



Department of Energy
Office of Civilian Radioactive Waste Management
Office of Repository Development
1551 Hillshire Drive
Las Vegas, NV 89134-6321

QA: N/A
Project No. WM-00011

MAY 20 2005

OVERNIGHT MAIL

ATTN: Document Control Desk
Director, Division of High-Level Waste
Repository Safety
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852-2738

RESPONSES TO TWO AUDIT OBSERVER INQUIRIES (AOI) FOLLOWING
PERFORMANCE-BASED AUDIT BY U.S. DEPARTMENT OF ENERGY (DOE)
OFFICE OF QUALITY ASSURANCE AND OBSERVED BY U.S. NUCLEAR
REGULATORY COMMISSION (NRC) STAFF

During the week of January 24 - 28, 2005, DOE conducted a performance-based audit of activities in support of the Preclosure Safety Analysis. In the course of conducting this audit, DOE received two AOI forms, both submitted by Timothy J. Kobetz (NRC). Enclosed with this letter are copies of the AOIs along with the respective DOE responses.

If you have any questions regarding this matter, please contact David C. Haught at (702) 794-5474 or e-mail david_haught@ymp.gov.


Joseph D. Ziegler, Director
Office of License Application & Strategy

OLA&S:DCH-0840

Enclosures:

1. AOI Form – AP-3.12Q, Rev. 2 ICN 2;
and Response
2. AOI Form – AP-3.13Q; and Response

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MAY 20 2005

cc w/encls:

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cc w/o encls:

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OCRWM
AUDIT OBSERVER INQUIRY FORM

QA: N/A

Audit No. OCRWMP-OOA-05-20 Sequence No. _____
Name (Observer) TIM KORETZ
Organization NRC

Requirement Reference AP-3.12Q, Rev. 2 ICN12 3/10/04

Question/Concern: THE PROCEDURE (SECTIONS 5.1 & 5.3) DISCUSS

PRELIMINARY & FINAL CALCULATIONS OR ANALYSIS. HOWEVER
IT IS NOT CLEAR FROM THE PROCEDURE AND INTERVIEWS
(AND OTHER DISCUSSIONS WITH DOE STAFF) WHEN A CALC.
OR ANALYSIS SHOULD BE MADE FINAL. IN ADDITION,
IT IS NOT CLEAR IF A CALC. OR ANALYSIS MUST BE
FINAL TO SUPPORT CONCLUSIONS STATED IN A POTENTIAL
LICENSE APPLICATION.

Response:

see attached response (1)

Audit Team Leader: _____

Acknowledgement of Receipt: _____

Observer Signature

Date: _____

ENCLOSURE 1

Audit No. OCRWMP-OQA-05-20
Response to AOI on AP-3.12Q, Revision 2, ICN 2

Response

The U.S. Department of Energy's LA will provide design and safety analysis information in appropriate detail to demonstrate compliance with 10 CFR 63 for the U.S. Nuclear Regulatory Commission to docket the LA, prepare safety evaluations, conduct hearings, and make conclusions relative to the safety of the facility. Supporting material that is referenced, or otherwise available, will be prepared and approved under Yucca Mountain Project Quality Assurance Program provisions and will be fully suitable as the basis for the safety analysis and its conclusion.

Under the current version of the procedure, AP-3.12Q *DESIGN CALCULATIONS AND ANALYSES*, there are two types of calculations, preliminary and final. Calculations and analyses performed to this procedure and issued are suitable for regulatorily required safety analyses.

- Preliminary calculations are issued to support internal use, estimates, client review and regulatorily required safety analyses. Preliminary calculations are identified by using upper case alpha revision designators (the last three alphanumeric characters of the document number).
- Final calculations support the above purposes as well as support bids, procurement, fabrication, construction and operations. Final calculations are identified by using numeric revision designators (the last three alphanumeric characters of the document number).

AP-3.12Q is currently undergoing a revision, which will contain three types of calculations, preliminary, committed, and final. Once the procedure change is implemented:

- Preliminary calculations will be defined as being issued to support internal use, and estimates. Preliminary calculations will be identified by using upper case alpha revision designators (the last three alphanumeric characters of the document number) and marked preliminary on the cover sheet.
- Committed calculations will be defined as suitable to support regulatorily required safety analyses. Committed calculations will be identified by using upper case alpha revision designators (the last three alphanumeric characters of the document number) and marked committed on the cover sheet.
- Final calculations will be defined as being issued to support bids, procurement, fabrication, construction and operations. Final calculations will be identified by using numeric revision designators (the last three alphanumeric characters of the document number).

