Department of Energy
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JUL 09 1987

Distribution: Linehan, Hoest., Still, RDM, Waster, Kennedy, Dellisanti, Donnelly, Riddle
(Return to WM, 623-SS)

Enclosures are voluminous

Those on Attached List

Ladies and Gentlemen:

BRIEFING ON THE PARTIAL LIFTING OF THE STOP WORK ORDER JUNE 4, 1987

During the June 4, 1987, briefing on the partial lifting of the Stop Work Order, the Department of Energy (DOE) committed to provide additional information regarding the Q-List development and the Graded Quality Level process.

In accordance with the commitment, enclosed are the following documents:

1. OGR QA Plan Supplements 3 and 8 (DOE OGR/B-3)
2. Guidance for developing the SCP-CDR and SCP Q-List (Weston, April 1986)
3. Responses to July 1986, SCP Q-List Methodology Workshop (March 26, 1987)
4. QA Program Requirements Manual-Section E (Rockwell QA-MA-3)
5. Project Directive - Q-List Task Force (Rockwell PD 86-011)
6. Procedure - Graded Quality Assurance (Rockwell PMPM 4-121)
7. Preliminary Q-List (SD-BWI-TA-025)
8. Example of Quality Level Grading Reports (DC 24/25)

We would like to point out that the Project developed Q-List is preliminary and is in the process of being revised to incorporate requirements from the Q-List workshop (item 3 above), as well as comments provided by reviewers of the document. Also, the Graded Quality Assurance procedure, based on the procedure being implemented a limited number of times, is being reviewed for improvements based on the experience gained.

If you desire a meeting to discuss the Q-List and/or the Graded Quality Level Program after reviewing the enclosed documents, please contact Mr. O. L. Olson of my staff on 376-7591.

Sincerely,

O. L. Olson

for John H. Anttonen, Assistant Manager
for Commercial Nuclear Waste

QSD:CKK

Enclosures SEE FILE JACKET

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SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

SUPPLEMENT No. 8

APPLICATION OF GRADED QUALITY ASSURANCE

JULY, 1986

U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Office of Geologic Repositories

SUPPLEMENTAL QA REQUIREMENTS

APPLICATION OF GRADED QUALITY ASSURANCE

1.0 GENERAL

This Supplement provides amplified requirements for the application of graded quality assurance. It supplements the OGR QA Plan and ANSI/ASME NQA-1-1983 (Basic Requirement 2). The requirements in this Supplement are to be used in conjunction with the requirements specified or referenced in the governing QA plans and procedures.

2.0 PURPOSE

The purpose of this Supplement is to specify requirements for the application of graded quality assurance to mined geologic disposal systems.

3.0 SCOPE

The requirements of this Supplement are applicable (as defined herein) to all items and activities required during geologic repository site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, decommissioning and dismantling of surface facilities.

The purpose of a graded QA program is to select the quality assurance requirements and measures to be applied to items and activities in the Repository Program consistent with their importance to safety, waste isolation, and the achievement of DOE mission objectives. This will be accomplished by deliberate quality planning and selective application of QA requirements on the item or activity to be performed, with varying degrees of quality assurance applied depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations.

This approach involves identifying those items and activities whose failure could cause undue risks to the public and facility personnel and/or extended interruption of facility operation with critical economic losses, and ensuring that these items and activities are covered by a commensurate quality assurance program. On the other hand, an item whose failure or malfunction could result only in operational inconvenience or negligible economic loss may deserve only a quality inspection by the purchaser upon delivery of the item. Between these two extremes, there are varying degrees of quality assurance to achieve the desired confidence in the quality of the completed item or activity.

The graded approach set forth here provides flexibility in the selection of the level of the quality assurance program to be applied to an item or activity that is commensurate with the relative importance of the role or function assigned to the item or activity.

4.0 DEFINITIONS

4.1 Quality Level 1 — The highest quality level available for assignment on geologic repository projects. This level is assigned to Q-list items and activities and requires a comprehensive quality assurance program for compliance with applicable requirements.

4.2 Quality Level 2 — The intermediate quality level available for assignment on geologic repository projects. This level is assigned to items and activities with importance to DOE mission objectives. It requires a quality assurance program for compliance with applicable requirements that are less extensive than for Quality Level 1.

4.3 Quality Level 3 — The lowest quality level available for assignment on geologic repository projects. This level is assigned to all items and activities included in the QA program but are not assigned Quality Levels 1 or 2. It requires good management, engineering, or laboratory work practices for compliance with quality assurance requirements.

5.0 REQUIREMENTS

The requirements specified in this Supplement are to be used in conjunction with the requirements embodied in the governing documents identified in the OGR QA Plan.

