusion, or requiring a documented rationale of why they are intended flexibility, are considered minor in nature and relatively easy to resolve. These are intended to be addressed in the preparation of a Staff Position.

In addition to the uncertainties identified by the CNWRA, the NRC staff has also identified regulatory uncertainties. These are as listed in Enclosure 5 of the "Regulatory Strategies and Schedules for the High-Level Waste Regulatory Program," SECY 90-207, and are included here as Appendix B.

### B. PURPOSE, OBJECTIVES, AND SCOPE

The purpose of the this task effort is: 1) to prepare a report that identifies those uncertainties that have intended flexibility, those that require uncertainty reduction, and the recommended uncertainty reduction approach; and, 2) prepare a Staff Position that provides the clarifying language or proposed rule text change to resolve those uncertainties that can be readily addressed within the time period and scope of this task.

The objectives to be achieved are:

- o Establish an NRC position as regards the need to resolve or reduce the identified uncertainty and provide a rationale where no further action is required
- o Propose the follow-on uncertainty reduction activity to be undertaken to reduce the uncertainty, if any, and provide the rationale
- o Prepare a report recommending the uncertainty reduction approach for the identified uncertainties
- o Prepare a Staff Position, that provides clarification or proposed rule change text for all those regulatory or institutional uncertainties which can be readily resolved without establishing a separate task effort

The scope of the review will include the regulatory and institutional uncertainties identified in CNWRA 90-003 and the formally identified NRC regulatory uncertainties. Regulatory uncertainties as may be identified by the functional analysis being conducted by the CNWRA will be included to the extent that they can be incorporated within the schedule and resource allocation of this task. Reduction of technical uncertainty will not be included in the scope of this task.

#### B. APPROACH

A task team will be formed to develop guidance and criteria for the evaluation of uncertainties, to coordinate the proposed work and prepare the Staff Position and uncertainty reduction recommendation report. Criteria to be developed will cover: 1) decisions as to whether an uncertainty requires reduction; 2) selection of the uncertainty reduction approach; and, 3) which uncertainties are candidates for resolution and inclusion in the Staff Position. A task team member will be appointed by each of the Division of High-Level Waste Management Branch Chiefs and both the CNWRA and the Office of General Counsel (OGC) will provide staff to assist and advise the task team. Since the uncertainties cover a wide range of subject matter and since the resolution of regulatory uncertainties is the responsibility of the Branches, the evaluation of the individual uncertainties, preparation of clarifying language and rule text change, or the selection of uncertainty reduction approach will be performed by appropriate Branch staff. The task team member will coordinate with the Section Leaders and Branch Chiefs on staff assignments and schedule for specific uncertainty topic reviews. The task team member will provide assistance to assigned staff in the uncertainty evaluation, preparation of clarifying language and revised rule text, and selection of uncertainty reduction approaches. The task team as a group will develop decision criteria noted above for management approval, provide the consistency review for the separate contributions and will integrate the results into a Staff Position and recommended uncertainty reduction report.

The task team will also provide recommendations regarding the prioritization of the uncertainty reduction activities. To the extent possible the prioritization will incorporate criteria being developed under the License Application Review Strategy on-going effort under the Special Projects CNWRA Program Element. This is intended only as general guidance for planning and budget considerations since other program requirements (review of study plans, etc.) and the technical uncertainties will not be included.

### C. UNCERTAINTY REDUCTION APPROACHES

The following general approaches to uncertainty reduction will be considered:

1. "No Action", uncertainty does not require reduction
2. Clarification of regulatory intent
3. Minor revision, correction, or addition to rule
4. Development of technical or policy basis

The "No Action" option covers those uncertainties where the NRC staff considers that the regulation is adequately clear and requires no further explanation or where there is "intended uncertainty." Intended uncertainty is frequently incorporated in regulations where the uncertainty is stated in general policy terms, leaving the application of those policies to be considered in the context of the variable factual situations that may arise. The CNWRA report recognized the existence of intended uncertainty but did not identify it specifically since it would have required a judgement decision beyond the scope of the project. In general, if a regulatory uncertainty has been identified, it will require a documented response or explanation but not necessarily a change in the regulation. It is intended that the rationale for "No Action" will be incorporated in the task Staff Position. This is to serve as documentation for the uncertainty resolution decision.

A "clarification of regulatory intent" is an explanation or clarification of the identified regulatory uncertainty as to what was intended by the Commission but should be non-controversial and of minor significance such that it does not require a rulemaking action. Where the clarifying language is not complex and can be readily prepared, i.e., written in a few days or other time period agreed to by the task team member and line management, it will be included in the Staff Position. This will serve as documentation of the uncertainty reduction. The clarifying language may also be incorporated in other NRC guidance such as the License Application Format and Content Guide. Where the uncertainty is more complex, the need for a separate task to develop the clarifying language will be proposed and presented in the recommended uncertainty reduction report. The results of this separate task, when completed, may then be documented in one of methods listed in the Appendix A.

