

November 28, 2001

MEMORANDUM TO: King Stablein

THROUGH: Jim Firth */RA/ jrf*
Raj Nataraja */RA/ raj*
Larry Campbell */RA/ kc for lc*

FROM: Kien Chang */RA/ kc*

SUBJECT: RESOLUTION OF EIGHT ITEMS DEALING WITH QUALITY
ASSURANCE IN YUCCA MOUNTAIN PROJECT

This memorandum documents the closing of eight items in the Open Item Tracking Systems (OITS). All eight items in the OITS pertain to quality assurance topics in DOE's Yucca Mountain Project. These are identified by their Item IDs, filenames and Key Technical Issues (KTI) to which they belong.

I have discussed the contents of these items with their KTI Leads and NRC's On-Site Representative and we agree that these items are closed. The documents containing discussions supporting their "closed" status are identified..

Following the distribution of this memorandum, the OITS records will be updated to document the status of these items.

Attachment: As stated

cc: W. Belke
J. Andersen

November 28, 2001

OPEN ITEM TRACKING SYSTEM ITEMS DEALING WITH QUALITY ASSURANCE

	Item ID	D:\Filename	KTI	Status
1.	OQA013OCT1994Q001	199	RDTME	Closed*
2.	OQA013OCT1994Q002	200	RDTME	Closed*
3.	OQA013OCT1994Q003	201	RDTME	Closed*
4.	OQA013OCT1994C001	206	RDTME	Closed*
5.	OQA019DEC1994C001	334	TSPAI	Closed@
6.	OQA027JAN1995Q001	335	TSPAI	Closed@
7.	OQA015NOV1995Q001	478	Not Tracked	Closed@
8.	OQA002NOV1995Q001	479	USGS Item Not Tracked	Closed#

*These are closed as documented in RDTME IRSR Rev. 3 page 66

#This item is closed per Mar/April 1998 OR Report

@ These are recorded as closed (resolved) in OIT's data base

Attachment

OPEN ITEM STANDARD REPORT

OITSID: OQA013OCT1994Q001

LAST UPDATE: 27 Jun 1995

STATUS: Resolved

DATE RESOLVED: 09 Mar 1995

TOPIC OF THE OPEN ITEM/UNCERTAINTY: Question regarding the various phases of proposed design and construction of the Exploratory Studies Facility (ESF) under the different phases of Design Package 2C.

RESPONSIBLE BRANCH/SECTION: HLUR/HLW & Quality Assurance Section

ACTION AGENCY: DOE

IDENTIFICATION DATE: 13 Oct 1994

SOURCE TYPE: Comment letter on DOE QA Program

SOURCE DOCUMENT: NRC letter to DOE (Bernero to Dreyfus) dated October 13, 1994, "CONCERNS WITH QUALITY ASSURANCE PROGRAM"

DOE ACTIVITY CODE/WBS NO.: 1.2.11

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Concerns with DOE QA Program - Question (1)

OPEN ITEM TEXT: What are the differences between the various phases of design and construction proposed under the different phases of Design Package 2C?

RATIONALE/BASIS: In telephone calls and meetings with the U. S. Department of Energy (DOE), the staff understood that DOE would implement the design and construction of Design Package 2C in phases. Within each phase, certain design and construction work would be completed. Because some of the terminology and activities for the phases have been unclear and evolving, DOE needs to provide the staff with written documentation that will allow the staff to fully understand the work that will be conducted in the various phases of Design Package 2C. This information is needed so the staff can review DOE's response to Question 2 regarding potential adverse impacts on site characterization or the waste isolation capability of the site.

RECOMMENDATIONS: DOE should provide a description of the work, including design and construction, that will be completed in each phase of Design Package 2C. This information should relate the completion of construction to significant site features such as the Bow Ridge Fault, or issues raised on ESF construction such as pneumatic pathways.

UNCERTAINTY RESOLUTION METHOD TYPE: Other - In-field Verification

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION: DOE letter to NRC (Dreyfus to Bernero) dated November 14, 1995.

HISTORY:

October 13, 1994 - NRC staff identifies comment via letter from R. Bernero to D. Dreyfus (DOE).

November 14, 1994 - DOE response to comment via letter from D. Dreyfus to R. Bernero.

March 9, 1995 - Letter from J. Holonich (NRC) to R. Milner (DOE) notifies DOE that, based on staff's evaluation of DOE response, the item is closed.

CROSS REFERENCE

CITATION: §60.150, §60.151, and §60.152 (Subpart G. Quality Assurance).

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES: None

OPEN ITEM STANDARD REPORT

OITSID: OQA013OCT1994Q002

LAST UPDATE: 27 Jun 1995

STATUS: Open

DATE RESOLVED:

TOPIC OF THE OPEN ITEM/UNCERTAINTY: The potential of construction work to impact site characterization or the waste isolation capability of the site.

