POLICY ISSUE
(Information)

February 12, 1991 SECY-91-040

For: The Commissioners

From: James M. Taylor
Executive Director for Operations

Subject: INTERACTIONS WITH EPA RELATED TO EPA'S REMANDED HIGH-LEVEL WASTE STANDARDS

Purpose: To inform the Commission of recent interactions between the staff and the U.S. Environmental Protection Agency (EPA) related to EPA's ongoing actions to revise their remanded high-level waste (HLW) standards, and the staff's intent regarding future such interactions.

Summary: Significant progress has been made in resolving concerns about the probabilistic format of EPA's standards and in reaching a common understanding of the test to be applied when evaluating compliance with the standards (reasonable assurance). Progress in resolving other issues has been hampered by the loss of key technical personnel at EPA.

Background: SECY-89-319, dated October 17, 1989, described the staff's views regarding EPA's high-level waste standards and recommended that the staff continue to maintain close contact with EPA to identify and resolve potential implementation issues. Since then, the staff has had several informal contacts with EPA and, on August 27, 1990, the staff formally transmitted comments to EPA on Working Draft No. 2 of EPA's standards. On December 20, 1990, the staff met with EPA to discuss issues related to the reissue of EPA's standards, including a contract recently let by EPA to explore the feasibility of a negotiated rulemaking. Notes from the meeting with EPA are enclosed. Also enclosed is a copy of EPA's Statement of Work to scope the feasibility of a negotiated rulemaking.

NOTE: TO BE MADE PUBLICLY AVAILABLE IN 10 WORKING DAYS FROM THE DATE OF THIS PAPER

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Discussion: During the past year, the staff has had a number of informal interactions with EPA aimed at resolution of potential implementation difficulties associated with EPA's environmental standards for disposal of high-level waste. The current status of several potential issues is discussed below.

Probabilistic format of the standards. For many years, the Commission has been concerned about the workability of standards that require numerical probability estimates for very unlikely processes and events. The staff's August 27, 1990, comments on Working Draft No. 2 of EPA's standards suggested alternative wording for the standards that would retain the probabilistic format for relatively likely releases, but would address the impacts of unlikely releases with a consequence limit to be applied individually to each unlikely release. The staff argued that the alternative wording would impose almost exactly the same level of safety on a repository, while avoiding the potential pitfalls of probability estimation for very unlikely and speculative events that could occur far in the future.

EPA has been receptive to the staff's suggestion. Several of the staff's recent interactions with EPA have involved preparation of explanatory text that could be used by EPA in its Notice of Proposed Rulemaking to explain the alternative wording to other interested parties. The staff continues to believe that adoption of this wording by EPA would alleviate the Commission's concerns about the probabilistic format of EPA's standards, and the staff will continue to work with EPA to facilitate such adoption by EPA.

Stringency of the standards. The staff's August comments to EPA summarized the basis for derivation of EPA's release limits, expressed concern that the release limits might be overly stringent, and recommended that EPA reexamine the stringency of the standards in light of other risks experienced by society and risk levels used as the basis for other safety standards. The staff encouraged EPA to place increased emphasis on comparisons with other regulatory standards and to deemphasize its analyses of hypothetical repository performance when presenting its release limits.

Interactions between EPA and the staff have confirmed that EPA intends to retain the "technical achievability" basis for its standards. EPA is willing to consider comparisons with other risks as a supplement to its current technical basis for the standards, but does not wish to have such comparisons serve as the primary foundation for the release limits. The staff will continue to encourage EPA to increase its emphasis on risk comparisons.

Reasonable assurance. In its 1985 standards, EPA used the term "reasonable expectation" and contrasted the term with "reasonable assurance" as used by the Commission. When the NRC proposed to adopt EPA's standards in 1986, the NRC argued that the term "reasonable assurance" as used in 10 CFR Part 60 has the same meaning as that intended by EPA. However, the U.S. Department of Energy (DOE) and others argued that EPA's term is a much less stringent standard than NRC's term, and that NRC should not impose the "reasonable assurance" test when evaluating compliance with EPA's standards.

Interactions with EPA have confirmed that there is no substantive disagreement between the staff and EPA regarding the stringency of the test to be applied when evaluating compliance with EPA's standards. Both agencies anticipate a test of compliance that is reasonable in light of the likelihood that compliance will be achieved and of the consequences of possible noncompliance. The staff has initiated an effort to develop explanatory text that both agencies can use to explain the reasonableness test expected for application of the standards.

Dose limit alternative. The containment requirements of EPA's 1985 standards were expressed in terms of allowable releases of radioactive materials to the environment. The NRC supported this format for the standards, rather than a limit on projected doses or health effects, because it precludes the need for long-term speculation about population locations, lifestyles and metabolic characteristics when evaluating compliance with the standards. Recently, DOE and others have suggested to EPA that an alternative standard be added that would provide limits based on projected doses or health effects. Such an alternative standard might be beneficial if it would allow DOE to take credit for the remoteness of the repository sites now being considered for repositories.

