~~QA INFO TO WITTMAN/WARD~~

MAR 24 1986

Mr. Jack Wittman, Associate Director
Utah High-Level Nuclear Waste Office
355 West North Temple
3 Triad Center, Suite 330
Salt Lake City, UT 84180-1203

Dear Mr. Wittman:

Enclosed for your information are two recent letters concerning the December 4-5, 1985 Quality Assurance meeting that you attended.

1. Linehan to Knight, dtd., March 7, 1986, preliminary responses to questions on implementation of Q-list methodology.

2. Browning to Loux, dtd., March 7, 1986, response to comments and concerns raised by Robert Loux, State of Nevada.

Sincerely,

Donna R. Mattson, Section Leader
Program Control and Analysis Section
Division of Waste Management

Enclosures:
As stated

WM Record File 106.1
WM Project 16
Docket No.
PDR ✓
LPDR ✓
Distribution:
(Return to WM, 623-SS)

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MAR 07 1986

Mr. James Knight
Director
Licensing and Regulatory Division
Office of Geologic Repositories
U. S. Department of Energy
RW-20
Washington, DC 20585

Dear Mr. Knight:

Prior to the U. S. Department of Energy/U. S. Nuclear Regulatory Commission (DOE/NRC) Quality Assurance (QA) meeting December 4-5, 1985, the DOE provided the NRC with a series of 13 questions referencing "implementation of Q-list methodology". In the minutes of this meeting NRC Staff committed to sending formal responses to each question. The purpose of this letter is to transmit preliminary responses to these questions to the DOE. The subjects addressed are complex and will require additional interaction between our staffs. The information contained in these responses is therefore preliminary and intended to provide a basis for discussion between our staffs.

During development of these responses a number of the questions were subject to interpretation. In these cases the response has been directed to address what appeared to be the underlying concern. In addition, some questions suggest a misunderstanding of the legal constraints associated with NRC regulations. Should you have any questions concerning these responses, please feel free to contact S. Bilhorn of my staff (FTS 427-4682).

In addition to these responses, the staff is in the process of developing a draft generic technical position paper (GTP) on the methodology for determining what items and activities are important to safety and important to waste isolation. The draft positions were summarized in the December QA meeting and

are contained in the minutes to that meeting. The GTP is scheduled for publication as a draft document within the next 6 months.

Sincerely,

John J. Linehan, Acting Chief
Repository Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Response to DOE Questions on
Implementation of Q-list Methodology

Response to DOE Questions
on Implementation of Q-List Methodology

1. Allowable Dose Criteria (Operations Phase)

1.1 Question - 60.111(a) and 60.2 indicate that 0.5 rem is the threshold value for making a determination on "important to safety." Should this be considered an upper level accident dose limit as well?

The staff response to this question has been combined with response to question 1.2 below.

1.2 Question - What should the dose limit for design basis accidents be?

10 CFR 60.111(a) states that "the geologic repository operations area shall be designed so that until permanent closure has been completed, radiation exposures and radiation levels, and releases of radioactive materials to the unrestricted area, will at all times be maintained within the limits specified in Part 20 of this chapter and such generally applicable environmental standards for radioactivity as may have been established by the Environmental Protection Agency." The applicable EPA standard, 40 CFR Part 191, requires reasonable assurance that the combined annual dose equivalent to any member of the public in the accessible environment not exceed 25 mrem to the whole body, 75 mrem to thyroid, and 25 mrem to any other critical organ (40CFR191.15). 10 CFR Part 20 places the annual whole body dose limit to any individual in unrestricted areas at 0.5 rem (10CFR20.105). 10 CFR 60.2 establishes 0.5 rem as the threshold value for determining what systems, structures and components are "important to safety" in order to ensure that those items whose failure could lead to higher exposures will function as required. Therefore the design bases for the period before permanent closure should consider the off site dose limit for an accident as 0.5 rem.

In the context of licensing other types of facilities, the NRC has defined "design basis accidents" as those accidents whose likelihood of occurrence is deemed to be credible and for which engineering safety features assure that public health and safety will not be endangered. For these other facilities, protection of public health and safety involves the identification of the credible accidents against which the design of the facility will be tested. After identifying the credible accident scenarios, the potential consequences of the design basis accidents are then evaluated to determine whether the predicted consequences fall within the appropriate dose guidelines. The purpose of the design basis accident and the associated dose guidelines has been to test the facility design to determine if the safety features can adequately cope with accidents, and to evaluate the suitability of the proposed site. In addition, past reactor licensing practice has used the accident dose guidelines as one of the criteria for determining what equipment was "safety related," and therefore subject to 10 CFR Part 50, Appendix B.

Unlike the reactor site criteria in 10 CFR Part 100.11, or the independent spent fuel storage installation (ISFSI) criteria in 10 CFR Part 72.68, 10 CFR Part 60 does not specifically refer to a "design basis accident" and does not explicitly establish pre-closure accident dose guidelines. However, 10 CFR Part 60 does specify a dose limit for determining what items will be "important to safety". The term "important to safety" in 10 CFR Part 60 is used to determine what pre-closure items should be on the Q-list. The rationale behind placing a system, structure or component on the Q-list is to assure, via application of additional QA and design requirements (10CFR60.152 and 10CFR60.131(b) respectively), that it will perform its intended function. Establishing a design basis accident dose limit higher than 0.5 rem would not be consistent with the dose limit specified in the 10 CFR 60.2 definition of important to safety.

1.3 Question- 60.2 states in part that "...engineered structures, systems and components essential to the prevention or mitigation of an accident that could result in a radiation dose of 0.5 rem or greater..." are important to safety. In light of questions 1.1 and 1.2, should mitigative systems be deleted from that definition?

As noted in response to Questions 1.1 and 1.2, 10CFR 60.111(a) requires systems, structures and components to be designed to maintain the dose to the unrestricted area to 10 CFR Part 20 limits. The DOE should note that the object of the "important to safety" definition in 10 CFR 60.2 is to provide assurance that the 0.5 rem dose is not exceeded during pre-closure accidents. Those systems, structures and components essential to mitigate doses to the 0.5 rem level are considered important to safety to assure, through QA, design and other applicable requirements, that they will perform their safety function.

1.4 Question - The 0.5 rem threshold dose is based on the permissible annual dose to the off-site population resulting from normal operation, as defined in 10 CFR 20. If 10 CFR 20 is revised, will the 0.5 rem threshold also be revised? Can we interpret the 0.5 rem dose as a whole body equivalent dose?

