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June 10, 1988

STATE OF NEVADA  
AGENCY FOR NUCLEAR PROJECTS  
NUCLEAR WASTE PROJECT OFFICE

QUALITY ASSURANCE MANUAL  
VOLUME 1 of 6

CONTROLLED COPY NO. 8

ISSUED TO James Kennedy - Nuclear Regulatory Commission  
(Name)

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STATEMENT OF QUALITY ASSURANCE POLICY**

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**Statement of Quality Assurance Policy**

The quality assurance (QA) program, implementing QA and technical procedures, and other parts of this QA manual govern significant activities performed by the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) and its contractors, subcontractors, and vendors/suppliers in connection with the U. S. Department of Energy's (DOE's) characterization of the Yucca Mountain site, Nevada, as a potential repository for high-level nuclear waste. The purpose of these activities is to investigate the potential impact of any such repository on the health, safety, and environment of the residents of the state of Nevada. In particular, NWPO and its contractors/subcontractors (1) monitor DOE activities, (2) critically review and analyze data and analyses from DOE and other sources, and (3) conduct such independent investigations as may be needed to (a) appraise DOE data, assumptions, conclusions, and designs and (b) to establish NWPO's own data bases and interpretation techniques.

It is NWPO's policy to ensure that NWPO and its contractors and subcontractors perform their activities in conformance with applicable written QA and technical implementing procedures that conform to the NWPO Quality Assurance Program. To help accomplish this purpose, NWPO uses procurement contract documents to require conformance of vendor-supplied materials and equipment, and of contractor/subcontractor services to NWPO's Quality Assurance Program and procedures.

Controlled copies of Volume 1 of the NWPO Quality Assurance Manual (which includes the QA program and QA procedures) are assigned and issued by the Quality Assurance Manager to NWPO, contractor and subcontractor personnel responsible for implementation of activities controlled by the program. Likewise, the Quality Assurance Manager ensures that these persons receive controlled manual volumes containing the technical procedures necessary for their activities. (See Table of Contents, herein.) Revisions of the QA manual are distributed to holders of controlled copies by the QA Manager and each manual holder is responsible for maintaining his/her volumes up-to-date.

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NWPO and contractor/subcontractor personnel assigned to activities governed by the NWPO QA Manual are required to become familiar with policies and provisions of the manual pertaining to their activities and each person is required to comply with the manual in his or her work.

No portion of the NWPO QA Manual shall be construed to require activities contrary to the State of Nevada Administrative Code or to the laws of the United States or of the State of Nevada.



Robert R. Loux  
Executive Director

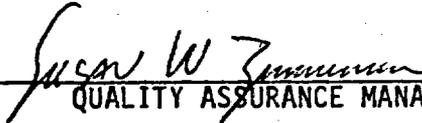
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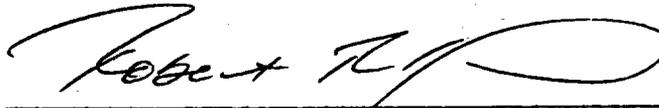
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QUALITY ASSURANCE PROGRAM

APPROVED BY:

  
\_\_\_\_\_  
QUALITY ASSURANCE MANAGER

  
\_\_\_\_\_  
EXECUTIVE DIRECTOR

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## Section 00 - INTRODUCTION

This Quality Assurance (QA) program is a part of the Agency for Nuclear Projects/Nuclear Waste Project Office's (NWPO's) QA Manual. The manual which is divided into six volumes also consists (1) of QA implementing procedures (QAPs), primarily of an administrative nature and prepared by NWPO; (2) of technical procedures (TPs), primarily of a technical nature and prepared largely by NWPO's contractors and subcontractors; (3) of a Statement of Quality Assurance Policy; (4) of a glossary of definitions; and (5) of appurtenant sections, such as tables of contents. See the Table of Contents, herein, for details of manual organization.

NWPO management has instituted this program to ensure that activities performed by NWPO's and its contractors'/subcontractors' and vendors'/suppliers' personnel, in connection with U.S. Department of Energy (DOE) site characterization at Yucca Mountain, comply with relevant quality assurance requirements. The purpose of the activities addressed by the program is to investigate the potential impact on the health, safety, and environment of the residents of Nevada of any nuclear waste repository the DOE may wish to establish. NWPO and its contractors/subcontractors do this (1) by monitoring (surveillance) of DOE activities, (2) by critically reviewing and analyzing data and analyses from DOE and other sources, and (3) by conducting independent investigations as needed to (a) appraise DOE data, assumptions, conclusions, and designs and (b) to establish NWPO's own data bases and interpretation techniques.

As a matter of NWPO policy, compliance with the NWPO QA Program and procedures is mandatory for all NWPO, contractor/subcontractor, and vendor/supplier personnel performing activities significant to NWPO's objectives. There are no separate contractor or subcontractor QA manuals that govern NWPO-sponsored activities.

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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:

1. 10CFR50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," 1975;
2. 10CFR60, Subpart G, "Disposal of High Level Radioactive Waste in Geologic Repositories, Quality Assurance," 1983;
3. ANSI/ASME NQA-1-1986 Edition, "Quality Assurance Program Requirements for Nuclear Facilities";
4. U.S. NRC, "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories," June 1984;
5. U.S. NRC NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," June 1983;
6. U.S. NRC NUREG-1297, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," February 1988; and
7. U.S. NRC NUREG-1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," February 1988.

## Section 01 - ORGANIZATION

Organization of NWPO's and its contractors', subcontractors' and vendors'/suppliers' activities is shown on Figures 01-1 through 01-5, organization charts, which indicate lines of authority and major project tasks and activities, and which identify contractors, subcontractors, and key position titles. As illustrated by the charts, there is a close integration of NWPO, contractor, and subcontractor activities under the control of NWPO.

Ultimate authority resides with the Governor and Legislature of the State of Nevada. Overall responsibility for management of NWPO and for implementation of the State's objectives and QA policies is exercised by NWPO's Executive Director. Reporting to the Executive Director is the Administrator of Technical Programs, who is responsible for NWPO contractor(s) and subcontractor(s) performing activities within the scope of the QA program. The Administrator of Technical Programs coordinates contractor, subcontractor, and vendor/supplier activities through the contractor Project Managers and ensures furnishing of proper documentation by vendors/suppliers furnishing equipment for NWPO's direct use. In addition, he/she directs NWPO's own technical staff. The Administrator of Technical Programs also arranges peer reviews of contractor and subcontractor documents and activities, as necessary.

The Project Managers coordinate the activities of the Principal Investigators. The Principal Investigators perform the technical tasks assigned to them by the procurement contract documents with the aid of associate investigators, support staff, subcontractors, and vendors/suppliers whose activities they supervise and/or coordinate. Laboratory Directors direct contractors' and subcontractors' laboratory activities. Interface relations between Principal Investigators are coordinated by the Project Managers; relations between

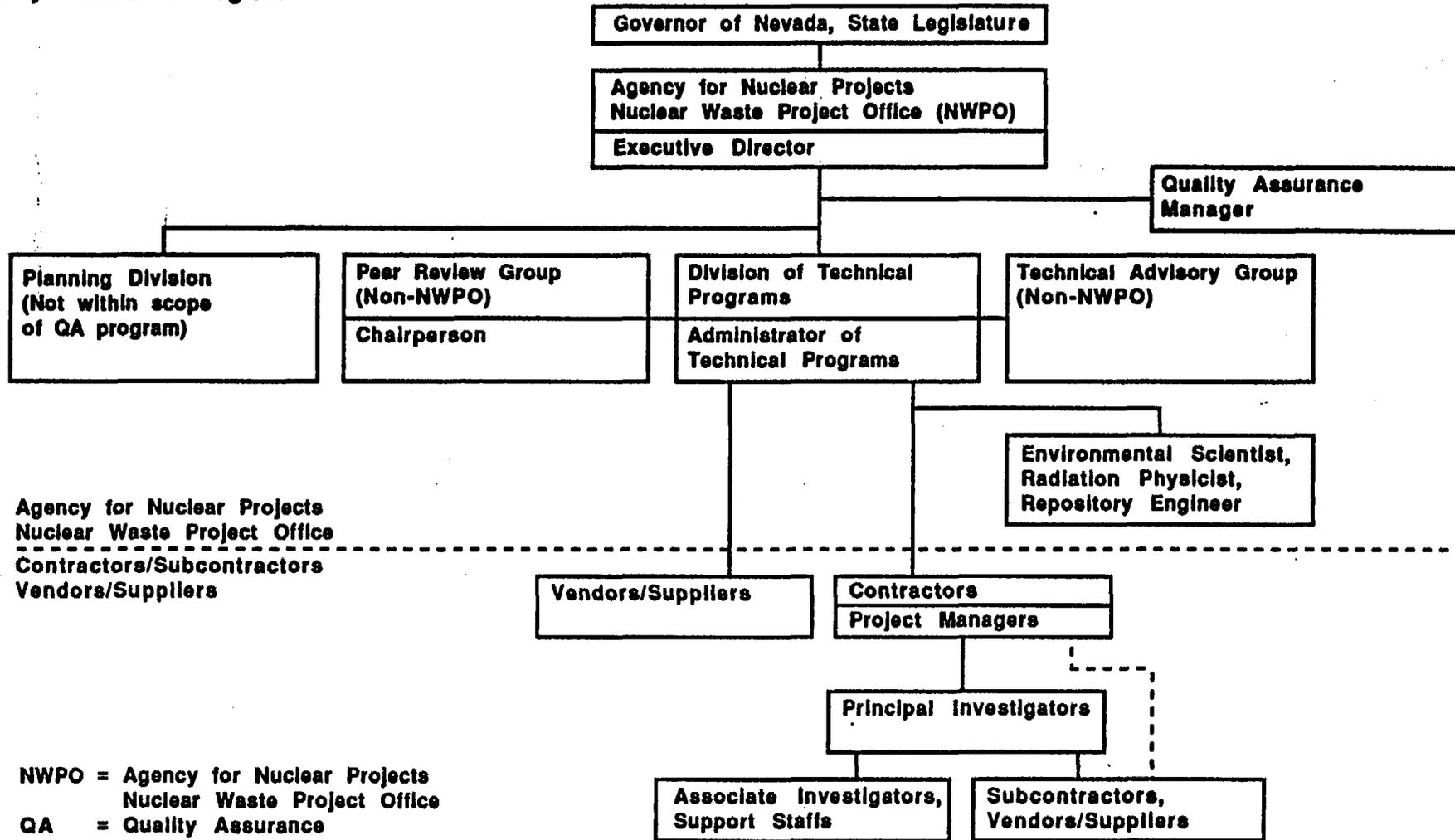
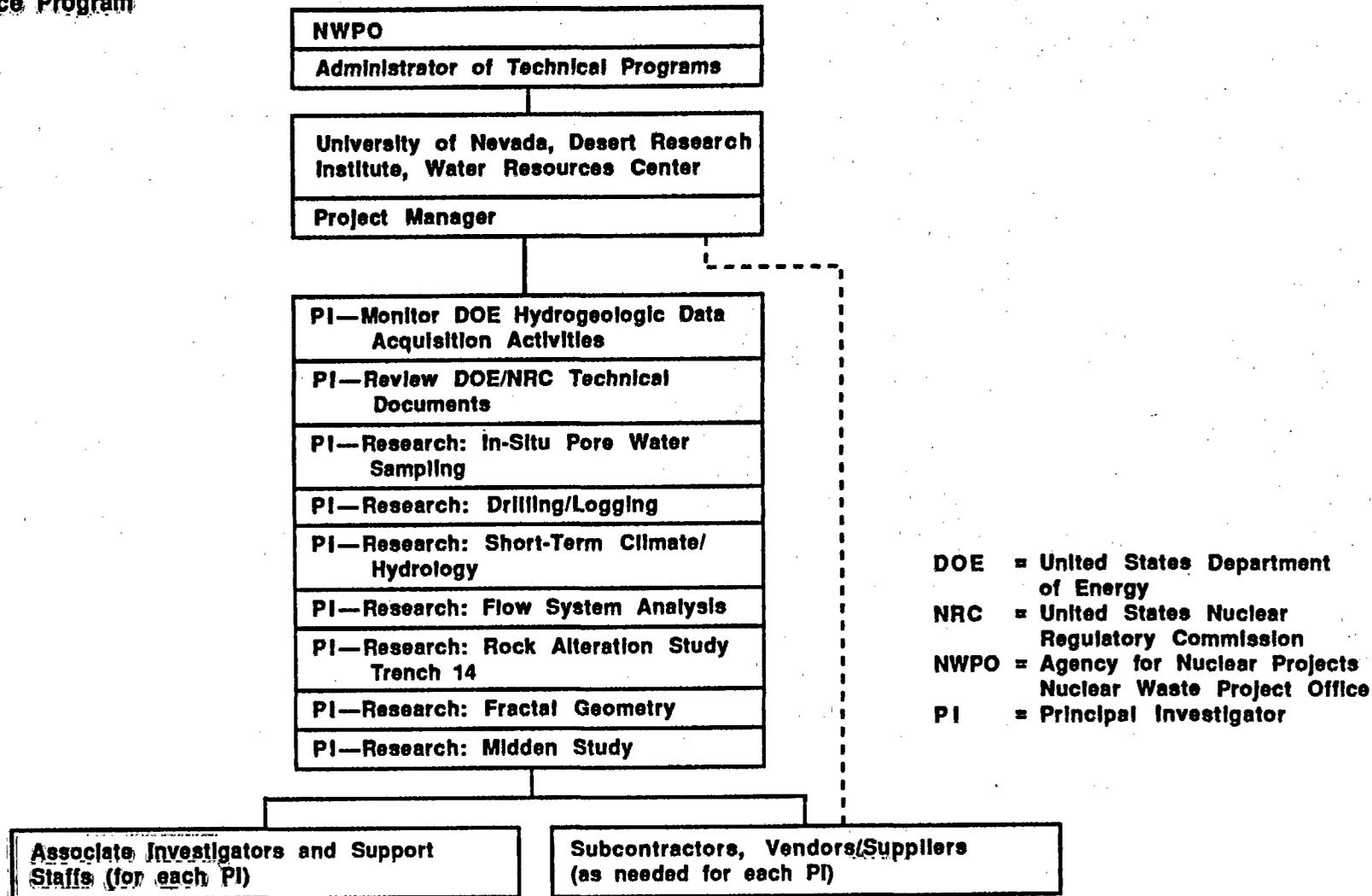


Figure 01-1, General Project Organization Chart

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Figure 01-2, Contractor Organization Chart for Desert Research Institute, Water Resources Center, University of Nevada

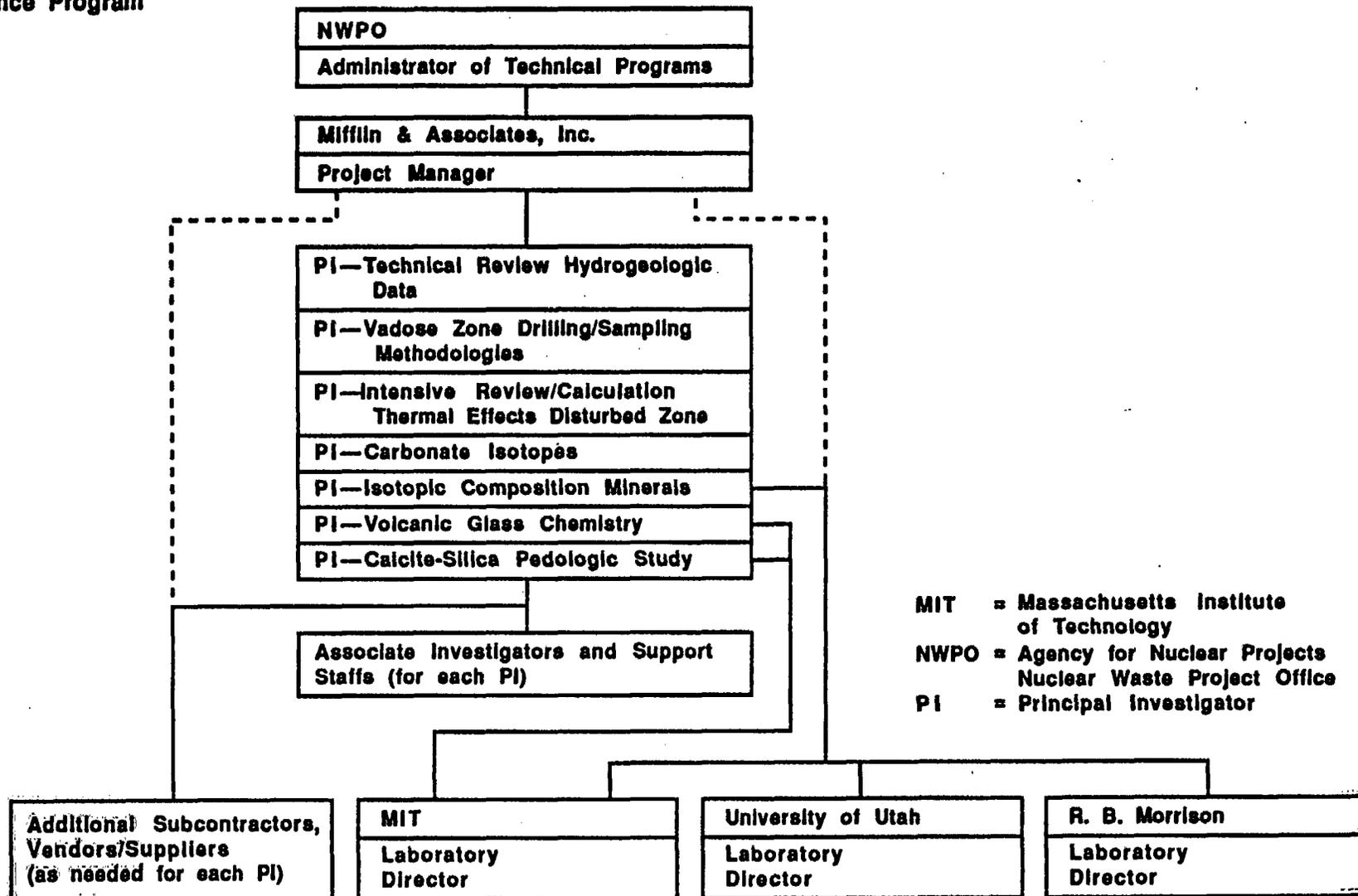
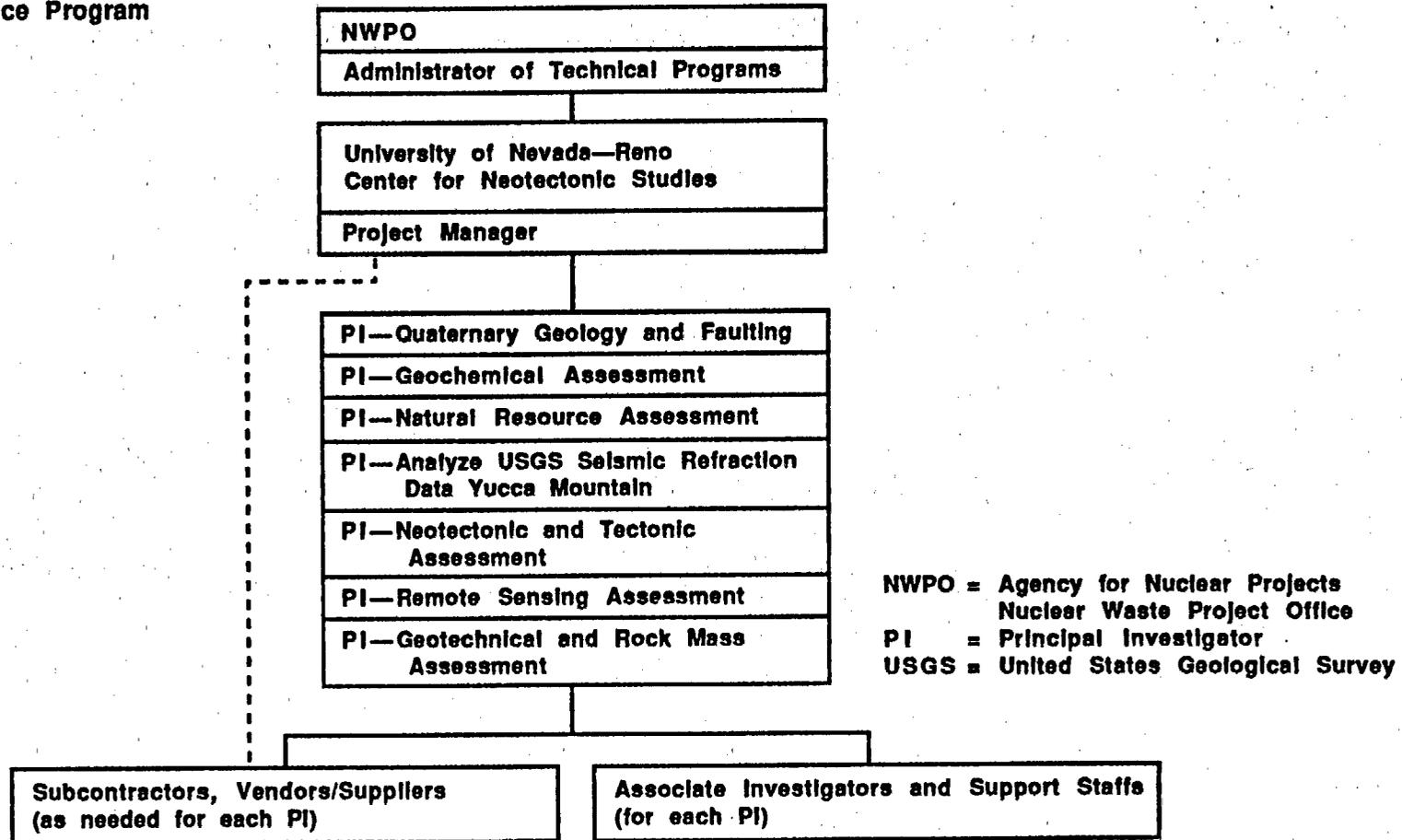


Figure 01-3, Contractor Organization Chart  
 Mifflin & Associates, Inc.

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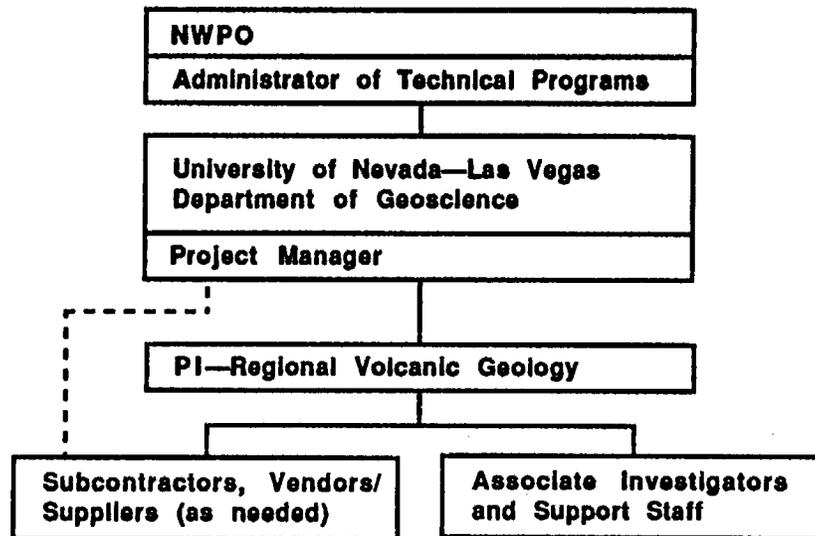
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Figure 01-4, Contractor Organization Chart for Center for Neotectonic Studies  
 University of Nevada—Reno



NWPO = Agency for Nuclear Projects  
Nuclear Waste Project Office  
PI = Principal Investigator

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Figure 01-5, Contractor Organization Chart for  
Department of Geoscience,  
University of Nevada—Las Vegas

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contractors are regulated by the Administrator of Technical Programs. Additional specific responsibilities of the Executive Director, Administrator of Technical Programs, Project Managers, Principal Investigators, and of Laboratory Directors and others are indicated in QA and technical procedures.

With reference to the responsibilities of the Technical Advisory Group and QA Manager, the Technical Advisory Group is a high-level council of independent consultants retained by NWPO to provide non-mandatory guidance as requested. The Technical Advisory Group interfaces with the Administrator of Technical Programs. The QA Manager is responsible for the QA program and procedures and reports directly to the Executive Director. The QA Manager devotes his/her time exclusively to quality assurance functions. Specific responsibilities and qualifications of the QA Manager are indicated later in this section.

Documentation of qualifications of individuals performing activities covered by the QA program is addressed by procedure QAP-1.1, governing position titles and descriptions, employee experience records, and employee qualifications of NWPO's, contractors', and subcontractors' participating staffs and by procedure QAP-3.3, governing qualifications of peer reviewers. In addition NWPO requires all NWPO, contractor/subcontractor, and vendor/supplier personnel to follow the QA program and QA and technical implementing procedures as documented by the NWPO QA Manual.

Concerning organizational responsibilities of NWPO and its contractors/subcontractors, NWPO is responsible for quality assurance, for defining, administering, directing, and coordinating work activities, for procurement of contractor services and for some materials and equipment, for review and audit of NWPO's, and contractors'/subcontractors' activities and vendors/suppliers, and for some technical work of its own. Contractors' responsibilities are to perform technical tasks consistent with the objectives

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and strategy outlined in Section 00, herein, and in procurement contract documents. NWPO's Division of Technical Programs (Administrator of Technical Programs) and the Project Managers, Principal Investigators, Laboratory Directors, and other persons are responsible for the quality of work and for liaison and coordination.

NWPO's specific responsibilities are indicated in QA and technical procedures, and contractors' and subcontractors' specific responsibilities are indicated in QA and technical procedures and in procurement contract documents. Contractors and their major tasks are identified in Figures 01-1 through 01-5. Contractors perform the indicated activities directly for NWPO. In cases where a contractor cannot perform certain specialized services, such as core drilling or K-Ar age determination, or cannot supply certain materials or equipment, a subcontractor or vendor/supplier is retained by the contractor with NWPO's approval. In these cases the contractor assumes responsibility for vendor/supplier documentation requirements.

With reference to duties of the QA Manager, specific responsibilities are detailed in implementing procedures. The QA Manager has the responsibility and authority to:

1. communicate directly with the Executive Director, the Administrator of Technical Programs, the Project Managers, and the Principal Investigators, and also with the peer reviewers, if any;
2. approve the QA manual, prepare and/or approve changes thereto, and interpretations thereof;
3. by means of audits, or otherwise, identify quality problems, initiate solutions, and verify their implementation;
4. recommend the stopping of unsatisfactory work;
5. train and instruct NWPO's and its contractors' and subcontractors' personnel in implementation of the QA program and relevant QA procedures (QAPs);

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6. perform audits of NWPO's and its contractors', subcontractors', and vendors'/suppliers' activities, as appropriate;
7. maintain a records center for filing and storage of NWPO, contractor, subcontractor, and vendor/supplier records;
8. review changes to relevant NRC, DOE, and other documents, such as ANSI/ASME NQA-1, for their effect on the NWPO QA Program;
9. review and concur with procurement contract documents for compliance with QA requirements;
10. maintain a list of position titles and position descriptions; and
11. discharge other responsibilities indicated in the QA program and as detailed in implementing procedures.

Differences of opinion between the QA Manager and other NWPO personnel or contractor/subcontractor or vendor/supplier staff are resolved by the Executive Director.

Minimum requirements for the position of QA Manager include:

1. a bachelor's degree in engineering or science from an accredited college or university;
2. five years of practical experience in geoscience or engineering with a minimum of two years of quality assurance work in the nuclear industry, preferably in the high level waste program;
3. two years of management experience;
4. certification as a Lead Auditor in accordance with NQA-1-1986, Supplement 2S-3; and
5. good oral and written communication skills.

## **Section 02 - QUALITY ASSURANCE PROGRAM**

The NWPO QA Program is a part of the NWPO QA Manual. The Manual, divided into six volumes, also includes QA and technical procedures and a glossary of definitions. The program is the sole QA program governing activities of NWPO, and its contractors/subcontractors, and vendors/suppliers working as an integrated organization. The program has been written to control activities essential to attainment of NWPO's objectives as specified in the Statement of Quality Assurance Policy and Section 00, herein, and in procurement contract documents. In brief, the purpose of these activities is to investigate the potential impact of any high-level nuclear waste repository, that the DOE may elect to propose at Yucca Mountain, on the health, safety, and environment of the residents of Nevada. NWPO and its contractors/subcontractors do this (1) by monitoring and surveillance of DOE site characterization activities, (2) by critically reviewing and analyzing data and analyses from DOE and other sources, and (3) by conducting such independent investigations as may be necessary (a) to appraise DOE data, assumptions, conclusions, and designs and (b) to establish NWPO's own data bases and interpretation techniques. The program is in compliance with requirements of 10CFR50, Appendix B, and with other documents listed in Section 00, herein, including NUREG-0856, as they apply to NWPO objectives, needs, and activities. Ultimately, QA program content and policy is determined by the Executive Director and QA Manager who approve all parts of the program and changes thereto. The QA manual and revisions thereto are prepared, reviewed, approved, controlled, and distributed in accordance with procedures QAP-2.1 and QAP-2.2.

The NWPO QA Program is implemented by quality assurance procedures and by NWPO and contractor/subcontractor technical procedures listed in the Tables of Contents of each manual volume. All procedures and revisions thereto are prepared, reviewed, approved, distributed, and controlled in accordance with QA procedures QAP-2.1 and, as applicable, QAP-2.2. QA procedures are prepared

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by the QA Manager; most technical procedures are prepared by the Principal Investigator or subcontractor specialist personnel. All technical procedures are reviewed by a technically qualified reviewer in accordance with procedures QAP-2.1 and QAP-2.2. The QA Manager approves all QA procedures and reviews and approves all technical procedures for conformance to QA requirements and to the Statement of Quality Assurance Policy, herein. The Executive Director, Project Managers, and Administrator of Technical Programs also approve technical and/or QA procedures as indicated by procedures QAP-2.1 and QAP-2.2. The current revision status of all procedures is indicated in NWPO QA Manual Tables of Contents included in each volume of the manual.

QA procedures (QAPs) and technical procedures (TPs) are numbered to correspond to the section of the program they implement. For example, procedures QAP-2.1 and 2.2 are related to Section 02 of the program and procedure QAP-6.1 addresses Section 06 of the program. See procedure QAP-2.1, Figure 4.1-1 for further details.

To ensure early interaction between the QA Manager and NWPO, contractor, and subcontractor organizations, all NWPO, contractor, and subcontractor activities that NWPO considers significant to its objectives must be authorized and controlled by QA and/or technical procedures and also by procurement contract documents (for contractors and subcontractors). The QA Manager also maintains close contact with technical activities by means of progress reports issued per a QA procedure.

Standard technical activities of a predictable nature, such as surface geologic mapping or routine water analyses, that employ established techniques, are performed in accordance with methodologies specified in advance by guiding technical procedures. The procedures are written in enough detail to permit repetition of the activity by a knowledgeable independent investigator. Technical activities of a research or experimental nature, such as isotope determination of fluid inclusions, where techniques and procedures

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must be developed, do not require advance specification of methodologies to be employed. In these cases the technical activity performed must be documented in accordance with a technical procedure prepared by the contractor or subcontractor. The technical procedure requires documentation sufficient to permit a knowledgeable independent investigator to retrace the activity. In particular, the technical procedure provides for the following documentation, and documentation instructions, as applicable.

