



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555
SEP 29 1988

MEMORANDUM FOR: Quality Assurance Section
Project Management and Quality Assurance Branch
Division of High-Level Waste Management

FROM: Bill Belke, Quality Assurance Section
James Donnelly, Quality Assurance Section

SUBJECT: ITEMS LIST

Please find attached: (1) Items List Form (Attachment A) and
(2) Items List (Attachment B).

Background

Over the past five years, numerous quality assurance (QA) items have been identified in meetings with the Department of Energy (DOE), On-site Licensing Representative (OR) reports, reviews of DOE documents, etc. In a September 3, 1986 management meeting with DOE, both DOE and NRC agreed to independently develop lists of items for helping plan future work. The NRC's items list is attached and provides a concise list of issues that will be used to focus on problem areas, develop plans to review DOE's QA programs, and to plan future audits.

The list was developed from documents in Jim Kennedy's issue file, the OR monthly reports, Jim Kennedy's personal correspondence file with DOE, meeting minutes from 12/84 and 12/85 meetings with DOE, staff observation audits, and discussions with DOE and NRC staff. The issues represent a variety of concerns ranging from staff impressions to documented regulatory concerns. For example, numerous issues are management issues and have no direct regulatory basis for NRC action. These items are included as an indicator of the function of the overall program. The issues which have a regulatory basis will be submitted to DOE in order to aid them in establishing a program that meets the regulatory requirements.

It should be noted that this is not an active list but rather a historical record. This list was used to prepare for the July 7, 1988 meeting with DOE in which open items were discussed and resolved. This list has since been superseded by a computerized open items tracking system which will be issued in the near future.

The list (Attachment B) contains eight columns. The explanation of these columns is as follows:

Column 1: This is a numerical listing of the particular item. It has no meaning other than to indicate the number of items the NRC staff has identified.

Column 2: Item and Item Number - The item (i.e., issue) will be briefly summarized in order to give the user of the document a workable understanding of the concern.

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Column 3: Open - by using "Y" for yes and "N" for no, this indicates whether the item is still open or has been satisfactorily closed out.

Column 4: Project Participation - This column will list the organization the concern applies to, (e.g., NNWSI, OCRWM, USGS, etc.)

Column 5: Level of Importance. This can be either Level I, II, III, IV, or O and is classified in accordance with the following.

Level 1 - Indicates a critical staff position and failure to address it would affect the ability of DOE to provide the documentation of the data or analyses needed in licensing. Site characterization work should not be started until the position is incorporated into the appropriate document and implemented.

Level 2 - Same as Level I but documentation can be generated while work continues without jeopardizing the defensibility of data in licensing, e.g., incomplete qualification records of personnel.

Level 3 - A staff position which is not specifically addressed but which is believed by the staff to be in place, based on the staff's information from audits, procedure reviews, etc. This assumption will need to be verified by DOE. A decision on the need for a revision to the appropriate documents and work in progress will be made after receiving information from DOE.

Level 4 - A deviation from a staff position which describes a "good practice" based on the staff's experience with power reactor lessons learned, but which does not directly affect the production of documentation describing the quality of data or analyses, compliance with the regulations or the quality of data or analyses. Work can continue and revisions to the appropriate documents may be incorporated at a later date when other revisions are incorporated. DOE may also elect to justify why their existing program need not have "good practices" incorporated.

Level 0 - Indicates that a level assignment is not applicable.

Column 6: Source - For ready reference, this column will identify the actual reference, document, meeting or individual from which the item originated.

Column 7: Appendix B Criteria - The affected Appendix B criterion of 10 CFR Part 50 is identified. If Appendix B does not apply, the column will indicate "O" (not applicable).

Column 8: NRC/DOE Action - Will identify the corrective action or the proposed corrective action to be taken by either DOE or NRC, as appropriate, in order to close the item. Two commonly used responses are noted as footnotes. They correspond to the following:

Footnote #1: This is a site specific concern and does not affect the Yucca Mountain site or related data. This footnote is primarily for SRPO and BWIP concerns which are site specific in nature. This item should be closed out.

Footnote #2: This is a staff impression. Staff impressions have no supporting evidence and are not regulatory requirements. Consequently, these items should be closed out.

For future items, the items list form (Attachment A) should be filled out and submitted to the appropriate staff for incorporation into the items list.

Instructions

1. Filling out the items list form:

The headings in Attachment A are identical to those used for the attached items list. Consequently, the same format and information, as described earlier, should be provided. Nonetheless, some additional points should be made.

- A. For sorting purposes, it is important that a common format be used when indicating the organization involved. For example, when a concern is listed which affects the DOE Project Office use "NNWSI" not YMPO." Likewise, use "OCRWM" instead of "OGR" for a DOE headquarters concern.

Other acronyms which should be used are SNL, LLNL, LANL, USGS, F&S, H&N, REECO, and All. "All" indicates a project wide concern.

- B. When describing the "NRC/DOE Action" necessary to resolve the concern, two common footnotes should be used for similar action. They are as follows:

1. This is a site specific concern and does not affect the Yucca Mountain site or related data. This footnote is primarily for SRPO and BWIP concerns which are site specific in nature. This item should be closed out.
2. This is a staff impression. Staff impressions have no supporting evidence and are not regulatory requirements. Consequently, these items should be closed out.

When referencing the footnotes above use the following statement "See Footnote # ____."

- C. Sign and date the bottom of the items list form.
- D. Attach the form to the source document and submit to W. Belke or J. Donnelly.

The items list will be updated on a quarterly basis. Should there be any questions, please contact Bill Belke (x20445) or Jim Donnelly (x20453).

10/1
B. Belke, Quality Assurance Section

11/1
J. Donnelly, Quality Assurance Section

Attachments: As stated

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NAME: JKennedy	: BBelke	: JDonnelly	:	:	:	:
DATE: 09/29/88	: 09/29/88	: 09/29/88	:	:	:	:

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ATTACHMENT A

ISSUES LIST FORM

PROJECT PARTICIPANT:

ITEM:

SOURCE:

NRC/DOE ACTION:

LEVEL OF IMPORTANCE:

OPEN:

APPENDIX B CRITERIA:

NAME:

DATE:

