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

SEP 14 1990

MEMORANDUM FOR: Commissioner Curtiss

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: NRC STAFF ANALYSIS OF "RETHINKING HIGH LEVEL WASTE DISPOSAL"

Enclosed is the staff analysis dated September 12, 1990, of "A Position Statement of the Board of Radioactive Waste Management" of the National Research Council. This document supersedes the version provided to you on August 29 and will serve as the basis for Mr. Bernero's remarks at the September 17-18, 1990 Symposium on Radioactive Waste Repository Licensing sponsored by the Board on Radioactive Waste Management of the National Research Council. No formal remarks are being prepared. After the discussion at the symposium, the staff will prepare a formal analysis for transmission to the Commission.

Also enclosed is a draft of EPA's presentation at this symposium.

James M. Taylor
Executive Director
for Operations

Enclosures:
As stated

cc: Chairman Carr
Commissioner Rogers
Commissioner Remick
W. Parler, OGC
SECY

Draft

Presentation for U.S. Academy of Scier
National Research Council
Symposium on Radioactive Waste Repositor

September 17-18, 1990

Bernie -
This is an early draft of the EPA presentation for your info.
RGB
9/14/90

By Richard J. Guimond
Assistant Surgeon General, U.S. Public Health Serv.
Director, Office of Radiation Programs
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Introduction

The last five years have been an interesting period in the regulation and development of the Nation's high-level radioactive waste disposal system. Recently, long after Congress mandated promulgation of standards, there has been a plethora of guidance and advice from numerous committees and scientific groups. Since EPA is required to reissue the disposal provisions of our standards, it is an appropriate time for us to receive this advice. Much of the advice, however, concerns major changes in well established provisions of laws and regulations that would require in-place systems be torn down and new ones built. There certainly needs to be a careful analysis made of the present system's viability and a consensus reached before such a drastic and expensive step is taken. Personally, at least from a regulatory perspective, I am not convinced such steps are necessary.

In my remarks today I do not intend to discuss the larger societal and philosophical issues involved in disposal of high-level radioactive waste. Rather, in the first portion of this talk I will discuss some of the regulatory advice offered in recent reports and will indicate EPA's views on the issues involved. While we in EPA agree with most of the recent advice, there are at least several areas in which we disagree. I will focus my final remarks on three of these issues.

Highlights of Reports

ICRP 46-Radiation Protection Principles for the Disposal of Solid Radioactive Waste (1985)

In 1985, the ICRP issued a report that discussed how the principles of radiation protection could be applied to the problem of radioactive waste disposal. They pointed out that the principles of justification and optimization should be retained, that normal releases should be subject to annual dose limits, and that some exemptions from disposal regulations were appropriate. These are all views that we generally agree with. However, the committee also called for probabilistic risk limits to be applied

to individual annual radiation doses. This is one of the areas of disagreement that I will address in more detail later.

NEA PAAG/DOC(90)4 Disposal of Radioactive Waste-Review of Safety Assessment Methodologies

This document, developed by the Committee on Radioactive Waste Management and still undergoing final review by the OECD/NEA, reviews the performance assessment capabilities for radioactive waste disposal. Although much of the report discusses techniques that are beyond the scope of this presentation, some of its findings are worth highlighting here.

The task group noted that "performance assessment is multi-disciplinary and iterative in approach." They also noted that "the calculated long term consequences of a repository must be considered with respect to their probability of occurrence." In this context they also stated, "However, in most cases of probability estimates, human judgement has to be used in conjunction with incomplete or only partially relevant data and observations." Like so many others,they also indicated that more work needs to be done and that "It is not obvious, however, how compliance should be demonstrated for the long term safety of repositories."

NEA RWM/DOC(90)2 RWMC Collective Opinion on Safety Assessment

The same NEA committee has followed up its review of methodologies to develop this draft collective opinion. In carrying out this effort they considered whether 1) disposal systems and their impacts on people and the environment could be sufficiently understood, 2) specialist and regulatory authorities could be convinced that the predicted behavior is representative of what might actually happen, and 3) the potential impacts and means of estimating these can be illustrated transparently for a wider audience. They concluded that "...safety assessment methodologies exist today to illustrate the long-term radiological impacts that a proposed radioactive waste disposal system could have on man and his environment."

GAO NUCLEAR WASTE-Quarterly Report as of December 31, 1989-(Published April 1990)

This General Accounting Office (GAO) quarterly report is particularly pertinent to today's discussion. The report reflects some NRC staff concerns as to whether the EPA containment requirements may make it difficult, if not impossible, to satisfactorily demonstrate compliance in an NRC licensing proceeding. GAO notes that "Specifically, the staff believes that the standard can be implemented successfully in a licensing proceeding only if the inherent uncertainties involved

in making long-term projections of repository performance can be satisfactorily taken into account." They further note, however, that "NRC's staff believes that meaningful, though not statistically rigorous probability estimates can be developed and reasonably defended for repository sites that are not complex or unusually geologically active. In fact, the staff believes that the required probability estimates will help determine how well a site is understood and, therefore, how much confidence can be placed in its future performance as part of a repository."

This subject of concern over uncertainties and how they are handled in an NRC licensing forum is the second of the three areas I will discuss later.

