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

Reply to:  
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Las Vegas, Nevada 89119 '85 NOV 25 A11:16  
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WM Project

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DATE: November 20, 1985

FOR: Jim Kennedy

FROM Paul T. Prestholt

PTP

SUBJECT: QA

In accordance with our telephone conversation of this afternoon, attached are following documents:

1. Letter dated November 7, 1985 Weston to Ralph Stein
2. Comparative Analysis of the 3-Level and 4-Level Quality Programs for Graded QA Application
3. Memorandum dated November 8, 1985 from DOE to Neff, Mann, Olson & Vieth

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ROCKVILLE, MARYLAND 20850  
PHONE (301) 963-6800

November 7, 1985

Mr. Ralph Stein  
Acting Director  
Licensing and Regulatory Division  
Office of Geologic Repositories  
Office of Civilian Radioactive  
Waste Management  
U.S. Department of Energy  
RW-23 (Forrestal) Room 7F-091  
Washington, D.C. 20585

Subject: Q-List Methodology and Graded QA Application

Dear Mr. Stein:

Enclosed is a draft report on Q-List Methodology and on Graded QA Application. The Q-List Methodology portion provides a general method for identifying structures, systems, and components important to safety and to waste isolation, but does not contain specific design guidance. This is in agreement with our meeting on 5 November 1985. In accordance with the requests from the projects expressed during the meeting in the Forrestal Building on 1 October 1985, the report (a) does not include a generic Q-List; (b) assumes a constant dose threshold of 0.5 rem; and (c) provides for a low probability cutoff of  $1 \times 10^{-5}$  per year for accident scenarios below which an accident need not be considered.

As per your request, also enclosed to this letter is a list of concerns we recommend to be submitted to NRC. Agreements with NRC on these concerns would provide much needed guidance to all project designers for implementing the Q-List Methodology.

The Graded QA portion of the report is based on the draft prepared on 8 and 9 October 1985 by a special working group consisting of representatives of the four projects plus DOE/HQ and Weston, and includes review comments from DOE/HQ, Weston and from the four projects. The report recommends four levels of QA. NNWSI strongly prefers three rather than four levels of QA, mainly because they have a three-level system in place and a change to a four-level system would result in significant cost and schedule penalties. In a subsequent QA Coordinating Group Meeting BWIP expressed support for the NNWSI position. However, the SRP and CRP Projects as well as OCRWM, OGR and Weston QA personnel have all supported the four-level approach. Weston believes that the NNWSI approach does not meet current NRC and DOE requirements because it lacks provisions for upgrading those items which are not now on the Q-List but which may be so identified in the future and does not provide for grading within levels. We recommend the OGR adopt a four-level approach. For your convenience a comparison of the 3-level and 4-level QA grading is enclosed. Because of schedule concerns, we recommend that the reports be provided to the projects as soon as possible. Should any changes be required they could still be discussed before the meeting with NRC now scheduled for 4 - 5 December 1985.

Office of Civilian Radioactive Waste Management (OCRWM) - Technical Support Team  
WESTON in association with: Jacobs Engineering Group Inc. • ICF Incorporated • Williams Brothers Engineering Co.  
Rogers and Associates Engineering • United Engineers and Constructors, Inc.

**WESTON**

Mr. Ralph Stein

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Should you have any questions, please call me at (301) 963-5241, Ed Sulek at (301) 963-5216, or Hank Bermanis at (301) 963-5236.

Sincerely,

ROY F. WESTON, INC.

