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87-QSD-243

SEP 11 1987

Those on Attached List

Ladies and Gentlemen:

RELATIONSHIP OF QUALITY ASSURANCE PROGRAM FEATURES TO EXPRESSED CONCERNS

The closing session of the January 1987 Quarterly Project Status meeting between DOE-RL and the affected Indian Tribes and States included a workshop showing how the BWIP Quality Assurance (QA) program mitigates risks inherent in many of the concerns expressed by the affected parties relative to the repository site characterization activities. The first part of the workshop involved identification of these concerns. However, due to the time constraints and with the consensus of the participants, the second part of the workshop describing how mitigation of risks through QA would be effected was developed separately and is hereby transmitted.

The enclosed study results indicate that the QA program provides a considerable measure of assurance in the areas of concern that were raised. However, as recognized during the meeting, many of the concerns fall outside the purview of the QA program.

Any questions regarding the enclosure should be directed to Mr. R. P. Saget at (509) 376-7250.

Sincerely,

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QSD:RPS

Enclosure

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QA PROGRAM FEATURES RELATED TO EXPRESSED CONCERNS

CONCERN # 1: That this is a one time project with no opportunity to do things over if they are discovered to be incorrect or inadequate.

Applicable QA Program Features:

The basic purposes of the formal QA program as a whole are (a) to prevent mistakes, and (b) where mistakes do occur, to detect them early and correct any effects they may have had. Quality assurance is defined in the federal regulations as "...all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service..." [10CFR60, 60.150]

The NRC specifies further [10CFR60, 60.11] that the QA program is required "...to provide confidence in the data gathered during site characterization..."

For site characterization, the features of the QA program that most directly provide insurance in a one shot project are those concerned with multiple review of work as it is done. These are, specifically:

1. "Design information and design activities refer to data collection and analysis activities... They include general plans and detailed procedures for data collection and analysis activities..." [from Section 3.0, Discussion, of the NRC Review Plan for QA Programs for Site Characterization]

2. "Test plans and procedures [shall be]...reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9..." [NRC Review Plan, Section 11.2]

3. "Procedures are established...for verification of [test plans and procedures]..., the verifier of which is not directly responsible for [the test plan or procedure]..." [Section 3.7 of the NRC Review Plan]

4. "For design or design activities [test plans and test procedures] which involve use of untried or state-of-the-art testing and analysis procedures or methods...a peer review [shall]...be conducted... A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required." [Section 3.8 of NRC Review Plan]

5. "The responsibilities of the verifier, the areas and features to be verified, and the extent of documentation [shall be]...identified in...procedures." [Section 3.9 of NRC Review Plan]

6. "Participants responsible for strategy or test planning, test procedures, site characterization studies and/or for the design of (a) facilities or equipment that could subsequently be utilized if the site is selected as a repository site, (b) of equipment whose characteristics could affect validity of site characterization, or (c) conceptual designs upon which site characterization approaches or analyses will be based, will perform such activities in accordance with approved procedures that provide the following controls:

   a. Traceable documentation of design inputs, including the rationale for design decisions,

   b. Documentation of design assumptions, including rationale,

   c. Approved computer software controls,

   d. Competent independent review,

   e. Approval by designated authority,

   f. Independent design verification,

   g. Control of design interfaces,

   h. Control of design changes equivalent to the controls applied to original design, and

   i. Review of design drawings, specification, criteria, and analyses by personnel of the cognizant QA organization to ensure compliance with governing procedures and QA program requirements." [BWI Project QA Plan]

In summary, these measures offer the best insurance available for a one-shot project.

CONCERN # 2: How can the QA program ensure that the work is done right the first time?