The "minor revision, correction, or addition to the rule" is to be applied where there is a need or desire to amend the rule but it is of minor significance and non-controversial, for example the incorrect use of the term "environmental report" vs "EIS". As above, where possible, the revised text will be developed and included in the Staff Position, however, the correction to the rule will be done in a separate task as an Executive Director Office rulemaking or rider to other rulemaking action. Where required, i.e., the uncertainty reduction is more complex, a separate task will be proposed and presented in the recommended uncertainty reduction report.

It is anticipated that in a number of instances there will be a need to "develop a technical or policy basis" before a decision can be made on the uncertainty reduction. For example, it is necessary to develop a technical understanding before a decision can be finalized on rulemaking or other uncertainty reduction method to clarify the meaning of the uncertainty "substantially complete containment." Uncertainties that fall into this category will require separate task plans and the uncertainty reduction may ultimately be documented by one or several of the methods delineated in Appendix A. The separate task requirement and rationale will be included in the recommended uncertainty reduction report.

#### D. TASK TEAM

The task team will be composed of one member each from DHLWM appointed by the Branch Chief. The WSE&I Program Element Manager will act as the task team leader. The CNWRA will be available to provide clarification of their reports if required, i.e., to act in an advisory position. The CNWRA may also undertake evaluation of specific uncertainty or perform specific task as may be assigned by the task team, agreed to by the CNWRA, and contractually approved. The CNWRA will also review and provide comments on the task team products. OGC staff will be assigned to provide assistance. The task team will establish their operating procedures and formalize the task description as their first order of business. Operating procedures will include provision for achieving consensus.

The role of the task team member is: to assist in the preparation of criteria and guidance for the uncertainties analysis; to provide coordination with their respective Branch, particularly as regards conduct of work and schedules; to coordinate staff in preparation of clarifying language or rule text and selection of uncertainty reduction methods; to ensure consistent inputs from the Branches; to integrate inputs from the Branches and participate in the preparation of a Staff Position and recommended uncertainty reduction report. The Branch Chiefs will retain the responsibility to approve proposed uncertainty reduction methods and regulatory clarifying language or recommended rule changes.

## E. ESTIMATED RESOURCES AND SCHEDULE

The task effort is estimated to require approximately six weeks effort for each of the task team members over a six month period. Additionally, 200 technical staff days are estimated to be required over a two month period to analyze and prepare the rationale. The effort to be expended for each uncertainty, or set of uncertainties, will be agreed to by the task team member, section leaders and branch chiefs. Note that those uncertainties that are more complex and require more time for analysis will only be evaluated to recommend the uncertainty reduction approach. The actual resolution of the uncertainties will be under a separate task.

Elapsed time for the task effort is estimated to be six months.

The PPSAS charge number for this task effort is 41117, "Systematic Analysis of Regulations."

### Proposed Schedule

o Appointment of task team members	August 31, 1990
o Management Approval of Staff Assignments, Criteria and Guidance for Uncertainty Reduction Analysis	October 1, 1990
o Complete Branch Analysis of Individual Regulatory and Institutional Uncertainties	December 15, 1990
o Draft Recommended Uncertainty Reduction Report	January, 1991
o Draft Staff Position	February, 1991
o Final Staff Position and Uncertainty Reduction Report	March, 1991

## F. SUPPORTING MATERIAL

The following material will be utilized in the analysis of uncertainty reduction methods:

1. Report CNWRA 89-003, Analysis and Evaluation of Regulatory Uncertainties in 10 CFR Part 60 Subparts B and E, May 1989
2. Report CNWRA 90-003, "Identification and Evaluation of Regulatory and Institutional Uncertainties in 10 CFR Part 60", February 28, 1990
3. CNWRA Responses to NRC Comments on the January 5, 1990 Draft CNWRA 90-003, March 2, 1990
4. Additional Regulatory And Institutional Uncertainties Identified By The Staff in SECY-90-207 (included as Appendix B)

## APPENDIX A

### UNCERTAINTY REDUCTION DOCUMENTATION METHODS

There are a number of uncertainty reduction documentation methods the Division will use, ranging from a rulemaking action to a Staff Position. Although various activities are performed in reducing regulatory and institutional uncertainty, such as preparation of clarification text or development of a policy position, each reduction or resolution requires documentation.

#### 1. RULEMAKING

- a. **LEGISLATIVE RULEMAKING** - Rulemaking with public comment period. Legislative and EDO rulemaking are the only uncertainty reduction methods that carry the force of law. Legislative rule making typically requires two years to complete.
- b. **EDO RULEMAKING** - The EDO has been delegated authority to issue regulations that do not involve significant questions of policy or do not amend Parts 7 and 9 Subpart C (reference NUREG/BR-0053, December 1989 and 47 FR 11816, March 19, 1982). EDO rulemaking does not require public comment.
- c. **RIDER TO OTHER RULEMAKING** - Incorporating rule changes in other rulemaking actions may be a convenient approach.

