BOB MILLER
Acting Governor

STATE OF NEVADA

ROBERT R. LOUX
Executive Director

AGENCY FOR NUCLEAR PROJECTS
NUCLEAR WASTE PROJECT OFFICE
Capitol Complex
Carson City, Nevada 89710
(702) 885-3744

February 6, 1989

Mr. John Linehan, Acting Director
Repository Licensing Project Directorate
Division of High-Level Waste Management
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Linehan:

Please find enclosed the State of Nevada Nuclear Waste Project Office's proposed responses to the NRC comments on the NWPO Quality Assurance Manual, Vol. 1. The responses are the result of your letter of November 25, 1988 which contained a Request for Additional Information. I hope that these proposed responses fulfill the request adequately.

A meeting has been set up between your staff and the NWPO. The date of this meeting is February 22, 1989 at your facilities in Rockville. I look forward to this meeting to resolve any further comments that might result from these responses.

Sincerely,

Robert R. Loux
Executive Director

Add: ACNW

WM-11
102.7
NH06

STATE OF NEVADA
AGENCY FOR NUCLEAR PROJECTS
NUCLEAR WASTE PROJECT OFFICE

NWPO QA MANUAL, VOLUME 1, REVISION 0

PROPOSED RESPONSES TO NRC COMMENTS ON NWPO QA MANUAL

GENERAL COMMENTS

Comment

A. On page 1 of the Table of Contents for the NWPO QA Manual, it is indicated that the NWPO QA Manual is comprised of 4 sections, namely Statement of Quality Assurance Policy, Quality Assurance Program, Quality Assurance Procedures, and Glossary. These four sections of the NWPO QA Manual have formed the basis for the staff's review and a determination of whether the NWPO QA Manual meets the staff review criteria. Consequently, provisions should be included in the NWPO Manual to notify the staff of any changes that reduce the commitments in the NWPO QA Manual.

Response

In addition to Volume 1, reviewed by the NRC, the NWPO QA Manual will consist of five other volumes containing technical procedures by NWPO and its contractors. (See pages 3 and 4 of the Table of Contents.)

With reference to the comment, NWPO will revise the QA program and procedure QAP-2.1 to require that the NRC be notified of any changes to the NWPO QA Manual that would reduce any commitments of the manual. NRC staff has a controlled copy of the NWPO QA Manual and will receive any revisions to the manual.

B. There was no comment received from the NRC listed as General Comment B. We have assumed that this was a typographical error.

Comment

C. Page 17-2 of the QA Manual, item 8, lists "topical reports" as a quality assurance record. Clarification or a definition should be provided on what a "topical report" is.

Response

NWPO will delete the expression "topical reports" from the QA Manual.

SPECIFIC COMMENTS

Comment

1. The QA Program consistently references its application to "significant activities performed by the Agency for Nuclear Projects/Nuclear Waste Project Office..." The Glossary Section of the QA Manual defines "significant activity" as, "A technical or administrative activity which has important impact on NWPO's technical goals and objectives, synonymous with the words, "important activity".

   A clarification of the definition for "significant activity" would assist the staff in understanding the scope of the program's application and the specific types of activities that are included. The Compliance Demonstration Report states, on Page 01-9, "...NWPO considers all NWPO-sponsored activities equally significant for purposes of QA control..." Since this is not clearly defined in the QA Program manual and the Compliance Demonstration Report is not identified as part of the QA Manual, clarification of the term 'significant activity' should be added to the QA Program Manual. Clarify how the Compliance Demonstration Report will be used in the overall structure of the NWPO Program and whether it will be used as a controlled document.

   Response

   The term "significant activities" has been introduced as a substitute for the term "quality-related activities" to indicate that NWPO-sponsored activities do not directly address waste isolation and public safety in the sense that the DOE's site characterization and design activities do. As stated in the Glossary definition of Quality Assurance, NWPO is concerned with performance of activities important to its own goals which are not necessarily the same as the DOE's.

   With reference to page 01-9 of the Compliance Demonstration Report, the intent of the wording is that NWPO does not negotiate QA controls with its contractors (line staff). This is consistent with NWPO's exception to numerical performance objectives or a graded QA approach. See compliance responses to Subcriteria 2.1, 2.5, and 3.2. NWPO's policy is to consider each activity on its own merits for purposes of QA control.

See response to Comment 8.

NWPO is prepared to add to the QA Manual language similar to the Compliance Demonstration Report regarding "significant activities".

With reference to the final part of the comment, the Compliance Demonstration Report was written to facilitate the NRC's review of the NWPO QA Manual. It is not a part of the QA Manual; it is not a controlled document. The NWPO QA Manual is intended to stand alone.

Comment

2. Page 00-2 of the NWPO QA Program states that it is committed to relevant requirements of several master documents as they apply to NWPO's objectives and activities and then cites 10 CFR 50, App. B; 10 CFR 60 Subpart G; ANSI/ASME NQA-1-1986; NRC Review Plan; NUREG-0856; NUREG-1297; and NUREG-1298. Clarification is needed in the following areas:

   a. There are several references throughout the QA Manual which state that the program meets/conforms to the intent of a referenced NUREG; for example:

      - Pg. 03-2 states: "...computer programs by NWPO conform to the intent of NUREG-0856;

      - Pg. 03-3 states: "...peer reviews are conducted in accordance with QAP-3.3 which conforms, as applicable, to the intent of...NUREG-1297.