Attachment A provides a matrix of QA program requirements and indicates their applicability to Quality Levels. Attachment A also provides brief descriptions of selected requirements from the various governing documents.

5.1 Selection of Quality Level and QA Requirements

The appropriate Quality Level for any item or activity shall be determined by the application of decision criteria such as shown in Attachment A. The criteria shown in Attachment B is for guidance only. The actual decision criteria to be used to determine Quality Levels and assign QA requirements to each item or activity shall be defined and documented by each project. The basis for the selection of the Quality Level and assigned QA requirements shall also be documented.

5.1.1 Selection of Specific QA Requirements to be Applied Within a Quality Level

Once a quality level is selected, the appropriate QA criteria/requirements (See Attachment A) shall be applied. Further grading beyond the selection of the quality level shall be undertaken to select the criteria/requirements to be applied to specific items and activities. This shall be accomplished by technical and quality system personnel working as teams to evaluate the scope and type of work involved and other factors as appropriate that may influence the selection of those criteria/requirements that are necessary and sufficient.

The scope of work involved in completing an item or activity may be further divided into sub-elements and the criteria/requirements contained in Attachment A evaluated for application to these sub-elements.

For example, one Quality Level 1 (Q-List) item may involve an engineered piece of equipment that is very complex to design and manufacture which calls for special design controls, verification, and development tests in addition to special controls during manufacture. Thus, it may be subject to all the requirements, supplements, appendices, and other requirements set forth in Attachment A for Quality Level 1. On the other hand, another Quality Level 1 Q-List item may actually be a commercial off-the-shelf item that has a proven design, is easy to build, has a good quality history, and is well within the state-of-the-art. The appropriate quality program requirements for this second example should rightly be less than the first example involving the newly engineered piece of equipment, and several of the criteria/requirements listed in Attachment A may properly and appropriately be omitted.

Additional guidance for determining appropriate QA requirements is provided in NQA-1, Appendix 4A-1.

5.1.2 Grading Within a QA Requirement

Grading of the QA requirements shall also be accomplished within individual, applicable criteria/requirements. The depth of coverage and comprehensiveness of individual QA criteria/requirements shall be additionally increased, decreased, or modified as deemed necessary for each item or activity. The technical and quality assurance system personnel, working as a team, shall evaluate each item or activity to determine the appropriate measures necessary for compliance with each applicable criterion/requirement.

Factors to be considered in making this determination include: complexity of design or fabrication; uniqueness of the item or activity; the need for controls over special processes or tests; ability to demonstrate functional compliance by inspection or test; and the quality history of the item or activity.

For example, NQA-1 Basic Requirement 10, Supplement 10S-1, and Appendix B criterion 10 may all apply to sealing a repository shaft and welding a shaft liner. Both processes require inspections to verify conformance with design requirements. As it may be difficult to verify that the shaft sealing has been properly performed after placement, continuous surveillance may be appropriate. Conversly, welding is normally verified after completion and only normal examinations and inspections of completed weldments may be necessary.

5.2 Justification for Deviations

Written justification shall be provided for deviations from NQA-1 basic requirements, supplementary requirements, appendices, and/or QA criteria of 10 CFR 50, Appendix B, or other requirements, specified in Attachment A as being necessary and sufficient for a certain quality level. The term "deviation" as used here means the deletion, addition, or modification of any requirement listed in Attachment A. Deviations may be additions of specified requirements, deletions of specified requirements, or modifications to the specified requirements. The written justification for additions is necessary to support and explain the basis for the additional QA requirements and thus justify the corresponding additional cost and effort.

For special items and activities, such as potential Q-list items and activities that HQ-OGR has specified QA requirements for, the written justification may consist of a reference to the HQ-OGR direction.

5.3 Quality Levels

Graded QA shall be applied to all items and activities covered under the QA program. The applicable quality level will depend upon the item or activity being in the Q-List or its relative importance to the achievement of DOE program objectives other than regulatory licensing. Each item or activity shall be assigned to one of the following quality levels:

- o Quality Level 1
- o Quality Level 2
- o Quality Level 3

These quality levels, presented in descending order, have decreasing scope of QA program criteria/requirements. This is evident in the matrix comparison of quality levels shown in Attachment A.

A description of each quality level and guidance for application of each level follows.

5.3.1 Quality Level 1

5.3.1.1 Description

This is the highest quality level available and requires the responsible organization to implement a comprehensive quality assurance program. Quality Level 1 programs require quality planning; preparation of a QA Manual/Plan and supporting administrative and technical procedures; adherence to procedures and drawings; personnel qualification and training programs; documentation of activities performed and results obtained; and comprehensive review, inspection, management assessment, verification, surveillance, and auditing activities.

