

April 17, 2003

Joseph D. Ziegler, Acting Director
Office of License Application and Strategy
U.S. Department of Energy
Office of Repository Development
P.O. Box 364629 M/S 523
North Las Vegas, NV 89036-8629

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION STAFF REVIEW OF
REVISION 13 OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE
MANAGEMENT QUALITY ASSURANCE REQUIREMENTS AND
DESCRIPTION

Dear Mr. Ziegler:

This is in response to the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), April 2, 2003, letter. In that letter, DOE provided additional information requested by the U.S. Nuclear Regulatory Commission (NRC) on February 21, 2003. NRC requested the additional information as a result of its review of the proposed Revisions 13 to the DOE, OCRWM, Quality Assurance Requirements and Description (QARD), DOE/RW-033P, originally submitted for NRC's review on January 30, 2003.

NRC staff reviewed the additional information provided by DOE in its April 2, 2003, letter, along with the changes to the QARD described in Revisions 13, in accordance with the requirements of 10 CFR 63, "Disposal of High-level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada." The staff has determined that the additional information provided by DOE and the changes described in Revision 13 of the QARD are acceptable, and that NRC considers the QARD adequate for controlling DOE's present work activities.

However, in your April 2, 2003, letter, you state twice that Procedure AP-3.15Q, "Managing Technical Product Inputs," will be concurrently revised with the implementation of QARD, Revision 13. Because AP-3.15Q implements those QARD requirements regarding technical product inputs, it is NRC's understanding that AP-3.15Q will be revised and issued at the same time that Revision 13 of the QARD is issued. Similarly, Deficiency Report BSC(O)-03-D-080, dated January 30, 2003, identified that Procedure AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," incorrectly allows the use of "Not Established Fact Data" as "Accepted Data." It is NRC's understanding that Procedure AP-SIII.2Q will also be revised and issued at the same time that Revision 13 of the QARD is issued. You are requested to inform NRC if AP-3.15Q or AP-SIII.2Q will not be revised and issued at the same time that Revision 13 of the QARD is issued, and provide adequate justification for such a decision.

We noted in our February 21, 2003, letter, that the proposed Revision 13 to the QARD, continues to reference 10 CFR Part 60. However, 10 CFR 63.1 states that "As provided in 10 CFR 60.1, the regulations in part 60 of this chapter do not apply to any activity that is subject to licensing under...part [63]." As stated in your April 2, 2003, letter, we understand that DOE intends to incorporate 10 CFR part 63 into Revision 14 to the QARD.

NRC requirements contained in Subpart G-Quality Assurance, of 10 CFR 63, specify the quality assurance (QA) criteria that the DOE Yucca Mountain Project QA program must meet. Pursuant to 10 CFR 63.21(c)(20), the DOE Yucca Mountain Project Safety Analysis Report must include a description of the QA program to be applied to the structures, systems, and components (SSCs) important to safety and to the engineered and natural barriers important to waste isolation. The description of the QA program must include a discussion of how the applicable requirements of 10 CFR 63.142 will be satisfied.

Because DOE is not yet an applicant for the potential High Level Waste Repository at Yucca Mountain, NRC staff did not perform a comprehensive review of the QARD in accordance with the guidance in the Yucca Mountain Review Plan, NUREG-1804, Draft Final Revision 2. However, prior to any license application, DOE should modify certain sections of the QARD to clarify DOE commitments and adequately describe QA program requirements for design, procurement, construction and preclosure activities. These modifications should include, but not be limited to, changes to sections such as those addressing the organization structure, including delegation of QA program responsibilities, QA program commitments, graded QA, commercial grade item dedication, records, including storage of records using electronic media, audits, and the use of Technical Assessment processes to evaluate unqualified data.

Prior to any license application, DOE should also modify the QA program to explicitly identify the SSCs subject to the QA program, the major participating organizations and their functions, and the control of activities affecting the quality of the identified SSCs, consistent with their importance to safety. The categorization process, methods, and criteria for determining the SSC functional requirements and grading of QA controls must be adequately defined. The Q-list process and QL-1, 2, or 3 SSC categorization were discussed in the April 25-26, 2002 Technical Exchange Meetings, and were addressed in the NRC letter, C. William Reamer, NRC, to Stephen J. Brocoum, DOE, Subject: Q-List Methodology and Graded QA, February 25, 2000.

J. Ziegler

3

Should DOE submit a license application, we would expect that modifications, such as those discussed above, would be incorporated in the QARD prior to license application. Clearly, DOE has the option of revising the QARD in the near future, since a variety of organizational changes and delegations are in progress, and various organizations are currently performing activities that utilize the Q-list process and SSC QL categorization methods.

If you have any questions regarding this letter, please contact me at (301) 415-7264, Tom Matula at (301) 415-6700.