The staff thinks it is important to stress that the 0.5 rem dose limit referenced in 10 CFR Part 20 is <u>not</u> the permissable annual dose to the off site population resulting from normal operation, but rather the maximum annual dose to an individual in the unrestricted area. DOE should consider the EPA standard of 25 mrem to the whole body, 75 mrem to thyroid, and 25 mrem to any other critical organ as the permissable annual doses to the off site population resulting from normal operation (40CFR191.15).

The Supplementary Information accompanying the proposed revisions to 10 CFR Part 20 indicates that the NRC will update other parts of its regulations <u>after</u> the revisions to 10 CFR Part 20 become final. The staff anticipates that the 0.5 rem figure in the definition of "important to safety" will be considered in that update.

As stated in the Supplementary Information to this proposed revision, the NRC staff considers the "effective whole body dose equivalent" concept to be more technically appropriate than the "dose to the whole body, or any organ" concept currently used in defining "important to safety" (10CFR60.2). For this reason, the staff agrees that the "whole body dose equivalent" concept may be used pending resolution of the 10 CFR Part 20 rulemaking.

2. Analytical Assumptions (Operations Phase)

2.1 Question - When design details are lacking, what is an acceptable basis for estimating dose consequences of design basis accidents?

A primary objective at this stage of the repository program should be to determine the specific functions and functional requirements of a structure, system, or component and to identify scenarios which may exceed the functional requirements. The information obtained from this analysis should then be applied to determine what design details are necessary to assure that the requirements will be met.

As noted in response to Questions 1.1 and 1.2, 10 CFR Part 60 does not explicitly address design basis accidents. The following response therefore addresses the question restated as follows: At the early stage of this first-of-a-kind program, when design is in a conceptual phase but work is ongoing, what is an acceptable method and information base for estimating dose consequences of accidents?

The staff acknowledges that this is a difficult task based on the limited information available upon which to base major decisions. Accident scenarios including initiating events as well as dose consequences for accidents will need to be identified and estimated based on conservative engineering judgment and existing information. The available information base may include data collected and analyzed for other similar activities, such as external events for reactor facilities and design basis accidents for ISFSI's and refueling operations at nuclear power plants where these can be shown to apply directly to the HLW facility. Although the respository operational system represents a unique nuclear facility, perhaps correlations can be made with other similar nuclear facilities in order to enable knowledgeable decisions to be made and to avoid repetition of effort and prior mistakes.

Extrapolation of analyses conducted with analogous facilities must be carefully conducted and the information obtained rigorously examined to assure that key differences in facilities have not been overlooked. Many factors need to be taken into account when estimating the consequences of an accident and the potential dose to the unrestricted area. These factors include release rate, source term, meterologic conditions at the site, and location of release.

2.2 Question - Part 60 contains numerous references to "credible" events to be considered in design. What is an appropriate definition of credible event?

The term "credible" with reference to events to be considered in design is used in 10 CFR 60.130(b)(3) "credible fires or explosions" and 10 CFR 60.133(a)(2) "credible disruptive events, such as flooding, fires and explosions". The former is a criterion for the geologic repository operations area, while the latter is a criterion for the underground facility. As noted in the Supplementary Information to the rulemaking establishing the technical criteria in 10 CFR Part 60, the design criterion pertaining to continued operation during and after fires has been limited to such events as are "credible." This revision was made in response to comments that suggested that the proposed language could be interpreted to require protection against any fire or explosion that might be physically possible. 48 Federal Register 28194, 28213, June 21, 1983.

Events, internal or external to the HLW facilities, are initiators of accident scenarios. Internal events, such as equipment malfunction or operator error, are direct initiators while external events, such as floods or earthquakes, are indirect initiators that may result in an internal event which then initiates an accident scenario.

The term "credible event" would refer to that event which is sufficiently likely to warrant consideration in design of the facility in order to prevent or mitigate the consequences of their occurrence.

2.3 Question - What is an appropriately conservative probability value for credible events/accident scenarios?

The intent of equating credible events with accident scenarios is unclear. Accident scenarios include the initiating event, all related common mode failures and any additional independent failures, and release and transport of radionuclides to the unrestricted area. Events, defined as above, are potential initiators of accident scenarios.

The following response addresses a similar question previously posed by DOE: What does the staff consider an appropriate lower probability limit for accident scenarios considered in the design basis.

It is the staff's position that credible initiating accidents should not be bound by a specific probability value at this stage in the repository program. It is important to note that for new types of facilities where it may be difficult to evaluate the safety of the facility due to limited experience with the technology, the NRC has factored extremely low probability, high consequence events into their evaluation of the facility. For example, because of the difference in technology and experience between the Clinch River Breeder Reactor and a typical light water reactor, additional measures were required for Clinch River against accidents beyond the established design basis. It should also be emphasized that in terms of reactor licensing requirements and analysis, probability has generally not been used to identify design basis accidents. The staff expects to follow the same general approach in reviewing a repository license application.

2.4 Question - At what accident scenario probability value should the 5 rem limit proposed in the response to question 1.2 apply?

Response to this question is not appropriate as the 5 rem level proposed by DOE has not been accepted (see response to Questions 1.1 and 1.2). See also response to Question 2.3 for discussion regarding establishment of probability based values.

2.5 Question - The Commission's Part 60 rule at various places alludes to the need for ...redundant systems to the extent necessary to maintain... the ability to perform their safety functions" (e.g. 60.131(b)(5)(ii)) (emphasis added). In other places, the rule specifies redundancy as in 60.131(b)(10)(iv), "...shall be designed to include two independent indicators..." Does the Commission intend there to be a uniform rule on redundancy and therefore the necessity to design for independent single failure?

The Commission does not require redundancy except as specified in 10 CFR Part 60. The rule is to design to ensure that the continued function of the equipment is retained. Redundant equipment should be employed where necessary and appropriate. Single failure of components which result in loss of capability of systems to perform independent safety functions should be analyzed. Where necessary to assure the dose limit is not exceeded, systems must be designed to address independent single failures.

2.6 Question - For structures, systems and components whose failure to perform their intended function could result in an accident resulting in a dose commitment greater than 0.5 rem, can the accident be precluded by design or will non-mechanistic failures be imposed?

The staff supports the concept that non-mechanistic failures should not be imposed as a design condition if, via analysis, the failure of those structures, systems, or components can be demonstrated not to exceed the dose limit to the unrestricted area. The purpose of placing a system, structure or component on the Q-list is to assure, via application of additional design and QA requirements, that it will perform its intended function.

3. Waste Isolation

3.1 Question - What criterion should be used to define Important to Waste Isolation?

The term "isolation" is defined in 10 CFR Part 60 as: "inhibiting the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits." Based on this definition, and the performance objectives of 10 CFR 60 Subpart E, the term "barriers important to waste isolation" (10CFR60.151) means those natural or engineered barriers that contribute to meeting the containment and isolation requirements of 10 CFR Part 60. 10 CFR Part 60 references 40 CFR

Part 191, the Environmental Protection Agency (EPA) standard for overall repository system performance.

