UNITED STATES
NUCLEAR REGULATORY COMMISSION
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MEMORANDUM FOR: Robert E. Browning, Director
Division of Waste Management
Office of Nuclear Material Safety and Safeguards

FROM: Brian K. Grimes, Director
Division of Quality Assurance, Vendor,
and Technical Training Center Programs
Office of Inspection and Enforcement

SUBJECT: REVIEW OF NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT'S DATA ACCEPTANCE SOP AND NONCONFORMANCE SOP

In response to a request from the Repository Projects Branch, the QA Branch reviewed the Nevada Nuclear Waste Storage Investigations (NNWSI) Project's "Acceptance of Data or Data Interpretation Not Developed Under the NNWSI QA Plan," NNWSI-SOP-03-03, Revision 0, effective January 31, 1986. This 12-page document was reviewed against the QA requirements of 10 CFR Part 60 as described in the June 1986 draft GTPs on "Qualification of Existing Data" and "Peer Review."

Similarly, the Licensing Section of the QA Branch reviewed the NNWSI Project's "NNWSI Nonconformance Control System," NNWSI-SOP-15-01, Revision 1, effective January 31, 1986. This 8-page document was reviewed against the QA requirements of 10 CFR Part 60 as described in Section 15 of the "Criteria for QA Program (High-Level Waste Repository Program Part 60)," (Appendix A of Enclosure 1 to the Browning to Bennett letter of June 29, 1984). In DOE/RW-0032, the Office of Civilian Radioactive Waste Management's "Quality Assurance Management Policies and Requirements," DOE includes ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities," as one of the governing documents of the high-level radioactive waste repository program. Because of this commitment, NNWSI-SOP-15-01 was also reviewed against the requirements of supplement 15S-1 of NQA-1, even though the NRC has not required that the high-level radioactive waste repository program meet the requirements of NQA-1. Comments 5,6, and 7 of Enclosure 2 to this memorandum result from this review against NQA-1 requirements.

The reviews resulted in the enclosed comments. We suggest the enclosed comments be forwarded to DOE for response. We also suggest that the scope of the meeting proposed in my memorandum to you of July 11 be further expanded to include DOE's proposed response to these comments. We believe one meeting would be appropriate to discuss the results of our review of all the NNWSI QA documents.

Contact: J. Spraul X-24530

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Your staff or DOE representatives should contact J. Spraul before the suggested working meeting if clarification of the enclosed comments is desired.

Brian K. Grimes, Director
Division of Quality Assurance, Vendor,
and Technical Training Center Programs
Office of Inspection and Enforcement

Enclosures: As stated

NRC COMMENTS REGARDING THE
NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS
ACCEPTANCE OF DATA OR DATA INTERPRETATION NOT DEVELOPED
UNDER THE NNWSI QA PLAN, REV. 0
NNWSI-SOP-03-03

A. Major Concerns

1. The SOP was written prior to the NRC's June 1986 draft generic technical positions (GTPs) on "Qualification of Existing Data" and "Peer Review." An evaluation should be made against the draft guidance of these GTPs and differences between the revised SOP and the draft GTPs addressed.

2. Consistent with the GTPs noted above, SOP-03-03 should address the 4 methods of qualifying existing data, i.e., peer review, corroborating data, confirmatory testing, and an equivalent QA program. It is unlikely that "technical reviews" (as opposed to "peer reviews" as defined in the NRC draft GTP on peer review) will be adequate to qualify existing data in the majority of cases. The SOP should distinguish between such reviews and give criteria or guidance on when each kind of review is to be performed. For example, technical reviews do not include all the peer review attributes listed in Section V.A of the draft GTP on data qualification such as qualifications of personnel or organizations generating the data compared to the qualification requirements of personnel generating similar data under the approved 10 CFR 60, Subpart G program; the technical adequacy of equipment and procedures used to collect and analyze the data; the environmental conditions under which the data were obtained if germane to the quality of data; the quality and reliability of the measurement control program under which the data were generated; the extent to which conditions under which the data were generated may partially meet Subpart G; prior uses of the data and associated verification processes; prior peer or other professional reviews of the data and their results; extent and reliability of the documentation associated with the data; extent and quality of corroborating data or confirmatory testing results; the degree to which independent audits of the process that generated the data were conducted; and importance of the data to showing that the proposed DOE repository design meets the performance objectives of 10 CFR 60, Subpart E. Clarify the SOP accordingly.

3. Section 2.0 of the SOP addresses the applicability of the procedure. Its applicability should be extended to data collected prior to NRC acceptance of the NNWSI QA program and NRC verification of acceptable implementation of the program.

B. Other Comments

1. Section 3.4 of this SOP indicates that a principal investigator (PI) is responsible for day-to-day technical direction and quality control of an item or activity, while section 3.3 of NNWSI-SOP-02-02 lists the same requirement except that "quality control" is just "control." This difference should be rectified. Also, clarify whether it is the intent of the NNWSI Project to have PIs as leaders of peer review groups.

