

United States Government

Department of Energy

memorandum

DATE: DEC 31 1985

REPLY TO
ATTN OF: RW-24

SUBJECT: Minutes of DOE/NRC Meeting on Quality Assurance

TO: Distribution

Enclosed is a signed copy of the minutes of the subject meeting which was held December 4-5, 1985, in DOE's Forrestal Building, Washington, DC. Please contact me if any additional information is needed (FTS 252-1248 or commercial 202-252-1248).

Carl Newton

Carl Newton
Quality Assurance Manager
Office of Geologic Repositories

Enclosures

WM DOCKET CONTROL
CENTER

86 JAN -6 PM 2:48

WM Record File

405

WM Project 1

Docket No.

PDR ☒

LPDR

8601240069 851231

PDR WASTE
WM-1

PDR

Distribution:

REB	MJB	*JKennedy	*HJM
MDellagatti	DRM	*SBilhorn	
(Return to WM, 623-SS)	DHedges	Sac	

DISTRIBUTION

M. E. Langston, RW-40
W. J. Purcell, RW-20
J. Leahy, RW-25 (20 copies)
R. Stein, RW-23
K. Mihm, RW-24
T. Isaacs, RW-20
D. Alexander, RW-23
C. Head, RW-24
R. Gale, RW-40
G. Oertel, EH-30
N. Goldenberg, EH-32
J. Reese, DOE-CH-SRPO
J. Clark, DOE-RL
M. Flannigan, DOE-CH
J. Blaylock, DOE-NV
B. Kehew, DOE-CH; CPO
R. Purple, RW-43
H. Steinberg, RW-33
J. Morris, RW-22
S. Frank, PE-252
E. Gause, Weston
B. Hewitt, Weston
D. J. Brown, Weston
E. W. Sulek, Weston
L. Ibe, Weston
H. L. Bermanis, Weston
J. Nelson, Weston
C. Williams, Battelle-Columbus, OH
I. J. Lefman, Battelle-Columbus, OH
C. O. Wright, Holmes & Narver
Las Vegas, NV
J. W. Estella, SAIC

S. Metta, SAIC
R. G. Baxter, DuPont Co,
Savannah River
B. G. Kitchen, Savannah
River Lab
T. Wood, PNL/BWO
R. Johnson, Rockwell
M. Frei, RW-23
D. August, RW-22
R. Blaney, RW-22
E. Burton, RW-25
B. Gale, RW-25
J. Parker, RW-25
J. Rhoderick, RW-24

H. J. Miller, NRC ✓
S. Bilhorn, NRC ✓
M. E. Ginevan, NRC-RES
M. S. Delligatti, NRC ✓
F. Forscher, NRC-I&E
S. Grace, NRC ✓
T. Verma, NRC-Columbus
J. Wittman, State of Utah
J. Donnelly, NRC-I&E
C. Cameron, NRC
B. Grimes, NRC
T. Ankrum, NRC
W. D. Altman, NRC
C. Walenga, NRC
KyungKoh, Newman & Holtzinger
D. Mausshardt, NRC
P. Brooks, IC-43 ✓
R. E. Browning, NRC
F. Swanberg, NRC
T. Cardone, NRC ✓
D. Fehring, NRC ✓
D. Gupta, NRC ✓
D. S. Ward, Geotrans/Yakima
L. Yang, NRC
J. Pearring, NRC ✓
J. S. Trapp, NRC ✓
K. Stablein, NRC ✓
T. McCartin, NRC ✓
J. Kennedy, NRC ✓
L. August, Geotrans/Yakima
Indian Nation
C. Robert McFarland, State of
Mexico
E. J. Hennelly, Savannah River
R. Belyea, SAIC/NV

R. Richards, Sandia
H. Z. Dokzoguz, SAIC/NV
V. Lowery, RW-23
D. Stucker, RW-23
D. Youngberg, RW-24
C. Klingsberg, RW-24
A. Jelacic, RW-24
S. Grodin, RW-24
J. Fiore, RW-22

Minutes of DOE/NRC Meeting on Quality Assurance

December 4 - 5, 1985

The meeting was held on December 4-5, 1985 in DOE's Forrestal Building, 1000 Independence Avenue, in Room 1E-245. Material that was discussed at this meeting has been collected and is included as enclosures to these minutes. Enclosure 1 is an index to the enclosures. Enclosure 2 is a list of the attendees at the meeting. The agenda for the meeting is included as enclosure 3.