The items and activities important to waste isolation will be dependent upon what barriers are relied on to meet the performance objectives of 10 CFR Part 60 and will include:

A. Components of the engineered barrier system (waste package and underground facility),

B. Components of the natural barrier system,

C. Items and activities necessary to support the determination of whether the performance objectives will be met,

D. Items and activities whose behavior could significantly degrade postclosure performance, and

E. Items and activities important to safety that could affect postclosure performance.

3.2 Question - Should systems, structures, and components important to waste isolation be included on the Q-list?

Yes. As stated in staff comments 9 and 11 from the December 4-5, 1985 quality assurance meeting minutes, structures, systems and components important to waste isolation and certain activities should be included on the Q-list.

3.3 Question - Will the NRC require the application of the single failure criterion to repository facilities prior to closure?

As this question relates to preclosure and single failure, it has been addressed in response to Question 2.5 above.

405/SB/86/02/09

- 1 - MAR 07 '86

Mr. Robert Loux
Director
Nuclear Waste Project Office
State of Nevada
Capitol Complex
Carson City, NV 89710

Dear Mr. Loux:

Several comments were made by the State of Nevada following review of the minutes for the U. S. Department of Energy/U. S. Nuclear Regulatory Commission (DOE/NRC) meeting on Quality Assurance, December 4-5, 1985 (letter from R. Loux to R. Browning, 1/22/86). Enclosed is the staff's response to those comments and concerns.

We appreciate your comments and the opportunity to address the States' concerns as they arise. In responding to these comments we acknowledged a basic agreement between the State of Nevada and NRC staff on the issues addressed. The staff realizes that having not been able to attend the subject meeting, the State may have found it difficult to interpret the content of a meeting based on summaries presented in the meeting minutes. We would like to note, however, that these meeting minutes represent observations which should be read in the context of the specific areas of quality assurance discussed in the meeting.

We hope the enclosed responses provide adequate information. If you have any questions or comments please feel free to contact J. Linehan, Acting Chief of the Repository Projects Branch at (301) 427-4177.

Original signed by

Robert E. Browning, Director
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. NRC Staff's Response to State of Nevada Comments in Letter to R. Browning, 01/22/86.
2. Minutes from DOE/NRC QA Meeting, December 4-5, 1985.
3. Preliminary Draft NRC "Q-list" Positions Presented December 5, 1985 at DOE/NRC QA Meeting.
4. Letter from NRC to DOE - Level of Detail in SCP, December 12, 1985.

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Enclosure 1

Response to State of Nevada
Concerns and Comments from 01/22/86 Letter

1) The NRC's role with respect to QA on non-Q-list items and pre-site characterization activities.

The NRC is committed to the "ideals of quality assurance" and plans to assess all areas of the DOE program related to assuring that a geologic repository will function as required to protect public health and safety. We think our commitment is demonstrated in the level of effort expended by NRC staff to identify and provide guidance on QA issues through the QA and technical interactions conducted with DOE over the past several years. We acknowledge that DOE observation number 1 in the minutes from the December 1985 QA meeting (Enclosure 3) may somewhat obscure the intent of our overview of non-Q-list items and activities. However, staff positions on the Q-list presented during the same meeting (Enclosure 3; 1.1, 1.2 and 1.3) provide more detail in defining our oversight responsiblities.

The Q-list is comprised of those items and activities that, due to their importance to safety and to waste isolation, need high levels of assurance to prove that a repository can operate as required. However, the staff will review all items and activities necessary to meet the licensing requirements and support a license application. Any information necessary to demonstrate compliance with these requirements must have adequate assurance of quality. Those items and activities that are determined by DOE not to be on the Q-list or not to be used or referenced in the license application will also be assessed by the staff to evaluate the adequacy of that determination.

NRC's recommendation in the Ford Amendment Study (NUREG-1055), referenced by Nevada, addresses an issue unique to reactor licensing and not applicable to the repository program. In reference to quality assurance in the reactor program, there are two classes of safety items - safety-related and important to safety - that have been referenced in the regulations. The distinction between and requirements associated with these two classes has been the cause of much discussion. Important to safety is a broader class of items that includes items necessary to meet the statutory requirements of providing reasonable assurance that the facility can operate without undue risk to public health and safety. Items classified as safety-related are a subset of those important to safety and require the use of 10 CFR 50, Appendix B QA requirements while items important to safety can use lesser QA measures.

The NRC has taken a conservative approach in the repository program by requiring that all items and activities that are important to safety or important to waste isolation be subject to 10 CFR 50, Appendix B QA requirements and NRC review. As indicated above, anything necessary to demonstrate compliance with the requirements in 10 CFR 60 will be reviewed by the staff and must be supported by adequate information.

The staff has considered the results of the Ford Amendment Study (NUREG-1055) and is using the appropriate recommendations in the repository program. We consider this a valuable source of information as it represents a unique review of lessons learned in quality assurance through the experience in the nuclear power reactor program. To enhance our use of this experience, we have involved two of the authors of NUREG-1055 in the repository QA activities. Both were key participants in the December 1985 DOE/NRC QA meeting.

The State of Nevada also expressed a concern in this comment that the NRC will not give "proper QA scrutiny" to pre-site characterization activities. The NRC has continually stated that all information to be used or referenced in the license application will need to have adequate assurance of quality and will be reviewed by the staff. This includes, of course, pre-site characterization activities that will be used or referenced to support licensing findings. This is clearly addressed in the staff position 1.4 on the Q-list as presented in the December 1985 QA meeting (Enclosure 3). The staff has to date been involved in review and evaluation of pre-site characterization activities through participation in numerous QA and technical interactions including workshops, data reviews and other DOE/NRC meetings on generic issues.

Qualification of existing data, that is pre-site characterization data collected before implementation of the QA program, is a subject of concern and the focus of much discussion. The staff presented a summary of the draft staff generic technical position (GTP) on qualification of existing data in the QA meeting (see Enclosure 12 to the meeting minutes). This draft GTP is scheduled to be released for public comment within the next several months.

In addition to oversight of the DOE activities, it is important to note that the NRC will maintain awareness of the States' testing programs, insofar as to evaluate whether DOE's information is adequate and that the States' programs do not adversely impact the site. In the NRC review of the DOE site characterization program, the NRC will evaluate whether DOE has taken into account the information from and potential impacts of the States' testing programs. We think it is necessary to note that a consideration in NRC's evaluation of information collected by the States will be the extent to which that information is supported by an adequate QA program.