      The staff is unclear as to the degree of commitment to a requirement when the program states that it meets the "intent" of a document. Clarification is needed.

   b. The NWPO QA Program does not clearly state which relevant requirements, of the documents referenced on Page 00-2, apply to the scope of the program and which do not.

Response

With respect to part "a" of the comment, as indicated in pages I-1 and I-2 of the Compliance Demonstration Report, NWPO reserves the right to deviate from the NRC review plan and other listed documents where they do not apply to NWPO's objectives, intentions, or circumstances. This is necessary because NWPO does not design nuclear facilities nor perform the site characterization activities for which the listed controlling documents were written.

To dispell any possible misunderstanding, NWPO is prepared to delete the term "intent of" and substitute a commitment to comply with the "applicable" requirements of the controlling documents.

With reference to part "b" of the comment, the NWPO QA Program does indicate some major exceptions to controlling documents. See, for example, page 03-1, first paragraph; page 09-1; page 11-1, first paragraph; page 14-1; and page 17-1, second paragraph. However, from the point of view of the manual user, NWPO does not consider it desirable or feasible to spell-out every possible point of divergence that may arise in the conduct of highly varied NWPO-sponsored activities. The intent is for the manual user to follow the QA program and procedures which incorporate any omissions of or modifications to document requirements.

NWPO is prepared to delete the work "relevant".

Comment

3. Position 1.7 of the RP requests that organization charts clearly identify the "onsite" and "offsite" organizational elements which function under the cognizance of the QA Program and the lines of responsibility.

   The NWPO QA Program includes organization charts which describe the NWPO, contractor and subcontractor organizational reporting lines.

   Provide clarification by describing the responsibilities and activities that will be conducted by each of the organizational elements shown.

   Response

   There are no "onsite" or "offsite" organizations for NWPO activities. We believe that the organizational charts (Figures 01-2, 01-3, 01-4, and 01-5) for the contractors shown in the manual clearly identify the organizational elements functioning under the NWPO QA Program.

Comment

4. Position 2.8 of the RP requests that personnel qualification programs be established and that qualified personnel be certified in accordance with applicable codes and standards. In addition, Position 10.3 of the RP requests that a

qualification program for inspectors be established and documented and the qualifications and certifications of inspectors be kept current.

The NWPO QA Program, Section 02 Page 02-5 states, "Personnel are qualified in accordance with applicable standards and procedures." Provide clarification as to which standards are required as the basis of personnel qualifications and provide a description of the qualification program that will be implemented.

The QA Program, Page 01-9, references NQA-1-1986 Supplement 2S-3 as the basis for certification of a Lead Auditor. The Program does not currently reference or contain an implementing procedure for qualification/certification of Lead Auditors. In addition, the program is not specific on the qualification standards to be used for inspection personnel and the implementing procedure that will be used to describe and implement the qualification activity.

Response

With reference to the first part of the comment, Subcriterion 2.8e addresses certification of personnel and Subcriterion 10.3 addresses certification of inspectors. There are no standards or qualification programs for certification (of non-auditors) because NWPO does not foresee any activities that will require certificated personnel. (see Compliance Demonstration Report, pages 02-10 and 10-4).

Qualifications of NWPO and contractor/subcontractor personnel are addressed in procedure QAP-1.1, "Position Titles, Position Descriptions, Employee Experience Records, and Employee Qualification Statements" (see page 01-7 of the program, third paragraph). Also, as a condition of contract award, contractors must furnish evidence that their personnel are properly qualified (see procedure QAP-4.1, Subsection 4.12 and the QA program, page 04-2, item 3b(2)).

For the NWPO QA program, there will be no "inspections" in the sense of the Appendix B definition of inspection. The only inspection activity that will be performed under the NWPO QA program will be receiving inspections of purchased items affecting quality for use by NWPO personnel or contractors/ subcontractors. These receiving inspection activities will be controlled and performed by technical procedures that are reviewed and approved by the QA Manager prior to the inspection activity. The qualifications of the personnel performing the receiving inspections are also established in technical procedures (page 10-2 of the program, second paragraph), again reviewed and approved by the QA Manager prior to the activity, and, the Employee Experience Records

(EERs) and the Employee Qualification Statements (EQSs) of the personnel who will be performing such receiving inspections are examined by the QA Manager prior to the start of work.

Qualifications of peer reviewers are addressed in procedure QAP-3.3.

There is no special qualification procedure for Lead Auditor because there is only one Lead Auditor, the QA Manager, who must be qualified before he/she is hired. NWPO is prepared to add wording to Section 01 of the program requiring the Executive Director to add requirements of NQA-1, 2S-3, Subsection 6.2, to the QA Manager's Employee Qualification Statement.

NWPO has no plans for additional Lead Auditors.