Introductory remarks were made by Mr. Ben Rusche, Director of DOE's Office of Civilian Radioactive Waste Management. Mr. Rusche stressed the commitment of DOE management to quality and noted many recent accomplishments.

Mr. John Davis, Director of NRC's Office of Nuclear Material Safety and Safeguards, also made introductory remarks. Mr. Davis reviewed some of the mistakes made by the Nuclear Power industry in quality assurance and encouraged DOE to try to avoid making the same ones. Mr. Davis also reaffirmed NRC's commitment to provide timely guidance to DOE on quality assurance matters.

DOE Observations

1. NRC indicated that their involvement with non-Q-List items not utilized in the license application would be limited to a review and evaluation for the purpose of assuring that none of these items and activities should be on the Q-List.
2. NRC indicated that the only activities they expect DOE to list in the SCP are major site characterization activities on the Q-List. Individual tests and experiments would not, in general, be required to be listed. Major, significant tests, however, will need to be listed in the SCP.
3. DOE felt they might, at some sites, be able to prove that the natural barriers and waste form could meet the NRC containment objective and thus that a waste package would not need to be on the Q-List. NRC indicated that the waste package should be on the Q-List because of the containment performance objective in 10 CFR 60.113(a)(1).

4. DOE requested an opinion from NRC as to whether the DOE project office QA organizations met the NRC requirement for independence. NRC indicated that either of the two arrangements DOE projects now have can work. NRC indicated that they were not yet in a position to determine whether the DOE organization arrangements meet the NRC criterion for QA independence from cost and schedule. NRC indicated that a variety of different organizational arrangements can work; the key factors are whether the quality message received at the level to which QA reports is as strong as the cost and schedule messages it receives and the conduciveness of the organizational structure to escalating quality problems to higher 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. NRC committed to reviewing the projects' QA plans as soon as they are submitted to NRC by DOE HQ.

5. DOE presented an overview of the current size of the DOE project office staffs, the current size of the QA organizations supporting each project and the projected growth for these. DOE requested feedback from NRC on the suitability of these staffing levels. No opinion on the adequacy of the numbers was offered by NRC at the meeting. NRC noted the increase in staffing levels and indicated that a key consideration is the ability of the project to oversee and manage the activities and quality assurance programs of the contractors and participating organizations.
6. All six of the DOE draft supplements to the OGR QA Plan were furnished to NRC two weeks prior to the meeting for NRC review and comment. NRC offered general comments during the meeting and committed to provide detailed written comments by February 1, 1986.
7. NRC was unable to provide to DOE prior to the meeting copies of four NRC Technical Position Papers which were discussed during the meeting.

8. DOE provided to NRC two weeks prior to the meeting a series of questions on Q-List Methodology/Design Guidance and requested NRC's response. NRC offered general comments during the meeting and NRC committed to provide detailed written comments by February 1, 1986.
9. DOE is committed to providing NRC a schedule by January 31, 1986, showing when NRC can expect:
 - (1) to receive copies of the revised OGR-HQ QA Plan and Procedures for review and comment.
 - (2) to receive copies of the DOE first - repository project office QA plans and procedures for review and comment.
 - (3) to receive from DOE the rationale for why the DOE QA programs are considered to be fully qualified and ready for audits.

NRC OBSERVATIONS:

1. The staff outlined its plans for the next year for giving guidance to DOE on quality assurance and assessing the implementation of the QA program. In order for the NRC staff to not delay the schedules established by DOE for site characterization, DOE should furnish schedules within 60 days for detailed QA program milestones, such as availability of approved QA plans and procedures for the project offices and prime contractors, plans for additional DOE position papers or supplements which address selected QA issues, and the DOE rationale that programs are fully qualified and ready for NRC audits. The NRC staff needs this information for planning purposes so that it may respond quickly to DOE requests for reviews. This approach has been previously discussed in the letter from William Purcell, DOE, to R. Browning, NRC, dated September 3, 1985, and the NRC's analysis of aerospace techniques applied to the waste program as described in NUREG/CR-4271.
2. The DOE staff provided responses to most of the issues raised by the NRC staff during the December, 1984 QA site visits. Several remain to be addressed, however. These issues should be responded to by the DOE in the future, and a schedule for this response provided. Additional information on these issues can be found in the meeting minutes for the site visits.
3. In the DOE letter of November 19, 1985, confirming the arrangements for the December 4-5 meeting on QA, the DOE transmitted nine enclosures related to QA for the repository project (See Enclosure 4 to these meeting minutes). Enclosures 1-6 of the DOE letter are supplements to the OGR QA Program Plan. Enclosure 7 describes the DOE Systems Engineering Management Plan (SEMP) for the repository project. Enclosure 8 is DOE's response to issues raised by the NRC staff in the series of site QA visits in December 1984, and Enclosure 9 contains questions for the NRC on implementation of Q-list methodology.

