

MAR 25 1993

Mr. Robert R. Loux
Executive Director
Agency for Nuclear Projects
Nuclear Waste Project Office
Capital Complex
Carson City, Nevada 89710

Dear Mr. Loux:

SUBJECT: STAFF RESPONSE TO THE STATE OF NEVADA'S COMMENTS ON THE ADVISORY
COMMITTEE ON NUCLEAR WASTE CONCERNS RAISED IN THE DECEMBER 1, 1992,
LETTER

Chairman Selin has asked me to respond to your letter of February 24, 1993, providing the State of Nevada's comments on issues identified by the Advisory Committee on Nuclear Waste (ACNW) that the ACNW believes have the potential for delaying or otherwise interfering with the timely development of a high-level waste repository (December 1, 1992, letter from D. Moeller, ACNW, to Chairman Selin, NRC). Enclosure 1 is the staff's response to the ACNW's letter (February 11, 1993, memorandum from James M. Taylor, NRC to D. Moeller, ACNW), and Enclosure 2 contains the staff's response to the State's comments on the ACNW's issues. I trust that the enclosed information responds to any concerns the State of Nevada has.

If you require any additional information, please feel free to contact me or Mr. Joseph Holonich of my staff. I can be reached at (301) 504-3352 or Mr. Holonich can be reached at (301) 504-3391.

Sincerely, Original signed by
Robert M. Bernero
Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

Enclosures: As stated

cc: See Attached List

Distribution: See Attached List
*see previous concurrence

OFC	<i>MD</i> HLPD	<i>E</i>	HLPD*		HLPD*		HLWM*	
NAME	MDelligatti/dh		RJohnson		JHolonich		JLinehan	
DATE	03/23/93		03/ /93		03/ /93		03/ /93	
OFC	HLWM*		OGC*		NMSS		NMSS	
NAME	BJYoungblood		STreby		GArlotto		RBernero	
DATE	03/ /93		03/ /93		03/ /93		03/25/93	

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cc: D. Shelor, DOE
T. J. Hickey, Nevada Legislative Committee
C. Gertz, DOE/NV
M. Murphy, Nye County, NV
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

89001791

February 11, 1993

MEMORANDUM FOR: Dade W. Moeller, Chairman
Advisory Committee on Nuclear Waste

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: SIGNIFICANT ISSUES IN THE HIGH-LEVEL WASTE REPOSITORY PROGRAM

I am responding to the December 1, 1992, letter from the Advisory Committee on Nuclear Waste (ACNW) to the Chairman. In that letter, the ACNW identified a list of issues that it believed have the potential for delaying or otherwise interfering with the timely development of a high-level waste repository. The staff agrees with the ACNW that many of these issues have the potential for delaying the timely development of a high-level waste repository and has, in some form, taken action to address those issues. A general overview is provided below, and the staff's response to each of the individual ACNW issues is contained in the enclosure.

Basically, the staff's interpretation of 10 CFR Part 60 is that it is a broad-based, performance-oriented regulation. This interpretation is consistent with the Commission's position given in the Statement of Consideration that was issued with the final rule. The staff's approach to regulation is, therefore, intended to not be overly prescriptive in this "first-of-a-kind" undertaking, but to provide some flexibility such that the Department of Energy (DOE) can best achieve public protection. The staff's program recognizes that DOE has the primary responsibility to develop the methodology and data to "demonstrate" compliance with Nuclear Regulatory Commission regulations and protection of public health and safety, particularly as regards site-specific or design-specific considerations.

To ensure timely guidance and regulatory acceptability, the NRC staff and DOE have in place a pre-licensing consultation process that involves NRC staff review and comment on DOE documents and frequent interactions with DOE on a variety of technical subjects. In particular, there are interactions in technical workshops - such as the iterative performance assessment workshop - and review of DOE products - such as progress reports, topical reports, study plans, and format and content annotated outlines. Also, the staff is in the process of developing the License Application Review Plan (LARP) that it will use to review DOE's application. The work the staff is conducting in preparing the LARP will allow it to continue to evaluate many of the issues the ACNW identified in its letter.

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Finally, by letter of November 18, 1992, to John Bartlett from Robert Bernero, DOE was strongly encouraged to identify any specific areas where, it believes, NRC needs to conduct additional rulemakings or to provide guidance. To date, DOE has not identified any needs beyond the work presently being undertaken by the staff.

I trust this responds to the ACNW's concerns.

Original signed by
James M. Taylor

James M. Taylor
Executive Director
for Operations

Enclosure:
Staff responses to ACNW issues

cc: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque
SECY
OGC

**STAFF COMMENTS ON ADVISORY COMMITTEE ON NUCLEAR WASTE
SIGNIFICANT ISSUES IN THE HIGH-LEVEL WASTE REPOSITORY PROGRAM**

By letter of December 1, 1992, the Advisory Committee on Nuclear Waste (ACNW) advised the Chairman of the Nuclear Regulatory Commission of issues it believes have the potential for delaying or otherwise interfering with the timely development of a high-level waste (HLW) repository. Sixteen specific issues were identified under four separate groupings along with a summary. The NRC staff has reviewed the issues identified by the ACNW and its comments are provided below.

ACNW ISSUE 1: A number of issues have been identified under the heading of regulatory considerations pertinent to site characterization and licensing of a repository.

ACNW ISSUE 1(a):

The NRC staff should develop positions that can serve as a basis for recommendations to the National Academy of Sciences (NAS) relative to the Academy's role, mandated by the Energy Policy Act of 1992, of providing findings and recommendations on reasonable standards for the protection of public health and safety for the proposed HLW repository at Yucca Mountain.

STAFF COMMENT:

The Commission has requested background information relevant to formulation of NRC positions on the three major standard-setting issues identified in the Energy Policy Act of 1992 (EnPA). The staff's response to this request was provided in SECY-93-013, "Analysis of Energy Policy Act of 1992 Issues Related to High-Level Waste Disposal Standards." It presents discussions of the three issues, as well as pros and cons of possible recommendations that might evolve from the NAS review. A copy of this paper was provided to the ACNW for its information.

ACNW ISSUE 1(b):

It is likely that regulations, issued by the NRC and other agencies, will not be wholly compatible or consistent. It is not clear what constitutes resolution of the issue of compatibility and the stage at which this should be accomplished. The Commission should request the NRC staff to clarify this issue and, if appropriate, initiate rulemaking.

ENCLOSURE

STAFF COMMENT:

The Nuclear Waste Policy Act (NWPAA) affirmed NRC authority to develop regulations for licensing a HLW repository. Regarding the content of the NRC's regulations, the NWPAA, Section 121(b)(1), directed that:

(B) Such criteria shall provide for the use of a system of multiple barriers in the design of the repository and shall include such restrictions on the retrievability of the solidified high-level radioactive waste and spent fuel emplaced in the repository as the Commission deems appropriate.

(C) Such requirements and criteria shall not be inconsistent with any comparable standards promulgated by [EPA] under subsection (a) [of the NWPAA].

Also, Section 801(b) of the EnPA provides that the Commission "...shall, by rule, modify its technical requirements and criteria under section 121(b) of [NWPAA], as necessary, to be consistent with the Administrator's standards promulgated under subsection (a)."