NRC Advisory Committee on Nuclear Waste letter to Chairman Carr of May 1, 1990; Subject: CRITIQUE OF THE ENVIRONMENTAL PROTECTION AGENCY'S STANDARDS FOR DISPOSAL OF HIGH-LEVEL WASTES

This NRC advisory committee has been conducting a review of the EPA High-level Radioactive Waste Standards over an extended period. They, too, indicate concern over showing compliance in the context of an NRC licensing hearing. Also, as in some of the other advisories, they state: "Although lower level standards can be stated probabilistically, they should be expressed in terms of annual risk limits from a disposal facility in an undisturbed and a disturbed state." This is, of course, an area where I have already noted I will have further comments.

This committee has also made several other specific suggestions concerning the EPA standards. We have evaluated those suggestions and have asked for clarification on several of them.

IAEA Safety Series No. 99- Safety Principles and Technical Criteria for Underground Disposal of High-Level Radioactive Wastes (1989)

This report reflects a number of the precepts that have become the basic criteria for high-level waste disposal. One of the overlying objectives noted the largely accepted approach to the intergenerational question and the role of institutional controls. The report states that the objective is "to isolate high-level wastes from the human environment over long time-scales without relying on future generations to maintain the integrity of the disposal system, or imposing upon them significant constraints due to the existence of the repository."

For limits on exposure from gradual processes, the document recommends the application of upper-bound dose limits that are less than the ICRP recommended 100 millirems per year. This is to prevent the overall limit from being exceeded by multiple sources. This is the approach that EPA has taken.

The report recommends considering the risks of disruptive events in a probabilistic approach using individual risk based on the ICRP-46 approach. The recommended limit for these events is a health effects risk increase of one in a hundred thousand per year. This is a higher risk than the EPA usually uses. The report also differs, as have many of the others, from the EPA decision to use total releases rather than annual dose for the probabilistic criteria.

National Research Council Board on Radioactive Waste Management Position Statement "Rethinking High-Level Radioactive Waste Disposal" (1990)

This document is critical of the whole U.S. high-level radioactive waste program. It basically calls for redoing the entire system beginning with the law. Concerning regulations, the statement implies that we would be better off without so much quantitative regulation and that we should just move forward studying the matter and doing the best possible job. This is the third area I will be specifically addressing later.

This report does contain some recommendations that are in line with suggestions we have made. For instance, it calls for performance assessments to be done on an iterative basis, an area we had suggested to DOE regarding their WIPP assessment. We further agree that one should not expect to get an analysis right the first time. Indeed, one of the major purposes of early site assessments should be to ascertain the significant areas requiring further examination.

The report makes three specific recommendations for EPA's consideration:

1) We should reconsider the detailed performance standards to determine how they will affect the level of health risks that will be considered acceptable.

We are doing this as a part of our repromulgation effort. It includes a comparison of the standard with other risk management standards EPA has promulgated in the last five years.

2) We should reexamine the use of quantitative probabilistic release criteria and examine what will constitute a reasonable level of assurance.

This is an area we are reviewing, but it should be realized that this is only partly our responsibility, since it largely falls to the NRC in their licensing process. Our standards authority is restricted to general applicability, and most of this determination is clearly related to site-specific issues. One of the issues that I will discuss later will highlight how

EPA has considered this matter of "reasonable assurance" in the drafting of its standards.

3) The report notes that all other countries use only a dose requirement and that the EPA should consider doing the same.

This, again, is the area where we most consistently disagree with many of the recommendations that have been made.

The Nuclear Waste Technical Review Board- First Report to the U.S. Congress and the U.S. Secretary of Energy (March, 1990)

This is the first in what can be expected to be a series of reports from this statutorily created advisory panel. It contains many excellent suggestions on the subjects that need to be examined during the assessment of potential repositories. It points out the critical need for preliminary performance assessments to see if the computations are possible for a site and whether any characteristics that would disqualify the site have been detected.

The report contains a listing of six different comments based on a review of a preliminary draft of EPA's reproposal of 40 CFR 191. We are adding several statements to clarify the areas that the report found ambiguous. We are also giving special attention to comments that call for changes in the standard. As the report suggests, we have already decided to drop the ALARA requirement from the next draft. We are also exploring the ^{14}C release issue, and we agree that this needs to be understood.

<u>EPA Issues</u>

As I mentioned earlier there are then at least three areas where EPA has differences with some of these advisories. First, should there be quantitative standards before a repository is developed; second, what level of compliance assurance does EPA believe to be appropriate; and third, why have we chosen to express the probabilistic-related part of our standard in terms of total releases rather than individual annual dose? I will now explore these issues in more depth.

The Need For Quantitative Probabilistic Standards

Probabilistic standards are necessary because of the long time period over which one must judge the repository's suitability. Without taking the probability of events into consideration, a standard has no meaning for these types of facilities. If a site has any type of geological integrity at all, and all proposals certainly indicate this will be the case, the releases from undisturbed performance are not expected to be the ones of major concern. As we extend the analysis into the

thousands and tens of thousands of years, we realize releases of some kind are indeed possible, despite the geological integrity. The releases that might occur in the longer term are dependent on disturbed performance and, therefore, are not susceptible to the classic type of standard that prescribes limits on "routine releases." Nor can they be brushed aside as of no consequence. The releases of concern for any reasonably considered geology usually result from such things as human intrusion or seismic disturbances. To ignore this reality is to develop standards that have no effect on the releases of concern.

