USEC
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Docket No. 070-03089

February 23, 1998
L-98-001

Mr. Robert C. Pierson, Chief
Special Projects Branch
U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555

Subject: **AVLIS Quality Assurance Program Description, Response to Request for Additional Information**

Reference:

(A) R.C. Pierson (NRC) letter to R.L. Woolley (USEC), dated December 18, 1997, "AVLIS Quality Assurance Program Description"

(B) S.A. Toelle (USEC) letter to R.C. Pierson (NRC), dated March 26, 1997, L-97-001, "AVLIS Quality Assurance Program Description"

(C) R. L. Woolley (USEC) letter to R.C. Pierson (NRC), dated October 3, 1997, L-97-003, "AVLIS Quality Assurance Program Description, Response to Additional Information"

Dear Mr. Pierson:

This letter provides responses to your Reference (A) request for additional information concerning our AVLIS Quality Assurance Program Description of Reference (B) as revised by Reference (C).

Enclosure (1) provides individual responses to the requests of Reference (A). In some cases, we have revised our Quality Assurance Program Description (QAPD). The changes are pointed out in Enclosure (1). Enclosure (2) provides the revised QAPD; areas which have changed are

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annotated by a vertical line in the right margin. The changes include those identified in Enclosure (1) and two minor editorial changes, in Section 1 and in the beginning of Section 7.

We look forward to your concurrence with this QAPD as acceptable for AVLIS licensing. This correspondence contains no new commitments beyond those incorporated into the QAPD. If you have any questions concerning this matter, please contact me at your convenience (301) 564-3413.

Sincerely,

Robert Woolley
Manager, AVLIS Nuclear Regulatory Policy
and Licensing

cc:
Drew Persinko
Jack Spraul

Enclosures:
(1) Response to Request for Additional AVLIS QA Information
(2) USEC - AVLIS Quality Assurance Program Description, Revision 2/23/98

Enclosure (1) to L-98-001

RESPONSE TO REQUEST FOR ADDITIONAL AVLIS QA INFORMATION

The following responds to the NRC request for additional information dated December 18, 1997, concerning the AVLIS Quality Assurance Program Description (QAPD) dated October 3, 1997.

1. **Comment 14** - Response 2 commits to NQA-1 supplements for proficiency testing of personnel. However, NQA-1 Supplement 4 that addresses indoctrination and training of personnel outside the QA arena does not require testing, capability demonstration, or periodic evaluations. The response should commit to performance testing those who perform activities relied upon for safety (the "doers") as well as those who assess the quality of these activities (the "QA types"), and this should be addressed in the QAPD as well.

   Response: Section 2 of the QAPD (second paragraph on page 7) has been changed to include the following sentence: "In addition, records of proficiency evaluation are maintained for personnel who operate, maintain, or modify QAL-1 items."

2. **Comment 32** - The 10 CFR Part 21 QA requirement for "dedication" of commercial "off-the-shelf" items that will be relied upon for safety needs to be addressed in the QAPD. (See discussion of commercial grade items after the General comment on the next page.)

   Response: The following has been added in item 3 of section 4 of the QAPD: "(The requirement for the supplier to have a documented quality assurance program may be waived for commercial grade items)". In addition, the following has been added to the end of section 7 of the QAPD:
   "Commercial grade items are subject to the following controls:
   1. **Changes to commercial grade items specified in design documents are subject to design control measures in accordance with section 3.**
   2. **Supplier evaluation, when deemed necessary, is in accordance with this section 7.**
   3. **Commercial grade items are identified in procurement documents by manufacturer's published product descriptions, in accordance with section 4.**
   4. **Acceptance of items is accomplished in accordance with this section 7 using receiving inspection and one or more of the following:**
      a. **Special test**
      b. **Commercial grade survey of the supplier**
      c. **Source verification**
      d. **Acceptable supplier/item performance record"**

   (Also see responses to the discussion of commercial grade items at the end.)