The extant provisions of 10 CFR Part 60 set forth the Commission's views regarding use of multiple barriers and retrievability, as well as other relevant matters. The staff is aware of no obvious or substantive inconsistencies with the HLW standards issued in 1985 by the Environmental Protection Agency (EPA), although the staff did propose "conforming amendments" to Part 60 to incorporate EPA's numerical limits and to clarify some differences in terminology and similar minor issues. The staff still plans to proceed with conforming amendments whenever EPA promulgates its standards. The public comment process will contribute to ensuring that the requirements are not inconsistent with EPA's standards. Should EPA's standards change significantly from those issued in 1985, of course, more substantive changes to Part 60 might be needed in the development of conforming amendments. In any event, the staff's issuance of such conforming amendments should constitute resolution of the question of compatibility.

It should be emphasized that there is no requirement, in the NWPAA or elsewhere, that the NRC's regulations be identical to EPA's standards. Rather, the NWPAA directs EPA to develop standards for the overall performance of a repository system, and anticipates that the NRC regulations will address more detailed considerations such as requirements for multiple barriers and retrievability. Thus, it is to be expected that there will be differences in the regulatory criteria of the two agencies.

ACNW ISSUE 1(c):

The DOE has promulgated 10 CFR Part 960 but its relationship to 10 CFR Part 60 as far as the licensing process is concerned is not clear. There may be a need to clarify this relationship, especially in light of the emphasis of the DOE on 10 CFR Part 960 in its Early Site Suitability Evaluation to the exclusion of inferences from 10 CFR Part 60. The Commission should request the NRC staff to identify the role, if any, of 10 CFR Part 960 in the licensing process.

STAFF COMMENT:

10 CFR Part 960 does not have a role in the NRC's repository licensing process. Rather, it codifies the Department of Energy's (DOE's) general guidelines for the evaluation of sites for HLW repositories. The NWPA directed DOE to issue general guidelines for the recommendation of sites for repositories and to obtain NRC concurrence. The Commission set the following criteria for concurrence: (1) the siting guidelines must not be in conflict with Part 60; (2) the siting guidelines must not contain provisions that might lead DOE to select sites that would not be reasonable alternatives for an environmental impact statement; and (3) the siting guidelines should not contain provisions that are in conflict with NRC responsibilities, as embodied in the NWPA. The Commission concluded that the DOE siting guidelines met its conditions and gave its concurrence on July 10, 1984. (49 FR 9650 and 49 FR 28130.) This concurrence was limited to the guidelines promulgated in 10 Part 960, and did not extend to any revisions that DOE may issue at a later date.

ACNW ISSUE 1(d):

Considerable data that are useful or necessary for a licensing application and are anticipated to be involved in the licensing process will be or have been obtained without use of the rigorous quality assurance (QA) procedures now being implemented. The Licensing Support System (LSS) has been established to encompass pertinent data but has not yet been inaugurated. Further, the LSS may contain data or results that have similar deficiencies. Also, the guidance for the application of QA procedures to development and validation of models, and to decision-making among competing conclusions is at present substantially absent. The inclusion of QA-deficient data or protocols in selection, validation and evaluation of uncertainties in models could pose significant difficulties in the licensing process. The Commission should request the NRC staff to initiate a comprehensive review of the guidance to the DOE that is necessary to define the quality requirements for the use of all important data obtained prior to promulgation of the QA requirements and for relevant models developed for the licensing-related repository description.

STAFF COMMENT:

The staff has provided guidance to DOE on acceptable methods of qualifying existing data in NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories," which was published in February 1988. DOE has developed a procedure, Yucca Mountain Site Characterization Project Office (YMPO) Administrative Procedure AP-5.9Q, "Qualification of Data or Data Analyses Not Developed under the Yucca Mountain Project Quality Assurance Plan," Revision 1, July 5, 1990, that implements the guidance of NUREG-1298.

In addition, DOE stated, in a September 3, 1992, letter from J. Roberts, DOE, to J. Holonich, NRC, that it is, at this time, concentrating on obtaining data under qualified quality assurance (QA) programs. DOE further stated that the need for qualified data applies to its license application, not plans for characterizing a site, and it would be inappropriate to undertake a general review of the totality of data that might need to undergo a qualification process at this time. The staff agreed to this approach in its evaluation of Site Characterization Analysis (SCA) Comment 125. DOE intends to address the need for data qualification when sufficient information has been developed to support a DOE technical position.

With respect to the QA requirements of the LSS, it should be noted that the LSS Administrator (LSSA) is responsible for ensuring that the information that must be placed in the LSS is done consistent with applicable LSS procedures. However, it is not the function of the LSSA to ensure that the information placed in the LSS, such as data reports, is qualified.

The NRC staff believes that there is sufficient guidance in place to allow DOE to qualify data that were not collected under an acceptable QA program. However, staff is still investigating the concept of model validation, for application over the long time period of interest, under its iterative performance assessment program. When it has completed that investigation, it will look at the applicability of QA procedures and the need for further guidance in that area.

ACNW ISSUE 1(e):

Expert judgment will be a necessary and important part of the licensing process. Acceptance of expert judgment, its methodologies and its results in the waste management arena continues to be controversial and could disrupt a licensing process. The Commission should request the NRC staff to proceed with rulemaking to delineate the processes and standards for application of expert judgment to ensure that this technique can make a useful contribution to the licensing process and that its application will be accepted in an adversarial setting.

STAFF COMMENT:

The staff believes it would be premature to pursue rulemaking on the application of expert judgment in the repository licensing process. There already exists a generally accepted system of legal evidentiary rules that can

be followed in NRC licensing proceedings on the admissibility of expert judgment as evidence. Moreover, licensing boards have successfully applied that system to expert opinion issues in numerous reactor licensing proceedings, many of which involved expert opinion issues that were an important and controversial part of the licensing process. Further, the legal rules on admitting expert opinion, to a great extent, are more readily satisfied when the expert scientific judgment to be offered as evidence is "good science." This point will not be lost on DOE, which has access to experienced licensing counsel who understand how to prepare DOE's case for a licensing proceeding.

As part of its iterative performance assessment activities, in fiscal year 1993, the staff will evaluate the use of elicitation of expert opinion in performance assessment. Depending on the outcome of these activities, the staff will consider whether there are any "lessons learned" that could be the basis for possible guidance to DOE on its use of such techniques for obtaining expert judgment. Specifically, the staff will evaluate the extent to which formal elicitation methods appear to improve judgments, the costs of using those formal methods, and the types of judgments for which use of formal methods might be appropriate.