1. vehicle of documentation (e.g., laboratory notebook, field book);
2. activity objectives and general work plan;
3. name of person(s) performing the activity or subactivities and date(s) activity performed;
4. equipment, apparatus, and materials used;
5. description of methodologies and experimental techniques employed;
6. calibration techniques used;
7. calculations including computer techniques and codes;
8. sampling techniques and sample history;
9. environmental conditions of activity;
10. dated signature(s) of person(s) performing activity;
11. verification, document control, and transmittal to the NWPO Records Center in accordance with Sections 03, 06, and 17 of the NWPO QA Program and implementing procedures;
12. potential sources of error and uncertainty in results;
13. conclusions (e.g., success or lack of success in attainment of objectives of activity); and
14. as needed, other documentation to assure reconstructibility of activity performed.

Technical activities of a research nature are summarized in a technical report prepared in accordance with procedure QAP-3.2. When the purpose of the activity is to provide additional data on a repetitive basis the final methodology is documented as a technical procedure. When no repetition of the activity is contemplated the methodology is presented in the technical report.

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Independent assessment of the scope, status, adequacy, and compliance of the program with 10CFR50, Appendix B, and other controlling documents, is accomplished by the Executive Director who maintains close and continuous contact with the QA program through frequent informal meetings and reports from the QA Manager and other program participants. In accordance with procedure QAP-2.4, the Executive Director also receives an annual effectivety report from the QA Manager summarizing the effectiveness of the QA program and procedures in attaining NWPO's quality assurance objectives. The Executive Director also performs an annual preplanned and documented assessment of program effectivity and compliance, either directly or through an outside consultant and ensures any necessary corrective action.

Indoctrination and training for proficiency in the QA Manual is detailed in procedure QAP-2.3, as follows.

1. All NWPO and contractor/subcontractor staff performing significant activities governed by the QA program are trained in the QA program and appropriate QA procedures by the QA Manager prior to performing their tasks.
2. Prior to performing their activities, all contractor/subcontractor and NWPO personnel receive training in appropriate technical procedures by the Principal Investigator, Project Manager (or designee), or by the Administrator of Technical Programs (NWPO personnel only).
3. Trainees are instructed in the purpose, scope, and implementation of the program and procedures as they apply to their activities. As detailed in procedure QAP-2.3, training is adequately documented.

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4. Appropriate management monitors performance of staff personnel and provides for retraining as needed.
5. As necessary, appropriate management institutes retraining in response to changes in duties or revisions to the QA manual.

Personnel are qualified in accordance with applicable standards and procedures.

To maintain the program and procedures current the QA Manager, Administrator of Technical Programs, Project Managers, Principal Investigators, and others, as appropriate, conduct continued, organized review of current NRC, DOE, and industry codes, regulations, and guidelines, and of technical documents, for their impact on the NWPO QA Program and implementing procedures. Changes to the program or procedures are instituted as needed. See procedure QAP-2.5.

Section 03 - DESIGN CONTROL  
(ANALYSIS OF SITE CHARACTERIZATION DATA)

Activities performed by NWPO and its contractors and subcontractors in connection with site characterization at Yucca Mountain consist of data acquisition and data analyses. For purposes of NWPO's QA Manual the terms "data acquisition" and "data analyses" correspond substantially to the terms "design information" and "design activity" as these terms are defined by the U.S. NRC "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories," June 1984, Appendix A, page 5. Neither NWPO, nor its contractors or subcontractors design repository systems but, rather, are concerned with activities related to acquisition and analyses of data, largely of a geologic/geotechnical nature, that DOE may or should use as a basis for any design it may choose to propose or any feasibility recommendations it may choose to make. 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 designs. In connection with NWPO's own data acquisition and research programs, the contractors and subcontractors perform activities such as, but not limited to, core drilling, sample collection, sample handling, field analysis, laboratory tests and analyses of an investigative nature (e.g., X-ray, trace element K-Ar age dating), geologic mapping, and computer analyses of U.S. Geological Survey seismologic data.

NWPO, through the Administrator of Technical Programs, ensures documented preparation, independent review (or other forms of verification), and (as needed) approval and validation of NWPO-generated data acquisition or analyses documents in accordance with the QA program and procedures. In a like manner, the contractors, through the Project Managers, Principal Investigators, Laboratory Directors, or designees, ensure the same for documents generated by contractors or subcontractors. Output documents, such as technical reports,

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are reviewed by independent technical reviewers and approved prior to issue. Input/support documents, such as field notes, are reviewed by technical reviewers or otherwise verified, as appropriate. The term "Verification" encompasses review, checking, or other means of establishing conformity of documents to specified requirements. All development, control, and/or use of computer programs by NWPO or its contractors/subcontractors conforms to the intent of NUREG-0856, referenced in Section 00, herein. See Sections 06 and 17, herein, and the glossary for further discussion of output documents and input/support documents.

Review/verification of data acquisition/analyses documents and activities, including the reviewer's/verifier's responsibilities and techniques, the scope of review/verification, and the extent of documentation, is governed by procedures. (See, for example, QAP-3.1 and QAP-3.2.) It is NWPO's policy to require that reviewers/verifiers be independent, qualified persons not directly involved in the work they review. However, review/verification may be performed by the preparer's supervisor if either of the following two conditions exists:

1. The supervisor is the only individual in the organization competent to perform the review/verification, or
2. The supervisor did not specify a singular data acquisition/analysis approach, or rule out certain data acquisition/analyses considerations, and did not establish the inputs used in the data acquisition/analyses.

In accordance with procedures such as QAP-3.1 and QAP-3.2, supervisors are responsible for assigning qualified reviewers/verifiers. Procedures, activities, data, assumptions, extrapolations, and results that involve untried or beyond the state-of-the-art investigation, data acquisition and analyses procedures and methods of a type for which technical criteria are nonexistent or under development are controlled by procedure QAP-3.3, "Peer Reviews." Peer reviewers are specially qualified persons selected by the

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Administrator of Technical Programs, Executive Director and QA Manager with the advice of the Technical Advisory Group, and/or others, such as the Project Manager or Principal Investigator, as needed. Activities of the peer reviewers, review of work in progress, as well as selection of peer reviewers are conducted in accordance with procedure QAP-3.3 which conforms, as applicable, to the intent of the NRC Generic Technical Position on peer reviews (NUREG-1297), referenced in Section 00, herein.

Changes in data acquisition/analyses activities are accomplished by revisions to their controlling QA or technical procedures as indicated by the procedures themselves and retraining is instituted as necessary in accordance with Section 02, herein, and procedure QAP-2.3.

#### **Section 04 - PROCUREMENT DOCUMENT CONTROL**

This section of the program addresses control of the procurement contract process employed by NWPO and its contractors in procurement of services, equipment, and materials. The section does not address financial, legal, or other non-QA aspects of procurement, nor procurement of standard, "off-the-shelf" items such as measuring tapes or standard laboratory supplies.

In general, NWPO is responsible for overall procurement planning, for procurement of contractor services, for procurement of materials and equipment for its own direct use, for review and approval of contractors' procurement activities, and for other items indicated below. The contractors are responsible for procurement of subcontractor services, for procurement of materials and equipment from vendors/suppliers for contractor/subcontractor use, and for other items indicated below. As appropriate, and as detailed below, NWPO and contractors prepare procurement contracts, conduct (as necessary) qualification investigations of contractors/subcontractors and vendors/suppliers, evaluate proposals (bids), and award and execute contracts.

Requirements of QA program Sections 04 and 07, herein, are implemented by procedure QAP-4.1 and by ancillary technical procedures. Procedure QAP-4.1 addresses requirements for the control of procurement activities for NWPO and its contractors, subcontractors and vendor/suppliers. Technical and QA responsibilities of contractors/subcontractors and vendors/suppliers are indicated in a procurement contract. In outline, procedure QAP-4.1 includes the following requirements:

1. The Executive Director and Administrator of Technical Programs (in consultation with others) set procurement goals and initiate preparation of procurement documents for contractor services and for materials and equipment furnished by vendors/suppliers for NWPO's own use. The contractors' Project Managers and Principal Investigators initiate procurement documents for subcontractor services and for materials and equipment furnished by vendors/suppliers for contractor/subcontractor use.

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2. The procurement documents are prepared, reviewed, and approved as indicated in procedure QAP-4.1. The QA Manager performs a documented review of all procurement documents for compliance with QA requirements.
3. Either directly or by appropriate reference, procurement documents include the following requirements, as applicable, and as detailed in procedure QAP-4.1. Some items apply to procurement of services and others to procurement of materials and equipment.
  - a. a statement committing the contractor, subcontractor, vendor, or supplier to comply with the NWPO QA Program and implementing procedures and with laws and regulations of the State of Nevada, as applicable;
  - b. a statement of scope, purposes, and objectives of the work including but not limited to: (1) an outline of methodologies, (2) qualifications and assignments of Principal Investigators and other key personnel, and (3) identification of work to be performed by subcontractors and of equipment/materials to be used or procured from vendors/suppliers;
  - c. technical requirements and methodologies including, for example: (1) accuracy and precision criteria, (2) special handling, packaging, shipping, and storage requirements, (3) acceptance or rejection criteria, and (4) calibration requirements, etc.;
  - d. a statement by the contractor/subcontractor guaranteeing right of access of NWPO auditors or monitors and contractor monitors to contractor/subcontractor and vendor/supplier premises;
  - e. requirements for the contractor and/or subcontractor, to supply NWPO with documents such as (1) inspection and test records, (2) chemical and physical property data,

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- (3) identification of purchased material or equipment,
  - (4) employee experience records, (5) reports of receiving inspections, (6) vendor/supplier documents, and (7) other items required by QA and technical procedures;
  - f. a requirement for the contractor/subcontractor to perform documented receiving inspections of purchased materials, equipment, apparatus, or instruments before accepting delivery of same and to perform vendor/supplier inspections or surveillances as needed;
  - g. a requirement that the contractor/subcontractor furnish NWPO with a certificate of conformance to procurement specifications when requested by NWPO, and a requirement for the contractor to inform NWPO, in writing, of any proposed departure (i.e., nonconformance) in specified services or material, equipment, or apparatus;
  - h. a requirement for the contractor to inform NWPO of any activities that may require peer review;
  - i. a requirement for the contractor/subcontractor to prepare technical procedures as necessary to implement procurement document requirements;
  - j. a requirement that in cases of procurement of materials or equipment by NWPO for its own use the vendor/supplier provides documentation in compliance with procurement documents.
4. The Executive Director/Administrator of Technical Programs or Project Manager/Principal Investigator, draft contracts and requests for proposals, as needed, incorporating the procurement documents, and solicit proposals (bids) from qualified contractors/subcontractors and vendors/suppliers. The Executive Director/Administrator of Technical Programs/QA Manager (or Project

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Manager/Principal Investigator/QA Manager) investigate and evaluate the qualifications of potential contractors, subcontractors, and vendors/suppliers of interest.

5. NWPO's Executive Director or the contractor's Project Manager (or other Responsible Person) executes the final contract. All final contracts are reviewed by the QA Manager and Administrator of Technical Programs.
6. Contracts include a statement that no contract technical activity is authorized without a corresponding approved technical procedure (except for vendor/supplier contracts).
7. Contract revisions are processed in the same way as original contracts.
8. The QA Manager audits any contractors' and subcontractors' certificates of conformance to the procurement documents in accordance with procedure QAP-18.1. NWPO and contractors may perform surveillances of contractors' and subcontractors' activities and of vendors'/suppliers' premises. The QA Manager, Administrator of Technical Programs, Project Manager, Principal Investigator and others, as appropriate, receive copies of surveillance reports and any corrective action is implemented per procedures QAP-15.1 and QAP-16.1.
9. The Principal Investigator informs the Administrator of Technical Programs and Project Manager of any proposed deviations of services or materials/equipment, from procurement documentation requirements, submitted by contractors, subcontractors, or vendors/suppliers. The Administrator of Technical Programs/QA Manager and, as appropriate, the Project Manager/Principal Investigator approve, in writing, acceptable deviations which then become authorized nonconformances.

**Section 05 - INSTRUCTIONS, PROCEDURES AND DRAWINGS**

Significant NWPO, contractor, and subcontractor activities are governed by QA and technical implementing procedures issued in accordance with the NWPO QA Program and procedures QAP-2.1 and QAP-2.2. When instructions and drawings are used to specify activities they are included as parts of the procedures. As appropriate, technical procedures include criteria for selection of particular data (from among "raw" data) to be analyzed and the method of analysis to be used. If required by the nature of the activities governed, implementing procedures include or reference quantitative or qualitative acceptance criteria for determining that the activities have been satisfactorily accomplished. Contractor, subcontractor, and vendor/supplier activities are governed by procurement contracts.

**Section 06 - DOCUMENT CONTROL**

This section of the program addresses control of documents generated by NWPO and its contractors/subcontractors and vendors/suppliers. Document control encompasses all documents necessary to demonstrate that NWPO and contractor/subcontractor activities are conducted by qualified personnel to acceptable technical and quality assurance levels of performance. Types of documents controlled include, but are not limited to, the items listed below. Control of geotechnical samples, such as rock cores or water, is addressed in Section 13 of the program.

1. the NWPO Quality Assurance Manual and revisions (including the QA program, QA procedures and technical procedures);
2. position descriptions, employee experience records, employee qualification statements, and documentation of personnel qualifications;
3. training documents;
4. audit reports, schedules, checklists, and audit report responses; nonconformance, surveillance, and inspection reports;
5. corrective action reports;
6. calculations;
7. drawings (e.g., geologic maps and remote sensing imagery) as parts of technical reports;
8. topical reports and reports of technical investigations;
9. field and laboratory data and data books; annotated maps and photos;
10. computer tapes, computer code control procedures, computer code documentation (user manuals, program listings, printouts), computer code test problems and acceptance criteria, computer runs used for reported data or analyses and in general a software summary and other documentation required by NUREG-0856;

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11. procurement contract documentation, purchase order and bid documentation, preaward qualification of contractors and subcontractors and of vendors/suppliers;
12. technical review comment documentation including resolution; peer review proceedings and reports;
13. master document lists;
14. explanation of the filing system and category file index;  
and
15. sample storage location records.

Preparation, verification, review, issuance, and revision of data acquisition/analyses and other types of documents, such as technical procedures, are controlled by QA and technical procedures. These procedures ensure technical adequacy and inclusion of appropriate quality assurance requirements and are approved by the QA Manager. For data acquisition/analyses and other output documents, such as calculations, technical reports, procurement documentation or QA or technical procedures, the procedures assign preparation, review, and approval responsibilities and mandate review and approval prior to issuance of documents. For input/support documents, such as laboratory or field data books not requiring formal approval, the procedures require review or other form of verification of data authenticity and completeness, as appropriate, prior to issuance (e.g., submission to the NWPO Records Center). Documents released for any reason prior to review or other form of verification (as applicable) are suitably identified. The contractor, subcontractor, or NWPO, as appropriate, assumes responsibility for control of vendor/supplier documents. Computer activities adhere to the intent of NUREG-0856. Revisions to documents are accomplished in the same way as for the original issue. Changes are reviewed for their effect on other documents.

Availability of correct, current, and applicable documents at the proper locations prior to start of work is ensured (1) by procedures QAP-6.1 and QAP-6.2 controlling document (and revised document) distribution, file indexing,

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progress reports, and master document lists; (2) by procedures such as QAP-2.1 and QAP-2.2 controlling distribution of QA and technical procedures; and (3) by procedures, such as procedure QAP-3.2, requiring use of current and verified input data as feasible. Procedure QAP-6.1 and other procedures such as QAP-2.1, require recipients of revised documents to promptly destroy the superseded documents or to promptly mark them "Void" or "Superseded." In accordance with procedure QAP-6.2 document holders are notified of obsolete or withdrawn documents and required to promptly destroy or suitably mark the affected documents. Compliance with these requirements is audited in accordance with procedure QAP-18.1.

NWPO exercises control of NWPO, contractor, subcontractor, and vendor/supplier documents. The Administrator of Technical Programs maintains master lists of current documents. Lists of current QA and technical procedures are included as part of NWPO's QA Manual (Table of Contents). NWPO has also established a uniform filing system for NWPO, contractor/subcontractor, and vendor/supplier documents (see procedure QAP-6.1) and a records center, maintained by the QA Manager, for these documents (see procedure QAP-17.1).

All QA and technical implementing procedures provide for control of all documents generated by each procedure.

### Section 07 - CONTROL OF PURCHASED MATERIALS, EQUIPMENT, AND SERVICES

This section of the NWPO QA Program addresses control of purchased materials, equipment, and services but not control of standard, "off-the-shelf" items such as measuring tapes or standard laboratory supplies. NWPO exercises control of services purchased from contractors, control of equipment and materials purchased by NWPO for its own use, and final control of all contractor and subcontractor purchases on NWPO's behalf. The contractors control services purchased from subcontractors and materials and equipment purchased from vendors/suppliers for contractors' and subcontractors' use. NWPO evaluates contractor/subcontractor services and contract compliance by means of periodic audits. NWPO reviews contractor surveillance reports of contractor/subcontractor activities. In accordance with technical procedures, NWPO may also conduct its own surveillances of contractor and subcontractor activities. NWPO also audits any contractors' and subcontractors' certificates of conformance to procurement documents to ensure that they are valid. In accordance with procedure QAP-18.1, NWPO audits vendors/suppliers, as needed.

In addition to technical procedures, requirements of Section 07 are implemented by the procurement contract control procedure, QAP-4.1, of Section 04, herein. The procedure requires the Executive Director, Administrator of Technical Programs, and QA Manager to conduct evaluation and selection of contractors and the QA Manager, Project Manager, and Principal Investigator to do the same for subcontractors, and vendors/suppliers providing services, equipment, or materials. Contractor, subcontractor, and vendor/supplier activities are audited by the QA Manager and may be monitored by him/her or by other NWPO personnel. Contractors and subcontractors are required to perform receiving inspections, as appropriate. NWPO is responsible for receiving inspections of materials and equipment purchased for its own (i.e., non-contractor) use. Procedure QAP-4.1 also requires the contractor to provide NWPO with documentation of any deviations in specified contracted services or

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equipment, materials, apparatus, or instruments, proposed by the contractor, subcontractor, or vendor/supplier. The Administrator of Technical Programs/QA Manager and, as appropriate, the Project Manager/Principal Investigator approve in writing acceptable (i.e., authorized) proposed deviations which then become authorized nonconformances.

Equipment used for data collection is addressed in appropriate technical procedures. As needed, the technical procedures specify performance verification requirements.

**Section 08 - SAMPLE IDENTIFICATION AND CONTROL**

This section of the program addresses sample identification and control. Program requirements are implemented by technical procedures.

The procedures assign control and identification of samples to the appropriate contractors and subcontractors. Sampling is confined largely to materials of a geological or geotechnical nature such as rock, soil, and water.

The procedures ensure that legible and permanent identification is maintained either on the samples or on their containers and that persons responsible for performing and verifying this activity are identified by position title.

The procedures provide for tracing of the samples to an appropriate document such as a drilling log or geologic map. Sample identification and storage locations are placed on a list, together with necessary identification, and this list is maintained in file by a designated person. A copy of the list is sent to NWPO's Records Center in accordance with procedure QAP-17.1. Correct identification of samples is verified and documented prior to release of the samples for use or analysis. Samples of missing or uncertain identity are not used.

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**Section 09 - CONTROL OF SPECIAL PROCESSES**

There are no NWPO-sponsored activities that fall within the scope of the term "special process" as understood by the NRC review plan or by NQA-1-1986 referenced in Section 00, herein. NWPO-sponsored activities are described throughout in the QA program.

### Section 10 - INSPECTION, SURVEILLANCE, AND MONITORING

This section of the QA program addresses inspection, monitoring, and surveillance. For purposes of the program objectives, the terms "surveillance" and "monitoring" are identical, both meaning observation and documentation of an activity by a qualified, but nonparticipating and independent observer. Inspection is the documented examination or measurement of an item or activity, by a qualified and independent non-supervisory person, for compliance to specified requirements. Inspection is confined to NWPO-sponsored activities.

Many technical activities outlined in Sections 00 and 02 of the program consist of surveillance/monitoring of DOE and contractor/subcontractor activities by NWPO and/or contractor personnel. Some activities, such as drilling and sampling by subcontractors, require inspection by contractor personnel. The decision of whether to inspect an activity or monitor it or to rely entirely on auditing to verify satisfactory performance, is made by NWPO's Administrator of Technical Programs, Executive Director and QA Manager and, as appropriate, by the contractor's Project Manager and Principal Investigator. Their decision, as a minimum, depends on the following questions:

1. Is the activity under the control of NWPO?
2. Is inspection feasible?
3. Are errors in performance detectable after the fact?
4. How serious are consequences of unobserved nonconformances in procedure?

Surveillance/monitoring and inspection activities are performed by qualified personnel and controlled by technical procedures. Persons conducting surveillances or inspections are NWPO or contractor/subcontractor staff members, as appropriate, and are appointed by the Administrator of Technical Programs, Project Manager, Principal Investigator, or others. The inspector

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or monitor is required to submit written reports to specified persons with copies to the QA Manager, Administrator of Technical Programs, Project Manager, Principal Investigator and others, as appropriate. Inspectors and monitors of NWPO and contractor/subcontractor activities are required to report apparent nonconformances to the QA Manager for investigation and correction per procedures QAP-15.1 and QAP-16.1. (See Sections 15 and 16, herein.) Deviations (authorized nonconformances) proposed by contractors/subcontractors are addressed in Sections 04 and 07, herein, and by procedure QAP-4.1.

QA and technical procedures establish documented qualification requirements for inspectors and surveillance personnel. In addition, technical procedures provide for the following documentation as applicable and feasible:

1. identification of characteristics and activities to be monitored or inspected and of the observations to be made;
2. a description of the method of surveillance or inspection;
3. identification of individual(s) performing the surveillance or inspection, or of the data recorder, and the date of the surveillance or inspection;
4. acceptance and rejection criteria (inspections only);
5. identification of required inspection or surveillance procedures (including drawings and specifications), and revisions thereof;
6. specification of necessary measuring and test equipment including accuracy requirements;
7. mandatory hold points beyond which work cannot proceed without inspection (inspections only);
8. evaluation of data and results and acceptance, as appropriate, by the Principal Investigator, Project Manager, and Administrator of Technical Programs; and
9. a description of the method for controlling the application and removal of status indicators.

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Section 11 - TEST CONTROL

There are no NWPO, contractor, or subcontractor activities that fit the definition of testing of ANSI/ASME NQA-1-1986, Supplement S-1, or the definition implied by the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories," (June 1984), i.e., Does an item meet certain prespecified requirements? In accordance with technical procedures and procurement documents, the contractors and subcontractors perform technical activities of an investigative nature including laboratory research. These investigations establish new methods, techniques, and data bases used in accomplishing NWPO's goals identified in the "Statement of Quality Assurance Policy," and in Sections 00 and 02 of the QA program, herein. The technical procedures are prepared in accordance with procedures QAP-2.1 and QAP-2.2 and include the following items, as appropriate:

1. instructions for performing the activity;
2. prerequisites for conducting the activity such as calibrated instrumentation, suitable and controlled environmental conditions, and provision for data collection and storage;
3. mandatory inspection hold points (as required);
4. methods of data analysis;
5. methods of documenting or recording data and results;
6. provisions for assuring that prerequisites have been met;  
and
7. identification of potential sources of uncertainty and error.

Review of activities and procedures and the evaluation and documentation of results are addressed in procedures that implement Sections 02, 03, and 04 of the program. See, for example, procedures QAP-2.2, QAP-3.2, and QAP-4.1.

## Section 12 - CONTROL OF MEASURING AND TEST EQUIPMENT

Requirements of this section of the QA program are implemented by technical procedures prepared by the contractors or subcontractors in accordance with procedures QAP-2.1 and QAP-2.2. The equipment control procedures address all measuring and testing equipment in which faulty accuracy or precision can significantly affect data generated by the equipment and analyses based thereon. Examples of measuring and test equipment include analytical balances, pH meters, strain gauges, topographic survey instruments, and X-ray diffraction apparatus. Commercial-type, off-the-shelf equipment, such as rulers or measuring tapes are not included in the program. As required by procurement contracts, the contractors and subcontractors are responsible for establishing procedures for the control of calibration and for the use of correct measuring and test equipment.

The controlling technical procedures are required to address the following items:

1. a description of calibration techniques and frequencies of calibration;
2. maintenance and control of equipment used for measurement, testing inspection, and monitoring, and documentation thereof;
3. specification of calibration intervals, based on required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions that could affect measurements; and
4. documentation of date of next scheduled calibration of measuring and testing equipment so as to provide traceability to calibration test data.

The technical procedure(s) also includes instructions that require traceability of calibration standards to nationally recognized standards or provision for documentation of acceptability of the calibration standard used where recognized standards do not exist.

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Any measuring or testing equipment found to be out of calibration after data acquired with the equipment have been incorporated into output or input/support documents, is reported to the QA Manager for appropriate action as prescribed by Sections 15 and 16 of the program and by procedures QAP-15.1 and QAP-16.1. The technical procedure mandates documented evaluations to determine the validity and acceptability of measurements performed since the last calibration. As necessary, measurements or tests of suspect items are repeated. Out-of-calibration equipment is marked or tagged as such.

### Section 13 - SAMPLE HANDLING, STORAGE, AND SHIPPING

Section 13 of the QA program is implemented by technical procedures developed by the contractors and subcontractors, and approved by the Project Manager, the QA Manager, and the Administrator of Technical Programs. Most samples collected are of a geotechnical nature such as rock, soil, water, microfossils, or minerals.

The contractors and subcontractors are responsible for custody, handling, preservation, storage, packaging, shipping and retrieval of samples acquired through their own activities, or from the DOE or others, in accordance with the following requirements as detailed by procurement documents and implementing technical procedures:

1. Activities are performed by trained qualified individuals in accordance with predetermined work procedures and instructions, as appropriate.
2. Samples are stored under conditions of adequate security. A reference collection of samples is stored permanently, as permitted by the properties of the sample.
3. Samples are appropriately identified and are protected from damage, loss, or physical deterioration from temperature, humidity, or other environmental agents. As necessary, special handling, equipment, packaging, or controlled environments are provided.
4. Sample location and storage documentation is submitted to the QA Manager for retention in NWPO's Records Center in accordance with procedure QAP-17.1.

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5. Samples are traceable from initial acquisition through final disposition. By use of sample transmittal forms, record of custody forms, or equivalent means, physical location and custody of samples is known at all times. Any interface relations between multiple organizations concerning sample custody and management are clearly described.

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**Section 14 - INSPECTION, TEST AND OPERATING STATUS**

Neither NWPO nor its contractors or subcontractors perform inspection, test and operating status activities controlled by Criterion 14 of 10CFR50, Appendix B or by the NRC review plan referenced in Section 00, herein.

### Section 15 - NONCONFORMANCES

This section of the QA program addresses the identification, investigation, documentation, and tracking of nonconformances to prevent the inadvertent use and impact of nonconforming items and activities. Corrective action for nonconformances is addressed in Section 16, herein, and in procedure QAP-16.1, "Corrective Action." Identification of nonconformances by means of audits is addressed in Section 18 and in procedure QAP-18.1, "Audits."

For purposes of the NWPO QA Program, a nonconformance is defined as a deficiency in a service, activity, or procedure, or of an in-service or installed material, item of equipment, apparatus, or instrument that renders the quality of an item or activity unacceptable or indeterminate. Nonconformances may arise from activities performed by NWPO or by NWPO's contractors, subcontractors, or vendors/suppliers. Nonconforming items and activities are identified. The inadvertent use and further impact of nonconforming items and activities is prevented. All NWPO, contractor, subcontractor, and vendor/supplier personnel are responsible for identifying and reporting nonconformances and apparent nonconformances to the QA Manager.

An authorized nonconformance is a proposed deviation from requirements of procurement documents, submitted by a contractor, subcontractor, or, as appropriate, a vendor/supplier, that has been reviewed and approved (found acceptable), in writing, by the Administrator of Technical Programs/QA Manager, and, as appropriate, by the Project Manager/Principal Investigator. Acceptance and approval by NWPO of authorized nonconformances is further addressed in Sections 04 and 07, herein, and in procedure QAP-4.1.

Examples of nonconformances include, but are not limited to:

1. loss of single copy records;
2. use of inappropriate computer programs;

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3. discovery that untrained and/or unqualified persons are performing quality-affecting activities;
4. loss, theft, or damage to records or samples;
5. errors and deficiencies in approved output documents and, as appropriate, other verified documents;
6. unauthorized use of technical apparatus different from that specified by procurement documents or corresponding implementing procedures; and
7. use of incorrect samples in a laboratory analysis.

Requirements and responsibilities for reporting, issuing, and tracking nonconformances are specified in procedure QAP-15.1. Corrective action for nonconformances is documented and resolved per procedure QAP-16.1, "Corrective Action."

Nonconformances are reviewed periodically by the QA Manager to determine trends. Significant results are reported to management, per procedure QAP-16.1, "Corrective Action."

### Section 16 - CORRECTIVE ACTION

This section of the QA program addresses corrective action necessary to resolve nonconformances and significant conditions adverse to quality. This section also addresses the related topic of stop-work orders.

A significant condition adverse to quality is defined as a condition that has, has had, or could have a serious effect on the quality of the data or conclusions generated by NWPO-sponsored activities critical to NWPO's objectives. Examples of significant conditions adverse to quality are system deficiencies in the QA program, unsatisfactory work being approved and released, and recurring nonconformances involving the same item or activity.

Nonconformances are corrected in a timely manner. Significant conditions adverse to quality are corrected as soon as practical. Corrective actions address actions taken to correct the condition and to ensure against future recurrence.

Corrective action is implemented in accordance with the requirements of procedure QAP-16.1, "Corrective Action," that specify the responsibilities and requirements by which the QA Manager assures that nonconformances and significant conditions adverse to quality are documented, evaluated, reported to immediate and upper management, and corrected. Root causes are determined for nonconformances and significant conditions adverse to quality. Implementation of corrective action is verified and documented.

If a significant condition adverse to quality is determined to exist, the QA Manager may recommend to the Executive Director, per procedure QAP-16.1, the stopping of work in order to safeguard the achievement of quality. Issuance of a stop-work order depends on the circumstances involved.

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The QA Manager implements a tracking system to assist in monitoring and closing out corrective actions in a timely manner. Follow-up action is taken by the QA Manager to verify the proper implementation and effectiveness of the corrective action. Nonconformances, significant conditions adverse to quality, and corrective actions are reviewed periodically to determine trends and significant results are reported to upper management, per procedure QAP-16.1.

### Section 17 - QUALITY ASSURANCE RECORDS

This section of the QA program addresses collection, processing, filing, storage, and retrieval of quality assurance records generated by NWPO and its contractors, subcontractors and vendors/suppliers. Quality assurance records are defined as completed documents, accepted for the NWPO Records Center per stated requirements, that furnish evidence of the quality of items and/or activities significant to NWPO's objectives.

For purposes of this section of the QA program, records can be "paper" items, such as technical reports, procurement contracts, or photographs, or can be other items, such as films or computer or video tapes. However, geotechnical or other samples, such as rock cores or water, which are addressed in Section 13 of the program, are not classified as records, herein. Output documents, such as technical procedures, procurement documents, or technical reports, for which implementing procedures require formal review and approval, are not considered complete until they have been dated and until they have been signed by the approver or reviewer and approver, as appropriate. Input/support documents, such as field notes or laboratory data books, for which formal review and approval may not be required, are not considered complete without dated evidence of verification and completeness, as specified by implementing procedures.

Requirements of this section of the program are implemented by procedure QAP-17.1 and by other controlling QA and technical procedures.

Examples of quality assurance records include, but are not limited to, the following types and revisions thereto. See the implementing procedures for additional examples of quality assurance records.