Leonard T. Skoblar, Manager  
Licensing and Safety Assessment

Approved by:

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William M. Hewitt  
Program Manager

COMPARATIVE ANALYSIS OF THE 3-LEVEL AND 4-LEVEL  
QUALITY PROGRAMS FOR GRADED QA APPLICATION

BACKGROUND INFORMATION

In recent interactions with the U. S. Nuclear Regulatory Commission (NRC) relative to the Geologic Repository Program, the U.S. Department of Energy (DOE) Office of Geologic Repository (OGR) has committed to submit, for NRC consideration, a DOE/OGR plan on the methodology and application of a graded quality assurance (QA) program to items and activities at the geologic repository that are important to safety or waste isolation and to the achievement of DOE programmatic performance objectives. A DOE/OGR Working Group, composed of representatives from the four DOE/OGR Project Offices (BWIP, CRPO, SRPO and WMPO) Project Contractors and Weston, Inc., was assigned the task of developing a methodology for graded QA to be applied the the Repository Program. The Working Group arrived at a graded QA approach which calls for 4 quality program levels. At that time the representative of the Nevada Nuclear Waste Storage Investigation (NNWSI) project, for WMPO; maintained his preference for a 3-Level QA program because that program is already under implementation. The Working Group's report was subsequently incorporated in a DOE Draft Report on "Methodology for Formulating a Q-List and for Applying Graded Quality Assurance to Mined Geologic Disposal Systems." At the recent OGR QA Coordinating Group (QACG) quarterly meeting on October 22 - 23, 1985, the BWIP representative expressed preference to the 3-Level program thereby supporting the NNWSI position. The other two Project Offices (SRPO and CRPO) maintained their preference for the 4-Level QA program.

In view of this situation, the DOE/OGR expressed the need for further study on which of the two programs should be adopted.

COMPARISON OF PROGRAMS

For purposes of this comparative study, the following documents were used as references:

- a. DOE Draft Report on "Methodology for Formulating a Q-List and for Applying Graded Quality Assurance to Mined Geologic Disposal Systems" dated October 18, 1985.
- b. NNWSI Quality Assurance Plan, NVO-196-17, Revision 3.
- c. Assignment of Quality Assurance Levels to NNWSI Activities and Items, NNWSI-SOP-02-02, Revision 0.

The Draft Report describes the methodology and application of the proposed 4-Level QA Program. The other two documents describe the 3-Level QA Program currently being applied to the NNWSI Project under the WMFO direction.

The relevant features of the 3-Level and 4-Level QA programs, such as QA requirements, program applicability and other considerations are tabulated in a Comparison Matrix which is attached hereto. A scrutiny of the Matrix will reveal the following for the two QA programs.

#### A. Similarities

1. The Level I of the 3-Level (NNWSI) program and the Level 1 of the proposed 4-Level (DOE/OGR) program have practically the same QA requirements and applicability. Both Level 1 programs are intended to satisfy NRC licensing concerns on Safety, Waste isolation and retrievability (Q-List items and pertinent site characterization activities).
2. The NNWSI Level III program is essentially the same as the DOE/OGR Level-4 program in that no formal QA requirements are imposed. The quality requirements to be imposed will be in accordance with good engineering, administrative and work practices. These programs will be applied to items and activities that have no, or negligible, impact on the DOE programmatic objectives or NRC concerns.

## B. Differences

1. The NNWSI program Level I or Level II does not address or provide for the possibility of a non Q-List item to be upgraded later as a Q-List item. The DOE/OGR program, on the other hand, already assigns Quality Level 1 to those items falling under this category.
2. The NNWSI Level II QA requirements are between the DOE/OGR Level 2 and Level 3 QA requirements. The NNWSI Level 3 program does not call for the 6 NQA-1 Supplementary Requirements and is not yet addressing the DOE/OGR Quality Requirements already being called for in the DOE/OGR Level 2 program. The NNWSI Level II program includes all 18 Basic Requirements of NQA-1 as against only 14 Basic Requirements for the DOE/OGR Level 3 program.
3. Worker (occupational) radiological health and safety is included in the NNWSI Level I program and Worker Non-radiological health and safety is placed in the NNWSI Level II program. The DOE/OGR considers the occupational health the safety under Level 2, 3 or 4 programs, depending on the severity of the potential impact of the failed item or activity on such consideration.
4. The NNWSI Plan places items and activities whose failure could have potential major impact on DOE programmatic objectives (schedule, cost, operational reliability, etc.) in Level II. The DOE/OGR program places items and activities important to the DOE program success in Levels 1, 2, 3 or 4 depending on whether the potential impact of their failure will be critical, major, minor or negligible to the attainment of DOE programmatic objectives.
5. The DOE/OGR program provides for increasing or decreasing the depth and comprehensiveness of QA requirements for items or activities within a Quality Level. When the QA requirements are increased, no justification for the increase is required. However, when a mandatory QA requirement is not included, a written justification for the deletion must be provided.