3. **Comment 34** - The comment was meant to refer to the routine identification and traceability of items relied upon for safety to "an applicable design or other pertinent specifying document" as required by Section 2.1 of NQA Supplement 8S-1. The response refers to traceability to "specific records when required by codes, standards, or specifications" as required by Section 3.1 of NQA Supplement 8S-1. While the reader can infer from Section 8 of the QAPD that items relied upon for safety shall be identified and traceable to applicable design, procurement, and/or other pertinent specifying documentation, the QAPD should include a commitment to that effect - even when not required by a code, standard, or specification

Response: The first sentence in the QAPD section 8 commits to identification and control to assure only the correct items are used. This means the specified item. No change to the QAPD appears necessary.

4. **Comment 35** - The response states: "No change to the QAPD appears necessary" because the QAPD states: "items are identified and controlled as necessary from initial receipt and fabrication up to and including installation and use; this complies with ASME NQA-1-1994." The response also states: "No commitment is made for additional documentation." The comment was not made to request "additional documentation." The comment was made to obtain a clear commitment that the correct identification of each item relied upon for safety is verified and documented before the item is released for fabrication, assembling, shipping, or installation. Such documentation should be routine, not "additional." The QAPD should include such a commitment.

Response: Section 8 of the QAPD has been changed to include the following sentence: "Documentation is provided to show that items released for use are the items specified."

5. **Comment 45** - It appears that "depositions" should be "dispositions."

Response: The original response should have been "dispositions". The QAPD uses the correct word. No change to the QAPD appears necessary.

6. **Comment 46** - The response indicates that as-built configurations will be shown on drawings if important for operation and maintenance purposes. It appears that as-built configurations should be shown on drawings if important for operation, maintenance, or decommissioning purposes. Also clarify how individuals who disposition nonconforming items will know they need to determine the need for as-built records. For example, will there be an item on the nonconformance disposition form indicating something like: Drawing to be changed to show as-built condition: Yes☐ No☐ ?

Response: Section 15 of the QAPD has been changed to include the following sentence (as the next to last sentence in the fifth paragraph): "The disposition process includes consideration of the need for design documents to be "as-built" to facilitate operations, maintenance, or decommissioning."

6. **Comment 51** - The protection of nonpermanent QA records for their lifetime and the

protection of permanent QA records for up to 6 months prior to their being entered into record storage and for some undefined length of time when checked out from record storage by some undefined "normal business practice" does not provide reasonable confidence that the records will be available and retrievable if and when needed. Clarify what is meant by "normal business practice," indicating whether it requires storage in a one hour fire rated container. Also, provide further justification for not requiring lifetime QA records to be "entered into record storage" in less than six months after validation. Finally, it appears that the reference to Section 16 (of the QAPD) in the response to Comment 51 should rather be to Section 17.

Response: USEC has elected to assume the risk of having to recreate a record that is lost or destroyed. The risk of loss is minimized by requiring lifetime records to be stored in accordance with NQA-1 within six months (see QAPD section 17). Protection of lifetime records prior to entry into storage and protection of non-permanent records is normal business practice, meaning office environment, workplace security, routine filing practice, etc.

Temporary storage of a lifetime record checked out of the storage facility is addressed in the last paragraph of QAPD, section 17. We did not commit to one-hour fire rated containers; instead we committed to the restrictions listed in the last paragraph of QAPD section 17.

ASME NQA-1 does not specify a time limit for entering lifetime records into storage. Six months was chosen as a time limit that is both practical and with acceptable risk.

The response to comment 51 should have referenced section 17 rather than section 16. No change to the QAPD appears necessary.

7. **General** - Based on the responses to Comments 41, 44, 45, and 50, it appears that Enclosure 3, "List of New Commitments," should be expanded to include the commitment that specific organizational responsibilities (including custodial responsibilities for records) will be defined in procedures during the procurement, construction, operations, and decommissioning phases.

Response: This commitment has been addressed by adding the following sentence to the end of section 1 of the QAPD: "Specific organizational responsibilities are defined in the implementing project procedures in accordance with section 5."

