

SUMMARY OF U.S. NUCLEAR REGULATORY COMMISSION (NRC)/
U.S. DEPARTMENT OF ENERGY (DOE) TECHNICAL EXCHANGE ON
PROPOSED RESPONSES TO NRC ADDITIONAL INFORMATION NEEDS (AINs) ON
THE QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION (QARD) REVISION 17
LAS VEGAS, NEVADA
FEBRUARY 10, 2005

Introduction:

Staff from the U.S. Nuclear Regulatory Commission (NRC) and the Office of Civilian Radioactive Waste Management (OCRWM), U.S. Department of Energy (DOE), held a public Technical Exchange to discuss DOE's proposed responses to NRC Additional Information Needs (AINs) on the QARD Revision 17. The agenda for the Technical Exchange is provided with this meeting summary (Enclosure 1). The meeting was held at the facilities of DOE located in Las Vegas, Nevada, with videoconferencing provided for NRC Headquarters in Rockville, Maryland, and the Center for Nuclear Waste Regulatory Analyses (CNWRA) in San Antonio, Texas. Those in attendance included representatives from the NRC, DOE, CNWRA, Bechtel SAIC Company, LLC (BSC), the State of Nevada, and members of the public. During opening remarks, Mr. D. Brown (DOE) thanked the NRC for their thorough review of the QARD.

Mr. T. Matula (NRC) indicated in opening remarks that this was a Category 1 meeting and there would be opportunity at the conclusion of the meeting for public comments and questions. The list of attendees is Enclosure 2 to this Technical Exchange summary.

The DOE submitted QARD Revision 17 to the NRC on September 17, 2004. The NRC provided Additional Information Needs (AIN) to DOE on December 22, 2004. At the Technical Exchange, DOE staff presented proposed responses to NRC AINs.

It was clarified at the outset of the Technical Exchange that the NRC would, upon receipt from DOE, review the formal responses to AINs on QARD Revision 17. None of the comments or discussions during the Technical Exchange should be interpreted to indicate a complete review or acceptance of the QARD Revision 17 or of the proposed responses to AINs.

Presentations:

Mr. M. Ulshafer (DOE) lead the discussion of DOE's proposed responses to the AINs as follows:

AIN-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.

Proposed Response: QARD Subsection 1.3 will be revised to address the criteria delineated in NUREG-1804, "Yucca Mountain Review Plan," Acceptance Criteria AC-1 (5). In addition, QARD Subsection 1.3.5 will be revised to address activities specified in QARD Supplement I, Software, Supplement II, Sample Control, Supplement III, Scientific Investigation, and Supplement IV, Field Surveying.

The QARD will be changed to add a commitment to develop and maintain current organization charts. Further, an organization chart will be made available to NRC with QARD Revision 17.

Mr. Matula indicated that this appeared to be reasonable and appropriate; however, the NRC role during this Technical Exchange was to gather information and not to reach conclusions.

AIN-2: Regarding QARD paragraph 6.2.3 F.3., clarify that the Yucca Mountain Project (YMP) will review quality-affecting procedural controls and changes to procedural controls of the principal contractors.

Proposed Response: QARD Subsection 6.2.3 F.3. will be revised to provide for the review of the principal contractor's procedures governing the development and maintenance of their quality-affecting procedures.

AIN-3: Clarify how QARD paragraph 3.2.3 E.6. describes a process for "individual verification of calculations" as indicated by QARD paragraph 3.1 C. Rather, QARD paragraph 3.2.3 E.6. appears to describe software qualification approach similar to QARD Supplement I, "Software."

Proposed Response: QARD Subsection 3.2.3 E.6. does not describe a process for "individual verification of calculations," nor does it describe a software qualification approach similar to QARD Supplement I, Software; this was not the intent of the subsection. Subsection 3.2.3 E.6. describes when software qualified in accordance with QARD Supplement I may be used without reverification in accordance with QARD Supplement I. QARD Subsection 3.1 C. will be revised to provide this clarification.

Mr. J. Ziegler (DOE) clarified that this Subsection 3.2.3 E.6 is specifically directed at activities that are Important to Safety (ITS) or Important to Waste Isolation (ITWI). Mr. F. Brown (NRC) agreed that the section was only applicable to activities within the scope of the QA program.

AIN-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.2.4 B. ("data from site characterization activities . . . shall be qualified" and 3.2.1 C. ("data from scientific investigations . . . shall; be qualified").