1. NWPO QA Manual and revisions (including the QA program, QA procedures, and technical procedures);

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2. position descriptions, employee experience records, and employee qualification statements and certification of personnel qualifications;
3. training documents;
4. audit reports, schedules, checklists, and audit report responses; nonconformance, surveillance, and inspection reports;
5. corrective action reports;
6. calculations;
7. drawings (e.g., geologic maps and remote sensing imagery) as parts of technical reports;
8. topical reports and reports of technical investigations;
9. field and laboratory data and data books; annotated maps and photos;
10. computer tapes, computer code control procedures, computer code documentation (user manuals, program listings, printouts), computer code test problems and acceptance criteria, computer runs used for reported data and analyses and in general a software summary and other items required by NUREG-0856;
11. procurement contract documentation, purchase order and bid documentation, and preaward qualification of contractors/subcontractors and vendors/suppliers;
12. technical review comment documentation, including resolutions (processed with corresponding document as a package); peer review proceedings and reports;
13. master document lists;
14. explanation of the filing system and category file index; and
15. sample storage location records.

Controlling QA and technical procedures require that records generated by NWPO, contractors, subcontractors, or vendors/suppliers be sent to the NWPO Records Center by the Administrator of Technical Programs, Principal Investigator, QA Manager, Laboratory Director, or other designated individual, as appropriate, on a continuous basis as soon as feasible after generation.

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Vendor/supplier records are processed and submitted by NWPO, the contractor, or the subcontractor, as appropriate. Records must be legible, of reproducible quality, physically durable (e.g., of good quality paper) and complete as defined above.

Records must include the name of the record-generating organization, identification as an NWPO record, identification of record type (e.g., trench log, computer tape), record title (e.g., report title), record revision designation and/or completion date, as appropriate, and the category file index designation as specified by controlling procedure QAP-6.1.

The QA Manager is in charge of an NWPO Records Center in NWPO's offices and ensures that properly marked NWPO, contractor/subcontractor, and vendor/supplier records are correctly processed and, when of satisfactory quality, filed in the center under his/her control. All records are permanently retained. As detailed by procedure QAP-17.1, the QA Manager maintains a stored records index (with any explanatory notes) in the NWPO Records Center. A copy of the index is sent to the Administrator of Technical Programs.

Records are stored in metal file cabinets located in the NWPO Records Center. Records are firmly attached in binders, folders, or envelopes, and are protected from moisture and from excessive heat or pressure. Sensitive records, such as film negatives or computer tapes, receive special protection from hazards such as excessive light, magnetic fields, or stacking. The QA Manager controls access to the file cabinets.

Procedure QAP-17.1 requires that requests for retrieval of records be made in writing to the QA Manager who arranges the forwarding of a copy of the stored record to the requestor, if feasible. Special arrangements are made for documents such as photographs or computer tapes.

Transmittal of records to the NWPO Records Center is also controlled by appropriate QA and technical procedures.

## Section 18 - AUDITS

This section of the NWPO QA Program addresses audits of NWPO's, contractors'/subcontractors', and vendors'/suppliers' activities and corrective action and tracking of audit findings and audit observations. The QA Manager, who is a certified Lead Auditor, is responsible for all audits. All audits are performed by the QA Manager in accordance with procedure QAP-18.1, with the aid of qualified independent Technical Auditors, as needed. There are no contractors', subcontractors', or vendors'/suppliers' audit organizations that audit NWPO-sponsored activities. See Section 02 of the program and procedure QAP-2.4 for optional management assessment audits of the QA Manager's activities.

The QA Manager performs planned and periodic audits of activities, procedures, documents, records, and facilities to seek-out and evaluate objective evidence of compliance with the NWPO QA Program, implementing procedures, and procurement documents. He/she also uses audits to evaluate the effectiveness and implementation of all significant aspects of the program and implementing procedures. As required by procedure QAP-18.1, all parts of NWPO, and of contractors', subcontractors', and vendors'/suppliers' organizations engaging in significant activities within the scope of the NWPO QA Program are subject to audit. Quality of work audited is a major audit goal. Audits are conducted according to a predetermined schedule identifying audits to be performed, and their frequencies and dates. As specified by procedure QAP-18.1, there are required and scheduled special audits to verify (follow-up) implementation of corrective action arising from significant conditions adverse to quality (SCAQs). As needed, there are also follow-up audits in response to nonconformances, findings, and observations, and also special audits in response to requests, or as the QA Manager may deem necessary.

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All significant aspects of the program and all participating organizations and their activities are audited. Likewise, output documents are audited to ensure that they are being prepared, reviewed, and approved in accordance with their controlling procedures and input/support documents are audited for preparation and adequate verification, as appropriate. As needed, the Technical Auditors may use technical verification of work or other means to confirm effectiveness of revision/verification and quality of work. Scheduling and timing of audits depends on the nature and duration of the activity being audited.

Procedure QAP-18.1 provides for audit planning and execution, for evaluation of results, for preaudit and postaudit conferences with audited individuals, for a written audit report, and for a written response indicating proposed corrective action for findings/observations. The procedure also addresses tracking and trend analysis of audit findings/observations.

An audit plan is developed for each audit indicating the audit scope, the activities to be audited, the applicable documents and requirements, the audit schedule, and the names of auditors. Audits are performed in accordance with written checklists which may be altered during the audit.

Procedure QAP-18.1 requires audit reports that are prepared, signed, and dated by the QA Manager and distributed to the Responsible Individuals audited, and, to the Executive Director, the QA Manager, the Administrator of Technical Programs, and, as applicable, to the Project Manager, Principal Investigators, and others. The audit report includes a statement of any audit comments, audit observations, audit findings classified as nonconformances, and other audit findings. The Responsible Individual audited is required to submit a written response to the audit report, to the QA Manager, within a specified time. The response must indicate corrective action (including root cause determination and implementation date) for audit findings and observations.

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(Audit findings classified as nonconformances are processed per procedures QAP-15.1, "Nonconformances," and QAP-16.1, "Corrective Action." See procedure QAP-18.1 for a discussion of audit comments, audit observations, audit findings, and nonconformances.)

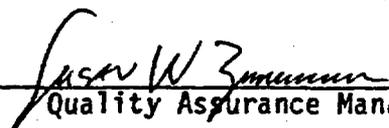
Procedure QAP-18.1 also requires the QA Manager to maintain a tracking system to ensure that all audit findings and observations are promptly addressed. The QA Manager is also required to perform trend analyses of audit findings and observations and to report any adverse trends to the Executive Director.

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QAP-1.1  
REVISION 0  
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TITLE: POSITION TITLES, POSITION DESCRIPTIONS, EMPLOYEE EXPERIENCE RECORDS,  
AND QUALIFICATION STATEMENTS

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for the preparation, review, approval, distribution, and control of position titles/position descriptions, employee experience records (EERs), and employee qualification statements. The procedure applies to persons responsible for the direction, management, or implementation of activities governed by the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) QA Program. The intent is to require approved employer qualification statements for all such persons prior to start of work. This procedure does not apply to Peer Reviewers whose qualifications are addressed in procedure QAP-3.3, "Peer Reviews."

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

2.1.1 Contractor

2.1.2 Responsible Individual

2.1.3 Subcontractor

3.0 INTERFACING PROCEDURES

3.1 QAP-6.1, "Document Distribution List and File Index"

3.2 QAP-17.1, "Quality Assurance Records"

4.0 PREPARATION, REVIEW, AND APPROVAL

Position Titles and Position Descriptions

General

4.1 As prescribed by Subsections 4.2 through 4.7, each NWPO, contractor, or subcontractor individual performing activities governed by the NWPO QA Program shall be assigned a position title and each position title shall be assigned a corresponding position description

indicating the duties, responsibilities, authority, and qualifications of the position title. Position titles and descriptions shall be consistent with the QA program.

NWPO Position Titles and Descriptions

- 4.2 The Administrator of Technical Programs shall prepare a list of position titles and corresponding position descriptions of NWPO personnel in conformity with the requirements of Subsection 4.1, and then forward the signed and dated list to the QA Manager. Position descriptions shall include educational, training, and experience requirements.
- 4.3 The QA Manager, as reviewer, and the Executive Director, as approver, shall each review the list, and when it is satisfactory they shall sign and date the list as reviewer and approver.

Contractor Position Titles and Descriptions

- 4.4 Each Principal Investigator shall prepare a list of position titles and corresponding position descriptions of all contractor persons within his/her work group in conformance with the requirements of Subsection 4.1, and then forward the signed and dated list to the Project Manager. Position descriptions shall include educational, training, and experience requirements.
- 4.4.1 The Project Manager shall prepare position descriptions/position titles for Project Manager and other persons not under jurisdiction or a Principal Investigator.
- 4.5 The Project Manager and QA Manager, as reviewers, and the Executive Director, as approver, shall each review the list, and when it is satisfactory they shall sign and date the list as reviewers and approver. Insofar as possible, the reviewers shall ensure uniformity of titles and descriptions between work groups and between contractors. (Exception: The Administrator of Technical Programs, Executive Director and QA Manager shall review the position description for Project Manager and others not under jurisdiction of a Principal Investigator).

Subcontractor Position Titles and Descriptions

- 4.6 The Principal Investigator or Project Manager shall ensure the preparation of position title and description lists by Responsible Individuals of subcontractors within their span of control.
- 4.6.1 The Responsible Individual shall prepare, sign, and date the list, as indicated in Subsection 4.1, and forward it to the Project Manager.

- 4.7 The Project Manager, QA Manager, and Executive Director shall review and approve the list as indicated in Subsection 4.5, as applicable.

Employee Experience Records and Employee Qualification Statements

- 4.8 The Administrator of Technical Programs or Project Manager, as appropriate, shall ensure preparation of EERs by all NWPO, contractor, and subcontractor individuals performing activities controlled by the NWPO QA Program.

- 4.8.1 Each EER shall provide the following information:

Printed/typed name of the individual

Name, location(s), dates of enrollment at each educational institution attended with course type(s), and degree received

Professional engineer license, or other relevant licenses, registrations, or certifications, with numbers

Membership in professional and technical organizations

Publication(s)

Work experience, including name(s) and address(es) of employer(s), dates of employment, and description(s) of work

Signature of individual and date.

- 4.9 NWPO Individuals shall transmit their completed, signed, and dated EERs to the Administrator of Technical Programs, and Contractor/Subcontractor Individuals shall transmit their completed, signed, and dated EERs to the Project Manager. However, the Administrator of Technical Programs and QA Manager shall submit their EERs to the Executive Director, and the Project Managers shall submit their EERs to the Administrator of Technical Programs.

- 4.10 The Administrator of Technical Programs, Project Managers, and Executive Director shall each review the EERs forwarded to them in accordance with Subsection 4.9, and the Executive Director shall also review EERs prepared by the Project Managers.

- 4.11 When the EER has been found satisfactory, the Reviewer(s) of the EER, identified in Subsection 4.10, shall complete, sign, and date the employee qualification statement, Form QAP-1.1.1, as Approver, as shown in Figure 4.11-1, "Sample Employee Qualification Statement," and forward it to the QA Manager. Both the Administrator of Technical Programs and Executive Director shall sign the Project Managers' Form QAP-1.1.1. As desired, an equivalent form may be substituted for Form QAP-1.1.1.



- 4.11.1 Signature on the employee qualification statement warrants that the signer has confirmed the professional qualifications of the employee, has confirmed his/her suitability for the position and has ensured documentation of essential elements of the EER such as degrees earned.

## 5.0 OUTPUT DOCUMENTS

- 5.1 The QA Manager shall ensure marking of the category file index designation on the following documents and distribution to persons listed on the document distribution list in accordance with procedure QAP-6.1, "Document Distribution List and File Index." The QA Manager shall also ensure transmittal and processing of the documents in the NWPO Records Center in accordance with procedure QAP-17.1, "Quality Assurance Records."

- 5.1.1 Position Title and Position Description Lists

- 5.1.2 Employee Experience Records

- 5.1.3 Employee Qualification Statements

- 5.2 Document Recipients shall maintain the documents in file as needed to facilitate audits.

## 6.0 REVISIONS

- 6.1 Revisions to position titles or descriptions, to EERs, or to employee qualification statements shall be accomplished by producing new editions in accordance with the requirements stated in this procedure for the original issues. Revised documents shall be issued in their entirety. Document Recipients shall either promptly destroy the superseded documents or promptly mark them "Void" or "Superseded."

- 6.1.1 New EERs shall be prepared whenever individuals are transferred to different positions or when qualifications of their positions are changed.

- 6.1.2 A new employee qualification statement shall be prepared and approved whenever an individual is transferred to a different position, and, as necessary, whenever position titles or descriptions are revised.

- 6.2 Revised portions of documents shall be identified by bold face type or by other means if necessary. Previous revision identification shall be deleted.

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7.0 REFERENCES

- 7.1 NWPO QA Program, Section 01, Organization
- 7.2 NWPO QA Program, Section 06, Document Control
- 7.3 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975
- 7.4 10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983
- 7.5 ANSI/ASME NQA-1 -Quality Assurance Program Requirements for Nuclear Facilities - 1986
- 7.6 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories -June 1984.

8.0 FLOW CHART

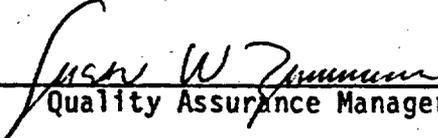
None

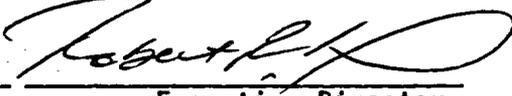
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QAP-2.1  
REVISION 0  
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TITLE: PREPARATION, CONTROL, AND DISTRIBUTION OF THE AGENCY FOR NUCLEAR PROJECTS/NUCLEAR WASTE PROJECT OFFICE QUALITY ASSURANCE MANUAL

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for the preparation, control, and distribution of the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) QA Manual, except for certain requirements unique to the preparation and control of technical procedures which are described in procedure QAP-2.2.

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

2.1.1 Contractor

2.1.2 Controlled Copy

2.1.3 NWPO Quality Assurance Manual

2.1.4 Quality Assurance Policy Statement

2.1.5 Quality Assurance Procedure

2.1.6 Quality Assurance Program

2.1.7 Subcontractor

2.1.8 Technical Procedure

3.0 INTERFACING PROCEDURES

3.1 QAP-2.2, "Preparation and Control of Technical Procedures"

3.2 QAP-6.1, "Document Distribution List and File Index"

3.3 QAP-17.1, "Quality Assurance Records"

4.0 PREPARATION AND CONTROL OF NWPO QA MANUAL

Preparation and Approval

- 4.1 The NWPO QA Manual shall be prepared by the QA Manager. The QA program shall comply with requirements of documents listed in Section 00 of the QA program and Section 7.0 herein, as they apply to NWPO activities, objectives, and management policies. QA procedures shall comply with QA program commitments.

The QA Manager shall initiate and prepare revisions to the NWPO QA Manual, or may prepare revisions in response to written requests. Anyone within the NWPO, contractor, or subcontractor organizations may suggest a revision to the QA manual by means of a written request to the QA Manager.

The NWPO QA Manual shall be divided into six volumes and arranged in accordance with Figure 4.1-1, "Organization of NWPO QA Manual."

Each QA procedure shall be organized as shown in Figure 4.1-2, "Outline for QA Procedures."

Flow charts may be prepared, if needed. If a flow chart is prepared, it shall be arranged according to the format shown in Figure 4.1-3, "Flow Chart Instructions and Legend."

- 4.2 The QA Manager shall distribute copies of drafts of revisions to the QA Manual to the Administrator of Technical Programs and to others, as appropriate, for review and comment. The QA Manager shall maintain a record of comments and reviewers in file for each draft.

- 4.3 The Administrator of Technical Programs and other Reviewer(s), as appropriate, shall comment on the draft and return his/her (their) comments or indication of no comments to the QA Manager.

- 4.4 The QA Manager shall resolve comments with the Reviewer(s), and shall document their resolution by memorandum. The QA manual shall then be redrafted per the resolved comments.

All comments and comment resolution documentation shall be processed in accordance with Section 5.0 of this QA procedure.

- 4.5 With all comments resolved, the QA Manager shall sign the affected part of the QA manual as approver, indicating that the document complies with NWPO QA policies and commitments. The document shall be dated and forwarded to the Executive Director.

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**Number of Volumes** - The NWPO QA Manual is divided into six volumes. Volume 1 includes the statement of Quality Assurance Policy, QA program, QA procedures, and Glossary. Volumes 2 through 6 include technical procedures.

**Title Page** - This page contains the title "State of Nevada, Agency for Nuclear Projects, Nuclear Waste Project Office Quality Assurance Manual," the volume number and total number of volumes (e.g., Volume 2 of 6), the controlled copy number of the volume, and the name of the manual volume holder. Each volume has its own title page.

**Table of Contents** - Each volume has its own table of contents. The table of contents in Volume 1 includes a summary table of contents for Volumes 2 through 6. The table of contents lists all sections of the NWPO Quality Assurance Manual in the particular volume, their revision numbers, and revision dates. An appropriate revised table of contents is issued with each revision of the manual indicating the latest revision for each section.

**Statement of Quality Assurance Policy** - The statement of NWPO Quality Assurance Policy establishes NWPO's commitment to a Quality Assurance Program and implementing procedures.

**Quality Assurance Program** - The NWPO Quality Assurance Program describes how NWPO controls NWPO, contractor, subcontractor, and vendor/supplier activities relative to site characterization of Yucca Mountain as a repository for high-level nuclear waste.

The NWPO Quality Assurance Program is subdivided into sections, with each section having a descriptive title and number, corresponding to the eighteen criteria listed in NRC's 10CFR50 -Appendix B.

Each page of a section is identified with the revision number, with the date of revision, with the words State of Nevada, Agency for Nuclear Projects, Nuclear Waste Project Office, and Quality Program, and with a page number at the bottom which indicates the section of the program as well as the page of the section. (Example; page 02-1). Final pages of each section are so identified.

Where figures or tables are required, they are identified as such and include an identification number and a descriptive title. The figure or table is identified with the section number in which it is first referenced and inserted following the page on which it is referenced (Example; Figure 02-1 or, where more than one figure is referenced in the same section, Figure 02-2, Figure 02-3, etc.).

**Quality Assurance and Technical Procedures** - QA procedures (QAPs) and technical procedures (TPs) identify the guidelines and requirements regulating activities of NWPO and its contractors, subcontractors, and vendors/suppliers. See Figure 4.1-2.

Procedures are numbered as follows:

QAP or XTP - Y.Z

QAP = Quality Assurance Procedure

X = NWPO, individual contractor, or individual subcontractor  
alphabetical code (A,B,C,etc.) developed by QA Manager

TP = Technical Procedure

Y = Pertinent Quality Assurance Program Section

Z = Sequential Number

Numbers are assigned by the QA Manager.

All pages of QAPs and TPs are identified by a QAP or TP number, revision number, and revision date in the upper right-hand corner, with the words State of Nevada, Agency for Nuclear Projects, Nuclear Waste Project Office, and Quality Assurance Procedure or Technical Procedure in the upper left-hand corner, and with a page number at the bottom which indicates the number of the page and the total number of pages in the procedure. (Example; Page 3 of 4). The original issue shall be designated Revision 0. The first page shall also include a procedure title and provision for Approvers' signatures.

When figures or tables are required, they are identified as such and include an identification number and descriptive title. The figure or table is identified with the subsection number in which it is first referenced and inserted in the procedure following the page on which it is referenced (Example; Figure 4.1-1 or, where more than one figure or table is referenced in the subsection, Figure 4.1-1, Figure 4.1-2, etc.).

Any forms required by a procedure have a revision number and are numbered sequentially using the procedure number associated with the form. For example, if procedure QAP-2.1 required three separate forms, they would be identified as Forms QAP-2.1.1, QAP-2.1.2, and QAP-2.1.3. The form number and revision number are located in the lower left-hand margin of the form. Forms are completed, stamped "SAMPLE," reduced in size and included as figures in the procedure.

**Glossary of Definitions** - The Glossary of Definitions is an alphabetical listing of specialized terminology used in the NWPO Quality Assurance Manual. Each term is defined, and a list of references is included. Each page is suitably identified using the procedure implementation requirement, herein, as a guide. The Glossary includes terms of a quality assurance nature rather than purely technical terms.

**FIGURE 4.1-1, ORGANIZATION OF NWPO QA MANUAL**

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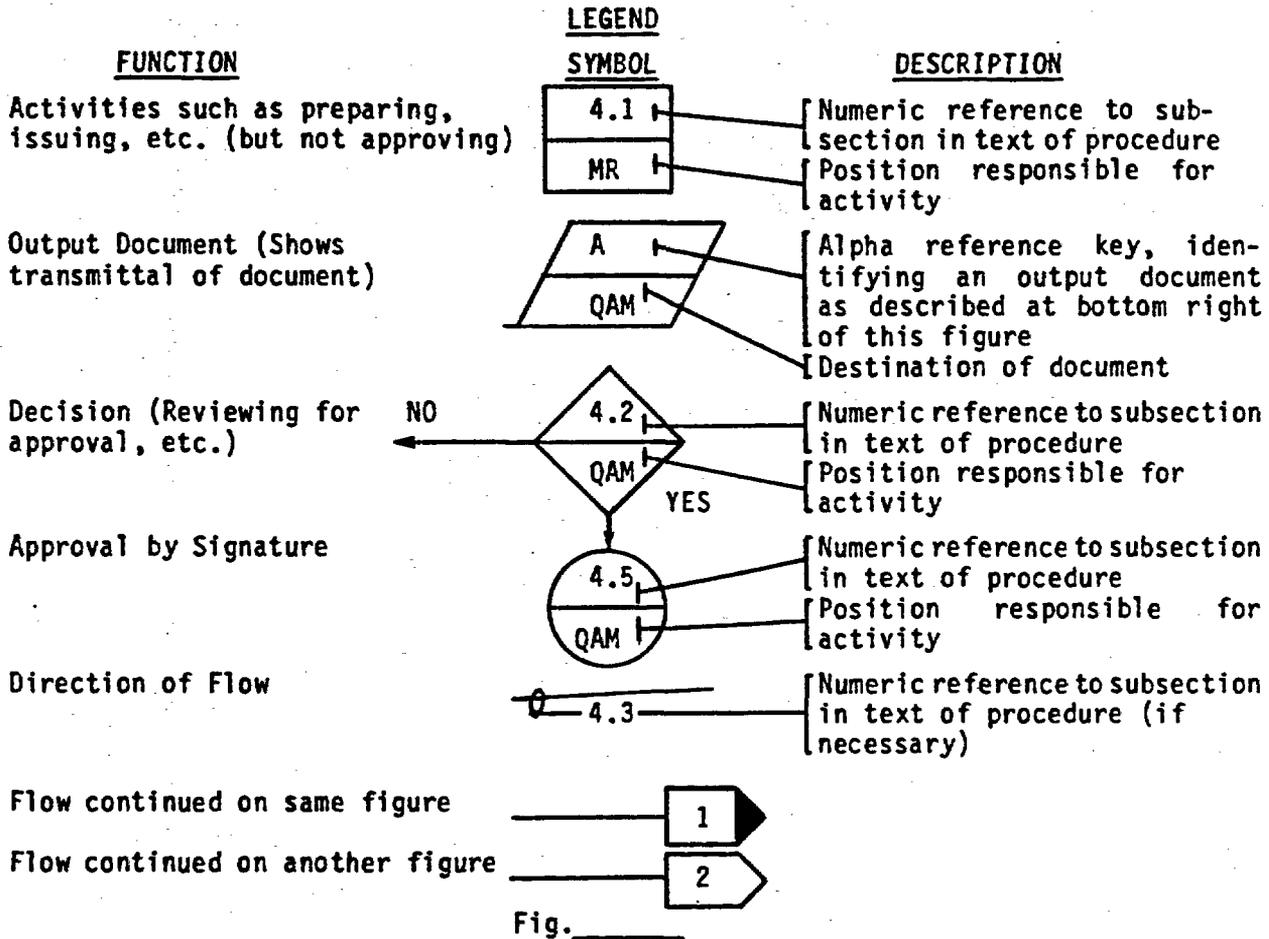
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SECTION NUMBER	SECTION TITLE	DESCRIPTION/OUTLINE
1.0	<u>Purpose</u>	This section describes the scope and applicability of the procedure.
2.0	<u>Definitions</u>	This section lists specialized terminology used in the procedure and defined in the Glossary of Definitions and/or definitions of specialized terms unique to a procedure but not defined in the glossary.
3.0	<u>Interfacing Procedures</u>	This section lists any procedures which interface with the subject procedure.
4.0	<u>Activities Involved, or QA Requirements</u>	<p>This section may be written as a sequential narration of the required activities involved in the procedure or as a description of the minimum QA requirements to control specified activities.</p> <p>When written as a sequential narration, the individuals performing the activities are identified by position title. When written as a description of the minimum QA requirements, the individual(s) responsible for ensuring that these requirements are implemented are identified by position title.</p> <p>The sequential narration or minimum QA requirements are described in subsections identified by numerical designations. The numerical designations follow in such a manner as to show the assignment of responsibility and the transition in activities or to list each QA requirement.</p> <p>Example: 4.1    The <u>QA Manager</u> shall review the document for.....</p> <p>          4.1.1   If the <u>QA Manager</u> has any comments, he/she shall.....</p> <p>          4.1.2   If the <u>QA Manager</u> has no comments, he/she shall.....</p> <p>          4.2    The <u>Project Manager</u>.....</p> <p>Position titles of persons performing an activity shall be capitalized and underlined.</p>
5.0	<u>Output Documents</u>	This section lists documents produced as a result of meeting the requirements of this procedure and indicates their disposition.
6.0	<u>Revisions</u>	This section describes how revisions to documents controlled by the procedure are to be processed.
7.0	<u>References</u>	This section identifies the section of the NWPO QA Program that the procedure implements, and includes any regulations, codes, standards, or other documents which form the basis of requirements included in the procedure.
8.0	<u>Flow Chart (Optional)</u>	This section references the flow chart, if any, and identifies it by figure number. The flow chart enables the user of the procedure to read the sequential narration and follow the flow at the same time. The flow chart indicates, diagrammatically, the activities addressed by the procedure. If no flow chart is used, the word "None" shall be written in Section 8.0. See Figure 4.1-3.

FIGURE 4.1-2, OUTLINE FOR QA PROCEDURES

INSTRUCTIONS

1. Flow chart information should flow from top-to-bottom.
2. Acronyms or abbreviations may be used on flow charts to identify the organization (such as NWPO, Desert Research Institute, etc.), responsible for an activity. Acronyms and abbreviations shall be defined on the flow chart.



TYPICAL LIST OF DEFINITIONS

DEFINITIONS

MR - Manual Recipient  
 QAM - Quality Assurance Manager

TYPICAL OUTPUT DOCUMENT BLOCK

OUTPUT DOCUMENTS REQUIRED		
KEY	FORM NO.	TITLE
A	QAP-2.1.1	QA Manual Transmittal and Receipt

FIGURE 4.1-3, FLOW CHART INSTRUCTIONS AND LEGEND

- 4.6 The Executive Director shall review the document, and shall resolve any comments with the QA Manager. When all parties are satisfied, the Executive Director shall approve the affected part of the QA manual by signature and shall return the approved document to the QA Manager who shall ready it for distribution.
- 4.6.1 The QA Manager does not sign the Statement of Quality Assurance Policy.
- 4.6.2 As needed, the QA Manager shall institute changes to parts of the manual affected by the revision.
- 4.7 The QA Manager shall direct the preparation of the table of contents portion of the QA manual, Volume 1, and shall have the table of contents revised to reflect the latest revisions. The NWPO QA Manual and its revisions shall be distributed in accordance with Subsections 4.8 through 4.13 of this QA procedure. The requirements of the affected part of the manual shall be implemented as soon as practical following the revision date. When a portion of a manual is revised, activities completed prior to the revision date need not meet the newly authorized requirements unless so specified.

#### Distribution

- 4.8 The QA Manager shall prepare and maintain a separate distribution list for controlled (i.e., individually assigned) copies of each volume of the NWPO QA Manual and revisions thereto. The QA Manager shall determine assignment of controlled copies of individual manual volumes to NWPO, contractor, and subcontractor personnel. The individuals who are assigned controlled copies of a manual volume shall be listed on the appropriate distribution list by name, by NWPO or contractor/subcontractor position title, by location, and by an individually assigned controlled copy number. The controlled copy number and manual holder's name shall be included on the manual title page. Each list shall be identified by volume number. Each volume shall have its own controlled copy number.
- 4.8.1 Assignment of controlled copies of the NWPO QA Manual shall be made in a manner which will assure that a manual or reasonable access to a manual is provided for the Executive Director, the QA Manager, the Administrator of Technical Programs, the Project Managers, the Principal Investigators, the Laboratory Directors, and for all other individuals performing activities within the scope of the NWPO QA Program. QA manuals shall be distributed prior to start of activities governed by the manual, as appropriate.

