UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 22, 1995

Mr. Don Schlesinger, Member
Commission on Nuclear Projects
Capitol Complex
Carson City, NV 89710

Dear Mr. Schlesinger:

At the September 29, 1994, meeting of the Nevada Commission on Nuclear Projects, you asked me three questions concerning U.S. Nuclear Regulatory Commission regulation of high-level waste disposal. My response has taken longer than I originally intended, and I regret that it has not been more timely. However, at this time I do have answers, which, along with your questions, are provided below.

1 Has the NRC ever had reason to regret the use of the expression "reasonable assurance" in granting any of its licenses?

Not to the best of our knowledge. I searched my memory and consulted the Office of the General Counsel. None of us are aware of any instance in which the NRC found the use of "reasonable assurance" in granting a license diminished the power of that license to adequately protect public health and safety.

2 How does the use of "reasonable assurance" in 10 CFR Part 60 differ from its use elsewhere in the NRC?

The Commission addressed this issue both in its Statement of Considerations of 10 CFR Part 60 and in the rule itself. I have enclosed the applicable part of the Statement of Considerations (Enclosure 1) and reproduced the pertinent section of 10 CFR 60 below, which is 60.101(a)(2):

> While these performance objectives and criteria are generally stated in unqualified terms, it is not expected that complete assurance that they will be met can be presented. A reasonable assurance, on the basis of the record before the Commission, that the objectives and criteria will be met is the general standard that is required. For §60.112, and other portions of this subpart that impose objectives and criteria for repository performance over long times into the future, there will inevitably be greater uncertainties. Proof of the future performance of engineered barrier systems and the geologic setting over time periods of many hundreds or many thousands of years is not to be had in the ordinary sense of the word. For such long-term objectives and criteria, what is required is reasonable assurance, making allowance for the time

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period, hazards, and uncertainties involved, that the outcome will be in conformance with those objectives and criteria. Demonstration of compliance with such objectives and criteria 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 analog studies.

3 Why has the NRC refused to permit its staff members who reviewed the Szymanski report to be deposed?

The NRC's position on this issue was stated in a letter from the Chairman to Robert Loux dated October 14, 1994 (Enclosure 2), and has not changed. For the reasons given in the letter, it would be inappropriate for me to comment further.

I believe that the above responses address your questions. If your recollection of your questions differs, or if you wish additional information, please do not hesitate to contact me.

Sincerely,

Original signed by
Malcolm R. Knapp

Malcolm R. Knapp, Director
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

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Enclosure 1

Decision Methodology

Another nonsubstantive change is being made to § 60.101(a) in response to an observation of an inconsistency with the Commission's statement of considerations accompanying the proposed rule. As suggested by the comment, it is indeed the view of the Commission that "sole reliance on numerical predictions to determine compliance will [rather than may] not be appropriate. In reaching a determination of reasonable assurance, the Commission will [rather than may] supplement numerical analyses with qualitative judgments." The language is revised accordingly.

OTHER ISSUES RAISED BY THE COMMENTS

Uncertainties and "Reasonable Assurance"

The discussion of "reasonable assurance" that accompanied the proposed amendments included two figures that illustrate, respectively, the concept and form of a "Complementary Cumulative Distribution Function" and the representation of such a CCDF in relation to the EPA Containment Requirements. While these figures do in fact present the principal concepts, some further refinements are needed.

The two figures were as follows:

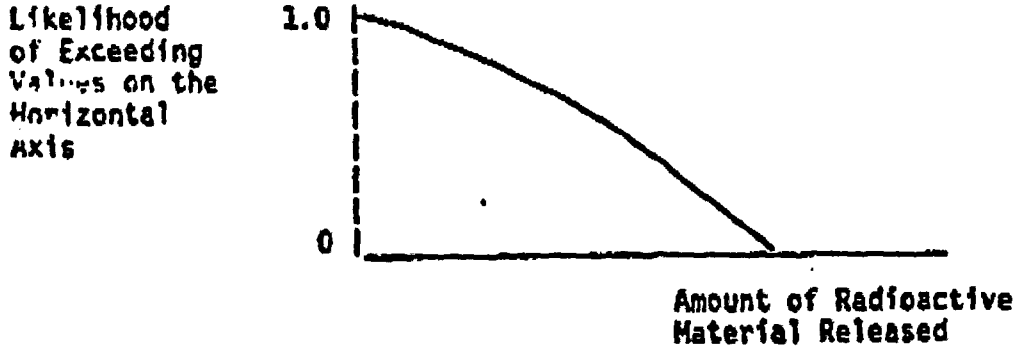

Figure 1. Illustrative "Complementary Cumulative Distribution Function."