The NNWSI program has no specific provision or mechanism for increasing or decreasing the QA requirements within a Quality Level. The following provisions are, instead, provided in the program:

- a. Activities controlled under the Level II program cannot subsequently be used to support Level I activities unless it can be substantiated that quality requirements equivalent to those which have been applied to a Quality Level I activity were implemented, or a written technical justification is applied.
- b. When assigning quality levels, it will be necessary to subdivide each item or activity into smaller items or activities .
- c. Each item or activity will be individually processed through the entire logic process to determine the QA level.
- d. Unless specifically stated otherwise, all activities required to obtain an item will have the same level of QA as the item.

#### DISCUSSIONS

1. A principal NRC concern is the QA program level to be applied to items that are initially not included in the Q-List but could be upgraded, at some later date, as Q-List items. The NNWSI program, at present, does not address this concern. As a non Q-List item, it will be subject to the NNWSI Level II program. When the item is subsequently upgraded to become a Q-List item, a serious problem of backfitting and ratcheting the previous QA applied to the equivalent of Quality Level I will arise. This situation will not be acceptable to the NRC,

The current NNWSI program needs to be revised in order to consider the application of Quality Level I program to non Q-List items with potential for being upgraded as Q-List items at a later date. Also considering that it is almost impossible to identify all such items at these early stages of the Repository Program, the NNWSI program should further describe its method or process of upgrading other items previously controlled under the

Quality Level II program to satisfy the QA requirements equivalent to the Quality Level I program.

The DOE/OGR proposed QA program, on the other hand, already gives due recognition to the possibility of items to be included in the Q-List at some later date. Such items will be subjected to a Quality Level 1 program up front. Furthermore, outside of the NRC QA Review Plan requirement, there is only a slight difference in the QA requirements called for between the DOE/OGR Level 1 and Level 2 quality programs. The QA upgrading required when an item becomes a Q-List item is not expected to pose problems as serious as that anticipated in the NNWSI program.

The DOE/OGR program also has a provision that allows the imposition of more depth and increased QA requirements over that which are mandatory without having to provide justification for the increased requirements. Therefore, non Q-List items can still be controlled under the equivalent of a Quality Level 1 program without having to reclassify the items.

The possibility of non-Q-List item to be upgraded and included in the Q-List, or the item to remain as a non Q-List item but may require a Level 1 quality program is very real. In a draft "Underground Design Safety Assessment Report" prepared in October 1985 by Roy F. Weston, Inc. for the DOE, it was stated that in each of the repository sites with salt, basalt or tuff media, "waste retrievability equipment associated with non-normal operations or functions have a strong possibility of being important to safety or waste isolation," and that "DOE will need to convince NRC that adequate QA and testing will be performed without necessity of Q-listing these systems."

2. Quality Level 1 of both (NNWSI and DOE/OGR) QA programs are aimed primarily at addressing concerns for public health and safety, waste isolation and waste retrievability and at satisfying NRC licensing requirements. The other quality program levels are intended to address the DOE programmatic objectives and concerns. Considering further that, in both QA programs, the lowest quality program level (Level III for NNWSI and Level 4 for DOE/OGR), no formal QA requirements are imposed, this



leaves only one formal quality program level (Level II) in the NNWSI project to cover items and activities important to the attainment of DOE programmatic objectives.

In the NNWSI QA program, the possibility of increasing or decreasing the depth and coverage of QA requirements within a given Quality Level was not mentioned or implied. The absence of this proviso practically reduces the graded QA concept to merely a selection of quality levels with no grading possible within each quality level. In order to truly reflect a graded QA approach, the NNWSI program may have to be revised to include the above stated missing proviso.