ACNW ISSUE 1(f):

The NRC staff has apparently taken the position that performance enhancement of the engineered barrier system (EBS) cannot be used to offset the potential deficiencies likely to be encountered in the geologic media. This position has caused significant concept and design difficulties, appears to be without technical justification and also appears to be without bases in regulations.¹ Owing to the inability to predict for any site if all of the attributes will meet all regulatory requirements, the Commission may wish to examine this position to ensure that the DOE is not burdened with a requirement that is neither necessary nor feasible to implement, and with one that contributes little additional assurance of protection of the health and safety of the public. The Commission should instruct the staff to devise means to ensure that major improvements in the EBS can and should be used to offset inadequate

¹ As specifically stated in 10 CFR 60.112, it is the total system that must be judged in terms of meeting the regulatory requirements, i.e., "The geologic setting shall be selected and the engineered barrier system...shall be designed to assure that releases of radioactive materials to the accessible environment following permanent closure conform to such generally applicable environmental standards for radioactivity as may have been established by the Environmental Protection Agency...." In addition, 60 CFR 102(e)2 indicates that "...special emphasis is placed upon the ability to achieve isolation by virtue of the characteristics of the geologic repository. The engineered barrier system works to control the release of radioactive material to the geologic setting and the geologic setting works to control the release of radioactive material to the accessible environment."

retention/confinement properties of the geologic environment of the waste. The NRC staff should identify functional criteria for such trade-offs.

STAFF COMMENT:

The history of the development of the subsystem performance objectives in Part 60 supports a position that these performance objectives were not generally intended to be used as a trade-off against one another. This position is grounded firmly in the provisions of the regulation, in particular 10 CFR 60.113(a), and the policy considerations that were spelled out when the regulation was adopted. The Commission then specifically gave consideration to having a single performance standard -- meeting the EPA release standard -- but rejected it in favor of a "defense-in-depth" approach that would prescribe minimum performance standards for each of the major elements of the geologic repository. (48 Federal Register 28194, 28196, June 21, 1983.) The Commission stated, in part:

...if the Commission were simply to adopt the EPA standard as the sole measure of performance, it would have failed to convey in any meaningful way the degree of confidence which it expects must be achieved in order for it to be able to make the required licensing decisions. More should be done. To that end, the Commission considers it appropriate to include reasonable generic requirements that, if satisfied, will ordinarily contribute to meeting the standards even though modifications may need to be made for some designs and locations.

The Commission's response, therefore, has been to apply, for illustrative purposes, an assumed EPA standard and to examine the values for particular barriers that would assist in arriving at the conclusion that the EPA standard has been satisfied.... In this way, the Commission has been able to demonstrate the logical connection which it makes between the overall system performance objective for anticipated processes and events, as set out in EPA's proposed standard, and the performance of specific barriers. One of the considerations that affects its judgment in this regard is the need to take proper account of uncertainties in the performance of any of the barriers. As one comment noted, "To provide a safety factor to compensate for this uncertainty, a multi-barrier system has many advantages. Since the Commission cannot answer the global problem and predict every possible combination of circumstances that might cause releases of waste, multiple independent mechanisms of slowing or limiting the discharge of radioactive materials to the environment are desirable." There is nothing inconsistent between the multiple barrier, defense-in-depth approach and a unitary standard; on the contrary, in view of the many possible circumstances that must be taken into account, the Commission firmly believes that the performance of the engineered and natural barriers must each make a definite contribution in order for the Commission to be able to conclude that the EPA standard will be met. The Commission's task is not only a mathematical one of modeling a system and fitting values for particular barriers into the model in order to arrive

at a "bottom line" of overall system performance. The Commission is also concerned that its final judgments be made with a high degree of confidence. Where it is practical to do so, the Commission can and will expect barrier performance to be enhanced so as to provide greater confidence in its licensing judgments. Accordingly, a variance between actual and assumed EPA standards will not necessarily require a change of corresponding magnitude in the individual barrier performance requirements.

In view of these statements by the Commission, as well as the express language of 10 CFR 60.113(a), the staff believes that its position is fully justified and has a basis in the regulations. It should also be recalled that, under NWPA Section 121(b)(1)(B), the Commission's technical criteria for repository licensing must "...provide for the use of a system of multiple barriers in the design of the repository." The Commission is on record (48 FR 28195, n.2) that the criteria set forth in its rule "...represent the criteria which, for purposes of this provision, the Commission deems appropriate." Regarding these criteria, the staff notes that, in its pre-licensing interactions with DOE, to date, there have been no indications that the defense-in-depth structure of the rule has been problematic in DOE's development of repository and engineered barrier system (EBS) concepts and designs. However, in response to interpretations by individuals outside of NRC, the staff did issue a staff position clarifying that the 300 - 1,000 year time period for substantially complete containment, 10 CFR 60.113(a)(1)(ii)(A), was the minimum requirement.

A premise of the multiple barrier approach is that barriers can be prescribed that act separately and thereby enhance the confidence that the waste will be isolated. As noted in the statement of considerations accompanying the final rule (48 FR 28196, June 21, 1983), the regulatory strategy favored use of the multiple barrier approach in which each of the major elements of the geologic repository had a prescribed minimum performance standard; achieving these standards collectively would assist the Commission to determine that the EPA's high-level radioactive waste standard would be met. Given this regulatory strategy, the fact that a licensee proposes an enhanced waste package design, for example, does not of itself relieve it from the requirements to demonstrate compliance with the other subsystem performance requirements. However, the text of the rule is sufficiently flexible that DOE could propose, and the Commission could approve or specify, some other values for the subsystem performance requirements (by virtue of 10 CFR 60.113(b), which allows consideration of "...particular sources of uncertainty in predicting the performance of the geologic repository.")

ACNW ISSUE 1(g):

The properties of HLW that was previously stored in pools or dry storage and is assumed to constitute a waste form suitable for disposal in a repository are uncertain. The Commission may wish to require the NRC staff to identify those properties of the stored spent fuel that are of importance to the repository and those tests that are considered necessary for qualification of this waste as the interim storage time lengthens. Similar considerations

should also be given to HLW glass that may have been stored for some time under various conditions.

STAFF COMMENT:

The design criteria for the waste package and its components are provided in 10 CFR 60.135, including several minimum requirements for the waste form. Minimum performance requirements for the repository engineered subsystems (e.g., engineered barrier system and waste package) are specified in 10 CFR

60.113; however, there are no specific performance requirements, per se, for the waste form or any other individual subsystem component. The combination of the minimum requirements in 10 CFR 60.135 and 60.113 was intended to give DOE broad flexibility in waste package design, including the allocation applied to performance of the waste form.

The staff identified, in NUREG/CR-5638, "Technical Considerations for Evaluating Substantially Complete Containment of High-Level Waste within the Waste Package," December 1990, many general technical points that must be considered (e.g. material chemical composition, surface properties, bulk properties, mechanical properties, and corrosion resistance) in assessing the performance of waste packages in a repository environment. However, the primary burden of allocating performance to the waste form and identifying those specific waste form characteristics and properties important to performance rests with DOE. Whatever changes or alterations that occur to the waste form, while in interim or long-term storage, it is DOE's responsibility to determine what they are and their importance so that the information can be factored into required repository and subsystem performance assessments. In this regard, DOE has extensive research programs in progress on both the spent fuel and glass waste forms, focusing on a variety of specific issues (e.g., spent fuel oxidation and dissolution, effects of fuel burnup, and vapor phase hydration of glass), to assist in the identification of important performance-related waste form characteristics and properties. Specifically, DOE is evaluating the physical changes to spent reactor fuel (e.g., cladding failure, oxidation of UO_2) stored for long periods of time under conditions of both dry and wet storage. Additionally, DOE is studying the release rate of radionuclides from the spent fuel and vitrified waste forms in an aqueous environment. Some of these tests use fuel subjected to the simulated effects of long-term storage in air.