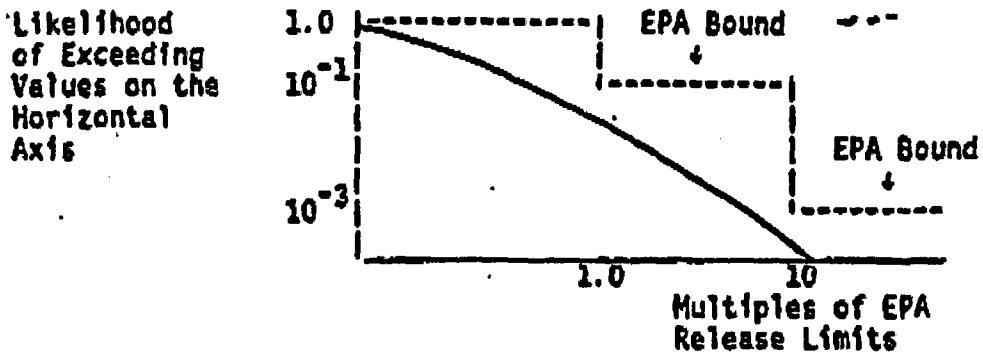

Figure 2. Graphic Representation of EPA Containment Requirements.

The Commission explained that an overall probability distribution of releases of radionuclides to the environment would be displayed in the format shown in Figure 1 and that the entire probability distribution must lie below the "stair-step" constraints illustrated in Figure 2. It is the Commission's intention that the licensing hearings should be directed toward the development of a curve of that form. What we perhaps should also have said explicitly is that however good the record of the proceedings may be, there will remain residual uncertainties which cannot be directly displayed in that format.

Figure 1 depicts the distribution as a curve of probabilities plotted .. cumulative releases. Such a curve can be constructed so as to incorporate many variables that lend themselves to statistical analysis. The curve cannot, however, include some types of uncertainties such as those that may be associated with the accuracy of the models that are used. The Commission recognizes that these uncertainties must be considered when evaluating the acceptability of a particular repository. This idea can be illustrated by examining Figure 3, which represents the same CCDF as in Figure 2, but with an associated error band. The limits of this band, Curves A and B, are conceptual representations of "optimistic" and "pessimistic" views of the

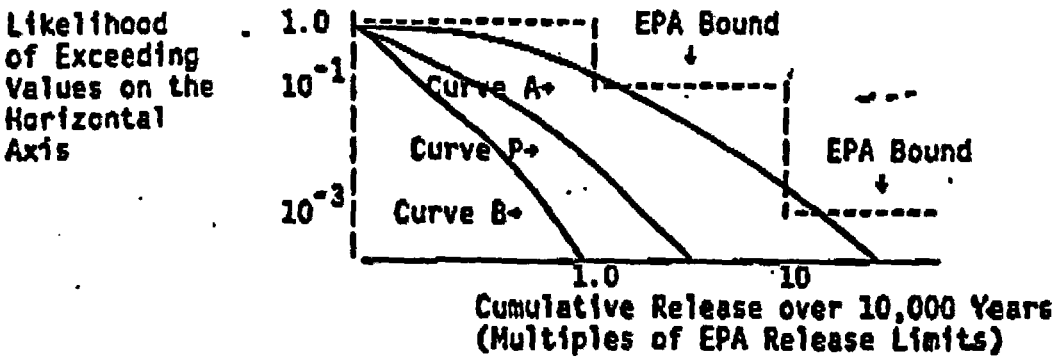

Figure 3. Conceptual Representation of Uncertainties in CCDF.

residual uncertainties, representing the extremes of radionuclide release probabilities. That is, Curve A is exceedingly conservative: it represents the highest probability of releases exceeding a particular level that is technically supportable. (Curve A might represent, for example, the estimated repository performance using a very unlikely, but plausible, mathematical description of a key physical phenomenon.) Conversely, Curve B represents the lowest probability of releases exceeding a particular level that is technically supportable. Somewhere between these limits lies Curve P, a CCDF that the presiding officer (i.e. the Atomic Safety and Licensing Board) finds best reflects a reasoned judgment, based on the record, as to the correlation of probability and size of radionuclide release over the relevant time period.

