APR 4 1991

JMURPHY/MEMO

MEMORANDUM FOR: Joseph A. Murphy, Deputy Director
Division of Systems Research
Office of Nuclear Regulatory Research

FROM: Ronald L. Ballard, Chief
Geosciences & Systems Performance Branch
Division of High-Level Waste Management, NMSS

SUBJECT: REQUEST FOR REVIEW OF UNCERTAINTIES PAPERS

The enclosed draft Commission paper responds to a Commission request for information regarding implementation of the high-level waste standards of the U.S. Environmental Protection Agency (EPA). EPA's standards require analyses of a repository performance similar in some respects to probabilistic risk analyses for nuclear power plants. Expert judgment is expected to play a role in such analyses, and I would therefore appreciate receiving your views (and any differing views of which you might be aware) on the expert judgment section (pages 14-18) of the enclosed paper. The Office of Nuclear Regulatory Research has already concurred in this paper, but your informal comments will help us prepare for an April 23 briefing on this subject for the Advisory Committee on Nuclear Waste. Comments can be phoned to Seth Coplan (x20410) or Dan Fehringer (x20426), or can be mailed to me at Mail Stop 4-H3.

/s/
Ronald L. Ballard, Chief
Geosciences & Systems Performance Branch
Division of High-Level Waste Management, NMSS

Enclosure:
Draft Commission Paper

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For: The Commissioners

From: James M. Taylor
Executive Director for Operations

Subject: STAFF'S APPROACH FOR DEALING WITH UNCERTAINTIES IN IMPLEMENTING THE EPA HLW STANDARDS

Purpose: To describe the staff's views on dealing with uncertainties in implementing the U.S. Environmental Protection Agency's (EPA's) probabilistic high-level radioactive waste (HLW) standards.

Background: A 1986 staff paper (SECY-86-323, dated October 30, 1986) discussed approaches to licensing a geologic repository. The paper described ways to streamline the hearing process, to identify and resolve licensing issues early, and to improve 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 was a foundation for the staff's regulatory framework, and was elaborated on in a later staff paper, SECY-88-285, dated October 21, 1988. The 1988 paper, which was updated in 1990 as SECY-90-207, described: (1) the existing regulatory framework for licensing a repository; (2) approaches for identifying uncertainties in the framework; and (3) a strategy and schedules for reducing uncertainties by using a mix of rulemakings, technical positions, and regulatory guides. (SECY-90-207 classified uncertainties as technical, regulatory, or institutional.) SECY-88-285 and SECY-90-207 both discussed general uncertainties associated with repository licensing, but did not examine the specific uncertainties involved in implementing the probabilistic HLW standards promulgated in 1985 by EPA. (The 1985 EPA standards are not currently effective, having been vacated in 1987 by the Court of Appeals for the First Circuit.)

CONTACT:
Daniel Fehringer, NMSS
492-0426

Another staff paper (SECY-89-319, dated October 17, 1989) informed the Commission of: (1) the status of EPA's efforts to reissue its HLW disposal standards; (2) the staff's reevaluation of its views on implementation of probabilistic standards; and (3) the staff's recommendation for development of procedures and rules that are needed for implementing the standards. After review of that staff paper, the Commission requested the following additional information from the staff.

> "In carrying out the proposed EPA HLW standards which are probabilistic, it may be necessary to have in place an agreed-upon methodology for characterizing and propagating the uncertainties in order for any site to achieve compliance with the EPA standard. These methodologies can have many forms (such as those used in NUREG-1150 and other probabilistic studies) and, as the staff recognizes and experience has shown, can become controversial. Staff should submit a summary on the staff's current approach to dealing with uncertainties/methodologies in implementing the EPA probabilistic standard so as to avoid [as] many of the controversial aspects as possible."

Discussion: EPA's HLW standards differ significantly from more traditional radiation protection standards, causing uncertainty about the means to be used for evaluating compliance. The enclosure to this paper analyzes some of the more controversial features of EPA's standards and evaluates alternatives to those standards, including the recommendations of the International Commission on Radiological Protection (ICRP). The staff concludes that the technical information and analyses needed to evaluate compliance with EPA's standards will be less demanding than the information and analyses required by the ICRP recommendations. Thus, from a technical perspective, EPA's standards seem to be easier to implement than the ICRP criteria.

Significant uncertainties will be encountered in implementing EPA's standards regardless of the form those standards might ultimately take. Therefore, the enclosure to this paper provides a discussion of the staff's views regarding uncertainties and potential means for dealing with them. Uncertainties in our understanding of a repository system can be generally categorized as: (1) "data uncertainty," defined here as uncertainty in our knowledge of the state of the system at the time of repository closure; (2) "future states uncertainty," reflecting our imperfect ability to predict the future states of the environment within which the repository will exist; and (3) "model uncertainty" -- uncertainty in our ability to forecast the performance of a repository within its future environment. A number of methods for dealing with these uncertainties are discussed in the enclosure. These include development of data through site characterization, use of natural analogues, development of a performance assessment capability, and use of rulemakings, technical positions and regulatory guides.

The "agreed-upon methodology for characterizing and propagating the uncertainties" referred to by the Commission is not yet complete, but significant elements of such a methodology have been developed. These include a general procedure for scenario identification and screening; an uncertainty analysis technique (the Latin Hypercube variation of Monte Carlo analysis); a regression analysis methodology for sensitivity analysis; models of groundwater travel and contaminant transport; and models for environmental transport, dosimetry, and health effects projections. Areas where additional development is needed include some of the details of scenario development; models of waste package and engineered barrier performance; ways to estimate the probabilities of potentially disruptive events; methods for extrapolating short-term test data for long-term performance modeling; and methods for model validation. Additional studies are also underway regarding use of natural or man-made analogues in repository performance assessments. The staff and its contractor, the Center for Nuclear Waste Regulatory Analyses (CNWRA), are currently evaluating the existing methodology by conducting iterative performance assessments for the Yucca Mountain candidate repository site and through CNWRA's Systematic Regulatory Analysis process.