If we take the disturbances into consideration and apply only deterministic standards, we have only two choices for the possible events: we assume they either will or will not occur. If we assume they will occur, it will be difficult to find a repository that can pass the test. If we assume they will never occur, or ignore consideration of these events, we will have abandoned having a meaningful standard. If we do not state these criteria in some type of quantitative terms, we will have no yardstick for decision. This will invite litigation.

Another reason we think that a quantitative standard is necessary is that it provides a criterion against which to measure success or failure. We are very much aware of the potential contentious nature of the forthcoming repository licensing process. Without quantitative standards in place that have gone through a public review and promulgation process, each proposed site will require extensive justification, much of which will be subjective. This could result in an adversarial situation. By having an existing quantitative measure, much of the contention could be avoided since both the licensing board and any subsequent court will have a yardstick against which to judge the arguments.

The final reason for quantitative standards is that we do not believe that the disposal of high-level radioactive waste can be approached on the basis of just doing the best job that we can. Even the most experimental of engineering designers must have in mind some design goal. The country started out on this approach, which resulted with a proposed repository at Lyons, Kansas, that most now agree would not have been adequate. Furthermore, we do not believe that the public is willing to accept a nonquantitative standard as adequately protective of their health and the environment.

Compliance Assurance

The determination of whether a proposed repository complies with the EPA standard will not be made through measurement, monitoring, or inspection. For these facilities, we must depend

on mathematical models to carry out the long-term predictions of performance upon which the decisions will be made. Again, we realize that this will be taking place in a rather contentious setting. We are also aware that there is no way to make these types of predictions over such extended time periods and have total certainty as to their correctness. In fact, we would expect that there would be a good deal of uncertainty. We have dealt with this issue by indicating in our standard that we are looking for the analysis to show only a reasonable expectation of the standards being met. We purposefully avoided using the term "reasonable assurance" because it has been extensively used in the licensing of nuclear reactors and has acquired connotations that could complicate the waste repository decision. We have not developed any quantitative definition for "reasonable expectation" because we felt that it was both premature and that it was the responsibility of the NRC to do it in its licensing process.

Although we did not numerically define "reasonable expectation", there were other areas in the 1985 promulgation of the EPA standards in which we gave guidance on how we would handle uncertainty. For instance, in discussing how the implementing agencies might assure compliance where predictions of performance are made, we said:

> Substantial uncertainties are likely to be encountered in making these predictions. In fact, sole reliance on these numerical predictions to determine compliance may not be appropriate; the implementing agencies may choose to supplement such predictions with qualitative judgments as well.

Also, to assure that there is appropriate truncation to the probabilistic analysis, we included the following guidance:

> The Agency assumes that such performance assessments need not consider categories of events or processes that are estimated to have less than one chance in 10,000 of occurring over 10,000 years. Furthermore, the performance assessments need not evaluate in detail the releases from all events and processes estimated to have a greater likelihood of occurrence. Some of these events and processes may be omitted from the performance assessments if there is a reasonable expectation that the remaining probability distribution of cumulative releases would not be significantly changed by such omissions.

Because it was clear that uncertainties were very much a part of the analysis, we included some thoughts on how they might be handled with guidance that:

> When the uncertainties in parameters are considered in a performance assessment, the effects of the uncertainties considered can be incorporated into a single such distribution function for each disposal system considered. The Agency assumes that a disposal system can be considered to be in compliance with 191.13 if this single distribution function meets the requirements of 191.13(a).

And similarly, regarding the analysis of undisturbed performance, we said:

> When the uncertainties in undisturbed performance of a disposal system are considered, the implementing agencies need not require that a very large percentage of the range of estimated radiation exposures or radionuclide concentrations fall below limits established in 191.15 and 191.16, respectively. The Agency assumes that compliance can be determined based upon "best estimate" predictions (e.g., the mean or the median of the appropriate distribution, whichever is higher).

Also, relative to inadvertent intrusion, we wanted to appropriately limit the discussion when we included the following in our guidance:

> The Agency believes that the most productive consideration of inadvertent intrusion concerns those realistic possibilities that may be usefully mitigated by repository design, site selection, or use of passive controls (although passive institutional controls should not be assumed to completely rule out the possibility of intrusion).

As further substantiation that EPA fully understood the uniqueness of the repository venture and the uncertainties that went with it, we provided a mechanism for calling for alternative provisions (section 191.17). In describing the purpose of this provision in the preamble to the rule, EPA wanted to go on record to provide perspective for any future reviewer, such as a licensing board or court. In this context, following are some of the examples of statements we made in the preamble:

> In developing the disposal standards, the Agency has had to make many assumptions about the characteristics of disposal systems that have not been built, about plans for disposal that are only now being formulated, and about the probable adequacy of technical information that will not be collected for many years.

Thus, although the Agency believes that the disposal standards being issued today are appropriate based upon current knowledge, we cannot rule out the possibility that future information may indicate needs to modify the standards.