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COMMERCIAL GRADE ITEMS (Revised from Rev. 3 of the GDPs' QAP, May 31, 1996)

Methods for determining whether an item can be purchased as commercial grade and dedicated for use in a QAL-1 or QAL-2 application have been established. Procedures are established governing the procurement and use of commercial grade items:

Response: The QA Program sections 4 and 7 allow us to purchase commercial grade items for use in QAL-1 and QAL-2 applications. Supplier selection and acceptance of deliverables is as described in section 7 of the QAPD. See response to comment 32, above.

1. A commercial grade item is an item satisfying all of the following:
    a. Not subject to design or specification requirements that are unique to the nuclear facility.
    b. Used in applications other than nuclear facilities.
    c. Is ordered from the manufacturer/supplier on the basis of a specification set forth in the manufacturer's published product description (for example, a catalog).

    Response: We commit to the definitions in ASME NQA-1 as stated in QAPD section 2 (top of page 7).

2. The criteria and methods for identifying the critical characteristics that are essential to ensure that the item will perform its intended safety function.

    Response: Covered by QAPD section 3, third paragraph; section 7 page 12 "Acceptability verification..."; and section 10, third paragraph. See response to comment 32, above.

3. The criteria for determining the type and depth of product acceptance and the criteria for determining the point of dedication at which USEC assumes the responsibility for reportability. Dedication of a commercial grade item occurs after receipt when that item is designated for use in a QAL-1 or QAL-2 application.

    Response: Type and depth of acceptance activity is covered in changed QAPD section 7. See response to comment 32, above. USEC responsibility for reportability under Part 21 applies to all "basic components", and is addressed in QAPD section 15, last sentence.

4. Methods used to accept (dedicate) a commercial grade item are receipt inspection as required by Section 7 of this QAPD and one or more of the following as determined by the design organization:
    a. Special test
    b. Commercial grade survey of supplier
    c. Source verification
    d. Acceptable supplier and item performance record.

    Response: These items addressed in changed QAPD section 7. See response to

comment 32, above.

5. The selection of the combination of methods in 4. above is based on the following:
   a. Selected critical characteristics
   b. Available supplier information
   c. Quality history
   d. Degree of standardization
   e. Item complexity

   Response: See QAPD section 7, page 12 "Acceptability verification activities are based on importance to safety, complexity, and quantity of items and services supplied", and QAPD section 10, third paragraph. See response to comment 32, above.

6. Source evaluation and selection, when used, shall be in accordance with the requirements of Section 3.1 of Supplement 7S-1 of ASME NQA-1-1994.

   Response: See changed QAPD section 7and response to comment 32, above.

7. Procurement documents are issued and controlled in accordance with the requirements of Section 4. of this QAPD.

   Response: Agree. No change to the QAPD appears necessary.

8. Commercial grade items are identified in the purchase order by the manufacturer's published product description.

   Response: See changed QAPD section 7 and response to comment 32, above.

9. Receipt inspections are performed to determine that damage was not sustained during shipment, to determine that the item received is the item ordered, to determine that inspection and testing are performed as required to ensure conformance with the manufacturer's published requirements, and to ensure that required documentation is received and is acceptable.

   Response: See the description of receiving inspection in QAPD section 7.

10. The requirements of other sections of this QAPD apply once a commercial grade item is dedicated and determined acceptable for use in a QAL-1 or QAL-2 application

    Response: The requirements of the QAPD apply to QAL-1 and QAL-2 as stated in section 2, third paragraph.

Reference:

Federal Register / Volume 60, No. 181 / Tuesday, September 19, 1995 / Rules and Regulations - NRC, 10 CFR Part 21, "Procurement of Commercial Grade Items by Nuclear Power Plant Licensees." Note that 10 CFR Part 21, "Reporting of Defects and Noncompliance," is applicable to Part 70 licensees as well as to Part 50 nuclear power plant licensees.

Background References:

1. NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," March 21, 1989.

2. NRC Generic Letter 91-05, Licensee Commercial-Grade Procurement and Dedication Programs," April 9, 1991.