- 4.8.1.1 All Manual Recipients shall be supplied with or have reasonable access to Volume 1 of the manual, which includes the QA program, QA procedures, and glossary, and to an appropriate additional volume(s) of technical procedures.
- 4.8.2 The Project Managers shall advise the QA Manager by memorandum if any changes are required in contractor/subcontractor manual assignments.
- 4.8.3 Assignment of a controlled copy entitles the manual holder to receive current manual revisions. Only holders of controlled copies shall receive current manual revisions.
- 4.9 The QA Manager shall determine the distribution of controlled copies of the manual for non-NWPO and non-contractor/subcontractor personnel.
- 4.10 To distribute controlled copies of the manual or revisions, or parts thereof, the QA Manager shall prepare Form QAP-2.1.1, as shown in Figure 4.10-1 "Sample QA Manual Transmittal and Receipt," for each individual receiving a controlled copy. The transmittal shall list the recipient's name and address, the controlled copy number, volume number, and the transmittal date. Each transmittal shall be attached to the appropriate controlled manual copy or revised part thereof and forwarded to the individual indicated on the transmittal.
- 4.11 The Recipient shall sign the receipt form acknowledging that the document(s) listed on the form was (were) received, date the signature, and return the receipt to the QA Manager within 15 working days of the transmittal date. The Recipient shall insert received documents into the manual and remove superseded parts from the manual and promptly destroy them or promptly mark them "Void" or "Superseded."
- 4.11.1 Manual Recipients shall maintain their copies of the manual intact exactly as received. There shall be no insertions, deletions, marginal notes or other changes.
- 4.12 The QA Manager shall document the receipt of each transmittal and receipt form.
- 4.12.1 If a signed and dated QA Manual transmittal and receipt form is not received from an internal (i.e., NWPO or contractor/subcontractor) manual holder within 15 working days of the transmittal date, the QA Manager shall inform the manual holder that his/her manual will not be considered a controlled copy, that he/she will receive no further

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Category File Index Designation <u>XYZ123</u> To: <u>Jason Roberts</u> Address: <u>Univ.NV.</u> Controlled Copy No. <u>12</u> Reno, NV 89506 Volume No. <u>1</u>	QA Manual Transmittal and Receipt Transmittal Date: <u>July 20, 1988</u>								
Return this form on or before: August 10, 1988	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;">           Return to            R. T. Armstrong         </td> <td style="width: 50%; padding: 5px;">           Address            NWPO, Capitol            Complex,            Carson City, NV            89710         </td> </tr> </table>	Return to R. T. Armstrong	Address NWPO, Capitol Complex, Carson City, NV 89710						
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<table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Copy No. , Volume No. , Rev. of the NWPO QA Manual is hereby assigned to your care.             OR  <input checked="" type="checkbox"/> Remove and insert the revisions listed below. Dashes (--) indicate no action required.   <table style="width: 100%;"> <tr> <td style="text-align: center;"><u>REMOVE</u></td> <td style="text-align: center;"><u>INSERT</u></td> </tr> <tr> <td style="padding: 5px;">               Table of Contents .... Rev. 0                (2 pages), Volume 1             </td> <td style="padding: 5px;">               Table of Contents .... Rev. 1                (2 pages), Volume 1             </td> </tr> <tr> <td style="padding: 5px;">               Procedure QAP-2.1 .... Rev. 0                (9 pages)             </td> <td style="padding: 5px;">               Procedure QAP-2.1 .... Rev. 1                (9 pages)             </td> </tr> </table> </td> <td style="width: 50%; vertical-align: middle; text-align: center; font-size: 2em; font-weight: bold;"> <b>SAMPLE</b> </td> </tr> </table> <p>NOTE:          Before returning this transmittal form, note corrections in name, address, copy number, volume number, and organization, plus any discrepancies in the attached documents, so that corrective action may be taken.</p>		<input type="checkbox"/> Copy No. , Volume No. , Rev. of the NWPO QA Manual is hereby assigned to your care.  OR <input checked="" type="checkbox"/> Remove and insert the revisions listed below. Dashes (--) indicate no action required.  <table style="width: 100%;"> <tr> <td style="text-align: center;"><u>REMOVE</u></td> <td style="text-align: center;"><u>INSERT</u></td> </tr> <tr> <td style="padding: 5px;">               Table of Contents .... Rev. 0                (2 pages), Volume 1             </td> <td style="padding: 5px;">               Table of Contents .... Rev. 1                (2 pages), Volume 1             </td> </tr> <tr> <td style="padding: 5px;">               Procedure QAP-2.1 .... Rev. 0                (9 pages)             </td> <td style="padding: 5px;">               Procedure QAP-2.1 .... Rev. 1                (9 pages)             </td> </tr> </table>	<u>REMOVE</u>	<u>INSERT</u>	Table of Contents .... Rev. 0 (2 pages), Volume 1	Table of Contents .... Rev. 1 (2 pages), Volume 1	Procedure QAP-2.1 .... Rev. 0 (9 pages)	Procedure QAP-2.1 .... Rev. 1 (9 pages)	<b>SAMPLE</b>
<input type="checkbox"/> Copy No. , Volume No. , Rev. of the NWPO QA Manual is hereby assigned to your care.  OR <input checked="" type="checkbox"/> Remove and insert the revisions listed below. Dashes (--) indicate no action required.  <table style="width: 100%;"> <tr> <td style="text-align: center;"><u>REMOVE</u></td> <td style="text-align: center;"><u>INSERT</u></td> </tr> <tr> <td style="padding: 5px;">               Table of Contents .... Rev. 0                (2 pages), Volume 1             </td> <td style="padding: 5px;">               Table of Contents .... Rev. 1                (2 pages), Volume 1             </td> </tr> <tr> <td style="padding: 5px;">               Procedure QAP-2.1 .... Rev. 0                (9 pages)             </td> <td style="padding: 5px;">               Procedure QAP-2.1 .... Rev. 1                (9 pages)             </td> </tr> </table>	<u>REMOVE</u>	<u>INSERT</u>	Table of Contents .... Rev. 0 (2 pages), Volume 1	Table of Contents .... Rev. 1 (2 pages), Volume 1	Procedure QAP-2.1 .... Rev. 0 (9 pages)	Procedure QAP-2.1 .... Rev. 1 (9 pages)	<b>SAMPLE</b>		
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Procedure QAP-2.1 .... Rev. 0 (9 pages)	Procedure QAP-2.1 .... Rev. 1 (9 pages)								
<table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Sign below acknowledging you have:            Received and accepted responsibility for the above volume of the NWPO QA Manual and compared its contents with the appropriate Table of Contents.             OR  <input checked="" type="checkbox"/> Received and inserted new documents and removed superseded documents as shown above in your NWPO QA Manual. All removed documents have been destroyed or marked as void or superseded.         </td> <td style="width: 50%; vertical-align: bottom; padding-top: 20px;"> <div style="text-align: center;"> <u>Jason Roberts</u>      <u>August 5, 1988</u>              (Signature)                      (Date)           </div> </td> </tr> </table> <p>Date Form Returned: <u>8-9-88</u></p>		<input type="checkbox"/> Sign below acknowledging you have: Received and accepted responsibility for the above volume of the NWPO QA Manual and compared its contents with the appropriate Table of Contents.  OR <input checked="" type="checkbox"/> Received and inserted new documents and removed superseded documents as shown above in your NWPO QA Manual. All removed documents have been destroyed or marked as void or superseded.	<div style="text-align: center;"> <u>Jason Roberts</u>      <u>August 5, 1988</u>              (Signature)                      (Date)           </div>						
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FORM QAP-2.1.1, REV. 0

FIGURE 4.10-1, SAMPLE QA MANUAL TRANSMITTAL AND RECEIPT

manual revisions, and that he/she cannot participate in activities controlled by the manual until the receipt form is returned. The QA Manager shall inform the Administrator of Technical Programs of such action.

- 4.12.2 Completed receipt forms shall be filed in accordance with Section 5.0 of this QA procedure.

#### Uncontrolled Copies

- 4.13 The QA Manager may distribute uncontrolled copies of the QA manual or parts thereof at his/her discretion. Each copy shall be marked "Uncontrolled Copy, for Information Only."

#### Requesting NWPO QA Manuals

- 4.14 NWPO, Contractor and Subcontractor Personnel and Others may request inclusion on the manual distribution list by preparing a memorandum stating the volume requested and why the manual is needed and forwarding the memorandum to the QA Manager.

- 4.15 If the QA Manager approves the request, he/she shall sign the request as approver, date the signature, revise the appropriate distribution list to include the approved request, and forward the requested manual volume to the requestor per Section 4.10 of this QA procedure.

#### Return of NWPO QA Manuals

- 4.16 A Manual Holder no longer having a need for the QA Manual, shall return his/her assigned copy to the QA Manager with a covering memorandum/letter. The memorandum/letter shall state the reason for return of the manual, the controlled copy number, volume number, and the name of the manual holder.

- 4.17 The QA Manager shall remove the manual holder's name from the appropriate distribution list.

### 5.0 OUTPUT DOCUMENTS

- 5.1 The QA Manager shall ensure marking of the category file index designation on the following documents in accordance with procedure QAP-6.1, "Document Distribution List and File Index." The QA Manager shall also ensure transmittal to and processing of the documents in the NWPO Records Center in accordance with procedure QAP-17.1, "Quality Assurance Records."

- 5.1.1 NWPO QA Manual
- 5.1.2 Revisions to the NWPO QA Manual
- 5.1.3 QA manual distribution lists, completed QA transmittal and receipt forms
- 5.1.4 Reviewer comments and resolutions
- 5.2 The QA Manager shall ensure distribution of the NWPO QA Manual and revisions, thereof per Subsections 4.8 through 4.12 of this procedure.

## 6.0 REVISIONS

- 6.1 Revisions to the NWPO QA Manual shall be prepared, reviewed, approved, and distributed in accordance with the requirements stated in this procedure except that proposed deletions shall be prepared and processed by means of a memorandum that identifies and justifies the deletion.
  - 6.1.1 Individual pages of the QA manual shall not be revised and issued separately. When any part of the manual is revised, the entire part (e.g., QA procedure), shall be issued with a revised table of contents.
  - 6.1.2 Each revised portion of the NWPO QA Manual, except for flow charts and forms, shall be identified by boldface type or by other means when necessary. When a new revision is made, previous revision identification shall be deleted.

## 7.0 REFERENCES

- 7.1 NWPO QA Program, Section 02, Quality Assurance Program
- 7.2 10CFR50, Appendix B -Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants -1975
- 7.3 10CFR60, Subpart G -Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance -1983
- 7.4 ANSI/ASME NQA-1 -Quality Assurance Program Requirements for Nuclear Facilities -1986
- 7.5 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories -June 1984

## 8.0 FLOW CHART

None

STATE OF NEVADA  
AGENCY FOR NUCLEAR PROJECTS  
NUCLEAR WASTE PROJECT OFFICE  
QUALITY ASSURANCE PROCEDURE

~~QAP-2.2~~  
REVISION 0  
JUNE 10, 1988

TITLE: PREPARATION AND CONTROL OF TECHNICAL PROCEDURES

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for the preparation, review, and approval of technical procedures prepared by the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) or by NWPO's contractors and subcontractors. This procedure shall be used in conjunction with procedure QAP-2.1. Technical procedures are an integral part of the NWPO QA Manual.

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

2.1.1 Contractor

2.1.2 NWPO Quality Assurance Manual

2.1.3 Peer Review

2.1.4 Quality Assurance Procedure

2.1.5 Quality Assurance Program

2.1.6 Reviewer; Technical Reviewer

2.1.7 Subcontractor

2.1.8 Technical Procedure

3.0 INTERFACING PROCEDURES

3.1 QAP-2.1, "Preparation, Control, and Distribution of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual"

3.2 QAP-3.3, "Peer Reviews"

3.3 QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification"

3.4 QAP-6.1, "Document Distribution List and File Index"

3.5 QAP-17.1, "Quality Assurance Records"

#### 4.0 CONTROL OF TECHNICAL PROCEDURES

##### General

- 4.1 Technical activities performed by NWPO, contractors, subcontractors, and vendors/suppliers shall be controlled by technical procedures. Technical procedures governing NWPO technical activities shall be prepared by NWPO, and technical procedures governing contractor, subcontractor, or vendor/supplier activities shall be prepared by the appropriate contractors or subcontractors. See Subsection 4.18 of this procedure for discussion of technical procedures governing activities of a research or experimental nature.

##### Technical Procedures Prepared by NWPO

##### Authorization and Preparation

- 4.2 Technical activities performed by NWPO must be authorized by the Administrator of Technical Programs with the approval of the Executive Director, taking into account NWPO's objectives and policies. Technical procedures governing NWPO technical activities must be authorized by the Administrator of Technical Programs.
- 4.3 The Administrator of Technical Programs shall assign a technically qualified Preparer and independent technical Reviewer for each technical procedure and provide them with background information concerning the procedure and with a technical procedure number obtained from the QA Manager. (See procedure QAP-2.1, Figure 4.1-1.)
- 4.4 The Preparer shall prepare the NWPO technical procedure for the designated purpose in accordance with requirements of the NWPO QA Program, of procedure QAP-2.1, and of this procedure.
- 4.4.1 The Preparer shall transmit a copy of the NWPO technical procedure to the assigned technical reviewer for review and comment.

##### Review

- 4.5 The Reviewer of the technical procedure shall review the draft for technical adequacy and for conformance with requirements of this procedure.
- 4.5.1 If the Reviewer determines that the draft is technically inadequate and/or does not conform with the requirements of this procedure, he/she shall indicate his/her comment(s) on the draft and return the comment(s) to the Preparer. The Preparer shall resolve comments with the Reviewer, and, when all comments have been resolved, the Reviewer shall document his/her acceptance by signing and dating the review draft.

4.5.2 If the Reviewer determines that the draft procedure is technically adequate and conforms with requirements of this procedure, he/she shall document his/her acceptance by writing "no comments," his/her signature and date on the review draft.

4.6 The review draft containing the Reviewer's acceptance of the draft procedure as well as all comments and their resolution shall be processed in accordance with Section 5.0 of this QA procedure.

4.7 The Preparer shall ensure transmittal of an unsigned "clean" copy of the reviewed draft procedure to the Administrator of Technical Programs.

#### Approval

4.8 The Administrator of Technical Programs, QA Manager, and Executive Director, respectively, shall each review the draft technical procedure and when satisfied shall each sign the procedure as approver. Signature of the Administrator of Technical Programs signifies that the procedure was properly authorized and is technically adequate. Signature of the QA Manager signifies compliance with QA requirements and policies. Signature of the Executive Director signifies compliance with NWPO policies.

#### Distribution

4.9 The QA Manager shall incorporate approved NWPO technical procedures into the appropriate volume of the NWPO QA Manual and revise the appropriate table of contents. The procedures shall then be distributed in accordance with the requirements of procedure QAP-2.1 prior to start of activities governed by the procedure.

4.9.1 In on-the-job situations where the procedure user may not have access to the QA manual, the Administrator of Technical Programs shall provide access to the technical procedure(s).

#### Preparation of Contractor and Subcontractor Technical Procedures

##### Authorization and Preparation

4.10 Technical activities performed by contractors, subcontractors, and vendors/suppliers must be authorized by the Administrator of Technical Programs and Executive Director in consultation with the appropriate Project Manager and/or Principal Investigator taking into account commitments and obligations of the procurement document. Technical procedures governing activities of contractors, subcontractors, and vendors/suppliers must be authorized by the Principal Investigator or Project Manager and approved by the Project Manager, QA Manager, and Administrator of Technical Programs. See procedure QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification."

- 4.11 The Principal Investigator shall prepare the technical procedure or ensure preparation by another qualified person (e.g., from laboratory or other subcontractor staff).
- 4.11.1 The Principal Investigator shall obtain a technical procedure number from the QA Manager (See procedure QAP-2.1, Figure 4.1-1).
- 4.12 The Preparer shall prepare the technical procedure for the designated purpose in accordance with the requirements of the NWPO QA Program, of procedure QAP-2.1, and of this QA procedure.
- 4.12.1 The Preparer shall transmit a copy of the technical procedure to a reviewer assigned by the Project Manager.

Review

- 4.13 The technical procedure shall be reviewed as indicated in Subsections 4.5 through 4.6 of this procedure.
- 4.14 The Preparer shall ensure transmittal of an unsigned, reviewed "clean" copy of the technical procedure to the Project Manager.

Approval

- 4.15 The Project Manager, QA Manager, and Administrator of Technical Programs shall each review the draft technical procedure and when satisfied shall each sign the procedure as approver. Signature of the Project Manager signifies that the procedure was properly authorized and is technically adequate. Signature of the QA Manager signifies compliance with QA requirements. Signature of the Administrator of Technical Programs signifies authorization of the activity addressed by the procedure and compliance with NWPO policies.

Distribution

- 4.16 The QA Manager shall incorporate the approved technical procedure into the appropriate volume of the QA manual and revise the appropriate table of contents. The procedure shall then be distributed as indicated in procedure QAP-2.1 prior to start of activities governed by the procedure.
- 4.16.1 In on-the-job situations where the procedure user may not have access to the NWPO QA Manual, the Principal Investigator shall provide access to the procedure(s).

Format and Content of Technical Procedures

- 4.17 Technical procedures shall be organized as shown in Figure 4.17-1, "Outline for Technical Procedures."

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 AGENCY FOR NUCLEAR PROJECTS  
 NUCLEAR WASTE PROJECT OFFICE  
 QUALITY ASSURANCE PROCEDURE

QAP-2.2  
 REVISION 0  
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SECTION NUMBER	SECTION TITLE	DESCRIPTION/OUTLINE
1.0	<u>Purpose</u>	This section describes the scope and applicability of the technical procedure.
2.0	<u>Definitions</u>	This section defines specialized terminology used in the procedure. The Glossary is reserved for QA terminology.
3.0	<u>Interfacing Procedures</u>	This section lists any procedures which interface with the subject procedure, including a reference to relevant QA/technical procedures of the NWPO QA Manual.
4.0	<u>Activities Involved or Requirements</u>	<p>This section may be written as a sequential narration of the required activities involved in the procedure or as a description of the minimum requirements to control the activities. This section may be supplemented by appendices.</p> <p>When written as a sequential narration, the individuals performing the activities are identified by position title. When written as a description of the minimum requirements, the individual(s) responsible for ensuring that these requirements are implemented is identified by position title.</p> <p>The sequential narration or minimum requirements will be described in subsections identified by a numerical designation. The numerical designations follow in such a manner as to show the assignment of responsibility and the transition in activities, or to list each requirement. See procedure QAP-2.1, Figure 4.1-2.</p>
5.0	<u>Output Documents</u>	This section lists documents which are produced as a result of meeting the requirements of this procedure and indicates their disposition.
6.0	<u>Revisions</u>	This section describes how revisions to documents controlled by the procedure are to be processed.
7.0	<u>References</u>	This section identifies the section of the NWPO QA Program upon which the procedure is based, and includes any regulations, codes, standards, or other documents which form the basis of requirements included in the procedure. It also cites relevant technical and scientific references.
8.0	<u>Flow Chart (Optional)</u>	This section references the flow chart, if any, and identifies it by figure number. The flow chart enables the user of the technical procedure to read the sequential narration and follow the flow at the same time. The flow chart diagrammatically indicates the activities covered by the procedure. If no flow chart is used, the word "None" shall be written in Section 8.0. See Figure 4.17-2.
	<u>NOTE:</u>	See, also, procedure QAP-2.1, Figures 4.1-1 and 4.1-2.

FIGURE 4.17-1, OUTLINE FOR TECHNICAL PROCEDURES

Flow charts may be prepared, if applicable. If a flow chart is prepared, it shall be arranged according to the format shown in Figure 4.17-2, "Flow Chart Instructions and Legend."

- 4.18 Depending on the nature of the activity controlled, technical procedures should address applicable items listed in Figure 4.18-1, "Content of Technical Procedures." Procedures shall be written in enough detail to permit repetition of the activity by a knowledgeable independent investigator. Technical procedures addressing activities of a research or experimental nature, where techniques and methodologies must be developed, should follow guidelines presented in Section 02 of the NWPO QA Program.

#### Peer Review

- 4.19 Peer review, if needed, shall be performed in accordance with the requirements delineated in procedure QAP-3.3.

### 5.0 OUTPUT DOCUMENTS

- 5.1 The QA Manager shall ensure marking of the category file index designation on the following documents in accordance with procedure QAP-6.1, "Document Distribution List and File Index." The QA Manager shall also ensure transmittal to and processing of the documents in the NWPO Records Center in accordance with procedure QAP-17.1, "Quality Assurance Records."

- 5.1.1 Contractor and subcontractor technical procedures
- 5.1.2 NWPO technical procedures
- 5.1.3 Review drafts of technical procedures with review comments
- 5.1.4 Revisions to technical procedures

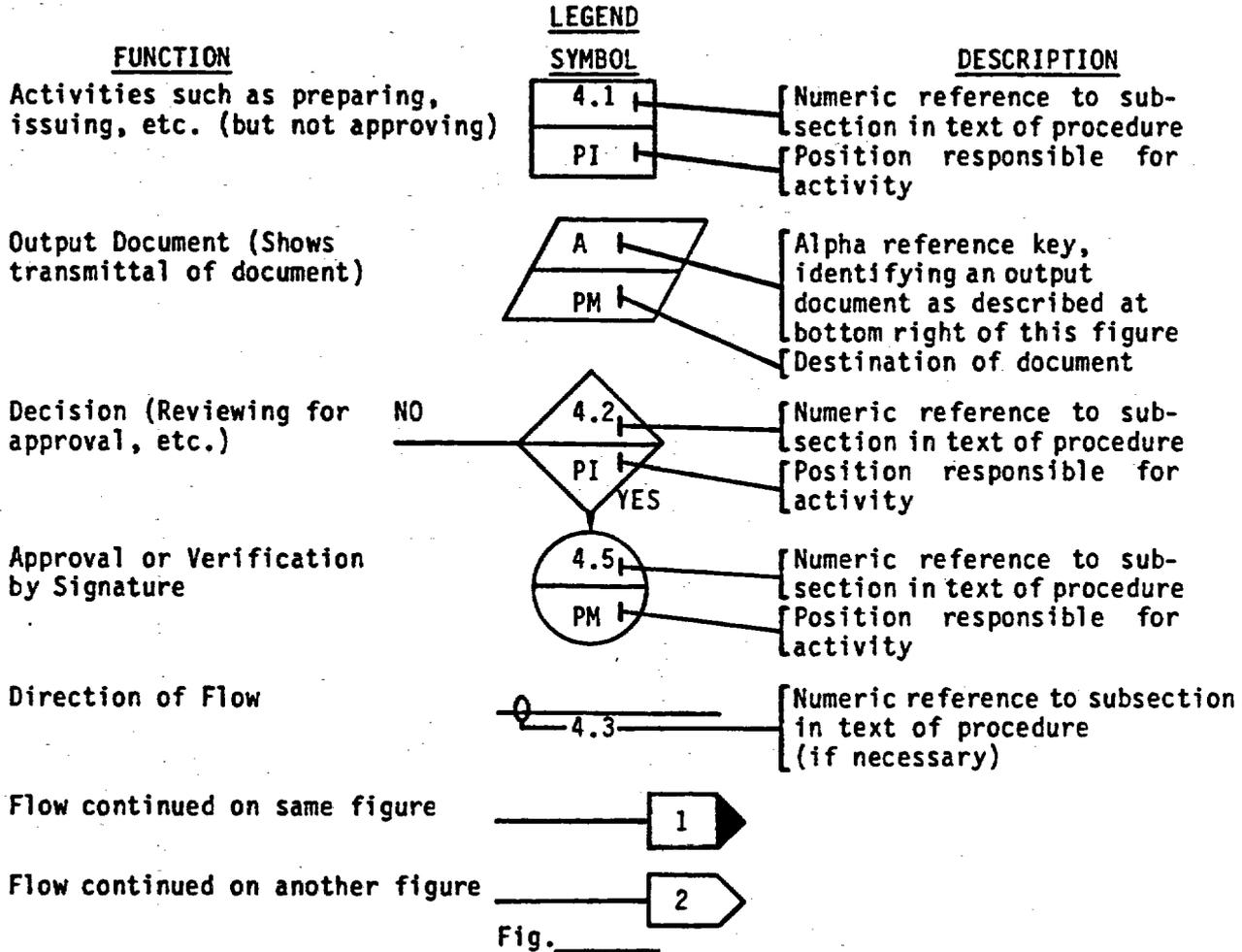
- 5.2 The QA Manager shall ensure distribution of technical procedures and revisions in the same way as prescribed by Subsections 4.16 and 4.16.1, herein.

### 6.0 REVISIONS

- 6.1 Revisions to technical procedures shall be processed and distributed in the same way as the original issue and in conformity with procedure QAP-2.1 as applicable.

INSTRUCTIONS

1. Flow chart information should flow from top-to-bottom.
2. Acronyms or abbreviations may be used on flow charts to identify the organization (such as NWPO, Desert Research Institute, etc.), responsible for an activity. Acronyms and abbreviations shall be defined on the flow chart.



TYPICAL LIST OF DEFINITIONS

DEFINITIONS

PI - Principal Investigator  
 PM - Project Manager

TYPICAL OUTPUT DOCUMENT BLOCK

OUTPUT DOCUMENTS REQUIRED		
KEY	FORM NO.	TITLE
A	----	Technical Report

FIGURE 4.17-2, FLOW CHART INSTRUCTIONS AND LEGEND

STATE OF NEVADA  
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This figure is intended to supplement the requirements of Figure 4.17-1 and of procedure QAP-2.2 in general but is not meant to be all inclusive. Some items may not be considered for inclusion depending on the nature of the activity described. Items may be addressed directly or by citation of other procedures.

Identify the individual(s) assigning responsibility for activity.

Provide a step-by-step narrative of the activities to be performed identifying the personnel performing the activities by position title and/or provide a description of minimum requirements to control the activity.

Identify subactivities controlled by other QA or technical procedures, and indicate how and by whom subactivities will be accomplished.

- Examples: a. 4.3 All calculations shall be manual and shall be prepared, reviewed, and approved in accordance with procedure QAP-3.1.
- 4.4 The Principal Investigator shall prepare the calculations and the Project Manager shall designate the Reviewer and the Approver.
- b. 4.17 The Associate Investigator shall ensure calibration of all gauges in accordance with Technical Procedure ATP-12.1.

Identify all output documents and samples, and indicate their disposition and destination, and identify responsible persons by position title. (See procedures QAP-6.1 and QAP-17.1.) A copy of all documents must be sent to the QA Manager for filing and storage per procedure QAP-17.1, and to others per procedure QAP-6.1. See glossary definitions of Output Document and Input/Support Document.

- Examples: a. 4.10 The Observer shall record his/her observations on field log forms as indicated in Technical Procedure ATP-10.1, and shall forward the completed log to the Principal Investigator.
- 4.11 The Principal Investigator shall sign the log as approver when the log is satisfactory, and shall mark it with the category file index designation per procedure QAP-6.1.
- 4.12 The Principal Investigator shall then transmit the log to the QA Manager for processing in the NWPO Records Center per procedure QAP-17.1. He/she shall also distribute the log to persons identified on the document distribution list per procedure QAP-6.1.
- b. 4.15 The Inspector shall retain all drill cuttings, envelopes, and sample boxes in accordance with Technical Procedure BTP-8.1. He/she shall instruct the drilling foreman to package the samples and ship them to the Desert Research Institute storage facility in accordance with Technical Procedure BTP-13.1.

FIGURE 4.18-1, CONTENT OF TECHNICAL PROCEDURES  
(Continued on Page 9 of 10)

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Indicate special requirements, if any, of personnel performing the activity beyond those required by procedure QAP-1.1, "Position Descriptions, Employee Experience Records, and Qualification Statements."

Be certain that technical procedures conform to stated program requirements. For example, any procedure addressing sample handling, storage, and shipping must honor the stated requirements of Section 13 of the NWPO QA Program. Any procedure addressing calibration of measuring and test equipment must honor the requirements of Section 12.

Identify the type of data to be acquired. Address data accuracy, precision, and potential sources of error. As appropriate, indicate criteria for selection of particular "raw" data for analysis and for selection of method of analysis.

Indicate how data and conclusions will be recorded (e.g., laboratory notebook) and presented (e.g., maps, tables, graphs, technical report, etc.). Provide for recording such that data are readily traceable to the corresponding generating activity.

As applicable, technical procedures must address the following general topics directly and/or by reference to other QA or technical procedures:

- Drawings, including geologic maps
- Calculations
- Technical Reports
- Peer Reviews
- Calibration
- Sample Identification, Handling, Shipment and Storage
- Special Apparatus and/or Equipment
- Inspection and Surveillance/Monitoring

Discussion of methodology of activity, including a description of experimental techniques, if any. Include special instructions and drawings, if needed.

Identify the quantitative and qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Include the type of equipment used, if any.

Describe the calibration of measuring and test equipment, if any, including identification and marking of equipment along with statement of traceability to standard.

Include requirement that the Administrator of Technical Programs, Project Manager, Principal Investigator, Laboratory Director, or Designee ensure documented preparation, review/approval, or verification, of documents generated by the procedure.

Describe analytical techniques, if applicable.

Provide for suitable environmental conditions for accomplishing the activity, such as cleanliness, if applicable.

Provide for assurance that all prerequisites for the given activity have been satisfied.

Require verification of quality by inspection and testing, if applicable.

Describe control of computer codes and tapes, as relevant.

**FIGURE 4.18-1, CONTENT OF TECHNICAL PROCEDURES  
(Continued from Page 8 of 10)**

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7.0 REFERENCES

- 7.1 NWPO QA Program, Section 02, Quality Assurance Program
- 7.2 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975
- 7.3 10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983
- 7.4 ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986
- 7.5 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

8.0 FLOW CHART

None

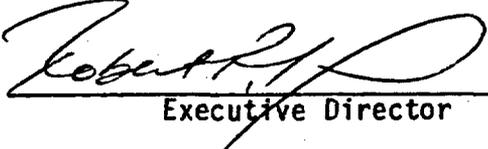
STATE OF NEVADA  
AGENCY FOR NUCLEAR PROJECTS  
NUCLEAR WASTE PROJECT OFFICE  
QUALITY ASSURANCE PROCEDURE

QAP-2.3  
REVISION 0  
JUNE 10, 1988

TITLE: INDOCTRINATION AND TRAINING IN THE AGENCY FOR NUCLEAR  
PROJECTS/NUCLEAR WASTE PROJECT OFFICE QUALITY ASSURANCE MANUAL

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for the indoctrination and training of individuals in the purpose, scope, and implementation of the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) QA Manual. The procedure applies to NWPO and its contractors' and subcontractors' personnel. It does not address specialized training, nor does it apply to peer reviewers.

2.0 DEFINITIONS

2.1 See the Glossary for the following definitions:

2.1.1 NWPO Quality Assurance Manual

2.1.2 Quality Assurance Procedure

2.1.3 Significant Activity

2.1.4 Technical Procedure

3.0 INTERFACING PROCEDURES

3.1 QAP-1.1, "Position Titles, Position Descriptions, Employee Experience Records, and Qualification Statements"

3.2 QAP-6.1, "Project File Index and Project Distribution List"

3.3 QAP-17.1, "Quality Assurance Records"

4.0 TRAINING

General

4.1 The Administrator of Technical Programs, the Project Managers, and the QA Manager shall ensure that no NWPO, contractor, or subcontractor individual performs significant activities governed by the NWPO QA Program until that individual has satisfactorily completed training in the QA program, and in those QA and technical procedures applicable to his/her responsibilities.

- 4.2 There shall be three kinds of training in the NWPO QA Manual:
- Training in the NWPO QA Manual, except technical procedures (conducted by the QA Manager)
  - Training in technical procedures used by NWPO personnel (conducted by the Administrator of Technical Programs)
  - Training in technical procedures used by contractor or subcontractor personnel (conducted by the Project Manager, Principal Investigator, or designee).

- 4.2.1 In particular, personnel shall require training or retraining as appropriate when one or more of the following criteria applies:

When the QA Manager, Administrator of Technical Programs, Project Manager, Principal Investigator, or designee determines that training is necessary

When an individual is promoted, transferred, or loaned from one position or organization to another and his/her changed responsibilities indicate the need for further training

When an individual is hired or rehired

When an individual is contracted for work which is controlled by the NWPO QA Program

When an individual exhibits an inadequate proficiency in implementing the NWPO QA Program, QA procedures, or technical procedures (e.g., as determined from audit reports or examination results)

When an individual's responsibilities are substantially affected by a revision to the NWPO QA Program, QA procedures, or technical procedures.

Exemptions from Training

- 4.3 The QA Manager and Executive Director may exempt certain individuals from QA training in whole or in part.

- 4.3.1 Exemptions shall be based on the individual's knowledge, familiarity, and experience with the NWPO program and procedures. For example, the Preparer or Reviewer of a technical procedure may be exempted from training in the procedure prepared or reviewed.

- 4.3.2 Exemptions shall be documented by memoranda prepared and signed by both the QA Manager and the Executive Director after consultation with the Administrator of Technical Programs, Project Managers, or Principal Investigators, as appropriate.

Training in the NWPO QA Manual Except Technical Procedures

- 4.4 The QA Manager shall establish and supervise the program for indoctrinating and training individuals in the purpose, scope, and implementation of the NWPO QA Program and QA procedures, and shall prepare, sign, and date course/lesson plans.
- 4.4.1 The QA Manager shall prepare and maintain a training schedule, and a list of persons requiring training (and training required) and a list of persons who have completed training.
- 4.4.2 Training shall be required to the extent necessary to assure that each individual has achieved and maintained a suitable knowledge of the requirements of the NWPO QA Program and of QA procedures relevant to his/her responsibilities. The QA Manager shall consult position descriptions and with appropriate supervisors concerning selection of training subject matter.
- 4.5 The QA Manager shall conduct training in classes or in informal training sessions using one or more of the following techniques:
- Reading assignments
  - Live or videotaped lectures
  - Discussions
  - Slide presentations
  - Other suitable method.
- 4.6 Each Trainee shall sign an attendance record during each training class, or informal training session and the attendance record shall be filed by the QA Manager per Section 5.0, herein. Attendance shall be mandatory.
- 4.7 The QA Manager shall use written or oral examinations or personal discussion to establish suitable knowledge of the subject matter on the part of the trainee.
- 4.8 Satisfactory completion of training shall be documented by a memorandum written by the QA Manager. The following information shall be included in the memorandum as a minimum:
- Name of individual trained
  - Date(s) of training
  - Subject of training
  - Statement that individual has satisfactorily completed training
  - Signature of QA Manager and date.

4.9 The QA Manager shall provide the Executive Director, Administrator of Technical Programs, and the Project Managers with a list of persons who have successfully completed training, including date of training and a list of non-attendees at scheduled training classes or informal training sessions. The Executive Director, Administrator of Technical Programs, or Project Manager shall take appropriate action with respect to untrained persons in accordance with Subsection 4.1 herein.