NRC has conducted limited testing of simulated glass waste obtained from DOE. Mainly, however, NRC has followed the work of others (e.g., DOE laboratories and the Canadian nuclear waste program) to develop expertise in the area of waste form characterization. This collective experience has enabled NRC to construct reasonable computer models, for release of radionuclides in the liquid phase and gas phase, suitable for preliminary evaluation of total system performance under its Iterative Performance Assessment (IPA) program. The staff is also developing a more comprehensive source-term model for engineered subsystem performance. Based upon information and experience from its IPA, source-term modeling, and license Application Review Plan (LARP) development activities, the staff will evaluate the need for additional guidance on waste form issues.

ACNW ISSUE 1(h):

A significant part of the licensing process for an HLW repository involves the selection and analysis of scenarios of postulated events in the repository, coupled with the application of a variety of models of the physical system. The processes by which models are designed, tested and, where appropriate, validated to be representative of the present and future behavior of part of the repository system are not included in regulations or guidance to DOE. Particularly, the protocols for obtaining agreement that a specific model adequately describes the future state of a system have not been defined. The Commission should request the staff to define a methodology for obtaining agreement on this issue in advance of the licensing process. We recommend that this topic be included in early rulemaking, in order to provide guidance to DOE for the performance assessment process.

STAFF COMMENT:

The NRC staff and DOE have in place a pre-licensing consultation process that involves NRC staff review and comment on DOE documents and frequent interactions with DOE on a variety of technical subjects. For example, on December 14-15, 1992, the staff met with DOE to discuss the performance assessment activities of the two organizations. During interactions of this type, the NRC staff anticipates that the assumptions used to develop models will be clearly identified, the technical bases will be defined, and relevant information will be organized in a manner to facilitate understanding and public scrutiny. The NRC staff anticipates that the combination of these prelicensing activities will provide a process, to reach agreement on model design, tests, and validation, that is adequate to describe the present and future state and behavior of a system. At that point, guidance, rulemakings, or other means can be pursued to document the agreements reached.

The staff sees no need for a separate rulemaking to establish a "protocol" for obtaining agreements, since an established, agreed upon mechanism already exists. Basically, the staff and DOE have agreed that issues can be resolved at the staff level during the pre-licensing phase of the program. This means that there are no more questions and no more disagreements at a particular point in time. However, the staff has both the right and the responsibility to reopen any issue, or to request further information on any issue, at any time when warranted by new information or analysis. This position was also agreed to by the State of Nevada.

Rulemaking could be used to resolve selected generic methods. However, the application of any such methods at a particular site, or to a particular situation, would still be an issue that could be raised during the hearing process. In the case of methodologies which are likely to continue to evolve during the prelicensing period (e.g., performance assessment methodologies), the staff would be extremely cautious in proposing to resolve these through rulemaking. The staff believes that such cases might be better addressed through other forms of guidance (e.g., staff technical positions). The NRC staff also wishes to avoid being overly prescriptive in its dealings with DOE. It does expect that, given a successful design, site, and site characterization program, there will be several avenues or strategies

available, to DOE, to demonstrate compliance. Specifying a methodology for model development and certification would cause the NRC staff to be overly prescriptive, removing the ability of DOE to choose from among various strategies.

ACNW ISSUE 1(i):

The Environmental Protection Agency (EPA) regulations have not been codified and considerable uncertainty remains about the existing standards for ¹⁴C and other gaseous radionuclides. In addition, the NRC has not developed specific and comprehensive guidance to DOE on its requirements for the confinement of such radioactive material. This uncertainty could strongly influence the entire EBS design, testing and analysis. The Commission may wish to instruct the NRC staff to begin development of such guidance in the near future, recognizing that the new environmental standards will influence the details of such guidance.

STAFF COMMENT:

As the ACNW points out, final EPA requirements related to the work in progress on 40 CFR Part 191 have not been promulgated and there may be significant modification of the standards for release of carbon-14 and other gaseous radionuclides. However, this would not necessarily require any change in the Part 60 subsystem performance requirements, since those requirements are independent of (i.e., neither necessary nor sufficient conditions for compliance with) the EPA standard. The subsystem performance requirements were developed as the minimum standards for waste package containment and EBS release and reflect the judgment that the state of the technology exists to comply.

In this regard, the staff has a study in progress to assess what the current state of the art in waste package and EBS design can achieve in terms of radionuclide containment and release. The containment portion of the study is scheduled to be completed in May 1993, and the preliminary release rate assessment will be completed in September 1994. This study will help to place perspective on the subsystem performance requirements as minimum standards. The staff is actively pursuing this concern and will, as appropriate, consider the need for regulatory guidance or desired changes to the rule.

ACNW ISSUE 1(j):

Protocols for testing of the EBS and its components under repository-relevant conditions have been difficult to define and apparently such testing has not been conducted in a manner agreed to be satisfactory. The DOE, as well as the Center for Nuclear Waste Regulatory Analyses (CNWRA), has initiated tests that are believed to be repository-relevant. Owing to the extensive time requirements for tests whose results are to be extrapolated over the expected life of the EBS, the Commission should initiate development of guidance, perhaps in the form of staff technical positions, on the criteria for determining when test conditions are repository-relevant.

STAFF COMMENT:

The staff agrees with the ACNW that it is difficult to define the broad range and possible characteristics and conditions of the repository environment for the purpose of testing the EBS and its components. However, the primary burden for this responsibility rests with DOE through the implementation of its extensive program of research, site characterization, and performance-confirmation testing. Some of the in-situ testing that will be performed during site characterization will continue during repository construction and operation. The results from these tests will provide the most repository-relevant data.

In this regard, the staff has requested that DOE submit its proposed study plans, in a timely fashion, to enable the staff to provide early feedback on DOE's site characterization activities. The staff will also continue its reviews of Site Characterization Plan (SCP) progress reports, topical reports, remaining issues from the staff's initial review of the SCP, and performance confirmation results. These activities will include technical exchanges and laboratory visits, with DOE and its contractors, as a means of providing additional feedback to DOE on its site characterization and laboratory testing programs.

ACNW ISSUE 1(k):

The DOE has indicated that the overall performance assessment of the repository system may not include an allocation from the performance of the waste form. This approach apparently does not agree with the view of the NRC staff and has resulted in exchanges that appear to be at an impasse. Since the waste form (spent fuel, glass) is now either prepared or in the process of being prepared in facilities that are substantially completed, the Commission should request the NRC staff to clarify the details of this disagreement and adjudicate, at an early stage, the position it wishes to take in this matter.

STAFF COMMENT:

The staff agrees with the ACNW that this is an important issue as it relates to understanding the requirements in Part 60 and, that DOE must address in its license application. The staff has consistently maintained that DOE has the flexibility to allocate performance to EBS and waste package components in any manner it chooses, including, in the extreme, zero allocation to the waste form. However, as explained in the staff's May 19, 1992, letter to DOE (J. Holonich, NRC, to J. Roberts, DOE), assigning zero allocation to the waste form does not relieve DOE of the requirements of 10 CFR 60.21 to consider alternatives to design features of the waste package and EBS that are important to waste isolation, especially those alternatives that would provide longer radionuclide containment and isolation.