RESPONSIBLE BRANCH/SECTION: PAHB/Hydrologic Transport Section

ACTION AGENCY: DOE

IDENTIFICATION DATE: 13 Oct 1994

SOURCE TYPE: Comment letter on DOE QA Program

SOURCE DOCUMENT: NRC letter to DOE (Bernero to Dreyfus) dated October 13, 1994, "CONCERNS WITH QUALITY ASSURANCE PROGRAM"

DOE ACTIVITY CODE/WBS NO.: 1.2.11

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Concerns with DOE QA Program - Question (2)

OPEN ITEM TEXT: What are the impacts to site characterization and the waste isolation capability of the site that are associated with the completion of work under Design Package 2C? At what point in the construction of the ESF north ramp is there the potential to impact site characterization and the waste isolation capability of the site?

RATIONALE/BASIS: The staff needs to fully understand the construction work that will be completed by the operation of the TBM, and its potential to impact site characterization or the waste isolation capability of the site. Without this information, the staff is unable to determine the point beyond which construction should not proceed without DOE and the M&O having demonstrated effective implementation of a quality assurance program. Examples of where site characterization could be impacted include recent concerns raised on pneumatic pathways.

RECOMMENDATIONS: DOE should provide the requested information along with its rationale for where site characterization or the waste isolation capability of the site could be impacted. If DOE determines that there is no impact from work being completed for Design Package 2C, it should provide justification.

UNCERTAINTY RESOLUTION METHOD TYPE: Other - In-Field Verification

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION: DOE letter to NRC (Dreyfus to Bernero) dated November 14, 1995.

HISTORY:

October 13, 1994 - NRC staff identifies comment via letter from R. Bernero to D. Dreyfus (DOE).

November 14, 1994 - DOE response to comment via letter from D. Dreyfus to R. Bernero.

March 9, 1995 - Letter from J. Holonich (NRC) to R. Milner (DOE) notifies DOE that, based on staff's evaluation of DOE response, the item remains open pending in-field verification on April 3-6, 1995.

April 3-6, 1995 - NRC performed in-field verification of DOE/M&O.

CROSS REFERENCE

CITATION: §60.150, §60.151, and §60.152 (Subpart G. Quality Assurance).

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES: None

OPEN ITEM STANDARD REPORT

OITSID: OQA013OCT1994Q003

LAST UPDATE: 27 Jun 1995

STATUS: Open

DATE RESOLVED:

TOPIC OF THE OPEN ITEM/UNCERTAINTY: Questions request more details regarding QA concerns as well as the design of the Exploratory Studies Facility

RESPONSIBLE BRANCH/SECTION: ENGB/Geosciences/Geotechnical Engineering Section

ACTION AGENCY: DOE

IDENTIFICATION DATE: 13 Oct 1994

SOURCE TYPE: Comment letter on DOE QA Program

SOURCE DOCUMENT: NRC letter to DOE (Bernero to Dreyfus) dated October 13, 1994, "CONCERNS WITH QUALITY ASSURANCE PROGRAM"

DOE ACTIVITY CODE/WBS NO.: 1.2.11

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Concerns with DOE QA Program - Question (3)

OPEN ITEM TEXT:

- a) What is the current reference conceptual design for the geologic repository operations area (GROA)?
- b) What is the current ESF design and testing strategy?
- c) What is the current control mechanism to ensure compatibility and integration among the GROA conceptual design and the ESF, including design, construction, operation and the proposed testing strategy?

RATIONALE/BASIS: In order to ensure that ongoing ESF design and construction do not impact the ability to meet 10 CFR Part 60 requirements for future repository, DOE needs to have considered at least a conceptual design of the GROA in designing the ESF. The staff has requested in its letters dated March 24, 1993, and August 20, 1993, a description of DOE's conceptual GROA design so it can confirm that DOE is incorporating repository design considerations into the ESF. To date, DOE has not provided the requested information.

If Yucca Mountain becomes the site for the repository, construction of the ESF north ramp will determine the horizon for the main drift of the underground facility. Because DOE is beginning construction of the ESF north ramp, and it is the staff's understanding that over a third of it will be completed prior to Spring 1995, the staff needs to have an understanding of how the ESF relates to the various GROA options under consideration.

DOE is completing the Title II design of the ESF in individual packages rather than as a complete facility. Because of this, DOE needs to ensure tight control of interfaces among the individual design packages as well as integration with the conceptual design of the GROA options. DOE has not shown the staff that it is fully considering the interfaces among individual packages or their relationship to the GROA.

The location of in situ tests is continuing to change even as the TBM has started excavating the rock. The acceptability of the ESF design cannot be judged in isolation, without a reference test plan.

RECOMMENDATIONS:

- 1) DOE should provide a description of the conceptual design of the GROA that shows how the individual design packages being prepared for the ESF relate to the repository design.
- (2) DOE should provide the latest thinking on its testing strategy and in situ test locations.