Despite the staff's efforts to reduce uncertainties, there will be "residual uncertainties" regarding data, models, and future states of the repository. The significance of these uncertainties will need to be addressed in deciding whether there is reasonable assurance that the EPA standards will be met. In general, residual uncertainties must be addressed in a judgmental manner. The enclosure to this paper distinguishes between two types of judgment. The first, "technical expert judgment," is used to quantify residual uncertainties to the extent practical, to estimate the effect of those uncertainties on repository performance, and to assess the effects of unquantifiable uncertainties on repository performance. The second type of judgment, "decision-maker judgment," addresses the regulatory significance of residual uncertainties. In general, the staff anticipates examining uncertainties in NRC's traditional manner, i.e., using a process that considers all available data, variances of opinion regarding physical and chemical mechanisms important for performance, statistical evidence, and other relevant information. The staff recognizes that expert judgment will be widely used in a repository performance assessment, but would not consider it acceptable to substitute expert judgment for experimental data or other more technically rigorous information that is reasonably available or obtainable.

Conclusions: The staff recognizes the existence of significant uncertainties associated with implementation of EPA's HLW standards. The enclosure to this paper describes the staff's current views on dealing with uncertainties in implementing the EPA HLW standards, whatever the final form of those standards might be. While an "agreed-upon methodology for characterizing and propagating the uncertainties" referred to in the Commission's information request does not yet exist, the staff considers that the approaches discussed in the enclosure to this paper will allow licensing decisions to be made.

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

James M. Taylor
Executive Director
for Operations

Enclosure:
Staff's Approach for Dealing with
Uncertainties in Implementing
the EPA HLW Standards

STAFF'S APPROACH FOR DEALING WITH UNCERTAINTIES IN IMPLEMENTING THE EPA HLW STANDARDS

CONTENTS

STAFF'S APPROACH FOR DEALING WITH UNCERTAINTIES IN IMPLEMENTING THE EPA HLW STANDARDS

Much uncertainty about implementing the high-level waste (HLW) standards of the U.S. Environmental Protection Agency (EPA) results from several differences between those standards and more traditional radiation protection standards, such as the recommendations of the International Commission on Radiological Protection (ICRP). EPA's standards have been controversial and have led many observers to question the workability of those standards in a formal licensing review. The first section of this enclosure analyzes some of the more controversial features of EPA's standards and evaluates alternatives to those standards.

The second section of this enclosure discusses the staff's approach for dealing with uncertainties in implementing EPA's standards. Uncertainties in projecting the performance of a repository are discussed, as are potential methods for reducing those uncertainties.

Finally, this enclosure presents a discussion of residual uncertainties and the staff's views on use of expert judgment in projecting repository performance and evaluating the acceptability of a repository. The discussion distinguishes "technical expert judgment" (used to identify uncertainties and to quantify them to the extent practicable) from "decision-maker judgment," which evaluates the regulatory significance of uncertainties in projected performance.

1. ANALYSIS OF EPA'S HLW STANDARDS

The principal feature of EPA's 1985 HLW standards was a probabilistic limit on cumulative releases of radioactive materials to the environment during the first 10,000 years after disposal. EPA's standards also contained limits on potential dose rates to future individuals, but these limits applied only for the first 1,000 years after disposal and only for conditions involving no disruption of a repository.

In developing its Publication 46, the ICRP recognized that existing guidance on radiation protection would need to be modified for application to activities like waste disposal. In Publication 46, the ICRP considered many of the same issues addressed by EPA in developing its HLW standards, especially the need for standards for low-probability, high-consequence release scenarios. The following discussion summarizes some of the major features of EPA's standards, describes possible alternatives to those standards, and provides a comparison with equivalent recommendations of ICRP Publication 46.*

*The Advisory Committee on Nuclear Waste has endorsed the ICRP recommendation in a letter from D. Moeller to Chairman Carr, dated January 29, 1991.

1.1 Release Limits

EPA's containment requirements are expressed in terms of allowable releases of radioactive materials from a repository. EPA's release limits were derived from a health-effects goal, using a generic biosphere model with world-average characteristics. Because few, if any, actual repository sites will conform to this world-average model, the actual number of health effects to be expected for a repository will probably vary from EPA's goal. An alternative format, as recommended in ICRP Publication 46, would limit the doses (or health risks) that might result from those releases.

The advantage of the release-limit format is that it provides a usable measure of repository performance while greatly simplifying demonstrations of compliance by excluding speculative dosimetry-related issues such as future population sizes, locations, and lifestyles that a dose-limit format would entail. One disadvantage of the release-limit format is that, for a specific site, the generic release limits might be more or less stringent than the desired health-effects goal. The release-limit format also makes it difficult to compare the standards to natural sources of radiation exposure or to other radiation-protection standards that are usually expressed in terms of allowable doses.

The U.S. Nuclear Regulatory Commission (NRC) staff has long supported EPA's release-limit format for the standards, because it would eliminate many potentially contentious issues from a licensing review.

1.2 Population Impacts Basis

EPA's standards emphasize protection of populations by imposing "containment requirements" that limit the cumulative amount of radioactive material released over 10,000 years. The cumulative release limits correspond to EPA's population impacts goal of 1,000 premature cancer deaths for a 100,000 metric tonne (MTHM) repository. Only limited protection of individuals is provided for "undisturbed performance" during the first 1,000 years. Thus, for most of the circumstances and time period of concern, radiation doses to individuals could be either very high or very low, depending on specific site characteristics. The alternative to EPA's cumulative release limits, as recommended in ICRP Publication 46, would be limits that emphasize protection of individuals rather than populations.

EPA's decision to base its standards on population impacts rather than on protection of individuals was EPA's most significant departure from the traditional concepts of radiation protection. EPA argued that limits corresponding to protection of individuals might be very difficult to meet and that cumulative release limits would be more practical to achieve. (See 50 FR 38077, dated September 19, 1985.) It was also noted that standards based on protection of individuals might encourage selection of disposal sites where any release of wastes would be substantially diluted, even if such sites offered less than optimal containment of wastes.