Quality Level 1 programs for Q-List items and activities shall meet the criteria/requirements listed in Attachment A for Quality Level 1 as a minimum, unless appropriate written justification for any deviation is provided as required in Paragraph 4.2.4. Other specific requirements that are unique to the item or activity may be specified during the quality level selection process. Certain items and activities with potential for inclusion on the Q-list may be identified and/or directed by HQ-OGR to be treated as a Quality Level 1.

5.3.1.2 Application

Quality Level 1 shall be applied to all items which have been identified as important to safety or waste isolation (Q-List items). Activities covered under Quality Level 1 include: site selecting, designing, fabricating, purchasing, handling, shipping, storing, cleaning, erecting, installing, emplacing, inspecting, testing, operating, maintaining, monitoring, repairing, modifying, decommissioning, and site characterization.

5.3.2 Quality Level 2

5.3.2.1 Description

This is the second highest level available for assignment to items and activities on geologic repository projects. Responsible organizations are required to implement quality assurance programs. A QA manual/plan and supporting procedures are required. The same basic NQA-1 QA requirements that apply to Quality Level 1 also apply to Quality Level 2. However, 10 CFR 50, Appendix B and the NRC QA Review Plan do not apply to Quality Level 2. Fewer NQA-1 supplemental requirements apply to Level 2 with corresponding reductions in QA controls.

Quality Level 2 programs shall meet the criteria/requirements listed in Attachment A for Quality Level 2, as a minimum, unless appropriate written justification for any deviation is provided as required in Paragraph 4.2.4. Other specific requirements that are unique to the item or activity may be specified during the quality level selection process.

5.3.2.2 Application

Quality Level 2 shall be applied to those items or activities which are not Q-List items but which are of major importance to the attainment of DOE programmatic objectives. Quality Level 2 is also to be applied to items and activities that have potential impact on public and occupational radiological health and safety under 10 CFR 20, and to items involving a significant number of field and laboratory investigations, and complex manufacturing, assembly, and construction processes.

5.3.3 Quality Level 3

5.3.3.1 Description

This is the lowest quality level available for assignment and does not require the responsible organization to implement a formal quality assurance program. However, Quality Level 3 items and activities may be required to meet appropriate quality and administrative requirements as determined on a case-by-case basis. The quality requirements to be met for each item or activity, including any required documentation, shall be identified and justified as described in 5.2 above Quality Level 3 items and activities generally require the use of good management, engineering or laboratory work practices to prepare them for their intended use.

5.3.3.2 Application

Quality Level 3 shall be applied to those items and activities which are not Levels 1 or 2. This quality level shall be applied to items that can be inspected for acceptance upon completion or delivery, or to activities that can be accepted by evaluation of a final report. The quality requirements of subpart 46.202-1 of the Federal Acquisition Regulations, which require that the Contractor perform an inspection, are applicable to Level 3 activities. When deemed appropriate, the requirement to obtain a "Certificate of Conformance" from the supplier may be invoked.

Typical items and activities that shall be covered by this quality level include the following:

(a) Items which are noncomplex and are normally considered commercially available standard hardware.

(b) Activities which are routine or purely developmental in nature and will not produce data or results which will be used for design, environmental, or licensing applications.

5.4 Project Procedures

Each Project Office shall develop a Project Specific Procedure for the application of graded QA. The procedure shall be in consonance with the QA program requirements specified herein and shall be submitted to Headquarters OGR for approval.

GRADED QUALITY PROGRAM REQUIREMENT MATRIX

Quality Program Requirements	Quality Level 1	2	3*
NQA-1 BASIC REQUIREMENTS			
. Organization	X	X	-
. Quality Assurance Program	X	X	-
. Design Control	X	X	-
. Procurement Document Control	X	X	-
. Instructions, Procedures, and Drawings	X	X	-
. Document Control	X	X	-
. Control of Purchased Items and Services	X	X	-
. Identification and Control of Items	X	X	-
. Control of Processes	X	X	-
0. Inspection	X	X	-
1. Test Control	X	X	-
2. Control of Measuring and Test Equipment	X	X	-
3. Handling, Storage, and Shipping	X	X	-
4. Inspection, Test, and Operating Status	X	X	-
5. Control of Nonconforming Items	X	X	-
6. Corrective Action	X	X	-
7. Quality Assurance Records	X	X	-
8. Audits	X	X	-
10 CFR 50 APPENDIX B 18 QA CRITERIA	X		
NRC QA REVIEW PLAN	X		