Proposed Response: Since the site characterization phase has been completed, QARD Subsection III.2.4 B. will be revised to make the language consistent with Subsection 3.2.1 C. This change is consistent with the terminology used in NRC NUREG-1804, *Yucca Mountain Review Plan, Revision 2 (Final Report)*, Section 2.5, AC(15)(b). In particular, QARD will be revised to read as follows: III.2.4 B. Data from scientific investigation activities that are used as direct input to scientific analysis or performance modeling that address safety and waste isolation issues shall be qualified

AIN-5: Clarify why the definition of data in QARD Glossary includes only "site characteristics or standard references" but omits data from other sources (e.g., from physical measurements and analyses).

Proposed Response: The definition of data in the QARD Glossary is the same definition as provided in the NUREG-1804 Glossary. However, application of this definition to the Yucca

Mountain Project (YMP) excludes, as data, other sources supporting the License Application that are not derived from site characteristics or standard references. Therefore, the QARD Revision 17 definition of data will be revised to include data from scientific investigation activities. Scientific investigation is defined in the QARD Revision 17 Glossary as “Any observation, identification, description, experimental study, or analysis and explanation of natural phenomena.” This definition of scientific investigation is limited in that it does not explicitly include investigations relative to engineered materials as applied to repository system performance. To address this limitation, the QARD definition of scientific investigation will be expanded to make it explicitly applicable to investigations of engineered materials. The revised definition of data in conjunction with the revised definition of scientific investigation encompasses the NUREG-1804 definition, and it incorporates data from other sources (e.g., physical measurements and analysis).

QARD Change:

In particular, it is proposed to change the QARD Revision 17 definitions of data and scientific investigation to read as follows:

Data – Information measured or derived from scientific investigation activities both in the field and the laboratory. Parameters that have been derived from raw data are sometimes themselves considered to be data.

Scientific Investigation – An analysis consisting of an explanation, observation, identification, description, or experimental study either of natural phenomena or of engineered materials that describe the postclosure repository system or its performance.

Mr. Matula indicated that this appeared on the surface to be satisfactory, but that the NRC will need to evaluate the response further upon submittal.

AIN-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.

Proposed Response: QARD Subsection 18.2.3 G. will be revised to limit its application to the Office of Repository Development (ORD) and YMP Contractors. The QA programs of YMP Contractors are accepted by the Office of Quality Assurance.

Mr. Matula requested clarification that this is intended to mean these entities and no others. DOE confirmed that this is the case.

AIN-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.

Proposed Response: QARD Subsection 18.2.3 B. will be revised to address the “status and importance” of activities in determining the audit frequency.

AIN-8: Clarify why the notes in parenthetical statements of NUREG-1804, Yucca Mountain Review Plan, Revision 2, Acceptance Criteria 18(6)(h) and (l) are included in the QARD.

Proposed Response:

In relation to Acceptance Criterion 18(6)(h):

The content of the parenthetical statement was included in the QARD at Subsection 7.2.13 A. to ensure that the users of the QARD are aware of the limitations imposed by the NRC on the use of ANSI/ASME NQA-1, *Quality assurance Program Requirements for Nuclear Facilities*, 1993 Edition. These limitations are: “. . . the NRC has only endorsed certain editions and Addenda of the American Society of Mechanical Engineers Section III Code (*American Society of Mechanical Engineers*, 1998)....”

So that users of the QARD will recognize that the NRC has not endorsed all editions of and addenda to Section III of the ASME code, the QARD makes reference to the “NRC endorsed version of the Code.” Therefore, prior to the purchase of ASME Code Section III items, users of the QARD are required to determine which editions of and addenda to Section III of the ASME Code have been endorsed by the NRC. This limiting statement is not contained, to our knowledge, in any other requirement source document (e.g., Regulation, Regulatory Guide, or endorsed ANSI/ASME standard) that is applicable to the YMP. Because the limitation pertains to procurement activities, it was deemed appropriate to include it in the QARD Section 7.0, Control of Purchased Material, Equipment, and Services. In addition, the QARD includes a clause that provides additional flexibility in relation to the selection of the edition and addenda of the ASME Code that may be used by the YMP. This clause, “editions of the ANSI/ASME NQA-1 identified ... or otherwise approved ... version of the Code,” is intended to provide for the use of the edition and addenda, which might be approved for use upon a specific request by YMP to the NRC. “...when the referenced edition of the NQA-1 is used in conjunction with other quality assurance, administrative, and reporting requirements.”

