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- 1 -

Mr. William J. Purcell
Director
Office of Geologic Repositories
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy
RW-20
Washington, DC 20585

Subject: NRC comments on DOE responses to NRC concerns expressed during site visits in December 1984 about DOE'S quality assurance program

Dear Mr. Purcell:

This letter is written to provide the subject comments as committed to in the Department of Energy/Nuclear Regulatory Commission Quality Assurance meeting held in Washington, DC on December 4-5, 1985. Should you have any questions, please contact Dale Hedges of my staff at (301) 427-4491.

The staff comments are in enclosure 1.

/S/

John J. Linehan, Acting Chief
Repository Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Staff Comments

WM Record File 405
WM Project 1
Docket No.
PDR ✓
LPDR
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*See previous concurrence

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NRC COMMENTS ON DOE RESPONSES TO NRC
CONCERNS EXPRESSED DURING SITE VISITS IN DECEMBER 1984
ABOUT DOE'S QUALITY ASSURANCE PROGRAM

GENERIC ISSUES

1. Issue

The size of the DOE technical staff may not be sufficient to provide adequate oversight of such a large and complex project.

Response

Continued increases in staff are planned for all projects. The number of staff, their expertise, experience, and responsibilities are examined each year as part of the budget process. The requirements for staff will be changing with the start of site characterization. These changes have been projected in the planning of each of our projects.

NRC Comment

In the NRC's past reactor experience, no one specific staff size exists for every situation. Based on the nature and size of a particular project, a preliminary judgment can be drawn indicating general staff number inadequacy or overabundance. The present increase and proposed future increases in DOE HQ and project technical staff appear to address the initial NRC concerns of insufficient technical staff. However, an increase in numbers does not necessarily mean an improvement in the management, supervision and quality of the work being done. The NRC is presently unable to provide an assessment of the adequacy of increased staff numbers. A more detailed assessment by the NRC will be made after sufficient review and audit of the DOE program are undertaken. A key consideration in the determination of an adequate staff size will be the determination of DOE's ability to oversee and manage the activities and QA programs of the contractors and participating organizations.

2. Issue

The size of the DOE QA staff may also not be sufficient.

Response

At the time of the NRC site visit each project had at least one full-time, dedicated Quality Assurance position filled by a DOE employee. Additional QA personnel have been added since then and will continue to be added prior to initiation of site characterization activities. Additional support is and will continue to be supplied by contractors, matrix support from the Quality Assurance group within each field office, and from other qualified and independent (technical) project personnel.

NRC Comment

The NRC does not hold to any one, rigid staff size. However, based to the NRC's reactor experience and the size and nature of the DOE projects, the relatively small size of the QA staff was apparent. DOE has taken positive steps to increase the QA staff capabilities for each project. The NRC staff cannot determine if these numbers are sufficient at present. Planned NRC reviews and audits will allow the NRC to determine the effectiveness of the separate QA staffs in performing their appropriate QA overview functions for the entire project.

3. Issue

U.S. Nuclear Regulatory Commission (NRC) questioned the DOE emphasis on the line responsibilities for QA and advised DOE to be careful to avoid a situation where the NRC required independent QA organization does not or cannot fulfill its responsibilities.

Response

DOE plans to continue to hold the line managers in each project office responsible for the quality of the work performed by the staff and contractors. The QA manager for each project will continue to make an independent assessment, on behalf of the project manager, of the quality of the work performed by both the DOE project office and the contractors. The QA manager in each project will continue to report to the project manager. The QA manager may also use line personnel to assist him in the conduct of surveillances and inspections--providing the line personnel used have no direct responsibility for the work being audited, or surveilled, or inspected.

NRC Comment

NRC's reactor experience has shown that a variety of organizational arrangements can be acceptable and NRC does not insist on any one organizational structure. However, the NRC is not yet in a position to determine whether the DOE organizational arrangements meet the NRC criterion for QA independence from cost and schedule. An important factor is whether the "quality" message received at the management level to which QA reports is as strong as the cost and schedule messages management receives and the conduciveness of the organizational structure to escalating quality problems to higher management levels if sufficient redress is not received at a given level. NRC's review of the projects QA plans will address the independence issue on a site specific basis.

4. Issue

The extensive dependence on contractors for QA assistance was questioned.

Response

The manager of each project is ultimately responsible for the quality of work performed by that project. Each participating organization and contractor organization is responsible for assuring the quality of their work.

The DOE does rely heavily on contractors for QA assistance. It has been the policy of the Atomic Energy Commission (AEC), Energy Research and Development (ERDA) and DOE to have a small group of technically competent people manage major projects that are executed by contractors. We do not consider that any change is required in this policy.