There are several areas of uncertainty the Agency is aware of that might cause suggested modifications of the standards in the future. One of these concerns implementation of the containment requirements for mined geologic repositories. This will require collection of a great deal of data during site characterization, resolution of the inevitable uncertainties in such information, and adaptation of this information into probabilistic risk assessments. Although the Agency is currently confident that this will be successfully accomplished, such projections over thousands of years to determine compliance with an environmental regulation are unprecedented. If--after substantial experience with these analyses is acquired--disposal systems that clearly provide good isolation cannot reasonably be shown to comply with the containment requirements, the Agency will consider whether modifications to Subpart B were appropriate.

As we have proceeded in repromulgating this standard, the area of guidance for implementation is one that we have given particular attention to. This is especially true where misunderstanding or lack of clarity has been pointed out to us. It should be clear, however, from these references to the 1985 version, that we never intended "absolute proof", as some have contended.

Individual Annual Dose versus Total Release

Probably the area in which we have had the most consistent difference with the various advisories is that of probabilistic-related assessment. Although we have set individual annual exposure levels for the undisturbed performance over a 1,000 year period, we have taken the approach of setting limits on total releases over 10,000-years for the probabilistic-related standards. When we started this standard setting effort, it was our inclination to use individual dose, since that was how radiation standards had always been set. It was only after we examined what it would mean to have to comply with such a provision that we switched to our present approach. We believe that approach is much more appropriate in view of the long time periods and uncertainties involved. The easiest way to show why we came to this decision is through reference to Figure 1.

Figure 1 shows two symbolic spheres representing the boundary line around two repositories and the defined "accessible

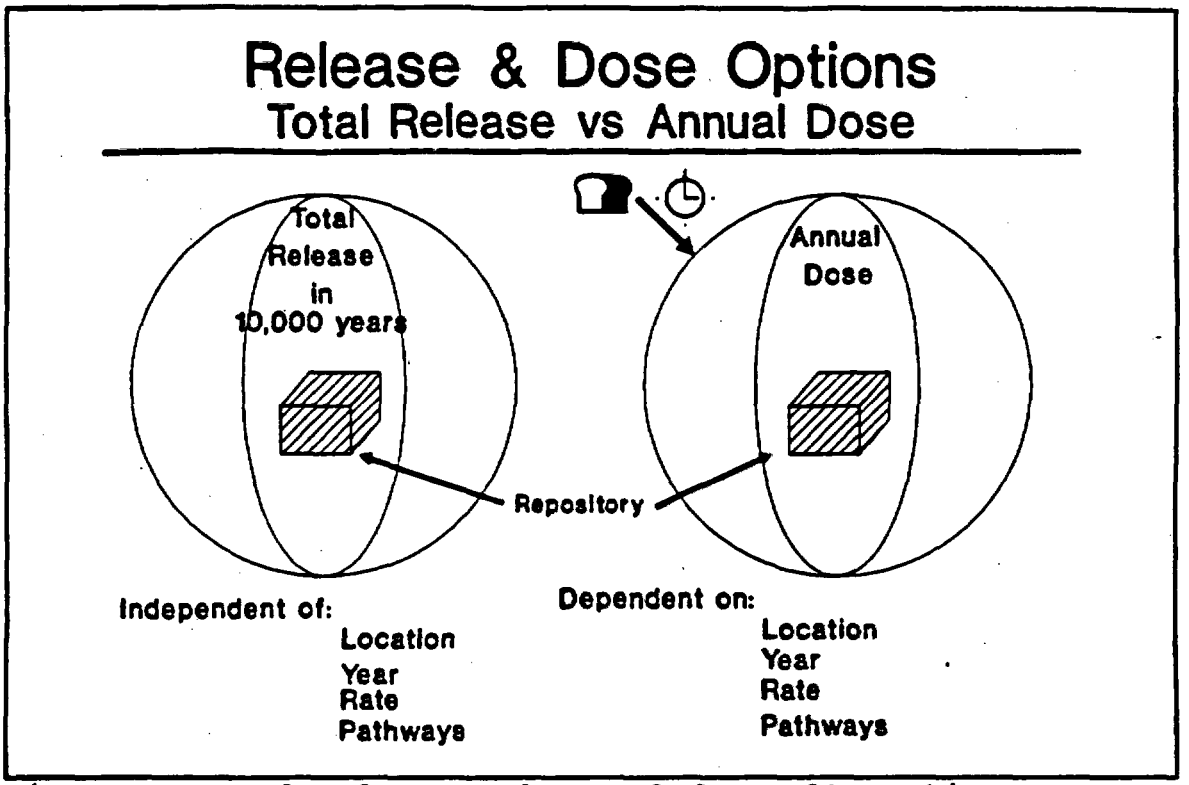

Figure 1: Total release and annual dose alternatives

environment". The sphere on the left represents the compliance case if you have the current structure of the EPA standards for probability related releases. In this instance, the release limits have been determined using fairly simple models related to the overall objective of having no greater than 1,000 health effects in 10,000 years. Under these circumstances, one only needs to estimate the probability and quantities of releases of radioactive material across this boundary at any time during the 10,000-year period. To demonstrate compliance, it is not necessary to identify where on that boundary sphere the release occurs (Location), when the release starts or stops during that 10,000 year period (Year), the time-related frequency of the amounts released (Rate), or how this material might interact with people and how they might be exposed (Pathways).