The principal advantage of EPA's cumulative release limits is that such limits encourage isolation, rather than dilution, of wastes. A significant disadvantage of EPA's cumulative release limits is inconsistency with more commonly applied radiation protection standards, which emphasize protection of individuals. Another disadvantage is that EPA's cumulative release limits do not recognize any de minimis or "below regulatory concern" level of radiation exposure. Thus, releases that cause very small doses to large numbers of people are considered equivalent to releases that cause larger doses to smaller populations.

The NRC staff has not previously objected to the population-impacts basis for EPA's standards. EPA's decision to protect populations rather than individuals was viewed as a decision properly within EPA's discretion, given EPA's authority to develop generally applicable environmental radiation-protection standards.

1.3 10,000-Year Period of Concern

Applicability of the containment requirements of EPA's standards is limited to the first 10,000 years after repository closure. In contrast, the recommendations of ICRP Publication 46 are open-ended, restricting individual doses and risks in perpetuity.

The advantage of a 10,000-year limit on releases is that very speculative long-term disruptions need not be evaluated in a licensing review. The disadvantage is the potential for significant releases to occur after the 10,000-year cut-off.

The NRC staff has supported EPA's 10,000-year limit on the period of concern. Projections of repository performance for a 10,000-year period will be uncertain, but such projections become significantly more uncertain as the projections are extended over longer periods of time. The staff agrees with EPA that a 10,000-year regulatory test is generally sufficient to evaluate the acceptability of repository performance.

1.4 As Low as Reasonably Achievable (ALARA)

EPA's standards are notable for the absence of a specific requirement that projected releases be ALARA. EPA's containment requirements, which were derived from analyses of the waste-isolation capabilities of hypothetical HLW repositories, are effectively "generic" ALARA levels. In contrast, an explicit ALARA requirement is a prominent feature of the recommendations of ICRP Publication 46.

The principal advantage of an explicit ALARA requirement would be consistency with other radiation-protection standards. The disadvantage would be significant difficulties in evaluating compliance with such a criterion. In the NRC staff's view, the large uncertainties in projected repository performance would make any case-specific ALARA analysis highly speculative. The NRC staff remains opposed to adoption of an ALARA requirement as a Standard for post-closure performance of an HLW repository.

1.5 Stringency

EPA's containment requirements were derived so as to limit potential health effects from a large repository to 1,000 premature cancer deaths over 10,000 years. EPA argued that this level of impacts is comparable to the impacts that might have occurred if uranium ore had never been mined for use as nuclear fuel, and that the level of impacts is therefore clearly acceptable. EPA's critics have charged that the level is excessively stringent and that the costs of achieving this level of safety will be excessive. An alternative commonly suggested is to increase the release limits by a factor of ten, as recommended by EPA's Science Advisory Board.

In SECY-89-319, the staff pointed out that the population risk associated with EPA's standards (10^{-1}/yr) is intermediate between the population risk typically posed by a single commercial nuclear power plant (10^{-2}/yr) and that represented by all commercial nuclear power plants in the U.S. (10^{0}/yr). The cumulative number of health effects committed by disposal of spent nuclear fuel (1,000 per 3,000 reactor-years of nuclear power generation) is significantly larger than the cumulative number of health effects anticipated during nuclear power generation (about 30). These comparisons would suggest that EPA's release limits are not overly stringent.

EPA's critics, on the other hand, have translated the 1,000 health-effects basis into an equivalent individual risk level. This is typically done by averaging the 1,000 health effects over the entire U.S. population over 10,000 years. Averaging over such a large population indicates risk levels very much smaller than those associated with other radiation-protection standards, including the recommendations of ICRP Publication 46. The NRC staff does not agree that such averaging is appropriate. Only a very small fraction of the U.S. population would actually be at risk from a repository (perhaps 0.1 percent or less), and the average risk within this smaller population would be more comparable to other radiation protection standards.

A different perspective on the stringency of EPA's standards can be gained by comparing EPA's allowable release limits with the inventory of a repository. The following table presents such a comparison. This table indicates that EPA's release limits are significantly restrictive only for the isotopes of americium (Am) and plutonium (Pu). Moderate restrictions are imposed on releases of neptunium (Np), uranium (U) and carbon-14 (C-14), whereas permissible releases of all other radionuclides may approach or exceed the entire repository inventory. Thus, the staff believes that EPA's standards are not particularly stringent in terms of the performance required of a repository.

1.6 Probabilistic Format

The "containment requirements" of EPA's standards prescribe two sets of release limits. Releases more likely than 1 chance in 10 (over 10,000 years) must not exceed the levels specified in a table of release limits, whereas releases less likely than 1 chance in 10 may be up to 10 times larger. Releases less likely than 1 chance in 1,000 are not restricted at all by the standards. EPA's standards require that the probabilities of disruptive processes and events be estimated with sufficient precision to determine that a projected release falls within one of the two ranges of likelihood addressed by the standards. Uncertainty exists regarding acceptable methods for estimating the probabilities of potentially disruptive processes and events.

In contrast to EPA's dual release limits, ICRP Publication 46 recommends that the risk to any individual be limited to a specified level. In this context,

Table 1

	@ 1,000 Yr	EPA (Ci)**	Amount (%)
Am-241	9.2E7	10,000	1.1E-2
Am-243	1.6E6	10,000	6.3E-1
C-14	1.0E5	10,000	10
Cs-135	2.2E4	100,000	450
Cs-137	1.0	100,000	----
I-129	3.8E3	10,000	260
Np-237	1.0E5	10,000	10
Pu-238	9.8E4	10,000	10
Pu-239	3.2E7	10,000	3.1E-2
Pu-240	4.4E7	10,000	2.3E-2
Pu-242	1.7E5	10,000	5.9
Ra-226***	2.8E2	10,000	3600
Sr-90	1.5E-1	100,000	----
Tc-99	1.4E6	1,000,000	71
Th-230***	1.6E3	1,000	63
Th-232	1.3E-3	1,000	----
Sn-126	5.6E4	100,000	180
U-233***	3.3E2	10,000	3000
U-234	1.9E5	10,000	5.3
U-235	2.0E3	10,000	500
U-238	3.1E4	10,000	32

*These inventory figures and release limits are for 100,000 MTHM (3,000 reactor-years) of spent nuclear fuel. The C-14 inventory is from R. A. Van Konynenburg presentation to the Advisory Committee on Nuclear Waste, October 26, 1990. Other inventories are from EPA 520/4-79-007, "Technical Support of Standards for High-Level Radioactive Waste Management," Arthur D. Little, Inc., 1977.