ATTACHMENT B

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
1. Generic QA issues are not being resolved by DOE.	N	ALL	0	Site visit summary for Davis, early 1985 Hub Miller.	0	Delete specific issues not identified
2. DOE headquarters needs to address how WV, WIPP, and DWPF info. will be QA'd for a licensed repository.	Y	ALL	3	SRPO meeting minutes, 12/19/84.	2	NRC/DOE discussed at 3/24/88 CDSCP meeting. Schedule for DOE submittal need to be developed.
3. DOE needs to define conceptual, Title I, Title II, and Title III designs.	Y	ALL	3	BWIP site visit minutes, 12/12/84.	3	NRC plans to ask for clarification with RAI when F&S QAPP is submitted for review.
4. 1. Will HQ or project office be the applicant for license? 2. The DOE is leaning too heavily on contractors.	Y	ALL	0	Note to H. Miller from D. Hedges draft: July 1, 1985.	0	1. Closed- 10CFR 60.3 says DOE, 6 ⁷ defines DOE. 2. Closed- DOE cannot do work by law, must contract. DOE must audit contractors.
5. DOE's use of lead auditors from non-Nevada Field Offices.	N	NNWSI	0	NNWSI site visit meeting minutes, 12/14/84.	18	If lead auditors are qualified as committed to in QAP, this is acceptable no matter where they are from.
6. SOP should be brought into compliance with GTPs.	Y	NNWSI	2	Memo to Browning from Grimes, "Review of NNWSI project's data acceptance SOP and nonconformance SOP" dated October 28, 1986.	3	RAI generated requesting commitment to GTPs. Will verify as part of QAP review process. Also, obj. #5 and comment #108 of the CDSCP review address this issue.
7. LLNL found inconsistent terminology in Brookhaven document: NUREG/CR 3091, BNL-NUREG 51630 Vol. 6.	Y	LLNL	0	Letter from Virginia Oversby, LLNL, to Vieth dated 11/4/85.	0	NRC to check NUREG to see if revised. Also, need to coordinate with technical group.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
8. Problem of mapping faults and determination of origin and nature of fault deposits. Some disagreement w/how management at HQ has handled the problem.	Y	USGS	1	Letter to Dudley (USGS) from Vieth.	2	Problem must be coordinated with NRC technical group.
9. DOE needs to provide detailed schedules and milestones for qualification of their QA program so that NRC can plan to respond quickly. This includes availability of QA plans and procedures. Otherwise NRC staff will be unprepared to respond.	Y	ALL	1	Dec. 5, 1985 meeting minutes.	0	Schedule partially submitted to NRC 9/18/87. Needs to be updated. Documented as obj. #5 of the CDSCP review. Discussed with DOE @ 3/24/83 mtg. Awaiting DOE response.
10. DOE committed to provide rationale on how and why QA programs are considered to be fully qualified and ready for audits. Staff would have insufficient basis for disagreeing that program is OK without DOE rationale.	Y	ALL	1	Dec. 5, 1985 meeting minutes.	0	Combined with #9.
11. DOE has a very long way to go to get QA programs in place and implemented, but HQ doesn't seem to be pushing hard enough.	Y	ALL	0	Internal note, staff impressions from meeting with Purcell, 7/10/85.	0	Combined with #9.
12. DOE has not yet laid out detailed milestones and schedules so NRC and DOE can have meaningful technical reviews.	Y	ALL	1	Note to John Davis from Robert Browning, "Topics for Discussion with Rusche," dated 7/2/86.	0	Combined with #9.
13. OGR needs to develop a master plan and schedule for determining the readiness of the HQ-OGR and project level QA programs, including tasks to be completed.	Y	MISC OGR	1	Internal DOE management appraisal, 11/7/86.	0	Combined with #9.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
14. OGR needs to develop a comprehensive management overview activity including management appraisals, tech. assessments, and audits.	Y	OCRWM	2	Internal DOE management appraisal, 11/7/86.	2	The NRC will verify that provisions exist during future audits and obs. audits.
15. DOE staff is too small and too inexperienced to oversee contractors.	Y	ALL	0	Internal note, from meeting with Purcell, 7/10/85.	1	NRC staff, through QAP reviews, will obtain a commitment that QA org. has sufficient auth. and qualifications. Draft NQA-3 has a statement on no. of personnel and NRC may endorse this if finalized. Place concern on a generic checklist and eval. during future audits and obs. audits.
16. HQ QA organization not strong or assertive enough, not large enough.	Y	ALL	0	Internal notes, staff impressions from meeting with Purcell 7/10/85.	1	Combine with #15.
17. DOE has only one staff member assigned to the NNWSI QA program.	Y	NNWSI	0	Trip report to Newton K. Stablein from Dale Hedges (to USGS) trip date May 20, 1986. Document dated June 9, 1986.	1	Combine with #15.
18. DOE HQ staff office is not large enough to oversee contractors, is not involved enough, is not aggressive enough.	Y	ALL	0	DOE QA program - NRC staff impressions - no date or signature.	1	Combine with #15.
19. Expertise and experience is with the contractors not DOE management.	Y	NNWSI	0	(Ford Amendment Study) "Perspectives on QA in the DOE HLW Repository Program" in HLW Focus - of the Radioactive Exchange no data by Robert Loux director NNWPO.	1	Combine with #15.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
20. Size and qualifications of DOE QA staff are inadequate resulting in heavy reliance on contractors.	Y	ALL	0	Note to John Davis from Robert Browning, "Topics for Discussion with Rusche," dated 7/27/86.	1	Combine with #15.
21. Insufficient overview of contractor activities by project office.	Y	ALL	0	Bilhorn, "Problems/issues from sites," fall 1985.	1	Combine with #15.
22. Small DOE staffs are unable to assure quality work by contractors.	Y	ALL	0	Note to Jim K. from Dale H., dated May 15th, "Minutes of Meeting NRC-DOE HQ," April 14, 1986.	1	Combine with #15.
23. Size of DOE staff at project, field offices and at HQ is small in comparison to the number of contractors.	Y	NNWSI	0	Site visit summary for Davis, early 1985/Hub Miller.	1	Combine with #15.
24. Adequate size and independence, and authority of OGR QA function need to be established.	0	MISC HQ	0	Internal DOE management appraisal, 11/7/86.	1	Combine with #15.
25. Relationship between DOE and Labs (as contractors is too informal).	Y	NNWSI	2	Bilhorn, "Problems/issues from sites," fall 85.	7	Combine with #26.
26. Informal agreements rather than contracts with labs as prime contractors.	Y	NNWSI	2	Coplan to Vieth regarding review of rock mechanics/design data.	7	NRC needs to formally identify this to DOE. Subsequent evaluation will take place during audits and obs. audits.
27. DOE has only one staff member assigned to the NNWSI QA program.	N	NNWSI	0	Trip report (NNWSI Las Vegas, NV) trip date 4/25-5/1/86 from Dale Hedges to King Stablein. Report dated 5/15/86.	1	Combine with #15.
28. Size and authority of NNWSI staff. Limited authority over contractors.	N	NNWSI	0	NNWSI site visit meeting minutes, 12/14/84.	1	Combine with #15.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
29. Lack of adequate staff in QA operations offices.	N	NNWSI	0	NNWSI Project Status Report, QACG Meeting 7/23/87, Consolidated Audit Findings.	1	Combine with #15.
30. DOE can't get the experienced QA people it needs.	N	ALL	0	Memo for Paul Hildenbrand from Dale Hedges, "Appendix 7 Visit to Discuss Suggested Changes to NRC Review Plan, and Discuss NRC Observations Relative to MAC Audits," dated 5/5/86.	2	NRC staff, through QAP reviews, will obtain a commitment that QA org. will have qualified personnel. This concern will be placed on a generic checklist and verified during future audits and obs. audits.
31. Some strong resistance to QA continues within DOE.	N	ALL	0	Internal note, staff impressions from meeting with Purcell, 7/10/85.	1	See footnote #3.
32. Indoctrination and training program limited.	Y	OCRWM	0	DOE management appraisal, 11/7/86.	2	Look at during audits and audits obs. Place on generic checklist.
33. NRC: The DOE has relegated the QA organization too far down in the organization for it to be effective.	Y	NNWSI	2	Perspectives on QA in the DOE HLW repository program in HLW focus - of the Radioactive Exchange - No date by Robert Loux Director, NNWPO.	1	DOE has supposedly reorganized and elevated QA to a higher authority. This will be verified during future audits and obs. audits.
34. OGR has relegated QA to the lowest levels in the organization.	Y	ALL	2	Points for Purcell by Kennedy, December 1985.	1	Combine with #33.
35. Lack of knowledge/understanding of QA as a discipline and the purpose of a QA program and its requirements by many people in the NNWSI program, particularly in the scientific disciplines.	N	NNWSI	2	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	2	This is a DOE identified problem. Place this issue on a generic checklist and evaluate during future audits and obs. audits.
36. QA documents from major contractors held as proprietary and unavailable for NRC or DOE review.	Y	ALL	3	Bilhorn, "Problems/issues from sites," fall 1985.	7	Place issue on a generic checklist and evaluate during future audits and obs. audits.

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37. Loux - inability of DOE management to implement a system that ensures adequate control over all aspects of the project.	N	NNWSI	1	Perspectives on QA in the DOE HLW repository program in HLW focus - of the Radioactive Exchange - No date by Robert Loux Director, NNWPO.	1	Lack of supporting detail. Place concern on a generic checklist and evaluate during future audits and obs. audits.
38. HQ uninformed of project activities.	N	OCRWM	1	Bilhorn, "Problems/issues from sites," fall 1985.	0	Place concern on a generic checklist and evaluate during future audits and obs. audits. This concern will be evaluated for the life of the project.
39. Regional/Field office involvement in National Lab activities weakens direction and control from project offices.	N	ALL	4	Bilhorn, "Problems/issues from sites," fall 1985.	0	Place concern on a generic checklist and evaluate during future audits and obs. audits.
40. DOE has <u>limited</u> oversight over the project offices and their contractors. 1. Audits too short. 2. Audits too infrequent. 3. Audits insufficient (potentially)	N	ALL	0	Points for Purcell by Kennedy, December 1985.	18	Combine with #47a.
41. DOE audits are inadequately planned. 1. Knowledge of work in progress is lacking. 2. Audits only consist of scheduled ones so that surveillance and monitoring of work in progress are not included. 3. Time required to conduct audit was insufficient.	N	BWIP	0	Note to Kennedy from Hedges "Audit 18 of PNL by DOE (Salt and BWIP)" dated 9/16-19/85.		Combine with #47a.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
42. DOE audit team does not have current knowledge of work schedules to plan effective audits.	N	NNWSI	0	Note to Kennedy from Hedges, "DOE Nevada Audit of USGS in Denver, and Menlo Park.	18	Combine with #47a.
43. Work is not in progress. Thus, it appears that performance is good but, in fact, performance cannot be measured.	N	NNWSI		Unknown	0	No supporting information. Delete.
44. DOE audits do not allow enough time when pre & post meetings are taken into account.	N	NNWSI	0	Note to Kennedy from Hedges, "DOE (Nevada) Audit of USGS in Denver and Menlo Park."	18	Combine with #47a.
45. Performance cannot be adequately assessed.		MISC				
46. DOE's audit checklist did not contain specific audit objectives or guidance for audit of Parsons' quality program.	N	MRS	0	From Ankrum to Rouse, "IE Comments on DOE's Audit of R.M. Parsons Co.," dated Aug. 5/85.	18	Combine with #47a.
47. Insufficient preparation for DOE's audit of Parsons' quality program.	N	MRS.	0	From Ankrum to Rouse, "IE Comments on DOE's Audit of R.M. Parsons Co.," dated Aug. 5/85.	18	Combine with #47a.
47a. DOE audit program is ineffective (e.g., poor preparation, lack of coordination between QA and tech. auditors, timing of audit was poor, not enough time to conduct a thorough audit, results poorly communicated to auditee, not enough audits).	Y	ALL	1	See item numbers from 40-47. Also, F&S obs. audit report dated 4/12/88, H&N obs. audit report dated 5/2/88, C. Walenga report dated 11/10/86.	18	These issues are now addressed in a checklist prepared for all future obs. audits. The results will be documented. Likewise, this would be evaluated during any future staff audits.