Quality Program Requirements	Quality Level 1	2	3*
NQA-1 SUPPLEMENTS			
S-1 Terms and Definitions	X	X	-
1S-1 Organization	X	-	-
2S-1 Qualification of Inspection and Test Personnel	X	-	-
2S-2 Qualification of Nondestructive Examination Personnel	X	-	-
2S-3 Qualification of Quality Assurance Program Audit Personnel	X	X	-
3S-1 Design Control	X	X	-
4S-1 Procurement Document Control	X	-	-
6S-1 Document Control	X	-	-
7S-1 Control of Purchased Items and Services	X	X	-
8S-1 Identification and Control of Items	X	-	-
9S-1 Control of Processes	X	-	-
10S-1 Inspection	X	X	-
11S-1 Test Control	X	-	-
12S-1 Control of Measuring and Test Equipment	X	-	-
13S-1 Handling, Storage, and Shipping	X	-	-
15S-1 Control of Nonconforming Items	X	-	-
17S-1 Quality Assurance Records	X	X	-
18S-1 Audits	X	X	-

*Quality program requirements for Level 3 will be developed on a case-by-case basis.

GRADED QUALITY PROGRAM REQUIREMENT MATRIX

Quality Program Requirements	Quality Level 1	2	3*
NQA-1 APPENDICIES			
1A-1 Organization	-	-	-
2A-1 Qualification of Inspection and Test Personnel	X	-	-
2A-2 Quality Assurance Programs	-	-	-
2A-3 Education and Experience of Lead Auditors	-	-	-
3A-1 Design Control	-	-	-
4A-1 Procurement Document Control	-	-	-
7A-1 Control of Purchased Items and Services	-	-	-
17A-1 Quality Assurance Records	-	-	-
18A-1 Audits	-	-	-
OGR QA PLAN SUPPLEMENTS			
S-1 Qualification of Personnel Performing and Verifying activities Affecting Quality	X	X	-
S-2 Overview of Quality Assurance Activities	X	X	-
S-3 Q-list Methodology	X	X	-
S-4 Quality Assurance Records	X	X	-
S-5 QA for (R&D) Experiments	X	X	-
S-6 (Reserved)			
S-7 Peer Review	X	X	-
S-8 Graded QA	X	X	-
S-9 Reliability of Data	X	X	-
S-10 (Reserved for Waste Form)			

Quality Program Requirements	Quality Level 1	2	3*
OTHER REQUIREMENTS			
Activity Planning	X		
Management Assessment	X		
Personnel Qualification and Certification	X		
Technical & Peer Reviews	X		
Trend Analysis	X		
Unusual Occurrence Reporting	X	X	
Software Control	X		
Sample Handling	X		
Configuration Control	X		
Reporting & Submittals	X	X	

(Note: See descriptions of the above requirements on page 3 and 4 of this Attachment)

* Quality program requirements for Level 3 will be developed on a case-by-case basis.

REFERENCE	
NRC Review Plan Para. 2.5	1. Activity Planning - Requires application of a graded approach commensurate with importance of work activities. Plans shall be developed and documented to describe how the activities shall be performed, the results expected, the major milestones, and other procedures to be used.
NRC Review Plan Para. 2.7	2. Management Assessment - Applies to performance of annual management assessments to determine the scope, status, adequacy, and effectiveness of the QA program.
NRC Review Plan Para. 2.8 DOE/OGR Quality Program Requirements	3. Personnel Qualification and Certification - Requires that personnel who perform quality-related activities be properly trained, indoctrinated and qualified. Personnel shall receive training in technical and quality assurance procedures. Management is required to monitor the performance of individuals involved in activities affecting quality and determine the need for retraining and/or replacement.
NRC Review Plan Para. 3.8	4. Technical and Peer Reviews - Requires and defines peer reviews and when they should be accomplished.
NRC Review Plan Para. 15.4 Para. 18.4	5. Trend Analysis - Requires that non-conformance reports be periodically analyzed to indicate quality trends and to help identify root causes of nonconformances. Results are to be reported to upper management for review and assessment.
DOE Order 5000.3	6. Unusual Occurrence Reporting - Requires that contractors report any significant event which results in any deviation from the planned or expected behavior of an activity or operation of course of events which has or could have significant programmatic, (reliability, cost, or schedule) safety, health, or environmental impacts. Significant events are to be reported in accordance with DOE Order 5000.3.
NRC Review Plan Para. 2.2	7. Software Control - Detailed computer software quality assurance requirements which include validation, verification, code custodial and transfer requirements, and conformance with NUREG-0856.