**The EPA standards require that a "sum-of-the-fractions" rule be applied if more than one radionuclide is released. "Unlikely" releases are allowed to be 10 times larger than the limits listed here.

***Inventory increases after 1,000 years.

"risk" means the product of the probability that an individual will receive a radiation exposure, and the probability that the resulting exposure will cause a fatal health effect. Thus, ICRP recommends a continuum of acceptable release levels, dependent on the likelihood that a release will occur.

EPA's containment requirements have been criticized by NRC and by others, because they require numerical predictions of the probabilities of human-initiated disruptions and of rare geologic events (those with probabilities on the order of one chance in 1,000 over 10,000 years). EPA's critics believe that the inability to estimate such probabilities in a scientifically rigorous way will preclude determination of compliance with the standards in a licensing review.

A range of alternatives exists for the probabilistic format of EPA's containment requirements. For example, EPA could limit applicability of the standards to relatively likely releases, as is the case for EPA's uranium fuel cycle standards. NRC would then need to develop some type of implicit or explicit safety standard for evaluating the acceptability of unlikely releases. Alternatively, EPA could replace its dual category standard with a pure risk standard, as recommended by the ICRP in its Publication 46. Such a standard would benefit from conforming more closely with other radiation protection standards. However, it would require probability estimates for disruptive processes and events that are at least as precise as the probability estimates required by the current standards. Other alternatives include a qualitative (rather than a numerical) description of the release categories, or elimination of release categories so that a single release limit would apply to any release regardless of its likelihood.

The NRC staff believes that some type of probabilistic formulation is needed for EPA's standards in order to accommodate the large uncertainties in potential geologic evolution, climate change, and human activities. At the same time, the staff is sensitive to the difficulties that would be associated with the numerical probability estimates required by the current EPA standards and, perhaps to an even greater extent, by ICRP Publication 46. As an alternative, the staff has suggested to EPA wording for the containment requirements that would retain essentially the same level of safety sought by EPA, but would eliminate the need for precise numerical predictions of the probabilities of unlikely processes and events. This alternative is discussed below.

1.7 Alternative Probabilistic Format

The staff's recent comments to EPA regarding "Working Draft No. 2" of EPA's standards (see August 27, 1990, letter from R. Browning to R. Guimond) included a recommendation for alternative wording for the probabilistic "containment requirements" of EPA's standards. This alternative retains the probabilistic format of the current standards for likely releases, but addresses unlikely releases with a deterministic consequence limit. (Extremely unlikely releases would continue to be unregulated.) Thus, precise numerical probability estimates would not be needed for unlikely external processes and events.*

Using the staff's recommendation, processes and events potentially affecting a repository would be divided into three categories.

-"Likely conditions" for which both the probabilities of occurrence and the effects on repository performance would be evaluated numerically. This category would include those processes and events that are so likely to occur that they must be considered to be part of normal operation ("anticipated operational occurrences" in reactor licensing). "Likely conditions" might include processes and events with likelihoods greater than about one chance in ten over the regulatory period of interest.

-"Unlikely conditions" for which the effects on repository performance would be evaluated numerically, but probabilities would only be qualitatively estimated as necessary to distinguish from "likely" or "very unlikely" conditions. This category would include processes and events which, although unlikely to occur, are nevertheless sufficiently likely that they are relevant to a safety analysis. "Unlikely conditions" might include processes and events with likelihoods greater than about one chance in one thousand over the regulatory period of interest.

-"Very unlikely conditions" for which neither probabilities nor effects on repository performance would be evaluated numerically. This category would include processes and events that are so speculative and unlikely that numerical consideration as part of a safety analysis would not be meaningful. Processes and events with probabilities less than about one chance in one thousand over the regulatory period of interest could be classified as being of "negligible likelihood."

Classification of processes and events as indicated above comports with the quality of information typically available for safety analyses. In the first category, sufficient information is likely to be available to predict both probabilities and consequences with some confidence. In the second category, one can "bound" the consequences, but numerically estimating probabilities may be very difficult, because the processes and events are so rare. Finally, in the "very unlikely" category, only qualitiative estimates for both probabilities and consequences can be made.

If EPA were to adopt the staff's alternative wording for the "containment requirements," a performance assessment for a repository would consist of the following steps.

1. All conceivable processes and events potentially affecting the repository would be listed.

*As used here, "external processes and events" are potentially disruptive occurrences external to the repository system, i.e., outside the boundary of the controlled area. Phenomena occurring within the repository system, such as waste package corrosion, would be incorporated into models that simulate the performance of the repository system in response to external processes and events.

2. Each process or event would be assigned to one of the three categories discussed above. The criteria for assignment could be numerical, as suggested above, or could be qualitative. Processes and events assigned to the third category (very unlikely) would not receive further analysis.

3. Scenarios would be constructed from the remaining list of processes and events (i.e., those in the first two categories). The construction process would use an event tree (or similar) methodology to ensure that the scenarios would be mutually exclusive.

4. The set of scenarios would receive a second screening, analogous to "pruning" an event tree, to eliminate those judged to be too unlikely to warrant further consideration. Screening could be based on "rough" numerical probability estimates or on purely qualitative considerations.

5. Consequences (releases) would be estimated for each remaining scenario. The staff's proposal would not allow any scenario to cause releases exceeding ten times EPA's current table of release limits.

6. For each of the more likely scenarios, probabilities would also be estimated, and the probability and release estimates would be combined to produce a "complementary cumulative distribution function" (CCDF) estimating the likelihood of exceeding EPA's table of release limits. The likelihood would be compared to the (current) one chance in ten limit of EPA's standards.

A critically important concept in the staff's alternative is the construction of mutually exclusive scenarios (step 3) and application of EPA's current consequence limit to each (step 5). Because scenarios would be mutually exclusive, only one of them could occur, and total releases in the future therefore could be no greater than ten times EPA's table of release limits. This is the same magnitude of releases permitted under EPA's current probabilistic standards. The only difference between the staff's alternative and EPA's current standards is that the staff's proposal would not require probability estimates for releases in the unlikely category. The staff's proposal would not alter EPA's current probabilistic treatment of relatively likely releases.