2) Information to be Provided by DOE in the SCP.

The concern raised in the State's second comment is related to the DOE Observation 2 in the minutes from the December 1985 QA meeting. NRC Observation 11 and staff position 2.2 in the (Enclosures 2 and 3) addresses the staff's position on this issue in the context of the QA meeting. The main purpose of the Q-list is to provide a general listing of the items and activities which fall under the 10 CFR 50, Appendix B QA program. It is a starting point for the staff's review of the scope of the QA program. The staff will utilize information in other sections of the SCP, such as in section 8.3 and its' references, to review the scope of the test program in detail. The staff's guidance with respect to the content of the SCP are addressed in Draft Reg. Guide 4.17 "Standard Format and Content of Site Characterization Plans for High-Level-Waste Geologic Repositories". Staff guidance and discussion, which basically agree with your comments, were most recently presented in the DOE/NRC meeting on October 29-30, 1985 and in the December 12, 1985 letter from NRC to DOE addressing the level of detail expected in section 8.3 of the SCP (Enclosure 4).

The staff believes that the DOE's QA program is an integral part of the SCP plans. NRC oversight of the development and implementation of the SCP activities, including a review of DOE's QA program, is designed to help assure that a geologic repository will function as required to protect public health and safety. This oversight is being conducted by the QA and technical staff through ongoing pre-licensing consultation and guidance activites including the On-site Licensing Representive involvement, data reviews and technical meetings.

3) Important to Waste Isolation and the Waste Package.

As stated in the 10 CFR 60.151, those barriers important to waste isolation and related activities are subject to QA program requirements specified in 10 CFR 60.152, and therefore comprise a part of the Q-list. The term "isolation" is defined in 10 CFR Part 60 as: "inhibiting the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits." Based on this definition and the performance objectives of 10 CFR 60 Subpart E, the term "barriers important to waste isolation" (10CFR60.151) means those natural or engineered barriers that contribute to meeting the containment and isolation requirements of 10 CFR Part 60. This rationale and definition was given in the staff's Q-list presentation during the December 1985 QA meeting. DOE Observation 3 and NRC Observation 9 of the meeting minutes were made in response to discussions that followed.

The question raised by DOE was that if they proved that the natural barriers and waste form could meet the containment objectives, would the waste package (we assume they mean those parts which are not the waste form, since the latter is by definition a part of the waste package) have to be on the Q-list. The staff agrees with the State that it is not feasible for DOE to determine with a high degree of confidence what components of the natural and engineered barrier system will meet the containment and isolation objectives prior to conducting site characterization. Therefore all characterization activities which might relate to natural or engineered barriers important to waste isolation should be conducted under a 10 CFR 60.151 QA program in the event that they ultimately are needed to support licensing findings.

4) NRC Involvement in DOE Readiness Reviews.

The staff is currently making plans for participation in DOE readiness reviews and, as with other NRC/DOE interactions, plans to keep the States and Tribes apprised of these plans as they develop. The States' involvement in DOE's readiness reviews should also be discussed with DOE at an early time.

5) DOE Distribution of Audit Reports and Approved QA Plans/Procedures.

The staff thinks it would be more appropriate for the State to raise this concern with DOE. We note that in a recent correspondence from Vieth to Loux (February 25, 1986) that NNWSI has committed to providing you with the QA plans and procedures for the Nevada Project Office and prime contractors of NNWSI.

ENCLOSURE 2

Minutes of DOE/NRC Meeting on Quality Assurance

December 4 - 5, 1985

The meeting was held on December 4-5, 1985 in DOE's Forrestal Building, 1000 Independence Avenue, in Room 1E-245. Material that was discussed at this meeting has been collected and is included as enclosures to these minutes. Enclosure 1 is an index to the enclosures. Enclosure 2 is a list of the attendees at the meeting. The agenda for the meeting is included as enclosure 3.

Introductory remarks were made by Mr. Ben Rusche, Director of DOE's Office of Civilian Radioactive Waste Management. Mr. Rusche stressed the commitment of DOE management to quality and noted many recent accomplishments.

Mr. John Davis, Director of NRC's Office of Nuclear Material Safety and Safeguards, also made introductory remarks. Mr. Davis reviewed some of the mistakes made by the Nuclear Power industry in quality assurance and encouraged DOE to try to avoid making the same ones. Mr. Davis also reaffirmed NRC's commitment to provide timely guidance to DOE on quality assurance matters.

DOE Observations

1. NRC indicated that their involvement with non-Q-List items not utilized in the license application would be limited to a review and evaluation for the purpose of assuring that none of these items and activities should be on the Q-List.

2. NRC indicated that the only activities they expect DOE to list in the SCP are major site characterization activities on the Q-List. Individual tests and experiments would not, in general, be required to be listed. Major, significant tests, however, will need to be listed in the SCP.

3. DOE felt they might, at some sites, be able to prove that the natural barriers and waste form could meet the NRC containment objective and thus that a waste package would not need to be on the Q-List. NRC indicated that the waste package should be on the Q-List because of the containment performance objective in 10 CFR 60.113(a)(1).

4. DOE requested an opinion from NRC as to whether the DOE project office QA organizations met the NRC requirement for independence. NRC indicated that either of the two arrangements DOE projects now have can work. NRC indicated that they were not yet in a position to determine whether the DOE organization arrangements meet the NRC criterion for QA independence from cost and schedule. NRC indicated that a variety of different organizational arrangements can work; the key factors are whether the quality message received at the level to which QA reports is as strong as the cost and schedule messages it receives and the conduciveness of the organizational structure to escalating quality problems to higher levels if sufficient redress is not received at a given level.

   NRC's review of the projects' QA plans will address the independence issue on a site-specific basis. NRC committed to reviewing the projects' QA plans as soon as they are submitted to NRC by DOE HQ.

5. DOE presented an overview of the current size of the DOE project office staffs, the current size of the QA organizations supporting each project and the projected growth for these. DOE requested feedback from NRC on the suitability of these staffing levels. No opinion on the adequacy of the numbers was offered by NRC at the meeting. NRC noted the increase in staffing levels and indicated that a key consideration is the ability of the project to oversee and manage the activities and quality assurance programs of the contractors and participating organizations.

6. All six of the DOE draft supplements to the OGR QA Plan were furnished to NRC two weeks prior to the meeting for NRC review and comment. NRC offered general comments during the meeting and committed to provide detailed written comments by February 1, 1986.

7. NRC was unable to provide to DOE prior to the meeting copies of four NRC Technical Position Papers which were discussed during the meeting.

8. DOE provided to NRC two weeks prior to the meeting a series of questions on Q-List Methodology/Design Guidance and requested NRC's response. NRC offered general comments during the meeting and NRC committed to provide detailed written comments by February 1, 1986.