Applicable QA Program Features:

See response to Concern #1. In addition, the required QA program is based on the philosophy that quality of work ultimately depends on the person who does the work, not on those who inspect or review it. Appendix B of Part 50 of Code of Federal Regulations Title 10 (10CFR50) defines the criteria that a QA program must meet to be licensable. Criterion I states that, "The authorities and duties of persons and organizations performing activities affecting...safety...shall be clearly established and delineated in writing. These activities include...the performing functions of attaining quality objectives..." That is, the QA program charges the doing organizations with doing it right the first time.

To improve the likelihood of good work, Criterion II of 10CFR50 Appendix B requires that, "The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

Doing it right the first time is an objective of the QA Program and many of the 18 point criteria. For example, control of procedures for doing work, training and indoctrination of personnel performing work, design control, procurement control, nonconformance control, audits and surveillance and records management contribute to the systematic way of performing work to approved procedures, by trained personnel, to prevent rework. In the event of a necessity to reject or to redo an item, we follow the requirements of the nonconformance control criterion.

Data collection and analytical work is performed by contractors, universities and other government agencies. The QA program covers that as follows:

1. "Qualified individuals or organization elements [shall be]...identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities." [NRC Review Plan, Section 1.5]

2. "Measures for evaluation and selection of procurement sources...shall include...[the] supplier's technical and quality capability..." [ANSI/ASME NQA-1-1986]

CONCERN # 3: **Can the QA programs influence high level decisions? That is, will it have any effect on what is perceived as a history of "political" decision making?**

Applicable QA Program Features:

Technical decisions at all levels of the geologic repository program are subject to the safeguards of the QA program. In its role in the licensing process, the NRC states that, "The responsibility for the overall program [shall be]...retained and exercised by the DOE at a level commensurate with the level of the DOE official who will submit the license application. "[NRC Review Plan, Section 1.1]

However, policy decisions are a part of the national political process. Such decisions may be based in part on technical factors that were subject to the QA program, but they may also involve considerations outside the scope of the program. Ultimately, the licensing process will likely include examination of any resulting policies.

CONCERN # 4: There is a history of past lack of management attention to QA.

Applicable QA Program Features:

The geologic repository QA program cannot be measured against past performance. The requirement in the Nuclear Waste Policy Act that DOE must obtain their license from the NRC creates an entirely new atmosphere. The NRC learned from its own failures and those of the commercial nuclear industry that management commitment is one of the chief ingredients in producing quality work. The result is that the NRC has placed great emphasis on the 10CFR50 Appendix B requirement that "The applicant shall be responsible for the establishment and execution of the QA program...[The individual(s) assigned the responsibility for assuring effectiveness of the quality assurance program...shall have direct access to such levels of management as may be necessary to perform this function." [Criterion I]

The Stop Work Order that was placed on Rockwell on May 1, 1986, in order to emplace management control systems is evidence of DOE management commitment to a strong QA system. Similarly DOE BWIP's own QA system upgrades that have taken place since June of 1985 are further evidence of this commitment.

CONCERN # 5: There is some question as to DOE credibility. How is the QA program related to this question?

Applicable QA Program Feature:

To the extent that this lack of credibility is based on inadequate identification and resolution of technical issues, the QA program is designed to prevent recurrence of these inadequacies. However, two aspects of credibility may be at issue -- credibility of technical results and controls and believability of DOE commitment. Believability is being approached on the basis of open personal communication. The DOE feels that such open communication will develop an environment of mutual trust, will help DOE QA personnel to become increasingly sensitive to your needs and concerns, and will enable DOE to focus the QA program more sharply.

Technical and controls credibility is addressed directly in the QA program. The most important provision in the program is the capturing (and accessibility) of records. Supplement 4 to the OGR QA Plan establishes record requirements and includes a lengthy list of those records that must be retained for the life of the repository license. The next most important aspect of the program in terms of technical credibility is the multiplicity of reviews and QA overview/verification.

Participation of States and affected Indian Tribes representatives in QACG meetings and as observers in DOE audits enhance the interactions and understanding between DOE and other representatives.

CONCERN # 6: Qualification of existing data.