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48. Lack of documentation to verify management control of contractors by the Director of WMPO and there is little indication that the Director would be given that responsibility.	Y	NNWSI	2	Memo to Purcell from Vieth Oct. 18th, "Management Control of Contractors."	1	NRC staff will evaluate during QAP reviews and will verify implementation through future audits and obs. audits.
49. All work is not being properly documented. (USGS noted).	N	ALL	1	Internal note, staff impressions from meeting with Purcell, 7/10/85.	1	DELETE. See footnote #3.
50. BWIP's definition of records does not require that the originator of records sign the records.	N	BWIP	0	Cook to Browning "Observations, Comments, Recommendations, June 14-July 18, 1986."	17	DELETE. See footnote #1.
51. Original records are not required to be retained and controlled according to definition of records by BWIP.	N	BWIP	0	Cook to Browning "Observations, Comments, Recommendations, June 14-July 18, 1986."	17	DELETE. See footnote #1.
52. All 3 projects have independent efforts to put QA programs in place.	N	ALL	0	Points for Purcell by Kennedy December 1985.	2	DELETE. Two projects cancelled due to N/WPA amendment.
53. IE staff concerned that DOE org. arrangements are similar to those that led to problems in the reactor area. Specific concerns: field office independent of HQ, no clear designation of who is responsible for license application.	Y	ALL	2	Internal note, staff impressions from meeting with Purcell, 7/10/85.	1	The staff will evaluate this through audits and obs. audits. Also, the NRC needs to arrange a mtg. with DOE to discuss who is responsible for license submittal.
54. DOE HQ-field office (FO) relationship unclear. Specifically, is FO independent of HQ and will submit license application.	Y	ALL	2	DOE QA Program - NRC staff impressions - no date or signature. Talking paper prepared for David-Rusche meeting late 1985.	1	Combine with #53.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
55. Lack of centralized management, specifically related to defining the role of field offices. Involvement of field offices tends to reduce OCRWM control. In fact, they have prohibited OCRWM from auditing project office contractors.	Y	ALL	2	Note to John Davis from Robert Browning, "Topics for Discussion with Rusche," dated 7/27/86.	1	Combine with #53.
56. Responsibilities assigned to the Director of Quality Assurance may compromise the independence of the QA organization as required by licensing related criteria.	Y	BWIP	2	Audit report RHO, BWIP, QA Program February 1984.	1	Combine with #53.
57. DOE commitment to meeting between May-August 1986 to discuss methodology, implementation and schedule for Q level assignments still outstanding.	Y	ALL	2	Summary of NRC/DOE meeting on the level of detail for site char. plans and study plans May 1986.	2	Combined with #66a.
58. DOE is not implementing or considering the application of QA requirements to design activities for the engineered barrier system and geol. setting prior to SCP.	Y	ALL	2	Cook, Report of Activities, Observations and Comments for the period Nov. 1 - Dec. 15, 1984.	2	Combined with #66a.
59. The QA levels, under which the data for the Tuff Data Base were acquired, are not included in the Data Base. They also are not included in published reports.	Y	NNSWI	2	Monthly report from P. Prestholt to Browning approximate date 12/85.	2	Combined with #66a.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
60. Engineered barriers are not on the Q-list.	Y	NNWSI	2	Memo from Prestholt for Browning w/excerpt from Sandia Report "Initial Q-list for the Prospective Yucca Mtn Repository Based on Items Important to Safety and Waste Isolation," by T. W. Laub and L. J. Jardine.	2	NRC staff documented this in comment #106 of the CDSCP review. Awaiting DOE response.
61. DOE QA is having difficulty in designating levels of QA.	Y	NNWSI	2	Trip report (NNWSI Las Vegas, NV) trip date 4/25-5/1/86 from Dale Hedges to King Stablein. Report dated 5/15/86.	2	Combined with #66a.
62. Q-level assignments at LLNL are inappropriate by Allen and Blaylock.	Y	NNWSI	2	Draft results of 2/2-7/86 audit of LLNL.	2	Combined with #66a.
63. DOE considers tests in G-Tunnel to be a level III as per discussions. The document does not specify the QA levels of these tests nor does it specify whether or not the tests in G-tunnel or exploratory shaft will be used in licensing.	Y	NNWSI	2	Draft SCP - 17 Mar 86 with attached Summary by Dale.	2	Combined with #66a.
64. QA levels of experiments at LLNL were designated level 3 but could possibly be graded level 1.	Y	NNWSI	2	Note to Jim K. from Dale H., "Notes on the Appendix 7 Visit to Las Vegas and Livermore," 6/23-28/1986.	2	Combined with #66a.
65. Incorrect application of QA level assignments.	Y	NNWSI	2	NNWSI Project Status Report on QACG Meeting, 7/23/87, Consolidated Audit Findings.	2	Combined with #66a.

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66. BWIP has tentatively concluded that waste forms, including spent fuel, are not to be Q-listed.	Y	BWIP	2	Cook to Browning, "Observations, Comments, Recommendations June 14-July 18, 1986."	2	Combined with #66a.
66a. Quality level assignments (Q-listed items and activities) are inappropriate.	Y	NNWSI	2	See items numbered 53-66.	2	Items addressed in comments #104 and #105 of the CDSCP review. Awaiting DOE's response. This concern will also be placed on a generic checklist and evaluated during future audits and obs. audits.
67. DOE approach to QA is not one that pays much heed to convention (i.e., attendees to lead auditor course had little QA background).	N	ALL	0	Memo to Browning from Delligatti- "DOE QA Training," dated 10/30/84.	18	How else are people supposed to learn? NRC obtains commitment in GAP that auditors will be qualified and subsequently, this will be verified during future audits and obs. audits.
68. 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. The NRC requested examples prior to the submittal of the SCP.	Y	ALL	3	Summary of NRC/DOE meeting on the level of detail for site char. plans and study plans May 1986.	0	NRC needs to find out more about this concern.
69. AO refers to NQA-1-1983 as a regulatory requirement but this has not been endorsed by NRC.	Y	ALL	3	From Kennedy to File, "AO Comments by QA," 2/5/85.	2	The NRC staff will review and possibly endorse NQA-1-1986 in the near future and will notify DOE.

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70. NQA-1 supplements are not used in their entirety in BQARD.	Y	BWIP	3	Memo to Browning from Grimes, "Review of Basalt QA Requirements Document (BQARD)," dated October 28, 1986.	2	Although site specific NRC will review NNWSI 88-9 GAP to determine extent of compliance with NQA-1.
71. The DOE agreed to provide a description of the QA program for development of the SCP. This description should include the rationale for assigning the SCP and related preparation activities to QA level II. The description will include the approach for assuring that internal reviews consider the rationale and integration of the SCP, and the control of changes associated with site characterization plans, studies, and individual investigations.	Y	ALL	0	Summary of NRC/DOE meeting on the level of detail for site char. plans and May 1986.	0	CDSCP submitted, QA comments issued.
72. The annotated outline (AO) for SCP states that a general description of the QA procedures for site exploration will be presented. However, RG 4.17 requires that detailed QA procedures be referenced.	N	ALL	0	From Kennedy to file "AO Comments by QA," 2/5/85.	0	Combined with #74a.
73. AO is unclear whether design will be addressed in detail in the SCP.	N	ALL	0	From Kennedy to file, "AO Comments by QA," 2/5/85.	0	Combined with #74a.