It would not be at all surprising, as appears in Figure 3, that Curve A (defined as above) in a particular proceeding might lie above parts of the EPA "stair-step" limits. In this event - as was stated in the preamble to the proposed amendments - such an apparent violation of the standard (based on conservative analyses) would not necessarily preclude the Commission from finding, with reasonable assurance, that repository performance would conform to the EPA standard. The Commission would need to examine the nature of the conservatisms upon which those analyses were based in deciding whether to accept the analyses or to reject them as being excessively conservative. Ultimately, a judgment will be required as to whether, considering the data and the uncertainties associated therewith,

there is reasonable assurance that the repository performance will conform to the EPA standard.

Whether the Commission has such "reasonable assurance" in a particular context will depend, as is stated in § 60.101, on such factors as the time period, hazards, and uncertainties involved. The lengthy time period and the uncertainties that decrease the precision with which the probability distribution can be defined necessitate increased conservatism in evaluating the record. On the other hand, the hazard associated with an incorrect decision on repository performance might generally be viewed as a relatively small incremental release - an undesirable outcome, to be sure, but not the potentially catastrophic consequence that often can be at stake where "reasonable assurance" determinations are made in the reactor licensing context.

EPA explicitly recognized that the level of confidence that the Commission applies in reactor licensing "may not be appropriate for the very long-term analytical projections" that are called for under its standard. It therefore provided that there must be a "reasonable expectation" that the containment requirements be met; this phrase, according to EPA, "reflects the fact that unequivocal numerical proof of compliance is neither necessary nor likely to be obtained." 50 FR at 38071. The Commission entirely agrees with this evaluation. Indeed, as has been explained above, a finding that the EPA standard has been satisfied can be made even though Curve A exceeds the stair-step - i.e., even though unequivocal numerical proof of compliance has not been obtained.

The Commission appreciates the sensitivity exhibited by EPA in this matter. Clearly, EPA sought not to have the Commission held to the rigorous proof that "reasonable assurance" implies in the case of nuclear reactor licensing. In effect, EPA expects us to take into account the time period, hazards, and uncertainties involved. When we do this, we will arrive at a decision just as EPA intended us to do - with reasonable confidence, but not necessarily with unequivocal numerical proof.

While it is hoped that this discussion clarifies the concept of reasonable assurance, a few additional remarks are needed in response to specific points raised in the comments. For example, one comment suggested that numerical analyses be viewed as supplementing qualitative judgments instead of having - as in § 60.101(a)(2) - the Commission supplement numerical analyses with the qualitative judgments. This is a fine point, and the Commission declines to make the change. As the licensing process is conceived, the initial effort will focus upon evaluations that are, to the extent practicable, quantitative. Although this part of the process comes first, it will not suffice in and of itself: it will need to be supplemented by qualitative judgment. This is the concept expressed in the proposed rule, and it is correct.

To take another example, we need to respond to a question raised to the Commission's reference to its concept of "reasonable assurance" being "somewhat different from previous usage in reactor licensing." It was intended merely to reflect the regulatory language that is unique in Part 60 - i.e., the specific reference to long time periods, the nature of the hazards, and the uncertainties involved, as well as the language regarding the difficulties of demonstrating compliance. It was not meant to suggest any impairment of the Commission's necessary flexibility in arriving at a judgment. As discussed above, the important concept is "reasonableness" in the context of the decision to be

In the final analysis, the Commission emphasizes its intention to apply the EPA standards with appropriate conservatism. How this will ultimately be done must await the development of a full record with respect to a particular site and design. The Commission recognizes the need to be as clear as it can regarding the way it will deal with the inevitable uncertainties that will be presented in the record, and it has tried to respond to this need with the statements accompanying both the proposed rule and final rule. And, the Commission may engage in additional rulemaking at a later date as a means to reduce further some of the uncertainties that would otherwise remain for disposition in the licensing proceeding. However, there must be balance. It would be a mistake to be overly prescriptive at this stage of repository

Enclosure 2

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

CHAIRMAN

October 14, 1994

Robert R. Loux
Executive Director
State of Nevada Agency for Nuclear Projects
Nuclear Waste Project Office
Capitol Complex
Carson City, Nevada 89710

Dear Mr. Loux:

I read with interest your letter of September 15, 1994, concerning Nevada's "Rule 27" lawsuit. It is my understanding that at this time, Nevada is continuing to pursue relief in court against the NRC, the Environmental Protection Agency, and the Department of Energy. Because the case is now before the Ninth Circuit Court of Appeals, it would be inappropriate for me to comment on the substance of your suit.