NRC Comment

The NRC's reactor construction experience has identified that in many cases utilities who relied extensively on contractor assistance lost a significant portion of knowledge or control of the status of the project. While DOE's policies make it imperative that a significant portion of project QA activities be assigned to contractors, this does not necessarily imply that there will be a degradation in project quality. However, it is important that DOE or the project manager ensures that the contractor and other participating organizations receive adequate oversight and management. The NRC will be able to evaluate the projects' ability to handle the numerous contractors during its planned reviews and audits.

5. Issue

NRC noted the need for developing an approach to graded Quality Assurance.

Response

We agree and are actively working on a common approach now. We expect to be able to submit this to NRC for comment in the near future. A status report will be provided during the December 4-5, 1985 meeting.

NRC Comment

As presented by DOE at the DOE/NRC QA meeting of Dec. 4-5, the DOE graded QA methodology will contain 3 or 4 grade levels. Since quality level 1 will contain items on the Q-list, items subject to the 10 CFR Part 60 QA requirements, and items or activities supporting the license application, this is the quality level of greatest importance to the NRC. Thus, graded QA within level 1 will receive the NRC's primary attention. Those items and activities on the remaining levels will only be reviewed to assure that the scope of quality level 1 included all items on the Q-list or supporting the license application. Upon submittal by DOE of a written graded QA plan, the NRC will provide comments and guidance as necessary. (Refer to 14 of NRC Observations in the meeting minutes of Dec. 4-5.

6. Issue

NRC noted the need for an approach for qualifying existing and historical data.

Response

We agree and are actively working on a common approach now. We expect to be able to present this to NRC in the near future. We do expect to limit the application of this to data needed to support the license application.

NRC Comment

The NRC is developing a Generic Technical Position covering the topic of qualification of existing data. This GTP will describe approaches acceptable to the NRC staff for providing confidence in the quality of such data. The NRC acknowledges the fact that other methods could prove acceptable to the NRC staff. The NRC will review the DOE plan for qualifying existing data. As mentioned by DOE representatives at the DOE/NRC QA meeting on Dec. 4-5, existing data will be used in support of DOE's license application. Thus, it is imperative that an acceptable and workable approach be developed.

7. Issue

NRC noted the value of readiness reviews and suggested they be included as participants in such reviews.

Response

We agree this would be useful for major decision points in each project and are now planning the scope, schedule, and method of participation by NRC. We would expect the first such review to be conducted just prior to the start of the exploratory shaft.

NRC Comment

The staff would appreciate being kept advised of the progress and in particular would like copies of early planning of scope, schedule and method of participation by NRC.

BWIP SPECIFIC ISSUES

8. Issue

The NASA consultant to NRC noted that separate technical design review teams provided useful additional checks.

Response

The NASA consultant identified this as one means of verifying the quality of technical work. We agree these types of reviews can add value to the project and have included them in our QA program for use as appropriate. Our expectation is that the BWIP QA program will be fully implemented by January, 1986.

NRC Comment

Recognizing the value of separate technical design review teams and implementing such review teams in the design process are poles apart. The NRC staff believes that the use of the separate technical design review teams will be beneficial to DOE, if used. The NRC review process will evaluate the future use of such teams in the design process.

9. Issue

USGS has not accepted the project QA requirements.

Response

This issue was raised by DOE during the December 10-11, 1984, meeting and discussions continue with USGS to reach agreement on the necessary USGS actions to satisfactorily resolve this issue.

NRC Comment

As stated in the NRC/DOE QA meeting on Dec. 4-5, the problem with the USGS acceptance of the project QA requirements still remains unresolved. The NRC staff is cognizant of the fact that DOE/USGS discussions continue, and cannot overemphasize the need for DOE to resolve this problem quickly. The NRC staff requests that it be informed of the progress of these discussions and notified if any agreement is reached.

10. Issue

The NASA consultant noted the value of a central reporting system for problems.

Response

We agree with the usefulness of this tool and are planning to begin its use in FY-86 both within the projects and by DOE-HQ.

NRC Comment

The staff would like to receive copies of approved procedures for the implementation of this process.

11. Issue

More trend analysis would be useful.

Response

We agree with the usefulness of this tool and are planning to initiate its use in FY-86 by both the projects and DOE-HQ.

NRC Comment

The NRC has found that properly applied trend analysis to be very beneficial to the maintenance of quality on a project. DOE's plans to increase the use of trend analysis in FY-86 should prove trend analysis to be an important management tool. The NRC will evaluate the implementation of trend analysis techniques as part of its normal reviews process.

NNWSI SPECIFIC ISSUES

12. Issue

NRC noted that research activities may have questionable value in licensing.

Response

The results of research activities that DOE will use in licensing will be subjected to the same degree of quality controls that are applied to activities important to safety and waste isolation. We believe NRC will find such results fully acceptable. Research activities that are not important to safety and waste isolation, and which will not be used to support DOE's license application, may not have the same degree of quality controls and, therefore, could not be used by DOE in licensing without a careful review and evaluation of the quality controls used.