1.8 <u>Overall Evaluation</u>

Several features of EPA's HLW standards are intended to facilitate implementation of the standards in a licensing review, including the release-limit format, the 10,000-year cut-off for application of the release limits, and the absence of a requirement that releases be ALARA. NRC staff has long supported these features of the standards.

Other features of the standards, including the population impacts basis for the release limits and the level of stringency, are considered to be within EPA's discretion, given EPA's authority to develop generally applicable environmental radiation protection standards. NRC staff considers EPA's release limits to be achievable (with the possible exception of Carbon-14 at an unsaturated site), but has not commented on whether EPA's standards are more or less stringent than other radiological or non-radiological safety standards.

The most significant potential implementation problem associated with EPA's standards is the probabilistic format of the "containment requirements." If EPA retains the probabilistic format, the staff will continue to encourage adoption of alternative wording for the standards that would eliminate the need for precise numerical probability estimates for unlikely processes and events.

2. TREATMENT OF UNCERTAINTIES

It is inevitable that projections of the performance of an HLW repository will be highly uncertain, whatever form the EPA standards may take. The nature of the activity -- forecasting geologic evolution, climate change, and human activities for thousands of years -- ensures it.

The following discussion first describes the different types of uncertainties involved in projecting repository performance, and then discusses methods available or under development for reducing or eliminating uncertainties.

2.1 Types of Uncertainty

Uncertainties in our understanding of a repository system can be generally categorized as: (1) "data uncertainty," defined here as uncertainty in our knowledge of the state of the system at the time of repository closure; (2) "future states uncertainty," reflecting our imperfect ability to predict the future states of the environment within which the repository will exist; and (3) "model uncertainty" -- uncertainty in our ability to forecast the performance of a repository within its future environment. Each type of uncertainty is discussed below.

2.1.1 Data Uncertainty

The most fundamental type of uncertainty in a repository performance assessment involves our knowledge of the existing state of the system. Uncertainties in our knowledge of the existing system limit our ability to develop the analytical techniques necessary to project repository performance far into the future.

Many features of a repository system can be measured directly in situ or in a laboratory (e.g., groundwater levels or corrosion rates) or can be inferred from direct measurements (e.g., hydraulic conductivity). However, there are both spatial and temporal limitations to our ability to characterize a repository system fully. Many site-exploration techniques disrupt the site and potentially reduce its ability to isolate waste. Therefore, these techniques must be used sparingly. Similarly, the time available for testing is limited to a few decades, requiring uncertain extrapolations of measured information over the regulatory period of interest (currently proposed by EPA to be 10,000 years). Finally, even when measurements are possible, there may be significant uncertainties associated with the applicability of test methods, potential instrument errors, and procedural errors.

When direct measurements of repository characteristics are not possible, the geologic record of a repository site and analogies with similar geologic structures elsewhere may provide information about characteristics of the system, such as the rates of active tectonic processes and the likelihood of potentially disruptive events. The usefulness of such sources of information will depend on the completeness of the geologic record or on the closeness of the analogy with another location, but will inevitably be a source of uncertainty.

2.1.2 Future States Uncertainty

Another source of uncertainty in a repository performance assessment involves describing the possible future states of the environment within which the repository system will exist. The repository environment may remain essentially unchanged, or the repository may be subject to various perturbations, such as tectonic activity or climate change. Because of the length of the regulatory period of interest, it will be impossible to identify all potential phenomena, such as those involving human activities, that might affect repository performance. Also, the wide variation in conceivable future conditions will make it impossible to analyze all potential perturbations of a repository system. Therefore, it will be necessary to define a representative range of conditions as an approximation to be used in a performance assessment. For example, a single type of drilling event might be sufficiently representative to approximate all other conceivable types of human intrusion into a repository. Both the inability to forecast precisely the future of the site and the need to limit the scope of the analysis to a manageable degree will be sources of uncertainties in the results of the analysis.

In any type of repository safety analysis, it would be necessary to evaluate, at least crudely, the likelihood of the potentially disruptive phenomena that have been identified. However, the probabilistic format of EPA's standards requires some precision in the estimation of probabilities of occurrence of disruptive phenomena. This feature of the standards constitutes an additional source of uncertainty in repository-performance assessments, and has been the cause of past concerns about the workability of the standards, as discussed extensively here and in SECY-89-319.

2.1.3 Model Uncertainty

A mathematical model is an abstraction of a real system. As such, there are two sources of uncertainty -- the conceptual description of the system, and the mathematical approximation of that conceptual model.

A conceptual model describes the assumed physical and/or chemical processes taking place in the system, the variables, parameters, and boundary conditions chosen to represent those processes, and the spatial and temporal scales of the assumed processes. Simplifications are made, as necessary, to permit development of a mathematical model of the system that provides a reasonable approximation of actual system performance without being so detailed as to be unworkable. For example, the tuff at the Yucca Mountain site is known to be highly fractured, but it would not be feasible to develop a mathematical model that simulates groundwater flow through each of the thousands of individual fractures. Instead, a conceptual model needs to be developed that describes flow through the bulk rock, and does so in a way that provides a reasonable description of the effects of fractures. Development of such a conceptual model represents a significant source of uncertainty, as does development of the mathematical description of that conceptual model. A third source of uncertainty -- implementation of the mathematical model in a computer program

-- should be less significant with the observance of good quality assurance practices.

2.2 Dealing with Uncertainties

2.2.1 Technical Methods

Several well-developed techniques exist for propagating data uncertainties (e.g., variations of the Monte Carlo technique), although none of these has yet been determined to be the most appropriate for repository uncertainty analyses. For repository performance assessments, the real difficulty lies in characterizing uncertainties, especially model and future states uncertainties, and in reducing them to manageable levels. The staff plans to pursue the following "technical" means for addressing uncertainties.

a. Review of site characterization. Site characterization by the U.S. Department of Energy (DOE), including laboratory and field testing, is carried out to collect more complete, more accurate information about a repository system, and thus is an obvious way to reduce data uncertainty. Site characterization can also help to reduce future state and model uncertainty by providing information about the physical and chemical processes occurring at and near the site. Site characterization plans are an important way to reach agreement on acceptable testing and analysis methods and information needs. Site characterization activities may also be expensive, and the desire to avoid disrupting the repository site and the limited time available for testing place practical limits on the amount of information that can be acquired. Therefore, it is important that an optimal plan be developed for site characterization that will maximize the useful information to be acquired while minimizing potential disruptions to the site, delays in the schedule for repository development, and development costs.