4.9.1 Trainees shall be informed whether they have passed the training course or not.

4.10 Training documentation shall be processed and distributed as indicated in Section 5.0.

Training in Technical Procedures

4.11 The Administrator of Technical Programs shall prepare a list of NWPO persons requiring training in technical procedures and the procedures in which training is required, and the Project Managers, Principal Investigators, or Designee, as appropriate, shall prepare a similar list for contractor and subcontractor persons.

4.11.1 Copies of both lists shall be sent to the QA Manager.

4.12 The Administrator of Technical Programs, Project Managers, Principal Investigators, or Designees, as applicable, shall serve as Training Instructors and conduct the required training.

4.12.1 Training shall be performed by informal methods, such as meetings, conferences, or personal discussion, to the extent necessary to ensure that the individual has achieved and maintained a suitable knowledge of the technical procedure(s) as it applies to his/her responsibilities. Oral or written examinations may be given if needed. Attendance shall be documented.

4.12.2 Training of Training Instructors shall be conducted by the Preparer(s) of the particular technical procedure, as appropriate, or may be waived in accordance with Subsection 4.3.

4.13 Satisfactory completion of technical training shall be documented by a memorandum, written by the Training Instructor conducting the training. The following information shall be included in the memorandum as a minimum:

Name of individual trained

Date(s) of training

Subject of training

Statement that individual has satisfactorily completed training

Signature of Training Instructor and date.

- 4.14 The Training Instructor shall forward to the Project Manager a list of persons who have satisfactorily completed training and their training memoranda and a list of non-attendees at training sessions.
- 4.15 The Project Manager shall transmit this information to the QA Manager, and the Project Manager, QA Manager, and Executive Director shall take appropriate action in accordance with Subsection 4.1 herein with respect to untrained persons.
- 4.15.1 When the Training Instructor is the Administrator of Technical Programs, he/she shall transmit the documentation to the QA Manager, and the QA Manager and Administrator of Technical Programs shall take appropriate action.
- 4.16 Training documentation shall be processed and distributed as indicated by Section 5.0.
- 5.0 OUTPUT DOCUMENTS
- 5.1 The QA Manager shall ensure marking of the following training documents with the category file index designation per procedure QAP-6.1, "Document Distribution List and File Index" and transmittal processing, filing, and retention of the documents in the NWPO Records Center per procedure QAP-17.1, "Quality Assurance Records."
- 5.1.1 Lists of personnel requiring QA program and QA procedure training
- 5.1.2 Lists of personnel requiring technical procedure training
- 5.1.3 Lists of personnel who have completed training
- 5.1.4 Attendance records and training schedules
- 5.1.5 Training completion memoranda
- 5.1.6 Exemptions from training (memoranda)
- 5.1.7 Examinations (if any)
- 5.1.8 Course/lesson plans
- 5.2 The QA Manager shall also ensure appropriate distribution of the above documents in accordance with procedure QAP-6.1, "Document Distribution List and File Index."
- 5.2.1 Document Recipients shall maintain documents in file as needed to facilitate audits.

6.0 REVISIONS

6.1 The QA Manager shall ensure that persons who perform significant activities governed by the NWPO QA Program are informed of and receive training in significantly revised portions of the QA manual.

Indoctrination and training in revised portions of the QA manual as well as revisions to training documents shall be accomplished in the same way as indoctrination and training in the original manual.

6.2 Course/lesson plans, examinations, lists of persons requiring training and other training documents shall be revised as necessary in response to changes in the NWPO QA Manual and in the same manner as the original. Revised documents shall be issued in their entirety.

6.3 Revised portions of documents shall be indicated by bold face type or by other means as necessary and previous revision identification shall be deleted.

6.4 Recipients of revised documents shall promptly destroy superseded documents or promptly mark them "Void" or "Superseded."

6.5 The Administrator of Technical Programs, Project Managers, Principal Investigators, or Designees shall monitor performance of personnel and institute retraining or other appropriate action as necessary.

7.0 REFERENCES

7.1 NWPO QA Program Section 02, Quality Assurance Program

7.2 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975

7.3 10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983

7.4 ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986

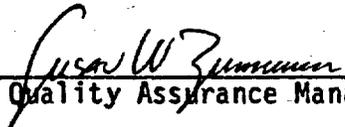
7.5 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

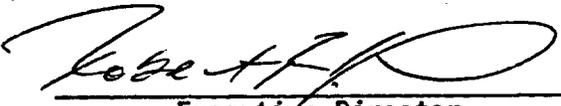
8.0 FLOW CHART

None

TITLE: MANAGEMENT ASSESSMENT OF THE AGENCY FOR NUCLEAR PROJECTS/NUCLEAR  
WASTE PROJECT OFFICE QUALITY ASSURANCE PROGRAM

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the methods used by senior management of the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) to assess the scope, status, adequacy, and compliance of the NWPO Quality Assurance (QA) Program with 10CFR50, Appendix B, and other controlling documents as they apply to NWPO's program and objectives. This assessment is distinct from audits performed by the QA Manager in connection with procedure QAP-18.1, "Audits."

2.0 DEFINITIONS

- 2.1 Refer to the Glossary for the following definitions:
- 2.1.1 Audit Finding
  - 2.1.2 Audit Observation
  - 2.1.3 Corrective Action Report
  - 2.1.4 Nonconformance Report

3.0 INTERFACING PROCEDURES

- 3.1 QAP-6.1, "Document Distribution List and File Index"
- 3.2 QAP-15.1, "Nonconformances"
- 3.3 QAP-16.1, "Corrective Action"
- 3.4 QAP-17.1, "Quality Assurance Records"
- 3.5 QAP-18.1, "Audits"

4.0 PERFORMANCE OF MANAGEMENT ASSESSMENT OF COMPLIANCE

General

4.1 The Executive Director shall be responsible for an annual management assessment of the NWPO QA Program and shall base his/her assessment on the following considerations:

Close contact with the QA program through frequent informal meetings and reports from the QA Manager and other program participants

An annual effectivity report prepared by the QA Manager.

4.1.1 The Executive Director may also initiate a management audit of the QA Manager's activities, to be performed by the Executive Director and/or an outside consultant retained by NWPO, and use the results in his/her assessment.

4.2 The Executive Director shall document his/her program assessment either (1) by preparing a report based on his/her contact with the QA program, on the effectivity report, and on the management audit, if any, or (2) by signing a similar assessment prepared by an outside consultant.

Contact with Program Activities

4.3 The Executive Director shall maintain close and frequent contact with the QA program as indicated in Subsection 4.1. He/she shall examine selected audit reports and audit report responses, nonconformance reports, corrective action reports, and trend analysis reports to assess the status of compliance with the NWPO QA Program and procedures.

Effectivity Report

4.4 The QA Manager shall prepare an annual effectivity report. As a minimum, the report shall include the following information:

Title - "Report on Effectivity of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Program"

Period covered by the report

Issue date of the report

Page identification on each page of the report, e.g., Page 4 of 11.

The signature of the QA Manager.

The report shall also contain a statement of the effectiveness of the QA program and procedures in assuring compliance of NWPO, contractor, subcontractor, and vendor/supplier activities with NWPO objectives and with 10CFR50, Appendix B, and other master documents referenced in Section 7.0, herein. Suggestions for improvement of the NWPO QA Program and procedures and/or their implementation shall likewise be included, as appropriate.

- 4.5 The QA Manager shall distribute the report to the Executive Director and others as indicated in Section 5.0, herein.

Optional Management Audit

- 4.6 At the discretion of the Executive Director, an audit team led by the Executive Director and/or an Outside Consultant retained by NWPO may perform audits of the QA Manager's activities using Section 18 of the program and procedure QAP-18.1, "Audits," as a guide. The purpose of the audits shall be to examine objective evidence of the QA Manager's performance to determine if he/she is satisfactorily discharging the responsibilities assigned by the NWPO QA Program and procedures.

- 4.7 If conducted, the audit shall include the following elements:

Preaudit and postaudit conference with the QA Manager and with others as needed

Audit checklist

Audit report.

- 4.7.1 The audit checklist shall include questions to establish completeness and effectiveness of the QA Manager's activities.

- 4.8 The Audit Team shall conduct the audit by interviewing the QA Manager and others, as needed, using the audit checklist, and by examination of documented evidence. Departures from the checklist shall be permitted provided they are documented.

- 4.9 On completion of the audit, the Executive Director or the Audit Team Leader of the Outside Consultant shall prepare an audit report. As a minimum, the audit report shall contain the following information:

Title - Management Audit of QA Manager's activities, Agency for Nuclear Projects/Nuclear Waste Project Office

Date(s) of audit

STATE OF NEVADA  
AGENCY FOR NUCLEAR PROJECTS  
NUCLEAR WASTE PROJECT OFFICE  
QUALITY ASSURANCE PROCEDURE

QAP-2.4  
REVISION 0  
JUNE 10, 1988

Purpose of audit - To furnish the Executive Director (1) with an assessment of the QA Manager's overall compliance with the Agency for Nuclear Projects/Nuclear Waste Project Office QA Program and implementing procedures and (2) with an evaluation of how well the QA Manager is conducting his/her assigned activities

Audit Team Members

Individuals interviewed

Any audit findings, audit observations, or nonconformances (see procedure QAP-18.1)

A summary of audit results, positive and negative, and conclusions and recommendations, including a statement evaluating the scope, status, adequacy, and compliance of the QA program as it applies to the QA Manager's activities.

- 4.10 The audit report shall be signed, approved as indicated in Subsections 4.10.1 and 4.10.2 below, and sent to the QA Manager.
- 4.10.1 When the Audit Team is headed by the Executive Director, the Executive Director shall sign the report as approver after resolving any comments with other team members, if any.
- 4.10.2 When the audit is conducted by an outside consultant, the Audit Team Leader shall sign the report as preparer, and the Executive Director shall sign the report as approver after resolving all comments.
- 4.11 The Executive Director shall require the QA Manager to determine and schedule appropriate corrective action including action to identify the root cause and to prevent recurrence of the condition described in the audit finding, audit observation, or nonconformance, and to respond within 30 calendar days after receipt. The response shall clearly state the corrective action taken or to be taken to correct the condition and the corrective action taken or to be taken to prevent recurrence, along with the scheduled completion date of that action. In special cases, the Executive Director may require faster response and implementation of corrective action.
- 4.11.1 Corrective action shall be verified by the Executive Director or his Designee by either written communications or special follow-up audit reports stating the corrective action taken and the date the action was completed.
- 4.12 The QA Manager shall distribute the audit report as indicated in Section 5.0 herein.

Management Report

- 4.13 The Executive Director or Outside Consultant shall be responsible for the preparation of an annual management report on the status and adequacy of the NWPO QA Program and procedures as indicated in Subsection 4.2. The basis for the report shall be the effectivity report prepared by the QA Manager, the Executive Director's close contact with the QA program, and the optional management audit, if any, of QA Manager activities. The report shall contain recommendations for correcting compliance problems, if any.
- 4.13.1 When the report is prepared by the Executive Director, the Executive Director shall forward the report to the QA Manager for comment and, when all comments are resolved, shall sign the report as approver.
- 4.13.2 When the report is prepared by an outside consultant, the Preparer shall sign the report and forward it to the Executive Director and QA Manager. When all comments have been resolved, the Executive Director shall sign the report as approver.
- 4.14 The QA Manager shall distribute the management report as indicated in Section 5.0 herein.
- 4.15 The QA Manager shall be responsible for implementation of any corrective action or recommendations of the management report, for any recommendations taken from the effectivity report, as well as for any corrective action resulting from any management audit that may have been performed. The Executive Director shall be responsible for documented tracking and verification of implementation.

5.0 OUTPUT DOCUMENTS

- 5.1 The QA Manager shall ensure marking of the category file index designation on the following documents and distribution in accordance with procedure QAP-6.1, "Document Distribution List and File Index." The QA Manager shall also ensure transmittal and processing of the documents in the NWPO Records Center in accordance with procedure QAP-17.1, "QA Records"
- 5.1.1 Audit checklist (if any)
- 5.1.2 Audit and follow-up audit reports and audit report responses (if any)
- 5.1.3 Effectivity report
- 5.1.4 Management report

STATE OF NEVADA  
AGENCY FOR NUCLEAR PROJECTS  
NUCLEAR WASTE PROJECT OFFICE  
QUALITY ASSURANCE PROCEDURE

QAP-2.4  
REVISION 0  
JUNE 10, 1988

5.1.5 Corrective action and verification of corrective action documentation and related documents

5.2 Recipients shall maintain the documents in file as needed to facilitate audits.

6.0 REVISIONS

6.1 Revisions to effectivity reports, to management reports, and to any audit documentation shall be processed in the same manner as the original issue. Revised documents shall be issued in their entirety.

6.2 Revised portions of documents shall be indicated by bold face type or by other means as necessary and previous revision identifications shall be deleted.

6.3 Recipients of revised documents shall promptly destroy superseded copies or promptly mark them "Void," or "Superseded."

7.0 REFERENCES

7.1 NWPO QA Program, Section 02, Quality Assurance Program

7.2 NWPO QA Program, Section 15, Nonconformances

7.3 NWPO QA Program, Section 16, Corrective Action

7.4 NWPO QA Program, Section 18, Audits

7.5 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975

7.6 10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983

7.7 ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986

7.8 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

8.0 FLOW CHART

None

STATE OF NEVADA  
AGENCY FOR NUCLEAR PROJECTS  
NUCLEAR WASTE PROJECT OFFICE  
QUALITY ASSURANCE PROCEDURE

QAP-2.5  
REVISION 0  
JUNE 10, 1988

TITLE: REVIEW OF DOCUMENTS AND TECHNICAL INFORMATION FOR IMPACT ON THE AGENCY  
FOR NUCLEAR PROJECTS/NUCLEAR WASTE PROJECT OFFICE QUALITY ASSURANCE  
MANUAL

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure provides a mechanism for systematic review of U.S. Nuclear Regulatory Commission (NRC), ANSI/ASME, and other documents for their potential impact on the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual (NWPO QA Manual). It also provides for review of current technical and scientific information for its impact on technical activities and technical procedures. The purpose of these reviews is to keep the NWPO QA Manual current with the latest NRC and industry practice with respect to characterization of high level nuclear waste repositories.

2.0 DEFINITIONS

None

3.0 INTERFACING PROCEDURES

3.1 QAP-2.1, "Preparation, Control, and Distribution of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual"

3.2 QAP-2.2, "Preparation and Control of Technical Procedures"

3.3 QAP-6.1, "Document Distribution List and File Index"

3.4 QAP-17.1, "Quality Assurance Records"

4.0 REVIEW AND CONTROL OF DOCUMENTS

General

4.1 There shall be two types of reviews: (1) reviews initiated by the QA Manager and (2) reviews initiated by the Administrator of Technical Programs or by the Principal Investigators, Project Managers, Laboratory Directors and/or other contractor or subcontractor personnel. The first type of review encompasses, but is not limited

to, documents of an administrative or procedural nature; the second type of review encompasses, but is not limited to, documents, data, and other information of a technical nature.

Document Review Initiated by the QA Manager

- 4.2 The QA Manager shall obtain current revisions of NRC, ANSI/ASME, and other documents addressing subject matter encompassed by the QA program and QA procedures, and maintain the documents in file up-to-date.
- 4.2.1 Among the types of documents to be obtained are:
- Federal Regulations such as 10CFR50, Appendix B, and 10CFR60
  - NRC Review Plans such as "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Facilities"
  - NRC Reports such as NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High Level Waste Management"
  - NRC Generic Technical Positions (Draft and Final) such as "Draft Generic Technical Position on Peer Review for High Level Nuclear Waste Repositories"
  - U.S. Department of Energy (DOE) Quality Assurance Program Plans, Quality Assurance Plans, and procedures such as (1) "NVO-196-18, Waste Management Project Office Quality Assurance Plan" (2) "NVO-196-17, Nevada Nuclear Waste Storage Investigations Project Quality Assurance Plan" and (3) "QMP-06-01, Document Review and Approval"
  - Industry Consensus Standards and codes such as ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities"
  - Miscellaneous Documents such as papers presented at meetings of the American Society for Quality Control (ASQC) and of other technical organizations.
- 4.3 The QA Manager shall review the documents for their impact on the NWPO QA Manual and prepare written comments or a statement of "no comments" as detailed in Subsection 4.5.1.
- 4.4 The QA Manager shall also circulate copies of the documents and a written request for review and comment to the Administrator of Technical Programs, to the Executive Director, and, as appropriate, to others such as the Project Managers and Principal Investigators.
- 4.5 The Recipients shall review the documents for their impact on the NWPO QA Manual and return the documents and their written comments (or a statement of "no comments") to the QA Manager.

4.5.1 As appropriate, the comments shall consider consistency of the QA manual with governmental and industry regulations, standards, and guides and shall recommend manual revisions as required.

4.6 After ensuring receipt, the QA Manager shall compile and review all comments and, as appropriate, he/she shall initiate or ensure initiation of manual revisions in accordance with procedures QAP-2.1, "Preparation, Control, and Distribution of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual," or QAP-2.2, "Preparation and Control of Technical Procedures." The comments shall be filed as indicated in Section 5.0, herein.

Document Review Initiated by the Administrator of Technical Programs or by Principal Investigators, Project Managers, and/or other Contractor or Subcontractor Personnel

4.7 The Administrator of Technical Programs, Principal Investigators, Project Managers, Laboratory Directors, and/or Others, as appropriate, shall review technical documents and other information and, in general, maintain contact with current scientific and technical developments bearing on their technical activities.

4.7.1 Methods that may be used to satisfy document review responsibilities and to maintain scientific and technical contact include, but are not limited to, the following:

Reading of professional journals and books

Reading of unpublished papers

Documented attendance at scientific and professional meetings

Documented participation in short courses

Informal visits and contacts with knowledgeable persons (documented by summary memoranda).

4.8 The Administrator of Technical Programs, Principal Investigators, Project Managers, Laboratory Directors, and/or Others shall consider the effects of new technical documents and developments on their technical activities, the controlling technical procedures, and on the QA manual in general.

As appropriate, they shall initiate revisions to the QA manual in accordance with procedures QAP-2.2 and QAP-2.1. Attendance and participation documentation and summary memoranda referred to in Subsection 4.7.1 shall be sent to the QA Manager.

**5.0**      **OUTPUT DOCUMENTS**

5.1      The QA Manager shall ensure marking of the category file index designation on the following documents and distribution to persons listed on the document distribution list in accordance with procedure QAP-6.1, "Document Distribution List and File Index." The QA Manager shall also ensure transmittal and processing of the documents in the NWPO Records Center facility in accordance with procedure QAP-17.1, "Quality Assurance Records."

5.1.1    Review comment documentation (Subsections 4.3 and 4.5)

5.1.2    Attendance and similar documentation (Subsection 4.7.1)

5.2      Document Recipients shall maintain the documents in file as needed to facilitate audits.

**6.0**      **REVISIONS**

6.1      Review of revised documents shall be accomplished in the same manner as for the original issues. Revisions to review comment documentation shall be accomplished in the same manner as for the original issue. Documents shall be issued in their entirety.

**7.0**      **REFERENCES**

7.1      NWPO QA Program, Section 02, Quality Assurance Program

7.2      10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975

7.3      10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983

7.4      ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986

7.5      U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

**8.0**      **FLOW CHART**

None

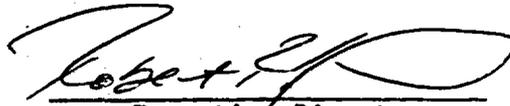
STATE OF NEVADA  
AGENCY FOR NUCLEAR PROJECTS  
NUCLEAR WASTE PROJECT OFFICE  
QUALITY ASSURANCE PROCEDURE

QAP-3.1  
REVISION 0  
JUNE 10, 1988

TITLE: CALCULATIONS

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the Quality Assurance (QA) requirements for the preparation, review, and approval of calculations generated by the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) and its contractors and subcontractors in their data acquisition, data analysis, and research activities.

The procedure addresses calculations included in technical reports, in whole or in part, and calculations issued as independent output documents (i.e., not included in reports). It does not address calculations included in input/support documents nor calculations related to peer reviews (see procedure QAP-3.3, "Peer Reviews").

The procedure governs computer produced plots and drawings and computer sorting and rearrangement of data such as in seismic evaluation or imagery analysis. The procedure adheres to the intent of applicable parts of NUREG-0856, referenced in Section 7.0, herein. Requirements of this procedure may be supplemented or modified by technical procedures issued in accordance with procedure QAP-2.2, "Preparation and Control of Technical Procedures."

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

2.1.1 Approver

2.1.2 Component Model

2.1.3 Computer Code

2.1.4 Computer Output

2.1.5 Input Data

2.1.6 Input/Support Document

2.1.7 Mathematical Model

2.1.8 Model

2.1.9 Numerical Method

- 2.1.10 Numerical Model
- 2.1.11 Output Document
- 2.1.12 Preparer
- 2.1.13 Reviewer; Technical Reviewer
- 2.1.14 Validation
- 2.1.15 Verification

**3.0 INTERFACING PROCEDURES**

- 3.1 QAP-2.2, "Preparation and Control of Technical Procedures"
- 3.2 QAP-3.2, "Technical Reports"
- 3.3 QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification"
- 3.4 QAP-6.1, "Document Distribution List and File Index"
- 3.5 QAP-6.2, "Progress Reports and Master Document Lists"
- 3.6 QAP-17.1, "Quality Assurance Records"

**4.0 PREPARATION, REVIEW, APPROVAL, AND DISTRIBUTION**

General Statement

- 4.1 Calculations issued independently of technical reports are addressed in Subsections 4.2 through 4.13, herein; calculations included in technical reports (issued per procedure QAP-3.2) are addressed in Subsections 4.14 through 4.14.6 and in Subsections 5.4 and 6.7. In cases where only a part of a calculation has been included in a technical report the calculation shall be processed as an independent calculation (see Subsection 4.15).

Independent Calculations

Preparation

- 4.2 The Administrator of Technical Programs, Project Managers, Principal Investigators, Laboratory Directors, or Designees shall identify the technical activities within their respective control requiring calculations, and shall assign a Preparer, independent technical Reviewer, and Approver for each calculation.

- 4.2.1 Procurement documents shall be consulted, as needed, in making this identification.
- 4.2.2 The Administrator of Technical Programs, Project Manager, Principal Investigator, Laboratory Director, or Designee may appoint himself/herself as Preparer, Reviewer, or Approver, but the Reviewer shall not be the Preparer's immediate supervisor except under special circumstances. (See Section 03 of the QA program.) See the Glossary definition of Reviewer; Technical Reviewer.
- 4.3 The Preparer shall assemble the necessary input data and prepare the calculation in accordance with the criteria indicated in Subsections 4.3.1 through 4.3.8, below, and any additional supplemental criteria indicated in technical procedures.

Format

- 4.3.1 The Preparer may use any suitable, readily reproducible calculation format provided the following information is included:

Purpose of the calculation  
NWPO - Yucca Mountain identification  
Computer code (if applicable)  
Signatures and dates of signatures of Preparer, Reviewer(s), and Approver.

(The above items may be placed on a cover page.)

Each page of the calculation or eye-readable title of each computer output shall contain the following information:

Unique calculation number  
Revision identification (the original issue is Revision 0)  
Responsible organization (e.g., Desert Research Institute)  
Page number and total number of pages (e.g., Page 2 of 3).

Input Data and Organization of Calculation

- 4.3.2 Insofar as possible, the Preparer shall use current and verified input data. The Preparer shall identify, after the statement of purpose, the input data used including assumptions that establish the basis of the calculation. The Preparer shall also identify unverified assumptions, data, or technical/scientific judgments, if any, indicating those items expected to be verified in the future as anticipated additional data or methods of analysis become available. See Subsection 4.11.1.

Sources of input data may include, for example, field or laboratory notes or other input/support documents, or other calculations.

External sources of input may include recognized industry or professional publications, as well as commercial sources, provided the Preparer is satisfied with their reliability and applicability to the purpose of the calculation. External sources of input shall be referenced in the calculation.

4.3.3 Calculations shall be legibly and logically composed such that a person technically qualified in the subject can review and understand the calculation without recourse to the Preparer. Each step in the calculation shall be recorded in a neat and orderly manner.

4.3.4 The Preparer shall reference and identify the sources of formulae not in ordinary technical/scientific usage and define symbols not generally understood.

#### Computer-Aided Calculations

4.3.5 Computer output shall be identified by a unique calculation number, computer run date, and computer code.

4.3.6 The Preparer shall ensure that computer codes based on sound physical and mathematical principles are correctly applied as described in NRC NUREG-0856.

4.3.7 The Preparer shall completely document the computer codes providing the following information as a minimum, as applicable. Documentation shall be considered a part of the calculation.

A one page software summary identifying the code, its version number, and its purpose

A complete description of mathematical models and numerical methods providing the theory and means of solution used in the code and containing derivations and justifications for the models

A user's manual which explains the use of the codes

Code assessment and support describing to what extent and how the codes have been validated and verified, and documenting the various code versions in use and the steps being taken to control and maintain these versions

Other applicable requirements of NUREG-0856.

4.3.8 With reference to hand-held or desk-top programmable calculators or computers the Preparer shall provide documentation sufficient to satisfy the intent of Subsections 4.3.5 through 4.3.7.

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4.3.9 The Preparer shall maintain control of computer tapes, cassettes, chips, mag cards, or similar items used in the calculation until the items are requested by the QA Manager per Subsection 5.3 herein.

4.4 Upon completion, the Preparer shall sign and date the calculation and forward it with the computer code documentation, if any, to the Reviewer(s).

Review

4.5 The Reviewer(s) shall review the calculation for technical adequacy, for compliance with any technical procedures, and for conformance to requirements of this procedure, and shall document the review method used.

4.5.1 The review of hand-prepared calculations shall be accomplished by one or more of the following methods:

A detailed review of the original calculation

A review by an alternate method of calculation

A review by another equally effective method of review.

4.5.2 The review of computer-aided calculations shall include the following considerations unique to computer usage, as applicable:

A review to determine if the calculation, regardless of the program used, contains all the necessary documentation for reconstruction at a later date

A review to verify that the computer program is suitable to the problem being analyzed

A review to determine if all applicable requirements of Subsections 4.3.4 through 4.3.8, herein, and of NUREG-0856, have been met

A review to determine if the input data as specified for program execution are sufficiently accurate to produce results within any numerical limitation of the program

A review to verify that the results obtained from the program are correct and within stated assumptions and limitations of the program, and are consistent with the input. Where applicable, methods such as alternative method solutions or comparison with solutions for similar analyses should be used to verify that the program has produced correct results for the given application.

4.5.3 In reviewing any calculation, the Reviewer(s) shall ensure that input data are current and have been verified or that any unverified assumptions, data, and judgments, comply with requirements of Subsection 4.3.2.

Review Comment

- 4.6 If the calculation is inadequate, the Reviewer(s) shall indicate his/her comments in writing and return the calculation and comments to the Preparer.
- 4.7 The Preparer shall resolve the comments with the Reviewer, correct the affected portions of the calculation, if necessary, and forward the calculation to the Reviewer. The Reviewer's comments and the documentation of their resolution shall be processed in accordance with Subsection 5.3 of this procedure.
- 4.8 If the calculation is adequate and all comments have been resolved, the Reviewer(s) shall sign and date the calculation and forward it to the Approver.
- 4.8.1 If there are no comments to begin with, the Reviewer shall so inform the Preparer in writing.

Approval and Release

- 4.9 The Approver shall review the calculation and resolve any comments he/she may have with the Preparer and Reviewer.
- 4.10 When all parties are satisfied, the Approver shall sign and date the calculation and ensure distribution in accordance with Section 5.0, herein.
- 4.10.1 The Approver shall ensure that all pages of the calculation are bound or stapled together.
- 4.11 Calculations based on unverified data, assumptions, and judgments may be approved and released.
- 4.11.1 When assumptions, data, or judgments have been verified, the calculation shall be revised in accordance with Section 6.0, herein. The Administrator of Technical Programs and QA Manager shall provide a suitable tracking system for verification of assumptions, data, and judgments.
- 4.12 Unapproved calculations released for any reason shall be marked "Unapproved" by the Preparer. The Preparer shall also obtain approval from the Administrator of Technical Programs prior to the release of the unapproved calculations.

Document Status

- 4.13 The Administrator of Technical Programs or the Administrator of Technical Programs and Project Manager shall ensure documentation of calculation status on a master document list per procedure QAP-6.2, "Progress Reports and Master Document Lists."

Calculations Included as Parts of Technical Reports

- 4.14 Calculations included as parts of technical reports are prepared, reviewed, approved, and processed in the same manner as independent calculations with the following differences.
- 4.14.1 The calculation Preparer, Reviewer, and Approver shall be the Preparer(s), Reviewer, and Approver of the technical report selected in accordance with procedure QAP-3.2, "Technical Reports."
- 4.14.2 Concerning the format requirements of Subsection 4.3.1, herein:  
Calculation purpose, NWPO-Yucca Mountain identification and responsible organization may be presented as part of the technical report text and need not be repeated with each calculation.  
No special space for Preparer, Reviewer, and Approver signatures is required on the calculation. Dated signatures of the report's Preparer, Reviewer, and Approver constitute Preparer, Reviewer, and Approver signatures of the calculation(s).  
No separate revision identification or page numbering system is required for the calculation(s). The technical report revision identification and pagination shall be used instead.  
Unique calculation numbers and computer codes (if any) may be included in the report text.
- 4.14.3 Computer documentation of Subsection 4.3.7 may be included in an appendix to the technical report.
- 4.14.4 Signature of the technical report Preparer(s) satisfies requirement for calculation Preparer's signature of Subsection 4.3.4.
- 4.14.5 Review comment and signature activities of Subsections 4.6 through 4.8.1 shall be processed as technical report comments per procedure QAP-3.2. Reviewer's signature of the technical report shall constitute Reviewer's signature of the calculation.
- 4.14.6 Approval and Release and Document Status activities of Subsections 4.9 through 4.13 shall be processed as technical report activities per procedure QAP-3.2. Calculations need not be separately bound or stapled. Approver's signature of the technical report shall constitute approval of the calculation. Calculations need not be listed separately on the progress reports and master document lists.
- 4.15 In cases where only a part of a calculation has been included in a technical report, the report Preparer and Reviewer shall ensure that said calculations are identified and that they have been prepared, reviewed and approved per this procedure.

5.0 OUTPUT DOCUMENTS

5.1 The calculation Approver shall ensure marking of the category file index designation on the approved calculation (including computer code and other documentation required by NUREG-0856) and distribution to the Principal Investigator, Administrator of Technical Programs, Laboratory Director, and others included on the document distribution list in accordance with procedure QAP-6.1, "Document Distribution List and File Index." Calculations shall be placed in office files as needed to provide reasonable access to calculation users.

5.1.1 As appropriate, calculations shall be bound in books or folders and maintained in an office file.

5.2 The Approver or Designee shall also ensure that the calculation is transmitted to the QA Manager in accordance with procedure QAP-17.1, "Quality Assurance Records."

5.3 The QA Manager shall obtain the calculation review and computer code documentation, and any computer program tapes, chips, mag cards, or similar documentation from the Preparer and then ensure processing of the calculation and documentation in the NWPO Records Center in accordance with procedure QAP-17.1.

5.4 With reference to calculations included as parts of technical reports, the document types are the same as for independent calculations, but the documents shall be processed as part of the technical report documentation in accordance with procedure QAP-3.2, "Technical Procedures." Calculations need not be bound separately in books or files. Computer code documentation and any computer program tapes, chips, mag cards or similar items must be processed as documents.

6.0 REVISIONS

6.1 Revisions to calculations shall be prepared, reviewed, approved, and distributed in accordance with the requirements stated in this procedure for original calculations except that the Preparer, Reviewer, and Approver shall sign and date the revision summary per Subsection 6.3 below.