9. DOE is committed to providing NRC a schedule by January 31, 1986, showing when NRC can expect:

   (1) to receive copies of the revised OGR-HQ QA Plan and Procedures for review and comment.

   (2) to receive copies of the DOE first - repository project office QA plans and procedures for review and comment.

   (3) to receive from DOE the rationale for why the DOE QA programs are considered to be fully qualified and ready for audits.

NRC OBSERVATIONS:

1. The staff outlined its plans for the next year for giving guidance to DOE on quality assurance and assessing the implementation of the QA program. In order for the NRC staff to not delay the schedules established by DOE for site characterization, DOE should furnish schedules within 60 days for detailed QA program milestones, such as availability of approved QA plans and procedures for the project offices and prime contractors, plans for additional DOE position papers or supplements which address selected QA issues, and the DOE rationale that programs are fully qualified and ready for NRC audits. The NRC staff needs this information for planning purposes so that it may respond quickly to DOE requests for reviews. This approach has been previously discussed in the letter from William Purcell, DOE, to R. Browning, NRC, dated September 3, 1985, and the NRC's analysis of aerospace techniques applied to the waste program as described in NUREG/CR-4271.

2. The DOE staff provided responses to most of the issues raised by the NRC staff during the December, 1984 QA site visits. Several remain to be addressed, however. These issues should be responded to by the DOE in the future, and a schedule for this response provided. Additional information on these issues can be found in the meeting minutes for the site visits.

3. In the DOE letter of November 19, 1985, confirming the arrangements for the December 4-5 meeting on QA, the DOE transmitted nine enclosures related to QA for the repository project (See Enclosure 4 to these meeting minutes). Enclosures 1-6 of the DOE letter are supplements to the OGR QA Program Plan. Enclosure 7 describes the DOE Systems Engineering Management Plan (SEMP) for the repository project. Enclosure 8 is DOE's response to issues raised by the NRC staff in the series of site QA visits in December 1984, and Enclosure 9 contains questions for the NRC on implementation of Q-list methodology.

   During the December 4-5 meeting on QA, each of these DOE documents was discussed. NRC staff handouts contain bulletized comments on the six supplements to the OGR QA plan and the SEMP (see Enclosures 14-20 of these minutes). The staff will provide specific written comments to DOE on each of the nine Enclosures in the near future (see schedule below). General comments regarding the six supplements are as follows:

   (a) DOE stated that supplements will be developed as the need for them becomes evident. Only two additional supplements are planned at this time, peer review and qualification of historical data. Drafts of both are to be made available for NRC staff review in February 1986.

   (b) In writing supplements, and in revising the six supplements discussed at the meeting, the DOE should give careful consideration to ensuring that the purpose of the supplement is clearly stated, its scope is clearly defined, and its relationship for the OGP QA Plan and other

supplements clearly delineated. The staff noted an impreciseness of language in two of the supplements discussed at the meeting "Calibration of Measuring and Test Equipment" and "Computer Software QA" and these steps should both help clarify the language and the intended use of the supplements.

The staff's schedule for providing written comments to DOE on the enclosures to the DOE letter of November 19 is as follows:

Enclosure	Date
1-6 QA Supplements	January 31, 1986
7 Systems Engineering Management Plan (SEMP)	January 31, 1986
8 DOE Response to Site Visit Issues	March 5, 1986
9 Q-list Questions	January 31, 1986

4. The NRC staff presented briefings on five potential Generic Technical Positions (GTP's) on QA for the repository project. The topics were Configuration Management for Conceptual Designs, Peer Review, Qualification of Existing Data, QA for Research and Exploratory Activities, and Q-list (see Enclosures 8-13 of the meeting minutes). The staff plans to publish them for public comment in the Federal Register in early 1986. The staff will accord completion of the draft GTP's and publication in the Federal Register a high priority. For one of the tentative GTP's, QA for Research and Exploratory Activities, the staff has not reached a conclusion on whether guidance on this topic should be promulgated in the form of a GTP or some other form. The staff plans, however, to publish for public comment the other four GTP's.

5. The subject of audits and quality program oversight by various levels in the repository program hierarchy was the subject of considerable discussion during the December 4-5 meeting. NRC's experience from the power plant program is that QA audit and management oversight programs often focus largely on paperwork and programmatic issues. NUREG-1055 provides a comprehensive analysis of this problem, its causes, and its results. In this report, the NRC staff identified comprehensive multidisciplinary team inspections as a particularly useful tool for the identification of major real or potential quality or safety problems and for synthesizing the inputs of technical specialists/inspectors in a number of disciplines into a comprehensive picture of the quality of the overall project. In response to quality, QA, and potential safety problems that developed in power plant design and construction, the NRC developed two headquarters level team inspection programs, Construction Appraisal Team (CAT) Inspections and Integrated Design Inspections (IDI). Other team inspections covering operating plants are conducted from headquarters as well. The IDI team inspection approach was described at the meeting and DOE requested sample copies of IDI team reports.

Approaches to audits, evaluations, or inspections less comprehensive than IDI's were discussed at the meeting. There was general consensus that, early in a project, it is important to establish that an adequate QA program, from a programmatic viewpoint, has been established. Once this baseline program has been established, subsequent audits should focus on implementation of the program. The NRC staff emphasized the importance of ensuring that audit team membership include representation by people with appropriate technical experience and expertise in the technical areas to be reviewed. The staff also emphasized the need for substantive audits covering technical areas and focusing on program effectiveness, and the importance of close attention to, input to, and involvement in audit and evaluation activity by senior management of the organization performing the audit.

The staff referred to several different activities or references that collectively provide perspective on what NRC expects in terms of substantiveness of audits or program reviews and the identification of root causes of quality and QA problems. In addition to the IDI's and the data reviews conducted by the NMSS staff, other activities or references identified by the staff in this context were the findings of the NRC QA site visits in December 1984 and the QA case studies in NUREG-1055.

Common threads that run through these evaluation methods include the following:

(1) a multidiscplinary team of experts in the major disciplines to be reviewed. The NMSS Division of Waste Management conducts interdisciplinary team data reviews which have similar objectives.

(2) Selection of specific safety systems, activities or QA problems for review.

(3) Comprehensive preparation in the details of what will be reviewed in the field before full field deployment of the team.

(4) Team meetings in which each team members findings and observations are discussed, parallels to other areas are identified, and information is synthesized.

(5) Involvement of appropriately skilled personnel (e.g., senior management from the reviewing organization) to help aggregate and sort findings, synthesize information, and put results from different disciplines into an overall project perspective.