The staff recently reviewed DOE's Site Characterization Plan (SCP) for the Yucca Mountain site, and provided comments to DOE on the plan (see NUREG-1347, "NRC Staff Site Characterization Analysis . . . ," August 1989). As site characterization proceeds, DOE will submit periodic progress reports and updates of the SCP to the staff for review and comment. The staff will continue to encourage DOE to evaluate its site characterization results periodically and to update its characterization plans, using performance assessments that include uncertainty and sensitivity analyses.

b. Analogues. Some natural or man-made systems or objects may be enough like an HLW repository or component so that useful analogies can be drawn to help reduce data and model uncertainty. Examples might include similar groundwater flow systems at other locations (e.g., at geothermal reservoirs), dispersal of radionuclides from natural deposits of radioactive materials, and performance of natural or man-made glasses in geologic systems. The Office of Nuclear Regulatory Research (RES) has had an ongoing program to investigate repository analogues, and the staff has encouraged DOE to pursue similar investigations.

c. Validation and performance confirmation. "Validation" refers to any of various techniques used to evaluate the correctness of the models used to project repository performance. These techniques may include comparisons of model results to experimental information obtained in the laboratory, at the repository site, or at another, similar, site. An important part of model validation will be the performance-confirmation program required by 10 CFR Part 60. This program, which is to be initiated by DOE during site characterization and continued until permanent closure of a repository, is to include in situ monitoring, laboratory and field testing, and in situ experiments, to verify that the natural and engineered components of the repository are performing as predicted.

Since there is currently no site-specific performance-confirmation program underway, the staff has been participating in a series of international modeling exercises (INTRACOIN, HYDROCOIN, and INTRAVAL) aimed at comparing the capabilities of groundwater flow and contaminant transport models and associated computer programs with predictions by other models and with experimental observations. Comparisons of this type are a first step in model validation, and have been very useful to the staff in developing its expertise and modeling capabilities. RES is also sponsoring laboratory and field-scale experiments in unsaturated media, which will be useful in support of model validation.

d. Systematic methods for identification of failure modes in future states. Analyses similar to fault tree methods (NUREG-0492, Fault Tree Handbook) may be useful for identifying ways in which repository performance could be adversely affected. The staff is investigating possible use of such analyses as a structured and systematic way to identify the future states of the repository system and, thereby, reduce the likelihood that important failure modes would be overlooked.

e. Development of a performance assessment capability. Nearly 15 years ago, the NRC staff initiated a program to develop a review methodology for evaluating the performance of a proposed HLW repository. (DOE, as the potential licensee for a repository, also began development of performance-assessment capabilities, at about the same time.) Since repository performance is inherently uncertain, the staff's program set out to adapt the concepts and techniques of probabilistic risk analysis. In the staff's review methodology, the goal of a performance assessment is not to produce a single estimate of how a repository will perform in the future. Rather, the goal is to determine the range of performance levels that might be achieved and, to the extent practical, to estimate the likelihood of each level of performance within that range.

Much of the staff's development to date was completed by Sandia National Laboratories and is summarized in NUREG/CR-5256, "Components of an Overall Performance Assessment Methodology," dated February 1990. The methodology developed by Sandia includes a procedure for scenario identification and screening; an uncertainty analysis technique (the Latin Hypercube variation of Monte Carlo analysis); a regression analysis methodology for sensitivity analysis; models of groundwater travel and contaminant transport in salt, basalt, and tuff; and models for environmental transport, dosimetry, and health effects projections. Sandia also evaluated methods for developing probability estimates for disruptive processes and events and techniques for incorporating expert judgment into a performance assessment.

The staff and its current contractor, the Center for Nuclear Waste Regulatory Analyses (CNWRA), are continuing development of a performance assessment capability, including uncertainty and sensitivity analysis techniques that can be used to quantify uncertainties and evaluate their significance. The staff plans to conduct iterative performance assessments of the Yucca Mountain site, with each iteration incorporating new data and improvements in assessment capabilities compared to the previous iteration. The staff recently completed its first iteration, and is now initiating the second phase of its analyses. Areas of particular interest for the second iteration include scenario development, probability estimation, unsaturated groundwater flow, and gaseous transport of C-14.

2.2.2 Institutional Methods

In addition to the "technical" approaches discussed above, the staff will pursue the following "institutional" ways of reducing or eliminating uncertainties.

a. Working with EPA. For over a decade, the staff has been working with EPA staff to develop wording for EPA's standards that would minimize potential implementation problems in a licensing review. The staff will continue its efforts to identify potential problems through the "Systematic Regulatory Analysis" process discussed below, as well as through more conventional means. The staff will particularly emphasize EPA adoption of the staff's recommendation (see August 27, 1990, letter from R. Browning to R. Guimond) for revised wording of the probabilistic containment requirements, so as to eliminate the need for precise probability estimates of unlikely processes and events.

b. Systematic Regulatory Analysis. In 1988, the staff commissioned a major CNWRA effort to conduct a systems engineering analysis of NRC's HLW program. One of CNWRA's activities, referred to as "Systematic Regulatory Analysis (SRA)," is to systematically identify regulatory, technical, and institutional uncertainties involved in repository licensing, and to propose ways to reduce or avoid those uncertainties, so as to ensure a timely and efficient review of a license application for a repository. CNWRA has reported on its identification of regulatory and institutional uncertainties associated with 10 CFR Part 60 in its reports CNWRA 89-003 and CNWRA 90-003, and in a progress report presented in the Commission briefing of March 14, 1990. Key technical uncertainties are to be identified and reported in FY 1991 and 1992. Also, CNWRA has initiated an SRA of EPA's HLW standards and of the relationship between those standards and 10 CFR Part 60. The uncertainties discussed in this paper are a subset of those being identified by CNWRA through the SRA.

c. Rulemaking, technical positions, or regulatory guides. When regulatory uncertainties have been identified through SRA, it might be possible to reduce or eliminate those uncertainties, using rulemaking, technical positions, or regulatory guides. For example, the current text of 10 CFR Part 60 specifies certain assumptions regarding the potential for human intrusion into a repository. Similar specifications in other areas of uncertainty would limit the range of uncertainties that would need to be considered during a repository licensing review. Reduction or elimination of uncertainties by such means was discussed in SECY-90-207. The staff recognizes that it will not be possible to eliminate all uncertainties in this way, but rulemaking, technical positions, and regulatory guides will be used to the extent practical.