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74. The AO only addresses 16 of 18 criteria in 10 CFR 50, Appendix B, and indicates that the other two won't be described.	N	ALL	0	From Kennedy to file, "AO Comments by QA," 2/5/85.	0	Combined with #74a.
74a. Annotated outline for SCP does not contain sufficient detail (i.e., detailed QA procedures need to be referenced and all 18 criteria of App. B need to be described).	N	ALL	0	See item numbers 72-74.	0	AO Revised to address concerns 8/87.
75. Validity of results of studies conducted on "representative" core samples.	Y	ALL	2	John Trapp, May 7, 1985.	8	Combined with #82a.
76. In general, procedures or core collection and handling are unavailable.	Y	NNWSI	2	Bilhorn, "Problems/issues from sites," fall 85.	8	Combined with #82a.
77. Lack of documentation for core drillings, water samples, etc. at NNWSI and Hanford.	Y	NNWSI	2	Science, Volume 233.	8	Combined with #82a.
78. DOE could not provide documentation of core custody and in some cases, segments of the core itself.	Y	NNWSI	2	Memo from Malcolm Knapp GT Branch Chief from John Trapp Geology - Geophysics Section. "Trip Report: Appendix 7 Visit to NNWSI September 17-19, 1985," dated October 3, 1985.	8	Combined with #82a.
79. Procedures for collecting and handling core not available at core library. Library staff unfamiliar with procedures.	Y	NNWSI	2	Coplan to Vieth regarding review of rock mechanics/design data.	8	Combined with #82a.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
80. Deficiencies in core sample control activities at NTS core library include procedural noncompliance, procedural inadequacies, and inadequate documentation to support traceability.	Y	NNWSI	2	Blaylock to Vieth, "Recommendation to Stop Work Based on Core Sample Control Surveillance," 2/28/85.	8	Combined with #82a.
81. LLNL questioned quality of work and lack of sample traceability for materials used in testing the waste container materials at Brookhaven.	Y	NNWSI	2	Letter from Virginia Oversby, LLNL, to Vieth dated 11/4/85.	8	Combined with #82a.
82. LLNL suggests that rock being used in testing at Brookhaven is not representative of repository horizon.	Y	NNWSI	1	Letter from Virginia Oversby, LLNL, to Vieth dated 11/4/85.	8	Combined with #82a.
82a. Several problems exist with the core samples collected at the Nevada site (e.g., poor documentation, no procedures, missing core intervals).	Y	NNWSI	2	See items numbered 75-82.	8	NRC staff audit of the entire coring activity from initial collection to final storage.
83. QA is lacking for corrosion studies at all 3 repository projects.	Y	ALL	3	Ad hoc Corrosion Panel Final Report, "Review of the Corrosion Programs of the Projects," dated 11/21/85.	1	DOE and ad hoc panel to schedule meetings including QA. NRC should monitor the program.
84. No standard exists for computer code requirements within DOE. Computer codes are a fundamental link between the data and the results of analyses.	Y	ALL	2	Meeting with John Voglewede, Bilhorn, Kennedy, and Riddle concerning John's meeting with Technical Code Coord. Group TCCG (DOE).	3	NRC staff conducting research to resolve problem.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
85. Computer software used that was not developed under the QA program requirements	Y	NNWSI	2	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	3	Combined with #84.
86. The document states that the G-tunnel field tests will be used to validate some of the computer codes - does this require QA regulation.	Y	NNWSI	2	Draft SCP - 17 Mar 86 with attached summary by Dale.	3	Combined with #84.
87. DOE and NRC need to agree on what constitutes an audit as referenced in the Purcell letter of September 3, 1985.	N	ALL	0	Points for Purcell by Kennedy, December 1985.	18	Based on obs. to date, DOE now appears to understand what audits are, how to conduct, etc.
88. USGS is not following the kind of documented procedures required for licensing.	N	USGS	0	DOE QA program - NRC staff impressions - no date or signature.	18	Delete. See footnote #3.
89. Failure to implement an adequate surveillance system.	N	NNWSI	0	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	18	Combined with #208.
90. Failure to perform required audits of suppliers.	N	NNWSI	1	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	18	Combined with #47a.
91. Minimum or lack of audits and surveillances of suppliers/contractors and internal activities.	N	NNWSI	1	NNWSI Project Status Report QACG Meeting 7/23/87 Consolidated Audit Findings.	18	Combined with #47a.
92. QA audits not effective due to lack of geotechnical expertise.	Y	ALL	1	Teek Verma, 1984.	18	Combined with #47a.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
93. Implementation of QA program is not being checked by a team surveillance approach. Surveillance teams do not have geotechnical specialists.	Y	ALL	2	Teek Verma, 1984.	10	Combined with #208.
94. QA criteria for purchased data not established. Purchased data constitutes a major portion of data base for all potential sites.	Y	ALL	2	Teek Verma, 1984.	4	Discuss with T. Verma. Place concern on generic checklist and evaluate during future audits and obs. audits.
95. Very little emphasis on independent review of technical procedures by contractors. No well defined criterion for evaluating qualifications of these independent reviewers.	Y	ALL	3	Teek Verma, 1984.	3	Same as above.
96. Audits are very generic and procedural in nature. The validity and applicability of technical procedures for geotechnical investigations are not being evaluated.	Y	ALL	1	Teek Verma, 1984.	18	Combined with #47a.
97. QA standards and criteria used by DOE and ONWI contractors and subcontractors are not consistent. No formal guidance provided by DOE for formulation of QA standards criteria.	Y	ALL	3	Teek Verma, 1984.	2	Discuss with T. Verma. Place concern on a generic checklist and evaluate during future audits and obs. audits.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
98. USGS audit revealed that QA program is not being effectively implemented.	N	ALL	0	Teek Verma, 1984.	0	Delete. This concern is merely informational.
99. State of Nevada questioned whether examples of "detailed procedures" supplied by USGS were in fact true procedures. Nevada felt they were detailed work plans.	N	NNWSI	0	NNWSI site visit meeting minutes, 12/14/84.	5	Combined with #106a.
100. "Change Order" procedures for changing field procedures due to unexpected conditions.	N	NNWSI	0	State of Nevada comments in NNWSI site visit meeting minutes, 12/14/84.	5	Combined with #106a.
101. QA at USGS inadequate. USGS work at Nevada is not being done using procedures in all cases. DOE is repeating mistakes that occurred in reactors where quality was alleged to exist but could not be proved.	N	NNWSI	0	Site visit summary for Davis early 1985, Hub Miller.	5	Combined with #106a.
102. Lack of and inadequate implementing procedures.	N	NNWSI	0	NNWSI Project Status Report, QACG meeting on 7/23/87, Consolidated Audit Findings.	5	Combined with #106a.
103. Failure to implement approved procedures	N	NNWSI	0	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	5	Combined with #106a.
104. Lack of inadequate implementing procedures.	N	NNWSI	0	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	5	Combined with #106a.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
105. General lack of familiarity with procedures.	N	NNWSI	0	Coplan to Vieth, 3/28/85.	5	Combined with #106a.
106. Working without WMPO approved QA level procedures	N	NNWSI	0	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	5	Combined with #106a.
106a. There is a lack of and/or failure to implement approved procedures.	N	NNWSI	3	See items numbered 99-106.	5	NRC to get commitment in QAP. Subsequently, this will be verified during future audits and obs. audits.
107. Inadequate documentation of calibration data, acceptance/rejection criteria, data reduction and test procedures, and changes to tests or data collection.	Y	NNWSI	2	Bilhorn, "Problems/issues from sites," fall 85.	12	Combined with #113a.
108. Calibration of instruments against a standard not performed regularly.	Y	NNWSI	2	Bilhorn, "Problems/issues from sites," fall 85.	12	Combined with #113a.
109. Inadequate doc. of calibration data, acceptance/rejection criteria, data reduction and test procedures, and changes during data collection and testing.	Y	NNWSI	2	Coplan to Vieth regarding review of rock mech./design data, 3/28/85.	12	Combined with #113a.
110. QA control of activities at LLNL are inadequate.	Y	NNWSI	2	Draft results of audit of LLNL 2/2-7/86 by Allen and Blaylock.	12	Combined with #113a.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
111. Documentation for equipment calibration unavailable. Procedures for technical reviews unavailable. LLNL has no one person to watch the QA area. No procedures for the handling, storage, shipping, and control of materials, parts and components.	Y	NNWSI	2	Draft results of audit of LLNL 2/2-7/86 by Allen and Blaylock.	12	Combined with #113a.
112. Inadequate calibration of M&TE	Y	NNWSI	2	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	12	Combined with #113a.
113. Inadequate practices for calibration of M&TE (traceability to NBS).	Y	NNWSI	2	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	12	Combined with #113a.
113a. Calibration problems include the following: inadequate documentation, calibrations not performed against NBS traceable stds., untimely calibrations, etc.	Y	NNWSI	2	See items numbered 107-112.	12	NRC will get a commitment in QAP. This concern will be placed on a generic checklist and evaluated during future audits and obs. audits.
114. Draft SCP G-tunnel testing states that QAPs have been written, approved, followed, and audited for thermal expansion, etc., tests. A question was raised as to the validity of this statement.	Y	NNWSI	0	Draft SCP - 17 Mar 86 with attached summary by Dale.	0	Need to verify during future audits and obs. audits. Also, review study plans on rock mechanics testing.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
115. Errors in QA record preparation.	N	NNWSI	0	NNWSI Project Status Report. QACG Meeting on 7/23/87, Consolidated Audit Findings.	17	NRC gets commitment in QAP. Will be verified during NRC audits and obs. audits.
116. Absence of implementation of corrective action programs to identify need for correction of repetitive problems.	Y	NNWSI	0	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	16	Will evaluate during future audits and obs. audits.
117. Inadequate documentation (traceability) of technical reviews.	Y	NNWSI	0	NNWSI Project Status Report, QACG Meeting on 7/23/87, Consolidated Audit Findings.	6	Will evaluate during future audits and and obs. audits.
118. NNWSI is taking more than 3 months to reply to requests for approval of nonconformance reports and technical reports (DOE recognized problem).	Y	NNWSI	0	NNWSI Monthly Report, 4/1987.	15	Will evaluate during future audits and obs. audits.
119. Design control for geotechnical testing and decisionmaking is not happening to any significant degree." Discussed 3/28 with Lawrence and Goldberg - immediate action noted. Suggested incorporating provisions to review this area during data reviews.	N	BWIP	0	None listed.	3	See footnote #1.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
120. System for document control, procedures for documentation of info. (Cook, 10/31/81) at RHO doesn't include definition of "completed record." (Suggest review this area during QA visits).	N	BWIP	0	None listed.	6	See footnote #1.
121. No definition of "complete record" in RHO. Many records, particularly those of sub-contractors, are not submitted to document control center. No specifics given in detailed report.	N	BWIP	0	Cook monthly report, 11/8/84.	17	See footnote #1.
122. Rockwell's QA program has problems (no specifics in detailed report, see NNSWI 20a).	N	BWIP	0	Draft of 85/10/02 of BWIP audit - Summary sheet.	2	See footnote #1.
123. Raw data is taken using loose, blank data pages which are not controlled in some manner such as bound notebooks.	N	BWIP	0	Cook Monthly Report, date unknown.	6	See footnote #1.
124. Impossible to verify that pages are not lost, modified, or discarded (in Cook's opinion).	N	BWIP	0	None given.	6	See footnote #1.
125. Long time delay between creation of a QA record and incorporation into QA records system. Includes contractor correspondence (going, coming).	N	BWIP	0	Cook Monthly Report, date unknown.	17	See footnote #1.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
126. USGS has not accepted BWIP QA requirements.	N	BWIP	0	BWIP site visit meeting minutes.	1	See footnote #1.
127. Lack of documentation for core drillings, water samples, etc. at NNWSI and Hanford.	Y	BWIP	2	Science, Volume 233.	17	Same item for NNWSI.
128. Inadequate documentation of: calibration data, acceptance/rejection criterion, data reduction and test procedures, and changes to tests or data collection.	N	BWIP	0	Bilhorn, "Problems/issues from sites," Fall '85.	17	Same item for NNWSI.
129. Calibration of instruments against a standard not performed regularly.	N	BWIP	0	Bilhorn, "Problems/issues from sites," Fall '85.	12	Same item for NNWSI.
130. Detailed field and office QA manuals were lacking.	N	BWIP	0	Bilhorn, "Problems/issues from sites," Fall '85.	2	See footnote #1.
131. Lack of a data management system.	N	BWIP	0	Bilhorn, "Problems/issues from sites," Fall '85.	17	See footnote #1.
132. Lack of adequate peer review.	N	BWIP	0	Wright to Olson, 5/22/84, "Rock Mechanics Testing and Data Review.	3	See footnote #1.
133. DOE-RL BWI reviewed Rockwell-supplied work evaluation sheets and found insufficient detail to support Rockwell conclusions. DOE audits have consistently found "lack of adequate procedures and training at Rockwell.	N	BWIP	0	Letter from Larson to Gen. Manager Rockwell Hanford Operations, "BWIP Work Evaluations," dated 5/1/86.	5	See footnote #1.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
134. Instrument design control w/in BWIP QA activities was not effective or was not implemented.	N	BWIP	0	Note to Browning from R.J. Wright, "BWIP Site Report for Period of May 13-26, 1984.	3	See footnote #1.
135. Lack of interest in QA by technical managers and leaders.	N	BWIP	0	Memo to file from Cook, "Comments on Waste Management Meeting 85," dated 3/5/85.	0	See footnotes #1.
136. Designation of authorities and responsibilities and qualification of personnel vis-a-vis their responsibilities.	N	BWIP	0	Cook monthly report Nov. 8, 1984.	0	See footnote #1.
137. DOE has insufficient manning in the QA organization to develop and implement a satisfactory program prior to site characterization.	N	BWIP	0	Memo for Browning from Cook, "Observations, Comments and Recommendations for the period of April 20 - May 22, 1985" dated June 18, 1985.	2	Same item for NNWSI.
138. DOE only allowed one observer of BWIP audit. This is not consistent w/DOE/NRC procedural agreement of August 20, 1984.	N	BWIP	0	Memo for Browning from Cook, "Observations, Comments and Recommendations for the Period April 20 - May 22, 1985."	18	Further discussions with DOE has permitted as many observers as practical and appropriate.
139. Recording of changes in hydrofracture test procedures are incomplete and procedures to obtain test results are only partially available.	N	BWIP	0	Letter to Olson from Wright, April 20, 1984.	5	See footnote #1.