UNCERTAINTY RESOLUTION METHOD TYPE: Other - In-field Verification

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION: DOE letter to NRC (Dreyfus to Bernero) dated November 14, 1995.

HISTORY:

October 13, 1994 - NRC staff identifies comment via letter from R. Bernero to D. Dreyfus (DOE).

November 14, 1994 - DOE response to comment via letter from D. Dreyfus to R. Bernero.

March 9, 1995 - Letter from J. Holonich (NRC) to R. Milner (DOE) notifies DOE that, based on staff's evaluation of DOE response of the item remains open pending in-field verification on April 3-6, 1995.

April 3-6, 1995 - NRC performed in-field verification of DOE/M&O.

CROSS REFERENCE

CITATION: §60.150, §60.151, and §60.152 (Subpart G. Quality Assurance).

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES: None

OPEN ITEM STANDARD REPORT

OITSID: OQA013OCT1994C001

LAST UPDATE: 27 Jun 1995

STATUS: Open

DATE RESOLVED:

TOPIC OF THE OPEN ITEM/UNCERTAINTY: The M&O QA program is not being effectively implemented in a manner that will assure acceptability of the Exploratory Studies Facility (ESF).

RESPONSIBLE BRANCH/SECTION: HLUR/HLW & Quality Assurance Section

ACTION AGENCY: DOE

IDENTIFICATION DATE: 13 Oct 1994

SOURCE TYPE: Comment letter on DOE QA Program

SOURCE DOCUMENT: NRC letter to DOE (Bernero to Dreyfus) dated October 13, 1994, "CONCERNS WITH QUALITY ASSURANCE PROGRAM"

DOE ACTIVITY CODE/WBS NO.: 1.2.11

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Concerns with DOE QA Program - Comment

OPEN ITEM TEXT: Based on 1) the observation of several DOE audits conducted in June and July 1994, 2) the 90 percent design review of Design Package 2C, and 3) a failure to demonstrate resolution of the issues identified in NRC's letter to DOE dated August 20, 1993; the U. S. Nuclear Regulatory Commission staff is concerned that the M&O QA program is not being effectively implemented in a manner that will ensure acceptability of the Exploratory Studies Facility (ESF). In addition, here in late 1994, the NRC staff questions DOE's and the M&O's ability to implement a program to correct the problems identified. Finally, although the concerns are based on findings from DOE audits, surveillance, and design reviews, the recurrence of problems and the inability to correct them erodes the NRC's confidence in DOE's oversight of the M&O's QA program.

RATIONALE/BASIS: The basic philosophy of the NRC is that the safety of any nuclear facility is the responsibility of the operator. As such, DOE is the primary party responsible for ensuring that a high-level waste repository meets the requirements of 10 CFR Part 60. In order to gain confidence that DOE is fulfilling its responsibilities in an acceptable manner, the NRC requires DOE and its contractors to establish and execute a QA program for those structures, systems, and components important to safety and waste isolation. This QA program should provide measures to assure structured and systematic methods exist for: 1) obtaining data; 2) performing analyses; 3) preparing designs; and 4) providing supporting documentation for the NRC licensing decisions. Effective implementation of a QA program is intended to show that work was done properly, and the design will acceptably perform its function. As part of the NRC licensing process, the NRC staff needs to acquire the necessary confidence that the ESF is being acceptably designed, and will be built consistent with an approved design.

Construction being performed by DOE at the ESF could cause irreparable adverse effects on DOE's ability to perform site characterization or maintain the waste isolation capability of the site. Without an effectively implemented QA program, the staff does not have confidence that DOE will include all necessary considerations in the ESF design, or identify and correct problems. Examples include: 1) drifting that will be part of the geologic repository operations area too close to a fault; 2) ramp constructed at an improper angle; or 3) an incorrect seismic acceleration used in the structural analysis.

The August 20, 1993, letter from the staff to DOE expressed concern with findings from DOE audits of the M&O's QA program. The findings demonstrated a lack of effective implementation of the M&O's QA program. Because of this, the staff requested the DOE provide a rationale for continuing ESF PPA design work being conducted by the M&O. The letter also requested that DOE submit a detailed plan for corrective actions for the M&O design deficiencies that were identified during audits and surveillances.

Although the staff found the Design Control Improvement Plan (DCIP) submitted in response to the August 20, 1993, letter acceptable, the NRC staff noted in its March 30, 1994, letter that acceptable and effective implementation of the DCIP still needed to be demonstrated. Subsequently, findings identified by DOE QA audits and design reviews since development of the DCIP demonstrated a recurrence of earlier problems. Therefore, at this time, the NRC staff does not have confidence that DOE and the M&O can effectively implement the "Management Plan for Resolving QA Issues Resulting from M&O and DOE Audits/Surveillances" developed in response to the latest findings on the M&O QA program.

