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SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

SUPPLEMENT No. 8

APPLICATION OF GRADED QUALITY ASSURANCE

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

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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. Conversely, 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			Quality Program Requirements	Quality Level		
	1	2	3*		1	2	3*
NQA-1 BASIC REQUIREMENTS				NQA-1 SUPPLEMENTS			
1. Organization	X	X	-	S-1 Terms and Definitions	X	X	-
2. Quality Assurance Program	X	X	-	1S-1 Organization	X	-	-
3. Design Control	X	X	-	2S-1 Qualification of Inspection and Test Personnel	X	-	-
4. Procurement Document Control	X	X	-	2S-2 Qualification of Nondestructive Examination Personnel	X	-	-
5. Instructions, Procedures, and Drawings	X	X	-	2S-3 Qualification of Quality Assurance Program Audit Personnel	X	X	-
6. Document Control	X	X	-	3S-1 Design Control	X	X	-
7. Control of Purchased Items and Services	X	X	-	4S-1 Procurement Document Control	X	-	-
8. Identification and Control of Items	X	X	-	6S-1 Document Control	X	-	-
9. Control of Processes	X	X	-	7S-1 Control of Purchased Items and Services	X	X	-
10. Inspection	X	X	-	8S-1 Identification and Control of Items	X	-	-
11. Test Control	X	X	-	9S-1 Control of Processes	X	-	-
12. Control of Measuring and Test Equipment	X	X	-	10S-1 Inspection	X	X	-
13. Handling, Storage, and Shipping	X	X	-	11S-1 Test Control	X	-	-
14. Inspection, Test, and Operating Status	X	X	-	12S-1 Control of Measuring and Test Equipment	X	-	-
15. Control of Nonconforming Items	X	X	-	13S-1 Handling, Storage, and Shipping	X	-	-
16. Corrective Action	X	X	-	15S-1 Control of Nonconforming Items	X	-	-
17. Quality Assurance Records	X	X	-	17S-1 Quality Assurance Records	X	X	-
18. Audits	X	X	-	18S-1 Audits	X	X	-
10 CFR 50 APPENDIX B							
18 QA CRITERIA	X						
NRC QA REVIEW PLAN	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			Quality Program Requirements	Quality Level		
	1	2	3*		1	2	3*
NQA-1 APPENDICIES				OTHER REQUIREMENTS			
1A-1 Organization	-	-	-	Activity Planning	X		
2A-1 Qualification of Inspection and Test Personnel	X	-	-	Management Assessment	X		
2A-2 Quality Assurance Programs	-	-	-	Personnel Qualification and Certification	X		
2A-3 Education and Experience of Lead Auditors	-	-	-	Technical & Peer Reviews	X		
3A-1 Design Control	-	-	-	Trend Analysis	X		
4A-1 Procurement Document Control	-	-	-	Unusual Occurrence Reporting	X	X	
7A-1 Control of Purchased Items and Services	-	-	-	Software Control	X		
17A-1 Quality Assurance Records	-	-	-	Sample Handling	X		
18A-1 Audits	-	-	-	Configuration Control	X		
				Reporting & Submittals	X	X	
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	-	(Note: See descriptions of the above requirements on page 3 and 4 of this Attachment)			
S-3 Q-11st Methodology	X	X	-				
S-4 Quality Assurance Records	X	X	-	* Quality program requirements for Level 3 will be developed on a case-by-case basis.			
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)							

REFERENCEOTHER REQUIREMENTS DESCRIPTIONS

- | | |
|---|---|
| NRC Review Plan
Para. 2.5 | 1. <u>Activity Planning</u> - Requires application of a <u>graded approach</u> 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. <u>Management Assessment</u> - Applies to performance of <u>annual management assessments</u> to determine the scope, status, adequacy, and effectiveness of the QA program. |
| NRC Review Plan
Para. 2.8
DOE/OGR Quality
Program Requirements | 3. <u>Personnel Qualification and Certification</u> - 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. <u>Technical and Peer Reviews</u> - Requires and defines <u>peer reviews</u> and when they should be accomplished. |
| NRC Review Plan
Para. 15.4
Para. 18.4 | 5. <u>Trend Analysis</u> - 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. <u>Unusual Occurrence Reporting</u> - Requires that <u>contractors report any significant event</u> 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. <u>Software Control</u> - 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

DOE/OGR Quality
Program Requirements

NRC Review Plan
Para. 3.10

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.
9. Reporting and Submittals - Identifies the types and frequency of reports to be submitted to the OGR.
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)

<u>CATEGORIES OF STATEMENTS OF WORK (SOW)</u>	<u>QUALITY LEVEL</u>		
	<u>1</u>	<u>2</u>	<u>3</u>
1. <u>ITEMS (HARDWARE)</u>			
A. <u>PUBLIC HEALTH AND SAFETY CONSIDERATIONS</u>			
o Is the item on the Q-List?			X
B. <u>DOE PROGRAMMATIC OBJECTIVES CONSIDERATIONS</u>			
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. <u>WORKER HEALTH AND SAFETY CONSIDERATIONS</u>			
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. <u>LEAD TIME AND COST CONSIDERATIONS</u>			
o Does procurement of the item involve long lead time and/or is the item extremely costly?			X

<u>CATEGORIES OF SOW'S</u>	<u>QUALITY LEVEL</u>		
	<u>1</u>	<u>2</u>	<u>3</u>
1. <u>ITEMS (HARDWARE) CONDT</u>			
E. <u>ASME - BPVC APPLICABILITY CONSIDERATIONS</u>			
o Section III applies			(Quality
o Section VIII applies			Level to be
			Determined
			by Projects)
2. <u>ACTIVITIES</u>			
A. <u>COMPUTER SOFTWARE MODELING/DEVELOPMENT</u>			
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

<u>CATEGORIES OF SOW'S</u>	<u>QUALITY LEVEL</u>		
	<u>1</u>	<u>2</u>	<u>3</u>
<u>2. ACTIVITIES CONTD.</u>			
<u>B. FIELD TESTING, DATA ACQUISITION, DATA ANALYSIS, AND REPORTS</u>			
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
<u>C. STORAGE OF RECORDS/SAMPLES</u>			
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

<u>CATEGORIES OF SOW'S</u>	<u>QUALITY LEVEL</u>		
	<u>1</u>	<u>2</u>	<u>3</u>
2. <u>ACTIVITIES CONTD.</u>			
4. If the collected data or records/samples were lost/discarded or of indeterminate quality repetition or schedular delay would be required			X
D. <u>HISTORICAL OR BACKGROUND STUDIES AND REPORTS</u>			
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. <u>ENVIRONMENTAL/SOCIOECONOMIC STUDIES AND REPORTS</u>			
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

<u>CATEGORIES OF SOW'S</u>	<u>QUALITY LEVEL</u>		
	<u>1</u>	<u>2</u>	<u>3</u>
<u>2. ACTIVITIES CONTD.</u>			
4. If the collected data or records were lost/discarded or of indeterminate quality repetition or schedular delay would be required			X
<u>F. LABORATORY EXPERIMENTAL (SCOPING) OR TESTING/ANALYSIS AND REPORTS</u>			
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
<u>G. CONSTRUCTION/MANUFACTURING ACTIVITIES</u>			
1. Is the construction/manufacturing activity supporting a Q-List structure system or component?			X

<u>CATEGORIES OF SOW'S</u>	<u>QUALITY LEVEL</u>		
	<u>1</u>	<u>2</u>	<u>3</u>
<u>2. ACTIVITIES CONTD.</u>			
<u>G. CONSTRUCTION/MANUFACTURING ACTIVITIES CONDT</u>			
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