6.2 Revisions may be made to single pages or to the entire calculation.

6.2.1 If single page revisions are made, only the revised pages need be issued and replaced.

6.2.2 Revised portions of calculations shall be identified by bold face type or by other means as necessary. When later revisions are made, the previous revision indication shall be deleted.

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6.3 A revision summary shall be included as a part of all revised calculations. The dated signatures of the Preparer, Reviewer, and Approver shall be included as part of the revision summary. The revision summary shall clearly indicate the page(s) revised.

6.4 Calculations shall be revised as early as possible after verification of unverified assumptions, data, or judgments.

6.5 Recipients of revised calculations shall promptly destroy superseded pages or promptly mark them "Void" or "Superseded."

6.6 The calculation shall be revised to reflect any changes in computer codes. There shall be continuing documentation and code listings which provide a means for documenting changes in the codes including a provision for file error reporting, revisions of the categories of documentation, and computer-readable and paper source listings of the current versions as they are released.

6.7 Calculations included as parts of technical reports shall be revised as technical reports per procedure QAP-3.2 but with the additional requirements of Subsection 6.6, herein.

7.0 REFERENCES

7.1 NWPO QA Program, Section 03, Design Control (Analysis of Site Characterization Data)

7.2 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975

7.3 10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance

7.4 ANSI/ASME - NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986

7.5 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

7.6 U.S. NRC NUREG-0856 - Final Technical Position on Documentation of Computer Codes for High-Level Waste Management - June 1983

8.0 FLOW CHART

None

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TITLE: TECHNICAL REPORTS

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for the preparation, review, approval, and distribution of technical reports issued by the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) and its contractors and subcontractors. The procedure governs reports based on NWPO or contractor/subcontractor activities. Reports based on peer group activities are addressed in procedure QAP-3.3, "Peer Reviews," and reports based on review of Department of Energy (DOE) activities or on activities of other non-NWPO sponsored organizations are covered in appropriate technical procedures.

The procedure addresses preparation of drawings (which are issued as parts of reports) and supplements procedure QAP-3.1, "Calculations" concerning calculations issued as parts of reports.

Requirements of this procedure may be supplemented or modified by technical procedures prepared in accordance with procedure QAP-2.2, "Preparation and Control of Technical Procedures."

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

2.1.1 Approver

2.1.2 Drawing

2.1.3 Input Data

2.1.4 Input/Support Document

2.1.5 Output Document

2.1.6 Preparer

2.1.7 Reviewer, Technical Reviewer

3.0 INTERFACING PROCEDURES

3.1 QAP-3.1, "Calculations"

- 3.2 QAP-3.3, "Peer Reviews"
- 3.3 QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification"
- 3.4 QAP-6.1, "Document Distribution List and File Index"
- 3.5 QAP-6.2, "Progress Reports and Master Document Lists"
- 3.6 QAP-17.1, "Quality Assurance Records"

4.0 PREPARATION, REVIEW, APPROVAL, AND DISTRIBUTION

Preparation

- 4.1 The Administrator of Technical Programs, Project Managers, Principal Investigators, Laboratory Directors, or Designees shall identify the technical activities within their respective control requiring technical reports and assign a Preparer, Reviewer, and Approver for each technical report.
  - 4.1.1 Procurement documents shall be consulted, as needed, in making this identification.
  - 4.1.2 The Administrator of Technical Programs, Project Manager, Principal Investigator, Laboratory Director, or Designee may appoint himself/herself as Preparer, Reviewer, or Approver, but the Reviewer shall not be the Preparer's immediate supervisor except under special circumstances. (See Section 03 of the QA program.) See the Glossary definition of Reviewer; Technical Reviewer.
- 4.2 The Preparer shall assemble the necessary input data and prepare the technical report in accordance with the criteria indicated in Subsections 4.2.1 through 4.3, below, and any additional supplemental criteria indicated in technical procedures.

Format and Content

- 4.2.1 The technical report may be prepared in any suitable, readily reproducible format provided the following items are included:
  - A title page containing:
    - A report title
    - The name of the organization preparing the report
    - An NWPO - Yucca Mountain identification
    - A unique technical report number and revision identification (The original report is Revision 0)
    - Dated signatures of the Preparer, Reviewer, and Approver

Subsequent pages containing the technical report number and revision identification.

All pages shall include the page number and total number of pages in the technical report (e.g., Page 4 of 21).

- 4.2.2 The technical report shall be written in a clear logical manner such that a person technically qualified in the subject matter can review and understand the report without recourse to the Preparer.

Each report shall include a table of contents, a clear statement of purpose, a summary, conclusions, and a recommendations section (if applicable), and a reference list identifying sources of all data used, including unpublished information (see Subsection 4.2.5). As appropriate, reports shall include methodologies of data acquisition and analysis and of conclusions.

All drawings, illustrations, tables, and calculations issued as part of the report shall be suitably numbered. Formulae or symbols not in common usage shall be adequately explained.

Each report shall address accuracy, precision, and potential sources of error in input data, results, and conclusions.

- 4.2.2.1 Calculations not issued as part of the report, but used as input data, shall be suitably referenced.

#### Input Data

- 4.2.3 Input data may be derived from sources such as, but not limited to, field or laboratory notebooks or other input/support documents, aerial photographs, boring logs, published or unpublished technical or scientific articles, or published drawings. NWPO, contractor, or subcontractor calculations or technical reports may be used, provided they are approved. All such calculations or reports shall be prepared in accordance with procedures QAP-3.1 or QAP-3.2, respectively.

- 4.2.4 Insofar as possible the Preparer shall use current and verified input data. The Preparer shall identify any unverified data, assumptions, or technical scientific judgments indicating those items expected to be verified in the future by anticipated additional data or methods of analysis as they become available. See Subsection 4.10.1.

- 4.2.5 All input data sources shall be readily available in the NWPO records storage facility or elsewhere. Category file index designations shall be indicated, as appropriate.

- 4.3 Upon completion, the Preparer shall sign and date the technical report on the title page and send the report and adequate back-up documentation to the Reviewer.

Review

4.4 The Reviewer(s) shall review the technical report considering the following as a minimum:

Technical adequacy

Compliance with the requirements of this procedure

Proper approval of input calculations derived from NWPO, or its contractors or subcontractors

Compliance with any technical procedures.

4.4.1 In general, the Reviewer(s) shall ensure that input data are current and have been verified or that any unverified assumptions, data, or judgments comply with requirements of Subsection 4.2.4.

4.5 If the report is inadequate, the Reviewer shall indicate his/her comments in writing and return the report and comments to the Preparer.

4.6 The Preparer shall resolve the comments with the Reviewer, correct the report, if necessary, and forward the report to the Reviewer. The Reviewer's comments and the documentation of their resolution shall be processed in accordance with Subsection 5.3 of this procedure.

4.7 If the report is adequate and all comments have been resolved, the Reviewer shall sign and date the report on the title page and forward the report to the Approver.

4.7.1 If there are no comments to begin with, the Reviewer shall so notify the Preparer in writing.

Approval and Release

4.8 The Approver shall review the technical report and resolve any comments he/she may have with the Preparer and Reviewer.

4.9 When all parties are satisfied, the Approver shall sign and date the report on the title page and ensure distribution in accordance with Section 5.0, herein.

4.10 Technical reports based on unverified data, assumptions, or on technical or scientific judgments (including NWPO or contractor or subcontractor calculations so based) may be approved and released.

4.10.1 When assumptions, data, and judgments have been verified, the report shall be revised in accordance with Section 6.0, herein. The Administrator of Technical Programs and QA Manager shall provide a suitable tracking system for verification of data, assumptions, or judgments.

4.11 Unapproved reports released for any reason shall be marked "Unapproved" by the Preparer and the Preparer shall obtain permission from the Administrator of Technical Programs prior to release.

#### Document Status

4.12 The Administrator of Technical Programs or the Administrator of Technical Programs and Project Manager shall ensure documentation of technical report status on a master document list per procedure QAP-6.2, "Progress Reports and Master Document Lists."

#### Peer Review

4.13 The Administrator of Technical Programs may initiate peer reviews of the technical report, as needed, per procedure QAP-3.3.

#### Calculations and Drawings

4.14 Calculations issued as parts of technical reports, including computer plots and drawings and computer sorting and rearrangement of data, shall be prepared, reviewed, approved, and processed in accordance with the requirements of procedure QAP-3.1 for calculations included as parts of technical reports. Calculations only parts of which are included with the report shall be processed per procedure QAP-3.1 in their entirety.

4.15 Drawings and illustrations issued as parts of technical reports are subject to the same requirements for input data sources, verification, and identification as other parts of the report. Drawings such as large scale geologic maps, which may not be convenient to bind with the report text, shall include sufficient identification to link them to the technical report of corresponding revision identification. The Preparer's, Reviewer's, and Approver's signatures on the technical report title page shall document responsibility for drawings and illustrations.

#### 5.0 OUTPUT DOCUMENTS

5.1 The technical report Approver shall ensure marking of the category file index designation on the approved report and distribution to the Principal Investigator, Administrator of Technical Programs,

Laboratory Director, and others included on the document distribution list in accordance with procedure QAP-6.1, "Document Distribution List and File Index." Technical reports shall be placed in office files as needed to provide reasonable access to report users.

- 5.2 The Approver or Designee shall also ensure that the report is transmitted to the QA Manager in accordance with procedure QAP-17.1, "Quality Assurance Records."
- 5.3 The QA Manager shall obtain review documentation and any back-up documentation from the Preparer and then ensure processing of the report and documentation in the NWPO Records Center in accordance with procedure QAP-17.1.
- 5.3.1 With reference to hand-prepared and computer aided calculations and to computer plots and drawings, the document types processed shall be those indicated by procedure QAP-3.1, "Calculations."

## 6.0 REVISIONS

- 6.1 Revisions to technical reports shall be prepared, reviewed, approved, and distributed in accordance with the requirements stated in this procedure for the original technical report except that the Preparer, Reviewer, and Approver shall sign and date the revision summary (instead of the title page) per Subsection 6.3 below.
- 6.2 Revisions may be made to a single page or to the entire report.
- 6.2.1 If single page revisions are made, only the revised pages need be issued and replaced.
- 6.2.2 Revised portions of reports shall be identified by bold face type or by other means as necessary. When later revisions are made, the previous revision identification shall be deleted.
- 6.3 A revision summary shall be included as a part of all revised technical reports. The dated signature of the Preparer, Reviewer, and Approver shall be included as part of the revision summary. The revision summary shall clearly indicate the pages revised.
- 6.4 Technical reports shall be revised as early as possible after verification of unverified assumptions, data, or judgments.
- 6.5 Recipients of revised technical reports shall promptly destroy superseded pages or promptly mark them "Void" or "Superseded."

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6.6 Calculations shall be revised in the same manner as other parts of the technical report but in accordance with applicable requirements of procedure QAP-3.1, "Calculations," concerning changes in computer codes and related activities.

7.0 REFERENCES

7.1 NWPO QA Program, Section 03, Design Control (Analysis of Site Characterization Data)

7.2 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975

7.3 10CFR60 Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983

7.4 ANSI/ASME - NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986

7.5 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Waste Repositories - June 1984

8.0 FLOW CHART

None

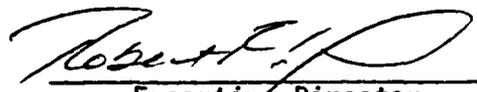
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TITLE: PEER REVIEWS

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure addresses peer reviews of documents, activities, and procedures generated or performed by the Agency for Nuclear Projects/Nuclear Waste Project Office's (NWPO's) contractors and subcontractors. The procedure is distinct from procedures, such as QAP-3.1, that address technical review of documents. (See Glossary definition of Review.) Subject to NWPO's special requirements, this procedure follows the intent of the Nuclear Regulatory Commission's (NRC's) Generic Technical Position (GTP) on Peer Review for High-Level Nuclear Waste Repositories (NUREG-1297, February 1988).

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

- 2.1.1 Peer Review
- 2.1.2 Peer Review Group
- 2.1.3 Readiness Review
- 2.1.4 Review
- 2.1.5 Validation
- 2.1.6 Verification

3.0 INTERFACING PROCEDURES

- 3.1 QAP-2.2, "Preparation and Control of Technical Procedures"
- 3.2 QAP-3.1, "Calculations"
- 3.3 QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification"
- 3.4 QAP-6.1, "Document Distribution List and File Index"
- 3.5 QAP-17.1, "Quality Assurance Records"

#### 4.0 INITIATION, CONDUCT, AND QUALIFICATIONS

##### Initiation of Peer Reviews

4.1 Peer reviews may be requested by the Administrator of Technical Programs, the QA Manager, the Project Manager, the Principal Investigator, the Laboratory Director, or by others, as appropriate.

4.2 The Requestor shall submit a written request to the Executive Director and Administrator of Technical Programs indicating the data, interpretations, test results, assumptions, technical procedures and methods, investigator qualifications, or other item or issue requiring peer review and the reasons why a peer review is necessary. If possible, the Requestor shall also identify potential candidate peer reviewers.

4.3 The Administrator of Technical Programs and/or Executive Director shall review the request for peer review with the Requestor and, as necessary, with others such as the Technical Advisory Group, Project Manager or Principal Investigator. Their review shall consider relevant criteria of Subsections 4.13 and 4.14, herein. In the broadest terms, peer review shall be performed on contractor/subcontractor activities involving use of untried or beyond the state-of-the-art testing or analysis methods, or involving situations where detailed technical criteria or requirements do not exist or are under development.

4.3.1 When a decision has been reached, the Executive Director or Administrator of Technical Programs shall so inform the Requestor in writing, giving reasons for the decision. Request memoranda and responses shall be filed as indicated in Section 5.0 herein.

4.4 Subject to the approval of the Executive Director, the Administrator of Technical Programs shall secure the services of individuals, satisfying the qualifications and requirements of Subsections 4.15 and 4.16, herein. In general, a peer reviewer is an independent, acknowledged authority in the subject matter to be reviewed.

4.4.1 Procurement of peer reviewer services, including documented verification of peer reviewers' credentials, shall be governed by procedure QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification."

##### Conduct of Peer Reviews

4.5 With the aid of the QA Manager, the Peer Reviewers shall constitute themselves into a Peer Review Group (PRG) electing one of their number as Chairperson.

- 4.6 The peer review shall be conducted as determined by the Chairperson and as dictated by the matter under review, by the requirements of the procurement documents, by the requirements of this procedure, and by the requirements of the GTP, as appropriate. In meetings and/or correspondence, the PRG shall evaluate and report on the following as applicable:

- validity of assumptions
- alternate interpretations
- uncertainty of results and consequences, if wrong
- appropriateness and limitations of methodology and procedures
- adequacy of application
- accuracy of calculations
- adequacy of conclusions
- adequacy of requirements and criteria.

In special circumstances, the PRG may perform readiness reviews of work in progress.

- 4.6.1 Before start of the review, the PRG Chairperson shall secure necessary data and background information from the Administrator of Technical Programs and QA Manager and, as appropriate, from the Project Manager, Principal Investigator, Laboratory Director, and others and distribute the information to the PRG. Before and during the peer review, the PRG should discuss their review with the performers of the original work under review.
- 4.6.2 Deliberations, meetings, and activities of the PRG shall be documented by the PRG Chairperson in written minutes to be distributed and filed in accordance with Section 5.0, herein.
- 4.6.3 In general, the QA Manager will participate in the peer review process as an observer and advisor to ensure that the PRG conducts itself in accordance with this QA procedure and with the intent of the NRC GTP. The QA Manager shall verify compliance in a memorandum to the Executive Director.

#### Peer Review Report

- 4.7 When the peer review group has completed its review, the PRG Chairperson shall ensure preparation of a peer review report and transmittal of the report to the Administrator of Technical Programs. The report shall include the following as a minimum:

- Title and clear statement of purpose

- Signatures and dates of the Chairperson and of each other member of the PRG (Unless otherwise noted, signatures signify concurrence with the report)

A clear statement of the work, data, procedure, or issue reviewed

An in-depth assessment of the issues involved, identifying areas of technical consensus and areas of disagreement

A critical review of data, assumptions, and conclusions pointing out errors in data or interpretation and topics requiring amplification

Conclusions and recommendations

As appropriate, supplementary statements or expression of dissenting or minority views by individual PRG members

On each page of the report, a revision number and date (the original issue is Revision 0), and a page number and total number of pages (e.g., Page 16 of 37), also identification as an NWPO document.

Also to be included in the peer review report are a listing of the reviewers and their qualifications and organizational affiliations, and a statement of any potential technical organizational partiality.

- 4.8 Upon receipt, the Administrator of Technical Programs shall distribute copies of the peer review report to the Executive Director and QA Manager, and to the appropriate Project Manager, Principal Investigator, and others, as needed.
- 4.9 The Recipients shall review the report and return their comments or a statement of "no comments" to the Administrator of Technical Programs.
- 4.10 The Administrator of Technical Programs shall review the comments with the PRG Chairperson who may initiate changes or clarifications of the report.
- 4.11 With all comments resolved, the Administrator of Technical Programs and Executive Director shall ensure that the report is acted upon in an appropriate manner.
- 4.12 The QA Manager and Administrator of Technical Programs shall ensure distribution of the report in accordance with Section 5.0, herein.

#### Applicability of Peer Reviews

- 4.13 Peer reviews shall be performed in situations where the uncertainties inherent in geotechnical/geological data, methodologies, interpretations, or conclusions can be resolved in no other way. Peer reviews shall be used to confirm judgments when decisions must be made in the absence of precedents and in spite of ambiguities.

4.14 In general, the following conditions are indicative of situations in which a peer review may be appropriate or necessary:

Critical interpretations or decisions in the face of uncertainty must be made

Decisions or interpretations having significant impact on performance assessment conditions

Novel or beyond the state-of-the-art testing, plans, procedures, or analyses (including NWPO or contractor/subcontractor technical procedures) are contemplated

There is doubt concerning the qualifications of individuals or organizations performing novel or beyond the state-of-the-art activities (e.g., laboratory analysis)

Detailed technical criteria or standard industry procedures do not exist or are being developed

Results of tests are not reproducible or repeatable

Data or interpretations are ambiguous

Data adequacy is questionable (e.g., data were not acquired with an established QA program)

Adequacy of a critical body of data can be established by several different means, but there is disagreement within the cognizant technical community over what is the best way to proceed.

Qualifications of Peer Reviewers and Structure of Peer Review Groups

4.15 Each peer reviewer shall possess the following minimum qualifications:

Willingness to comply with the requirements of this QA procedure and with applicable portions of the NWPO QA Manual and with the intent of the NRC GTP

Generally recognized and verifiable technical/scientific credentials in all or part of the subject matter under review

Technical/scientific qualifications at least equal to those needed for the work or analysis under review

Independence from the work being reviewed (i.e., peer reviewer was not involved as a participant, supervisor, technical reviewer, or technical advisor in the work being reviewed and, to the extent practical, has sufficient freedom from funding considerations to ensure impartial review of the work).

Note: A peer reviewer is permitted to review work based on his/her earlier work provided the earlier work has been validated by a consensus of the technical/scientific community.

4.16 The PRG shall be selected to span the technical issues and areas involved in the work under review including any differing schools of technical or scientific thought. The size of the PRG shall reflect the complexity of the work to be reviewed, the importance of the work to NWPO's goals and objectives, the number of technical/scientific disciplines involved, the degree of uncertainty in the data or technical approach involved, and the extent of differing viewpoints within the technical/scientific community regarding the matter at hand.

## 5.0 OUTPUT DOCUMENTS

5.1 The Administrator of Technical Programs shall ensure marking of the category file index designation on the peer review report, per procedure QAP-6.1, and distribution to the QA Manager in accordance with procedure QAP-17.1, "Quality Assurance Records," and to the Executive Director, Project Manager, Principal Investigator and others in accordance with procedure QAP-6.1, "Document Distribution List and File Index." Peer review reports shall be placed in office files, as needed.

5.2 The QA Manager shall ensure marking of the category file index designation on the following documents, per procedure QAP-6.1, and submittal of the documents to the NWPO Records Center for processing, filing and retention in accordance with procedure QAP-17.1, "Quality Assurance Records."

5.2.1 Minutes of meetings, deliberations, and activities of the Peer Review Group

5.2.2 Peer review reports (need not be marked again, see Subsection 5.1); comments on peer review reports

5.2.3 QA Manager's verification memoranda of PRG's compliance with this procedure and the intent of the GTP

5.2.4 Verifications of technical/scientific credentials of peer reviewers

5.2.5 Peer review request memoranda and responses

## 6.0 REVISIONS

6.1 Revisions to peer review reports and associated documents shall be performed in accordance with the requirements stated in this procedure for the original issue.

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6.1.1 Individual pages of peer review reports and associated documents shall not be revised and issued separately; revised peer review reports shall be issued in their entirety.

6.1.2 Each revised portion of a revised document shall be identified by bold face type or by other means as necessary. When a new revision is made, the previous revision identification shall be deleted.

6.2 Recipients of revised review reports or associated documents shall promptly destroy the superseded report/document or promptly mark it "Void" or "Superseded."

7.0 REFERENCES

7.1 NWPO QA Program, Section 02, Quality Assurance Program

7.2 NWPO QA Program, Section 03, Design Control (Analysis of Site Characterization Data)

7.3 NWPO QA Program, Section 04, Procurement Document Control

7.4 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975

7.5 10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983

7.6 ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986

7.7 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

7.8 U.S. NRC NUREG-1297 - Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories - February 1988

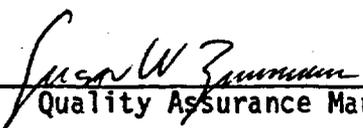
8.0 FLOW CHART

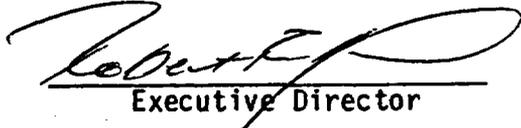
None

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TITLE: PROCUREMENT CONTRACT CONTROL AND CONTRACTOR/  
SUBCONTRACTOR QUALIFICATION

APPROVED:   
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the Quality Assurance (QA) requirements for procurement of services, materials, and equipment by the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO), and by its contractors and subcontractors on NWPO's behalf. The procedure addresses preparation, control, and content of procurement documents, evaluation of proposals, and pre-award qualification of contractors, subcontractors, vendors, and suppliers. Financial, legal, and other non-QA related aspects of procurement contracts are governed by laws and regulations of the State of Nevada. This procedure does not address procurement of standard "off-the-shelf" items such as measuring tapes or standard laboratory supplies.

2.0 DEFINITIONS

2.1 See the Glossary for the following definitions:

- 2.1.1 Approver
- 2.1.2 Authorized Nonconformance
- 2.1.3 Certificate of Conformance
- 2.1.4 Contract Award
- 2.1.5 Contractor
- 2.1.6 Nonconformance
- 2.1.7 Preparer
- 2.1.8 Procurement Contract
- 2.1.9 Procurement Document
- 2.1.10 Reviewer; Technical Reviewer
- 2.1.11 Right of Access
- 2.1.12 Service

- 2.1.13 Subcontractor
- 2.1.14 Supplier
- 2.1.15 Surveillance
- 2.1.16 Vendor

**3.0 INTERFACING PROCEDURES**

- 3.1 QAP-2.2, "Preparation and Control of Technical Procedures"
- 3.2 QAP-2.3, "Indoctrination and Training in the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual"
- 3.3 QAP-3.3, "Peer Reviews"
- 3.4 QAP-6.1, "Document Distribution List and File Index"
- 3.5 QAP-6.2, "Progress Reports and Master Document Lists"
- 3.6 QAP-15.1, "Nonconformances"
- 3.7 QAP-16.1, "Corrective Action"
- 3.8 QAP-17.1, "Quality Assurance Records"
- 3.9 QAP-18.1, "Audits"

**4.0 QUALIFICATION, PREPARATION, CONTROL AND CONTENT**

General Statement

- 4.1 Subsections 4.2 through 4.13 of this QA procedure address NWPO's procurement of contractor services and of materials and equipment for NWPO's own use in surveillance and other activities. Subsections 4.14 through 4.16.5 address contractor's procurement of subcontractor services and of materials and equipment for contractor/subcontractor use. Subsections 4.17 through 4.23 address nonconformances, audits and surveillances, and document status.

Procurement of Contractor Services, Procurement of Materials and Equipment by NWPO

Procurement Document

- 4.2 The Executive Director and/or Administrator of Technical Programs shall consult with the Technical Advisory Group and/or with other qualified individuals concerning activities, materials and equipment, and qualifications of persons and organizations necessary to achieve NWPO's goals and objectives. When satisfied, the Executive Director shall assign a Preparer(s), independent technical Reviewer(s) and Approver of the procurement document.

- 4.3 The Preparer(s) shall prepare the procurement document in accordance with applicable requirements of Figure 4.3-1, "Content of Procurement Documents."
- 4.3.1 The procurement document shall identify the following information:  
Project identification (NWPO Yucca Mountain)  
Identification as a NWPO contract  
Procurement title  
Provision for the Preparer's, Reviewer's, and Approver's signatures and for the signatures of the Administrator of Technical Programs and QA Manager.
- All pages of the procurement document shall include the following:  
Revision number (the original issue is Revision 0)  
A page number and total number of pages (e.g., Page 3 of 11).
- 4.3.2 In preparing the procurement document, the Preparer may consult with and obtain input from any knowledgeable person, whether from NWPO, a potential contractor, or other organization.
- 4.4 The Reviewer(s) shall review the procurement document for technical adequacy, clarity of expression, adherence to requirements of Figure 4.3-1, as relevant, and conformity with NWPO's objectives and return his/her comments or "no comments," in writing, to the Preparer(s).
- 4.5 The Preparer(s) shall discuss the comments with the Reviewer(s) and incorporate any necessary changes into the procurement document.
- 4.6 The Approver shall examine the procurement document and resolve his/her comments, if any, with the Preparer and Reviewer.
- 4.7 The Administrator of Technical Programs shall review the procurement document for overall technical adequacy and for conformance to NWPO's objectives.
- 4.8 The QA Manager shall review the procurement document to ensure that it was properly prepared, reviewed, and approved; that its content conforms with requirements of Figure 4.3-1; and that other QA requirements have been met.
- 4.9 When all parties are satisfied, the Preparer, Reviewer, and Approver and the Administrator of Technical Programs and QA Manager shall sign and date the procurement document.

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The procurement document shall include the following items, as a minimum and as applicable, either directly or by reference.

1. A statement that the contractor, subcontractor, vendor/supplier shall comply with the NWPO QA Program and implementing procedures, and with the laws and regulations of the State of Nevada as they apply to their activities.
2. A clear and complete statement of the scope, purpose, and objectives of the work including, but not limited to:
  - a. an outline of methodologies to be used
  - b. required qualifications of key personnel, including special qualifications; task assignments of Principal Investigators and other key personnel
  - c. a statement of equipment, materials, apparatus, or instruments to be procured and/or used, including specifications and manufacturer's model number, or appropriate drawings for custom-built equipment
  - d. an indication of work to be performed by subcontractors (e.g., laboratories, drilling contractors), and identification and specifications of work they are to perform.
3. Detailed technical requirements and methodologies. For example,
  - a. a listing of industry or government standards, regulations, codes, and guides to be followed
  - b. accuracy and precision requirements (e.g., map and air photo scale, instrument calibrations)
  - c. acceptance/rejection criteria, inspection and test requirements to be used, and hold points
  - d. special sample-handling, packaging, shipping, and storage requirements and special instructions (e.g., field installation of instrumentation).
4. A statement that the contractor/subcontractor guarantees right of access of NWPO auditors/monitors and contractor monitors to contractor/subcontractor premises (e.g., testing laboratory, sample-storage facility) and to vendor/supplier premises.
5. As appropriate, requirements for documentation to be furnished NWPO by the contractor/subcontractor such as:
  - a. inspection and test records
  - b. chemical and physical property data
  - c. identification of purchased material or equipment
  - d. employee experience records
  - e. reports of receiving inspections
  - f. vendor/supplier documentation
  - g. other items specified by QA procedures and technical procedures.
6. A requirement for the contractor/subcontractor to perform documented receiving inspections of purchased materials, equipment, apparatus, or instruments before accepting delivery of same; also to perform inspections and surveillances as needed.
7. A requirement that the contractor/subcontractor furnish NWPO with a certificate of conformance to procurement specifications when requested by NWPO. Also a requirement for the contractor to inform the Administrator of Technical Programs, in writing, of any proposed deviation (nonconformance) in specified services or specified materials, equipment, or apparatus in accordance with this QA procedure.
8. A requirement that the contractor inform the Administrator of Technical Programs of activities that may require peer review, in accordance with this QA procedure.
9. A requirement that the contractor/subcontractor prepare technical procedures as necessary to implement requirements of the procurement document.
10. A requirement that, in cases of procurement of materials or equipment by NWPO for its own use, the vendor/supplier provides documentation in compliance with the procurement document and that NWPO performs receiving inspections, as needed.

**FIGURE 4.3-1, CONTENT OF PROCUREMENT DOCUMENTS**

Contracts, Contractor Qualification, Proposal Evaluation, and Contract Award

- 4.10 Following final approval of the procurement document, the Executive Director and/or the Administrator of Technical Programs shall draft a preliminary contract and a request for proposal (RFP), if needed, both incorporating the procurement document, and then solicit proposals from qualified contractors or vendors/suppliers in accordance with the laws and regulations of the State of Nevada.
- 4.10.1 Prospective contractors shall be requested to submit an outline of a work plan, as applicable. Any RFP format may be used, depending on circumstances.
- 4.11 On receipt of proposals, the Executive Director, Administrator of Technical Programs, QA Manager, and Others, as needed, shall perform a preliminary evaluation based on the responses to the RFP or other solicitation documentation.
- 4.12 When preliminary evaluation has been completed, the Executive Director, Administrator of Technical Programs, and Others, as needed, shall perform a final evaluation of the proposals, select the preferred contractor or vendor/supplier, and negotiate and award the final contract. Only qualified organizations shall be awarded contracts.

As part of the evaluation the Executive Director, Administrator of Technical Programs, QA Manager and Others, as needed, shall investigate and document the qualifications of potential contractors or vendors/suppliers of interest based on the criteria listed below, as appropriate:

Qualifications, reputation, and availability of key contractor personnel; for example,

Education

Professional licenses

Experience

Publications

Awards

Membership in technical and scientific organizations

Contractor's experience and expertise in similar work (can be investigated by interviews with current or former clients)

Contractor's organizational structure and interface relations with potential subcontractors

Contractor's ability to maintain equipment, procedure, and personnel qualification records

Contractor's ability and willingness to comply with NWPO's QA Program and implementing procedures; for example,

Preparation of technical procedures

Independent review of calculations and reports

Contractor's ability to obtain acceptable materials, equipment, and apparatus

Availability and condition of materials, equipment, and apparatus; contractor procurement plans

Relevant qualifications of vendors/suppliers.

- 4.12.1 In special cases, NWPO may use the services of a Peer Review Group in investigating potential contractor's qualifications in accordance with procedure QAP-3.3.
- 4.12.2 Any significant changes to the procurement document shall be processed in accordance with Subsections 4.2 through 4.9, herein.
- 4.12.3 The contract shall include a statement that no technical contract activity will be authorized without a corresponding approved technical procedure and that, in general, technical activities shall be authorized by the Executive Director and/or the Administrator of Technical Programs.
- 4.12.4 The QA Manager shall perform a documented review of the final contract for conformance to QA requirements; and the Administrator of Technical Programs for technical requirements.
- 4.13 When all parties are satisfied, the Executive Director and contractor's or vendor's/supplier's Responsible Person shall execute the contract in accordance with the laws and regulations of the State of Nevada. Start of work or delivery of items shall then be authorized by the Administrator of Technical Programs and Executive Director.