In the DOE/OGR proposed QA program the determination of applicable Quality Levels is based principally on the graded assessment of potential adverse effects or impacts of the failure or malfunction of an item or activity on the DOE programmatic objectives. The QA program thus allows the assignment of items and activities to be covered under 4 quality program levels. Furthermore, the QA program allows for grading within a given Quality Level.

3. The NNWSI QA program places items and activities having major impact on worker (occupational) radiological health and safety under Quality Level I program and those with major impact on worker non-radiological health and safety under the Quality Level II program. The DOE/OGR QA program, on the other hand, considers items and activities with potential impact on occupational health and safety to be under 3 quality levels depending on the seriousness of the potential impact, the highest level being Quality Level 2.

Considering occupational radiological health and safety only, it could be surmised that the the NNWSI Quality Level II requirements are not adequate to satisfy this concern so that Quality Level I has to be applied. This assumption is made because repository workers will belong to the category of "radiation workers" whose radiation exposures are monitored in accordance with an established personnel radiation protection program. Accordingly, they merit a QA program coverage that need not be as

stringent as that intended to protect the general public. The DOE/OGR Quality Level 2 program, on the other hand, imposes more QA requirements than the NNWSI Quality Level II program, and appears to be adequate for satisfying requirements for the radiological health and safety protection of facility workers.

4. The task of determining and assigning quality levels to the various items and activities in the Repository Program will entail an equal degree of detail and involvement, whether it is for a 3-Level or 4-Level QA program. For the proposed DOE/OGR 4-Level quality program, Attachment A of the Draft Report may be used as the starting point and guide in the assignment of Quality Levels. With regard to the 3-Level QA program, so far only the NNWSI project is the one far along in this QA program implementation. The other 3 projects have not yet formally implemented a graded QA program so that no problem is anticipated for these projects in adopting a 3-Level or 4-Level graded QA program.
5. If a 3-Level QA program will be adopted by DOE/OGR, the current NNWSI QA program would still have to be revised for the reasons already stated in Discussion Items 1 and 2 above. If the 4-Level QA program will be decided to be implemented by all the projects, the NNWSI will have to be modified as follows:
  - a. The missing provisions regarding potential Q-List items and increasing or decreasing the QA requirements within a Quality Level, as already discussed in Discussion Items 1 and 2 above, are to be added to the QA Plan;
  - b. Items and activities currently covered under the NNWSI Quality Level II program will be reevaluated and categorized as:
    - (i) having potential to become Q-List items
    - (ii) those to be controlled under the DOE/OGR Quality Level 1 program; and

(iii) those that can be downgraded to the equivalent of those falling under the DOE/OGR Quality Level 3 program.

- c. The DOE/OGR Quality Requirements, which will be incorporated in the OGR QA Plan, will be added.

The downgrading of items and activities for control under the DOE/OGR Level 3 quality program will not pose a problem because these items or activities are currently under more stringent QA requirements. The upgrading of items and activities for control under the DOE/OGR Level 2 quality program is not expected to present a real problem either because of the likelihood that the QA program that was implemented on these items and activities also satisfied the NQA-1 Supplementary Requirements. The only poser is thus the backfitting that will be necessitated in the upgrading of some items and activities that related to potential Q-List items. In order to reduce this problem to a manageable level, it is essential that these potential Q-List items be identified as early as possible.

#### CONCLUSION AND RECOMMENDATIONS

The foregoing discussions clearly point out that, irrespective of whether a 3-Level or 4-Level QA program will be decided by DOE/OGR, the present NNWSI QA Plan needs to be revised for incorporation of the following provisions and requirements:

- a. Inclusion of a provision that identified potential Q-List items be already covered under the Quality Level 1 program.
- b. Inclusion of a description of the process or mechanism for upgrading and backfitting the quality program applied to non Q-List items not previously identified as potential Q-List items to the equivalent of Quality Level I program when they become Q-List items.
- c. Inclusion of a provision for increasing or decreasing the depth and coverage of QA requirements on an item or activity within any Quality Level, subject to specified conditions or limitations.