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140. Recording of hydrofrac test procedures remains incomplete due, in part, to changing procedures. Pre-SCR hydrofrac data have little or no traceability to documented procedures and equip.	N	BWIP	0	Memo to Wright from Nataraja and Buckley, "NRC Comments Concerning BWIP Data Review."	5	See footnote #1.
141. Lack of reference point outside the zone of test is a serious short-coming in test setup and procedures.	N	BWIP	0	Memo to Wright from Nataraja and Buckley, "NRC Comments Concerning BWIP Data Review."	5	See footnote #1.
142. Instrumentation performance questionable (thermocouples, vibrating wire stress meters, multiple-position borehole extensometers, and borehole deformation gauges did not perform satisfactorily).	N	BWIP	0	Memo to Wright from Nataraja and Buckley, "NRC Comments Concerning BWIP Data Review."	12	See footnote #1.
143. Analysis of data from year old heater test is incomplete.	N	BWIP	0	Memo to Wright from Nataraja and Buckley, "NRC Comments Concerning BWIP Data Review."	17	See footnote #1.
144. RKE/PB, a contractor to DOE for design of BWIP exploratory shaft, does not have sufficient QA to demonstrate the quality required for licensing.	N	BWIP	0	Memorandum from Craig G. Walenga to Ted Ankrum, "Report of Observations Made During a DOE-Sponsored Audit of KE/PB Quality Program." Draft dated May 2, 1986.	1	See footnote #1.
145. Undefined QA policies and lack of QA documentation (particularly nonpartial peer reviews) are resulting in questions about uncertainties in data.	N	BWIP	0	Memo to Browning from Cook, "Observations, Comments and Recommendations for the Period February 4 - March 15, 1985."	2	See footnote #1.