During the December 4-5 meeting on QA, each of these DOE documents was discussed. NRC staff handouts contain bulletized comments on the six supplements to the OGR QA plan and the SEMP (see Enclosures 14-20 of these minutes). The staff will provide specific written comments to DOE on each of the nine Enclosures in the near future (see schedule below). General comments regarding the six supplements are as follows:

- (a) DOE stated that supplements will be developed as the need for them becomes evident. Only two additional supplements are planned at this time, peer review and qualification of historical data. Drafts of both are to be made available for NRC staff review in February 1986.
- (b) In writing supplements, and in revising the six supplements discussed at the meeting, the DOE should give careful consideration to ensuring that the purpose of the supplement is clearly stated, its scope is clearly defined, and its relationship for the OGR QA Plan and other

supplements clearly delineated. The staff noted an impreciseness of language in two of the supplements discussed at the meeting "Calibration of Measuring and Test Equipment" and "Computer Software QA" and these steps should both help clarify the language and the intended use of the supplements.

The staff's schedule for providing written comments to DOE on the enclosures to the DOE letter of November 19 is as follows:

<u>Enclosure</u>	<u>Date</u>
1-6 QA Supplements	January 31, 1986
7 Systems Engineering Management Plan (SEMP)	January 31, 1986
8 DOE Response to Site Visit Issues	March 5, 1986
9 Q-list Questions	January 31, 1986

4. The NRC staff presented briefings on five potential Generic Technical Positions (GTP's) on QA for the repository project. The topics were Configuration Management for Conceptual Designs, Peer Review, Qualification of Existing Data, QA for Research and Exploratory Activities, and Q-list (see Enclosures 8-13 of the meeting minutes). The staff plans to publish them for public comment in the Federal Register in early 1986. The staff will accord completion of the draft GTP's and publication in the Federal Register a high priority. For one of the tentative GTP's, QA for Research and Exploratory Activities, the staff has not reached a conclusion on whether guidance on this topic should be promulgated in the form of a GTP or some other form. The staff plans, however, to publish for public comment the other four GTP's.
5. The subject of audits and quality program oversight by various levels in the repository program hierarchy was the subject of considerable discussion during the December 4-5 meeting. NRC's experience from the power plant program is that QA audit and management oversight programs often focus largely on paperwork and programmatic issues. NUREG-1055 provides a comprehensive analysis of this problem, its causes, and its results. In this report, the NRC staff identified comprehensive multidisciplinary team inspections as a particularly useful tool for the identification of major real or potential quality or safety problems and for synthesizing the inputs of technical specialists/inspectors in a number of disciplines into a comprehensive picture of the quality of the overall project. In response to quality, QA, and potential safety problems that developed in power plant design and construction, the NRC developed two headquarters level team inspection programs, Construction Appraisal Team (CAT) Inspections and Integrated Design Inspections (IDI). Other team inspections covering operating plants are conducted from headquarters as well. The IDI team inspection approach was described at the meeting and DOE requested sample copies of IDI team reports.

Approaches to audits, evaluations, or inspections less comprehensive than IDI's were discussed at the meeting. There was general consensus that, early in a project, it is important to establish that an adequate QA program, from a programmatic viewpoint, has been established. Once this baseline program has been established, subsequent audits should focus on implementation of the program. The NRC staff emphasized the importance of ensuring that audit team membership include representation by people with appropriate technical experience and expertise in the technical areas to be reviewed. The staff also emphasized the need for substantive audits covering technical areas and focusing on program effectiveness, and the importance of close attention to, input to, and involvement in audit and evaluation activity by senior management of the organization performing the audit.

The staff referred to several different activities or references that collectively provide perspective on what NRC expects in terms of substantiveness of audits or program reviews and the identification of root causes of quality and QA problems. In addition to the IDI's and the data reviews conducted by the NMSS staff, other activities or references identified by the staff in this context were the findings of the NRC QA site visits in December 1984 and the QA case studies in NUREG-1055.