- d. Incorporating the DOE/OGR quality program requirements that are about to be included in the OGR QA Plan.

It is expected that, after these revisions are made, the NNWSI QA program will no longer be much different from the proposed DOE/OGR 4-Level program which, in its present formulation, does not have the deficiencies identified in the NNWSI QA Plan. In addition, the 4-Level program already provide for non Q-List items and activities to be covered under any of all 4 quality levels. The program description may, however, necessitate some elaboration on the extent of backfitting of the quality program applied to Quality Level 2 items or activities after they are determined to require a Quality Level 1 program.

The following are recommended to be proposed to the DOE/OGR for consideration:

1. That the 4-Level QA program be adopted for implementation by all 4 OGR Project Offices.
2. That, pending revision of the NNWSI QA Plan, the WMPO may allow the continued implementation of the current NNWSI QA Plan subject to the condition that due consideration be given for already increasing the depth and number of QA requirements to be imposed on items and activities that may merit higher Quality Levels.

# MATRIX COMPARISON OF 3-LEVEL AND 4-LEVEL QUALITY PROGRAMS

| CONSIDERATION FACTORS   | PROGRAM LEVEL 1  |  | PROGRAM LEVEL 2  |   | PROGRAM LEVEL 3   |  | PROGRAM LEVEL 4   |                    |
|---|--|--|--|---|---|--|---|--------------------|
|   | DOE/OGR  | NNWSI                                      | DOE/OGR  | NNWSI   | DOE/OGR   | NNWSI  | DOE/OGR   | NNWSI              |
| <b>QA REQUIREMENTS</b>  |  |  |  |   |   |  |   |                    |
| 10 CFR 50, APPENDIX B   | REQUIRED   | REQUIRED                                   | NOT REQUIRED   | NOT REQUIRED                                  | NOT REQUIRED  | NO FORMAL QA REQUIREMENTS IMPOSED, EXCEPT THE USE OF GOOD ENGINEERING, LABORATORY AND QUALITY PROCEDURES | NO FORMAL QA REQUIREMENTS IMPOSED, APPROPRIATE QUALITY & ADMINISTRATIVE REQUIREMENTS DETERMINED ON CASE-BY-CASE BASIS | NO PROGRAM LEVEL 4 |
| NRC REVIEW PLAN   | REQUIRED   | REQUIRED                                   | NOT REQUIRED   | NOT REQUIRED                                  | NOT REQUIRED  |  |   |                    |
| NOA-1 (1983) BASIC REQUIREMENTS   | ALL 18 REQUIRED  | ALL 18 REQUIRED                            | ALL 18 REQUIRED  | ALL 18 REQUIRED                               | 14 REQ'D (NOTE F)   |  |   |                    |
| SUPPLEMENTARY REQUIREMENTS  | ALL 17 REQUIRED  | ALL 17 REQUIRED                            | 8 REQ'D (NOTE C)   | NONE REQUIRED                                 | NONE REQUIRED   |  |   |                    |
| APPENDICES  | ONLY 2A-1 REQ'D  | (SEE NOTE A)                               | NONE REQUIRED  | NONE REQUIRED                                 | NONE REQUIRED   |  |   |                    |
| DOE/OGR QUALITY PROGRAM REQUIREMENTS  | ALL 12 REQUIRED  | (SEE NOTE B)                               | 9 REQ'D (NOTE D)   | (SEE NOTE B)                                  | 1 REQ'D (NOTE F)  |  |   |                    |
