



**Department of Energy**  
Office of Civilian Radioactive Waste Management  
Office of Repository Development  
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QA: N/A  
Project No. WM-00011

**JAN 28 2004**

OVERNIGHT MAIL

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RESPONSE TO U.S. NUCLEAR REGULATORY COMMISSION (NRC) AUDIT  
OBSERVATION INQUIRIES FOR AUDIT OQAP-BSC-03-10

Reference: Ltr, Schlueter to Brown, dtd 12/10/03

The enclosure to this letter provides the responses to the three audit observation inquiries identified during NRC's observation of the Office of Civilian Radioactive Waste Management audit, OQAP-BSC-03-10, entitled, "Performance-Based Audit of Analysis Model Report Processes and Products."

If you have any questions, please contact Neal K. Hunemuller of my staff at (702) 794-5081.

A handwritten signature in black ink that reads "Joseph D. Ziegler".

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

OLA&S:NKH-0490

Enclosure:  
Responses to Three Audit Observation  
Inquiries for Audit OQAP-BSC-03-10

NMSS07

JAN 28 2004

cc w/encl:

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## ENCLOSURE

### RESPONSES TO THREE AUDIT OBSERVATION INQUIRIES FOR AUDIT OQAP-BSC-03-10

#### AOI-OQAP-BSC-03-10-01: Technical Specialist Coverage of the Audit Scope

Paragraph 5.2.1 of the reference letter stated:

- “Long-term remobilization of potential volcanic tephra deposits is a process of apparent high risk significance<sup>1</sup> to calculations of postclosure repository performance. The conceptual model for tephra remobilization is presented in the Atmospheric Transport and Deposition AMR [MDL-MGR-GS-000002 REV00F].
- “Evaluation of potential tephra remobilization processes requires expertise in the general field of surface-process geology, with specific knowledge of sedimentary processes in arid terrains. Although the audit Technical Specialist assigned to audit this AMR has the technical expertise to audit the atmospheric transport processes also included in this AMR, his expertise does not include (by his own admission) processes associated with tephra redistribution.
- “The NRC staff are concerned this AMR evaluation may be inadequate to ascertain the technical adequacy of the conceptual model for potential tephra remobilization processes. Specific concerns include
  - Traceability in TWP for model development
  - Transparency in AMR to support model adequacy
  - Validity of model assumptions
  - Tests of model hypotheses
  - Appropriate evaluation of model uncertainties
  - Consideration of alternative conceptual models”

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“<sup>1</sup> The high risk significance to this conceptual model is supported by (i) the credit apparently taken in TSPA for redirection of potential airborne contaminant plumes away from the location of the reasonably maximally exposed individual in approximately 80 percent of the calculations, (ii) the Biosphere Technical Basis Document that credits rapid reduction in airborne particle concentrations and resulting inhalation dose in posteruption risk calculations based on results of remobilization modeling, and (iii) the high risk ranking of this topic in NRC Key Technical Issue Agreement 2.17.”

#### AOI-OQAP-BSC-03-10-01 Response:

The Office of Civilian Radioactive Waste Management recognizes that the technical expertise necessary to evaluate the conceptual model for potential tephra remobilization processes, which is a part of AMR MDL-MGR-GS-000002, *Atmospheric Transport and Deposition AMR*, was not available on the audit team (audit OQAP-BSC-03-10). Evaluation of the quality assurance aspects of traceability of the technical work plan was within the capabilities of the audit team and was addressed in the audit. There was no impact on the audit of AMR MDL-MGR-GS-000002 because tephra remobilization was not part of the original audit scope, and the activities audited were within the capabilities of the team.

## **AOI-OQAP-BSC-03-10-02: Informal Reviews**

Paragraph 5.2.2 of the reference letter stated:

“During review of the Seismic Consequence Abstraction AMR, the audit team became aware of the inappropriate use of undocumented technical reviews of a quality-affecting document. Specifically, the audit team determined that during the initial development of the Seismic Consequence Abstraction AMR, the principal investigator forwarded the draft document to DOE and MTS for comment, as well as to two additional unqualified reviewers. As established by the audit team, the incorporation of these unofficial comments resulted in substantial changes to the draft AMR. There was no record, however, of the review comments for this document or the review efforts associated with this quality-affecting activity.

“This practice is an apparent departure from the requirements of QARD Section 5.2, which states quality-affecting ‘work shall be performed in accordance with controlled implementing documents;’ Section 6.2.4, which states ‘documents shall be reviewed in accordance with Subsection 2.2.10, Document Review;’ which states, in part, that implementing documents and documents that specify technical or quality requirements ‘shall be reviewed in accordance with established criteria using pertinent background information by technically competent individuals other than the preparer, considering all aspects of the document.’”

### **AOI-OQAP-BSC-03-10-02 Response:**

During the course of audit OQAP-BSC-03-10, the Audit Team noted pervasive use of “informal reviews” as a means to improve product quality. These reviews were performed both during document development and subsequent to initiation of formal reviews. The use of such reviews is not governed by existing Project procedures. Condition Report (CR) 1149 was initiated to document this condition. The CR will track resolution.

### **AOI-OQAP-BSC-03-10-03: Checklist Distribution**

Paragraph 5.2.3 of the reference letter stated:

“In recent audits, the audit teams have provided checklists to the auditees prior to the start of the audit. NRC is concerned about potentially adverse impacts of this practice on the audit process and results.”

### **AOI-OQAP-BSC-03-10-03 Response:**

The checklist is a more detailed description of the information that is provided in the audit plan, i.e., what is going to be audited. Providing this information in advance can enhance audit performance by allowing the audited organization to better refine the support they need to provide and can aid in making the audit more thorough and complete. There are no Quality Assurance Program requirements that prohibit the Office of Quality Assurance (OQA) from providing the checklists to the audited organization. We believe this practice is helpful in meeting the objectives of audits and, therefore, OQA will continue to provide the checklists on a case-by-case basis.