Audit No. OCRWMP-OQA-05-20
Response to AOI on AP-3.12Q, Revision 2, ICN 2

The following flowchart shows the new types of calculations correspond with the old types of calculations and how to identify them.

Current Version of AP-3.12Q		Planned Revision of AP-3.12Q	Revision Designators
Preliminary	→	Preliminary	00A, cover sheet marked Preliminary
	→	Committed	00A, cover sheet marked Committed
Final	→	Final	001, cover sheet marked Final

Under the current version of AP-3.12Q as well as the planned revision, during document preparation, all drafts of the document will contain a unique identifier to insure traceability and version control. A lower case alpha draft designator following the revision designators can be used.

For example

	Final	Preliminary/Committed
Checking Draft	001a	00Aa
Backcheck Draft	001b	00Ab
Review Draft	001c	00Ac
Final Check Draft	001d	00Ad
Approved Version	002	00B

Version control of all approved calculations will be governed by the use of upper case alpha and numeric characters in the revision designators.

OCRWM
AUDIT OBSERVER INQUIRY FORM

QA: N/A

Audit No. OCRWMP-OOA-05-20 Sequence No. _____
Name (Observer) TIM ROBEZ
Organization NRC

Requirement Reference AP-3.13Q DESIGN CONDOX

Question/Concern: STEPS 5.1.5 & 5.1.6 DISCUSS THE PRELIMINARY DESIGN AS A BASIS FOR "LICENSE APPLICATION FOR CONSTRUCTION AUTHORIZATION" AND THE FINAL DESIGN AS THE BASIS FOR A "LICENSE TO RECEIVE AND POSSESS." THE PROCEDURE NOTES THAT THE PRELIMINARY DESIGN AND FINAL DESIGN CONTAIN DIFFERENT LEVELS OF DETAIL. THIS APPEARS TO CONTRADICT THE REQUIREMENTS OF 10 CFR 63.21 ~~AND 63.22~~ WHICH NOTES THAT THE APPLICATION MUST BE AS COMPLETE AS POSSIBLE IN THE LIGHT OF THE INFORMATION (OVER)

Response:
see attached response (2)

Audit Team Leader: _____

Acknowledgement of Receipt: _____
Observer Signature

Date: _____

ENCLOSURE 2

THAT IS REASONABLY AVAILABLE AT THE TIME
OF DOCKETING. 70 CFR 63.24 NOTES THAT THE
UPDATED APPLICATION SHOULD BE UPDATED WITH
"DATA OBTAINED DURING CONSTRUCTION." THIS
STATEMENT DOES NOT APPEAR TO ACKNOWLEDGE THAT
ADDITIONAL DESIGN DETAILS THAT WERE NOT INCLUDED
WITH THE INITIAL DESIGN SHOULD BE ADDED
DURING THE UPDATE BUT INSTEAD THE APPLICATIONS
WOULD BE UPDATED TO REFLECT DESIGN CHANGES
REQUIRED TO ADDRESS NEW INFORMATION LEARNED
ABOUT THE SITE CHARACTERISTICS DURING CONSTRUCTION.

Audit No. OCRWMP-OQA-05-20
Response to AOI on AP-3.13Q

Response:

AP-3.13Q is currently in the process of being revised and statements regarding the license application (LA) will be removed. The Yucca Mountain Project (Project) understands that the licensing process involves a single, periodically updated LA with multiple licensing decisions and license amendments, including Construction Authorization (10 CFR 63.31), License to Receive and Possess (10 CFR 63.41), Permanent Closure (10 CFR 63.51), and Termination of License (10 CFR 63.52).

Relative to the level of information available to support the U.S. Nuclear Regulatory Commission's (NRC) safety decision at the time of submittal, the Project will ensure that the Safety Analysis Report and its supporting documentation are sufficient to demonstrate the adequacy of the defined safety and waste isolation functions and their planned execution. The NRC has provided feedback on these matters through extensive interaction and correspondence; the Project has considered this feedback and will submit an LA that is adequately supported with design information. This does not mean that all the design information necessary for procurement, construction, or operational activities will necessarily be available at the time of LA submittal. Rather, that information needed for the LA will be available but the ongoing development of detailed design including such products as procurement specifications, physical installation and construction related design information, fabrication and installation drawing and specifications, etc. will continue through the construction phase. As the design progresses after the LA submittal, the design refinements will confirm the adequacy of the safety basis demonstrated in the LA.