The staff has indicated to EPA its continued preference for a release limit standard because such a standard would eliminate many potentially contentious issues from a licensing proceeding. However, EPA's willingness to consider a dose limit alternative has caused the staff to consider other means of simplifying long-term dose or health effect estimates. One alternative is to specify, by rule, that such estimates shall be based on current population locations, lifestyles and metabolic characteristics except where there is convincing evidence that changes will occur. EPA has not yet responded to the staff's suggestions.

C-14 release limits. The release limits of EPA's 1985 standards were derived from EPA's projections of the performance of hypothetical repositories located within saturated geologic media. For such repositories, gaseous releases of C-14 do not appear to be significant. In contrast, the candidate repository horizon at the Yucca Mountain, Nevada site is unsaturated, and gaseous releases of C-14 could exceed EPA's release limits. However, such releases would likely be quite dilute, and the resulting dose rates to individuals would be only a very small fraction of natural background radiation levels. Therefore, DOE and others have suggested that EPA revise the release limits for C-14.

The staff has advised EPA of its view that potential gaseous releases of C-14 would clearly meet the NRC's criteria for releases "below regulatory concern" (BRC). However, EPA has not yet indicated that it is willing to recognize any BRC level, even at the very low dose rates associated with gaseous C-14 releases. EPA is currently considering a wide range of alternatives regarding the release limits for C-14, and has given no clear indication that the 1985 limits will be revised.

Interagency cooperation. Progress on revisions to the High Level Waste Standard at EPA has been inhibited by recent losses of key contractor and in-house technical staff. During the staff's December 20, 1990, meeting with EPA, possible ways NRC staff could assist were discussed (e.g., helping train new EPA staff on the regulatory history and existing technical support base; helping develop technical support either in-house or at the Center for Nuclear Waste Regulatory Analyses). It was agreed that pending any management decisions on such additional assistance, the staffs would continue to work closely through the currently established informal communication links.

Summary: Interactions with EPA have been relatively successful, although the loss of key technical staff at EPA has hampered progress on resolution of major issues. As recommended in SECY-89-319, the staff will continue to maintain close contact with EPA to identify and resolve potential implementation issues to the extent practical.

Coordination: The Office of the General Counsel has reviewed this paper and has no legal objection.

James M. Taylor
Executive Director
of Operations

Enclosures:
1. NRC/EPA Meeting Notes
2. Statement of Work:
   Negotiated Rulemaking

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MEETING NOTES

EPA AND NRC STAFF

DECEMBER 20, 1990

A meeting was arranged for December 20, 1990, to discuss with EPA their plans for reissuance of the HLW Standard. Meeting participants included the following:

EPA	NRC
Richard J. Guimond	Robert M. Bernero
William J. Gunter	Robert E. Browning
Floyd L. Galpin	B.J. Youngblood
Raymond L. Clark	Ronald L. Ballard
	Daniel J. Fehringer

A number of topics were discussed that related to EPA's reissuance of the remanded Standard, ranging from EPA's schedule for release of the next working draft, staffing, and rule changes, to NRC plans for conforming rules, potential interagency cooperation, and related Department of Energy (DOE) activities. While the discussions were necessarily general, due to the informal structure of the meeting, a number of possible courses of action were discussed. The main points are summarized in the following paragraphs.

Schedules: EPA indicated its desire to maintain the previously stated schedule for issuance of a revised working draft (strawman) standard for comment in the February-March, 1991 time frame. The standard would take on the order of another year to assemble in final form. NRC indicated its desire to prepare conforming rules on a parallel schedule; issuing them either simultaneously with, or shortly following, EPA's issuance of its revised draft Standard. It was acknowledged that continuation of the close informal interactions between the two agencies would be essential for this objective to be met.

Rule Changes: Because of the elapsed time since the 1987 Court remand and expressed desires on the part of a number of organizations for substantive changes to the Standard, EPA indicated that changes would be broader than the issues identified in the court remand. Options under consideration include probabilistic individual or population dose limits, in addition to the current probabilistic release limits; revisiting the Carbon-14 issue; and possible restructuring of the environmental standard to separate low probability scenarios from those more likely to occur in constructing the Complementary Cumulative Distribution Functions (CCDF's). Most of the concerns raised by the NRC staff in their August 27, 1990, comments to EPA on the second working draft Standard are reflected in EPA's current list of options.

Negotiated Rulemaking: EPA has implemented a contract with the Conservation Foundation to investigate the feasibility of conducting a negotiated rulemaking as a means of issuing a satisfactory revised Standard. The NRC has gone on record as discouraging a formal structured rulemaking. However, a lengthy discussion of the feasibility of negotiating with stakeholders outside the formal rulemaking process followed, with optimism expressed on the part of both Agencies that a workable interactive approach could be structured.