| <b>APPLICABILITY OF PROGRAM</b>   |  |  |  |   |   |  |   |                    |
| • Q-LIST ITEMS  | INCLUDED   | INCLUDED                                   | —  | —   | —   | —  | —   | NO PROGRAM LEVEL 4 |
| • ITEMS THAT MIGHT BE ADDED TO THE Q-LIST AT A LATER DATE   | INCLUDED   | NOT MENTIONED                              | —  | —   | —   | —  | —   |                    |
| • ITEMS WHOSE FAILURE OR POOR PERFORMANCE WILL HAVE IMPACT ON   |  |  |  |   |   |  |   |                    |
| — ACHIEVEMENT OF MISSION PERFORMANCE OBJECTIVES   | INCLUDED FOR THOSE HAVING CRITICAL IMPACT                          | NOT INCLUDED                               | INCLUDED FOR THOSE HAVING MAJOR IMPACT   | INCLUDED FOR THOSE HAVING MAJOR IMPACT        | INCLUDED FOR THOSE HAVING MINOR IMPACT                              | —  | INCLUDED FOR THOSE HAVING NEGLIGIBLE IMPACT   |                    |
| — PROGRAM SCHEDULE OR COST  |  |  |  |   |   |  |   |                    |
| — RELIABILITY OF OPERATION  |  |  |  |   |   |  |   |                    |
| — OCCUPATIONAL HEALTH AND SAFETY OF PERSONNEL   | —  | INCLUDED FOR RADIOLOGICAL HEALTH & SAFETY  | INCLUDED FOR THOSE WITH CRITICAL IMPACT  | INCLUDED FOR NON-RADIOLOGICAL HEALTH & SAFETY | INCLUDE FOR THOSE WITH MAJOR IMPACT                                 | —  | INCLUDED FOR THOSE WITH MINOR IMPACT  |                    |
| • TECHNICAL DATA COLLECTION ACTIVITIES, COMPUTER CODE PROGRAMS, R&D, AND COLLECTION OF INFORMATION THAT HAVE POTENTIAL IMPACT ON SITE CHARACTERIZATION OR PROGRAM SCHEDULE & COST | INCLUDED FOR THOSE HAVING CRITICAL IMPACT ON SITE CHARACTERIZATION | INCLUDED FOR THOSE RELATED TO Q-LIST ITEMS | INCLUDED FOR THOSE HAVING MAJOR IMPACT ON PROGRAM SCHEDULE AND DATA GENERATION | —   | INCLUDED FOR THOSE HAVING MINOR IMPACT ON PROGRAM COST AND SCHEDULE | —  | INCLUDED  |                    |
| • ITEMS AND ACTIVITIES DEALING WITH FIELD TESTS, INVESTIGATIONS, AND EXPERIMENTS ESSENTIAL FOR ENGINEERING DESIGN AND SPECIFICATION OF FACILITY SYSTEMS AND COMPONENTS            | INCLUDED FOR QUALITY LEVEL 1 SYSTEM DESIGN                         | INCLUDED FOR THOSE RELATED TO Q-LIST ITEMS | INCLUDED FOR QUALITY LEVEL 2 SYSTEM DESIGN                                     | —   | —   | —  | —   |                    |
| • ACTIVITIES RELATED TO Q-LIST ITEMS  | INCLUDED   | INCLUDED                                   | —  | —   | —   | —  | —   |                    |
| • ITEMS AND ACTIVITIES RELATED TO EVALUATING ALTERNATIVE SOLUTIONS, MATERIALS OR CONCEPTUAL DESIGNS PRIOR TO FINAL SELECTION FOR USE IN THE REPOSITORY                            | NOT MENTIONED  | INCLUDED                                   | —  | —   | —   | —  | —   |                    |
| • BUILD-TO-PRINT ITEMS  | —  | —  | —  | —   | INCLUDED  | —  | —   |                    |
| • ROUTINE TESTS   | —  | —  | —  | —   | INCLUDED  | —  | —   |                    |
| • COMMERCIALY AVAILABLE HARDWARE  | —  | —  | —  | —   | —   | INCLUDED   | INCLUDED  |                    |
| • PURELY DEVELOPMENTAL ACTIVITIES   | —  | —  | —  | —   | —   | INCLUDED   | INCLUDED  |                    |