2. Section 5.2.1 item 2 of the SOP should require (perhaps as an attachment to the review sheet) the inclusion of the qualifications of the original investigator. Similarly, the complete package of documents which the PI forwards to the TPO per section 5.6 of the SOP should include the qualifications of the PI and other reviewers.

3. Sections 5.2.1 and 5.2.2 of this SOP indicate the acceptance action to be initiated by the PI depending upon the source of the data or data interpretation. It appears that items 4, 5, and 6 of section 5.2.2 should also be included in section 5.2.1. The word "cannot" in 5.2.1 item 4 and 5.2.2 item 3 appears too strong as most processes can be repeated under NNWSI QA Plan controlled conditions unless ruled out by cost and/or schedule considerations. The last part of 5.2.1 item 4, "including cost and schedule considerations," should be added to 5.2.2 item 3.

4. Although most definitions of QA indicate that QC is a subset of QA, section 5.2.1 item 5 would be more clear if it requires a description of the "quality control/quality assurance methods" rather than a description of just the "quality assurance methods." Also, a description of such methods that "may have been used" appears to be conjecture, and 5.2.1 item 5 should require a description of such methods that "were used." Objective evidence of the use of such quality control/quality assurance methods should be available.

5. A better description should be provided of the qualification requirements of the PI, the reviewers (section 5.3), the TPO (section 5.7), the "appropriate" WMPO Branch Chief (section 5.8), and the WMPO PQM (section 5.8). The SOP should indicate any allowable and/or any prohibited reporting relationships of these individuals. Further guidance in the area of peer qualification and independence is given in section 3 of the GTP on "Peer Review."

6. To indicate in section 5.4 of the SOP that the extent of a review "can be a spot check or similar checks" tends to minimize the importance of the reviews, and these words should be deleted.

NRC COMMENTS REGARDING THE
NNWSI NONCONFORMANCE CONTROL SYSTEM
NNWSI-SOP-15-01, REV. 1

1. Section 3.6 of the SOP defines Project QA as "The persons or organization responsible for quality implementation of NNWSI Project activities for their respective organizations." While not completely clear, this definition appears to be in error. The responsibility for "quality," for "quality achievement," for "quality implementation" (assuming these three quotations mean the same thing) rests with the performing, the doing, the line organization. The responsibility of the QA organization (whatever its title) in this regard is to verify that the required quality has been and is being achieved. In no way does this responsibility of the QA organization relieve the line organization of its responsibility to achieve the required quality. Thus, the definition of Project QA in section 3.6 of the SOP should be revised; and, if defined as persons or organization having certain responsibilities, the responsibilities should be keyed to those associated with the NNWSI nonconformance control system.

2. Section 5.1.1 of the SOP should reference Exhibit 1 and should specify that NCR stands for nonconformance report. This section indicates the originator shall assign an NCR number, but section 5.1.2 indicates the document clerk does this. Clarification is needed. Finally, section 5.1.2 refers to a "required nonconformance tag." As an NCR is shown in Exhibit 1, a nonconformance tag should be shown as Exhibit 2 and listed in section 7.0 of the SOP.

3. It is not clear whether the log referred to in section 5.1.3 of the SOP is the log of the NCR numbers issued required by section 5.1.2 of the SOP. This should be clarified. Responsibilities should be assigned in the SOP for furnishing the keeper(s) of the NCR log(s) with the NCR copy and other information required by SOP sections 5.1.2 and 5.1.3.

4. Section 5.1.4 of the SOP indicates the PQA shall ensure that open NCRs shall not remain idle. It should also indicate what action is to be taken by the PQA if activity toward disposition has apparently stopped.

5. The heading of section 5.2 of the SOP, "Segregation of Nonconforming Items," should be changed since section 5.2 addresses identification, segregation, and continued work of nonconforming items. Section 5.2.1 should require that identification of nonconforming items be legible, be easily recognizable, and not affect the end use of the items. Section 5.2.2 should require segregation in a clearly identified hold area.

6. Section 5.3.1 of the SOP requires that NCR dispositioners have demonstrated competence in the area they evaluate. It should also require that they have an adequate understanding of the requirements and have access to pertinent background information.

7. Section 5.3.5.1 of the SOP requires justification of disposition. Repair and use-as-is dispositions should be subject to design control measures commensurate with those applied to the original design.

8. Since section 5.3.6 of the SOP requires a QA review of each dispositioned NCR to ensure that appropriate QA requirements have been included, then section 5.3.5 should require the inclusion of appropriate QA requirements.

9. In section 5.3.3 of the SOP, clarify whether PQA or the NCR dispositioner sends a copy of the NCR to the responsible TPO Manager.

10. The SOP should address trending of nonconformances. Nonconformance reports should be periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances, and the significant results should be reported to upper management for review and assessment.