

**QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION (QARD)
DOE/RW-033P, REVISION 17**

ADDITIONAL INFORMATION NEEDS

1. Identify all on-site and off-site organizational elements that function under the cognizance of the quality assurance (QA) program. QARD Section 1.3, "Description," describes organizational responsibilities only at the Office level.
2. Regarding QARD paragraph 6.2.3F.3, clarify that the Yucca Mountain Project (YMP) will review quality-affecting procedural controls and changes to procedural controls of the principal contractors.
3. Clarify how QARD paragraph 3.2.3E6 describes a process for "individual verification of calculations" as indicated by QARD paragraph 3.1C. Rather, QARD paragraph 3.2.3E6 appears to describe software qualification approach similar to QARD Supplement I, "Software."
4. Clarify the basis for selecting site characterization as the limit for data to be qualified in QARD paragraph III.2.4.B. Clarify the apparent discrepancy between QARD paragraphs III.2.4B ("data from site characterization activities ... shall be qualified") and 3.2.1C ("data from scientific investigations ... shall be qualified").
5. Clarify why the definition of data in the QARD Glossary includes only "site characteristics or standard references" but omits data from other sources (e.g., from physical measurements and analyses).
6. Clarify whether the other purchasers involved with sharing audit results described in QARD paragraph 18.2.3.G will have NRC-approved QA programs that satisfy Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3.
7. Clarify if external audits scheduling described in QARD paragraph 18.2.3.B will consider "the status and importance" of the activities in determining the audit frequency.
8. Clarify why the notes in the parenthetical statements of NUREG 1804, Yucca Mountain Review Plan, Revision 2, Acceptance Criteria 18(6)(h) and (i) are included in the QARD.
9. Describe how spent nuclear fuel and high-level waste form producers described in QARD paragraph 1.3.6 will meet applicable QA criteria.
10. Describe how NRC SECY 03-117, "Approaches for Adopting More Widely Accepted International Quality Standards," July 9, 2003, described in QARD paragraph 4.2.1C.1 allows use of QA programs based on ISO 9001, "Model for Quality Assurance in Design/Development, Production Installation and Servicing."

Enclosure

11. Clarify why Quality Assurance Clarification Number 04-001, September 2, 2004, regarding the use of software to generate preliminary outputs is not incorporated into the QARD.
12. Editorial comments
 - Note the apparent inconsistency between Table 1, item A-8, 3rd paragraph and paragraph 6.2.6E. The cross reference in Table 1 should be paragraph 6.2.6 E instead of paragraph 6.2.3E.
 - Note that QARD paragraph 7.2.1 E uses term “interface capability” while NQA-1a-1983, paragraph 7S-1.2, Requirement 4, uses “interface compatibility.”
 - Clarify the apparent discrepancy in record retention requirements between QARD Table 1, item A10 (“until waste emplacement operations begins”) and paragraph 17.2.8.B (“at the end of the operating period”).
 - Regarding supplier record requirements, note that QARD paragraph 17.2.8C indicates that suppliers will retain records as specified in purchase documents, but Table 1, item A14 indicates that all supplier QA records will be submitted to YMP. Also, what is included in “all supplier QA records” in Table 1, item A14.