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WM DOCKET CONTROL CENTER

Department of Energy

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COMMENTS ON NRC REVIEW PLAN

- References:
1. Memo, Stein/Olson, NRC Review Plan, 10/29/84
 2. Memo, Olson/Purcell, BWID Quality Assurance Plan, 4/15/86
 3. Memo, Knight/Olson, Request for Comments on NRC Review Plan, 6/5/86

Comments on the NRC Review Plan, Quality Assurance Programs for Site Characterization of High Level Waste Repositories, are enclosed in response to the June 5, 1986, request by J. P. Knight. These recommendations are in addition to the exceptions and clarifications of Appendix A to the Project QA Plan. A copy of Appendix A is also included for information.

The recommended changes are intended to provide for clarification and to address one area in which NRC guidance seems desirable.

Please contact R. P. Saget, 444-7250, if there are questions.

ORIGINAL SIGNED BY
O. L. OLSON

O. L. Olson, Director
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Enclosures

- cc: J. P. Knight, RW-24 w/encl.
C. Newton, RW-24 w/encl.
J. Morris, RW-22 w/o encl.

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DATE ▶	6-26-86	6-26-86	7/1/86	7/1/86	7/1/86	

COMMENTS ON NRC REVIEW PLAN

The following comments are offered for consideration in revising the NRC Review Plan.

1. Para. 7.5 - The second sentence is confusing. Consider rephrasing or deleting this sentence to clarify the intent.
2. Para. 3.8 - Consider rephrasing this paragraph as follows for clarification: "Peer review should be utilized as part of the verification process for designs or design activities when judgement or interpretation is the sole criteria available to a reviewer to provide assurance that a final design or design activity is satisfactory. A peer review is an in-depth review performed by more than one individual such that assurance is achieved through the concensus of judgement rather than relying on the judgement of a single individual. A peer reviewer is an individual who is independent of, but is a competent authority in one or more of the disciplines relevant to the subject of the review. Procedures defining the peer reviewer selection process and the process by which peer reviewers conduct their review should be described."
3. Para. 5.1 - Review of procedures and instructions other than those related to data acquisition may be more appropriate under paragraph 6.2 than Section 3 which is primarily related to design activities.
4. The Review Plan is silent on criteria for evaluation of surveillance programs. Consider providing guidance in this area.

Additional clarifications and exceptions are contained in the attached Appendix A to the BWIP Quality Assurance Plan.

Appendix A: Exceptions/Clarifications to the NRC Review Plan

PREAMBLE

The DOE concept of project management for major acquisitions holds contractor technical processes and results to be inseparable from controls under which they are performed. These controls are integrated into an overall quality assurance program. It is essential that management responsibilities and authority relative to implementation of the quality assurance program and verification of its effectiveness be clearly delineated. In particular, it is important to distinguish between direct controls and the "quality assurance functions", as defined in Criterion I of 10 CFR 50 Appendix B; i.e., "(a) assuring that an appropriate quality assurance program is established and effectively executed and (b) verifying, such as by checking, auditing and inspection, that activities affecting the safety related functions have been correctly performed."

The attached exceptions/clarifications to the NRC Review Plan reflect the following perception of responsibilities:

1. Almost all controls that make up the quality assurance program are exercised by line organizations. Nothing in the working of regulatory requirements or DOE QA program descriptions should give the appearance of relieving the highest line official of responsibility for effective implementation of those controls.
2. The highest ranking DOE QA official on the project should be held accountable for QA functions, as defined in Criterion I of 10 CFR 50 Appendix B. That official should be at a level in the organization that provides sufficient authority so that he or she can deal directly and effectively with the top-line official and so that communication concerning status and effectiveness of the QA program produces timely, appropriate line action.

EXCEPTIONS/CLARIFICATIONS TO NRC REVIEW PLAN

1. NRC Review Plan Section 1.1

"The responsibility for the overall program is retained and exercised by the DOE at a level that is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls."

Clarification

Responsibility for overall QA program policy and direction is exercised by DOE Headquarters and the Office of Geologic Repositories. Within the Basalt Waste Isolation project field office, project management is exercised through DOE Basalt Waste Isolation Division technical staff monitoring (surveillance) and review. Surveillance includes evaluation of contractor technical performance and of the effectiveness of controls under which the work is performed. BWI Division technical staff is normally not involved in direct project work, but exercises technically oriented management functions. Thus, verification of proper performance of work is not limited to the DOE "QA organization". However, QA program controls are exercised by line functions.

2. NRC Review Plan, Section 1.5

"Qualified individual(s) or organizational element(s) are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities."