Two potential rulemakings have been identified by the staff in SECY-90-207. The first, the "conforming amendments," will revise 10 CFR Part 60 as needed for conformance with, and adoption of, EPA's standards. The second rulemaking, referred to as the "implementing amendments," would address more detailed matters related to implementing the standards, if appropriate.

d. Development of a License Application Review Plan (LARP). As noted in SECY-90-207, the staff plans to develop a LARP, which will be the primary document used by the staff for reviewing DOE's license application and prelicense application reports, including SCP progress reports, study plans, advanced conceptual designs, technical reports, topical reports, and issue resolution reports. The LARP would be analogous to the standard review plans used for nuclear power plant licensing, and would be developed as part of the SRA process.

e. Comparative Safety Analyses. A license application for an HLW repository must include "a comparative evaluation of alternatives to the major design features that are important to waste isolation, with particular attention to the alternatives that would provide longer radionuclide containment and isolation." In adopting this requirement, the Commission recognized that an alternative design feature might significantly increase its confidence that the performance objectives of 10 CFR Part 60 (including the EPA standards) would be satisfied. The Commission stated that, if the costs of such an alternative were commensurate with the benefits, it should not hesitate to insist that the alternative be adopted. (See 48 FR 28203, June 21, 1983.) The staff continues to believe that comparative safety analyses are a useful way to identify alternative designs that can reduce uncertainties regarding long-term repository performance.

3. TREATMENT OF RESIDUAL UNCERTAINTIES

Despite the staff's efforts to reduce uncertainties, there will be "residual uncertainties" regarding data, models, and future states of the repository. The significance of these uncertainties will need to be addressed in deciding whether there is reasonable assurance that the EPA standards will be met. No single mathematical procedure has been determined to be the most appropriate method for uncertainty analysis or for extrapolation of performance of a technology or activity far into the future. During a licensing review, the staff anticipates examining uncertainties in NRC's traditional manner, i.e., using a process that considers all available data, variances of opinion regarding physical and chemical mechanisms important for performance, statistical evidence, laboratory and field experiments, the suitability of a particular performance evaluation and the uncertainty methods used by an applicant. In general, residual uncertainties must be addressed in a judgmental manner, and two distinct types of judgments will be needed.

First, judgment by technical experts, "technical expert judgment," is needed to quantify residual technical uncertainties to the extent practical, to estimate the effect of those uncertainties on overall repository performance, and to assess the effects of unquantifiable uncertainties on repository performance.

A second type of judgment, referred to here as "decision-maker judgment," is needed to address the regulatory significance of residual uncertainties. The decision-makers (the licensing board and the Commission) must evaluate whether the residual uncertainties in a repository performance assessment are sufficiently unimportant that there is a "reasonable assurance" of compliance with the EPA standards. (Of course, all parties to the proceeding, as well as the decision-maker, will need to apply such judgment in arriving at their respective positions as to whether the requirements have been met.)

3.1 Technical Expert Judgment

Nearly every aspect of repository development and performance assessment involves the type of uncertainties that can only be addressed by the judgment of technical experts. These uncertainties include, for example, evaluating the validity of a particular conceptual model of the site, assessing the appropriateness of a proposed test method, and interpreting test results. The judgment may be provided by a DOE employee or contractor, or by one or more outside experts in a technical field, and may range from an informal estimate to a well-documented estimate produced through a formal elicitation process.

Two recently published NRC contractor reports* discuss elicitation procedures that can be used to obtain expert judgment in a formal, structured, well-documented manner. A formal elicitation process typically consists of the following steps: (1) identification of issues or information needs; (2) selection of experts; (3) training; and (4) the actual elicitation. Training includes educating experts about possible biases in their judgments and about ways to avoid those biases. The actual elicitation procedures used vary widely, but a common goal is to break ("decompose") a difficult question into a number of logically related questions that are easier to answer. Both the logic of the decomposition and the answers to the simpler questions then serve to document the basis for the expert's response to the more difficult question. The staff believes that formal elicitation procedures can be useful as a means to ensure that judgments are well-documented and that the technical reasoning used to reach a judgment is openly displayed for review. Formal procedures may also help groups of experts resolve differences in estimates by providing a common measurement scale and a common vocabulary for expressing their judgments.

The staff is concerned, however, about possible misuse of expert judgment. The following cautionary statement from NUREG/CR-5411 expresses the staff's reservations well.

> "The formal use of expert judgment in performance assessment is a complement, rather than a substitute, for other sources of scientific and technical information, such as data collection and experimentation.

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*M.A. Meyer and J.M. Booker, "Eliciting and Analyzing Expert Judgment -- A Practical Guide," NUREG/CR-5424, 1990, and E.J. Bonano, et al., "Elicitation and Use of Expert Judgment in Performance Assessment for High-Level Radioactive Waste Repositories," NUREG/CR-5411, 1990.

> Expert judgments should not be considered equivalent to technical calculations based on universally accepted scientific laws or to the availability of extensive data on precisely the quantities of interest. Expert judgments are perhaps most useful when they are made explicit for problems in which site data are lacking, since they express both what the experts know and do not know."

The staff recognizes that expert judgment will be widely used in a repository performance assessment, but would not consider it acceptable to substitute expert judgment for experimental data or other more technically rigorous information that is reasonably available or obtainable. Expert judgment should be substituted for "hard data" only when it is impractical to obtain such information. When expert judgment is used, it must be supported by a clear underpinning of facts and logic, and it must be presented by the expert in a manner that allows rigorous examination.