Sincerely,
/RA/

Janet Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Division of Nuclear Material Safety
and Safeguards

cc: See attached distribution list

Letter to J. Ziegler from J. Schlueter, dated: April 17, 2003

cc:

A. Kalt, Churchill County, NV	M. Corradini, NWTRB
R. Massey, Churchill/Lander County, NV	J. Treichel, Nuclear Waste Task Force
I. Navis, Clark County, NV	K. Tilges, Shundahai Network
E. von Tiesenhausen, Clark County, NV	M. Chu, DOE/Washington, D.C.
G. McCorkell, Esmeralda County, NV	G. Runkle, DOE/Washington, D.C.
L. Fiorenzi, Eureka County, NV	C. Einberg, DOE/Washington, D.C.
A. Johnson, Eureka County, NV	S. Gomberg, DOE/Washington, D.C.
A. Remus, Inyo County, CA	W. J. Arthur, III , DOE/ORD
M. Yarbro, Lander County, NV	R. Dyer, DOE/ORD
D. Carriger, Lincoln County, NV	J. Ziegler, DOE/ORD
M. Baughman, Lincoln County, NV	A. Gil, DOE/ORD
L. Mathias, Mineral County, NV	W. Boyle, DOE/ORD
L. Bradshaw, Nye County, NV	D. Brown, DOE/OCRWM
D. Chavez, Nye County, NV	S. Mellington, DOE/ORD
D. Hammermeister, Nye County, NV	C. Hanlon, DOE/ORD
J. Larson, White Pine County, NV	T. Gunter, DOE/ORD
J. Ray, NV Congressional Delegation	S. Morris, DOE/ORD
B. J. Gerber, NV Congressional Delegation	J. Mitchell, BSC
F. Roberson, NV Congressional Delegation	M. Mason, BSC
T. Story, NV Congressional Delegation	S. Cereghino, BSC
J. Reynoldson, NV Congressional Delegation	N. Williams, BSC
L. Hunsaker, NV Congressional Delegation	M. Voegele, BSC/SAIC
S. Joya, NV Congressional Delegation	D. Beckman, BSC/B&A
K. Kirkeby, NV Congressional Delegation	W. Briggs, Ross, Dixon & Bell
R. Loux, State of NV	P. Johnson, Citizen Alert
S. Frishman, State of NV	R. Holden, NCAI
S. Lynch, State of NV	B. Helmer, Timbisha Shoshone Tribe
M. Paslov Thomas, Legislative Counsel Bureau	R. Boland, Timbisha Shoshone Tribe
J. Pegues, City of Las Vegas, NV	J. Birchim, Yomba Shoshone Tribe
M. Murphy, Nye County, NV	R. Arnold, Pahrump Paiute Tribe

cc: (Continued)

R. Clark, EPA

R. Anderson, NEI

R. McCullum, NEI

S. Kraft, NEI

J. Kessler, EPRI

D. Duncan, USGS

R. Craig, USGS

W. Booth, Engineering Svcs, LTD

L. Lehman, T-Reg, Inc.

S. Echols, ESQ

M. Smurr, BNFL, Inc.

J. Bococho, Big Pine Paiute Tribe of the
Owens Valley

R. Mike, Duckwater Shoshone Tribe

T. Kingham, GAO

D. Feehan, GAO

E. Hiruo, Platts Nuclear Publications

G. Hernandez, Las Vegas Paiute Tribe

K. Finrock, NV Congressional Delegation

C. Meyers, Moapa Paiute Indian Tribe

R. Wilder, Fort Independence Indian Tribe

D. Vega, Bishop Paiute Indian Tribe

J. Egan, Egan & Associates, PLLC

J. Leeds, Las Vegas Indian Center

R. M. Saulque, Benton Paiute Indian Tribe

C. Bradley, Kaibab Band of Southern Paiutes

R. Joseph, Lone Pine Paiute-Shoshone Tribe

L. Tom, Paiute Indian Tribes of Utah

E. Smith, Chemehuevi Indian Tribe

V. McQueen, Sr., Ely Shoshone Tribe

R. Quintero, Inter-Tribal Council of NV
(Chairman, Walker River Paiute Tribe)

D. Eddy, Jr., Colorado River Indian Tribes

H. Jackson, Public Citizen

J. Wells, Western Shoshone National Council

D. Crawford, Inter-Tribal Council of NV

I. Zabarte, Western Shoshone National Council

NRC On-Site Representatives

J. Ziegler

3

Should DOE submit a license application, we would expect that modifications, such as those discussed above, would be incorporated in the QARD prior to license application. Clearly, DOE has the option of revising the QARD in the near future, since a variety of organizational changes and delegations are in progress, and various organizations are currently performing activities that utilize the Q-list process and SSC QL categorization methods.

If you have any questions regarding this letter, please contact me at (301) 415-7264, Tom Matula at (301) 415-6700.

Sincerely,

/RA/

Janet Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Division of Nuclear Material Safety
and Safeguards

cc: See attached distribution list

DISTRIBUTION:

File Center	HLWB r/f	ACNW	PUBLIC	OSR	LSN
CNWRA	LCampbell	LChandler	DDambly	MYoung	ACoggins
ACampbell	BSpitzberg	WMaier, RIV	LKokajko		

C:\ORPCheckout\FileNET\ML031060643.wpd *See Previous Concurrence **ML**

OFFICE	HLWB		HLWB		HLWB		
NAME	*T Matula: ijk		*NK Stablein		JSchlueter		
DATE	04/11/03		04/13/03		04/17/03		

OFFICIAL RECORD COPY