This limiting statement is not contained, to our knowledge, in any other requirement source document (e.g., Regulation, Regulatory Guide, or endorsed ANSI/ASME standard) that is applicable to the YMP. Because the limitation pertains to procurement activities, it was deemed appropriate to include it in QARD Section 7.0, Control of Purchased Material, Equipment, and Services.

In relation to Acceptance Criterion 18(6)(l):

NRC Information Notice (IN) 86-21, *Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders, (3/86)*, is identified as a “commitment document” in NUREG-1804, 2.5.1.5. In addition, IN 86-21 is coincidentally referred to in the parenthetical Note following AC-18(6)(l). The provisions of IN 86-21 are reflected in QARD Subsections 7.2.13 B. and 7.2.13 C. in response to the “commitment” expectation of NUREG- 1804, Section 2.5.1.5, which “commitment” is also reflected in QARD Revision 17 Table 1.

AIN-9: Describe how spent nuclear fuel and high-level waste form producers described in QARD paragraph 1.3.6. will meet applicable QA criteria.

Proposed Response: QARD Section 1.3.6 will be revised to direct the user to the new QARD Revision 17 Appendix A. Appendix A will describe the measures taken to ensure that

information supplied by waste custodians is suitable for use in supporting the license and that waste forms are suitable for acceptance.

Mr. Matula asked if Appendix A will be applicable to information only. The DOE clarified that it would be applicable to information and to the waste form. Mr. Matula asked if details would be provided in Appendix A and whether the applicability to the waste form included packaging. DOE responded affirmatively to both questions.

AIN-10: Describe how NRC SECY 03-117, “Approaches for Adopting More Widely Accepted International Quality Standards,” July 9, 2003, described in QARD paragraph 4.2.1 C.1. allows use of QA programs based on ISO 9001, “Model for Quality Assurance in Design/Development, Production, Installation and Servicing.”

Proposed Response: QARD Subsection 4.2.1 C.1. will be revised to remove references to other NRC approved programs.

AIN-11: Clarify why Quality Assurance Clarification Number 04-0001, September 2, 2004, regarding the use of software to generate preliminary outputs is not incorporated into the QARD.

Proposed Response: This was an oversight. Since QARD Revision 17 is a complete rewrite to comply with 10 CFR 63.142 and NUREG-1804, the clarification should have been incorporated into the body of the QARD. The QARD will be revised to incorporate Quality Assurance Clarification Number 04-0001.

AIN-12: Editorial comments

Note the apparent inconsistency between Table 1, Item A 8., 3rd paragraph and paragraph 6.2.6 E. The cross reference in Table 1 should be paragraph 6.2.6 E. instead of paragraph 6.2.3 E.

Proposed Response: The YMP Position A 8. in Table 1 will be clarified.
Note that QARD paragraph 7.2.1 uses term “interface capability” while NQA-1a-1983, paragraph 7S- 1.2 Requirement 4, uses “interface compatibility.”

Proposed Response: QARD Subsection 7.2.1 E. will be revised to be in conformance with the language of NQA-1-1983, Supplement 7S-1, Section 2, 3rd paragraph, 1st sentence.

Clarify the apparent discrepancy in record retention requirements between QARD Table 1, item A 10. (“until waste emplacement operations begins”) and paragraph 17.2.8 B. (“at the end of the operating period”).

Proposed Response: QARD Table 1, Item A 10., YMP Position, will be revised to conform the terminology to that of QARD Subsection 17.2.8 B.

Regarding supplier record requirements, note that QARD paragraph 17.2.8 C. indicates that suppliers will retain records as specified in purchase documents, but Table 1, Item A 14. indicates that all supplier QA records will be submitted to YMP. Also, what is included in “all supplier QA records” in Table 1, item A 14.

Proposed Response: “All supplier QA records” includes those records that are identified and included in procurement documents in accordance with QARD Subsection 7.2.1 D.9.

For the purpose of clarity, QARD, Table 1, Item A 14., YMP Position, will be revised. The revision will provide that these QA records shall thereafter be retained in accordance with the direction of the OCRWM Program Records Retention Schedule.