Contractors' Procurement of Subcontractor and Vendor/Supplier Services, Materials, and Equipment

Procurement Document

- 4.14 The Project Manager and/or the Principal Investigator shall consult with the Administrator of Technical Programs and others, as needed, and identify services to be procured from subcontractors and/or materials, equipment, apparatus, or instruments to be procured from vendors/suppliers. When satisfied, the Project Manager shall assign a Preparer(s), independent technical Reviewer(s), and Approver of a procurement document.

4.14.1 The Preparer is usually the Principal Investigator, and the Approver is usually the Project Manager.

4.15 The procurement document shall then be prepared, reviewed, and approved in accordance with Subsections 4.3 through 4.9, and with applicable requirements of Figure 4.3-1, as modified below.

4.15.1 The procurement document shall include a contractor identification.

4.15.2 The Preparer(s) may consult with and obtain input from any NWPO, contractor, or potential subcontractor or vendor/supplier source.

4.15.3 The technical Reviewer(s) shall also review the procurement document for conformity with the contractor's objectives.

4.15.4 The Project Manager shall also review, sign and date the procurement document.

Contracts, Contractor Qualification, Proposal Evaluation and Contract Award

4.16 In general, contracts shall be processed in accordance with Subsections 4.10 through 4.13 as modified below.

4.16.1 The Project Manager and/or Principal Investigator shall draft the preliminary contract and RFP, if needed, and solicit proposals from qualified subcontractors and/or vendors/suppliers.

4.16.2 The Project Manager, Principal Investigator, QA Manager and Others, as needed, shall investigate qualifications of potential subcontractors and vendors/suppliers of interest. If the services of a Peer Review Group are needed in selection of a subcontractor, the Project Manager shall so inform the Administrator of Technical Programs.

4.16.3 The Project Manager and Principal Investigator shall perform the final proposal evaluations and negotiate the final contract.

4.16.4 The Administrator of Technical Programs and QA Manager shall perform documented reviews of all final contracts.

4.16.5 The Project Manager or other Responsible Person in the contractor organization shall award and execute the contract with the subcontractor or vendor/supplier Responsible Person and authorize start of work or delivery of items.

Proposed Deviations from Requirements of Procurement Document;  
Authorized Nonconformances

- 4.17 The Principal Investigator shall inform the Administrator of Technical Programs and Project Manager, in writing, of any proposed deviations in services or items from procurement document requirements submitted by the contractor, subcontractor, or vendor/supplier and recommend acceptance or nonacceptance of the proposed deviation.
- 4.18 The Administrator of Technical Programs, QA Manager and Project Manager shall consider the proposed deviation in light of the following criteria, consulting with the Executive Director and others as necessary:
- Effect of proposed deviation on NWPO's objectives and goals
  - Adequacy of proposed nonconforming material, equipment, or apparatus
  - Availability of specified material, equipment, or apparatus.
- 4.19 The Administrator of Technical Programs, QA Manager, and, as appropriate, the Project Manager/Principal Investigator shall approve, in writing, acceptable (i.e., authorized) deviations which shall then become authorized nonconformances.
- 4.20 Proposed deviations of items supplied for NWPO's direct use shall be processed by the vendor/supplier Responsible Person instead of by the Principal Investigator.

Audits and Surveillances

- 4.21 The QA Manager shall audit any contractors' and subcontractors' certificates of conformance to the procurement document per procedure QAP-18.1. Corrective action, if any, shall be processed in accordance with procedures QAP-15.1, QAP-16.1, and QAP-18.1, as appropriate.
- 4.22 NWPO and contractors may perform surveillances of contractor and subcontractor activities or vendor/supplier premises in accordance with technical procedures. The Administrator of Technical Programs, QA Manager, Project Manager, Principal Investigator and others, shall receive copies of surveillance reports and any nonconformances shall be resolved per procedures QAP-15.1 and QAP-16.1.

Document Status

- 4.23 The Administrator of Technical Programs or the Administrator of Technical Programs and Project Manager shall ensure documentation of procurement document status on a master document list in accordance with procedure QAP-6.2, "Progress Reports and Master Document Lists."

5.0 OUTPUT DOCUMENTS

5.1 The Administrator of Technical Programs shall ensure marking of category file index designations on the final contract (including approved procurement document) and on nonconformance documentation. He/she shall ensure distribution of same to the Administrator of Technical Programs, Project Manager, Principal Investigator, and, as appropriate, to the Laboratory Director and others indicated on the document distribution list, in accordance with procedure QAP-6.1, "Document Distribution List and File Index." Procurement and other documents shall be placed in an office file as necessary to provide reasonable access to users.

5.2 The QA Manager shall ensure marking of the category file index designation on the following documents, per QAP-6.1, and submittal, processing, filing, and retention of the documents in the NWPO Records Center in accordance with procedure QAP-17.1, "Quality Assurance Records."

5.2.1 Executed (final) procurement contracts (including approved procurement document)

5.2.2 Contractor/subcontractor and vendor/supplier qualification documentation

5.2.3 Review documentation in general, including QA review of final procurement contract, resolution of Reviewer's comments on procurement document

5.2.4 Documentation of proposed deviation requests and dispositions (authorized nonconformances)

5.2.5 Requests for proposals and contractor/subcontractor and vendor/supplier proposals (successful bidders only)

6.0 REVISIONS

6.1 Revisions to procurement contracts (including approved procurement documents) and other documents shall be prepared, reviewed, approved, and issued in the same manner as for the original issue, as applicable.

6.1.1 Individual pages of procurement contracts or other documents shall not be issued separately. The revised contract shall be issued in its entirety.

6.1.2 Each revised portion of the contract or other document shall be identified by bold face type or by other means as necessary. When a new revision is made, the previous revision identification shall be deleted.

6.1.3 Document Recipients shall promptly destroy the superseded contracts or promptly mark them "Superseded" or "Void."

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7.0 REFERENCES

- 7.1 NWPO QA Program, Section 01, Organization
- 7.2 NWPO QA Program, Section 02, Quality Assurance Program
- 7.3 NWPO QA Program, Section 04, Procurement Document Control
- 7.4 NWPO QA Program, Section 07, Control of Purchased Materials, Equipment, and Services
- 7.5 NWPO QA Program, Section 10, Inspection, Surveillance, and Monitoring
- 7.6 NWPO QA Program, Section 15, Nonconformances
- 7.7 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975
- 7.8 10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983
- 7.9 ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986
- 7.10 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

8.0 FLOW CHART

Figure 8.0-1 is the flow chart for procurement contract control and contractor/subcontractor qualification.

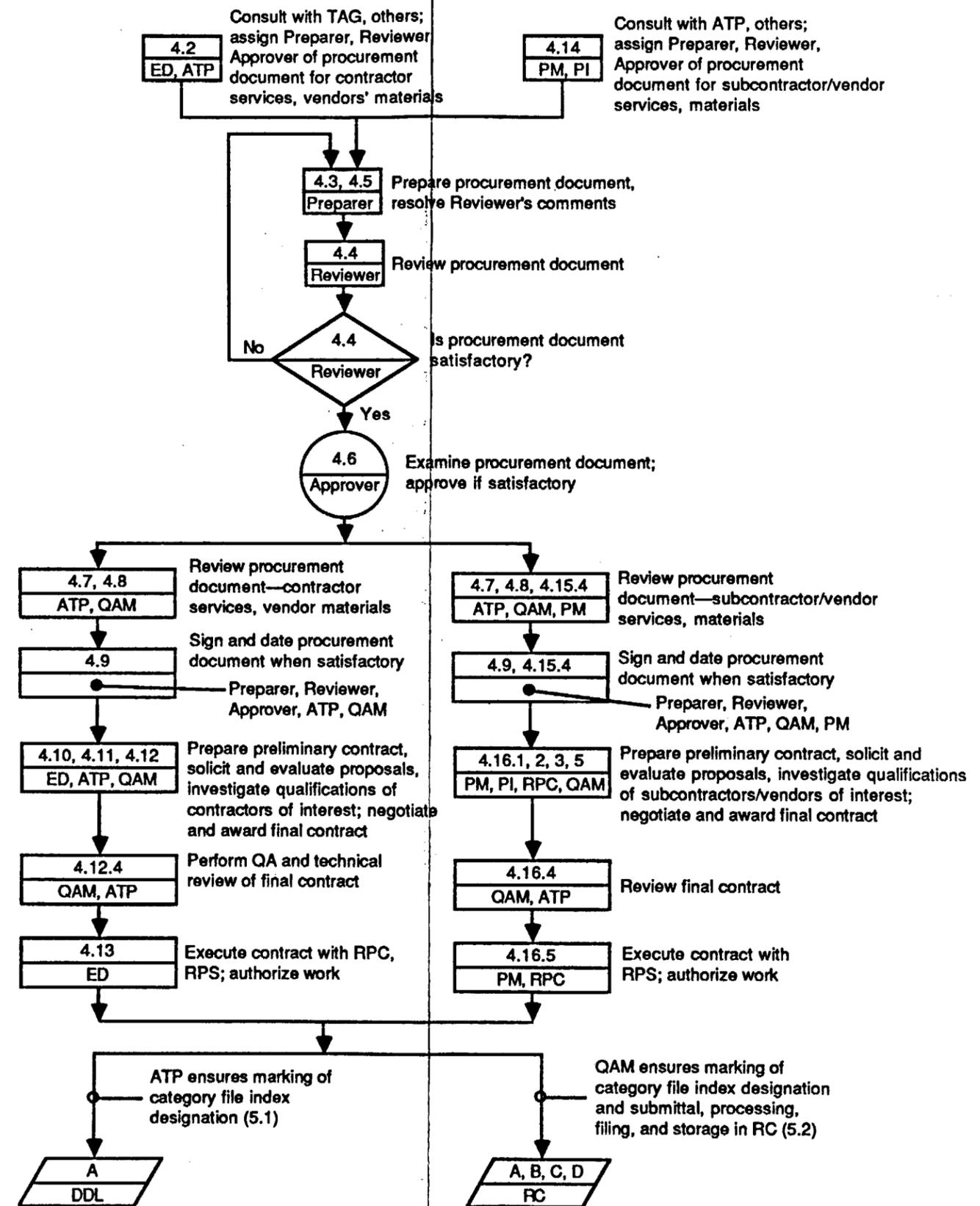
OUTPUT DOCUMENTS REQUIRED

<u>KEY</u>	<u>TITLE</u>
A	Final Procurement Contract (Including Approved Procurement Document)
B	Contract/Subcontractor and Vendor/Supplier Qualification Documentation
C	Review Documentation, in general, including Quality Assurance Review of Final Procurement Contracts and Resolution of Reviewer's Comments on Procurement Document
D	Proposal Solicitation Documentation and Contractor/Subcontractor and Vendor/Supplier Proposals (successful bidders only)

DEFINITIONS

- ATP - Administrator of Technical Programs
- DDL - Document Distribution List
- ED - Executive Director
- NWPO - Agency for Nuclear Projects/Nuclear Waste Project Office
- PI - Principal Investigator
- PM - Project Manager
- QA - Quality Assurance
- QAM - Quality Assurance Manager
- RC - NWPO Records Center
- RPC - Contractor's Responsible Person
- RPS - Subcontractor's or Vendor's/Supplier's Responsible Person
- TAG - Technical Advisory Group

FIGURE 8.0-1 - FLOW CHART FOR PROCUREMENT CONTRACT CONTROL AND CONTRACTOR/SUBCONTRACTOR QUALIFICATION



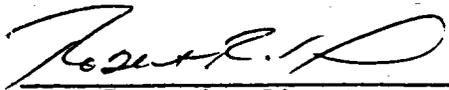
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REVISION 0  
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TITLE: DOCUMENT DISTRIBUTION LIST AND FILE INDEX

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for the preparation, approval, and control of the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) Document Distribution List and for the preparation and distribution of the NWPO File Index. The procedure (along with QA and technical implementing procedures) controls distribution and indexing of NWPO, contractor, subcontractor, and vendor/supplier documents and revisions thereto except that documents generated by procedures QAP-2.1 and QAP-2.2 are distributed in accordance with those procedures. This procedure addresses both input/support and output documents.

2.0 DEFINITIONS

2.1 See the Glossary for the following definitions:

2.1.1 Category File Index Designation

2.1.2 Document

2.1.3 Document Distribution List

2.1.4 Input/Support Document

2.1.5 NWPO File Index

2.1.6 Output Document

3.0 INTERFACING PROCEDURES

3.1 QAP-1.1, "Position Titles, Position Descriptions, Employee Experience Records, and Qualification Statements"

3.2 QAP-2.3, "Indoctrination and Training in the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual"

3.3 QAP-2.4, "Management Assessment of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Program"

- 3.4 QAP-3.1, "Calculations"
- 3.5 QAP-3.2, "Technical Reports"
- 3.6 QAP-3.3, "Peer Reviews"
- 3.7 QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification"
- 3.8 QAP-6.2, "Progress Reports and Master Document Lists"
- 3.9 QAP-17.1, "Quality Assurance Records"

#### 4.0 DOCUMENT DISTRIBUTION LIST AND FILE INDEX

##### Document Distribution List

##### Format

- 4.1 The Administrator of Technical Programs shall establish the format of the Document Distribution List (DDL). As a minimum, the DDL shall contain the following:

The title "Document Distribution List."

The dated signatures of the DDL Preparer and Approver.

All pages of the DDL shall contain the following:

NWPO identification

Revision designation and date (the original issue is Revision 0)

The page number and total number of pages (e.g., Page 2 of 3.)

##### Content

The DDL shall contain at least the following information:

A list of the documents identified by type and generating organization (e.g., Document Distribution List - NWPO; Technical Report - Mifflin)

Names, position titles, and organizations of document recipients

The number of copies of the document each document recipient is to receive

An instruction to document recipients to promptly destroy superseded documents or promptly mark them "Void" or "Superseded."

If it is necessary to use initials to designate individuals or position titles, the initials shall be listed and defined within the DDL.

Preparation and Approval

- 4.2 The Administrator of Technical Programs, shall consult with the QA Manager, Project Managers, Principal Investigators, Laboratory Directors, and others, as needed, and prepare the DDL. The DDL shall reflect distribution requirements indicated by QA and technical procedures and the QA program.
- 4.3 The Administrator of Technical Programs shall then sign and date the DDL as Preparer, and transmit it to the QA Manager.
- 4.4 The QA Manager shall review the DDL for currency and accuracy, and when satisfied shall sign and date the list as Approver, and transmit it to the Administrator of Technical Programs.
- 4.5 The DDL shall then be distributed in accordance with Section 5.0, herein. Persons responsible for distribution of listed documents shall be indicated in appropriate QA and technical procedures.

NWPO File Index

- 4.6 The Administrator of Technical Programs shall prepare a preliminary, unified NWPO File Index that controls NWPO, contractor, subcontractor, and vendor/supplier documents. The index may be in any suitable format but shall contain category titles and category file index designations that uniquely identify each document by category and generating organization. As a minimum, each page of the NWPO File Index shall contain the following information:
- The words "NWPO File Index"
  - Date of issuance
  - Revision identification (the original issue is Revision 0)
  - Page identification including the total number of pages (e.g., Page 3 of 5).
- 4.6.1 The NWPO File Index shall also include an explanation of the filing system.
- 4.7 The Administrator of Technical Programs shall submit the proposed NWPO File Index to the Executive Director, QA Manager, Project Managers, Principal Investigators, and others, as appropriate, for comments on the adequacy of the file index.
- 4.8 When all comments are resolved, the Administrator of Technical Programs shall sign and date the NWPO File Index as Preparer and transmit the index to the QA Manager.

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- 4.9 The QA Manager shall review the NWPO File Index for unique identification of documents, and when satisfied he/she shall sign and date the index as Approver and return it to the Administrator of Technical Programs for distribution.
- 4.10 The Administrator of Technical Programs shall maintain a master copy of the approved NWPO File Index in an office file, and shall ensure that copies of the index are distributed in accordance with Section 5.0 of this procedure.
- 4.11 In general, the Principal Investigator, Administrator of Technical Programs, QA Manager, Laboratory Director, and, as appropriate, designated Others shall ensure that documents under their control (including any vendor/supplier documents) are correctly marked with the category file index designation and placed in office files as needed to provide reasonable access to document users.

5.0 OUTPUT DOCUMENTS

- 5.1 The Administrator of Technical Programs shall ensure that the DDL is marked with the category file index designation and distributed to the QA Manager, per procedure QAP-17.1, "Quality Assurance Records," and to Document Recipients, Project Managers, Principal Investigators, and Laboratory Directors, to persons assigned the responsibility of document distribution by QA and technical procedures, and to others listed on the DDL. The DDL shall be placed in office files, as needed, to provide reasonable access to all document users.
- 5.2 The Administrator of Technical Programs shall ensure that the NWPO File Index is marked with the category file index designation and distributed to the QA Manager per procedure QAP-17.1, to other persons identified in Subsection 4.11, herein, and to others designated on the DDL. The NWPO File Index shall be placed in office files, as needed, to provide reasonable access to index users.
- 5.3 The QA Manager shall ensure processing of the Document Distribution List and NWPO File Index in the NWPO Records Center in accordance with procedure QAP-17.1.

6.0 REVISIONS

- The Project Manager shall notify the Administrator of Technical Programs, in writing, of any changes necessary to maintain the DDL current.
- 6.1 The Administrator of Technical Programs shall ensure revision and distribution of the Document Distribution List within 15 working days of any changes.

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- 6.1.1 Revisions to the Document Distribution List or to the NWPO File Index shall be made in the same manner as the original issue in accordance with this procedure. Recipients of revised DDLs or file indexes shall promptly destroy the superseded DDLs or file indexes or promptly mark them "Void" or "Superseded."
- 6.1.2 Revisions to the DDL or to the NWPO File Index shall be made by issuing the entire documents and suitably identifying the revised portions by means of bold face type or by other means as necessary. When a new revision is made, the previous revision identification shall be deleted.

7.0 REFERENCES

- 7.1 NWPO QA Program, Section 03, Design Control (Analysis of Site Characterization Data)
- 7.2 NWPO QA Program, Section 06, Document Control
- 7.3 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975
- 7.4 10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983
- 7.5 ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986
- 7.6 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

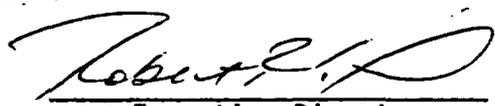
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None

TITLE:     **PROGRESS REPORTS AND MASTER DOCUMENT LISTS**

APPROVED:

  
\_\_\_\_\_  
Quality Assurance Manager

  
\_\_\_\_\_  
Executive Director

**1.0     PURPOSE**

This procedure describes the quality assurance (QA) requirements for the content, preparation, approval, and distribution of progress reports and master document lists pertinent to data acquisition, data analysis and research activities of the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) and its contractors and subcontractors. The purpose of the procedure is to track the current status of output documents and activities so as to prevent inadvertent use of superseded, obsolete, or withdrawn documents. The procedure does not address non-data acquisition/analysis documents, such as audit reports or the QA Manual, which are addressed by other procedures.

**2.0     DEFINITIONS**

2.1     See the Glossary for the following definitions:

2.1.1   Document

2.1.2   Input/Support Document

2.1.3   Master Document List

2.1.4   Output Document

2.1.5   Progress Report

**3.0     INTERFACING PROCEDURES**

3.1     QAP-3.1, "Calculations"

3.2     QAP-3.2, "Technical Reports"

3.3     QAP-3.3, "Peer Reviews"

3.4     QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification"

3.5     QAP-6.1, "Document Distribution List and File Index"

3.6     QAP-17.1, "Quality Assurance Records"

4.0 FORMAT, CONTENT, PREPARATION, APPROVAL, AND DISTRIBUTION

Progress Reports

4.1 The Administrator of Technical Programs shall prepare progress reports of NWPO and peer group technical activities, if requested by the Executive Director, and shall secure progress reports of contractor/subcontractor activities from the Project Managers. Reports shall be prepared/submitted at intervals commensurate with the activities being reported, as determined by the Administrator of Technical Programs.

4.1.1 The reports may be presented in any suitable format but shall include the following as a minimum:

Summary of activities performed and dates or expected dates of completion, including attendance at meetings, short courses, etc.

Lists of output documents identified by document type, title, number, and revision, and classified as follows:

Documents in preparation

Documents under review

Documents approved and distributed with date of distribution to NWPO Records Center

Documents classified as obsolete or withdrawn

Proposed new documents

Time interval addressed by report

Signature of Administrator of Technical Programs or Project Manager, as applicable, with organizational identification.

Each page of the progress report shall include:

Identification as progress report

Page number and total number of pages (e.g., Page 2 of 3).

4.1.2 Documents for which the indicated identification may not be feasible may be identified in an alternate manner. For example, computer programs may use a unique code that incorporates number and revision.

4.1.3 If there has been no activity during a particular reporting interval, the Administrator of Technical Programs or Project Manager may substitute a written statement of this fact in place of the report.

- 4.1.4 The progress reports and written statements shall be distributed as indicated in Section 5.0, herein.

Master Document Lists

- 4.2 The Administrator of Technical Programs shall ensure preparation of a master document list (MDL) for each output document type (e.g., procurement documents, technical reports, calculations not included in technical reports), incorporating information from the progress reports and/or from other sources.

- 4.2.1 The MDLs may be presented in any format but shall include the following as a minimum:

- Document title and identification number
- Current document revision
- Name of the organization generating document
- Identification of obsolete or withdrawn documents
- Signature of Administrator of Technical Programs as Preparer and of the QA Manager as Approver.

Each page of the MDL shall include:

- Identification as an MDL
- Identification of document type listed (e.g., technical reports)
- Revision and date of MDL (the original issue is Revision 0)
- Page number and total number of pages (e.g., Page 2 of 4).

- 4.2.2 Documents for which the indicated identification system, above, may not be feasible may be identified in an alternate manner. For example, computer programs may use a unique code that incorporates number and revision.

- 4.3 The Administrator of Technical Programs shall sign the MDL as Preparer and send it to the QA Manager.

- 4.4 The QA Manager shall review the MDL, using sources such as records listed on the stored records index of procedure QAP-17.1, and when satisfied shall sign the MDL as Approver.

- 4.5 The MDLs shall be distributed as indicated in Section 5.0, herein. The Administrator of Technical Programs shall maintain a file of all current MDLs.

5.0 OUTPUT DOCUMENTS

5.1 The Administrator of Technical Programs shall ensure that progress reports, substitute written statements, and master document lists are marked with the category file index designation and distributed to persons on the Document Distribution List in accordance with procedure QAP-6.1, "Document Distribution List and File Index." He/she shall also ensure transmittal of these documents to the QA Manager per procedure QAP-17.1, "Quality Assurance Records."

5.1.1 The Executive Director shall receive progress reports and substitute written statements.

5.1.2 Distribution of MDLs shall ensure that NWPO, contractor, and subcontractor persons have ready access to the current lists. MDLs shall be placed in office files as needed. See Subsection 6.3, herein.

5.2 The QA Manager shall ensure processing of progress reports, substitute written statements, and master document lists in the NWPO Records Center in accordance with procedure QAP-17.1, "Quality Assurance Records."

6.0 REVISIONS

6.1 Revisions to MDLs and progress reports shall be processed in the same manner as described by this procedure for the original issue.

6.2 Revised MDLs and progress reports shall be issued in their entirety with revised portions being identified by bold face type or by other means as necessary. When a new revision is made, the previous revision identification shall be deleted.

6.3 Revised MDLs shall be issued as soon as feasible in response to changes noted in the progress reports. Users of output documents shall consult MDLs to verify use of current revisions of documents prior to start of work affected by the documents.

6.4 Document Users shall promptly destroy superseded and obsolete or withdrawn MDLs and documents listed on MDLs or promptly mark them "Void" or "Superseded" or "Withdrawn."

7.0 REFERENCES

7.1 NWPO QA Program, Section 03, Design Control (Analysis of Site Characterization Data)

7.2 NWPO QA Program, Section 06, Document Control

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QAP-6.2  
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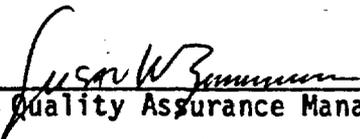
- 7.3 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975
- 7.4 10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983
- 7.5 ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986
- 7.6 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984
- 8.0 FLOW CHART  
None

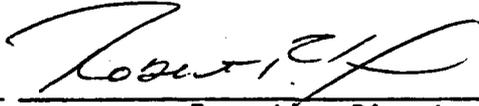
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QUALITY ASSURANCE PROCEDURE

QAP-15.1  
REVISION 0  
JUNE 10, 1988

TITLE: NONCONFORMANCES

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for identifying, documenting, and tracking nonconformances to assure that items, activities, or services found not to conform to program specifications and/or procedures are prevented from being used inadvertently. Authorized nonconformances are addressed in procedure QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification."

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

2.1.1 Authorized Nonconformance

2.1.2 Corrective Action

2.1.3 Nonconformance

2.1.4 Nonconformance Report

2.1.5 Significant Condition Adverse to Quality

3.0 INTERFACING PROCEDURES

3.1 QAP-16.1, "Corrective Action"

3.2 QAP-17.1, "Quality Assurance Records"

3.3 QAP-18.1, "Audits"

4.0 NONCONFORMANCES

Identification and Investigation

4.1 The QA Manager shall be made aware of nonconformances as well as apparent nonconformances by the following means:

Audits conducted by the QA Manager

Reports of surveillances conducted by or for NWPO

Direct mandatory notifications from inspectors or other NWPO, contractor, subcontractor, or vendor/supplier individuals observing apparent nonconformances

Other means

- 4.2 When a nonconformance is identified as a result of an audit, the QA Manager shall document the nonconformance separately in a nonconformance report (NCR) in accordance with this procedure. Corrective action for the nonconformance shall be initiated according to procedure QAP-16.1, "Corrective Action."
- 4.3 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. As needed, the QA Manager may perform a special audit (per procedure QAP-18.1) as part of the investigation.
- 4.4 When an apparent nonconformance is detected by an individual performing work within the NWPO QA Program, the Individual shall notify the QA Manager, in writing, as soon as possible. (The Individual may consult with his/her supervisor prior to formal notification.)
- 4.4.1 The Individual may use oral communication to notify the QA Manager of the apparent nonconformance; however, a signed and dated written notification of the apparent nonconformance must follow the oral notification within two working days.
- 4.4.2 The QA Manager shall investigate all notifications.
- 4.4.2.1 If there is no nonconformance, the QA Manager shall so indicate this on the NCR and inform the Individual in writing. The QA Manager shall then process the NCR according to Subsections 4.10 and 4.17.1.
- 4.4.2.2 If the QA Manager determines that there is a nonconformance, the QA Manager shall so indicate this on the NCR, inform the individual in writing and process the NCR per Subsections 4.10 through 4.21, herein. The QA Manager may also initiate a special audit.
- 4.5 If a special audit to investigate an apparent nonconformance is performed, the QA Manager shall indicate the NCR number on the audit schedule of procedure QAP-18.1, "Audits."
- 4.6 The QA Manager shall determine if any nonconformance is a potential significant condition adverse to quality (SCAQ) and shall indicate the decision on the NCR. If there is a potential SCAQ, the QA Manager shall proceed as indicated in procedure QAP-16.1, "Corrective Action." If there is not a potential SCAQ, the QA Manager shall proceed as indicated in Subsections 4.10 through 4.21 of this procedure.

- 4.7 All investigations and related activities shall be documented and the documentation distributed in accordance with Section 5.0, herein.
- 4.8 All nonconformances shall be resolved by corrective action, per procedure QAP-16.1, "Corrective Action."
- 4.9 Differences of opinion between the QA Manager and others with respect to nonconformances shall be resolved by the Executive Director.

Nonconformance Report

- 4.10 The QA Manager shall initiate a nonconformance report immediately upon notification of a nonconformance or apparent nonconformance and send a copy to the Responsible Individual and to the Administrator of Technical Programs or Project Manager, as appropriate, per procedure QAP-16.1. The report shall include at least the following items, as appropriate:
1. On each page the NCR identification number (assigned from a list maintained by the QA Manager), the NCR revision number (the original issue is Revision 0) and the page number and total number of pages (e.g., Page 2 of 3).
  2. Date of discovery of the nonconformance or apparent nonconformance.
  3. Origin of the NCR (audit identification, surveillance report identification, name and position title of individual, other).
  4. Determination of whether the apparent nonconformance was an actual nonconformance and justification for the determination.
  5. Nature and description of the nonconformance.
  6. Determination of whether the nonconformance is a potential significant condition adverse to quality, justification for the determination, and the corrective action report (CAR) number and special audit number, if applicable.
  7. Determination of whether or not the activity shall be re-performed and the justification for the re-performance (see Subsection 4.14).

8. Nature of the corrective action plan (in addition to item 7), agreed date of completion, and signature of the Responsible Individual.
9. Dated signature of the QA Manager.
10. Close-out date of the NCR and signature of the QA Manager.

#### Control of Nonconforming Items and Activities

- 4.11 For nonconformances by NWPO personnel, the Administrator of Technical Programs shall ensure that the nonconforming item is clearly identified to prevent its inadvertent use. If the nonconforming item is an activity, the Administrator of Technical Programs shall immediately inform all affected individuals by memo and shall send a copy of the memo to the QA Manager.
- 4.12 For nonconformances by contractor or subcontractor personnel, the Project Manager, Principal Investigator, or the Responsible Individual responsible for the area or activity in which the apparent nonconformance occurred, shall ensure that the nonconforming item is clearly identified to prevent its inadvertent use. If the nonconforming item is an activity, the Project Manager shall immediately inform all affected individuals by memo and shall send a copy of the memo to the QA Manager.
- 4.13 All nonconforming items shall be segregated, if practical.
- 4.14 The QA Manager shall confer with the Administrator of Technical Programs and the Executive Director to determine if the item or activity shall be re-performed and make appropriate recommendations for action by the Executive Director.

#### Corrective Action

- 4.15 Corrective actions associated with nonconformances, including any re-performance of activity, shall be conducted as specified in procedure QAP-16.1, "Corrective Action."
- 4.16 The QA Manager shall ensure that all corrective action documentation is attached to the NCR prior to closing out the nonconformance.

#### Close Out

- 4.17 After the QA Manager has verified that the corrective action for the nonconformance is complete and effective (per procedure QAP-16.1), the QA Manager shall close out the nonconformance by dating and signing the NCR.

- 4.17.1 In cases where a reported apparent nonconformance turns out not to be a nonconformance (see Subsection 4.4.2.1), the QA Manager shall close out the nonconformance report at the time of initiation (see Subsection 4.10).
- 4.17.2 The QA Manager shall inform the Administrator of Technical Programs, Project Manager and Principal Investigator, as appropriate, in writing, that the nonconformance has been closed.
- 4.18 If the corrective action for the nonconformance has not been satisfactorily or effectively implemented, the QA Manager may upgrade the nonconformance to a SCAQ and initiate a corrective action report (CAR), per procedure QAP-16.1, "Corrective Action." The QA Manager shall inform the Administrator of Technical Programs, and Project Manager or Principal Investigator, as appropriate, in writing, of the action taken.

#### Tracking of NCRs

- 4.19 The QA Manager shall initiate and maintain a NCR tracking log to facilitate monitoring and closing out nonconformances in a timely manner. The format shall provide for at least the following items:
1. Identification as an NCR tracking log.
  2. NCR identification number and revision number for each NCR.
  3. Date of issuance of the NCR.
  4. Name of organization and name/position title of individual responsible for corrective action.
  5. Date of required response and date received.
  6. Agreed date of completion for corrective action
  7. Date of final NCR close out and signature of the QA Manager on the log.
  8. On each page of the log, the date of log issuance and the page number and total number of pages (e.g., Page 2 of 3).

- 4.20 The QA Manager shall update the tracking log no less frequently than quarterly.