(6) Communication of the findings, both in the exit briefing and in the written report, to high levels of management of the reviewed organization.

DOE QA managers indicated their intent to perform substantive audits utilizing technical staff in conjunction with QA experts. Several DOE QA managers indicated that some audits of this nature have been conducted already. DOE staff indicated they are developing a QA auditor course emphasizing the measurement of QA program effectiveness specifically for waste management activities. The NRC staff expressed interest in this course and wishes to be kept informed of progress in its development.

6. During the meeting, the DOE and NRC staffs discussed the quality assurance information to be submitted or referenced in the Site Characterization Plans. Section 8.6 of the SCP will describe and reference the administrative QA procedures, and Section 8.3 will include and reference information on detailed technical procedures, including the specific implementation of the administrative QA requirements. The staff believes the general approach described is acceptable subject to the following: the staff is concerned that the traceability of QA requirements from the administrative procedures to the detailed technical procedures could be hindered by an insufficient level of detail in the QA administrative procedures referenced in the SCP. It would be helpful to the staff if examples could be provided before the SCP is submitted showing the hierarchy of documents which define and implement quality assurance measures. Certain of these documents should also be furnished for staff review.

   In a related matter, the DOE and NRC staffs discussed the use of separate QA procedures to accompany the detailed technical procedures, or alternatively, DOE's consolidation of detailed QA requirements and procedures into the technical procedures. The staff believes either approach would be acceptable.

7. In August 1985, the NRC issued Revision 3 to Regulatory Guide 1.28 which endorsed NQA-1 (with minor exceptions) as an acceptable way to meet the QA requirements of 10CFR50 Appendix B for design and construction of nuclear power plants. The ASME's Committee on Nuclear Quality Assurance (NQA Committee) has expressed a strong interest in having the NRC staff endorse NQA-1 for application to activities associated with nuclear waste repository.

   The DOE through a DOE order has endorsed NQA-1 as describing an acceptable program for meeting DOE QA requirements. During the December 4-5 meeting on QA, the DOE asked the NRC what NRC's plans were for endorsing NQA-1 for waste management, including its schedule.

   The NRC plans to endorse with some exceptions, NQA-1 as an acceptable way to meet most of the requirements of Appendix B for waste repositories. The staff does not believe that NQA-1 provides sufficient guidance in some areas pertaining to repositories, and pursuant to 10CFR60 Subpart G, the staff has supplemented and will further supplement the criteria of Appendix B with additional QA criteria and guidance as applicable.

In the hierarchy of supplementary guidance on QA, the primary program reference is and will continue to be the NRC QA Review Plan. Guidance in this plan supplemented as appropriate by staff GTP's and other guidance issued by the NRC staff. The staff plans to endorse NQA-1 for repositories via a GTP. In the interim, DOE should feel free to use NQA-1 for QA guidance to the extent that it does not conflict with the QA Review Plan and other GTP's and staff guidance that have been or may be issued.

The staffs plans are to publish a draft GTP in the Federal Register for public comment in early 1986 endorsing NQA-1 with some exceptions as describing an acceptable program for meeting the QA requirements of Appendix B.

8. During the meeting, the NRC and DOE staffs discussed the use of readiness reviews for assessing the adequacy of the DOE programs, including the quality assurance program. The staff believes such readiness reviews can help to provide a DOE rationale to the NRC that work has been or will be performed in accordance with NRC regulations. It has been an apparently successful technique employed in non-nuclear applications (e.g., aerospace). NRC oversight of DOE readiness reviews could also provide a part of the basis for the staff's overall evaluation of the DOE quality assurance program before the start of site characterization. The staff believes such readiness reviews would be an effective and efficient method for the staff to help fulfill its objective of assessing the DOE QA program before site characterization. The staff encourages DOE to propose methods for conducting their readiness reviews which would involve NRC staff oversight.

9. During NRC's presentation on the Q-list, the definition for "important to waste isolation" was provided. The NRC emphasized that the waste package and associated activities are included on the Q-list under this definition.

10. During discussion of the scope of the Q-list, retrievability was addressed. NRC emphasized that items and activities related to retrievability would need to be considered in development of the "Q-list."

11. NRC noted that in addition to "items", major site characterization activities need to be included in the Q-list as well. These activities need to be listed to enable the staff to evaluate, in its SCP review, the adequacy of the scope of site characterization activities planned to address the information needed to support licensing decisions.

12. DOE presented issues related to questions previously submitted to the NRC on implementation of the Q-list methodology. NRC committed to responding to these questions by January 31, 1986. Following discussion of these issues, both staffs agreed to the need for a separate meeting on the subject. Preliminary discussions identified two important issues needing follow-up:

(a) Applicability of a low probability cutoff for determining what items and activities are important to safety. DOE proposed a frequency of 10^{-5} per year and NRC indicated that this may not be sufficiently conservative. The justification for establishing such a limit needs to be explored further by both DOE and NRC staffs considering such documents as the recent draft ICRP report on waste disposal (ICRP/85/C4-8/12) and NUREG-0612.

(b) Design basis accidents for developing Q Lists are not explicitly addressed in Part 60. The NRC staff committed to evaluating whether Part 60 implicitly establishes a design basis of 500 mrem or whether the regulation is silent on the issue of design basis accidents and would allow the NRC flexibility to establish a specified design basis accident. DOE proposed a limit of 5 rem, as is currently allowed in Part 72 for determining the controlled area of similar facilities.

13. In order to enable NRC staff to maintain sufficient cognizance of DOE QA activities and provide guidance in a timely fashion, NRC requests that it be added to formal distribution of all audit reports and written responses to same and receive controlled copies of approved QA plans and procedures for OGR, OGR project offices, and the prime contractors for each office.

14. DOE presented the methodology recently proposed by Headquarters for grading QA. This methodology includes four quality levels with grading to be applied within each. Since quality level one will contain those items and activities on the Q-list and subject to 10CFR60 QA requirements, the NRC staff is interested in the details of applying graded QA within quality level 1. As noted in the DOE-NRC meeting minutes from the July 1, 1985 meeting on Q-list, DOE is permitted by Appendix B Part 50 to grade QA in accordance with the importance to safety or waste isolation of particular items. NRC also noted that DOE quality levels two through four would also be reviewed but only to assure that the scope of quality level 1 included all items and activities on the Q-list, or to be referenced in or supporting the license application (such as Part 20 requirements).

STATE OF NEW MEXICO OBSERVATIONS

Mr. C. R. McFarland of the State of New Mexico had four comments that he recommends be considered in setting limits for Design Basis Accidents:

1) Consider the curie content of the Waste Package.

2) Consider the fraction of the radioactive material that would be in respirable size particles (i.e., less than about 10 microns) for workers to inhale and for the fence post dose.