Mr. Matula stated that they appreciated the information on the proposed DOE approach to responding to the AINs, and that they would review the responses when they were provided. Mr. Matula indicated that NRC staff did not have any objections to what DOE proposed, that the DOE’s approach appeared on the surface to be satisfactory, but that the NRC staff will need to evaluate DOE’s formal response upon submittal to determine if the QARD is acceptable.

Discussion of additional changes

Mr. Ulshafer presented a number of additional changes that are anticipated in the QARD and were presented by DOE except as noted below:

Editorial and Consistency changes: All record types will be given the same treatment regarding record retrieval times in Section 17.2.7. The term “documentary evidence” has been removed from criterion 7, Table 1. References were added to source documents.

Site Characterization: The term “site characterization” was eliminated since site characterization formally ended at the time of Site Recommendation.

YMP Contractor/Supplier and ORD/YMP/OCRWM Terminology: The terminology has been changed to be consistent with appropriate current terminology.

Applying Qualifications Only to Office of Quality Assurance (OQA) Director/ Management & Operating Contractor (M&O) QA Manager, Sections 1.3.5 and 2.2.11 G.: The original wording was an over-commitment. This section has been modified to be consistent with NUREG-1804, and apply the qualification requirements only to the Director of OQA and the M&O QA Manager.

Software Applicability, Section 2.2.2 C.: The “related activities” described in Section 2.2.2 C. are limited to those functions ITS or ITWI. As such the relationship is to Section 2.2.2 A. and Section 2.2.2 B. This section means that the QARD is applicable to related activities only if those activities constitute a function that is ITS or ITWI. For example, the QARD is applicable to software development and use only if the software performs an ITS or ITWI function.

This is not a change in the QARD but a clarification believed necessary to avoid misinterpretation of QARD requirements as being applicable to such areas as business software which is not ITS or ITWI. Mr. Matula questioned this rationale and indicated that if a verbal clarification such as this is actually needed, it may need to be clarified formally in the QARD. NRC cited as suggested that the sentence in 10 CFR 63.142, “The pertinent requirements of this subpart apply to all activities that are important to waste isolation and important to safety functions of those structures, systems, and components,” as being a reasonable choice of wording to add to could be used to clarify the applicability of the QARD. DOE representatives indicated that they would consider this.

Consumables, Section 2.2.3: The “related consumables” described in Section 2.2.3 are limited to those that are intended to perform an ITS or ITWI function. In response to a question from NRC, DOE stated that their intent for discussing the scope of “related consumables” during the

Technical Exchange was to confirm what is already in the QARD on this topic. NRC staff stated no objections.

10 CFR 63.32 and 10 CFR 63.44, Section 3.2.6 G.: The proposed change in this case was to delete item G from Section 3.2.6. That item currently states: “Design changes shall be evaluated in accordance with 10 CFR 63.32 or 10 CFR 63.44.” After some discussion, there was general agreement that a better approach would be to modify item G to read: “Prior to the issuance of a design change initiated after the construction authorization, the design changes shall be evaluated pursuant to applicable regulatory requirements.”

Procurements subject to 10 CFR 21, Section 4.2.1 K.: The proposal is to add a new item K reading: “Provisions for identifying that the procurement is subject to the provisions of 10 CFR 21.” This assures that the requirement for compliance with 10 CFR 21 is properly incorporated into procurement documents.

Measures to prevent recurrence, Section 18.2.10 A.: Mr. D. Brown led this discussion. When Revision 15 to the QARD was implemented, line organizations assumed responsibility for Level C and D Condition Reports (CRs). The OQA is conducting a 100% overview of all organizations to double check the handling of Level C and D CRs until it is confirmed that the line organizations are properly handling disposition of these CRs. During final review of Revision 15 to the QARD, DOE failed to remove the phrase “including measures to prevent recurrence.” This change is being proposed in Revision 17 since the appropriate requirement is to implement measures to preclude recurrence only for Level A CRs.

Mr. F. Brown suggested that leaving the existing wording there and adding the phrase “when appropriate” might be a better solution. DOE stated that they would consider this.

Non-Q Procurement of Data, Supplement III and Table 1 E 2.: Mr. D. Brown led this discussion. In very limited circumstances, it may be necessary to qualify data that was obtained under non-Q procurement. A proposed change is considered for the future (in a possible Revision 18 to the QARD) to allow this. The approach would closely match the NUREG-1298 , *Qualification of Existing Data for a High-Level Nuclear Waste Repositories*, approach to qualifying data and would be generally similar to commercial grade dedication.