#### 2. INTERPRETIVE GUIDANCE

- a. **STAFF POSITION OR COMMISSION PAPER** - A Staff Position or Commission Paper may be used as a vehicle to identify or document the uncertainty reduction. This may be particularly useful in the case where it is concluded that no action is necessary to reduce a number of uncertainties but the rationale must be presented or where simple clarifying language will suffice to resolve an uncertainty. A Staff Position is used by the DHLWM to document regulatory positions and is signed by the Director NMSS and concurred in by the OGC.
- b. **LICENSE APPLICATION FORMAT AND CONTENT GUIDE** - This document provides guidance to DOE as to what is expected to be included in the license application.
- c. **LICENSE APPLICATION REVIEW PLAN** - This document is primarily guidance to the NRC staff but also informs DOE as to how NRC intends to review the license application; for example the types of methods, computer codes, and acceptance criteria that will be applied and, therefore, what DOE should expect in the review of their license application.
- d. **TECHNICAL POSITION AND NUREG REPORTS** - These contain various types of information and/or guidance to the licensee and public.

3. **MEMORANDUM OF UNDERSTANDING** - An agreement between government agencies regarding process by which the roles and responsibilities of each can effectively be achieved.

APPENDIX B  
(From SECY-90-207)

ADDITIONAL REGULATORY AND INSTITUTIONAL UNCERTAINTIES IDENTIFIED BY THE STAFF  
SINCE SECY-88-285 WAS ISSUED

Regulatory Uncertainties

1. Applicability of siting criteria to performance objectives (Subject of Separate Staff Position)

The phrase in 10 CFR 60.122, "to meet the performance objectives relating to isolation of the waste," could be interpreted to mean that the siting criteria in 10 CFR 60.122 apply only to the overall system performance objective in 10 CFR 60.112 or to the subsystem performance objectives in 10 CFR 60.113, as well.

2. Applicability of thermal load requirement to performance objectives (Subject of Separate Staff Position)

The thermal load requirement in 10 CFR 60.133 (1) could be interpreted to apply to only the pre-closure performance objectives in 10 CFR 60.111, or to the post-closure performance objectives in 10 CFR 60.112 and 10 CFR 60.113, as well.

3. Waste package containment timeframe (Subject of Separate Staff Position)

The 300 to 1,000-year waste package containment timeframe in 10 CFR 60.113 could be interpreted to mean the minimum period during which the waste package must remain substantially complete, or the maximum design lifetime for the waste package for which credit could be taken in demonstrating compliance.

4. Engineered barrier system radionuclide release rate limit

The annualized radionuclide release rate limits in 10 CFR 60.113(a)(ii)(E) are based on the inventory of radionuclides present at 1000 years following permanent closure of the repository. As such, for some radionuclides (e.g., Am-241 and Pu-240), the allowed releases from the engineered barrier system (EBS) can be several orders of magnitude greater than releases to the accessible environment permitted by the overall performance objective (i.e., the U.S. Environmental Protection Agency (EPA) Standards). The underlying purpose of the EBS release rate limit, together with other subsystem performance objectives, is to enhance the Commission's confidence that the EPA Standard will be met. For some radionuclides, it is unclear if the release rate limit does in fact enhance confidence that the EPA standard will be met.

5. Reference to applicable mine safety requirements

The reference in 10 CFR 60.131(b)(9) to the applicable mine safety requirements does not reflect the reorganization and renumbering of mine safety requirements in 30 CFR, Chapter I which occurred after 10 CFR Part 60 was issued.

6. Topical Guidelines for the Licensing Support System (LSS) (Regulatory Guide on Topical Guidelines is under preparation)

Interim topical guidelines, drafted by the parties to the LSS negotiated rulemaking were adopted by the U.S. Nuclear Regulatory Commission (NRC) with the statement that the topical guidelines would be revised later and set forth as a regulatory guide. The interim topical guidelines, partially modeled after the Environmental Assessments prepared in connection with the U.S. Department of Energy's site selection process, need to be revised to describe all of the information which should be submitted to the LSS to support the high-level waste repository licensing process. This revision will clarify the list of topics for which the LSS participants should submit documentary materials for entry into the LSS under 10 CFR 2.1003.

Institutional Uncertainties

1. NRC's role regarding EPA's implementation of the Resource Conservation and Recovery Act (RCRA) (Addressed in commission Paper)

EPA's RCRA regulations concern chemically hazardous wastes. Because RCRA created an overlapping regulatory authority with the Atomic Energy Act (AEA), EPA can regulate any high-level waste already regulated by NRC under 10 CFR Part 60 that is found to contain RCRA-defined chemically hazardous substances. As a consequence, it is not clear how the affected agencies (both EPA and NRC) would administratively implement their respective programs in the context of AEA and RCRA.