OTHER REQUIREMENTS DESCRIPTIONS

REFERENCE	
NRC Review Plan Para. 8.3 Para. 13.1, 13.2	8. Sample Handling - Requires that samples of geological media (rock, core, soil, etc.) be shipped, handled and stored in accordance with special procedures that describe the control of the activities related to handling of samples.
DOE/OGR Quality Program Requirements	9. Reporting and Submittals - Identifies the types and frequency of reports to be submitted to the OGR.
NRC Review Plan Para. 3.10	10. Configuration Control - Requires that a configuration system be established at the earliest practical time to assure that design changes are analyzed and properly identified and documented.

DECISION CRITERIA FOR DETERMINING QUALITY LEVELS OF ITEMS AND ACTIVITIES (FOR GUIDANCE ONLY)

CATEGORIES OF STATEMENTS OF WORK (SOW)	QUALITY LEVEL 1	2	3
1. ITEMS (HARDWARE)			
A. PUBLIC HEALTH AND SAFETY CONSIDERATIONS			
o Is the item on the Q-List?	X		
B. DOE PROGRAMMATIC OBJECTIVES CONSIDERATIONS			
o Is the item intended to control radiation exposure or release levels and/or effluent radioactivity within the limits prescribed in 10 CFR Part 20?		X	
o Failure or malfunction of the item could or potentially cause cost or schedule impact on DOE mission objectives	To be evaluated at the Project Level		
C. WORKER HEALTH AND SAFETY CONSIDERATIONS			
o Failure or malfunction of the item could have potential impact on the radiological or non-radiological health and safety of the workers		X	
D. LEAD TIME AND COST CONSIDERATIONS			
o Does procurement of the item involve long lead time and/or is the item extremely costly?	X		

CATEGORIES OF SOW'S	QUALITY LEVEL 1	2	3
1. ITEMS (HARDWARE) CONDT			
E. ASME - BPVC APPLICABILITY CONSIDERATIONS			
o Section III applies	(Quality		
o Section VIII applies	Level to be		
	Determined		
	by Projects)		
2. ACTIVITIES			
A. COMPUTER SOFTWARE MODELING/DEVELOPMENT			
1. Are the computer models used to support an item on the Q-List?	X		
2. Do the computer models and codes supply data to support a licensing decision such as performance assessment?	X		
3. Are the computer models complex and require review by peers or technical reviews?	X		
4. Does the work support critical DOE mission documents such as EA's, RCR's, AAR's, etc.		X	
5. If the collected data or records were lost/discarded or of indeterminate quality repetition or schedular delay would be required:		X	
6. Is the computer program only utilized for data sorting, collation, etc.			X

CATEGORIES OF SOW'S	QUALITY LEVEL 1	2	3
2. ACTIVITIES CONTD.			
B. FIELD TESTING, DATA ACQUISITION, DATA ANALYSIS, AND REPORTS			
1. Is the data utilized to support an engineering design criterion for a Q-List item?	X		
2. Do the data support a major licensing document?	X		
3. Will the data become part of the technical data base needed to support licensing?	X		
4. Does the work provide input to critical DOE mission documents such as EA's, RCR's, AAR's, etc.		X	
5. If the collected data or records were lost/discarded or of indeterminate quality repetition or schedular delay would be required		X	
C. STORAGE OF RECORDS/SAMPLES			
1. Do records/samples support licensing activities?	X		
2. Do records/samples support items on the Q-List items?	X		
3. Do records/samples support critical DOE mission documents?		X	

CATEGORIES OF SOW'S	QUALITY LEVEL 1	2	3
2. ACTIVITIES CONTD.			
4. If the collected data or records/samples were lost/discarded or of indeterminate quality repetition or schedular delay would be required		X	
D. HISTORICAL OR BACKGROUND STUDIES AND REPORTS			
1. Will the information produced be utilized in a licensing document?	X		
2. Do the studies support a computer model or design criterion for a Q-List item?	X		
3. Does the work support critical DOE mission documents such as EA's, RCR's, AAR's, etc.		X	
4. If the collected data or records were lost/discarded or of indeterminate quality repetition or schedular delay would be required		X	
E. ENVIRONMENTAL/SOCIOECONOMIC STUDIES AND REPORTS			
1. Do the reports or studies provide critical information to support requirements of NWPA 1982?	X		
2. Will the reports or studies be used for major portions of a licensing document?	X		
3. Does the work support DOE mission documents such as EA's, RCR's, AAR's, etc.		X	