Mr. F. Brown asked if DOE was referring to any specific unqualified data that was contemplated. Mr. D. Brown responded that although no actual unqualified data was being considered at this time, but that the consideration was in anticipation of unusual situations that could develop in the future. Mr. F. Brown suggested that such a change to the QARD should be considered at this time as an addition to the QARD Revision 17 review process to avoid the need for an exigenturgent change in the future. The DOE agreed to take Mr. F. Brown’s suggestion into consideration.

Timeliness of Design Work, Table 1: It is proposed that Item A 6. regarding timeliness of design activities be removed from Table 1.

NUREG-1298 and 10 CFR 63, Table 1: The intent is that YMP commits to the requirements and recommendations of Section IV, Staff Positions of NUREG-1298. In any case where NUREG-1298, “Qualification of Existing Data for High-Level Nuclear Waste Repositories,” is in conflict with 10 CFR 63, 10 CFR 63 takes precedence. Mr. Ziegler indicated that this was an area where DOE staff had identified a possible conflict regarding the reference of NUREG-1298 to 10 CFR 60 when the existing applicable regulation is 10 CFR 63. This clarification is

intended to be included in the meeting minutes to mitigate internal interpretation issues and to clarify the regulatory precedent of 10 CFR 63 over NUREG-1298. NRC staff stated no objections.

Revised Definitions:

Alternate Calculations – the term is used once in the document. The proposed change defines the term at its place of use and deletes it from the Glossary.

Design Input – make the definition consistent with NQA-1-1983.

Model, Abstract, Conceptual, Mathematical – It is proposed to change the definitions to match the definitions in NUREG-1804.

Unqualified Data – It is proposed to modify the definition for consistency with NUREG-1298, specifically the addition of the 3rd bullet under the A heading in QARD Revision 17 to add "Data published in technical or scientific publications. (NUREG-1298, 2/88)."

Witness Point – It is proposed to change the definition to be consistent with project use allowing work to proceed upon notification of the witness point. This area was discussed regarding how the notification would take place.

Public Comments and Questions

Ms. S. Lynch (State of Nevada) asked for clarification on several points:

With regard to ITS and ITWI, will relevant scientific activities still be covered. The DOE affirmed that they would. Regarding unqualified data, will the approach delineated in NUREG-1298 still be used. Mr. Ziegler affirmed that the NUREG-1298 approach will still be used. How documentation will be retained on Witness Point notifications. The response indicated that such documentation is normally provided as part of the work documentation in accordance with appropriate procedures.

Ms. S. Devlin (Pahrump/Nye County) directed attention to several areas:

Potential hazards due to lightning. She provided a copy of a report on the subject to DOE. That report is included as Enclosure 4. Ms. Devlin also indicated that an approximately 250-page report on transportation was prepared by the Nuclear Project in Pahrump. She characterized this report as having a lot of good work and indicated that an electronic version of the information would be available soon on compact disk. Recent declassification of a report on the Environmental Protection Agency Farm at the Nevada Test Site for the period 1952-1982 that may be useful. She reiterated her concern on the potential placement of classified U.S. Department of Defense waste at Yucca Mountain, on possible problems from microbes and fungi, and on the issue of colloids.

Mr. G. Hudlow raised a concern over what he identified as a failure to have a waste package design and whether chemical industry data needed to be considered. He also expressed support for alternative viable disposal methods, specifically transmutation.

Ms. J. Holmgren read a January 21, 2005, article from *The Australian* concerning an agreement between Australia and the United States for the United States to accept certain Australian nuclear waste (Enclosure 5) and directed a series of questions (Enclosure 6) to DOE. Representatives of DOE indicated that the right people to respond to those questions were not at the meeting.

Conclusion

The meeting was adjourned following the opportunity for public comments. The NRC will provide appropriate feedback subsequent to the DOE submittal of the responses to the AINs.

_____ Date: _____
Frederick D. Brown, Section Chief
Project Management Section A
Division of High-Level Waste Repository Safety
U.S. Nuclear Regulatory Commission

_____ Date: _____
Joseph D. Ziegler, Director
Office of License Application and Strategy
Office of Repository Development
U.S. Department of Energy

_____ Date: _____
R. Dennis Brown, Director
Office of Quality Assurance
Office of Repository Development
U.S. Department of Energy