



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

MAR 15 2004

OVERNIGHT MAIL

ATTN: Document Control Desk
Chief, High-Level Waste Branch, DWM/NMSS
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
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**RESPONSE TO U.S. NUCLEAR REGULATORY COMMISSION (NRC) AUDIT
OBSERVER INQUIRY AOI-OAR-03-04 REGARDING THE PATH FORWARD FOR
DEFINING AND QUALIFYING DATA**

References: (1) Ltr, Schlueter to Brown, dtd 10/17/03
(2) Ltr, Ziegler to Chief, High Level Waste Branch (NRC), dtd 2/11/04

During the NRC observation of the U.S. Department of Energy's (DOE) quality assurance audit OQAP-BSC-03-14 on September 8-19, 2003, one Audit Observer Inquiry (AOI) was made (Reference 1). The response to AOI-OAR-03-04 is enclosed.

With Reference 2, DOE requested an extension until March 15, 2004, to respond to this request.

There are no new regulatory commitments in the body or the enclosure to this letter.
If you have any questions, please contact Neal K. Hunemuller at (702) 794-5081.


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

OLA&S:NKH-0830

Enclosure:
Response to NRC Audit Observer Inquiry
AOI-OAR-03-04

NM5507
WM-11

MAR 15 2004

cc w/encl:

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cc w/o encl:

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ENCLOSURE

Response to NRC Audit Observer Inquiry AOI-OAR-03-04

NRC Audit Observer Inquiry AOI-OAR-03-04 states:

“NRC is concerned with the path forward for defining and qualifying data, particularly the consistency between NUREG-1298 and DOE AP-3.15Q, Rev. 4, ICN 2, and AP-SIII.3.Q. The Root Cause Determination for Corrective Action Report BSC (B)-03-B-107, *Reporting Deficiencies in the Management and Utilization of Data*, discusses the differences in the data definitions and the DOE history of data definitions. Of particular interest are

- Qualification status of Reference Only data as used to exclude model components (address possibility of bias in data selection).
- Qualification of Technical Information particularly in regard to the category of documented and substantiated information, including electronic databases (please clarify).”

Response:

The Quality Assurance Requirements and Description (QARD) commits the Yucca Mountain Project to compliance with NUREG-1298, *Qualification of Existing Data for High-Level Nuclear Waste Repository*. As corrective actions for Condition Report 16 (formerly Corrective Action Request BSC (B)-03-B-107); procedures AP-3.15Q, *Managing Technical Product Inputs*, AP-SIII.2Q, *Qualification of Unqualified Data*, and AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*, were revised to ensure consistency in definitions and approach to compliance with NUREG-1298. These revisions included the deletion of the terms “Reference Only” and “Technical Information.” In accordance with the revised procedures, the categories of inputs to the Document Input Reference System (DIRS) are data, established fact, vendor data, and qualified software. Also in accordance with the revised procedures, each entry will be designated as qualified, unqualified, or not applicable.