CATEGORIES OF SOW'S	QUALITY LEVEL 1	2	3
2. ACTIVITIES CONTD.			
4. If the collected data or records were lost/discarded or of indeterminate quality repetition or schedular delay would be required		X	
F. LABORATORY EXPERIMENTAL (SCOPING) OR TESTING/ANALYSIS AND REPORTS			
1. Will the data results be utilized to support licensing activities?	X		
2. Does the experimental testing provide analytical data to support functional design bases?	X		
3. If the collected data or records were lost/discarded or of indeterminate quality repetition or schedular delay would be required		X	
4. Is the experiment only to prove whether a theory will work? (Scoping)			X
G. CONSTRUCTION/MANUFACTURING ACTIVITIES			
1. Is the construction/manufacturing activity supporting a Q-List structure system or component?	X		

CATEGORIES OF SOW'S	QUALITY LEVEL 1	2	3
2. ACTIVITIES CONTD.			
G. CONSTRUCTION/MANUFACTURING ACTIVITIES CONDT			
2. Is the activity intended to control radiation exposure or release levels and/or effluent radioactivity within the limited prescribed in 10 CFR Part 20?		X	
3. Is the construction/manufacturing activity supporting a highly critical item with a high cost of repair or replacement?		X	
4. Is the system important for reliability?		X	

SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

METHODOLOGY FOR FORMULATING A Q-LIST

1.0 GENERAL

This Supplement provides amplified requirements for formulating a Q-List. It supplements the OGR QA Plan and ANSI/ASME NQA-1-1983 (Basic Requirement 2). The requirements in this Supplement are to be used in conjunction with the requirements embodied or referenced in the governing QA plans and procedures.

2.0 PURPOSE

The purpose of this Supplement is to specify requirements for formulating a Q-List for geologic repository projects.

3.0 SCOPE

The requirements of this Supplement are applicable to the methodology for identifying structures, systems, components, and activities that are important to safety and/or waste isolation for the mined geologic disposal system (MGDS).

4.0 DEFINITIONS

4.1 Q-List - A list of geologic repository structures, systems, components, and activities that have been determined to be important to safety and/or waste isolation and are thereby subject to the highest quality level (Quality Level 1) of the formal QA program.

5.0 REQUIREMENTS

Each geologic repository project shall prepare a procedure(s) for determining the items and activities to be placed on the project Q-List. Attachment A is a guideline for a methodology for formulating a Q-List.

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Attachment A

METHODOLOGY FOR FORMULATING A Q-LIST FOR MINED GEOLOGIC DISPOSAL SYSTEMS

May 1986

U.S. Department of Energy
Office of Civilian Radioactive Waste Management

TABLE OF CONTENTS

1.0 SUMMARY

This attachment describes a general philosophy to be used by DOE projects in determining the structures, systems, components and activities that are important to safety and waste isolation for the mined geologic disposal system (MGDS). The resulting list of structures, systems, components and activities which are important to safety and waste isolation is called the "quality list" or "Q-List". The items and activities on the list will be subject to the highest quality level, Quality Level 1, of a formal quality assurance (QA) program as required for site characterization and licensing of the geologic repository. As such, only these Q-List items and activities will be subject to NRC licensing review and oversight. NRC may examine any item or activity not in the Q-List to assure that no items or activities important to safety or waste isolation have been omitted from the Q-List. This is consistent with NRC's philosophy as set forth in a "Preliminary Draft NRC 'Q-List' Positions" paper, which states in part as follows:

> "For items and activities which are neither important to safety not 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.
>
> For all other items and activities supporting the development of a repository, DOE may apply QA programs based on realibility, 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."

The QA requirements and application of Quality Level 1 to Q-List items and activities are discussed in QA Supplement #8.

The Q-List will change over time with a final list emerging at the completion of NRC's review of DOE's license application. During the evolutionary period, two milestones stand out: (1) the Q-List to support the Site Characterization Plan (SCP) data gathering and design efforts and (2) the Q-List to support the License Application (LA) design stage. The methodology to generate the SCP stage Q-List is based primarily on engineering judgment and is described in Section 3.1 of this Supplement. As site characterization and design activities progress to the point of allowing quantification of key input parameters, the LA design stage methodology described in Section 3.2 will be followed.

This Supplement does not apply to the Monitored Retrievable Storage (MRS) facility or the safety-related aspects of the Transportation Subsystem.

The term "safety" as used in this document refers to preclosure radiological safety for members of the public, and "waste isolation" refers to postclosure control of radionuclides.