DOE and the M&O have not effectively trended and integrated findings from different review activities such as QA audits and design reviews in determining trends, root causes, and recurrence of problems. At the August 30, 1994, QA meeting, DOE reported that it did not see a recurrence of problems based on its analysis of Corrective Action Reports (CARs) from QA audits. It did not, however, consider similar findings from design reviews conducted on Design Packages 2A, 2B, and 2C. For example, as part of its observation of the design review for packages 2A and 2B, the NRC staff raised a concern about the lack of conservatism from the design reviews in determining whether similar concerns existed on the M&O's QA program.

The M&O continued to conduct design work on Design Package 2C, even though DOE and M&O QA audits and surveillances had found recurring deficiencies in the M&O's QA program. Only after DOE indicated that it would issue a stop work order as a result of findings on Design Package 2C did the M&O withdraw the design package. In addition, although minor in effort, the M&O continues to conduct design work on other ESF Design Packages.

DOE continued to allow work to proceed on Design Package 2C, and it still does allow design work to be done on other ESF design packages. This has been done despite numerous significant and repetitive findings on the M&O's QA program. In addition, DOE has not ensured that the M&O corrective action program required under Criterion 16 of its QA plan is being effectively implemented, or that root cause and trend analyses are identifying the reason for the problems. During the June 1994 DOE Audit of the M&O, DOE mentioned the M&O Trend Program as being ineffective in obtaining corrective action of identified trends.

Problems continue to be found with tracing the flowdown of design requirements from 10 CFR Part 60 to design specifications. This concern was raised 1) in 1989 as part of the basis for Objection 1 of the Site

Characterization Analysis; 2) by the NRC on-site representative in May 1993; and 3) most recently, by the DOE audit team in CAR-074. It also serves as another example of DOE's lack of effective integration in evaluating all findings from various reviews.

RECOMMENDATIONS: In order to build the staff's confidence that DOE and the M&O can develop and implement a QA program, it will be necessary for DOE to demonstrate that the work which has been or will be done is acceptable. Because DOE and the M&O have not demonstrated that they can effectively implement a "get well" program, the staff recommends that DOE allow the NRC an opportunity to determine the acceptability of DOE work prior to the start of any ESF construction that could impact site characterization or the waste isolation capability of the site. The acceptability of the get-well program will be determined based on observations of DOE reviews and audits as well as independent evaluations. In addition, the staff will gain confidence that the get-well program is effective if DOE demonstrates that the process under which the ESF is designed and constructed is identifying and correcting problems.

In addition, DOE should demonstrate that the work on Design Package 2C is acceptable. This should be done by conducting any necessary QA audits, design reviews, or readiness reviews that are needed to demonstrate the acceptability of the work. The number and significance of findings from these reviews can serve as a basis for demonstrating the acceptability of the process and design. DOE also should demonstrate that design work on other design packages is acceptable given the problems identified.

UNCERTAINTY RESOLUTION METHOD TYPE: Other - In-Field Verification

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION: DOE letter to NRC (Dreyfus to Bernero) dated November 14, 1995.

HISTORY:

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April 3-6, 1995 - NRC performed in-field verification of DOE/M&O.

CROSS REFERENCE

CITATION: §60.150, §60.151, and §60.152 (Subpart G. Quality Assurance).

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES: None

OPEN ITEM STANDARD REPORT

OITSID: OQA013OCT1994C001

LAST UPDATE: 27 Jun 1995

STATUS: Open

DATE RESOLVED:

TOPIC OF THE OPEN ITEM/UNCERTAINTY: The M&O QA program is not being effectively implemented in a manner that will assure acceptability of the Exploratory Studies Facility (ESF).

RESPONSIBLE BRANCH/SECTION: HLUR/HLW & Quality Assurance Section

ACTION AGENCY: DOE

IDENTIFICATION DATE: 13 Oct 1994

SOURCE TYPE: Comment letter on DOE QA Program

SOURCE DOCUMENT: NRC letter to DOE (Bernero to Dreyfus) dated October 13, 1994, "CONCERNS WITH QUALITY ASSURANCE PROGRAM"

DOE ACTIVITY CODE/WBS NO.: 1.2.11

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Concerns with DOE QA Program - Comment

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RATIONALE/BASIS: The basic philosophy of the NRC is that the safety of any nuclear facility is the responsibility of the operator. As such, DOE is the primary party responsible for ensuring that a high-level waste repository meets the requirements of 10 CFR Part 60. In order to gain confidence that DOE is fulfilling its responsibilities in an acceptable manner, the NRC requires DOE and its contractors to establish and execute a QA program for those structures, systems, and components important to safety and waste isolation. This QA program should provide measures to assure structured and systematic methods exist for: 1) obtaining data; 2) performing analyses; 3) preparing designs; and 4) providing supporting documentation for the NRC licensing decisions. Effective implementation of a QA program is intended to show that work was done properly, and the design will acceptably perform its function. As part of the NRC licensing process, the NRC staff needs to acquire the necessary confidence that the ESF is being acceptably designed, and will be built consistent with an approved design.