Comment

5. The NWPO QA Program, Section 03, Page 03-1, states, "...Specifically, NWPO and its contractors and subcontractors perform activities such as, but not limited to: critical review and analysis of existing data, monitoring (surveillance) of DOE-sponsored core drilling, monitoring of DOE acquisition of hydrogeologic data, and detailed review of DOE proposed design."

   The NWPO QA Program does not provide for procedures to:

   - conduct critical review and analysis of existing data (also, specify the requirements which are the basis for this procedure, i.e.: NUREG-1298, Generic Technical Position on Qualification of Existing Data for High Level Nuclear Waste Repositories);

   - monitor (surveillance) of DOE-sponsored core drilling or DOE acquisition of hydrogeologic data;

   - conduct detailed reviews of DOE-proposed designs.

   Response

   All the mentioned activities are controlled by technical procedures and the appropriate quality assurance procedures. The technical procedures are prepared by the contractors/subcontractors. Examples of quality assurance procedures that may be indicated in these activities are QAP-3.1, "Calculations", and QAP-3.2, "Technical Reports".

Whether or not NUREG-1298 is a suitable basis for critical review of existing data would depend on the specific objective of the review and the technical aspects involved. In NWPO's view, it would not be appropriate to mandate the use of any such document in advance. NWPO's principal use of NUREG-1298 will be to qualify data from NWPO-sponsored activities performed prior to the date the NWPO QA program goes into effect.

To clear up any misunderstanding, NWPO is prepared to add a statement to Section 03 of the manual that all of the mentioned activities are controlled by technical and QA procedures.

Comment

6. The NWPO QA Program, Section 00-Introduction, states in part: "...Through its QA Program, NWPO is committed to relevant requirements of the following master documents as they apply to NWPO's objectives and activities and as they do not contradict the State of Nevada Administrative Code or laws of the United States or of the State of Nevada."

Clarify/identify the "relevant requirements" of the documents listed and justification for those not invoked. Clarify/identify any requirements which are known to contradict the State of Nevada Administrative Code or the laws of the U.S. or the State of Nevada that will not apply to the NWPO Program.

Response

The first part of the comment (i.e., relevant requirements) is addressed in the response to Comment 2, above. NWPO is prepared to delete the word "relevant".

Inasmuch as NWPO is a State agency, the NWPO QA Manual is a state document which cannot conflict with state (or U.S.) law or state administrative codes. To the best of our knowledge, no part of NWPO's Qa Program or procedures or of any of the cited documents is in conflict with the State of Nevada Administrative Code or with the laws of the United States or the State of Nevada. The purpose of the statement is to avoid a situation where changes to the master documents, administrative codes, or laws might put NWPO in such a position. Should this occur, NWPO would reappraise its program and make changes as needed. The NRC would be apprise of any such changes.

Comment

7. The NWPO QA Program states, Pg. 01-8, that the QA Manager has the responsibility and authority to "...recommend the stopping of unsatisfactory work." Provide clarification as to whom, within the NWPO organization, this recommendation is made and where ultimate stop work authority rests.

Response

Recommendation of a stop-work order is made to the Executive Director who has the ultimate authority in issuance of a stop-work order. See page 16-1 of the program, fifth paragraph; see procedure QAP-16.1, Subsections 4.10.1 and 4.16.

Comment

8. Position 1.8 of the Standard Review Plan (RP) requests a description of how the QA organization is involved in the aspects of the high-level waste repository program that affect safety and waste isolation and that the extent of QA controls be determined by the QA staff in combination with the line staff dependent on the specific activity.

The NWPO Compliance Demonstration Report states, Page 01-9, "...NWPO considers all NWPO-sponsored activities equally significant for purposes of QA control. Contractors/subcontractors obligations are defined by the QA program...the QA Manager uses audits and other means to impose whatever degree of QA control is needed to assure the quality of any particular activity or item."

Clarify how the NWPO program establishes/defines the degree of QA controls needed to assure the quality of an activity or item prior to the conduct of an audit.

Response

The thrust of the compliance response is to disassociate NWPO from any negotiated or numerical or graded system of QA control. NWPO does not consider these approaches appropriate to its objectives or circumstances.
As indicated in the Compliance Demonstration Report, (pages 01-9 and 01-10), all technical activities are controlled by QA and/or technical procedures and by procurement contract documents for which the QA Manager has input. Thus, for example, the QA Manager has the authority to ensure an appropriate degree of documentation of a technical activity.

The program also provides that "All significant aspects of the program and all participating organizations and their activities are audited" (page 18-2, first paragraph); and that scheduling and timing of audits is controlled by the nature and duration of the audited activity. See Section 18 of the program and procedure QAP-18.1 for further details.

Application of these principles to any particular organization or activity is a matter of judgment on the part of the QA Manager and of the management team that audits his/her activities per procedure QAP-2.4. For example, a large volume of samples over a short time might require an audit of the contractor's sample management procedure almost immediately after start of work, whereas an individual consultant working on a theoretical analysis may not have to be audited until a technical report is written.