2.0 INTRODUCTION

The Mined Geologic Disposal System (MGDS) of the DOE Office of Civilian Radioactive Waste Management (OCRWM) encompasses structures, systems, and components. Those structures, systems, components, and activities which are important to the radiological safety of the public or to the control of the isolated waste are identified on the Q-List. The activities that are involved in the design, fabrication, testing, installation, and operation of these items, and in the characterization of the repository sites, will be performed in accordance with QA procedures corresponding to Quality Level 1. All items and activities are covered by a QA progam in which the requirements are graded, or varied, according to the importance of the item or activity to safety, waste isolation, or the accomplishment of DOE Mission objectives. Section 3 of this report addresses the criteria and methodologies used for identifying whether or not a given item or activity is placed on the Q-List and assigned to Quality Level 1. The graded approach to QA is discussed in a separate QA supplement (Supplement #8). Three levels of quality are defined and a methodology for grading within each level is set forth. This methodology requires that Q-List items and activities be assigned to Quality Level 1 and permits assignment to Quality Level 1.

3.0 ITEMS IMPORTANT TO SAFETY AND WASTE ISOLATION

3.1 DETERMINATION OF Q-LIST ITEMS FOR SCP DESIGN STAGE

3.1.1 ITEMS IMPORTANT TO SAFETY AT SCP DESIGN STAGE

Structures, systems, components, and activities that are important to safety are defined by the NRC in 10 CFR 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories," 60.2, as:

> "those engineered structures, systems and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, or 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure."

An equivalent statement used by the NRC in its draft "Generic Technical Position on Licensing Assessment Methodology for High-Level Waste Geologic Repositories" (USNRC-7/84), is

> "... structures, systems, and components are important to safety if, in the event they fail to perform their intended function, an accident could result which causes a dose commitment greater than 0.5 rem to the whole body or any organ of an individual in an unrestricted area."

Items important to safety must be on the Q-List to ensure that the design addresses their safety requirements and that appropriate QA controls are applied. Central to the above NRC definitions is the dose consequence of the failure of the items. The assessment of the dose consequences of the failure of structures, systems, or components, however, requires a detailed assessment of their functions under design basis conditions which are not available until (1) the design effort attains a certain maturity, (2) design basis conditions are identified, and (3) the analytical assumptions to be employed during safety analysis are established. Prior to that tine, the methodology which the DOE employs will be based on engineering judgment and is described herein. The methodology for the LA design phase (i.e., the mature design) is described in Section 3.2.

The NRC's definition of "important to safety" contains a criterion for assigning an item to the Q-List: whether the item can prevent or mitigate an accident that could result in a dose in the uncontrolled area of 0.5 rem or greater. Another criterion may be inferred from the definition, although not explicitly states: a determination that the accident scenario is credible. The term "credible accident" as used here implies that the accident has an overall probability of occurrence which is smaller than the probability for anticipated operational events but yet not so small as to be considered insignificant or incredible. The quantitative limit below which an event ceases to be considered credible is not identified in 10 CFR 60. For purposes of identifying structures, systems, components and activities to be placed on the Q-List, the DOE will disregard any scenarios which would have an annual probability of 1×10^{-5} or less. The probability of incurring a health effect from a one rem whole body exposure is approximately 1×10^{-4}*. The combined annual probability of incurring a health effect among the off-site population

is therefore less than $1x10^{-9}$ from a failure whose probability is $1x10^{-5}$ or less per year which could result in an off-site dose of 0.5 rem. This risk is significantly smaller than "risks that would be regarded as negligible by the exposed individuals", ** which are on the order of $1x10^{-6}$ health effects per year.

The dose consequence estimate should be based on a radiation transport model which uses conservatively estimated parameters where design and site details are lacking. One such model is set forth in NRC Regulatory Guide 1.25, "Assumptions Used for Evaluating the Potential Radiological Consequence of a Fuel Handling Accident in the Fuel Handling and Storage Facility for Boiling and Pressurized Waste Reactors".

To summarize, the Q-List at the SCP Design stage shall be comprised of the structures, systems, components, and activities essential to the prevention or mitigation of any scenario with probability of occurrence of $1x10^{-5}$ or greater and dose consequences exceeding 500 mrem.

3.1.2 ITEMS IMPORTANT TO WASTE ISOLATION AT SCP DESIGN STAGE

From 10 CFk 60.2, it may be inferred that structures, systems, and components important to waste isolation would be those natural and engineered barriers which are relied upon to inhibit ".... the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits." These items must function in a certain way in order to meet the long-term isolation objective after repository closure.

In 10 CFR 60, paragraph 60.113, the NRC has defined performance objectives for the repository after closure. the four performance objectives are related to the following performance measures:

- Waste package containment time
- rate of release of radionuclides from the engineered barrier system
- preemplacement ground-water travel time
- cumulative release to the accessible environment

Consequently, structures, systems, and components important to waste isolation may include engineered barriers (e.g., waste package), and features of the natural site system.