3.2 Decision-Maker Judgment

The technical expert judgment discussed above is concerned only with estimating future repository performance. As noted, such estimates will be inherently uncertain, and decision-makers must exercise their judgment in evaluating whether there is reasonable assurance that the release limits of EPA's standards will be met, given that uncertainty.

The staff considers "reasonable assurance" (or "reasonable expectation," as it is termed in the EPA standards) to mean simply the degree of assurance that is reasonable in light of (1) the uncertainties that must be taken into account in evaluating compliance with the regulatory criterion, and (2) the consequences if compliance is not achieved. The staff does not consider it possible to define "reasonable assurance" in terms of some quantitative probability of compliance. Instead, it is necessary to take into account, in a qualitative way, the uncertainties that inevitably affect the precision with which such probabilities may be calculated and stated. Moreover, it is appropriate to consider the consequences of non-compliance, as well. For example, in reactor licensing, some decisions consider the potential for large releases of radioactive material, and it is reasonable to require a high degree of confidence that such releases will not occur. On the other hand, some materials-licensing decisions involve a potential for only moderate releases, and a higher likelihood of release can be accepted as reasonable. The staff expects licensing considerations for a repository to resemble the latter example and decisions to be made in a manner similar to previous NRC practice.

Two aspects of decision-making judgment are of particular importance in determining compliance with the EPA standards, and are discussed below: (1) the need to choose among conflicting technical expert judgments presented by the different parties to a licensing review, and (2) the need to address limitations in scientific understanding of repository behavior (i.e., residual model and future states uncertainties).

3.2.1 Conflicting Expert Opinion

The staff anticipates that its analysis of conflicting judgments will be carried out by examining the technical basis (i.e., the data, assumptions, and reasoning) for each judgment and the effects of each judgment on overall repository performance. In some cases, one judgment may be clearly preferable to the others because of the plausibility of the underlying scientific basis and/or general acceptance within the scientific community. In such cases, the staff will accept the clearly preferable alternative. In other cases, it might not be possible to identify a clearly preferable alternative, but the most "conservative" reasonable estimate (the estimate leading to the largest releases) can nevertheless be shown to result in releases no greater than the limits of EPA's standards. In those cases, the staff would accept the conservative estimate.

The more troubling situation would occur where there is not a clearly preferable judgment among the alternatives presented, and where the most conservative reasonable estimate indicates unacceptable repository performance. In such cases, the theories of decision analysis suggest that some type of weighted average (mean, median, or other) of all available estimates be used. The staff would generally question such an approach, particularly where there is a potential for the applicant to resolve matters through additional scientific investigations. Suppose, for example, that two mutually exclusive models of a physical process (e.g., volcanic activity) exist for a particular repository site, with one model indicating compliance with EPA's release limits and the other indicating non-compliance. In the staff's view, a weighted average of the release estimates for the two models would be meaningless. Both models may be wrong. At best, only one of the models can be correct and the other must be incorrect -- they cannot each be partially correct. If it is not possible to determine that one model is clearly preferable, and if the more conservative of the models indicates clearly unacceptable performance, the staff would tend to oppose the issuance of a construction authorization.

Notwithstanding the discussion of the preceding paragraph, the staff recognizes that there may be cases (e.g., estimates of parameter values) where combining expert judgments may produce information that is more meaningful than a single judgment (e.g., by indicating the range of uncertainty in the parameter). However, as noted, the staff will view combined judgments skeptically, and would consider them only if accompanied by a demonstration that combining judgments produces information that would not be obtainable by other means.

3.2.2 Residual Model and Future States Uncertainty

After all reasonable efforts to reduce uncertainty have been made, there will remain uncertainty about whether unidentified processes or future states will have a significant effect on repository performance. Decision-maker judgment will need to address whether these residual uncertainties are sufficiently well-bounded to support a finding of reasonable assurance that the EPA standards will be met. Such judgment will certainly be applied in reviewing DOE's license application. Further, if the staff finds that it would be possible, it might propose that at least some of the needed judgments be made in advance of the license review through rulemaking. This contingency for a potential "implementing-amendments" rulemaking is what the staff considered in SECY-90-207.

Model uncertainty is normally addressed by model validation, a comparison of model results with empirical information over the domain of application of the model. Because the domain of interest includes tens of cubic kilometers for 10,000 years, literal application of this process will not be possible for a repository. This situation was foreseen in 10 CFR 60.101(a)(2), where recognition is given to the fact that proof of performance is not to be had in the ordinary sense of the word, that what is required is a reasonable assurance that performance will conform to the objectives and criteria of 10 CFR Part 60, and that demonstrations of compliance with the performance objectives ". . . will involve the use of data from accelerated tests and predictive models that are supported by such measures as field and laboratory tests, monitoring data and natural analogue studies." The staff considers that it may be possible to establish criteria for model validation that would be consistent with 10 CFR 60.101(a)(2). This possibility will be addressed through the SRA.

A similar situation exists regarding future-states uncertainty. It will not be possible to prove that all possible future states have been identified and considered in estimating repository performance. Normally, the source of confidence that significant, unforeseen, perturbations to a system are unlikely is a combination of systematic consideration of possible perturbing states (e.g., fault-tree analysis) and direct experience with the system in question. For a repository, there will be no direct experience; however, the waste programs of several nations are confronting this same problem. The Nuclear Energy Agency has plans to catalogue potential future states independently identified by participating nations. The staff considers that it may be possible, through rulemaking, to establish a dispositive list of future states to be considered in repository performance assessment, when such a catalogue is sufficiently mature.

4. CONCLUSIONS

The staff recognizes the existence of significant uncertainties associated with implementation of EPA's HLW standards. This enclosure describes the staff's current views on dealing with uncertainties in implementing the EPA HLW standards, whatever the final form of those standards might be. Although an "agreed-upon methodology for characterizing and propagating the uncertainties" referred to in the Commission's information request does not yet exist, the staff considers that the approaches discussed in this enclosure will allow licensing decisions to be made.