NWPO is prepared to amend the program and procedures to provide more explicit guidance for implementation of these policies. See response to Comment 31, below.

Comment

9. Position 2.4 of the RP requests that the QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements. Although there are several areas in the NWPO QA Program which repeat this requirement, i.e.: QAP-2.1 and 2.2, the QA Program/procedures does not describe/define the specific review criteria to be used during the review. Clarification which specifies the review criteria is requested.

Response

This comment is addressed in procedure QAP-4.1, subsection 4.1, which requires that the "QA program shall comply with requirements of documents listed in Section 00... as they apply to NWPO activities, objectives, and management policies. QA procedures shall comply with QA program commitments." More specifically, Subsection 4.1 requires that QA procedures adhere to requirements listed in Figures 4.1-1, 4.1-2, and 4.1-3 of QAP-2.1.

In reviewing technical procedures per Subsections 4.8 and 4.15 of procedure QAP-2.2, the QA Manager would be guided by requirements of Figure 4.1-1 of procedure QAP-2.1 and also by requirements of Figures 4.17-1, 4.17-2, and 4.18-1 of procedure QAP-2.2.

Comment

10. Position 2.6 of the RP requests that the existing or proposed QA procedures and detailed technical procedures which reflect each of the 10 CFR 50, App. B criterion, be identified. Although the QA Manual lists the QA procedures for Criteria 1-6 and 15-18, it does not list the procedures that will address Criteria 7-14. Also, a listing of the detailed technical procedures has not been provided. Clarification would assist the staff's review.

Response

In addition to technical procedures, Section 07 of NWPO's QA Program is implemented by procedure QAP-4.1 (page 07-1 of the program, second paragraph).

There are no QA procedures corresponding to Sections 09, 11, or 14 of the NRC's SRP because NWPO does not perform or sponsor the activities addressed by them. See pages 09-1, 11-1, and 14-1 of the program.

Sections 08, 10, 12, and 13 of the program are implemented solely by technical procedures. In NWPO's view, no special QA procedures are needed. See pages 08-1 (first paragraph), 10-1 (third paragraph), 12-1 (first paragraph), and 13-1 (first paragraph).

At the time of the submittal to the NWPO QA Manual to the NRC for review, the contractor procedures were not finalized and approved. Attached are copies of typical technical procedures from NWPO contractors. Because of the large number of technical procedures that will be generated by the NWPO program, a comprehensive list of technical procedures will take some time to compile.

Comment

11. Position 3.6 of the RP requests 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.

Page 03-6 of the Compliance Demonstration Report indicates the RP criterion is satisfied by the auditing process and review of procurement documents only. Audits generally are a random type activity which determine the adequacy and compliance of a particular procedure, code, standard, drawing, etc. Audits also generally are not performed to determine process control or product acceptance. A review, however, is a detailed

documented activity to assure the activity has been accomplished in accordance with a particular procedure, code, standard, drawing, etc., and reviewed to assure it includes prescribed QA requirements.

Clarification is needed to assure audits will accomplish the same purpose as a review.

Response

In addition to audits, the QA Manager reviews all technical procedures and all procurement documents. The QA Manager also reviews all documents submitted to the NWPO Records Center (e.g. technical reports, calculations, lab notes) for evidence of review and approval or other appropriate forms of verification as required by QA and technical procedures. Records generated by NWPO, contractors, subcontractors, and vendor/suppliers must be submitted to the NWPO Records Center on a continuous basis.

Comment

12. Position 3.3 of the RP requests that organizational responsibilities be described for...approving...and validating design and design information documents. The NWPO QA Program, Section-03, Page 03-1, states, "NWPO...ensures documented preparation, independent review (or other forms of verification) and (as needed) approval and validation of NWPO-generated data acquisition or analyses documents..." Clarify how the determination will be made as to when "...approval and validation of NWPO-generated data acquisition or analyses documents" will be needed.

Response

Documents of a formal nature (i.e., output documents) such as technical reports, calculations, or technical procedures are subject to approval, but approval is not required for documents of a less formal nature (i.e., input/support documents), such as field notes, or laboratory notebooks. Input/support and output documents alike are subject to review or other form of verification. Doubtful cases are resolved by the QA Manager (page 01-8, item 2). See Glossary definitions for Input/Support Documents and Output Documents.

Comment

13. Position 3.7 of the SRP requests that, in exceptional cases, when the designer's immediate supervisor can perform the verification, the need is individually documented and approved in advance with concurrence of the QA Manager. This position does not appear to be addressed in the NWPO QA Program; clarification is requested.

Response

The NWPO program complies with requirements of NQA-1-1986, Supplement 3S-1, Section 4, with respect to reviews (verifications) by supervisors, and NQA-1 does not require advance approval by the QA Manager. The QA Manager will audit for inappropriate use of supervisory review.

Comment

14. Position 4.1 of the RP requests that procedures be established for the review of procurement documents by QA personnel to determine that applicable requirements/criteria are addressed to include "design bases". The NWPO Compliance Demonstration Report specifically states, Pg. 04-1, "...the QA Manager reviews procurement documents for QA requirements but not for technical requirements as implied by items such as "design bases" and "accept/reject criteria"... These are reviewed by others as indicated in QAP-4.1."