Construction being performed by DOE at the ESF could cause irreparable adverse effects on DOE's ability to perform site characterization or maintain the waste isolation capability of the site. Without an effectively implemented QA program, the staff does not have confidence that DOE will include all necessary considerations in the ESF design, or identify and correct problems. Examples include: 1) drifting that will be part of the geologic repository operations area too close to a fault; 2) ramp constructed at an improper angle; or 3) an incorrect seismic acceleration used in the structural analysis.

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DOE and the M&O have not effectively trended and integrated findings from different review activities such as QA audits and design reviews in determining trends, root causes, and recurrence of problems. At the August 30, 1994, QA meeting, DOE reported that it did not see a recurrence of problems based on its analysis of Corrective Action Reports (CARs) from QA audits. It did not, however, consider similar findings from design reviews conducted on Design Packages 2A, 2B, and 2C. For example, as part of its observation of the design review for packages 2A and 2B, the NRC staff raised a concern about the lack of conservatism from the design reviews in determining whether similar concerns existed on the M&O's QA program.

The M&O continued to conduct design work on Design Package 2C, even though DOE and M&O QA audits and surveillances had found recurring deficiencies in the M&O's QA program. Only after DOE indicated that it would issue a stop work order as a result of findings on Design Package 2C did the M&O withdraw the design package. In addition, although minor in effort, the M&O continues to conduct design work on other ESF Design Packages.

DOE continued to allow work to proceed on Design Package 2C, and it still does allow design work to be done on other ESF design packages. This has been done despite numerous significant and repetitive findings on the M&O's QA program. In addition, DOE has not ensured that the M&O corrective action program required under Criterion 16 of its QA plan is being effectively implemented, or that root cause and trend analyses are identifying the reason for the problems. During the June 1994 DOE Audit of the M&O, DOE mentioned the M&O Trend Program as being ineffective in obtaining corrective action of identified trends.

Problems continue to be found with tracing the flowdown of design requirements from 10 CFR Part 60 to design specifications. This concern was raised 1) in 1989 as part of the basis for Objection 1 of the Site Characterization Analysis; 2) by the NRC on-site representative in May 1993; and 3) most recently, by the DOE audit team in CAR-074. It also serves as another example of DOE's lack of effective integration in evaluating all findings from various reviews.

RECOMMENDATIONS: In order to build the staff's confidence that DOE and the M&O can develop and implement a QA program, it will be necessary for DOE to demonstrate that the work which has been or will be done is acceptable. Because DOE and the M&O have not demonstrated that they can

effectively implement a "get well" program, the staff recommends that DOE allow the NRC an opportunity to determine the acceptability of DOE work prior to the start of any ESF construction that could impact site characterization or the waste isolation capability of the site. The acceptability of the get-well program will be determined based on observations of DOE reviews and audits as well as independent evaluations. In addition, the staff will gain confidence that the get-well program is effective if DOE demonstrates that the process under which the ESF is designed and constructed is identifying and correcting problems.

In addition, DOE should demonstrate that the work on Design Package 2C is acceptable. This should be done by conducting any necessary QA audits, design reviews, or readiness reviews that are needed to demonstrate the acceptability of the work. The number and significance of findings from these reviews can serve as a basis for demonstrating the acceptability of the process and design. DOE also should demonstrate that design work on other design packages is acceptable given the problems identified.

UNCERTAINTY RESOLUTION METHOD TYPE: Other - In-Field Verification

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION: DOE letter to NRC (Dreyfus to Bernero) dated November 14, 1995.

HISTORY:

October 13, 1994 - NRC staff identifies comment via letter from R. Bernero to D. Dreyfus (DOE).

November 14, 1994 - DOE response to comment via letter from D. Dreyfus to R. Bernero.

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April 3-6, 1995 - NRC performed in-field verification of DOE/M&O.

CROSS REFERENCE

CITATION: §60.150, §60.151, and §60.152 (Subpart G. Quality Assurance).

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES: None

OPEN ITEM STANDARD REPORT

OITSID: OQA019DEC1994C001

LAST UPDATE: 27 Mar 1996

STATUS: Resolved

DATE RESOLVED: 06 Mar 1996

TOPIC OF THE OPEN ITEM/UNCERTAINTY: The use of developer supplied test cases (and no other test cases) to validate the acceptability of procured software that was not developed under a QA program accepted by the user

RESPONSIBLE BRANCH/SECTION: HLUR/HLW & Quality Assurance Section

ACTION AGENCY: DOE

IDENTIFICATION DATE: 24 Jun 1994

SOURCE TYPE: Observation Audit Report

SOURCE DOCUMENT: Holonich, J., 1994. Observation Audit of M&O Contractor. Letter to R. Milner, OCRWM, U.S. Department of Energy, December 19, 1994. Washington DC: Nuclear Regulatory Commission.