If we were to pursue the second alternative, annual individual dose, as depicted by the sphere on the right of Figure 1, we have a much more difficult analytical task. It is no longer sufficient to just estimate how much radioactivity is likely to cross the boundary. We now must also estimate where (arrow) on that boundary it will occur and whether it is close to people. That would be only the beginning of the analytical chore, however. Since we must calculate an annual dose, we must know when the release starts and ends (clock) and how much will be released on an annual basis (time-related factors on an annual

basis). While we think all this is more than should be asked of a probabilistic analysis, it would not be sufficient. We would still be required to go on from that point and speculate on how this material might interact with people (pathway-bread?) at this specific location and what the subsequent annual dose might be. These are speculations we believe are feasible for the analysis of the undisturbed repository but that are beyond what should be considered reasonable for the probabilistic analysis,

CONCLUSION

There is no doubt that the country has set itself a considerable challenge in seeking to establish a high-level radioactive waste repository. Yet, we must do it. In our evaluation of the regulatory aspects of this issue we do not see the system as broken beyond repair. Certainly, the political and sociological issues appear to be much greater deterrents to success than do the technical requirements of an EPA standard. We have noted a large number of advisories concerning how these facilities should be regulated, some of which we have highlighted here. There are many ideas in these advisories that we agree with and have adopted. We find a few ideas we do not agree with, and we have pointed out our reasons for disagreeing at this meeting. We think that more such interchanges should take place and that improved communications would be helpful in resolving differences. In many ways we have an advantage because everything we do is subject to public review, generating comments from many sectors. It would be much more difficult to create responsible public policy from discussions among ourselves. We appreciate the opportunity to have participated in this exchange.

NRC STAFF ANALYSIS OF "RETHINKING HIGH-LEVEL WASTE DISPOSAL"--A POSITION STATEMENT OF THE BOARD ON RADIOACTIVE WASTE MANAGEMENT OF THE NATIONAL RESEARCH COUNCIL

BACKGROUND:

On July 18, 1990, the Board on Radioactive Waste Management of the National Research Council ("the Board") issued a report entitled "Rethinking High-Level Waste Disposal." The Board's report was developed from discussions at a study session convened by the Board in July 1988, to address U.S. policies and programs for high-level waste (HLW) management. The week-long study session was attended by representatives of the U.S. Department of Energy (DOE), the U.S. Nuclear Regulatory Commission (NRC), and the U.S. Environmental Protection Agency (EPA), as well as other knowledgeable persons from the United States and abroad.

The NRC staff has reviewed the Board's report, and this paper gives the staff's analysis. The staff has chosen to focus on what it considers to be the Board's major findings and recommendations related to NRC's regulatory responsibilities regarding high-level radioactive waste repository licensing. The staff's analysis is based on its understanding of the national HLW program as of August 1990, and thus reflects a number of important events that have occurred since the July 1988 study session. These events, some of which have caused or will cause changes to both the NRC and DOE programs, include DOE's issuance of the Site Characterization Plan (SCP) in December 1988, issuance of the NRC staff's comments on the SCP (i.e., NRC's Site Characterization Analysis (SCA)) in August 1989, DOE's announcement of revisions to its program and schedule in November 1989, the appointment of a permanent director of DOE's Office of Civilian Radioactive Waste Management, and the issuance of NRC staff's Regulatory Strategy in October 1988 and first update in June 1990.

CONCLUSIONS:

The staff's major conclusions are:

1. The staff agrees with many of the general principles described in the Board's report and more importantly considers that the NRC regulation and prelicensing process are already consistent with these principles.

2. Uncertainties associated with licensing a geologic repository, including those related to modeling, are recognized by the regulation.

3. The NRC regulation provides flexibility to adjust the subsystem performance requirements for site-specific conditions and designs.

4. The iterative prelicensing process is intended to implement the broad, generic NRC regulations at a specific site. If implemented properly, this process will permit DOE to propose adjustments to the performance allocation for subsystem barriers and their components, to fit the needs for a specific site and specific designs. These adjustments can then

be reflected in adjustments to the subsystem requirements, as permitted by 10 CFR 60.113(b). The staff would review DOE's proposed adjustments and advise DOE accordingly during prelicensing.

5. Proper implementation of the regulation, by both NRC and DOE programs, should continue through the prelicensing process. Features intended to allow flexibility need to be applied effectively by both NRC and DOE.

DISCUSSION:

I. Analysis of Board Findings and Recommendations

A. Overall Finding and Recommendation

The Board concludes that the current approach has resulted in lack of satisfactory progress by the U.S. program and that this is caused by the regulatory requirements (i.e., NRC's 10 CFR Part 60 and EPA's 40 CFR Part 191) and program implementation. Furthermore, it concludes that the current program is unlikely to succeed. The Board therefore recommends an alternative approach that "...will require significant changes in laws and regulations, as well as in program management."

This overall conclusion is primarily based on the following three major findings:

(a) Lack of recognition of uncertainties;
(b) Overreliance on modeling;
(c) Lack of flexibility in regulations and program.

The staff does not consider that the NRC regulation has contributed to any perceived lack of progress. The staff believes that the three major findings in the Board's report reflect a perception of the NRC regulation and implementing process that is different from the staff's view. The staff considers that the regulation is in fact consistent with the following general principles embodied in the Board's three major findings:

(a) Uncertainty must be recognized in safety decisions and absolute certainty cannot be achieved;

(b) Although indispensable, modeling cannot be solely relied on for safety decisions;

(c) Regulatory and programmatic flexibility are needed to best deal with uncertainty.