The staff's review of QAP-4.1 did not identify the inclusion of "design bases" as a review criteria for either QA or technical staff. Clarification as to whether this is included in the NWPO Program is requested.

Response

Neither NWPO nor its contractors or subcontractors design repository facilities. Therefore, there are no procurement contracts that address design bases as understood by Subcriterion 4.1. Technical aspects of procurement documents are reviewed by technical reviewers (procedure QAP-4.1, Subsections 4.4 and 4.15 and Figure 4.3-1)

Comment

15. Position 5.1 of the RP requests that instructions, procedures, and drawings be verified and approved as described in Section 3.0. Provide clarification as to where this is addressed in the program.

Response

As indicated on page 05-1 of the program, when instructions or drawings are used to specify activities, they are included as parts of technical or QA procedures. Verification (review) and approval of QA and technical procedures are addressed on page 02-1, second paragraph, and on page 02-2, first paragraph, of the program.

Comment

16. Positions 9.1-9.5 of the RP provide for program requirements which address activities related to the control of special processes. The NWPO specifies in both its QA Program and the Compliance Demonstration Report that there are not NWPO-sponsored activities that fall within the scope of the term 'special process'. Provide justification that special processes are not activities within the scope of the NWPO Program.

Response

The definition of special process of NQA-1, Supplement S-1, implies a manufacturer-product context not included in NWPO-sponsored activities. In informal discussions between NWPO and the NRC in Silver Spring, in the spring of 1987, the NRC indicated that NWPO's activities do not fall within the scope of special process as understood by the NRC review plan.

Comment

17. Position 10.2 of the RP requests that individuals performing inspections be part of the QA organization. However, the NWPO Compliance Demonstration Report, Page 10-2 states in its justification for not meeting this RP position that "...Inspectors are not part of the QA organization because such an arrangement would not be feasible or desirable considering the size and nature of NWPO's and contractor's organizations..."

The staff requests clarification that describes the type of QA overview activity that would occur for inspections, such that when the individuals performing inspections are not part of the QA organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule are reviewed and found acceptable by the QA organization prior to the initiation of the activity.

Response

This comment is addressed in part in the response to Comment 4. Again, the only type of inspection that will be performed will be receiving inspection of purchased items affecting quality. The QA Manager maintains overview of the inspection functions as follows:

With respect to review of inspection procedures, "...inspection (is) controlled by technical procedures..." (page 10-1, of the program, third paragraph) which are reviewed and approved by the QA Manager (page 02-2, first paragraph) prior to the start of inspection activities (procedure QAP-2.2, Subsections 4.8 and 4.16).

Personnel qualification criteria of inspectors are likewise established by technical procedures (page 10-2 of the program, second paragraph) which are reviewed and approved by the QA Manager prior to the start of work.

The question of independence of personnel performing these inspection activities is addressed on page 10-1 of the program, first paragraph, and in the Glossary definition of Inspection which requires inspectors to be qualified, independent, and non-supervisory persons.

NWPO is prepared to modify Section 10 to explain in more detail what types of inspections that NWPO will be performing and how these activities will be controlled. NWPO will also expand on the independence of inspectors to include freedom from undue pressures of cost, scheduling, etc.

The QA Manager will also use audits and surveillances to ensure that receiving inspections are properly performed according to technical procedures and by qualified personnel.

Comment

18. Position 11.0 of the RP discusses the programmatic aspects of an acceptable test control program.

The NWPO QA Program states that there are no NWPO, contractor or subcontractor activities that fit the definition of testing of NQA-1, 1986 or the NRC Review Plan. However, there are several examples throughout the QA Program which refer to "testing" activities, e.g.: QAP-2.2, Figure 4.18-1; QAP-4.1, Figure 4.3-1. [Note: Examples may not be inclusive of all references to "testing"]. Clarification is requested to establish whether testing activities are appropriate to the NWPO Program and, it they are, to have those aspects of the RP Position 11.0 described in the NWPO QA Program. If testing

is not appropriate, then justification as to how this determination is made needs to be provided.

Response

Activities sponsored by NWPO do not include testing as that term is defined in NQA-1, 1986 or defined by implication in the NRC Review Plan. To eliminate any possible ambiguity, NWPO is prepared to delete references to tests or testing activities from the manual where testing activities, as defined by NQA-1 and the NRC could be implied.

Concerning justification, neither NWPO or its contractors/ subcontractors are responsible for the design of nuclear waste repositories or site characterization investigations. In NWPO's view, the purpose of the QA program and procedures is to ensure that whatever activities NWPO chooses to sponsor are performed in accordance with accepted QA practice. In this context, NWPO does not foresee any activity that will require testing to specified requirements or to assure that a structure, system, or component will perform satisfactorily.

Comment

19. Position 11.4 of the RP establishes several criteria which are to be addressed in test plans and procedures. The NWPO QA Program, Section 11, establishes that these criteria will be used when technical procedures are developed/implemented for "technical activities of an investigative nature including laboratory research activities."