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146. OR restricted from DOE meeting to discuss strategy for planning large scale pump tests. Could be considered violation of NRC/DOE procedural agreement.	N	BWIP	0	Memo to Browning from Cook, "Observations, Comments, and Recommendations for the Period March 16 to April 19, 1985."	0	See footnote #1.
147. Lack of QA procedures to control the design of geotechnical testing and decision making.	N	BWIP	0	Memo to Browning from Cook, "Observations, Comments, and Recommendations for the Period March 16 to April 19, 1985."	5	See footnote #1.
148. DOE is not effectively implementing QA requirements to design activities for the engineered barrier system and the geologic setting during the period prior to issuance of a site char. plan described in NWPA or a site char. report required by 10 CFR 60.11.	N	BWIP	0	Memo to Browning from Cook, "Report of Activities, Observations and Comments for the Period November 1 to December 15, 1984."	3	See footnote #1.
149. Safety problem with concrete lining on facilities ceilings and walls.	N	BWIP	0	Memo to Browning from Cook, "Report of Activities, Observations and Comments for the Period November 1 to December 15, 1984."	0	See footnote #1.
150. Field sheets of data from DC-16 are duplicated but not filed separately - security of the raw data is in question.	N	BWIP	0	Memo from Adrian Brown to file, "Observations Made During Data Gathering Trip to Hanford, January 9-13, 1984." Dated January 19, 1984.	17	See footnote #1.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
151. No external review of reports produced by RHO.	N	BWIP	0	Memo from Adrian Brown to file, "Observations Made During Data Gathering Trip to Hanford, January 9-13, 1984." Dated January 19, 1984.	2	See footnote #1.
152. Long backlog of data to be analyzed at DC-16.	N	BWIP	0	Memo from Adrian Brown to file, "Observations Made During Data Gathering Trip to Hanford, January 9-13, 1984." Dated January 19, 1984.	.2	See footnote #1.
153. Computerized data analysis is being performed at DC-16 w/o documented procedures and unproven computer programs.	N	BWIP	0	Memo from Adrian Brown to file, "Observations Made During Data Gathering Trip to Hanford, January 9-13, 1984." Dated January 19, 1984.	5	See footnote #1.
154. Data custody/security controls are lacking at DC-16.	N	BWIP	0	Memo from Adrian Brown to file, "Observations Made During Data Gathering Trip to Hanford, January 9-13, 1984." Dated January 19, 1984.	0	See footnote #1.
155. MAC audit of Rockwell's audit and surveillance program was not effective in measuring the effectiveness of the audit and surveillance program.	N	BWIP	0	Memo for Linehan from Hedges, "Observation of BWIP Audit of the Effectiveness of Rockwell's Audit and Surveillance Program March 25-28, 1986." Dated June 16, 1986.	18	See footnote #1.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
156. Rockwell's audit program lacks completeness of personnel qualification records.	N	BWIP	0	Memo for Linehan from Hedges, "Observation of BWIP Audit of the Effectiveness of Rockwell's Audit and Surveillance Program, March 25-28, 1986." Dated June 15, 1986.	18	See footnote #1.
157. Rockwell's audit program lacks effective compliance of approved procedures.	N	BWIP	0	Memo for Linehan from Hedges, "Observation of BWIP Audit of the Effectiveness of Rockwell's Audit and Surveillance Program, March 25-28, 1986." Dated June 15, 1986.	18	See footnote #1.
158. Rockwell's audit program lacks effective indoctrination and training in the QA program.	N	BWIP	0	Memo for Linehan from Hedges, "Observation of BWIP Audit of the Effectiveness of Rockwell's Audit and Surveillance Program, March 25-28, 1986." Dated June 16, 1986.	18	See footnote #1.
159. Rockwell's audit/surveillance program is ineffective in control of non-BWIP procedures used by BWIP.	N	BWIP	0	Memo for Linehan from Hedges, "Observation of BWIP Audit of the Effectiveness of Rockwell's Audit and Surveillance Program, March 25-28, 1986." Dated June 16, 1986.	18	See footnote #1.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
160. Rockwell's audit/surveillance program lacks scheduled audits.	N	BWIP	0	Memo for Linehan from Hedges, "Observations of BWIP Audit of the Effectiveness of Rockwell's Audit and Surveillance Program, March 25-28, 1986." Dated June 16, 1986.	18	See footnote #1.
161. Rockwell management is not responsive to formal corrective action request by Rockwell QA as a result of Rockwell audits and surveillance.	N	BWIP	0	Memo for Linehan from Hedges, "Observation of BWIP Audit of the Effectiveness of Rockwell's Audit and Surveillance Program, March 25-28, 1986." Dated June 16, 1986.	16	See footnote #1.
162. Lack of management controls over computer codes.	N	BWIP	0	Memo for Linehan from Hedges, "Observation of BWIP Audit of the Effectiveness of Rockwell's Audit and Surveillance Program, March 25-28, 1986." Dated June 16, 1986.	3	See footnote #1.
163. The QA org in RHO reports to the general manager of BWIP and may therefore not have sufficient independence from cost-schedule.	N	BWIP	0	Memo from Cook to Browning, "BWIP Site Report for Weeks February 5 and February 12, 1984." Cook to Browning 2/25/88.	1	See footnote #1.
164. RHO project records are not now available for NRC review and/or retention (DOE have RHO a verbal notice to this effect).	N	BWIP	0	Memo from Cook to Browning, "BWIP Site Report for Weeks February 5 and February 12, 1984." Dated February 21, 1984.	17	See footnote #1.

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165. DOE's schedule is so tight that they don't feel that they can develop and apply adequate QA to raw data in the EA's and SCP's.	N	BWIP	0	Memo to Browning from Cook, "Observations, Comments and Recommendations for the Period February 4, 1985 - March 15, 1985." Dated March 22, 1985.	2	See footnote #1.
166. There are ~ 2000 references to the BWIP SCP.	N	BWIP	0	Same as below.	0	See footnote #1.
167. Comments highlighting uncertainties in data arose from speakers due to undefined QA policies and lack of QA documentation particularly non-partial data reviews.	N	BWIP	0	Memo to Browning from Cook, "Observations, Comments, and Recommendations for the Period February 4, 1985 - March 15, 1985." Dated March 22, 1985.	2	See footnote #1.
168. Lack of objectivity in the analysis and decisions presented in the EA for BWIP and the overall selection process.	N	BWIP	0	Memo to R. Browning from Cook, "Observations, Comments and Recommendations for the Period February 4, 1985 - March 15, 1985." Dated March 22, 1985.	2	See footnote #1.
169. BWIP is collecting water samples from DC-18 but are not analyzing them and do not plan to until SWO has been lifted.	N	BWIP	0	Note from Paul Hildenbrand to Neil Coleman. Information via Cook. November 21, 1986?	17	See footnote #1.
170. Inadequate planning and coordination between QA and procurement organizations to assure, i.e., contractual QA assurance requirements are accomplished in a timely manner.	N	BWIP	0	Audit report RHO, BWIP, QA Program February 1984.	4	See footnote #1.

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171. Availability and content of records necessary to provide objective evidence of performance fall far short of the requirement to demonstrate compliance of management program implementation.	N	BWIP	0	Audit report RHO, BWIP, QA Program, February 1984.	17	See footnote #1.
172. Insufficient evidence that work of contractors performed under QA program is adequate for BWIP requirements.	N	BWIP	0	Audit report RHO, BWIP, QA Program February 1984.	2	See footnote #1.
173. Significant areas of procedural noncompliance within the QA program were not detected or corrected by Rockwell's internal audit and surveillance programs.	N	BWIP	0	Audit report RHO, BWIP, QA Program February 1984.	5	See footnote #1.
174. Numerous examples of noncompliance to Rockwell approved procedures were detected in all areas reviewed during the audit.	N	BWIP	0	Audit report RHO, BWIP, QA Program February 1984.	5	See footnote #1.
175. The relationship between the various Rockwell policies, procedures, and organizations that effect BWIP need to be reviewed for continuity and clarity.	N	BWIP	0	Audit report RHO, BWIP, QA Program February 1984.	2	See footnote #1.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
176. Data collection procedures are inadequately documented, data custody and security are inadequate and data analysis procedures are inadequately validated and documented.	N	BWIP	0	Letter to Mathew Gordon from Jerry Rowe, Adrian Brown, Golder Assoc. "BWIP Hydrogeology, Contract #NRC 02-82-045."	5	See footnote #1.
177. 1. Measurement of formation head using uphole measurements are not qualified for use in licensing. 2. Pulse and slug tests used by RHO are not qualified for use in licensing.	N	BWIP	0	Letter to Mathew Gordon from Jerry Rowe, Adrian Brown, Golder Assoc. "BWIP Hydrogeology, Contract #NRC 02-82-045."	12	See footnote #1.
178. Field and office QA manual was lacking.	N	BWIP	0	Wright to Olsen (5/25/84) following hydro data/review.	2	See footnote #1.
179. Why was SCP exempted from SWO? Is SCP under any QA plan?	N	BWIP	0	Letter from Larson to General Manager Rockwell Hanford operations "BWIP Work Evaluations" dated 5/1/86.	0	See footnote #1.
180. Rockwell only considers documents with signatures and number official, but both signed and unsigned documents were presented for review.	N	BWIP	0	Unknown	17	Not traceable to source.
181. DOE recognizes deficiencies in Rockwell's assignments of quality levels, the logic used, and documentation of these assignments.	N	BWIP	0	Letter to Rockwell General Manager from J. J. Keating, Director BWI Division "Expedited Special Case Boreholes DC-24 and DC-25" dated 10/24/86.	2	See footnote #1.

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182. DOE/Rockwell does not seem to have a sound, well developed QA program at the field level that is compatible with industry standards. (Specifically a lack of written drilling procedures, and incomplete project records.)	N	BWIP	0	Memo to file 101 from Hartung, "Review of Drill Hole Logs and Core, BWIP." Dated 1983.	2	See footnote #1.
183. Dale and Jim are concerned that PNL's QA program is not being effectively implemented.	N	BWIP	0	QA audit report, dated 11/27/85, issued by Jerry Reese, audit team leader attached to letter to P.A. Craig, DOE-RL, from Reese dated 12/3/85.	2	See footnote #1.
184. Dale Hedges considers DOE's audit/surveillance program to be inadequate to measure effectiveness in their ability to acquire a license or to meet performance goals.	N	BWIP	0	"Critique of Auditing for Effectiveness" by Dale Hedges. Dated post 3/26/86.	18	See footnote #1.
185. Inconsistent records for hydrologic testing of DC-23GR and DC-18 due to lack of consistency in personnel.	N	BWIP	0	Summary notes of BWIP hydrogeologic data review December 2-4, 1986.	17	See footnote #1.
186. Limitations (lack of graphical presentation) in data presentation for DC-23GR resulted in impairment of independent review.	N	BWIP	0	Summary notes of BWIP hydrogeologic data review December 2-4, 1986.	17	See footnote #1.