Common threads that run through these evaluation methods include the following:

- (1) a multidisciplinary team of experts in the major disciplines to be reviewed. The NMSS Division of Waste Management conducts interdisciplinary team data reviews which have similar objectives.
- (2) Selection of specific safety systems, activities or QA problems for review.
- (3) Comprehensive preparation in the details of what will be reviewed in the field before full field deployment of the team.
- (4) Team meetings in which each team members findings and observations are discussed, parallels to other areas are identified, and information is synthesized.
- (5) Involvement of appropriately skilled personnel (e.g., senior management from the reviewing organization) to help aggregate and sort findings, synthesize information, and put results from different disciplines into an overall project perspective.
- (6) Communication of the findings, both in the exit briefing and in the written report, to high levels of management of the reviewed organization.

DOE QA managers indicated their intent to perform substantive audits utilizing technical staff in conjunction with QA experts. Several DOE QA managers indicated that some audits of this nature have been conducted already. DOE staff indicated they are developing a QA auditor course emphasizing the measurement of QA program effectiveness specifically for waste management activities. The NRC staff expressed interest in this course and wishes to be kept informed of progress in its development.

6. During the meeting, the DOE and NRC staffs discussed the quality assurance information to be submitted or referenced in the Site Characterization Plans. Section 8.6 of the SCP will describe and reference the administrative QA procedures, and Section 8.3 will include and reference information on detailed technical procedures, including the specific implementation of the administrative QA requirements. The staff believes the general approach described is acceptable subject to the following: the staff is concerned that the traceability of QA requirements from the administrative procedures to the detailed technical procedures could be hindered by an insufficient level of detail in the QA administrative procedures referenced in the SCP. It would be helpful to the staff if examples could be provided before the SCP is submitted showing the hierarchy of documents which define and implement quality assurance measures. Certain of these documents should also be furnished for staff review.

In a related matter, the DOE and NRC staffs discussed the use of separate QA procedures to accompany the detailed technical procedures, or alternatively, DOE's consolidation of detailed QA requirements and procedures into the technical procedures. The staff believes either approach would be acceptable.

7. In August 1985, the NRC issued Revision 3 to Regulatory Guide 1.28 which endorsed NQA-1 (with minor exceptions) as an acceptable way to meet the QA requirements of 10CFR50 Appendix B for design and construction of nuclear power plants. The ASME's Committee on Nuclear Quality Assurance (NQA Committee) has expressed a strong interest in having the NRC staff endorse NQA-1 for application to activities associated with nuclear waste repository.

The DOE through a DOE order has endorsed NQA-1 as describing an acceptable program for meeting DOE QA requirements. During the December 4-5 meeting on QA, the DOE asked the NRC what NRC's plans were for endorsing NQA-1 for waste management, including its schedule.

The NRC plans to endorse with some exceptions, NQA-1 as an acceptable way to meet most of the requirements of Appendix B for waste repositories. The staff does not believe that NQA-1 provides sufficient guidance in some areas pertaining to repositories, and pursuant to 10CFR60 Subpart G, the staff has supplemented and will further supplement the criteria of Appendix B with additional QA criteria and guidance as applicable.

In the hierarchy of supplementary guidance on QA, the primary program reference is and will continue to be the NRC QA Review Plan. Guidance in this plan supplemented as appropriate by staff GTP's and other guidance issued by the NRC staff. The staff plans to endorse NQA-1 for repositories via a GTP. In the interim, DOE should feel free to use NQA-1 for QA guidance to the extent that it does not conflict with the QA Review Plan and other GTP's and staff guidance that have been or may be issued.

The staffs plans are to publish a draft GTP in the Federal Register for public comment in early 1986 endorsing NQA-1 with some exceptions as describing an acceptable program for meeting the QA requirements of Appendix B.