Several of these criteria are not addressed in the NWPO QA Program and clarification is requested as to how the following are included:

11.4(a) requirements and acceptance limits are contained in applicable documents including precision and accuracy

11.4(c) Test prerequisites such as...adequate test equipment and instrumentation, completeness of item to be tested...

11.4(e) acceptance and rejection criteria, including required levels of precision and accuracy.

Response

As indicated on page 11-5 of the Compliance Demonstration Report (response to Subcriterion 11.4), items 11.4(a) and 11.4(e) have been omitted because they appear to imply that an item must meet certain pre-specified requirements that are not compatible with anticipated NWPO-sponsored activities (see response to Comment 18, above).

Considering that NWPO does not sponsor test activities as understood by the NQA-1-1986 and NRC SRP definitions but that it does sponsor investigative and research activities, NWPO believes that item 11.4(c) is addressed by item 2, page 11-1 of the program.

Comment

20. Position 12.1 of the RP requests that the scope of the measuring and test equipment control program be described.

The NWPO QA Program, Section 12, states in part "...The equipment control procedures address all measuring and test equipment in which faulty accuracy or precision can significantly affect data generated by the equipment and analyses based thereon...".

Provide clarification as to the criteria that are to be used to determine which instrumentation/equipment will (be) included in the scope of the NWPO program based on the definition above.

Response

NWPO believes that the quoted extract plus the examples cited immediately below it on page 12-1 of the program provide an adequate overall indication of the scope of the calibration program. NWPO is prepared to add a statement that the controlling technical procedures will specify the instruments/ equipment to be included in the calibration program depending on the nature of the particular instrumentation/equipment, the nature of the investigation, the uses to which acquired data will be put, and similar considerations.

Comment

21. Position 12.2 of the RP requests that QA and other organizations' responsibilities be described for establishing, implementing and assuring the effectiveness of the calibration program.

The NWPO QA Program, Section 12, provides for QA involvement in the measuring and test equipment control program during the review of related nonconformances and corrective action.

Provide clarification in Section 12 as to QA involvement in establishing, implementing and assuring the effectiveness of the calibration program.

Response

This comment is addressed in the Compliance Demonstration Report, pages 12-2 and 12-3. In addition to audits (which can be conducted as frequently as needed), and corrective action, the QA Manager reviews procurement documents for inclusion of QA requirements that include calibration procedures. The QA Manager also reviews and approves the technical calibration procedures.

Other aspects of QA involvement in the calibration program include receipt of calibration documentation in the NWPO Records Center. The QA Manager also receives copies of any surveillance/monitoring reports that address calibration. Furthermore, all out-of-calibration equipment must be reported to the QA Manager (page 12-2 of the program).

Comment

22. 10 CFR 50, App. B-Criterion XIII Handling, Storage and Shipping states in part, "Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with...instructions to prevent damage or deterioration..."

The NWPO QA Program does not address handling, storage and shipping requirements that apply to material and equipment per 10 CFR 50, App. B. Clarification as to how these requirements will be addressed in the program is requested.

Response

Section 13 of the NWPO program addresses the NRC's adaptation of Criterion XIII to site characterization as applicable to NWPO-sponsored activities, i.e., "Sample Handling, Storage, and Shipping" which NWPO interprets as applicable essentially to geotechnical samples. NWPO is aware that page 1, Appendix A, of the NRC SRP requires discussion of items in 10 CFR 50, Appendix B not mentioned in the body of Appendix A of the SRP, but does not think that this applies to omission of entire criteria.

Assurance that equipment used in NWPO-sponsored activities is in good order is provided by receiving inspection requirements and by calibration requirements.

Comment

23. Position 13.1 of the RP requests that for activities related to samples, requirements be established for sample, handling, preservation, storage, packaging, and shipping of same.

The NWPO QA Program does not specify the requirements to be implemented for these activities. Applicable requirements need to be established in the QA Program.

Response

Section 13 of the program, page 13-1, second paragraph, and page 13-2, first paragraph, establishes adequate overall requirements to be followed by contractors/subcontractors in preparation of detailed implementing procedures. In NWPO's opinion, it is not feasible or desirable to spell out detailed requirements in the QA program, but to allow the contractors/ subcontractors to adapt the overall requirements to their own circumstances. The QA Manager will review and approve the technical procedures that cover Section 13 activities.

Comment

24. Position 14.1 of the RP requests that procedures be established to indicate by the use of markings, the status of inspections and tests on individual items.

Although the NWPO QA Program takes exception to Criterion 14 of 10 CFR 50, App. B and the Standard Review Plan, the QA Program, Section 10 provides for: "...mandatory hold points, methods for controlling status indicators (application and removal) and accept/reject criteria for inspections." (Pg. 10-2, (4)(7)(9))

As the NWPO QA Program provides for conducting inspections, e.g.: receiving inspections of purchased materials, equipment, apparatus or instruments, there are portions of the program that will implement Criteria 14 as NWPO activities are conducted. Clarification is required as to whether this exception is appropriate based on implementation of this criteria within the NWPO Program.