Staffing: Losses of key technical staff in EPA's high level waste program during the past year have created substantial scheduling difficulties. They are recruiting to fill two engineering slots, and hope to have staff on board in the next couple of months. In recognition that the new employees will most likely be unfamiliar with the regulatory history of the Standard, the discussions focused on possible temporary assignments of new EPA hires at the NRC to expedite their orientation. The NRC indicated that such arrangements could be made.

Interagency Cooperation: A range of possible approaches for interagency cooperation were discussed during the meeting, including potential participation by the Department of Energy (DOE). Principal options were:

- Direct technical support to EPA in the development of supporting text for the rule could be provided by experienced NRC technical staff.

- Review by experienced NRC technical staff of the EPA supporting technical analysis, indicating where they thought improvements were needed.

- Contractual arrangements for technical support from the NRC's Center for Nuclear Waste Regulatory Analysis (CNWRA), although NRC noted that limited staff resources at the CNWRA were currently fully committed.

DOE involvement was also a subject of discussion. One possible option would be for DOE to publish a demonstration total system performance assessment of a real geologic repository that would provide the technical framework to which the revised rule could be referenced. Another alternative would be for EPA to request that DOE provide a critical review of the technical basis report that A. D. Little prepared in 1985 in support of the EPA Standard.

The meeting closed with agreement that concrete cooperative arrangements would be initiated by way of the informal communication links that have worked effectively to date.

DRAFT

Delivery Order # _____

Radioactive Waste Standard Negotiated Rulemaking

I. BACKGROUND

A. Political mandate, statutory or regulatory background for project:

Under authority derived from the Atomic Energy Act, Reorganization Plan No. 3 of 1970, and the Nuclear Waste Policy Act of 1982, the EPA has the responsibility to develop generally applicable standards for the safe management and disposal of radioactive waste. Once issued, these standards will apply to both Department of Energy (DOE) and Nuclear Regulatory Commission (NRC)-licensed facilities.

EPA began work on developing radioactive waste standards in 1976. The objective was and is to provide a regulatory framework for limiting the risks to both present and future generations from the management and disposal of defense and commercial spent nuclear fuel, high-level and transuranic radioactive wastes. EPA issued a proposed rule for comment--"40 CFR 191 Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes"--on December 29, 1982. On September 19, 1985 EPA issued a final rule. In 1987, following a legal challenge brought by environmental groups and several states, the U.S. Court of Appeals for the First Circuit remanded a portion of the standards relating to disposal back to the Agency for re-consideration.

The standards consisted of two Subparts. Subpart A, which was reinstated by the Court, applied to radiation exposures to members of the public from management and storage of radioactive wastes prior to disposal.

Subpart B established several different types of requirements for disposal of radioactive wastes. The primary standards for disposal were long-term containment requirements that were designed to limit projected releases of radioactivity to the environment for 10,000 years after disposal. A set of qualitative assurance requirements complemented and helped assure compliance with the containment requirements. A set of individual protection requirements limited radiation exposures to individual members of the public after disposal. Finally, a set of groundwater protection requirements were designed to protect underground sources of drinking water. Subpart B also contained informational guidance for implementation of the disposal standards to clarify the Agency's intended application of these standards. It was this portion of the standards--Subpart B--that was remanded to the Agency for reconsideration.

Since the Court remand, the Agency has initiated a program

to re-propose and re-promulgate these standards. We are considering the the issues identified by the Court as well as relevant developments in United States and international radioactive waste programs and standard-setting efforts. To date, the Agency has issued two "working drafts" of a revised set of standards to a spectrum of interested parties.

B. Brief outline of the project:

To assess the feasibility of revising 40 CFR 191 through a regulatory negotiation process. If it is determined that a regulatory negotiation is not feasible, assess the feasibility of convening policy dialogues, workshops or other potential means of addressing specific issues that have been raised in connection with the re-promulgation of 40 CFR 191.

II. SCOPE OF WORK

Phase 1:

1. Provide convening activities support as outlined in the contract. Select, in consultation with EPA a convenor/facilitator for this proceeding.

2. Meet with EPA to discuss substantive and procedural issues and potentially involved interests and parties.

3. Identify and contact affected interests and potential parties to discuss the regulatory negotiation process, and the issues involved in the regulation.

   If initial interviews with the key participants reveal that a regulatory negotiation is not feasible, the contractor shall notify the EPA contacts listed below , explain the difficulties (lack of interest, unequivocal opposition of a key party, disagreement about the definition of the problem, wrong forum or process, etc.) and await further EPA decision on whether to proceed to interview all potential participants.

4. The contractor shall provide verbal reports weekly to the program office contact on the general progress of the convening effort.