## MATRIX COMPARISON OF 3-LEVEL AND 4-LEVEL QUALITY PROGRAMS

| CONSIDERATION<br>FACTORS | 3-LEVEL PROGRAM<br>(NNWSI)  | 4-LEVEL PROGRAM<br>(DOE/OCR)  | NOTES  |
|--------------------------|---|---|--|
| OTHER PROGRAM FEATURES   | <ol style="list-style-type: none"> <li>1. WHEN ASSIGNING QUALITY LEVELS, EACH ITEM OR ACTIVITY IS TO BE SUBDIVIDED INTO SMALLER ITEMS OR ACTIVITIES. IF AN ITEM IS ASSIGNED A QA LEVEL WITHOUT FURTHER SUBDIVISION, ALL OF ITS SUBPARTS WILL HAVE THE SAME QA LEVEL.</li> <li>2. ALL ACTIVITIES REQUIRED TO OBTAIN AN ITEM WILL HAVE THE SAME LEVEL OF QA AS THE ITEM.</li> <li>3. ACTIVITIES CONTROLLED IN ACCORDANCE WITH A QUALITY LEVEL N PROGRAM CANNOT SUBSEQUENTLY BE USED TO SUPPORT LEVEL I ACTIVITIES, UNLESS IT CAN BE SUBSTANTIATED THAT THE QUALITY REQUIREMENTS EQUIVALENT TO THOSE WHICH HAVE BEEN APPLIED TO A QUALITY LEVEL I ACTIVITY WERE IMPLEMENTED, OR A TECHNICAL JUSTIFICATION IS APPLIED.</li> <li>4. ACTIVITIES CONTROLLED IN ACCORDANCE WITH A QUALITY LEVEL M PROGRAM CANNOT SUBSEQUENTLY BE USED TO SUPPORT LEVEL I ACTIVITIES.</li> <li>5. IN THE QUALITY LEVEL R EVALUATION, WHICH OF THE 16 POINT CRITERIA WILL APPLY TO AN ITEM OR ACTIVITY WILL BE RECORDED.</li> </ol> | <ol style="list-style-type: none"> <li>1. SUBJECT TO THE REQUIREMENT BELOW, THE DEPTH OF COVERAGE AND COMPREHENSIVENESS OF A QUALITY PROGRAM REQUIREMENT WITHIN A QUALITY LEVEL MAY BE INCREASED OR DECREASED AS DEEMED NECESSARY TO ASSURE QUALITY OF AN ITEM OR ACTIVITY.</li> <li>2. WRITTEN JUSTIFICATION MUST BE PROVIDED FOR ANY CASE WHERE ANY OF THE NQA-1 BASIC REQUIREMENTS, SUPPLEMENTARY REQUIREMENTS, APPENDICES AND/OR QA CRITERIA OF 19 CFR 19 APPENDIX B, OR OTHER REQUIREMENTS, IDENTIFIED AS BEING MANDATORY FOR A CERTAIN QUALITY LEVEL, ARE NOT INCLUDED IN THE ACTUAL QUALITY REQUIREMENTS ESTABLISHED FOR AN ITEM OR ACTIVITY.</li> </ol> | <ol style="list-style-type: none"> <li>A. THE REQUIREMENTS OF NQA-1 WERE MODIFIED BY APPENDIX C OF NNWSI QA PLAN, NVO-196-17, FOR PROGRAM LEVEL 1 CONSIDERATIONS. SOME OF THE MODIFICATIONS INCLUDED HAVE SPECIFIC PROVISIONS OF APPENDICES 2A-1, 2A-2, 2A-1, AND 17A-1 ADDED TO THE SUPPLEMENTARY REQUIREMENTS.</li> <li>B. THE DOE/OCR QUALITY REQUIREMENTS ARE PLANNED TO BE MADE INTEGRAL PART OF THE OCR QA PLAN. IT IS THUS PRESUMED THAT NNWSI WILL HAVE TO COMPLY WITH THESE REQUIREMENTS.</li> <li>C. IN THE DOE/OCR PROGRAM LEVEL 2, THE NQA-1 SUPPLEMENTARY REQUIREMENTS INCLUDED ARE:<br/> 25-3, QUALIFICATION OF QA PROGRAM AUDIT PERSONNEL<br/> 35-1, DESIGN CONTROL<br/> 75-1, CONTROL OF PURCHASED ITEMS AND SERVICES<br/> 105-1, INSPECTION<br/> 175-1, QA RECORDS, AND<br/> 185-1, AUDITS</li> <li>D. THE DOE/OCR QUALITY REQUIREMENTS NOT INCLUDED IN PROGRAM LEVEL 2 ARE<br/> <ul style="list-style-type: none"> <li>• MANAGEMENT ASSESSMENT</li> <li>• TECHNICAL AND PEER REVIEWS</li> <li>• CONFIGURATION MANAGEMENT</li> </ul> </li> <li>E. IN DOE/OCR PROGRAM LEVEL 3 THE NQA-1 BASIC REQUIREMENTS NOT INCLUDED ARE<br/> 1-ORGANIZATION      16-CORRECTIVE ACTION<br/> 3-DESIGN CONTROL      18-AUDITS</li> <li>F. THE DOE/OCR QUALITY REQUIREMENT STILL CALLED FOR IN DOE/OCR PROGRAM LEVEL 3 IS "REPORTING AND SUBMITTALS".</li> </ol> |