One point, however, warrants clarification. None of the agencies Nevada has sued has independent litigating authority in cases of this type. The United States Department of Justice has represented the Government throughout this litigation, both in the U.S. District Court for the District of Nevada and in the Ninth Circuit Court of Appeals. Your apparent impression that DOE is litigating the case on its own, or that the NRC dissents from the Government's position in court, is incorrect.

As you know, the Government opposes your "Rule 27" petition on the grounds that the Rule simply does not apply to requests to perpetuate evidence in the absence of likely or imminent Federal district court proceedings. This jurisdictional position does not reach the merits of any technical controversy at the potential Yucca Mountain repository site or the evidence necessary to resolve such a controversy.

The Commission is committed to fair licensing proceedings for a high-level waste repository. We have designed our adjudicatory procedures with that goal in mind. We welcome your thoughts or suggestions at any time.

Sincerely,

Ivan Selin

cc: James H. Davenport, Esq.

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BOB MILLER
Governor

STATE OF NEVADA

ROBERT R. LOUX
Executive Director

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September 15, 1994

The Honorable Ivan Selin
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Selin:

I want to take this opportunity to thank you for inviting us to give you some of our thoughts and concerns regarding the Department of Energy's High-Level Waste Program at the Commission's September 9, 1994 meeting. Because of questions you asked regarding socioeconomic issues related to the project in Nevada, I have taken the liberty of enclosing some descriptive materials published by this Office and our contractors on this issue that I thought you might have an interest in.

Regarding the question posed by Jim Davenport, Nevada Special Deputy Attorney General, at the September 9 meeting, I thought it might be helpful to you in ascertaining the Commission's position regarding Nevada's "Rule 27" lawsuit to provide you with some more specific information.

Nevada is concerned that the evidence produced by DOE contractors in the early phases of its program at Yucca Mountain will become stale or unavailable by the time a licensing proceeding may be conducted. DOE will presumably rely on this data, and its analysis by mere reference to early-published reports. We would expect that standard rules of evidence would apply and that such evidence would be inadmissible if it were not subject to examination by all parties to the proceeding. In order to address this problem, Nevada initiated a proceeding in the U.S. District Court for the District of Nevada, pursuant to Rule 27 of the Federal Rules of Civil Procedure. (CV-N-93-399-ECR) Rule 27 permits parties to invoke the court's jurisdiction in order to perpetuate testimony through depositions for later use in cases which are not yet ripe but are ultimately cognizable in court.

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Nevada named the Department of Energy, the Nuclear Regulatory Commission and the Environmental Protection Agency as potentially expected adverse parties and served each with a summons. The Justice Department entered an "opposition" but never a notice of appearance for any party. The opposition was essentially DOE's opposition. It is still not clear to Nevada what the NRC's formal position is regarding this type of perpetuation of evidence.

At the request of DOE, purportedly acting on behalf of NRC as well, the District Court dismissed Nevada's petition primarily on the grounds that Rule 27 jurisdiction should not be used for the perpetuation of testimony which could be introduced in an administrative agency proceeding reviewable in the federal district or appeals courts. Nevada appealed that issue and it is currently pending before the Ninth Circuit Court of Appeals (No. 93-17367). Mr. John F. Cordes, Jr., NRC solicitor, joined the DOE's brief to the Ninth Circuit on May 23, 1994.

Did the NRC staff consult the Commission on its position regarding this litigation? Did (or does) the Commission oppose Nevada's efforts to perpetuate testimony which may be introduced in a later NRC licensing proceedings. Given the length of time and potential loss of availability of technical experts who produced reports upon which the DOE will likely rely in licensing, we would expect the NRC to support the perpetuation of evidence. We would like to learn the Commission's position on this question prior to oral argument of this case before the Ninth Circuit. Although that has not yet been scheduled, an argument this fall is likely.

Thank you again for your continued concern that Nevada's opinions be heard.

Sincerely,

Robert R. Loux
Executive Director

RRL:cs
Enclosures