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187. Lack of procedures for running a multiple well hydrologic test on large scale and for analysis of data from single or multiple well tests.	N	BWIP	0	Summary notes for BWIP hydrological data review December 2-4, 1986.	5	See footnote #1.
188. Major deficiencies appear to exist in the reporting of hydrochemistry data in the NOMAD data base - insufficient information for independent reviews, no references identified for more information, etc.	N	BWIP	0	Summary notes for BWIP hydrological data review December 2-4, 1986.	17	See footnote #1.
189. Some data documents were signed over one year after they were completed.	N	BWIP	0	Summary notes for BWIP hydrological data review December 2-4, 1986.	6	See footnote #1.
190. PNL QA system requirements are not adequate for collection of information critical to safety.	N	BWIP	0	Memo to Browning from Cook, "BWIP Site Report for Week of January 29, 1984" dated 2/9/84.	17	See footnote #1.
191. Implementation of QA systems at RHO is inadequate.	N	BWIP	0	Memo to Browning from Cook, "BWIP Site Report for Week of January 29, 1984" dated 2/9/84.	2	See footnote #1.
192. The exception of "the preparation of test (?) plans and procedures" from the SWO. The letter did not identify to what the plans and procedures referred.	N	BWIP	0	Letter to O. L. Olson from L. R. Fitch, "Basalt Waste Isolation Project BWIP Work Evaluation" dated 4/11/86.	5	See footnote #1.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
193. Funding chain DOE-ONWI-PNL is inappropriate to effect changes in work performed by PNL.	N	SRPO	0	Note to file from M. Tokar "Parry Meeting."	0	See footnote #1.
194. DOE/RHO unable to identify documentation on how the training programs were developed and validated.	N	BWIP	0	Cook to Browning "Observations, Comments, Recommendations" April 4 - June 11, 1987.	2	See footnote #1.
195. Management control training program was cut significantly to meet schedule for partial restart of design activities.	N	BWIP	0	Cook monthly report, June 1987.	2	See footnote #1.
196. Procedures for validating design findings and decisions associated with other BWIP activities have insufficient attention (i.e., application of peer review is not delineated by procedure).	N	BWIP	0	Cook monthly report, June 1987.	3	See footnote #1.
197. The lack of procedural control of the subjective decision making and application of quality assurance to the subjective process is a short coming of the preparation being accomplished by DOE and RHO in my judgment. Clear identification of quality assurance functions and quality achievement activities are necessary to understand the overall quality assurance program for design control and in particular the control associated with validation.	N	BWIP	0	Cook monthly report, June 1987.	5	See footnote #1.

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198. Newspaper advertisement by Westinghouse indicated no QA manager in the upper company management structure.	N	BWIP	0	Cook monthly report, June 1987.	1	See footnote #1.
199. Certain items/actions may be of potential importance at licensing and should be on the Q-List even though reduced control and quality assurance may be acceptable.	N	BWIP	0	Cook to Browning "Observations, Comments, and Recommendations" January 17 to April 3, 1987.	2	See footnote #1.
200. KE/PB considers their QA adequate due to their interpretation of an audit in which NRC was an observer.	N	BWIP	0	Cook to Browning "Observations, Comments, Recommendations June 14-July 18, 1986."	2	NRC sent IE report to KE/PB w/letter clarifying NRC's status only as observer.
201. Need graded QA approach for OGR contractors. Implication is that OGR contracts are without QA.	Y	OCRWM	0	Internal DOE management appraisal, 11/7/86.	2	Need more specifics.
202. OGR needs QA issue tracking system.	Y	OCRWM	0	Internal DOE management appraisal, 11/7/86.	15	Need to check/verify with DOE. DOE intends to discuss at June 1988 management meeting.
203. LANL has not responded to several findings identified during a staff audit conducted the week of June 8, 1987.	Y	LANL	2	NRC staff audit of LANL, transmittal letter dated 10/9/87 from Browning to Kale.	18	NRC should send a memo indicating that findings are still unresolved and request a written response to all findings.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
204. WHC does not have a stand alone list which allows Quality Level I, II, and III procurements to be tracked. This could hinder the NRC's ability to determine the suitability of Quality Level II and III procurements.	Y	BWIP	3	Donnelly Audit Observation Report, transmittal letter dated 12/21/87.	7	Place this concern on a generic checklist and evaluate during future audits and observation audits.
205. During audits, Quality Level II and III designations should be investigated further to determine their appropriateness.	N	BWIP	3	Donnelly Audit Observation Report, transmittal letter dated 12/21/87.	2	Delete. This item has been placed on the observation audit checklist and will be evaluated during future observation audits.
206. DOE's audit checklist could be improved by the elimination of questions which can be answered during a QA program document review.	N	BWIP	3	Donnelly Audit Observation Report, transmittal letter dated 12/21/87.	18	Delete. This item has been placed on the observation audit checklist and will be evaluated during future observation audits.
207. When auditing a QA control system that deals primarily with a geologic or scientific item, technical specialists, knowledgeable in the area being audited, should be utilized.	N	BWIP	3	Donnelly Audit Observation Report, transmittal letter dated 12/21/87.	18	Delete. This item has been placed on the observation audit checklist and will be evaluated during future observation audits.
208. Limited use of surveillance.	Y	All	2	SRPO site visit meeting minutes, 12/19/84.	10	Request the WMPO surveillance schedule - for those completed and planned - and evaluate. Check during future audits and audit observations. Make generic checklist.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
209. Old data remains unqualified.	Y	All	1	SRPO site visit meeting minutes, 12/19/84.	3	NRC documented this as comment #108 of the CDSCP review. Also, make this a generic checklist question which will be addressed by the staff during future audits and observation audits.
210. DOE/SRP lacks adequate understanding of the principles required and preparation necessary to successfully assess the implementation effectiveness of a QA Program.	N	SRPO	2	Memo to H. Miller from C. Walenga "Report of Observations Made During a DOE-Sponsored Audit of Fluor Technology, Inc." dated 11/12/86.	1	Delete. See footnote #1.
211. DOE/SRP lacks experience to implement the QA program.	N	SRPO	3	Memo to H. Miller from C. Walenga "Report of Observations Made During a DOE-Sponsored Audit of Fluor Technology, Inc." dated 11/12/86.	0	Combined with #15.
212. SRPO's QA plan does not reflect the requirements established by NQA-1 specifically SNT-TC-1A as required by supplement 2S-2 of NQA-1. [It does not specify certification documentation required by supplements 2S-2 and 2S-3 of NQA-1.]	N	SRPO	3	Memo for Browning from Grimes, "Review of Salt Repository Project QA Plan" dated October 28, 1986.	10	Delete. This RAI was forwarded to DOE on 3/9/87. Nonetheless, the SRPO Project was cancelled due to the NWPA amendment.
213. The integration of contractor efforts is inadequate.	N	Unknown	1	Unknown	7	Delete. Inadequate documentation exists to substantiate concern.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
214. Funding chain DOE-ONWI-PNL is inappropriate to effect changes in work performed by PNL.	N	SRPO	2	Note to file from M. Tokar, "Parry Meeting."	7	Delete. This funding chain no longer exists due to the NWPA Amendment.
215. The SRPO QA plan does not specify how SRPO will meet the various QA requirements outlined by the plan.	N	SRPO	2	Memo to Jeff Neff SRPO-CH from William Purcell, OGR.	2	Delete. This is a site specific concern. WMPO QA plan <u>does</u> specify how requirements will be met.
216. DOE/SRPO audit of Fluor's QA Program found deficiencies with respect to the NRC Review Plan, NQA-1, and Fluor's QA manual.	N	SRPO	2	Letter to Reese, DOE QA Manager, from T. O. Mallone, Fluor project manager, dated 10/22/86.	18	Delete. Informational only.
217. DOE audit effectiveness could have been improved if auditors were better prepared. Coordination between QA specialists and technical observers was weak.	N	SRPO		Memo for H. Miller from Craig Walenga "Report of Observations Made During a DOE-Sponsored Audit of Batelle PNL," dated 11/10/86.	18	Combined with #47a.
218. Incomplete DOE QA program at Argonne NL. 1. The peer review process needs to be broadened to include testing goals and procedures. 2. Conclusions based on unavailable data and made during peer review needs further supporting evidence.	N	SRPO	3	SRP/NRC Waste package meeting; Summary meeting dates Jan. 22-24, 1986.	3	Presently, Argonne NL does not appear to be doing work for the WMPO office. However, if this changes, their QA plan would be reviewed for adequacy by the staff. Likewise, the question of peer review adequacy is covered by objection #5 of the CDSCP review. DELETE.
219. Inadequate QA for the waste package.	N	SRPO	3	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86. Cook to Browning 2/25/88, #39.	0	Delete. This is a site specific issue. The SRPO was cancelled due to the NWPA amendment.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
220. Inadequate QA management. Testing has begun on spent fuel leaching prior to the development of the waste package program (item 12). There is clear understanding how it will ultimately be used to demonstrate compliance with regulatory requirements.	N	SRPO	3	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86. Cook to Browning 2/25/88, #39.	0	Combined with #219.
221. Inadequate DOE QA control. Fugacity of H should be assessed for metal/environment systems.	N	SRPO	3	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86. Cook to Browning 2/25/88, #39.	0	Combined with #219.
222. Inadequate DOE QA control of work plan. Structural analyses are limited to date and NRC needs more detail concerning the structural failure modes and how they will be analyzed.	N	SRPO	3	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86. Cook to Browning 2/25/88, #39.	0	Combined with #219.
223. Inadequate DOE QA control of work plans. Use of probability distribution functions, how the analysis will be done, etc., is unclear.	N	SRPO	3	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86. Cook to Browning 2/25/88, #39.	0	Combined with #219.
224. Inadequate DOE QA control of experimental procedures. Radionuclide source term characterization program needs supporting work to verify complex experiments.	N	SRPO	3	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86. Cook to Browning 2/25/88, #39.	0	Combined with #219.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
225. Incomplete QA program. Brine and corrosion studies will be incomplete in supporting data and documentation of decision making process. This may result in an inadequate container design.	N	SRPO	3	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86. Cook to Browning 2/25/88, #39.	0	Combined with #219.
226. Ineffective QA at SRPO (lack of documentation). SRP may not be able to show compliance with the 300-1000 year containment requirement for the reference waste package design. They have not documented viable alternatives to the current design in terms of alternative materials or supporting data.	N	SRPO	3	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86. Cook to Browning 2/25/88, #39.	0	Combined with #219.
227. PNL's QA program is designed to comply with NQA-1 rather than NRC QA review plan and 10 CFR 50, App. B.	N	SRPO	2	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86.	2	Delete. The WMPO QA plan clearly states that the NRC QA Review Plan and 10 CFR 50, App. B are requirements which must be met.
228. Susan Bilhorn questioned the review processes such as technical review procedures, peer review, technical review and design review for how they differ and will be integrated into an overall QA program.	Y	SRPO	2	Memo from Bilhorn to Kennedy following SRPO/NRC waste package meeting, 1/22-26/86.	3	The staff will verify this through observation audits and audits. Also, these definitions are contained in the WMPO QA program and will be reviewed by the staff for adequacy. Likewise, the peer review concern was documented in objection #5 of the CDSCP review.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
229. Ineffective QA audits by SRPO. SRPO may have endorsed PNL's QA plan prematurely. PNL may have a false sense of security.	N	SRPO	1	SRP/NRC waste package meeting summary meeting dates 1/22-24/86.	18	Combined with #47a.
230. Qualification of existing information acquired under limited or lack of QA at PNL.	Y	SRPO	1	SRP/NRC waste package meeting, summary meeting dates 1/22-24/86.	3	Combined with #209.
231. Golder Assoc. may have to review their own work on in situ test plans and SCPs since they are becoming the lead subcontractor for DOE and ONWI and a key contractor to NMSS.	N	SRPO	0	Memo for R. Browning from Tilak Verma, "SRP Site Report for Week of April 2, 1984."	0	DELETE - This is an NRC problem which should be corrected by the establishment of the "center."
232. No formal documentation of QA training for USGS technical staff performing QA related activities.	Y	USGS	3	Memo for R. Browning from Tilak Verma, "SRP Site Report for Week of April 2, 1984."	1	Review during future staff audits and obs./audits. Place this concern on a generic checklist for future reference.
233. TBEG QA procedures are not in full compliance with NQA-1-1983.	N	SRPO	4	Observations relative to QA by D. Hedges. No date	2	Delete. TBEG is no longer a participant in the waste program due to the NWPA Amendment.
234. QA overview of TBEG activities may suffer due to lack of personnel directly responsible.	Y	SRPO	1	Observations relative to QA by D. Hedges. No date	1	Add this as a generic checklist question which will be evaluated during future audits and obs. audits.