3) Consider the transport medium and flow path, mitigating systems (natural and engineered), and travel time for emplaced waste - especially where drifts have been backfilled.

4) Consider K-effective for worst case analyses.

James E. Kennedy
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards
U. S. Nuclear Regulatory Commission

Carl Newton
Licensing and Regulatory Division
Office of Geologic Repositories
U. S. Department of Energy

Willard Altman
Division of Quality Assurance, Vendor, and
Technical Training Center Programs
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission

ENCLOSURE 3

PRELIMINARY DRAFT
NRC "Q-LIST" POSITIONS
FOR PRESENTATION TO DOE
BY S. G. BILHORN, DECEMBER 5, 1985

1.0 QUALITY ASSURANCE REQUIREMENTS

1.1 "Q-List" Items and Activities

DOE shall apply the 10 CFR 60, Subpart G quality assurance requirements to the items identified as important to safety or waste isolation, and activities related thereto.

1.2 Non-"Q-List" Items and Activities

For items and activities which are neither important to safety nor waste isolation but which will be referenced in the construction authorization application to support findings required by Part 60 (such as requirements for worker radiological safety and environmental monitoring contained in 10 CFR 60 Part 20), DOE should describe and reference the program for documenting and assuring that these requirements have been fulfilled in the construction authorization application. DOE should also describe, at least in general terms, such programs in the SCP.

1.3 Other Non-"Q-List" Items and Activities

For all other items and activities supporting the development of a repository, DOE may apply QA programs based on reliability, cost, and other programmatic considerations. The staff will review these non-"Q-List" items and activities only to assure that the "Q-List" is complete.

1.4 Information Which May Be Used In, or To Support the License Application

A) DOE should assure that all data collection, interpretation and analyses which may be used in or may support the license application will be performed under a QA program meeting the requirements of 10 CFR Part 60, Subpart G or, if collected prior to site characterization and the complete implementation of the QA program, be reviewed and qualified under an NRC approved method.

B) Prior to and during the early (exploratory) phases of site characterization when the ultimate importance of data to be collected is not known, DOE should apply a high level of quality assurance to all testing and data collection.

2.0 IDENTIFICATION OF THE "Q-LIST"

DOE shall identify the structures, systems, and components important to safety, the barriers important to waste isolation, and related activities, such as site characterization.

2.1 Construction Authorization Application

The DOE shall identify a complete "Q-List" in the Construction Authorization Application, either directly or through a reference available for staff review.

2.2 Site Characterization Plan

DOE should identify a preliminary list of systems and major structures and components important to safety and barriers important to waste isolation in the SCP. Major site characterization data collection activities such as waste package testing, excavation of the exploratory shaft, and surface and subsurface soil and rock testing should also be identified in the SCP.

3.0 METHODOLOGY FOR DETERMINING BARRIERS IMPORTANT TO WASTE ISOLATION

3.1 GTP on Licensing Assessment Methodology for HLW Geologic Repositories

DOE should use the performance assessment methods described in the staff's "Generic Technical Position on Licensing Assessment Methodology for High Level Waste Geologic Repositories" for determining which barriers contribute to or potentially affect the isolation of waste.

3.2 Use Performance Allocation Based on Available Data at SCP Stage

To tentatively identify barriers important to waste isolation for the SCP, the DOE should allocate performance among the various components of the natural and engineered systems. Preliminary performance assessments, using the waste isolation and containment performance objectives of 10 CFR Part 60 and available data, should be utilized where practicable as the bases for preliminary identification of barriers important to waste isolation.

4.0 METHODOLOGY FOR DETERMINING ITEMS IMPORTANT TO SAFETY

4.1 Analysis Techniques

DOE should use the following analysis techniques for determining the structures, systems, and components important to safety:

- Identification of credible events and accident scenarios. Some accident scenarios might be so unlikely that they can be considered

incredible, and such accidents need not be considered when identifying items important to safety.

- o Fault tree/event trees and failure modes and effects analysis.
- o Identification of a source term for radioactive releases and a rationale for same.
- o Accident consequence analysis.

4.2 Determining Probabilities of Scenarios

In determining the probability of various scenarios, DOE should use available data for initiating events and equipment reliability. Where data are sparse or unavailable, bounding assumptions should be used with a supporting rationale to demonstrate conservatism.

4.3 Preliminary Evaluations of Credible Accident Scenarios and Their Consequences for the SCP

In order to identify systems and major structures and components in the SCP, DOE should perform preliminary evaluations of credible accident scenarios and their consequences. Judgement will be required in assessing which items are important to safety, and a probablistic approach may not be realistic at this stage. A schedule for milestones in the design advancement should be included in the SCP.

5.0 GRADED APPLICATION OF QUALITY ASSURANCE MEASURES

5.1 Application

Appendix B of 10 CFR 50, Criterion 2 indicates that the quality assurance program shall provide control over activities affecting the quality of the identified structure, systems, and components to an extent "consistent with their importance to safety".

5.1 Considerations

DOE should apply graded QA measures to items and activities important to safety or waste isolation based on the follwing considerations:

- o The impact of malfunction or failure of the item to safety or waste isolation.
- o The complexity of design or fabrication of an item or the uniqueness of an item or test.

- o The special controls and surveillance needed over processes and equipment.
- o The degree to which functional compliance can be demonstrated by inspection or test.
- o The quality history and degree of standardization of the item or test.

5.3 DOE may also utilize the more detailed guidance on grading QA measures contained in the non-mandatory Appendix 4A-1 of NQA-1.

ENCLOSURE 4

DEC 12 1985

Dr. Donald H. Alexander
Acting Chief
Technology Branch, RW-23.2
Office of Geologic Repositories
U. S. Department of Energy
1000 Independence Avenue
Washington, DC 20585

SUBJECT: ADDITIONAL NRC COMMENTS ON LEVEL OF DETAIL IN SECTION 8.3 OF THE DOE SITE CHARACTERIZATION PLAN

Dear Dr. Alexander:

The U. S. Nuclear Regulatory Commission (NRC) and U. S. Department of Energy (DOE) conducted a technical meeting on October 29-30, 1985, to discuss section 8.3 of the DOE Site Characterization Plans (SCP). DOE presented their "Content Requirements for Descriptions of Studies in Chapter 8 of the SCP (referred to in this letter as "Content Requirements") and three examples of study descriptions prepared by each of the three DOE projects using the "Content Requirements" as a guide. During the meeting NRC provided some preliminary comments on the DOE material documented in the meeting summary (Enclosure 1) and agreed to provide DOE with additional comments on the appropriate level of detail in section 8.3 and the application of performance goals and confidence levels in the examples. Subsequent to the meeting DOE developed definitions of terms as requested by NRC in item number 2 of the meeting summary; these were also given to NRC for review in a November 8, 1985 letter from D. Alexander to J. Linehan. As agreed to in item number 4 of Enclosure 1, DOE and NRC further discussed during the December 4-5, 1985 meeting on quality assurance, the quality assurance information to be submitted or referenced in the SCP. NRC comments are documented in the minutes of this meeting.