DOE ACTIVITY CODE/WBS NO.: 1.2.11

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Concerns with DOE QA Program - Comment

OPEN ITEM TEXT:

In the area of software, most of the test cases used by the M&O to “validate” each of the programs were the test cases supplied by the computer software developer. That is, the M&O users of the software did not develop their own test cases, and the “validation” was primarily an installation test that showed that the computer software functioned the same on the user’s computer as it did on the developer’s computer.

RATIONALE/BASIS:

By not developing its own test cases, the M&O puts more reliance on the software developer than would be required if the M&O users of the software developed their own test cases. The vintage of the software programs varies, and most were not developed under the controls of a 10 CFR Part 50, Appendix B, QA program. On the other hand, most of the software programs have been used for a number of years and are generally accepted by knowledgeable personnel as being the best available for their intended use.

RECOMMENDATIONS:

The NRC staff recommends that acquired computer software (not developed under an Appendix B QA program) be “validated” by more than rerunning the developer’s test cases.

UNCERTAINTY RESOLUTION METHOD TYPE:

Review DOE response.

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION:

None

HISTORY:

June 24, 1994 - Item discussed with DOE/M&O at exit meeting of NRC Observation Audit 94-07 (DOE Audit HQ-94-02)

December 19, 1994 - NRC letter to DOE (J. Holonich to R. Milner) “Observation Audit of M&O Contractor” identifies the open item.

April 13, 1995 - A proposed change to the Quality Assurance Requirements and Description document (QARD - DOE/RW/0333P) was presented at the Nuclear Regulatory Commission-Department of Energy (DOE) quality assurance (QA) videoconference. A new requirement would be added to Supplement I, "Software," as follows:

I.2 REQUIREMENTS

I.2.1 Software Life Cycles, Baselines and Controls

B. Acquired software, including software successfully used in NRC licensing or certification applications, shall meet the following requirements, at a minimum:

2. Perform validation in accordance with I.2.4 D, E, F using test cases developed by the affected organization and/or test cases provided by the software supplier with justification for their use.

NRC noted that a formal response is required before the item can be resolved and later questioned the acceptability of the information provided.

March 6, 1996 - NRC letter to DOE (J. Austin to R. Milner) "Closure of Open Item on Software Validation" closes the issue. The letter states:

"The basis of closure is Revision 5 of DOE's Quality Assurance Requirements and Description document (QARD-DOE/RW-0333P) which was transmitted to the NRC (Holonich) by your letter dated December 28, 1995. Revision 5 requires, *inter alia*, that acquired software be validated using test cases developed independently of the software developer. This is a new requirement, and it is sufficient to allow the NRC staff to close the open item."

CROSS REFERENCE

CITATION: §60.150; §60.151; and §60.152 (Subpart G. Quality Assurance)

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES:

None

OPEN ITEM STANDARD REPORT

OITSID: OQA027JAN1995C001

LAST UPDATE: 09 Nov 1995

STATUS: Resolved

DATE RESOLVED: 25 May 1995

TOPIC OF THE OPEN ITEM/UNCERTAINTY: Controls specified for keeping scientific notebook type information on electronic media

RESPONSIBLE BRANCH/SECTION: HLUR/HLW & Quality Assurance Section

ACTION AGENCY: DOE

IDENTIFICATION DATE: 23 Sep 1994

SOURCE TYPE: Observation Audit Report

SOURCE DOCUMENT: NRC letter to DOE (Holonich to Milner) dated January 27, 1995, "OBSERVATION AUDIT OF LAWRENCE LIVERMORE NATIONAL LABORATORY"

DOE ACTIVITY CODE/WBS NO.: 1.2.11

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Concerns with DOE QA Program - Comment

OPEN ITEM TEXT: LLNL procedure TIP-YM-12, "Electronic Record Keeping," indicates that electronic records can be used instead of hard copy records generated in scientific notebooks. An "Audit Observer Inquiry" generated by the NRC questioned whether the controls in the procedure were specific enough and whether activities in accordance with the procedure could be audited. After some discussion, there was a commitment by LLNL management to respond, through the DOE, with an expanded response to the inquiry. The staff will carry this Audit Observer Inquiry as an Open Item until a satisfactory response is received through the DOE.

RATIONALE/BASIS: The thrust of the inquiry was to ascertain whether controls were in place to prevent changes of the text in electronic record keeping media just before the hard copy is printed and made a QA record for submittal to the local records center.

RECOMMENDATIONS: DOE should follow-up to ensure that LLNL adequately addresses the inquiry.

UNCERTAINTY RESOLUTION METHOD TYPE:

Review DOE response.

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION:

None.

HISTORY:

23 Sep 1994 - Item discussed with DOE/LLNL at exit meeting of NRC Observation Audit 94-12 (DOE Audit YMP-94-10)

27 Jan 1995 - NRC letter to DOE (Holonich to Milner) "OBSERVATION AUDIT OF THE LAWRENCE LIVERMORE NATIONAL LABORATORY"

10 Mar 1995 - A response to this open item was proposed by LLNL during NRC Observation Audit 95-05 (DOE Audit YM-ARC-95-05). The item remains open pending formal response from DOE.