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235. DOE does not conduct formal surveillance of work activities at TBEG but relies solely on the annual audit to measure the effectiveness of the QA program implementation.	Y	SRPO	1	Observations relative to QA by D. Hedges. No date	18	Combined with #47a.
236. Audit did not give PNL enough information.	Y	SRPO	1	Items to report based on observations of DOE Project/ Contractor audits. PNL/SRPO.	18	Combined with #47a.
237. Preparation of audit didn't take into account actual program and project status.	Y	SRPO	1	Items to report based on observations of DOE Project/ Contractor audits. PNL/SRPO.	18	Combined with #47a.
238. Audit ineffective in identifying problems and their root cause due to lack of understanding of contractor.	Y	SRPO	1	Items to report based on observations of DOE Project/ Contractor audits. PNL/SRPO.	18	Combined with #47a.
239. Audit timing was poor. Little to see since implementation was relatively new.	Y	SRPO	1	Items to report based on observations of DOE Project/ Contractor audits. PNL/SRPO.	18	Combined with #47a.
240. Dale Hedges and Jim Kennedy are concerned that PNL's QA program is not being effectively implemented.	Y	MCC	2	Note to Kennedy from Hedges, "Audit of PNL by DOE," dated 9/16-19/85.	2	The staff plans to review the PNL (MCC) QA plan in the near future. Adequate implementation will be checked during future audits and obs. audits.

Item and item number	Open	Project participant	Level of importance	Source	Appendix B criteria	NRC/DOE action
241. DOE Audits are inadequately planned. 1. Knowledge of work in progress is lacking. 2. Audits only consist of scheduled ones so that surveillance and monitoring of work in progress are not included. 3. Time required to conduct audit was insufficient.	Y	ALL	1	Note to Kennedy from Hedges, "Audit of PNL by DOE," dated 9/16-19/85.	18	Combined with #47a.
242. The rights of access between LLNL and its subcontractor PNL need to be clarified since LLNL's access to PNL appears contingent upon those times when an audit is planned by OCRWM or DOE-RL.	Y	LLNL	3	Voltura Obs. Audit Report dated 5/24/88.	18	Need to develop a strategy to resolve.
243. The audit team should receive adequate training prior to conducting the audit.	Y	OCRWM	3	Voltura Obs. Audit Report dated 5/24/88.	18	Add this concern to the obs. audit checklist and evaluate during future obs. audits.
244. DOE QA program documents should be consistent with endorsed consensus stds., are subject to document control measures, and describe the audit process, program criteria, and team responsibilities as reflected in the audit.	Y	OCRWM	3	Voltura Obs. Audit Report dated 5/24/88.	2	Need to develop a resolution strategy.

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245. The Quality Level assignments for the ESF design appear inadequate. For example, all the design work is apparently Q.L.II.	Y	NNWSI	2	Donnelly Obs. Audit Report dated 4/12/88.	2	Coordinate with the technical branch and bring this, through a mgmt. memo, to the attention of higher level DOE mgmt.
246. Resumes of DOE contractor personnel are considered as private information and are unavailable for NRC or DOE review.	Y	ALL	2	Donnelly Obs. Audit Report of F&S dated 4/12/88.	2	NRC needs to write a letter to the highest levels of DOE mgmt. informing them that this problem should be corrected.
247. No special processes have been identified for the repository program other than the traditional 'welding' and 'NDE.' Methodology does not exist for determining whether something is/is not a special process.	Y	ALL	3	Donnelly-Audit Observation; BWIP Audit #8705, Nov. 9-20, 1987.	9	The DOE and NRC should meet and determine whether such a methodology is needed and if something is classified as a special process, what additional controls are applied.
248. DOE needs to consider NRC conducting mini-audits prior to issuance of SCP.	Y	OCRWM	3	NRC Letter: J. Linehan to W. Purcell June 6, 1986. DOE Letter: W. Purcell to R. Browning Sept. 3, 1985.	18	DOE needs to be reminded that issue is outstanding.
249. DOE to provide listing of contractors and subcontractors performing/expected to perform activities important to safety/waste isolation.	Y	NNWSI	3	NRC Letter: J. Linehan to W. Purcell June 13, 1986.	0	Remind DOE of commitment.

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250. The qualifications of personnel handling core samples are inadequate.	Y	NNWSI	3	(NRC Letter: J. Linehan to D. L. Vieth, May 19, 1986. (2 issues; - core handling practices - Qualif. of personnel for handling core samples).	2	Evaluate concern during future audits and its obs. audits.
251. DOE needs to identify areas and purpose schedules for NRC technical & QA staff to conduct onsite review of ongoing data collection activities.	Y	NNWSI	4	Minutes of Management Meeting with DOE-HQ and NNWSI Project Manager on Dec. 22, 1987. Dated Jan. 21, 1988.	0	NRC needs to remind DOE of this commitment.
252. WMPO to provide updated schedule of release of study plans, dates for initiating studies and dates by which NRC comments on plans are needed.	Y	NNWSI	4	Minutes of Management Meeting on Dec. 22, 1987; dated 1/21/88.	5	Awaiting DOE response.