This applies especially to the glass waste form, as opposed to spent fuel, because DOE has direct control over the "development" of vitrified HLW. Therefore, it has the opportunity to produce glass with favorable performance characteristics in the repository environment. In this regard, DOE is, in effect, "designing" the glass that will ultimately be emplaced in a geologic

repository. It is DOE's obligation to at least consider alternative designs, including compositional variations of glass waste forms, as a means of further reducing uncertainties in making predictions of long-term EBS and waste package performance. Consideration of these alternative designs and justification for DOE's selection of its final waste form must be addressed in its license application.

The staff believes that it clearly stated its position on this issue in the May 19, 1992, NRC letter to DOE. Based on oral discussion with a DOE representative in December 1992, the staff was informed that DOE was in the process of developing its high-level requirements for waste form, and that it would not be responding to the May 19, 1992, letter until that was done. The DOE representative also indicated that the schedule for completion was January 1993.

ACNW ISSUE 2:

The Monitored Retrievable Storage (MRS) Facility has received attention by the Congress, DOE, various Indian Tribes, cities, counties, and States, but has not developed into an accepted project with a currently valid starting point or a schedule for its completion, licensing and operation.

STAFF COMMENT:

NRC has a Program Element Manager, for MRS licensing, and has included MRS, along with the repository, under contract with the Center for Nuclear Waste Regulatory Analyses (CNWRA), to provide technical assistance. This effort is part of the NRC established MRS Program Element Plan. NRC and the CNWRA have established four MRS-related tasks: 1) environmental and site investigation, 2) systems integration and regulatory analyses, 3) licensing review, and 4) monitoring and inspections. Each task has deliverables that are required and that constitute intermediate or major milestones, and anticipates the level of staff effort and cost through fiscal year 1997. NRC is interacting with DOE to provide comments on its "Monitored Retrievable Storage Annotated Outline Skeleton Text for the Preparation of a License Application" and its "Safety Analysis Report" (SAR) (Annotated Outline).

At this time, the staff's comments focus on the appropriateness of the information and technical methods expected to be used in order to provide guidance to DOE. NRC has provided comments to DOE on two Annotated Outlines and expects DOE to submit two revisions in fiscal year 1993 and two in fiscal year 1994. Each is an intermediate milestone and is to be submitted at 6-month intervals. The SAR and license application are major milestones. DOE's latest schedule indicates that the SAR will be submitted to NRC, in fiscal year 1994, for review, when the MRS Title II design is completed. The license application is expected in fiscal year 1995. DOE plans for NRC to review and issue a license authorization within 18 months of license application. However, this schedule does not include a hearing.

Both NRC and DOE treat the MRS as a project and have for some time. NRC has spent a considerable amount of project management and other effort toward facilitating the scheduling, licensing, and operation of an MRS. However, since the MRS is involved in a voluntary siting process that has an evolving nature, the task involves many pre-licensing interactions, and the schedule is subject to the Office of the Nuclear Waste Negotiator (OWN) progress in finding a volunteer site. NRC has cooperated with the OWN by holding public meetings with local citizen groups and Indian tribes, to explain the licensing process.

DOE recently introduced a new approach to interim spent fuel storage by 1998. In a letter from Admiral Watkins, Secretary of Energy, to Senator J. Bennett Johnston, dated December 17, 1992, DOE outlined a new strategy to provide interim storage of commercial spent nuclear fuel in 1998. DOE maintains that since the OWN has not been able to identify a candidate MRS site that can be recommended to Congress by June 1993, that DOE should be authorized and required, by Congress, to select candidate Federal sites by December 31, 1993.

ACNW ISSUE 2(a):

The required life of the MRS needs to be defined and the specifications, criteria for siting and construction, the content of licensing documents, and the anticipated licensing process need to be established, published and approved. The Commission should request the NRC staff to develop the details of regulations related to the licensing of an MRS.

STAFF COMMENT:

Part 72 establishes requirements, procedures, and criteria for the issuance of licenses to DOE to receive, transfer, package, and possess power reactor spent fuel, HLW, and other radioactive materials associated with spent fuel and HLW storage in an MRS. Section 72.42 establishes the duration of the MRS license and renewal. The license term for an MRS must not exceed 40 years from the date of issuance. Part 72 states that licenses may be renewed by the Commission at expiration, pursuant to the requirements of that part, and that applications should be filed at least 2 years before the expiration of the existing license.

In addition to Part 72, Regulatory Guide 3.48, Revision 1, "Standard Format and Content for the Safety Analysis Report for an Independent Spent Fuel Storage Installation or Monitored Retrievable Storage Installation (Dry Storage)," August 1989, exists as a guide to assist DOE in determining if the material presented in its SAR is sufficient to allow NRC to make determinations of compliance with the requirements in NRC regulations.

ACNW ISSUE 2(b):

There has been no substantial development of a backup concept to the MRS in the event that it is not feasible to locate, site, license, or operate such a facility. While the reasons for such a failure will be non-technical, their effect could be profound. There has been little planning for this

eventuality, and the Commission should request the NRC staff to initiate such studies in cooperation with the DOE and the Office of the Nuclear Waste Negotiator."

STAFF COMMENT:

The response to this issue is found in 10 CFR Part 72, the Commission's "Waste Confidence Decision," and the NWA. Part 72 establishes requirements, procedures, and criteria for the issuance of licenses to receive, transfer, and possess power reactor fuel and other associated radioactive material in an independent spent fuel storage installation (ISFSI). Spent fuel may be stored onsite at a 10 CFR Part 50 licensed power reactor, under a Part 72 general license or under a Part 72 specific license. The license term for an ISFSI is 20 years and is renewable, on expiration, pursuant to the requirements of Part 72.

Under the NWA, Congress directed DOE to submit a detailed study of the need for and feasibility of an MRS in the national nuclear waste management system, as well as a proposal for constructing one or more MRS facilities. The staff provided assistance to DOE by reviewing DOE's proposal for an MRS, and maintained in NUREG-1168, "Staff Evaluation of U.S. Department of Energy Proposal for Monitored Retrievable Storage," March 1986, that, from the standpoint of public health and safety, the MRS is feasible.

Under the Nuclear Waste Policy Amendments Act of 1987, Congress authorized the construction of an MRS, and created the Monitored Retrievable Storage Commission, to study and report to Congress on whether an MRS should be a part of the nation's nuclear waste disposal system. Congress essentially directed the MRS Commission to compare the options of a waste disposal system with and without an MRS. The Report of the Monitored Retrievable Storage Commission, "Nuclear Waste: Is There a Need for Federal Interim storage?," November 1, 1989, indicated that the "No-MRS alternative" required continued storage of spent nuclear fuel, at the existing sites of nuclear power plants, until the repository is operational.

The Commission completed its "Waste Confidence Decision," published in the Federal Register (49 FR 34658), on August 31, 1984. The purpose of that study was to assess the scientific evidence that formed the very foundation of the belief that spent nuclear fuel could be safely stored. In 1990, the Commission reassessed the Waste Confidence Decision. (55 FR 38474.) The Commission found reasonable assurance that, if necessary, spent nuclear fuel generated in any commercial power reactor can be stored safely and without significant environmental impact for at least 30 years beyond the expiration of the reactor operating license (which may include the term of a revised or renewed license) of that reactor at an onsite ISFSI.