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* International Commission on Radiological Protection, "Recommendations of the ICRP", ICRP Publication 26, Pergamon Press, Oxford, 1977

** International Commission on Radiological Protection, "Radiation Protection Principles for the Disposal of Solid Radioactive Waste", ICRP/85/C4-8/12, Section 8, Exemptions

Performance goals will be set for selected structures, systems, and components of the MGDS which, when attained, will provide appropriate assurance that the above performance objectives are met. Structures, systems, components and activities necessary to comply or demonstrate compliance with these performance objectives will be placed on the Q-List.

The designation of structures, systems, and components to be placed on the Q-List at the SCP design stage, and all site characterization activities that are essential to adequately evaluate these items, will be based on technical judgment of the items that will be found necessary to comply or demonstrate compliance with the repository performance objectives as the repository performance analyses are completed.

As the site characterization activities take place and as the understanding of the site changes, the performance goals may change. As a consequence, some changes to the Q-List are expected as the site characterization program progresses. All site characterization tests and activities must therefore be carefully planned and take into account not only the primary tests for the items initially placed on the Q-List, but must also include some contingency for items that may be later added to the Q-List. A conservative approach at the SCP design stage is recommended to ensure that data necessary to demonstrate compliance with 10 CFR 60 are obtained and preserved in accordance with quality assurance requirements.

3.2 DETERMINATION OF Q-LIST FOR LA DESIGN STAGE

3.2.1 ITEMS IMPORTANT TO SAFETY AT LA DESIGN STAGE

A risk assessment methodology is a tool for preclosure safety analysis. It can be used to help identify structures, systems, components, and activities important to safety. An example of such a methodology is described in NUREG/CR-4303. "High-Level Waste Preclosure Systems Safety Analysis, Phase 1 Final Report".

Q-List development will be accomplished by examining an event sequence frequency and dose consequence. the structures, systems, components, and activities that are involved in the event sequence will be examined to determine their contribution to risk. If an item is essential to the prevention or mitigation of an event sequence which has a probability of 1×10^{-5} per year or greater and could result in radiation dose of 0.5 rem at the nearest boundary of the unrestricted area, then that particular item should be on the Q-List.

3.2.2 ITEMS IMPORTANT TO WASTE ISOLATION AT LA DESIGN STAGE

The determination of the structures, systems, components, and activities important to waste isolation at the LA design stage shall be accomplished in a similar fashion to that required at the SCP stage. However, at this more mature stage, the evaluation of importance to isolation will be based on direct assessments of whether the performance objective will be met rather than indirect assessments based on the preliminary performance goals set at the SCP stage. Throughout site characterization and performance assessment, activities must be geared to demonstrate compliance with the performance objective of 10 CFR 60 including the release limits set in EPA's 40 CFR 191.

3.3 RETRIEVAL OF EMPLACED WASTE

Retrieval of the waste from the repository, for either public radiological safety or resource recovery, is a design contingency and shall be treated in the same manner as waste emplacement. Much of the equipment needed for retrieval is expected to be the same or similar to the equipment that was needed for waste emplacement. The same procedures and criteria used to classify the items and activities needed to emplace the waste shall be used to determine if equipment and activities needed to retrieve the waste should be included on the Q-List.

att: RL-ECB-13

DOE F 1320.8 (15-84)

United States Government | Department of Energy

memorandum

DATE: APR 15 1986

REPLY TO ATTN OF: RW-23

SUBJECT: Guidance for Developing the SCP-CDR and SCP Q-List

TO: D. Vieth, NNWSI
L. Olson, BWIP
J. Neff, SRP

Attached is Headquarters guidance on determining Q-List items for inclusion in the SCP-CDR and SCP. Project presentations, discussion, and specific comments at the March 25, 1986 meeting on this subject at Headquarters were considered in revising the proposed paper and this final paper reflects appropriate changes. It is expected that this guidance will be implemented unless we hear within 5 days of receipt of this letter that a major implementation problem exists which has not already been presented or discussed at the March 25, 1986 meeting.

Note that the enclosed guidance document does not incorporate a 5 Rem accident design criterion for maximum allowable pre-closure radiological dose at or beyond the boundary of the unrestricted area. However, the Department is currently developing the basis for establishing formal guidance in this regard prior to initiation of the ACD, and we anticipate having discussions with NRC on this topic in the near future.

The implementation schedule provided in Section 5.0 of the paper reflects our assumptions as to the dates required for each project to complete the Q-List development work and include the results in the SCP and SCP/CDR. If a potential for date slippage exists consistent with meeting the SCP schedule requirements, please inform us and then it will be taken into consideration.

If you have any questions concerning this guidance, please contact Virgil Lowery at 202-252-9313.

Ralph Stein

Ralph Stein, Director
Engineering and Geotechnology Division
Office of Civilian Radioactive
Waste Management

Attachment

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