The staff also observes that while the regulation has always been consistent with these principles, improvements which increase flexibility have been made by both NRC and DOE to the implementation of the prelicensing process since the Board's study session was held two years ago. Further, improvements can and should continue to be made, and the NRC staff is committed to do so.

One of the major difficulties in assuring the NRC and EPA regulations can be implemented is that they have never been applied to the full universe of data that is expected to come from site characterization and be included in the repository license application. As a result the debate necessarily takes on a theoretical tone, with few technical details. While recognizing this limitation, the staff believes that the case is not made for significant changes to the NRC regulation. Instead, proper implementation of the flexibility inherent in the NRC regulation by both NRC and DOE programs should continue through the ongoing, site-specific, iterative prelicensing process. Already existing features intended to allow flexibility in the application of the regulation and prelicensing process to a specific site need to be clearly understood by all parties and applied effectively by both NRC and DOE. If needed, changes to the regulation can be made during and after site characterization.

B. Specific Recommendations for NRC

Of the seven specific recommendations made by the Board, one is addressed to NRC. The NRC staff considers that two other recommendations, one addressed to DOE and one addressed to EPA, also involve NRC and are specifically addressed below.

1. Recommendation No. 3, addressed to NRC

The Board recommends that NRC reconsider the detailed licensing requirements which the staff understands to be directed at the subsystem performance objectives set out in 10 CFR 60.113. As a matter of fact, the staff is already reconsidering each of these subsystem performance objectives, with a view to possible clarifications or improved implementation. The staff's Regulatory Strategy (SECY-88-285 and SECY-90-207) further explains the staff's plans in this regard. As to the specific issues concerning the need for accommodating uncertainty (i.e., not requiring unreasonable levels of evidence) and preserving the flexibility to deal with new information, including consideration of design changes as appropriate, see Section C below. The staff notes, however, that the perception of insufficient flexibility may reflect some misunderstanding of what NRC regulations do in fact require -- as indicated, for example, by the incorrect interpretation that some parties have made regarding the "1000-year" containment period for waste packages (see Section C).

2. Recommendation No. 4, addressed to DOE

The Board also encourages DOE to become "... a more responsive player in these regulatory issues," and "... publically negotiate prelicensing agreements..." with NRC on the goals of the regulations, treatment of uncertainty, and performance assessments. The staff agrees with the Board's encouragement of DOE. NRC and DOE have had prelicensing consultations for many years. These consultations are open to the public and involve participation by the State of

Nevada and affected counties. However, the staff has often found in the past that DOE is reluctant to meet and discuss potential licensing issues in a open and public forum. The recent interactions with DOE indicate that future consultations may improve. The NRC staff has been meeting and will continue to meet regularly with DOE, to agree on important topics for consultations, including the topics suggested by the Board. It is important to recognize, however, that both as a matter of law and policy, final judgments with respect to the acceptability of a particular repository must await consideration in formal licensing.

3. Recommendation No. 2, addressed to EPA

The Board's recommendations for EPA regarding the quantitative probabilistic nature of the release standard, what will constitute a reasonable level of assurance, and the preference for a dose standard are also of interest to NRC, because of their significance to NRC's implementation of EPA's HLW standards. The NRC staff shares the Board's concern about the uncertainties associated with implementing the quantitative probabilistic approach in the EPA HLW standards and is actively discussing with EPA questions related to improving implementation. However, it should be kept in mind that although the EPA standard may be stated in probabilistic terms, the decision of whether or not a particular repository meets the standard rests ultimately on judgment in applying the qualitative "reasonable assurance" test, rather than absolute certainty. (See Section C1 for further discussion of what constitutes reasonable assurance.)

The staff recognizes that a standard expressed in terms of dose or risk like the one suggested by the Board is attractive because of its clear correlation with protection of public health and safety. When a standard limits releases of radioactive materials, as EPA's HLW standards do, the relationship to public health protection is not as readily apparent. There is, however, a major advantage to such a release limit standard -- a significant simplification in the analyses required to evaluate compliance. Standards that limit dose or risk require identification of environmental pathways and demographic assumptions (e.g., population distributions and dietary habits) far into the future, and thus introduce large uncertainties into analyses of compliance. The alternative approach adopted by EPA addresses and resolves these uncertainties by rulemaking, allowing a simpler evaluation of compliance for a specific repository. This simplification results in a somewhat less flexible standard, which precludes consideration of potentially beneficial environmental pathways and demographic characteristics of a specific site. The staff considers that this loss in flexibility would be outweighed by the advantage of precluding sources of additional uncertainty in repository performance assessments.

C. NRC Staff Views of the Board's Major Findings

1. Recognition of Uncertainties

10 CFR Part 60 and the NRC staff's implementation of this regulation clearly recognize the uncertainties inherent in a geologic repository. Both the regulation and statement of considerations state that reasonable assurance, not absolute proof, is the standard. 10 CFR 60.101 (a) (2) gives the following standard of proof:

> 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 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.

Moreover, the statement of considerations accompanying promulgation of 10 CFR Part 60 (48 FR 28194, June 21, 1983 at 28204) elaborated, in part as follows:

> This standard [reasonable assurance], in addition to being commonly used and accepted in the Commission's licensing activities, allows the flexibility necessary for the Commission to make judgmental distinctions with respect to quantitative data which may have large uncertainties (in the mathematical sense) associated with it.
>
> ...the Commission will not be able to rigorously determine the probability of occurrence of an outcome that fails to satisfy the performance standards. It must use some other language, such as "reasonable assurance," to characterize the required confidence that the performance objectives will be met.

The staff agrees with the Board's conclusion that recognition of uncertainty in decision-making is a necessary part of achieving public acceptability, but regards the Commission's policies and regulations to be fully consistent with this conclusion.

2. Use of Modeling

The staff agrees with the Board's observation that modeling is indispensable for understanding repository performance and focusing on uncertainties significant to performance. The staff also recognized the limitations of modeling and therefore 10 CFR 60.101 (a) (2), as quoted above, recognizes that predictive models will not be relied on solely but will need to be supported by field and laboratory tests, monitoring data, and natural analog studies. The staff also recognizes that expert judgment will factor into such areas as interpretations of data and model assumptions.

The staff's concern over limitations of present modeling, coupled with the value of modeling to focus both the DOE and NRC programs, has led the staff to place a high priority on iterative performance assessment. One of the major comments in the staff's SCA on DOE's SCP was the need for DOE to begin using iterative performance assessment to help guide its site characterization and design programs and to improve methodologies. Likewise, the staff has an ongoing program to develop its own capability to conduct iterative performance assessments as a tool to help determine acceptable and feasible methods and to knowledgeably review DOE's total systems performance assessments. However, to date, DOE has not come forward with any preliminary performance assessments of the Yucca Mountain Site.

3. Flexibility in Regulations and Program

The staff agrees with the Board's conclusions that flexibility is needed to deal with uncertainties. Flexibility was a major issue considered by the staff, Commission, and commenting parties as the regulation was developed. The significant differences between nuclear power plants and a geologic repository were recognized and resulted in a regulation and licensing process better suited for the unique problems expected in developing a first of a kind deep geologic repository. What resulted was a performance-oriented regulation that attempts to give a reasonable degree of flexibility within a framework of general regulatory requirements. This approach appears to be consistent with the Board's desire for broad requirements that are not immutable contraints.

Given the broad generic regulation, activities carried out during the prelicensing process are necessary to implement the regulation at a particular site. The successful implementation of the regulation depends to a large extent on efforts during the

prelicensing, site characterization phase to determine how a demonstration of satisfactory performance can best be accomplished. Both the regulatory language and the prelicensing interactions among all interested parties accommodate the very real need for flexibility. Flexibility features in both the regulation and prelicensing/licensing process are discussed further below.

a. Subsystem Performance Objectives

As mentioned previously, the staff considers the subsystem performance objectives and criteria are general requirements rather than detailed requirements prescribing specific engineering design. Furthermore, although the numerical nature of the subsystem performance objectives can give the impression of absoluteness, it should be recalled that "reasonable assurance" rather than absolute certainty is the standard of proof for meeting these requirements (see Section IC1). In addition, it should be emphasized that the numerical values themselves are subject to adjustment so as to take into account unique features of a specific site or design that would contribute to overall performance. This is not an exemption from the regulation, but a provision that is expressly set out in the regulation itself. 10 CFR 60.113 (b) states that:

> On a case-by-case basis, the Commission may approve or specify some other radionuclide release rate, designed containment period or pre-waste-emplacement groundwater travel time, provided that the overall system performance objective, as it relates to anticipated processes and events, is satisfied.

Questions have been raised by DOE and others about perceived limitations of the subsystem requirement for waste package containment in 10 CFR 60.113 (a)(1)(ii)(A). Specifically, it was unclear to DOE and others if this requirement was a cap on the waste package lifetime or a limitation on the credit that can be taken in engineered barrier system or overall repository system performance assessments. The requirement, if so interpreted, might indeed have the effect of unduly reducing DOE's flexibility. Such an interpretation could also give the incorrect impression that the regulation deemphasizes the importance of the engineered barrier system and therefore emphasizes the natural system.

In order to resolve this question about the regulation, the staff, based on the information in the statement of considerations, issued Staff Position 60-001 on July 27, 1990, which clarifies the meaning of this requirement and explains the flexibility in the regulation and the staff's interpretation of the regulation. The staff's position is that this requirement:

> ... is a minimum performance requirement which is not intended, and should not be interpreted, as a cap on the waste package lifetime or a limitation on the credit that can be taken (in engineered barrier system and overall repository system performance assessments) if the waste package is designed to provide containment in excess of 1000 years.

Yet, while the staff regards the subsystem performance objectives as having considerable flexibility, these objectives do have a role in implementing the Commission's defense in depth philosophy and will need to be implemented in a manner that enhances confidence in overall system performance.

b. Regulatory Strategy

The staff's Regulatory Strategy (SECY-88-285), issued in October 1988, reflects an internal process for identifying and correcting deficiencies with the regulation (including requirements that might prove to be unnecessary to protect public health and safety). The staff has recently had its contractor, the Center for Nuclear Waste Regulatory Analyses, complete an independent analysis of the regulation to identify potential deficiences. The staff also has used and will continue to use the experience of the staff and DOE with implementing the regulation, during site characterization at the Yucca Mountain site, to identify deficiencies.

Once potential deficiencies are identified, the staff's Regulatory Strategy also indicates generally how they will be corrected by using either rulemakings, staff positions, or regulatory guides. The first update to the Regulatory Strategy in SECY-90-207 lists a number of potential rulemakings, staff positions, and regulatory guides intended to address identified deficiencies and other regulatory needs. The Staff Position 60-001 mentioned previously is one example of how the staff has addressed a perceived deficiency. Work is also underway to examine each of the post-closure subsystem performance objectives (i.e., substantially complete containment, engineered barrier system release, and groundwater travel time/disturbed zone). The staff's strategy is to refine these requirements.

Although refinements may be beneficial, the staff sees no justification for eliminating the quantitative subsystem performance requirements. These requirements are a necessary feature of the regulation used to implement the multiple, independent barrier concept and to deal with uncertainties in estimating overall system performance. Most importantly, as discussed above, the explicit provision for adjustments (i.e.,

10 CFR 60.113(b)) assure that necessary accommodations can be made so long as there is no weakening of the protection of public health and safety.

c. Licensing and Prelicensing Process

The overall licensing process was also designed to account for an evolving program. The regulation and the Regulatory Strategy in SECY-88-285 describe the five phases of repository licensing. Each phase represents a step in an evolving decision-making process incorporating new information and design changes with each step.

More specifically, the staff considers that the prelicensing phase of the licensing process has been designed to allow additional program flexibility in many ways to accommodate the evolving and exploratory nature of the program. As mentioned previously, the prelicensing/site characterization process recognized by the Nuclear Waste Policy Act (NWPA) and implemented by both NRC and DOE is the intended mechanism to develop the detailed site, design, and performance information necessary for DOE to demonstrate compliance with the regulation for the Yucca Mountain site. It is through review and consultation, between NRC and DOE that the application of the generic regulation can be clarified for the Yucca Mountain site. The State of Nevada and units of local government have had and will continue to have the opportunity to participate in all such consultations between the staff and DOE, and the public is invited to observe. This ongoing, iterative prelicensing process also includes DOE's preparation of semi-annual progress reports which document progress and changes as the program evolves and adjusts to new information obtained about the site. Documentation is needed for purposes of licensing as well as informing the public. This process, therefore, anticipates and allows for changes to be made as site characterization and design activities proceed.

Within the site characterization process, NRC has also agreed to DOE's issue resolution strategy and performance allocation process. This process, described in DOE's SCP, is intended to be a decision-aiding process for eventually determining if enough information has been collected and adequately assessed, for the Yucca Mountain site, to demonstrate compliance with the regulatory requirements. This process gives direct consideration to how uncertainties should be treated. It also permits DOE to propose adjustments to the performance allocation of the subsystem barriers and their components, to fit the needs for a specific site and specific designs. These adjustments can then be reflected in adjustments to the subsystem requirements, as allowed for in 10 CFR 60.113(b). The staff would expect that initial performance allocation goals would change as new information about the site is

obtained and as DOE refines its conceptual designs. Finally, the staff would review DOE's proposed adjustments, and if the staff concluded that the adjustment was justified in light of the information at hand, it would so advise DOE as it completes the preparation of a License Application.

d. DOE Program Implementation and Quality Assurance

In the staff's view, DOE's schedule prior to its November 1989, announcement of a revised schedule was overly optimistic. NRC expressed concerns about DOE's unrealistic schedule in it's SCA and in a September 16, 1988, letter to DOE on the Draft 1988 Mission Plan Amendment. The time allocated in the old schedule for the prelicensing/site characterization process would have limited DOE's implementation of many of the flexibility features of the prelicensing process discussed previously in Section IC3c. The staff considers that DOE's revised schedule is an improvement. It is a more realistic schedule given the complex and exploratory nature of the program. It also provides DOE and other parties with the time needed to properly implement the prelicensing/site characterization process.

A source of perceived inflexibility that has been previously identified by the Board is in the area of quality assurance. This concern prompted the NRC staff to examine both its regulation and the implementation of the regulation by DOE. Discussions also have been held with DOE and other parties. As a result NRC and DOE have agreed that NRC's regulations and guidance have not restricted flexibility. Rather, the root cause of any such perceived problems is most likely DOE's and its contractors' overly restrictive implementing procedures. The staff understands that DOE is pursuing resolution of this matter. The staff intends to follow DOE's resolution of implementation problems to ensure that the current understanding of the root cause of the problems is correct.

Another source of inflexibility mentioned in the Board's report is DOE's attitude of "getting it right the first time." In the past, the staff has observed a somewhat different DOE attitude of taking a position and assuming that it is the right way, without fully considering differing or alternative comments and positions. For example, in DOE's consultation draft SCP, such an attitude was reflected in DOE's preference for optimistic assumptions and lack of consideration of alternative conceptual models of the Yucca Mountain site, despite the current limited level of knowledge about the site. (However, it needs to be noted that the staff's comments and consultations with DOE about this concern have ultimately resulted in improvements in DOE's consideration of alternative conceptual models in its SCP). Such a DOE attitude is also

reflected in the difficulties the NRC staff has had in obtaining indepth technical consultations on problems until DOE has developed a final position. The staff has noted this concern in its comments on the progress of the pre-license application consultation program in the Quarterly Progress Reports to the Commission.