ACNW ISSUE 3:

The scientific/technical investigations for the repository program being conducted by DOE are aimed at a comprehensive licensing document for NRC review. The studies that have been completed and those that are in progress

are likely to produce results of variable quality or applicability. Further, there will certainly not be enough time and resources devoted to these studies to provide full insight into all scientific/technical questions. The NRC staff has commented on the Site Characterization Plan (SCP) prepared by DOE and has provided DOE with a significant list of issues to be resolved. This list is in the form of the Site Characterization Analysis (SCA) issued by the NRC. The Commission should initiate inquiry about the importance of the function of NRC of having all of the issues and questions raised in the SCA resolved to the satisfaction of the NRC staff on a time schedule commensurate with the licensing needs. Similar questions should be answered regarding the importance of having all study plans which are based on the contents of the SCP completed and submitted to the NRC staff before work on the associated topics is initiated.

STAFF COMMENT:

The staff agrees with the ACNW that the resolution of all SCA concerns is of high priority now, not just before the license application. The letter transmitting the SCA (Bernero, NRC, to Rouso, DOE, July 31, 1989) emphasized the importance of resolving SCA concerns and stated that DOE should consider all SCA concerns as "serious" and "...give full attention to each in an attempt to resolve them early during site characterization." The staff has continued to encourage DOE to make progress in resolving SCA concerns through a number of letters, and in its reviews of DOE's semi-annual "Site Characterization Progress Reports" (letters from Bernero, NRC, to Bartlett, DOE - - June 25, 1990; October 27, 1992; and November 18, 1992).

In addition, in the Draft Regulatory Guide "Format and Content for the License Application for the High-Level Waste Repository," the staff included Section 1.6.2, "Status of DOE Resolution of NRC Objections to License Application Submittal." In that section, the staff stated the following:

All concerns documented by the NRC staff are important for DOE to resolve. However, the staff might also consider some comments and questions (out of the total set identified) to be critical to the NRC staff's LA review because lack of acceptable DOE resolution would prevent NRC from conducting a meaningful review and making a decision regarding construction authorization within the three-year statutory time period. For this reason, the staff considers this type of concern to be an objection to LA submittal...²

The NRC staff expects that DOE will make every effort to resolve all the NRC staff's concerns, particularly those identified as objections to LA submittal. . . . Therefore, as part of the acceptance review of the LA and before a decision on docketing the

²It should be noted that objections to the license application submittal are not the same as SCA objections previously identified by the staff. At present, the staff has not identified any objections to the license application (LA) submittal.

LA, the NRC staff will evaluate the effect of any unresolved objection to LA submittal, both individually and in combination with others, on the NRC staff's ability to conduct a meaningful review and make a decision regarding construction authorization within the three-year statutory time period.

Of the 198 open items (2 objections, 133 comments, and 63 questions) identified in the SCA, 60 have been resolved, including the two objections. In November 1992, based on information provided by DOE, the NRC staff lifted the final SCA objection, eight comments, and one question. At this time, the staff is reviewing DOE responses and requests for resolution of nine additional comments and one additional question. Although 128 of the original 198 SCA concerns are still unresolved, DOE continues to make progress in reducing that number. DOE has stated (letter from Bartlett, DOE, to Bernero, NRC, January 8, 1993) that, in the case of some open items, "Additional design, analysis, or testing will probably be required to resolve many of the 128 remaining concerns." Therefore, given the actions being taken by the staff today, and DOE's agreement that unresolved issues should be addressed as quickly as possible, the staff believes that it has taken and is taking appropriate actions to ensure that DOE addresses its concerns in a timely manner.

With respect to the need for DOE to submit all study plans before work on the associated topic is initiated, the staff and DOE have agreed that those study plans involving surface disturbance or subsurface penetrations will be provided to the staff 90 days before the initiation of work. For studies that involve no activities that may impact waste isolation at the site, DOE has the option to begin work, at its own risk, as soon as the study plan is submitted to NRC. This agreement is being documented in the DOE/NRC Agreement on the "Format and Content of Study Plans," which is presently being revised. The staff believes that this approach helps ensure that the NRC is involved in all activities, that could affect waste isolation, before they are begun, but allows DOE the flexibility to schedule activities without the need for continuous NRC approval of its overall program management.

Although, in many cases, it would be useful to the staff to have all related study plans submitted at the same time, DOE has no commitment to do so and provides study plans to NRC as they are completed or as they are revised. The NRC staff has deferred its Detailed Technical Review of some study plans, pending additional information that will be obtained from work conducted under other related study plans. In the case of study plans that integrate or synthesize information from a group of study plans, the staff gives consideration to the entire group of studies when conducting its review.

ACNW ISSUE 4:

The post-emplacement process for a repository involves a period during which the repository is to be monitored and for which retrieval is to be planned.

ACNW ISSUE 4(a):

There are no criteria for the thermal and other measurements that are to be made during this period. The Commission may want to explore the need for such criteria and, if found necessary, request the NRC staff to develop and promulgate them in order to ensure that technologies for data acquisition and interpretation can be provided in a timely fashion for the design of the EBS and the repository.

STAFF COMMENTS:

Part 60, Subpart F, provides general criteria for post-emplacement testing. These criteria are developed mainly for ensuring that design bases and assumptions used in the design and analyses of the geologic repository operations area (GROA) and the EBS would continue to fall within the observed/measured values, during the post-emplacement monitoring period. These general criteria are enumerated under 10 CFR 60.140 through 60.143. Specific references are made to thermal interaction effects and the need to start testing as early as practical, during the site characterization, and continue as long as possible/necessary during the performance confirmation period, until permanent closure. These general criteria are further supported by detailed discussions in the "Statements of Consideration."

The staff recently completed a staff technical position (STP) on "Geologic Repository Operations Area (GROA) Underground Facility Design--Thermal Loads" (NUREG-1466), in which a logic for an acceptable methodology for consideration of thermal loads was provided. This STP also touches upon the issue of thermal measurements and modeling during the post-emplacement period. As reflected in the SCP, DOE has identified the kinds of thermal measurements that need to be made, during the post-emplacement period, and is planning for the development of technologies and data acquisition and interpretation techniques. Because the measurements that DOE will make will be based on what is needed to support site specific and design specific issues, it would be premature for the staff to develop criteria. A number of study plans related to thermal testing will be reviewed by the staff and comments and questions will be raised in order to ensure that regulatory criteria are being implemented by DOE.

ACNW ISSUE 4(b):

The need to retrieve the waste after emplacement and backfilling influences the design of the repository and the EBS. The staff has not defined what type of retrieval will be required, the extent to which retrieval is likely to be needed, under what conditions retrieval is likely to be practiced, or the standards and criteria that would govern the retrieval. Owing to the importance of these issues to the design of the repository, the Commission should encourage the NRC staff to define more closely, prior to licensing, criteria for the various parts of the emplacement and retrieval process, the monitoring protocols that are expected to be applied by DOE, and the regulations that are needed for this part of the HLW disposal system.