8. During the meeting, the NRC and DOE staffs discussed the use of readiness reviews for assessing the adequacy of the DOE programs, including the quality assurance program. The staff believes such readiness reviews can help to provide a DOE rationale to the NRC that work has been or will be performed in accordance with NRC regulations. It has been an apparently successful technique employed in non-nuclear applications (e.g., aerospace). NRC oversight of DOE readiness reviews could also provide a part of the basis for the staff's overall evaluation of the DOE quality assurance program before the start of site characterization. The staff believes such readiness reviews would be an effective and efficient method for the staff to help fulfill its objective of assessing the DOE QA program before site characterization. The staff encourages DOE to propose methods for conducting their readiness reviews which would involve NRC staff oversight.
9. During NRC's presentation on the Q-list, the definition for "important to waste isolation" was provided. The NRC emphasized that the waste package and associated activities are included on the Q-list under this definition.
10. During discussion of the scope of the Q-list, retrievability was addressed. NRC emphasized that items and activities related to retrievability would need to be considered in development of the "Q-list."
11. NRC noted that in addition to "items", major site characterization activities need to be included in the Q-list as well. These activities need to be listed to enable the staff to evaluate, in its SCP review, the adequacy of the scope of site characterization activities planned to address the information needed to support licensing decisions.
12. DOE presented issues related to questions previously submitted to the NRC on implementation of the Q-list methodology. NRC committed to responding to these questions by January 31, 1986. Following discussion of these issues, both staffs agreed to the need for a separate meeting on the subject. Preliminary discussions identified two important issues needing follow-up:

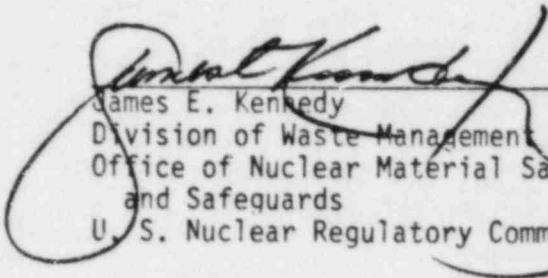
subject. Preliminary discussions identified two important issues needing follow-up:

- (a) Applicability of a low probability cutoff for determining what items and activities are important to safety. DOE proposed a frequency of 10^{-5} per year and NRC indicated that this may not be sufficiently conservative. The justification for establishing such a limit needs to be explored further by both DOE and NRC staffs considering such documents as the recent draft ICRP report on waste disposal (ICRP/85/C4-8/12) and NUREG-0612.
 - (b) Design basis accidents for developing Q Lists are not explicitly addressed in Part 60. The NRC staff committed to evaluating whether Part 60 implicitly establishes a design basis of 500 mrem or whether the regulation is silent on the issue of design basis accidents and would allow the NRC flexibility to establish a specified design basis accident. DOE proposed a limit of 5 rem, as is currently allowed in Part 72 for determining the controlled area of similar facilities.
13. In order to enable NRC staff to maintain sufficient cognizance of DOE QA activities and provide guidance in a timely fashion, NRC requests that it be added to formal distribution of all audit reports and written responses to same and receive controlled copies of approved QA plans and procedures for OGR, OGR project offices, and the prime contractors for each office.
 14. DOE presented the methodology recently proposed by Headquarters for grading QA. This methodology includes four quality levels with grading to be applied within each. Since quality level one will contain those items and activities on the Q-list and subject to 10CFR60 QA requirements, the NRC staff is interested in the details of applying graded QA within quality level 1. As noted in the DOE-NRC meeting minutes from the July 1, 1985 meeting on Q-list, DOE is permitted by Appendix B Part 50 to grade QA in accordance with the importance to safety or waste isolation of particular items. NRC also noted that DOE quality levels two through four would also be reviewed but only to assure that the scope of quality level 1 included all items and activities on the Q-list, or to be referenced in or supporting the license application (such as Part 20 requirements).

STATE OF NEW MEXICO OBSERVATIONS

Mr. C. R. McFarland of the State of New Mexico had four comments that he recommends be considered in setting limits for Design Basis Accidents:

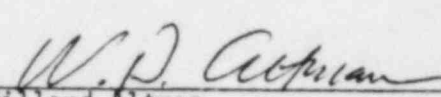
- 1) Consider the curie content of the Waste Package.
- 2) Consider the fraction of the radioactive material that would be in respirable size particles (i.e., less than about 10 microns) for workers to inhale and for the fence post dose.
- 3) Consider the transport medium and flow path, mitigating systems (natural and engineered), and travel time for emplaced waste - especially where drifts have been backfilled.
- 4) Consider K-effective for worst case analyses.



James E. Kennedy
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards
U. S. Nuclear Regulatory Commission

Carl Newton

Carl Newton
Licensing and Regulatory Division
Office of Geologic Repositories
U. S. Department of Energy



Willard Altman
Division of Quality Assurance, Vendor, and
Technical Training Center Programs
Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission