UNITED STATES
NUCLEAR REGULATORY COMMISSION
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MAR 21 1988

MEMORANDUM TO: J. Kennedy, Section Leader
Operations Branch
Division of High-Level Waste Management

FROM: N. Voltura, Project Manager
Operations Branch
Division of High-Level Waste Management

SUBJECT: REVIEW OF SOUTHWEST RESEARCH INSTITUTE - CENTER FOR NUCLEAR WASTE REGULATORY ANALYSIS DRAFT QA MANUAL - DATED FEBRUARY 1988

Per your direction on February 29, 1988, I have conducted a review of the subject QA Manual. In addition, this review also included specific sections of the Southwest Research Institute Nuclear QA Program Manual since it was referenced as being applicable to portions of the work conducted by the Center.

It must be noted that this was not a detailed review because of the time constraints and voluminous amount of material involved. Per our conversations, the review criteria for determining the Manual's acceptability were:

a) 10 CFR 50, Appendix B
b) ANSI/ASME NQA-1, 1983 Edition
c) CNWRA Contract Requirements #NRC-02-88-005
d) NRC Standard Review Plan

Based on these documents, the review was conducted to determine broad compliance with the above requirements. The program does not meet the above listed documents for compliance with 10 CFR 50, Appendix B. It should also be noted that in certain areas DHLWM may, after consideration of the impacts of an App. B program on SWRI, wish to grade or reduce QA measures. SWRI should identify these areas first. The following summary of comments is provided:

CNWRA QA Manual Review

I. Organization:

1. The QA Manual should address the specific activities to which it applies and identify the specific organizational responsibilities for conducting same. (Ref. ¶1.1 of CQAM)
(e.g.: Several Sections in the Center's Contract provide specific activity/work descriptions for the Center's work: Attachment 1, Pgs 1-9; Attachment 8, Page 2, ¶4.)

   a) Section/Chapter I - Organization ¶1.2.2 makes a general statement that the Center is organized into Elements and Subelements with Technical Objectives...Element and Subelement Managers...are responsible for the execution of individual tasks to accomplish their objectives.

Delete all dist. except PDR, LPDR, CF, CNWRA & TLSS

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- The specific elements/subelements need to be addressed/identified along with the individuals/organizations responsible for the quality of the delegated work prior to initiation of activities.

2) The Center QA Manager is not at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality.

   a) Center QA responsibilities need to be specifically identified/summarized in this Section.

   b) If SWRI QA is to provide QA support to the Center, the reporting lines need to be indicated on the organization charts (interfaces).

3) The SWRI QA Manual does not address the work specified by the Center's Contract as being covered per its activities. (¶1.2.3.(2)) (i.e.: What Section(s) discuss research or confirmatory testing; CQAM, ¶2.2 & 2.3.1/2)

   a) Clarify statements such as: ¶2.3.3.(2) - "...considerable work will be accomplished by SWRI as directed by the Center..."

      - These activities/work need to be identified, as well as responsibilities for conducting same.

4) Clarify what the specific functions of the OPRAC are so that the last sentence in ¶1.2.3(3) can be applied.

5) Figure 3 needs clarification on <u>which</u> of the QA Manuals will apply to NRC-related activities.

6) The organization charts (figures) in the "Introduction" section would better support Section 1 descriptions if all areas on the charts were discussed - (i.e., responsibilities of Director Tech. Dept; Technical Dir. etc.), also , QA interfaces with line organizations.

7) Clarify who is responsible for identifying those activities "important to licensing." Clarify NRC involvement, i.e., review/approval, etc.

II. <u>QA Program</u>

1) Clarify that the Center's QA program is more extensive than just this manual. Per previous references in Section 1, the SWRI QA Manual applies - See comments 2(b) and 3 from Section I.

2) ¶2.1 states that the Center QA Program will be implemented by Operations Plans...etc. However, the Manual does not specify how these plans are developed, reviewed, controlled, etc. per Section 5.0 or 6.0. Clarify, whether these plans are reviewed and approved by QA. There are specific information requests for Ops. Plans in Contract - Pg. 9-13 to include QA requirements, which need to be addressed in the CQAM.

3) ¶2.2 discusses QA Program application in general terms. Needs to identify the services to which the QA Program applied. Also, are those services identified as being "...consistent with their importance to safety, reliability and performance" the same as "...important to licensing?"

4) ¶2.3(1) adds "instructional memorandums" to the list of documents used to "control" the Program. However, neither Section 5.0 or 6.0 address the controls/use of these documents.

5) ¶2.3(3) - Who is responsible to conduct the annual audit of the Center QA Program?

6) Training program is addressed in Introduction Section - should be addressed in Section 2.0, but, needs clarification to include:

   a) whether indoc. and training is to be based on responsibilities/ assignments (position description) for all Center personnel.

   b) ¶ entitled "Scope" on Pg. 13 appears to establish different training requirements for those individuals working on the Center NRC activities and those SWRI and subcontractor personnel working on Center-delegated NRC activities. Clarify the differences and the basis for the distinctions.

   c) Clarify the differences between "indoctrination and training" and "QA indoctrination and training."

   d) Clarify the types of "...related information" is necessary for training files.

   e) Clarify what defines/determines need for follow-up training.

7) ¶ on Regulatory Analyses - Clarify where the program controls are specified for "specific memoranda" for Element/Subelement inputs to Reg. Analyses. Clarify how these are generated, reviewed, approved, controlled, revised, issued, NRC involvement - etc.

III. Design Control

1) Clarify how the Center controls the development, review, approval, issue, revisions for drawings, specifications and other "design" documents. Discuss verification controls, design inputs, interfaces, adequacy reviews.

   a) Clarify design controls for any equipment that may be designed.

2) Clarify control of computer programs used for design analysis.

3) Clarify control of software/computer programs developed for use by the Center for data analysis, modeling, performance assessment, etc.

4) Describe the organizational responsibilities for preparing, reviewing, approving, verifying and validating design and design information documents.

5) Clarify that errors and deficiencies in approved design and design information documents are documented and action is taken to assure that all errors and deficiencies are corrected.

6) Describe interface controls among organizations or groups involved in design development and other design activities.

7) Provide for definitions of design, design information and design activities as specified in the Standard Review Plan (SRP) which relate to design specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system.

   - SRP Section 3.1 also includes program provisions for data analysis which includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters.

8) Clarify that procedures require that design drawings, specifications, criteria and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

9) Clarify that procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design... In exceptional cases, the designer's immediate supervisor can, however, perform the verification, provided:

   a) the supervisor is the only technically qualified individual

   b) the need is individually documented and approved in advance with concurrence of the quality assurance manager

   It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.

10) Clarify that for design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted... Ref. SRP ¶3.8

11) Clarify that the responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in the procedures.

12) Clarify that design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affected groups and individuals.

13) Describe design documentation and records generated as a result of the design/design verification process need to be identified, collected, stored and maintained.

14) NRC interface/review of design documents needs to be described, if appropriate.

IV Procurement Document Control

1) Clarify whether procurement controls apply for purchase of services, equipment, materials and software related to research activities which support NRC work.

2) Clarify the QA requirements that need to be addressed in a purchase order (Q-related) (Rel. to licensing)

- scope of work
- technical req'ts
- QA req'ts
- etc.

3) Clarify QA role in review of Q-related purchase orders. CQAM indicates QA role as one of surveillance and audit only.

4) Clarify which QA program is implemented by SWRI Purchasing when they place POs. (Ref. ¶4.3.3)

5) Clarify how qualification of contractors for quality program req'ts is addressed.

6) Clarify how the following are addressed:

- right of access
- documentation req'ts
- nonconformances and corrective action
- spare and replacement parts
- procurement document reviews
- procurement document changes
- bid evaluation and award

V. Instructions, Procedures and Drawings

1) Clarify whether "activities affecting quality or validity" are the same as "activities important to licensing" since this section only applies to "activities affecting quality or validity."

2) Clarify whether instructions, procedures and drawings are only needed for testing as stated. Research and other NRC-work are not required to be controlled by procedures per ¶5.1.1.

3) Clarify how OPs plans, Proj. Plans, QAMs, SEMP, etc. are developed.

4) ¶5.4.4 - Clarify how drawings used for test development and equipment design are controlled per Section 3.0.

VI. Document Control

1) Clarify how document control measures are applied to drawings, specifications, purchase requisitions, memoranda (Pgs. 13 and 17), SWRI NQAPM, when these documents are not included within the scope of this Section.

2) Provide a complete list of all documents that are to be controlled per this CQAM.

3) Clarify that the QA organization reviews and concurs with controlled documents with respect to quality requirements.

4) Clarify that program/procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.

5) Change control system is cumbersome in that it uses both a "revision" and "change" status process.

- Discuss several examples where problems are evident with the SWRI QA Manual which uses the same system. (i.e.: Section 6.0)

VII. Control of Purchased Material, Equipment and Services

1) Clarify whether this Section also applies to items and services used for research and any other NRC HLW-related activities.

2) Provide for program to address Standard Review Plan items 7.3, 7.4 and 7.5.

3) Clarify how the following areas are addressed:
NQA-1, 1983:
Para. 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0

VIII. Identification and Control of Materials, Parts and Components

1) Clarify program requirements for the following:

- item identification
- physical identification
- markings
- identification and traceability of items
- limited life items
- maintaining identification of stored items

IX. Control of Special Processes

1) Clarify program requirements for the following:

- control of "processes" per NQA-1, 1983
- control of special processes to include paragraph 3.0 of NQA-1, 1983

2) Clarify whether NDE personnel will be qualified and certified to meet SNT-TC-1A, as appropriate to the scope of work conducted.

X. Inspection

1) Clarify the program requirements for the following as per NQA-1, 1983:

- Paragraph: 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0

2) Clarify whether inspections will be done on "important-to-licensing" hardware or services supplied by Southwest Research Institute. Section 10.1.1 of the Manual states that this Manual only applies to important-to-licensing hardware or services being supplied by the Center.

- Also address outside sources which may supply related hardware or services.

3) Are inspections conducted and documented per a "Project Plan" - ref. Para. 10.3.1. Provide clarification as to how they are conducted.

4) Clarify that inspection records are to contain the information described in Standard Review Plan Para. 17.3.

5) Program clarification needs to address Standard Review Plan Para. 10.1, 10.2, 10.3, 10.4, 10.5, 10.6.

XI Test Control

1) Clarify program requirements for control of research and experiments.

2) Provide clarification to address Standard Review Plan Para. 11.1, 11.2, 11.3, 11.4, 11.5.

3) Clarify the following requirements from NQA-1, 1983; Section 11.0 - 4.0, 5.0.

XII Control of Measuring and Test Equipment

1) Clarify the program requirements for control of M&TE per NQA-1, 1983; Section 12, Para. 2.0, 3.0, 4.0, 5.0.

2) Clarify ¶12.4.1.1 statement: "...or to a natural phenomenon..."

3) Clarify ¶12.4.1.1. statement: "...At any time the accuracy of an instrument is questionable, it shall be recalibrated or not used."

   a) Clarify that these instruments are tagged or segregrated to preclude use of equipment that is suspect.

4) Clarify ¶12.4.1.2 to specify that if M&TE is consistently out-of-calibration, it shall be repaired or replaced (NQA-1, 1983 - ¶3.2)

XIII Handling, Storage and Shipping

1) Clarify ¶13.1.1 statement that "...Any special handling, storage or shipping requirements shall be identified in the Project Plans." Are these requirements not transferred to implementing instructions as is stated in previous sentence? Clarify whether "special" handling, storage and shipping requirements are retained at the Project Plan level as stated.