This letter provides DOE with the results of NRC's review by giving the following additional comments:

Level of Detail in the SCP

The comments below conclude that rigorous use of the revised "Content Requirements" (Enclosure 2) will likely result in study plans with the

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appropriate level of detail. However, as we have said for some time (e.g., NUREG-0960 and Regulatory Guide 4.17), it is DOE's decision on the location of study plans, i.e., if these plans are presented in section 8.3 of the SCP or presented as references to section 8.3. While we agree with DOE's goal of producing a fully integrated and consistent SCP, DOE can best decide how to achieve this while also considering appropriate approaches to product production. NRC's basic need is to have the plans provided in some form for review at the time the SCP is issued. This was not done for the BWIP SCR and the Draft EAs (i.e., some key references to these documents were supplied much later) and resulted in an inefficient review by the NRC staff.

Specific Comments on "Content Requirements"

1. Enclosure 2 contains our suggested corrections and deletions to the "Content Requirements." These include only some changes which make it more consistent with the Annotated Outline. We suggest that DOE cross check the "Content Requirements" with Section 8.3 of the Annotated Outline to ensure complete consistency as was agreed to in item number 5 of the meeting summary (Enclosure 1).

   With the addition of our suggested corrections and additions (Enclosure 2) we consider that the "Content Requirements" will provide sufficient guidance at this time to prepare substantially complete drafts of study plans at an appropriate level of detail. We anticipate, however, that there might be details that should be in study plans that are specific to the site, study, test, or analysis. We are available to review this type of material before SCP release, and upon DOE request we will provide feedback and guidance on a case by case basis.

2. It appears to us that DOE's approach in the "Content Requirements" assumes that all information on a study (e.g., types, numbers, locations, sequence and duration of tests) should be identified and described in detail and with certainty. In NUREG-960 and Regulatory Guide 4.17 NRC recognized that plans may be more defined and detailed for more immediate studies and less defined and detailed for more distant studies. We anticipate that for some studies there will be initial uncertainty regarding items such as the location, number, duration of tests or even the most appropriate type of test. An example of this situation is the hydrologic testing at BWIP.

An acceptable solution to this case was the development of a hydrology testing strategy agreeable to both NRC and DOE (BWIP) which is documented in NRC's BWIP Site Technical Position No. 1.1. This position describes a strategy with decision points established to determine options for use of various types of tests and various scales and durations of tests. This strategy is particularly well suited for an evolving testing program where there is considerable initial uncertainty. From the information we have received it is not clear if other Section 8.3 descriptions (of plans for investigations, specific programs and generic programs) would contain strategies. Therefore, DOE should consider incorporating some form of the testing strategy concept as described above into Section 8.3 at whatever level(s) appropriate. Such an approach would be supplemented by SCP semiannual updates providing revisions to the strategy and plans as the new information is developed and as decisions are made.

Specific Comments on Project Examples

1. We recognize that the examples DOE prepared are preliminary and represent a first attempt to apply the "Content Requirements." The evaluations we have developed for each example (Enclosure 3) identify those items in the "Content Requirements" that are not addressed, addressed to some degree, and which need more information. Considering the preliminary nature of the examples this limited evaluation was felt to be appropriate at this time. We believe that the examples could be made more complete and consistent among projects by revising them based on a consistent and vigorous application of the revised "Content Requirements."

Definitions and Consistent Use of Terms

We have no additions or corrections to the definitions of terms provided. However, we believe that the consistency by all DOE projects in the use of these terms and number of hierarchial terms in section 8.3 will minimize confusion for those reviewing all three SCP's and will facilitate our review of all three SCP's.

Performance Allocation

Although the "Content Requirements" and the project examples relate the information needs to performance goals, none relates the tests to the set

performance goals and desired confidence levels. In the September 26-27, 1985 meeting on Subsystem Performance Allocation it was agreed that a rationale would be provided for every test or suite of tests in the SCP and that where the tests relate to resolution of performance issues, this rationale would include the relationship of the test to the set performance goals and confidence levels. (This was noted in the summary of NRC/DOE Meeting on the SCP's, Section 8.3, Item No. 6.) We recognize that there has been little time since the September meeting to incorporate this agreement into SCP guidance and to implement the guidance. However, this omission makes it difficult to comment in specific terms about what level of detail would be appropriate in the examples. We would be pleased to provide such comments on suitably modified examples. Also, this comment presumes that the references made in the examples to specific performance goals link to a complete performance allocation in another section of Chapter 8.

Future NRC Reviews of Plans

It is important to repeat again that for NRC to complete its review of the SCP's in five months, we must at a minimum be current on the existing data for each site. We expect that the extent and nature of our comments on the SCP's will be directly related to the success of our consultations with DOE on plans as they are developed before the issuance of the SCP.

Our preparations for future pre-SCP reviews and early feedback on plans during their development would be enhanced by receiving the section 8.3 hierarchy of plans referred to in the DOE/HQ meeting presentation. This includes the specific breakdown for each site of generic programs, specific programs, investigations, studies, tests, analyses and procedures. In addition the Correlation Matrix for each site also referred to in the DOE/HQ meeting presentation would be useful early in our reviews to see the integrated framework of the program expressed by various correlations among tests, 10CFR60, issues, and information needs.

In the DOE letter from W. Purcell to R. Browning (NRC) of September 3, 1985, DOE committed to meet with NRC in the near future to discuss planned activities, milestones, and appropriate points for consultation with NRC. We consider this step to be critical to planning timely and successful pre-SCP interactions during the next year as well as the post-SCP interactions.

We believe that the quality, completeness, and consistency of the SCP's will be significantly improved by the guidance DOE is developing in conjunction with NRC's review and comment. While we have noted where we consider improvements are needed, the process of DOE/NRC interaction on this subject has been appropriate and constructive. If you have any questions regarding our comments please contact R. Johnson at 427-4674.

Sincerely,

"ORIGINAL SIGNED BY"

John J. Linehan, Section Leader
Repository Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. Summary of NRC/DOE meeting on the SCP's Section 8.3
2. NRC Mark-up of DOE "Content Requirements for Descriptions of Studies in Chapter 8 of the SCP."
3. NRC Evaluations of DOE Project Examples of Study Plans