Response

In NWPO's opinion, Criterion 14 of 10 CFR 50, Appendix B, is oriented towards plant operating equipment and is therefore out of context with NWPO's activities. NWPO feels that Subcriterion 14.1 is more appropriately included in Section 10 of the program and has so placed it there. NWPO is prepared to cross-reference Section 10 with Section 14.

Comment

25. Position 15.1 of the RP requests that procedures be established for controlling nonconformances which address...identifying, segregating, dispositioning and notifying affected organizations of nonconforming items and activities.

NWPO QAP-15.1 does not describe the nonconformance system controls for: identifying, i.e.: by marking, tagging or other means; segregating, i.e.: by placing the item in a clearly identified and designated hold area or other means; disposition, i.e.: final dispositions, such as use-as-is, reject, repair, or rework or nonconforming items; notifying affected organizations, i.e.: the NWPO QAP-15.1 provides for notification of affected individuals only when a nonconforming activity has been identified. It is not clear whether affected organizations are notified of nonconforming items. Clarification of the types of dispositions which may be provided in the QA Program is requested. (i.e.: use-as-is; repair; rework; reject).

In addition, the Compliance Demonstration Report states, Page 15-3, "...With reference to dispositioning,...the only disposition of a nonconformance is corrective action." Clarification as to the types of dispositions, that are included in the corrective action program, would assist the staff's review.

Response

With reference to identifying, procedure QAP-15.1, Subsections 4.11 and 4.12 state that the "...Administrator of Technical Programs...Project Manager, Principal Investigator or the Responsible Individual...shall ensure that the nonconforming item is clearly identified to prevent its inadvertent use..." NWPO is prepared to add examples of identification techniques such as marking or tagging.

Concerning segregation, see procedure QAP-15.1, Subsection 4.13, which states that "All nonconforming items shall be segregated, if practical." NWPO is prepared to elaborate on this point.

Concerning disposition, by the definition in the Glossary and on page 15-1 of the program, a nonconforming item in essence is an item that is deficient enough to render the quality of an item unacceptable or indeterminate. From this, it follows that the only thing to do with a nonconforming item is to implement corrective action. Such corrective action might include repair or rework, but never use-as-is. By NWPO's definition of nonconformance, a nonconforming item must always be rejected as is.

With respect to notifying affected organizations, NWPO is prepared to extend the notification requirements of QAP-15.1, Subsections 4.11 and 4.12 to nonconforming activities.

Comment

26. Position 15.4 of the RP requests that nonconformance reports are periodically analyzed by the QA organization to "...help identify root causes of nonconformances and the significant results are reported to upper management for review and assessment."

The NWPO QA Program, QAP-16.1, (Subsection 4.23) discusses the trend analysis process but needs to provide clarification as to whether identification of root causes and upper management review and assessment of the trend analysis results will be addressed in the program.

Response

NWPO is prepared to add a requirement that trend analysis reports include identification of root causes and a requirement for the Executive Director to review the reports.

Comment

27. a. The NWPO QA Program, QAP-15.1 discusses the program for control of nonconformances. The discussion provides for "authorized nonconformances", "apparent nonconformances" and "nonconformances".

"Authorized nonconformances" are discussed in QAP-4.1, (Subsection) 4.17, as part of the procurement process for handling "proposed deviations in services or items from procurement document requirements".

"Apparent nonconformances" and "nonconformances" are discussed in QAP-15.1 which implies that there are differences between these conditions but does not define the differences. Provide clarification as to how "apparent nonconformances" are documented and whether they are dispositioned as discussed in RAI 24 above. Provide clarification as to the programmatic guidance which is to be used to distinguish/define an "apparent nonconformance" and a "nonconformance".

b. QAP-15.1, (Subsection) 4.3 states in part: "When a nonconformance is identified by means of a surveillance report, the QA Manager shall investigate the condition, inform the report author of the results of the investigation in writing, and initiate an NCR."

Provide clarification as to why nonconformances, which are identified during a surveillance, are not documented on an NCR and then controlled within the system. It would appear that the process described per (Subsection) 4.3 would allow for nonconformances, which are described in the text of a surveillance report and not documented on an NCR when detected, to provide the potential for inadvertent use or installation until such time that the QA Manager can investigate and make a determination of the condition.

Response

Concerning Comment 27a, the rationale behind the term "apparent nonconformance" is that ultimately only the QA Manager has the authority to decide whether a nonconformance exists (except for management assessments of the QA program). Others may identify what they think may be a nonconformance but such identifications remain "apparent nonconformances" until confirmed as a nonconformance by the QA Manager.

Apparent nonconformances are documented in surveillance reports (except those by the QA Manager), receiving inspection reports, and in other direct, mandatory communications from persons participating in NWPO-sponsored activities. Apparent nonconformances are disposed of by the QA Manager who decides whether an apparent nonconformance should be elevated to a nonconformance or dropped. In either case, the QA Manager must take appropriate action as indicated in procedure QAP-15.1 and QAP-16.1.