United States Government

Department of Energy

# memorandum

DATE NOV 8 1985  
REPLY TO  
ATTN OF RW-24  
SUBJECT Project Review of Revised Q-List Methodology and Graded QA

TO: Jeff Neff  
Sally Mann  
Lee Olson  
Don Vieth

The documents describing the Q-List Methodology and graded approach to QA have been revised and combined into a single document, "Methodology for Formulating a Q-List and for Applying Graded Quality Assurance to Mined Geologic Disposal Systems". Five copies of this document were sent via overnight mail delivery on Friday, November 8, 1985. I am asking that you give the highest priority possible to performing an expedited review of this document. It is necessary that we furnish an agreed-upon document to NRC by November 20, so that NRC will have time to review it before the December 4-5 meeting. Accordingly, I need your comments no later than November 14.

The Q-List Methodology set forth in this document is responsive to the comments we received from NRC at our July 1, 1985 meeting with them on this topic. It also incorporates the agreements reached in the meeting with your representatives which was held here at HQ on October 1, 1985.

The graded approach to QA set forth in this document was formulated by the task group comprised of representatives from all projects that met here the week of October 7, 1985. This graded approach to QA was also discussed at the October 22-23, 1985 meeting of the Quality Assurance Coordinating Group.

Thus we feel that representatives from your project are familiar with most of the material in this document and hope this will make possible the expedited review that I am requesting. I would appreciate receiving your concurrence with the approaches set forth in this document by November 14, or, in the event you cannot endorse the approaches presented, a description of the changes that you are suggesting. Carl Newton will be telephoning you on November 14 for your concurrence and/or comments.

ACTION Blaylock  
C: VIETH  
C: \_\_\_\_\_  
CC: \_\_\_\_\_  
CC: \_\_\_\_\_

Please contact Carl Newton if you have any questions about this request.

  
Ralph Stein, Acting Director  
Licensing and Regulatory Division



November 7, 1985

TO: Don Vieth, WMPO  
Jeff Neff, SRPO  
Lee Olson, BWIP  
Sally Mann, CRPO

FROM: Carl Newton, DOE/HQ

*Carl Newton*

Copies of the revised DOE report "Methodology for Formulating a Q-List and for Applying Graded Quality Assurance to Mined Geologic Disposal Systems," have just been received by DOE/HQ from Weston and are being furnished to each project in advance of the DOE/HQ review. In the event DOE/HQ does approve the report, you will be requested to perform an expedited review. We expect to notify you of the HQ decision on Friday, November 8, 1985.