25 May 1995 - NRC accepts DOE actions to close the open item (letter Holonich to Milner, "Open Item Regarding Scientific Notebooks").

CROSS REFERENCE

CITATION: §60.150, §60.151, and §60.152 (Subpart G. Quality Assurance)

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES: None

OPEN ITEM STANDARD REPORT

OITSID: OQA015NOV1995Q001

LAST UPDATE: 25 Apr 1996

STATUS: Resolved

DATE RESOLVED: 08 Apr 1996

TOPIC OF THE OPEN ITEM/UNCERTAINTY: DOE's Quality Assurance Requirements and Description document (QARD - DOE/RW-0333P) does not establish requirements for the qualification of scientific investigation methods

RESPONSIBLE BRANCH/SECTION: HLW Projects & Quality Assurance Section

ACTION AGENCY: DOE

IDENTIFICATION DATE: 14 Nov 1995

SOURCE TYPE: NRC Observation of DOE Audit YM-ARP-96-01 of USGS

SOURCE DOCUMENT:

U.S. Nuclear Regulatory Commission, 1995. Observation Audit Report OA-96-01. Washington DC: Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of Waste Management.

DOE ACTIVITY CODE/WBS NO.: 8.3.1.17.3.1; 8.3.1.17.4.2 / 1.2.3.2.8.3.1; 1.2.3.2.8.4.1; 1.2.3.2.8.4.2

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Concerns with DOE Program - Question

OPEN ITEM TEXT:

Section III.2.2.B of the Quality Assurance Requirements and Description document (QARD - DOE/RW-0333P, Rev. 4, Supplement III - "Scientific Investigation") requires that scientific notebooks contain: "Method(s) to be used." This is adequate when the methods are generally accepted by the technical community involved (e.g., those methods published by ASTM, IEEE, and ASME). However, when other methods are used, the QARD does not require verification of their acceptability. For example, uranium trend and rock varnish cation ratio age dating methods have been used in scientific investigations performed by USGS, but their validity has not been established, and the methods are not widely accepted in the geologic community.

RATIONALE/BASIS:

The use of methods that are not generally accepted by the technical community involved will require justification during the licensing process.

RECOMMENDATIONS:

The QARD should include requirements for verifying the acceptability of methods used to gather, generate, manipulate, interpret, analyze, and report information that will be used or referenced in the

license application. Justification should be required for the selection and use of any method that is not generally accepted by the technical community involved. The justification should be equivalent to that necessary to qualify existing data and to validate computer models.

UNCERTAINTY RESOLUTION METHOD TYPE:

Review DOE response.

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION:

None

HISTORY:

October 25-27, 1995 - NRC noted the deficiency during observation of DOE's audit of the USGS and reported it to the audit team leader.

November 15, 1995 - Observation Audit Report OA-96-01 and this Open Item transmitted to DOE by letter from Holonich to Milner.

February 26, 1996 - Letter from R. Milner (DOE) to J. Austin (NRC) indicates DOE's Quality Assurance Requirements and Description Document (QARD) imposes requirements that adequately ensure acceptability of scientific methods.

April 8, 1996 - Letter from J. Austin to R. Milner resolves this open item. The letter states:

"The bases of closure are your letter dated February 26, 1996, to the NRC (Austin) and a discussion of the open item at the NRC-DOE quality assurance (QA) meeting on March 27, 1996...

However, as the NRC pointed out at the March 27, 1996, NRC-DOE QA meeting, USGS reports continue to use dates based on the uranium-trend dating technique in spite of a report (USGS - Yucca Mountain Project Branch 1995 Milestone Report 3GCH510M, "Progress Report on Dating Quaternary Surficial Deposits") having the words: "Some of the problems inherent (to uranium-trend dating) ... became apparent during ... the late 1970's ... The method has never received wide-spread use by the Quaternary geochronologic community." And, later: "uranium-trend dating methods are considered fundamentally flawed from a technical viewpoint. ... we recommend in the strongest terms that all subsequent reference to and consideration of previously-published uranium-trend "ages" from soil profiles at Yucca Mountain and elsewhere be abandoned with regards to numerical age significance. No other uranium-series geochronologists have ever come (sic) to the defense of the technique or the published results resulting from its application." The consensus of those participating in the discussion seemed to be that this was more of a technical/management problem than a QA problem. That is, USGS/M&O/DOE technical reviewers and management personnel should be familiar enough with the lack of technical support of the uranium-trend dating technique such that...[missing text in original]

It was also noted at the meeting that this may be more of an isolated incident rather than [sic] a pervasive problem. While we understand that the rock varnish cation method of age dating is also contentious, it does appear to have some support outside the Yucca Mountain project.