To dispell any misunderstanding, NWPO is prepared to add a definition of "apparent nonconformance" to the Glossary and to reword procedure QAP-15.1 and other parts of the manual to indicate that surveillances report only apparent

nonconformances and to clarify the use of apparent nonconformance in general. NWPO is also prepare to change "authorized nonconformance" to "authorized deviation".

With reference to Comment 27b, NWPO is prepared to change the term "nonconformance" in Subsection 4.3 of procedure QAP-15.1 to "apparent nonconformance". Subsection 4.3 will then read, "When an apparent nonconformance is identified by means of a surveillance report, the QA Manager shall...initiate an NCR...". See, also, Subsection 4.10 which states that "The QA Manager shall initiate a nonconformance report immediately upon notification of...an apparent nonconformance..". As further explained in the response to Comment 27a, an apparent nonconformance is not considered or treated as a nonconformance until the QA Manager decides that it is indeed a nonconformance. This is necessary to maintain order and responsibility in establishing and confirming nonconformances. The QA Manager will promptly investigate all reports of apparent nonconformances.

Comment

28. Position 16.2 of the RP requests that the QA organization be involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied. The NWPO QA Program, QAP-16.1, (Subsection) 4.6, states "...The QA Manager approves all corrective action plans prior to their implementation..." Provide clarification as to the scope of the QA organization's review as described in the Review Plan.

Response

The scope of the QA Manager's review is to confirm that the corrective action plan complies with requirements of Subsection 4.5 of procedure QAP-16.1, which states that "Corrective action plans shall address the root cause(s) of the nonconformance, the effect on any previously completed work or any current work underway, any required remedial action to be taken, and action necessary to prevent recurrence."

Comment

29. Position 17.1 of the RP requests that the scope of the QA records program includes geotechnical samples.

The NWPO Compliance Demonstration Report, Page 17-2, states: "...However, geotechnical or other samples, such as rock cores or water...are not classified as records..."

Justify this exemption to the Review Plan position.

Response

This position of the NRC SRP has been deleted from Rev. 1 of the SRP; therefore, from informal communications with the NRC, a response is no longer necessary.

Comment

30. Position 17.4 of the RP requests that suitable facilities for the storage of records be described and utilized.

The NWPO QA Program, QAP-17.1, (Subsection) 4.5.1 establishes that, "All NWPO, contractor, subcontractor and vendor/supplier records shall be stored in a single set of metal file cabinets located in the NWPO Records Center..."

Justify the exemption from the single or dual facility records storage criteria discussed in NQA-1-1986. It is noted by the staff that ANSI/ASME NQA-1-1986 is listed as a program requirements document in Section 00-Introduction of the QA Program; yet, specific exemption to certain requirements is not defined. Clarification would assist the staff's review.

Response

This requirement is not applicable to NWPO because NWPO is not responsible for site characterization activities, the design or construction of the repository. NWPO is not the applicant for the license permit for the repository. Single records storage is adequate for the goals and objectives of NWPO. NWPO is prepared to add wording in Section 17 of the program to this effect.

Comment

31. Position 18.2 of the RP requests that audits be regularly scheduled based on the status and safety importance of the activities being performed and are initiated early enough to assure effective QA.

The NWPO QA Program, Page 18-2, states "...All significant aspects of the program and all participating organizations and their activities are audited...Scheduling and timing of audits depends on the nature and duration of the activity being audited.

In addition, the NWPO Compliance Demonstration Report, Page 18-3, states: "...The term "safety importance of the

activities" is not directly relevant to NWPO's goals and objectives. NWPO considers all NWPO-sponsored activities equally significant for purposes of QA control. The frequency and scope of audits depend on the nature and duration of activities being audited."

Provide clarification as to the criteria that will be used to assure that audits are regularly scheduled based on their status and safety importance and to provide that they are initiated early enough to assure effective QA.

The staff's position on audit, scheduling is provided in Position C.3 of Regulatory Guide 1.28, Revision 3, August 1985. Clarification needs to be provided as to why this position does not apply to the NWPO QA Program.

Response

This comment is addressed in the response to Comments 1,2, and 8. NWPO is prepared to amend page 18-1 and/or 18-2 of the program and Subsection 4.1 of procedure QAP-18.1 to require at least one audit per year or at least one audit during the life of an activity, whichever is sooner, but with adjustments to the one year requirement for intermittent activities (to take cognizance of many of NWPO-sponsored activities). The program/procedure will also require performance of audits early enough in the activity to assure adequate QA control.

Comment

32. Position 18.4 of the RP requests the QA organization analyze audit data and report the results to responsible management for review, assessment, and appropriate corrective action.

Page 18-3 of the NWPO QA Manual indicates the QA Manager performs a trend analysis of the audit findings and reports adverse trends to the Executive Director.

Clarification is needed as to whether all audit results, i.e., not just adverse trends, are reported and whether the Executive Director reviews, assesses, and takes appropriate corrective action when appropriate.

Response

NWPO is prepared to modify page 18-1 of the program and Subsection 4.18 of procedure QAP-18.1 and 4.23 of QAP-16.1 to require that completed trend reports be sent to the Executive Director for review and action as needed.