Clarification

Qualified individual(s) or organizational element(s) will be identified within DOE's organization, prior to initiation of activities, as responsible for assuring that delegated work meets established quality standards.

3. NRC Review Plan, Section, 1.10

"DOE and its prime contractor identify a management position within each respective organization that retains overall authority and responsibility for the QA program..."

Clarification

DOE and its prime contractors will identify a management position within each contractor organization that retains overall authority and responsibility for performing the "QA functions" of the QA program. DOE will identify a DOE management position that retains overall authority and responsibility for: (1) performing QA functions relative to direct quality affecting activities within DOE, (2) verifying effectiveness of quality-related controls applicable to quality affecting work performed by DOE personnel, and (3) verifying proper performance of QA functions within contractor QA programs.

4. NRC Review Plan, Section 1.11

"Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization..."

Clarification

DOE verification of conformance to established requirements will be accomplished both by DOE project technical staff, during technical surveillance activities, and by personnel of the DOE QA organization. Contractor verification of conformance to established requirements will be performed by personnel or organizational elements who did not perform the work or directly supervise its performance. Such personnel may belong to the contractor's QA organization or may be assigned on the basis of technical expertise, depending on the nature and complexity of the work whose conformance is being verified.

5. NRC Review Plan, Section 1.15

"The persons responsible for directing and managing the overall QA program are identified ...This [sic] individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented."

Clarification

The director of the DOE project office responsible for the selected repository program will be responsible for directing and managing line function implementation of the overall QA program. A DOE management level individual in the selected DOE field office will be assigned responsibility for directing and managing QA functions with respect to quality affecting activities performed by DOE personnel and for tracking effective performance of contractor QA functions. This will be a dedicated QA assignment.

Assessment and verification of effectiveness of project QA program controls will be addressed as integral to DOE assessment and verification of contractor technical performance.

Individuals responsible for directing and managing quality assurance functions will be free from non-QA duties and will thus be able to give their full attention to assuring that the QA program is being effectively implemented.

6. NRC Review Plan, Section 3.6

"Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements."

Clarification

Contractor design control procedures will require that design drawings, specifications, criteria, and analyses be reviewed by the contractor QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.

7. NRC Review Plan, Section 9.1

"The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided."

Clarification

DOE will identify special processes as those processes for which end results cannot be fully characterized by nondestructive means. Contractors will be required to identify and list applicable processes. Geological data acquisition "testing" is not considered to belong to the "special process" category for purposes of process demonstration.

8. NRC Review Plan, Section 11.3

"The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled..., are identified."

Clarification

Contractors will be required to perform documented evaluations of uncertainties associated with testing and data acquisition. Potential sources of uncertainties will be identified and quantified to the greatest extent practicable.

9. NRC Review Plan, Section 13.1

"Sampling, handling, preservation..."

Clarification

This requirement is taken to address "Sample handling, preservation..." rather than "Sampling, handling, preservation..."

10. NRC Review Plan, Section 14.1

"Procedures are established to indicate by the use of markings the status of inspections and test on individual items."

Exception

Procedures will be established to assure that inspection, test and operating status is clearly indicated by means of markings, tagging, boundary markers, etc., as appropriate to the nature of the equipment or natural region affected and of the inspection, test or operation involved.

11. NRC Review Plan, Section 16.2

"Corrective action is documented and initiated following a nonconformance to preclude recurrence..."

Exception

Nonconformances that do not meet the criteria for significance (see Review Plan Section 16.4) will be evaluated to determine whether or not action to preclude recurrence would serve the best interests of the project. Evaluation will involve consideration of such factors as cost of remedial action for repetitive occurrence, nuisance value of repetitions, potential impact of repeated occurrences on more significant aspects of the work, potential for repeated occurrences to produce a negative perception of overall control effectiveness and cost to isolate cause(s) and implement preventive action(s).

12. NRC Review Plan, Section 16.4

"Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper of management for review and assessment."

Clarification

Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition will be documented and reported to immediate management and upper levels of management for review and assessment. Conditions adverse to quality will be considered significant if they are determined to have a potential adverse impact on safety or waste isolation or on the integrity of the record relative to safety or waste isolation.

13. NRC Review Plan, Section 17.1

"The scope of the records program is described. QA records include geotechnical samples and data;..."

Exception

The scope of the records programs is described. QA records include geotechnical data;..." "Geotechnical samples will be afforded archival controls and protection for the period during which additional examination or analysis by DOE or the NRC may be needed, or during which natural time-dependent deterioration processes inherent to the sample materials have not destroyed or substantially changed sample properties."