5. Provide a convening report to EPA: Summarize the results of convening discussions including such things as discussions of the chances of a successful regulatory negotiation, recommendation of potential parties at the table, discussion of issues which will bring parties to the table, and issues which the parties cannot negotiate. Discussions should utilize as a guideline EPA's Selection Criteria for Regulatory Negotiations.

If a regulatory negotiation appears to be feasible, propose a design for the process including such things as number, length, location and frequency of meetings, recommendation of potential participants whom EPA should invite, information or research necessary prior to or during the negotiation, and estimated resources (EPA and facilitation) recommended for the success of the negotiation.

If a regulatory negotiation does not appear feasible, propose an alternative means of addressing specific issues that have been raised in connection with the re-promulgation of 40 CFR 191 (i.e., through policy dialogues, workshop series or the like).

Phase 2:

Upon EPA decision to proceed with a regulatory negotiation (policy dialogue, workshop series):

1. Assist EPA in contacting potential parties to obtain commitments to participate in the negotiation (dialogue, workshop series).

2. Arrange an initial (organizational or informational) meeting of the parties to discuss the issues involved in revising the regulation, to get public commitments to go forward from each of the parties, and to discuss groundrules for the process.

3. Provide meeting management support for this initial meeting, including such activities as meeting arrangements and recording of minutes.

4. Provide assistance and materials in conducting an orientation or training for committee members in the consensus-building process prior to the negotiation.

The program office envisions completing negotiations and proposing a regulation by December 1991.

If EPA proceeds with the negotiation, this delivery order may be amended to provide for facilitation and evaluation services for the negotiation.

III. FUNDING AVAILABILITY

Funds in the amount of $ 25,000 are available for this task. The contractor shall not exceed this amount without a modification of this delivery order.

The government estimates that the project will involve the

use of the following contract hours and costs:

80 hours of senior convenor/facilitator
50 hours of junior convenor/facilitator
20 hours of non overhead clerical
15 hours of trainer
20 hours of program administration
20 hours of other (direct support coordinator, assessment coordinator, documentor)

$ 2500 in other direct costs

IV. WORK APPROACH

The Contractor shall approach this task in accordance with terms of the basic contract.

In gathering information or performing research with parties outside the EPA, the contractor will identify him/her self as a contractor to EPA not an EPA employee.

The contractor shall provide input or make recommendations based on the information gathered, however, decisions on all substantive issues will be made by EPA. THE CONTRACTOR SHALL NOT INTERPRET EPA POLICY ON BEHALF OF EPA AND SHALL MAKE NO DECISIONS ON ITEMS OF POLICY, REGULATION OR STATUTE. THE CONTRACTOR SHALL NOT TAKE A STAND ON THE MERITS OF SUBSTANTIVE ITEMS UNDER DISCUSSION.

V. REPORTS

The contractor shall send EPA all reports in accordance with the terms of the basic contract.

Copies of all reports and written deliverables shall be sent to the program office contact listed below.

A copy of each written deliverable shall be provided to the Project Officer for this contract. This includes all meeting notices, agendae, and summaries, all training materials, and all other written reports. If oral briefings are scheduled for EPA staff, the Project Officer shall be notified in time to attend.

VI. EPA CONTACTS

Project Officer:

Deborah Dalton, Deputy Director
Regulatory Negotiation Project PM 223
Environmental Protection Agency
401 M Street, S.W.

Washington, D.C. 20460
Phone: (202) 382-5495 Fax: (202) 252-0513
E-mail: EPA2178

Program Office:

Ray Clark, Project Leader, WMSB
Office of Radiation Programs ANR-460
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460
Phone: (202)475-9633 Fax: (202)475-8351

VII. PERIOD OF PERFORMANCE

The period of performance of this delivery order shall be until May 31, 1991.

VIII. LIST OF ATTACHMENTS

1. 40 CFR 191 as issued in 1985.
2. Working Draft #2: revisions to 40 CFR 191 as of 1/31/90.
3. Synopses of comments received to date.
4. List of potentially interested parties.

Potentially Interested Parties to a Negotiated Rulemaking on 40 CFR 191

Federal Agencies

U.S. Environmental Protection Agency
U.S. Department of Energy
U.S. Nuclear Regulatory Commission
U.S. Office of Management and Budget

State Governments

State of Nevada
State of New Mexico
State of Washington

Scientific/Technical Oversight Groups

National Research Council/National Academy of Sciences
Nuclear Waste Technical Review Board
New Mexico Environmental Evaluation Group

National Environmental Groups

Natural Resources Defense Council
Environmental Defense Fund

Local Environmental Groups

New Mexico -- Southwest Research and Information Center
Nevada -- Citizen Alert
Nuclear Waste Study Committee

Industry Groups

Edison Electric Institute