NRC Comment

In stating that certain research activities have questionable value in the licensing process, the NRC is focusing on the need for a sound QA program prior to research commencement. Essential QA functions are necessary to provide confidence that all research activities are done with a high degree of quality and will be able to withstand the rigors of the licensing process. DOE has stated that "research activities which are not important to safety and waste isolation, and which will not be used to support DOE's license application, may not have the same degree of quality controls." This view fails to recognize the potential problems which could develop. Research activities involve the collection of data in which the results cannot reasonably be predicted beforehand. Due to the unpredictability of the results it would behoove DOE to embrace a conservative approach to QA for research activity. It is quite possible that certain research projects which were assumed to have no impact on the license application will produce results which could provide substantial license support. Therefore, by adopting a conservative attitude toward QA for research, unanticipated results which could prove useful in the licensing process, will receive a high degree of QA.

13. Issue

Some Project participants appear to hold a view of QA as unnecessary, burdensome, and an imposition.

Response

The view that the NNWSI Project QA program was unnecessary, burdensome, and an imposition stemmed from a statement made during the DOE/NRC QA meeting in December 1984. The NNWSI Project has strived to train, educate, and integrate the Project technical staff into the QA program and is continuing to do so. A very high percentage of technical staff has accepted and adopted a sound, healthy attitude toward QA. There will always be a few people in any large group that will require more attention to realize the importance of QA to the successful completion of the Project. There is also a potential for people to say things that they do not mean in a moment of frustration. We believe the single comment at an inappropriate moment is not representative of the majority of personnel in the NNWSI Project and should not be overly emphasized.

NRC Comment

The issue that some NNWSI project participants appear to hold a view of QA as unnecessary, burdensome, and an imposition was meant to be overemphasized by the NRC. However, the NRC staff considered it appropriate to draw the attention of management to the attitude that may prevail among the project participants. Management must continually emphasize to their employees that each individual is responsible for quality and management must, through training and an active QA function, attempt to assure that the highest quality standards are maintained. During the upcoming NRC audits, the project's prevailing QA attitudes should be identified through the project's performance.

14. Issue

NRC expressed concern over NNWSI's possible lack of authority and leverage over contractors and Project participants.

Response

Since the NRC site visit in December, 1984, the WMPO Director has been delegated Contracts Administrator Representative Authority for NNWSI project activities conducted by Fennix and Scission, Holmes and Narver, and the Reynolds Electrical and Engineering Company. A management agreement with the Albuquerque Operations Office which greatly strengthens the WMPO Director's authority has been signed. WMPO is continuing to pursue some additional management authorities to further extend the management control over participants.

NRC Comment

The staff provided comments on the NNWSI management control of projects in a letter dated March 11, 1986. The staff believes that the agreement between the Nevada Operations Office and Albuquerque Operations Office provides sufficient control, but that further improvements are needed in other agreements.

15. Issue

NRC was concerned over the USGS management structure (matrix support).

Response

The USGS has examined the existing internal organizational structure for USGS NNWSI Project activities and recommendations proposing alternate organizational structures have been forwarded to the Director, USGS.

NRC Comment

The NRC staff requests that any changes to the USGS management structure be expedited and details of any changes be forwarded promptly to the NRC for review.

SRPO SPECIFIC ISSUES

16. Issue

NRC noted the limited use of surveillances by SRPO.

Responses

SRPO agrees with NRC concerning the importance of an active surveillance program to assess the effectiveness of subtier QA programs. Some surveillances have been performed by contractors in the past, although with limited SRPO participation.

As SRPO enters the Site Characterization phase of the project, it will initiate an expanded surveillance program commensurate with the importance of the activities being performed. A SRPO QA procedure for surveillance has been drafted and will be in place prior to beginning site characterization.

NRC Comment

It seems it would also be useful to the SRPO to conduct surveillances of contractors and subcontractors to measure their progress in preparing for site characterization.

17. Issue

NRC noted the usefulness of an umbrella form and content document, like NNWSI's and the lack of one for SRPO.

Response

SRPO, utilizing those aspects of the NNWSI umbrella document appropriate for the SRP program, is developing similar, project-wide QA guidance on the development, description and implementation of contractor and subcontractor QA programs in order to obtain maximum uniformity of QA programs utilized on the Salt Repository Project. This guidance is being incorporated into the SRPO QA Plan rather than published as a separate document. This effort is scheduled for completion early in FY-86.

NRC Comment

The staff will review and discuss this plan during the next visit to the site.

18. Issue

NRC questioned traceability of ONWI reports to subcontractor reports.

Response

ONWI has developed an action plan in response to this comment to correct the noted conditions. This plan has been submitted to and approved by SRPO. Periodic checks to assure the Plan is being followed are made by SRPO.

NRC Comment

The staff will review and discuss the plan during the next visit to the site.