Applicable QA Program Feature:

The NRC staff issues "Generic Technical Positions" (GTPs) to provide their interpretation of what they will consider acceptable in certain special areas, of which qualification of existing data is one. The GTP for qualification of existing data was issued for public comment during the summer, 1986, and will be issued formally when comment resolution is complete.

Qualification will consist primarily of researching and documenting the controls under which existing data were collected and determining the degree of confidence those controls provide.

Indications to date are that evidence assembled during that research effort will be subjected to formal board-type reviews to determine adequacy.

BWIP will be undertaking a fairly substantial effort over the next year or two to qualify much of the existing data that has been developed in preceding years. This work will be performed in compliance with proper procedures with due regard for NRC guidance contained in the GTPs.

CONCERN # 7: What about QA on execution of the procedural requirements of the Nuclear Waste Policy Act?

Applicable QA Program Feature:

It is presumed that this concern addresses procedural requirements related to the licensing process. These procedural steps are not within the scope of the mandated QA program. Instead, the Act specifies [in Section 119] that the United States courts of appeal "...shall have original and exclusive jurisdiction over any civil action--

(a) for review of any final decision of the Secretary, the President, or the [Nuclear Regulatory] Commission...;

(b) alleging the failure of the Secretary, the President, or the Commission to make any decision, or take any action, required under [the Act]...;

(c) challenging the constitutionality of any decision made, or action taken, under any provision of [the Act]...", etc.

CONCERN # 8: What will prevent decay of awareness in the years after repository closure?

Applicable QA Program Feature:

The Environmental Protection Agency (EPA) recognized this concern explicitly in Volume 50 No. 182 of the Federal Register (September 19, 1985), when it published its final rule on "Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes", 40CFR, Part 191. Specifically, the summary of Subpart B stated, "...Standards must be implemented in the design phase for these disposal systems because active surveillance cannot be relied upon over such periods... The various provisions of Subpart B are intended to be met through a combination of steps involving disposal system site selection, design, and operational techniques (i.e., engineered barriers)..."

Subpart B, Paragraph 191.14 (Assurance requirements) of 40CFR191 specifies the following safeguards:

"(a) Active institutional controls over disposal sites should be maintained for as long a period of time as is practicable after disposal; however, performance assessments that assess isolation of the wastes from the accessible environment shall not consider any contributions from active institutional controls for more than 100 years after disposal."

"(b) Disposal systems shall be monitored after disposal to detect substantial and detrimental deviations from expected performance..."

"(c) Disposal sites shall be designated by the most permanent markers, records, and other passive institutional controls practicable to indicate the dangers of the wastes and their locations."

"(d) Disposal systems shall use different types of barriers to isolate the wastes from the accessible environment. Both engineered and natural barriers shall be included."

"(e) Places where there has been mining for resources, or where there is a reasonable expectation of exploration for scarce or easily accessible resources, or where there is a significant concentration of any material that is not widely available from other sources, should be avoided in selecting disposal sites..."

"(f) Disposal systems shall be selected so that removal of most of the wastes is not precluded for a reasonable period of time after disposal."

EPA's 40CFR191 also requires that the Federal government establish and maintain Federal ownership of the disposal site in order to prevent "inadvertent human intrusion" (such as by exploratory drilling).

Applicable elements of the QA program are required to remain in place, and will be subject to NRC verification, throughout the life of the repository construction and operating licenses (assuming the Hanford site were selected).

CONCERN # 9: The use of newly developed coupled models may entail risk. How will complex (coupled) models be validated and controlled?

Applicable QA Program Feature:

The design control elements of the QA program require peer review for all activities that involve "...use of untried or state-of-the-art testing and analysis procedures and methods..." Where trial problems with known solutions do not exist for validation of state-of-the-art models (and resulting computer codes), and where mechanisms or relationships portrayed by models are of such a nature that empirical data cannot be gathered to permit experimental validation, the peer review process would have to provide the first line of defense. However, the NRC's 10CFR60 requires that uncertainties inherent in the use of unproven hypotheses or models be clearly identified and characterized during site characterization. Such uncertainty analyses are also subject to peer review.