STAFF COMMENT:

Retrievability of waste is a pre-closure performance objective in the rule. The rule requires that any or all of the waste emplaced should be retrievable for a period of time up to 50 years after the initiation of the waste emplacement activity. The rule also requires that the GROA be designed to preserve the option of waste retrieval throughout the period of waste emplacement and thereafter until the completion of the performance-confirmation period. This means that the GROA design should include the retrieval option under all reasonable scenarios. The general standards and criteria that apply to the retrieval operation are also clear in the rule, in that protection against radiation exposures is governed by the requirements of 10 CFR Part 20. (Part 20 provides detailed criteria regarding public and worker health and safety requirements.)

Because retrievability considerations are closely linked to the site and design-specific information, to go beyond the current rule and provide specific criteria for retrieval would require site-specific and design-specific information. The staff believes it is DOE's responsibility to develop detailed plans for retrieval, under different scenarios, and present them in the license application, as indicated in 10 CFR 60.21(c)(12). These retrieval plans developed by DOE will be based on site-specific and design-specific information, and must be in compliance with 10 CFR 60.111(b). The staff will present, in the appropriate LARP sections dealing with the retrieval performance objective, the acceptance criteria it will use for determining if DOE has acceptably demonstrated compliance with 10 CFR 60.111(b).

Beyond the development of the LARP, the staff does not believe any additional work is needed. This is based on the fact that the CNWRA recently completed a systematic analysis of all pre-closure regulatory requirements. The purpose of this study (NUREG/CR-5804, "Repository Operations Criteria Analysis") was to identify any areas in Part 60 where additional requirements governing pre-closure operations might be needed. It did not identify any uncertainties related to the issue of retrievability. In addition, DOE, on its own initiative, prepared a technical position paper on retrievability, in 1985, on which the staff provided extensive comment and input. Since that time, DOE has not asked for any further guidance on this topic.

ACNW SUMMARY:

The ACNW listed its issues in order of "impact" and "rulemaking" importance. Also, the ACNW summary stated that: "The importance of rulemaking as a process that can remove from contention selected aspects of the licensing process appears to be rising" and that: "The Commission should initiate a more aggressive rulemaking process and seek to complete, at an early date, those rulemaking items that impact the repository design and the development of the experimental data."

STAFF COMMENT:

The staff would agree that rulemaking has a role in resolving issues that might unnecessarily delay repository development or the licensing hearing, and will consider the ACNW issues prioritization in its program planning. However, it believes that the regulations should not be overly prescriptive. Because of this, it is the staff's position that rulemakings should be used only where authoritative and binding clarification or elaboration is needed on the meaning of requirements or definitions in Part 60. Rulemaking could also be used to resolve select generic issues. Application of any such methods at a particular site or to a particular situation would still be an issue that could be raised during the hearing process. In either case, rulemaking will be pursued only where practicable.

At present, the staff has identified 12 regulatory uncertainties that it believes are appropriate for reduction through the use of six rulemakings. The topics covered by these proposed rules would deal with: (1) conforming to the EPA standard; (2) criteria for implementing the EPA standard; (3) establishment of a controlled-use area through the analysis of design basis events; (4) clarification of the relationship of the siting requirements of 10 CFR 60.122 and the performance objectives of 10 CFR 60.112 and 60.113; (5) establishment of emergency planning criteria; and (6) minor changes, to Part 60, needed to fix small, non-technical errors in the rule. Beyond these, the staff has not identified the need for any additional rulemaking work. However, its ongoing effort to reduce regulatory uncertainties might identify additional rulemakings that were warranted.

In the case of methodologies that are likely to continue to evolve during the pre-license period (e.g., performance assessment methodologies), the staff would be extremely cautious in proposing to resolve these through rulemaking. Because technology is evolving and information will change over the lifetime of the repository program, the staff believes it is important to maintain a high degree of flexibility. Therefore, as stated earlier, the staff does not plan to complete rulemakings on the topics of expert judgment or model selection and qualification, at this time. The staff will reconsider this decision as future work warrants.

Staff Response to Comments Provided by the State of Nevada
on the December 1, 1992 Letter from the Advisory Committee on Nuclear Waste

Interaction With National Academy of Sciences Regarding EPA Standards

In its letter, the Advisory Committee on Nuclear Waste (ACNW) proposed that the staff should develop positions that can serve as a basis for recommendations to the National Academy of Sciences relative to the Academy's role, mandated by the Energy Policy Act of 1992, of providing findings and recommendations on reasonable standards for the protection of public health and safety for the proposed high-level radioactive waste repository at Yucca Mountain. The State of Nevada has raised a concern about the extent of the Nuclear Regulatory Commission's role in this process. It is the staff's understanding that the State of Nevada believes that the NRC should not participate in this process in any manner until the Environmental Protection Agency (EPA) has promulgated generally applicable standards, since earlier participation might compromise NRC's adjudicative role.

The staff recognizes that it is the responsibility of EPA, acting in accordance with the Energy Policy Act of 1992 and other law to determine the numerical limits that will provide an adequate level of protection to public health and safety. However, NRC has the right and even the obligation to express its views to EPA with respect to the standards including those aspects that impact upon the exercise of its authority. NRC's views with respect to the practicability, implementability, scope, and technical basis of the standards are all appropriate matters for comment. Heretofore, NRC has consistently taken an active commenting role in EPA standard-setting activities. It is equally appropriate to do so in the particular context of the Energy Policy Act of 1992. The staff believes these actions are proper and do not compromise NRC's adjudicative role.

NRC's Consistency Regulations

The State of Nevada letter stated that it was "inadvisable" to undertake a rulemaking on establishing a definition of what consistency or compatibility of regulations is as recommended by the ACNW in its December 1, 1992 letter. In its response to the ACNW, the staff noted that it did not see a need for a rulemaking on this subject. The staff further stated that it will proceed with conforming amendments to 10 CFR Part 60 whenever EPA promulgates its standards, and expects the public comment process will contribute to achieving "consistency" among regulations.

Expert Judgment in Licensing Proceedings

The State of Nevada raised two issues in the area of expert judgment. First, it was concerned that the Department of Energy would use expert judgement to fill any gaps in objective evidence. And, second, the State of Nevada opposes the definition in advance of the actual hearing process of who may be qualified as an expert.

Enclosure 2

With respect to the first comment, the staff position is that expert judgement should not generally be used as a substitute for obtaining data where such data can reasonably be obtained. This position was most recently provided to the Department of Energy (DOE) in a letter on the Early Site Suitability Evaluation (July 22, 1992 letter to J. Roberts, DOE, from J. Holonich, NRC). In that letter, the staff informed DOE that expert judgement should not generally be viewed as a substitute for analyses, field or experimental data, or other more technically rigorous information that is reasonably available or obtainable. In response to the second comment, as discussed in the staff's response to the ACNW, the staff believes any rulemaking pertaining to the application of expert judgment would be premature. Further, the staff position was that there is already a generally accepted system of legal evidentiary rules that can be followed in NRC licensing proceedings on the admissibility of expert judgement as evidence.