2. Clarify QA responsibilities.

3. Clarify how the following sections in NQA-1, 1983 are addressed:

   Para. 2.0, 3.0, 4.0

4. Clarify how Standard Review Plan ¶13.2 is addressed.

XIV Inspection, Test and Operating Status

1. Clarify how the basic requirements of this criteria are applied to the testing activities to be conducted by the Center and how the inspection and operating status of these activities is controlled.

XV Nonconforming Materials, Parts or Components

1) ¶15.1.1 - Clarify how "...inconsistencies and uncertainties that the Center identifies in the regulatory analyses tasks" are documented and controlled through resolution.

2) ¶15.3.2 - Clarify whether NRC is to receive copies of nonconformances that are generated and whether NRC response, resolution, input to disposition or other interface is required.

3) ¶15.4 - Clarify/define "significant requirements" as used in this text. Clarify whether this implies that failure to meet other than significant requirements does not require an NCR to be written.

4) Clarify how the following paragraphs of NQA-1, 1983 are defined for Criteria 15:

   - 2.0, 3.0, 4.0

5) Clarify ¶15.4.4 - Under what conditions would corrective action not be specified? Paragraph needs some clarification as to scope of "processing", individuals/organizations involved in disposition and authorizations for "continuing processing", etc; more specific details for controlling this type of activity are needed.

6) Stop work authority should also be addressed in Section 1.0 - Organization or 2.0 - QA Program.

7) The criteria for stopping work, lifting the stop work, method for verifying and documenting acceptable corrective action prior to lifting the stop work need to be addressed.

8) Clarify the basis for an override of a QA stop work order.

9) Clarify how the following are addressed from the Standard Review Plan: ¶15.1, 15.2, 15.3, 15.4.

XVI Corrective Action

1) Clarify whether this section only applies to "testing" activities.

2) Clarify how the following are addressed from the Standard Review Plan: ¶16.1, 16.2, 16.3 and 16.4.

3) Clarify provisions for analysis for quality trends.

XVII QA Records

1) Program does not address record retention, storage, preservation and safekeeping; Details needed per NQA-1, 1983 - ¶1.0, 2.0, 3.0, 4.0, 5.0 6.0.

2) Clarify the following areas from the Standard Review Plan: ¶17.1, 17.2, 17.3, 17.4.

XVIII Audits

1) Clarify whether external audits are to be included within the scope of this Section.

2) Clarify definition of "quality-related functions" as used in ¶18.1.2.

3) Clarify how the following paragraphs of Standard Review Plan are addressed: 18.1, 18.2, 18.3, 18.4, 18.6, 18.7, 18.8.

4) Clarify how qualification and certification requirements for audit personnel are established and documented.

5) When SWRI personnel are used to participate in QA audits, describe program provisions for precluding the use of personnel who have had or have direct responsibilities in the areas being audited - since, in their "matrix" responsibility role, other responsibilities may be impacted by their auditing role.

6) Clarify how the following paragraphs from NQA-1, 1983 are addressed: ¶2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0.

Appendix A Definition Section

1) Clarify who determines those activities, items, services, etc. that are "important-to-licensing". Clarify NRC role and interface with the Center. Clarify how these activities, items, services etc. are to be identified.

2) Clarify how inspections can be done by "observation." Inspection, as defined, does not include "activities."

3) Peer Review - Clarify this definition to meet the GTP on Peer Reviews.

4) Verification - Term has broader application than just in area of software; Include NQA-1, 1983 definition.

It should be noted that these comments were presented to the CNWRA QA Manager, Bruce Mabrito in a meeting on 3/10/88.

Nancy Voltura, Project Manager
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Division of High-Level Waste Management

cc: B. Mabrito
J. Bunting
M. Delligatti

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