CONCERN # 10: Availability of resources for proper implementation of the QA program.

Applicable QA Program Feature:

DOE Order 5700.6, Quality Assurance, requires that Department program and project managers "...provide the resources necessary for implementation of effective QA programs..."

DOE/RW-0032, Office of Civilian Radioactive Waste Management Quality Assurance Management Policies and Requirements (QAMPR) states that, "...An essential element in the process of assuring equality achievement is adequate planning. An objective of such planning is to select and apply necessary and appropriate QA requirements and to provide for the necessary resources..."

The realities of the budget process include management perception of relative priorities, funding ceilings, etc. Allocation of manpower for BWIP QA in the DOE-RL Office has increased dramatically during the past year, and the Support Services Contract provides the Director, Quality Systems Division, a substantial work force of experienced contract QA personnel to supplement his staff. Inasmuch as much of DOE's technical overview of BWIP work consists of QA-type monitoring, the resource question appears to be reasonably well resolved.

CONCERN # 11: What steps are planned or under way to instill quality assurance awareness and understanding in all levels of QA staff?

Applicable QA Program Feature:

Three features address this concern directly:

1. Criterion II of the NRC's 10CFR50 Appendix B requires that, "...The program shall provide for indoctrination and training of personnel performing activities affecting quality..." Training and indoctrination programs throughout the project, from DOE-RL to subtier contractors, include intensive QA orientation at all management levels.

2. Audits, surveillances and management assessments, required as part of the QA program, are providing a high level of visibility of line responsibilities in the QA program.

3. Both technical reviews and readiness reviews include heavy emphasis on verification that management is actively engaged in QA program controls. In practice, the majority of rejections resulting from these reviews are related to QA questions (often raised by management or technical reviewers) rather than questions as to technical merit. The trauma of rejected work appears to be intensifying staff awareness throughout the project.

CONCERN # 12: Too great a dependency on the QA staff function to catch problems.

Applicable QA Program Feature:

Experience over the past year suggests that the proportion of problems identified by line personnel (as opposed to those detected by QA) has increased markedly, both within the DOE-RL project office and among the project participants. One significant factor in that trend has been project recognition of the requirement that "...Errors and deficiencies in...design and design information documents [shall be]...documented, and action...taken to assure that all errors and deficiencies are corrected..." [NRC Review Plan], as well as the NQA-1 requirement that, "...where a significant...change [to a technical document] is necessary because of incorrect [technical work]...the design process and verification procedure shall be reviewed and modified as necessary..."

The heightened awareness is illustrated by the increased frequency of requests from the (DOE) technical branches for QA investigation of, or action on, perceived deficiencies, and by similar interaction between contractor technical personnel and their QA organizations.

CONCERN # 13: **Proceeding too far into execution of work before properly reviewing plans and strategies that establish the need (or methods) for the work.**

Applicable QA Program Feature:

The planning process for the project is specified in documents such as the Mission Plan, Project Management Plan, and System Engineering Management Plan. Issues resolution strategy, information needs identification, Study Plans, and test planning are discrete, sequential steps in the process, and the QA program includes verification that these elements occur in the proper sequence and that the proper reviews are conducted for each step before the next step is accomplished.

The fact that considerable exploratory work was done before the NWPA was enacted imposes a considerable burden of back-fitting. The fact that various stages of the planning and strategy process were out of phase was a major factor in the DOE-RL decision to stop work.

CONCERN # 14: **Procedure development and validation for state-of-the-art testing.**

Applicable QA Program Feature:

The QA program elements cited in response to Concern # 1 also apply specifically to this concern. That is, procedure development and validation, where validation cannot be achieved by actual demonstration, require formal peer review.