Engineered Barriers

The State of Nevada position concerning engineered barrier system (EBS) was that it should not be taken into account when DOE is determining whether a site is "suitable" under the 112(a) Guidelines of the Nuclear Waste Policy Act. This subject was also highlighted in the staff's comments on the DOE's first application of the siting guidelines contained in 10 CFR Part 960 (the July 22, 1992 letter noted above). In that letter, the staff noted that, although the EBS design may provide for additional margins of safety in a licensed repository, one condition of NRC's concurrence in the 10 CFR Part 960 siting guidelines was that the guidelines make clear that "...engineered barriers cannot constitute a compensating measure for deficiencies in the geologic media.." (49 FR 9650).

Long-Stored Spent Fuel

In commenting on the ACNW's issues, the State of Nevada agreed with the ACNW recommendation to "...identify those properties of stored spent fuel, that are important to the repository and those tests that are considered necessary for qualification of this waste as interim storage time lengthens." As discussed in the staff's response to the ACNW, NRC regulations already define many properties of the waste form and waste package that are important to the repository and that therefore must be addressed by appropriate tests. Both 10 CFR 60.113(a) - pertaining to containment of high-level wastes within the waste packages - and 10 CFR 60.135 - design criteria for the waste package and its components - should be considered in this regard. NRC has also issued NUREG/CR-5638, "Technical Considerations for Evaluating Substantially Complete Containment of High-Level Waste within the Waste Package," which identified many general technical points that must be considered in assuring that these requirements have been met. However, the primary responsibility for identifying those specific waste form characteristics and properties important to performance rests with DOE.

NRC is also following work by DOE and others in addition to conducting limited testing on its own. Based on information gained from these studies, as well as information from the staff's iterative performance assessment activities, development and application of source-term modeling, and License Application Review Plan development which will include criteria the staff will use to evaluate the DOE license application, the staff will evaluate the need for additional guidance on waste form issues.

Performance Models

In its comments, the State of Nevada did not agree with the ACNW that the staff should prepare a rulemaking that would define a methodology for obtaining agreement that a specific model adequately describes the future state of a system. When it provided its response to the ACNW, the staff stated that it does not see a need for a rulemaking to establish a "protocol" for obtaining agreement on specific models. The NRC staff and DOE have in place a pre-licensing consultation process, in which the State of Nevada participates, that involves NRC staff review and comment on DOE documents and frequent interactions with DOE on a variety of technical subjects. This process provides an approach to model design, tests, and validation, that may contribute to the development of models that will be valuable in the regulatory context.

Guidance to DOE in Absence of EPA Standards

The State of Nevada comment related to NRC guidance to DOE in the absence of EPA standards was that it "was inappropriate for the NRC staff to telegraph to DOE the Commission's willingness to approve DOE's license application, even before the EPA standards are adopted or a license application is filed and docketed." The ACNW issue to which this comment is addressed was concerned with confinement of carbon-14 and other gaseous radionuclides. Although EPA standards have not been promulgated, NRC has in place a study on the current state-of-the-art to assess uncertainties in predicting the ability of the waste package and EBS design to contain radionuclides over time spans of interest. As this study progresses, the staff will, as appropriate, consider the need for regulatory guidance. Such guidance -- which is directed toward NRC's own subsystem performance objectives rather than the EPA standard -- would not compromise NRC's adjudicative role in any way.

Testing of Engineered Barrier Systems

In its comments, the State of Nevada took the position that until the most is known about the environment at Yucca Mountain, it is not possible to determine the adequacy of the EBS. As the staff stated in its response to the ACNW, the responsibility for carrying out those tests that will be necessary to demonstrate that the regulatory requirements have been satisfied, along with responsibility for designing the engineered barrier system, rests with DOE. Such activities will, of course, have to take into consideration the characteristics of the site, including those characteristics that are determined through site characterization.

Although the EBS design evaluation will not be complete until the necessary site information is obtained, the design of the EBS is an ongoing and iterative process that should factor in such information about the site as it is available from time to time. The staff is providing appropriate input in this process as part of its pre-licensing consultation role. It conducts its reviews through such means as responses to site characterization plan progress reports, study plans, topical reports, and, at a later date, the performance confirmation reports. Indeed, the staff will continue its evaluations beyond the initial licensing phase of the repository and during the construction and operation phases. The State of Nevada has the opportunity to participate in technical exchanges and review DOE documents through the processes noted above.

Waste Form

The State of Nevada commented that it did not believe that, as stated by the ACNW, the staff should adjudicate whether the waste form should be incorporated into the overall repository performance assessment. The staff does not believe that it is "adjudicating" whether the waste form should be incorporated into the overall repository performance assessment. The staff's position is that DOE has great flexibility to allocate performance to waste package components. However, DOE must consider alternatives to design features of the waste package that are important to waste isolation, especially those alternatives that would provide longer radionuclide containment and isolation. Therefore, it is the staff's position that DOE should look at alternatives that might be selected for the composition of the glass waste form.

Site Monitoring After Emplacement of Waste

The State of Nevada agrees with the ACNW that post-emplacement criteria should be developed for thermal and other measurements. As the staff noted in its response to the ACNW, general criteria for some of the tests that may be required during the post-emplacement period are enumerated under 10 CFR 60.140 through 60.143. These criteria were developed to ensure that the design bases and assumptions used in the design and analyses of the repository continue to fall within observed and measured values.

The performance confirmation program required by 10 CFR Part 60, Subpart F is to start during site characterization and continue until permanent closure of the repository. Because of this, the staff believes that the NRC has the option to require continued performance confirmation until it finds there is continued reasonable assurance that the repository will perform as expected. Until that time, the NRC will not issue the amendment terminating the license. Therefore, the staff believes that the opportunity for long-term monitoring of the repository is already available through 10 CFR Part 60, Subpart F, and that it is premature to establish more specific criteria that would be dependent on specific site and design considerations.

Closure of Issues Through Rulemaking

The State of Nevada has expressed concern about issue resolution during the preclicensing period. NRC has responded to each of the State's letters on issue resolution, providing the agency position on various questions of interpretation put forth. However, it should be noted that neither the April 8, 1992, memorandum, nor Commissioner Rogers' April 13, 1992, speech, which were quoted in Mr. Robert Loux's February 24, 1993, letter to NRC Chairman Selin were intended as direct responses to specific questions or concerns raised by the State. The May 6, 1992, letter from Mr. John Linehan, Deputy Director of the Division of High-Level Waste Management and the August 11, 1992, letter from Mr. B. J. Youngblood, Director of the Division of High-Level Waste Management, to Mr. Loux did respond specifically to concerns he raised on issue resolution during preclicensing. With respect to the State of Nevada comment that, "Although the February 6, meeting dealt primarily with staff discussion on technical issues, my specific understanding of that meeting was that rulemaking would also not be used to close issues," Mr. Linehan's letter stated:

It was stated by the NRC staff that rulemaking could be used to resolve selected generic methods. However, application of any such methods at a particular site, or to a particular situation, would still be an issue that could be raised during the hearing process. [Linehan/Loux letter, dated 5/6/92]

In addition, in its response to the ACNW, the staff stated that it would also use rulemakings where authoritative and binding clarification or elaboration is needed on the meaning of requirements or definitions in 10 CFR Part 60. Therefore, NRC's position on issue closure remains unchanged.