In light of the above, we consider this open item resolved. However, we suggest that DOE considers reviewing checklists/procedures used to review and approve technical documents to ensure that they require an assessment of the acceptability of the technical method(s) reported. A written response to this letter is not required...”

CROSS REFERENCE

CITATION: §10 CFR 60, Subpart G

LARP (REVIEW PLAN) NUMBER: 10.0

REFERENCES:

None

OPEN ITEM STANDARD REPORT

OITSID: OQA002NOV1995Q001

LAST UPDATE: 25 Apr 1996

STATUS: Open

DATE RESOLVED:

TOPIC OF THE OPEN ITEM/UNCERTAINTY: What policies or procedures will DOE require the USGS to implement to ensure acceptable quality of technical reviews of USGS documents?

RESPONSIBLE BRANCH/SECTION: HLW Projects & Quality Assurance Section

ACTION AGENCY: DOE

IDENTIFICATION DATE: 02 Nov 1995

SOURCE TYPE: NRC Observation of DOE Audit YM-ARP-95-20 of USGS

SOURCE DOCUMENT:

U.S. Nuclear Regulatory Commission,. 1995. Observation Audit Report. OA-95-11.
Washington DC: Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of Waste Management.

DOE ACTIVITY CODE/WBS NO.: 8.3.1.4.2.2; 8.3.1.4.2.3 / 1.2.3.2.2.1.2; 1.2.3.3.1.2.3

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Concerns with DOE Program - Question

OPEN ITEM TEXT:

The U.S. Geological Survey (USGS) technical review process has not been effective in assuring the correctness, technical adequacy, completeness, accuracy, and compliance with established requirements. What policies or procedures will DOE require the USGS to implement to ensure acceptable quality of technical reviews of USGS documents?

RATIONALE/BASIS:

The NRC staff participated as an observer of the DOE performance-based technical audit of the USGS in Denver, Colorado, from September 11-15, 1995 (Audit YM-ARP-95-20). The audit pertained to developing the unsaturated zone model for Yucca Mountain. The main technical issue associated with the audit was the hydrologic characterization of structural features which significantly affect water and vapor movement. In addition, the audit team reviewed LBL-37358/UC-814, "Preliminary Development of the LBL/USGS Three-Dimensional Site-Scale Model of Yucca Mountain, Nevada." This report was transmitted to DOE in October 1994. On December 12, 1994, the report was approved by DOE for distribution from a "programmatic and policy standpoint." A subsequent review of this report by DOE resulted in 47 technical comments, 37 of which were considered major. The audit team recognized this deficiency and documented it as part of Corrective Action Request (CAR) YMQAD-95-C-051. This condition appears to be repetitive, similar to conditions in CARs YM-95-045 and YM-95-046 written during the YMQAD June 1995 audit of USGS (Audit YM-ARP-95-12). Based on this finding, the NRC

staff questions the overall quality of the USGS technical reviews for correctness, technical adequacy, completeness, accuracy, and compliance with established requirements. This repetitive condition is listed as an Observation in Section 4.6.1 of NRC Observation Audit Report OA-95-11 and will be carried as an Open Item until satisfactory resolution.

RECOMMENDATIONS:

The USGS response to DOE CARs YM-95-045, YM-95-046, and YMQAD-95-C-051 should address the policies or procedures USGS will implement to ensure the quality of USGS technical document reviews.

UNCERTAINTY RESOLUTION METHOD TYPE:

Review USGS response to and DOE closeout of CARs YM-95-045, YM-95-046, YMQAD-95-C-051.

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION:

None

HISTORY:

September 11-15, 1995 - NRC noted the repeated deficiency during observation of DOE's audit of the USGS and documented this concern via NRC Audit Observation Report OA-95-11.

November 2, 1995 - Observation Audit Report OA-95-11 and this open item transmitted to DOE in letter from J. Holonich to R. Milner.

CROSS REFERENCE

CITATION: §10 CFR 60, Subpart G

LARP (REVIEW PLAN) NUMBER: 10.0

REFERENCES:

None

November 28, 2001

MEMORANDUM TO: King Stablein

THROUGH: Jim Firth /RA/
Raj Nataraja /RA/
Larry Campbell /RA/

FROM: Kien Chang /RA/

SUBJECT: RESOLUTION OF EIGHT ITEMS DEALING WITH QUALITY
ASSURANCE IN YUCCA MOUNTAIN PROJECT

This memorandum documents the closing of eight items in the Open Item Tracking Systems (OITS). All eight items in the OITS pertain to quality assurance topics in DOE's Yucca Mountain Project. These are identified by their Item IDs, filenames and Key Technical Issues (KTI) to which they belong.

I have discussed the contents of these items with their KTI Leads and NRC's On-Site Representative and we agree that these items are closed. The documents containing discussions supporting their "closed" status are identified..

Following the distribution of this memorandum, the OITS records will be updated to document the status of these items.

Attachment: As stated

cc: W. Belke
J. Andersen

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