#### Quarterly Reports

- 4.21 The QA Manager shall submit a Quarterly Report to the Executive Director that includes a listing of all NCRs issued in that quarter along with a short summary of each nonconformance, stating the nature of and the corrective action taken to correct the nonconformance.

**5.0**        **OUTPUT DOCUMENTS**

- 5.1        The QA Manager shall ensure that the documents listed below are marked with the category file index designation, in accordance with procedure QAP-6.1, "Document Distribution List and File Index," and submitted to and filed in the NWPO Records Center per procedure QAP-17.1, "Quality Assurance Records."
- 5.1.1      Closed out nonconformance reports with attached corrective action documentation
- 5.1.2      Investigation documentation of reported nonconformances
- 5.1.3      Notifications of apparent nonconformances
- 5.1.4      Nonconformance tracking log
- 5.1.5      Quarterly Reports
- 5.1.6      Surveillance reports indicating nonconformances
- 5.1.7      Other nonconformance documentation
- 5.2        The QA Manager shall distribute the above documents to persons identified on the Document Distribution List, per procedure QAP-6.1.
- 5.3        The QA Manager shall ensure that the appropriate Responsible Individual receives a copy of the closed out NCR with all attached documentation.

**6.0**        **REVISIONS**

- 6.1        Revisions to NCRs and to other documents shall be processed in the same manner as the original issue. Revised documents shall be issued in their entirety.
- 6.1.1      Each revised portion shall be identified by bold face type or by other means, if necessary, and previous revision identification shall be deleted.
- 6.1.2      Recipients of revised documents shall promptly destroy the superseded copy or promptly mark it "Void" or "Superseded."

**7.0**        **REFERENCES**

- 7.1        NWPO QA Program, Section 02, Quality Assurance Program
- 7.2        NWPO QA Program, Section 15, Nonconformances
- 7.3        NWPO QA Program, Section 16, Corrective Action
- 7.4        NWPO QA Program, Section 17, Quality Assurance Records

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- 7.5 NWPO QA Program, Section 18, Audits
- 7.6 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975
- 7.7 10CFR60, Subpart G - Disposal of High-Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983
- 7.8 ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986
- 7.9 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories - June 1984
- 8.0 FLOW CHART

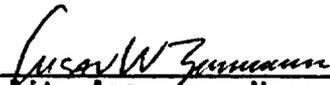
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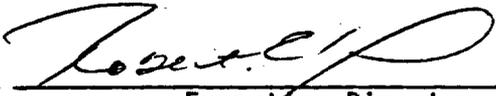
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QUALITY ASSURANCE PROCEDURE

QAP-16.1  
REVISION 0  
JUNE 10, 1988

TITLE: CORRECTIVE ACTION

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for correcting nonconformances and significant conditions adverse to quality (SCAQs). It also addresses the related topic of stop-work orders.

For purposes of this procedure, corrective action encompasses errors and deficiencies in approved output or verified input/support documents.

Corrective action for audit observations and for audit findings not classified as nonconformances is addressed in procedure QAP-18.1, "Audits."

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

2.1.1 Corrective Action

2.1.2 Corrective Action Report

2.1.3 Input/Support Document

2.1.4 Nonconformance

2.1.5 Nonconformance Report

2.1.6 Output Document

2.1.7 Significant Condition Adverse to Quality

2.1.8 Stop-Work Order

3.0 INTERFACING PROCEDURES

3.1 QAP-2.1, "Preparation, Control, and Distribution of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual"

- 3.2 QAP-2.2, "Preparation and Control of Technical Procedures"
- 3.3 QAP-2.4, "Management Assessment of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Program"
- 3.4 QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification"
- 3.5 QAP-15.1, "Nonconformances"
- 3.6 QAP-17.1, "Quality Assurance Records"
- 3.7 QAP-18.1, "Audits"

#### 4.0 CORRECTIVE ACTION ACTIVITIES

##### General Statement

- 4.1 Corrective action related to nonconformances is performed as indicated by Subsections 4.1 through 4.8, herein, and documented on nonconformance reports (NCRs) in accordance with procedure QAP-15.1, "Nonconformances." Corrective action related to significant conditions adverse to quality is performed as indicated by Subsections 4.9 through 4.19, herein, and documented as corrective action reports (CARs) per Subsection 4.11, herein.

##### Nonconformances

- 4.2 The QA Manager shall be made aware of nonconformances and initiate nonconformance reports as indicated in procedure QAP-15.1, "Nonconformances."
- 4.3 For nonconformances issued against NWPO personnel, the QA Manager shall submit the NCR from procedure QAP-15.1 to the Administrator of Technical Programs. The Administrator of Technical Programs shall confer with the QA Manager and others, as needed, and formulate a corrective action plan and an expected date of completion to correct the nonconformance and prevent its recurrence and shall document this on the NCR. The Administrator of Technical Programs shall then submit the NCR to the QA Manager within 15 calendar days from the date of issuance of the NCR and perform the corrective action.
- 4.3.1 The Administrator of Technical Programs may designate a Responsible Individual to perform his/her functions regarding nonconformance corrective actions. The Responsible Individual shall have demonstrated competence in the specific area in which the nonconformance occurred and have an adequate understanding of the requirements involved.

- 4.4 For nonconformances issued against contractor/subcontractor personnel, the QA Manager shall submit the NCR from procedure QAP-15.1 to the Project Manager, Principal Investigator, or other Responsible Individual responsible for the area or activity in which the nonconformance occurred. The Project Manager, Principal Investigator, or Responsible Individual shall confer with the QA Manager and others, as needed, and formulate a corrective action plan and expected date of completion to correct the nonconformance and prevent its recurrence and shall document this on the NCR. The Project Manager, Principal Investigator, or Responsible Individual shall then submit the NCR to the QA Manager within 15 calendar days from the issuance of the NCR and perform the corrective action.
- 4.5 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.
- 4.6 The QA Manager shall approve all corrective action plans prior to their implementation.
- 4.7 The QA Manager and technical personnel, as needed, shall verify and document that the corrective action for the nonconformance has been satisfactorily and effectively implemented. Verification may be accomplished by a special follow-up audit scheduled and performed per procedure QAP-18.1, "Audits."
- 4.7.1 If corrective action has been satisfactorily and effectively implemented, the QA Manager shall so indicate this by his/her dated signature on the NCR closing out the nonconformance and the NCR.
- 4.7.2 If corrective action has not been satisfactorily and effectively implemented, the QA Manager shall issue a written request to the Executive Director, Administrator of Technical Programs, Project Manager, or Principal Investigator for suitable action. The QA Manager may institute SCAQ and stop-work proceedings per Subsections 4.10 and 4.10.1, herein.
- 4.8 All activities relating to corrective action of nonconformances shall be documented and documentation processed as indicated in Section 5.0, herein.

Significant Conditions Adverse to Quality

- 4.9 A significant condition adverse to quality is defined as a condition that has, has had, or could have a serious effect on the quality of the data or conclusions generated by NWPO-sponsored activities critical to the objectives of NWPO. Examples of significant conditions adverse to quality are system deficiencies in the QA program, unsatisfactory work being approved and/or released, and recurring nonconformances involving the same item or activity.

- 4.10 For nonconformances identified as potential SCAQs per procedure QAP-15.1, "Nonconformances," or Subsection 4.7.2, herein, the QA Manager shall confer with the Administrator of Technical Programs, Project Manager, Principal Investigator, and others as necessary, to establish whether a significant condition adverse to quality exists.
- 4.10.1 If a nonconformance is a SCAQ, the QA Manager shall inform the Executive Director and initiate a Corrective Action Report (CAR). The Executive Director may issue a stop-work order to the Administrator of Technical Programs or Project Manager, as appropriate. Issuance of a stop-work order depends on the specific circumstances involved. See Subsections 4.16 through 4.19, herein.
- 4.10.2 If a nonconformance is determined not to be a SCAQ, it shall be processed as a nonconformance in accordance with procedures QAP-15.1 and QAP-16.1.

Corrective Action Reports (CARs)

- 4.11 The QA Manager shall establish the format for corrective action reports. The report shall include at least the following items:
1. On each page the CAR identification number (assigned from a list maintained by the QA Manager), the CAR revision number (the original issue is Revision 0), and the page number and total number of pages (e.g., Page 2 of 4)
  2. Dated signature of the QA Manager
  3. Origin of the CAR (NCR number, surveillance report, audit or special audit number, name and date of notification by individual, other)
  4. Nature and description of the significant condition adverse to quality
  5. Name of organization and name/position title of person(s) responsible for corrective action
  6. Required date of response to the CAR
  7. Nature of corrective action plan, agreed date of completion, and signature of Responsible Individual
  8. Date of follow-up audit
  9. Date of final CAR close-out and dated signature of QA Manager

- 4.12 The QA Manager shall complete items 1 through 6 of the CAR and transmit a copy to the Responsible Individual as soon as feasible.
- 4.13 The required date of response to a CAR shall not exceed 10 calendar days from the date of the CAR. Under special circumstances and following a written request from the Responsible Individual, the QA Manager may extend this to 15 calendar days.
- 4.14 The Responsible Individual shall confer with the QA Manager and others, such as the Project Manager or Administrator of Technical Programs, as appropriate, and formulate a corrective action plan and expected date of completion to correct the SCAQ and establish measures to prevent a recurrence. He/she shall then document this on the CAR, sign the CAR, return it to the QA Manager before the indicated response date and proceed with the corrective action.
- 4.14.1 Corrective action plans shall address the root cause(s) of the SCAQ, the effect on any previously completed work or current work underway, any required remedial action to be taken, and action necessary to prevent the recurrence of the condition.
- 4.14.2 The QA Manager shall approve all corrective action plans prior to implementation.
- 4.15 The QA Manager shall schedule and perform a special follow-up audit in accordance with procedure QAP-18.1, "Audits," to verify implementation and effectiveness of corrective action. The QA Manager may use Technical Auditors, as needed, on the follow-up audit.
- 4.15.1 If corrective action has been satisfactorily and effectively implemented, the QA Manager shall so indicate this by his/her dated signature on the CAR closing out the CAR and the SCAQ.
- 4.15.2 If corrective action has not been satisfactorily or effectively implemented, the QA Manager shall, in writing, request the Executive Director, Administrator of Technical Programs, Project Manager, or Principal Investigator, as appropriate, to take suitable action. The QA Manager shall request the Executive Director to issue a stop-work order.
- Stop-Work Orders
- 4.16 Any stop-work order shall be a written communication, signed and dated by the Executive Director and attached to the appropriate CAR, describing the nature of the SCAQ, the CAR identification number, the specific work that must be stopped, and the effective date of work stoppage.

4.17 The CAR shall be processed per Subsections 4.11 through 4.15.2, except that for stop-work orders issued to contractors/subcontractors, the Executive Director, Administrator of Technical Programs, and Project Manager in addition to the QA Manager, shall approve the corrective action plan. For stop-work orders issued to NWPO, the plan shall be approved by the QA Manager and the Executive Director. The Executive Director shall lift the stop-work order when the adverse condition addressed by the stop-work order has been substantially corrected.

4.18 All differences of opinion concerning significant conditions adverse to quality and stop-work orders shall be resolved by the Executive Director.

4.19 All activities related to CARs and stop-work orders shall be documented, and documentation processed as indicated in Section 5.0, herein.

Corrective Action Resulting from Management Assessment of NWPO  
QA Program (Procedure QAP-2.4)

4.20 Corrective action resulting from management assessment of the NWPO QA Program shall be performed, verified, and documented as indicated by procedure QAP-2.4, "Management Assessment of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Program."

Tracking of CARs

4.21 The QA Manager shall initiate and maintain a CAR tracking log to facilitate monitoring and closing out CARs in a timely manner. The format shall provide for at least the following items:

1. Identification as a CAR tracking log
2. CAR identification number and revision number on each CAR
3. Date of issuance of each CAR
4. Name of organization and name/position title of Responsible Individual
5. Date of required response
6. Date response received
7. Agreed date of completion for the corrective action
8. Date of final CAR close-out
9. Signature of QA Manager when CAR is closed out
10. On each page of the log, the date of log issuance and page number and total number of pages (e.g., Page 2 of 3)

4.22 The QA Manager shall update the tracking log no less frequently than quarterly.

Trend Analysis of NCRs and CARs

4.23 The QA Manager shall perform a trend analysis of all nonconformances, significant conditions adverse to quality and stop-work orders to determine any adverse trends. Trend analysis shall be done, at a minimum, semiannually. Any adverse trends shall be reported to the Executive Director and, as appropriate, to others.

4.24 Trend analyses shall be documented, and the documentation processed as indicated in Section 5.0, herein.

Quarterly Reports

4.25 The QA Manager shall include with the Quarterly Report to the Executive Director, per procedure QAP-15.1, a list of all CARs issued in the quarter with a short summary of each SCAQ stating the nature of the SCAQ and the corrective action taken.

5.0 OUTPUT DOCUMENTS

5.1 The QA Manager shall ensure that the documents listed below are marked with the category file index designation, in accordance with procedure QAP-6.1, "Document Distribution List and File Index," and submitted to the NWPO Records Center per procedure QAP-17.1, "Quality Assurance Records."

5.1.1 Closed-out corrective action reports

5.1.2 Corrective action tracking log

5.1.3 NCR corrective action documentation

5.1.4 Quarterly reports

5.1.5 Stop-work orders

5.1.6 Trend analyses

5.1.7 Other corrective action documentation

5.2 The QA Manager shall ensure processing of the above documents in the NWPO Records Center per procedure QAP-17.1, "Quality Assurance Records" and the distribution of these documents to the appropriate persons on the Document Distribution List of procedure QAP-6.1.

5.3 The QA Manager shall ensure that the Executive Director and Administrator of Technical Programs as well as the appropriate Project Manager, Principal Investigators and Responsible Individual receive a copy of the closed out CAR with attached documentation as needed.

**6.0**        **REVISIONS**

- 6.1        Revisions to CARs, stop-work orders, and other documents shall be processed in the same manner as the original issues. Revised documents shall be issued in their entirety.
- 6.2        Each revised portion shall be identified by boldface type or by other means as necessary. Previous revision identification shall be deleted.
- 6.3        Recipients of revised documents shall promptly destroy the superseded copies or promptly mark them "Void" or "Superseded."

**7.0**        **REFERENCES**

- 7.1        NWPO QA Program, Section 02, Quality Assurance Program
- 7.2        NWPO QA Program, Section 15, Nonconformances
- 7.3        NWPO QA Program, Section 16, Corrective Action
- 7.4        NWPO QA Program, Section 17, Quality Assurance Records
- 7.5        NWPO QA Program, Section 18, Audits
- 7.6        10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975
- 7.7        10CFR60, Subpart G - Disposal of High-Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983
- 7.8        ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986
- 7.9        U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories - June 1984

**8.0**        **FLOW CHART**

Figure 8.0-1 is the flow chart for processing of corrective action for nonconformances, significant conditions adverse to quality and stop-work orders.

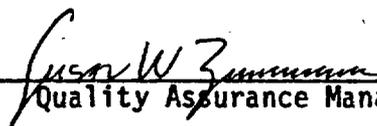


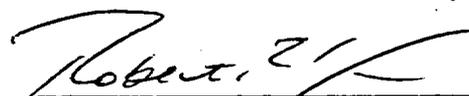
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QUALITY ASSURANCE PROCEDURE

QAP-17.1  
REVISION 0  
JUNE 10, 1988

TITLE: QUALITY ASSURANCE RECORDS

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for collection, storage, and retrieval of QA records generated by the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) and its contractors, subcontractors, and vendors/suppliers. This procedure encompasses records such as technical reports, computer tapes or photographs, but not storage of geotechnical or other samples such as rock or water, which is addressed in technical procedures applicable to Section 13 of the NWPO QA Program.

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

2.1.1 Input/Support Document

2.1.2 NWPO Records Center

2.1.3 Output Document

2.1.4 Quality Assurance Records

2.1.5 Stored Records Index

3.0 INTERFACING PROCEDURES

3.1 QAP-1.1, "Position Titles, Position Descriptions, Employee Experience Records, and Qualification Statements"

3.2 QAP-2.1, "Preparation, Control, and Distribution of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual"

3.3 QAP-2.3, "Indoctrination and Training in the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual"

3.4 QAP-2.4, "Management Assessment of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Program"

3.5 QAP-2.5, "Review of Documents and Technical Information for Impact on the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual"

- 3.6 QAP-3.1, "Calculations"
- 3.7 QAP-3.2, "Technical Reports"
- 3.8 QAP-3.3, "Peer Reviews"
- 3.9 QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification"
- 3.10 QAP-6.1, "Document Distribution List and File Index"
- 3.11 QAP-6.2, "Progress Reports and Master Document Lists"
- 3.12 QAP-15.1, "Nonconformances"
- 3.13 QAP-16.1, "Corrective Action"
- 3.14 QAP-18.1, "Audits"

**4.0 COLLECTION, STORAGE, AND RETRIEVAL OF QA RECORDS**

Record Collection

- 4.1 The Administrator of Technical Programs or QA Manager, as appropriate, shall ensure that records generated by NWPO (and vendors/suppliers dealing directly with NWPO) are transmitted to the NWPO Records Center, on a continuous basis, as soon as feasible after generation, and the Principal Investigator, Laboratory Director, or Others as designated, shall ensure the same for records generated by contractors, subcontractors, and their vendors/suppliers.
  - 4.1.1 Specific record submittal responsibilities of the Administrator of Technical Programs, the QA Manager, Principal Investigator, Laboratory Director, and Others are specified in QA and technical procedures. See Section 17 of the QA program and QA and technical implementing procedures for examples of QA records.
- 4.2 The Record Submitter specified in the QA and technical procedures shall transmit the record to the QA Manager for processing and storage in the NWPO Records Center and he/she shall also submit an attached transmittal communication with the record.
  - 4.2.1 The transmittal communication shall be identified as a records transmittal communication and shall include the following:
    1. The words, "Yucca Mountain Project"
    2. Submitters' name and position title
    3. Record generating organization

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4. Category file index designation as specified by procedure QAP-6.1, "Document Distribution List and File Index"
5. Record type (e.g., trench log, computer tape)
6. Record title, record number (e.g., calculation number), and revision designation and/or completion date as appropriate
7. Date of record submittal, number of records submitted, and number of pages for each record.

4.2.2 A single transmittal communication may be used to transmit more than one record at one time provided all the records transmitted are from the same organization and have the same category file index designation.

4.3 The Record Submitter shall ensure that the records are acceptable using the following criteria:

Records shall be legible and of reproducible quality.

Records shall be legibly marked with data indicated by items 2 through 5 of Subsection 4.2.1

Records shall be submitted on durable paper or equivalent material such as film when there are negatives

Records shall include signature of a reviewer and approver or other evidence of record verification and completeness, as appropriate and as required by QA or technical procedures. (See Glossary definitions of input/support document and output document.)

4.3.1 For records such as computer tapes where requirements of Subsections 4.2.1 and 4.3 may not apply, the Record Submitter shall ensure that the records are properly identified and verified.

4.4 The QA Manager shall review the records to verify that the records are acceptable and that they have been properly described on the transmittal communication.

4.4.1 If the records are not acceptable or the transmittal communication is incomplete, the QA Manager shall so inform the Record Submitter who shall then resubmit the record or transmittal communication.

4.4.2 In cases where the QA Manager is the Record Submitter, the QA Manager shall provide for independent review of the records such as to satisfy the intent of Subsections 4.2.1 through 4.4.1, and of 4.5.4, herein.

Record Filing and Storage

- 4.5 The QA Manager shall file and store satisfactory records in accordance with the file index established by procedure QAP-6.1, "Document Distribution List and File Index."
- 4.5.1 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 in NWPO's offices.
- 4.5.2 Records shall be firmly attached in binders or in folders or envelopes and protected from moisture, excessive heat, or pressure. Sensitive records, such as film negatives or computer or video tapes, shall receive special protection from hazards such as excessive light, magnetic fields, or stacking.
- 4.5.3 The records stored in the file cabinets in the NWPO Records Center are a historical file not to be used for day-to-day reference. The QA Manager shall control access to the stored records.
- 4.5.4 When the records have been stored, the QA Manager shall return the original transmittal communication to the submitter with a signed and dated statement indicating that the records have been stored in the NWPO Records Center.
- 4.5.4.1 The Record Submitter shall maintain the original transmittal/statement documentation in an office file and the QA Manager shall process another copy per Subsection 5.2. For records submitted by the QA Manager, the originals shall be kept in his/her office file.
- 4.6 Records placed in storage shall be permanently retained. Records later superseded, made obsolete, or withdrawn shall be maintained unchanged in the file cabinets.

Stored Records Index

- 4.7 The QA Manager shall prepare and maintain a stored records index which shall indicate the following information on each page:

The words, "NWPO Stored Records Index"

Location of records (e.g., street address, room number)

The words, "Yucca Mountain Project"

Date of Issue

Page identification indicating the number of the page and the total number of pages in the index (e.g., Page 2 of 3).

The index shall also include the following information for each record stored:

- Category file index designation
- Organization generating the record
- Date of submittal
- Date of completion
- Record type (i.e., calculation, computer tape, technical report, etc.)
- Record title and number (e.g., calculation number)
- Revision (as applicable)
- Date of revision (as applicable)
- Number of pages or other indication of length for records such as computer tapes.

- 4.8 The QA Manager shall distribute copies of the index in accordance with Section 5.0, herein.

#### Record Retrieval

- 4.9 Any NWPO, Contractor, or Subcontractor Person may request copies of records in storage by sending a written request to the QA Manager. The request shall indicate the title, responsible organization, category file index designation, record type, revision, (as applicable), and date of each record.
- 4.10 The QA Manager shall retrieve the requested record from storage and send a copy to the Requestor, as feasible. There shall be special arrangements for documents such as photographs or computer tapes.
- 4.11 The QA Manager shall return the original retrieved record to its proper storage location.

#### 5.0 OUTPUT DOCUMENTS

- 5.1 The QA Manager shall mark the stored records index with the category file index designation, per procedure QAP-6.1, and distribute copies to the Administrator of Technical Programs and to others on the Document Distribution List at least semiannually. A copy of the index and any needed explanation of the file/storage system shall be maintained in the NWPO Records Center and in the file cabinets.
- 5.2 The QA Manager shall also mark a copy of the transmittal documentation of Subsection 4.5.4, per procedure QAP-6.1, and store it in the NWPO Records Center.

**6.0**      **REVISIONS**

6.1      The QA Manager shall ensure revisions of the stored records index as required by the volume of records but not less than semiannually. Revisions of the stored records index shall be processed in accordance with the requirements stated in this procedure for the original. If there is no change to the index, a memorandum stating this fact may be substituted in place of the revision. Memoranda shall be processed per Subsection 5.1, herein.

6.1.1    Individual pages of the stored records index shall not be revised and issued separately. When any part of the index is revised, the entire index shall be issued.

6.1.2    Each revised portion of the stored records index shall be identified by bold face type or by other means as necessary. When a new revision is made, the previous revision identification shall be deleted.

6.1.3    Index Recipients shall promptly destroy superseded indexes or promptly mark them "Void" or "Superseded."

6.2      Collection, processing, storage, and retrieval of revised records (i.e., records from revised documents) shall be accomplished in the same manner as for the original issue.

**7.0**      **REFERENCES**

7.1      NWPO QA Program, Section 17, Quality Assurance Records

7.2      10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975

7.3      10CFR60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983

7.4      ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986

7.5      U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

**8.0**      **FLOW CHART**

None

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QAP-18.1  
REVISION 0  
JUNE 10, 1988

TITLE: AUDITS

APPROVED:

  
Quality Assurance Manager

  
Executive Director

1.0 PURPOSE

This procedure describes the quality assurance (QA) requirements for planning, performing, and documenting audits of the activities performed by the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) and its contractors, subcontractors and vendors/suppliers for their conformance to the NWPO QA Program and procedures. The procedure is the sole auditing procedure for NWPO-sponsored activities. There are no contractors', subcontractors', or vendors'/suppliers' auditing organizations that audit NWPO-sponsored activities. Quality of work audited is a major audit goal.

This procedure also addresses corrective action for audit findings not classified as nonconformances and corrective action for audit observations.

2.0 DEFINITIONS

2.1 Refer to the Glossary for the following definitions:

2.1.1 Audit

2.1.2 Audit Comment

2.1.3 Audit Finding

2.1.4 Audit Observation

2.1.5 Auditor

2.1.6 Document

2.1.7 Lead Auditor

2.1.8 Nonconformance

2.1.9 Objective Evidence

2.1.10 Technical Auditor

3.0 INTERFACING PROCEDURES

- 3.1 QAP-15.1, "Nonconformances"
- 3.2 QAP-16.1, "Corrective Action"
- 3.3 QAP-17.1, "Quality Assurance Records"

4.0 SCHEDULING, PLANNING, PERFORMING, AND DOCUMENTING AUDITS

Audit Scheduling

- 4.1 The QA Manager shall prepare and maintain a current audit schedule identifying audits to be performed and their frequencies and dates. The schedule shall provide coverage and coordination with ongoing NWPO, contractor, subcontractor, and vendor/supplier activities. Audits shall be scheduled at frequencies and dates commensurate with the nature, status, and expected duration of the activities audited. The schedule shall ensure that all significant aspects of the program and all participating organizations and their activities, documents, records, and facilities are adequately audited.

Regularly scheduled audits shall be supplemented by special audits, when necessary, to provide adequate coverage and to verify completion of corrective action.

- 4.1.1 The audit schedule shall be updated and reissued as needed to indicate the audits completed (including special audits), new audits that are scheduled, and any special audits that are required. Each issue of the audit schedule shall be identified by a revision designation and date of issue. Each audit shall be identified by a unique designation to be assigned by the QA Manager.
- 4.1.2 In the case of special audits to investigate an apparent nonconformance per procedure QAP-15.1, the QA Manager shall indicate the NCR number on the schedule.
- 4.2 The QA Manager shall sign and date the original issue and updates to the audit schedule as approver, and ensure distribution of the schedule as indicated in Section 5.0, herein. Inasmuch as the QA Manager is, in effect, NWPO's entire QA organization, the QA Manager is the Preparer and Approver of the audit schedule.

Audit Plan

- 4.3 All audits shall be led and performed by the QA Manager, who shall be a certified Lead Auditor. The QA Manager may be assisted by an independent qualified Technical Auditor(s) as necessary.

The QA Manager shall develop a written audit plan for each audit and file it in a QA audit file and elsewhere as indicated in Section 5.0, herein.

The audit plan shall identify the audit scope, requirements, the Technical Auditors (if any) and activities to be audited, organizations and individuals to be notified, the applicable documents to be examined, and the schedule and time of audit.

4.4 Prior to the performance of each audit, the QA Manager shall issue a memorandum to the Responsible Individual(s) who are to be audited. The memorandum shall advise the individual(s) of the scope and schedule of the pending audit, and shall identify the QA Manager as the Lead Auditor. The QA Manager may perform unannounced and unscheduled audits under special circumstances.

4.5 For each audit, the QA Manager shall review the applicable procedures, procurement documents, and other pertinent documents, and prepare a checklist comprised of questions to be used in the audit. The purpose of this checklist is to ensure depth and continuity of the audit and to aid in the evaluation of objective evidence of compliance with requirements of the QA program and procedures. As appropriate, the checklist shall address topics such as activities, records, items, and corrective action implementation.

4.6 The QA Manager shall sign and date the audit checklist as Approver, furnish each assigned Technical Auditor, if any, with a copy of the approved audit checklist, and discuss with the Technical Auditor(s) any pertinent documents or previously documented audit findings and audit observations. Inasmuch as the QA Manager is, in effect, NWPO's entire QA organization, the QA Manager is the Preparer and Approver of the checklist.

#### Performance of Audit

4.7 The audit shall begin with a preaudit conference between the QA Manager and Technical Auditors and the Responsible Individuals being audited and, as appropriate, the Administrator of Technical Programs, Project Manager, Principal Investigator, and/or others. The purpose of the conference is to review the scope of the audit and to confirm the availability for audit of key personnel and documents.

4.8 The QA Manager and Technical Auditor(s), if any, shall conduct the audit by interviewing the responsible persons in accordance with the approved audit checklist.

- 4.8.1 The audit checklist is intended for use as a guide, and should not restrict the audit investigation when responses and discoveries raise further questions that are not specifically included in the checklist. However, all changes to the checklist shall be documented.
- 4.9 The QA Manager and Technical Auditors, if any, shall seek out, examine, and evaluate documents and other objective evidence verifying that NWPO, contractor, subcontractor, and vendor/supplier activities are being performed and controlled in compliance with the NWPO QA Program, implementing procedures, and procurement documents, that the QA program and procedures are effective in establishing quality of work, and that corrective action is being implemented. As appropriate, the Technical Auditors may use technical verification of work or other means to confirm effectiveness of review/verification activities and quality of work.
- 4.10 At the conclusion of the audit, the QA Manager shall conduct a postaudit conference with the Responsible Individuals audited and, as appropriate, with their supervisors, the Administrator of Technical Programs, Project Manager, Principal Investigator, and/or others to present any audit findings, nonconformances, and audit observations/comments, to clarify any misunderstandings, and to advise Responsible Individuals to plan corrective action.

Audit Documentation

- 4.11 At the completion of the audit, the QA Manager shall consult with the Technical Auditor(s), if any, and prepare an audit report containing the following minimum information:

Date(s) of audit

Names of audit team members and signature of the QA Manager

Audit scope

A summary and description of any audit findings, audit observations, audit comments, or nonconformances with a request for appropriate action or response from responsible individuals and suggestions for corrective action, as appropriate (see Subsections 4.13 and 4.14)

Personnel contacted and identification of their organizations and organizational areas

Description of audit detailing the areas, functions, and activities audited and listing documents and other objective evidence examined

Conclusion (a summary and evaluation of the audit results, positive and negative, including an evaluation statement regarding the effectiveness of the QA program and implementing procedures examined during the audit and any recommendations for improvement)

Each page of the audit report shall contain the following information:

Audit identification

Audit report revision number (the original is Revision 0)

Page number and the total number of pages in the audit report (e.g., Page 4 of 7)

- 4.12 Within 30 calendar days after the postaudit conference, the QA Manager shall distribute the audit report to the Responsible Individual audited, the Executive Director, the Administrator of Technical Programs, and to the appropriate Project Manager, Principal Investigators, and other responsible persons. Additional distribution shall be made as indicated in Section 5.0, herein.

#### Classification of Audit Results

- 4.13 In preparing the audit report, the QA Manager shall classify audit results into audit comments, audit observations, audit findings, and nonconformances as follows.
- 4.13.1 An audit comment is an opinion or suggestion, favorable or unfavorable, that the QA Manager (Lead Auditor) wishes to express to the Responsible Individual audited. Audit comments do not require corrective action.
- 4.13.2 An audit observation is an observed program weakness or practice which could lead to a more serious deficiency if not corrected. Audit observations shall be corrected per a response to the audit report as indicated in Subsection 4.14, below.
- 4.13.3 An audit finding is an observed item, activity, or condition in non-compliance with the QA program, implementing procedures, or procurement documents. Audit findings satisfying the definition of nonconformance (i.e., serious enough to render an item or activity unacceptable or indeterminate) shall be so classified and promptly processed and corrected in accordance with procedures QAP-15.1 and QAP-16.1. Other audit findings shall be corrected per a response to an audit report per Subsection 4.14, below. See Section 15 of the program and the Glossary for a complete definition of nonconformance.

Response to Audit Report and Corrective Action

- 4.14 The Responsible Individual audited shall confer with the QA Manager and, as appropriate, with others such as the Project Manager or Administrator of Technical Programs, and formulate a written response to the audit report. He/she shall then submit the response to the QA Manager within 30 calendar days after receipt of the audit report and proceed with corrective action as appropriate.
- 4.14.1 The QA Manager shall approve any corrective action to be taken. No response is necessary for audit comments. Corrective action for audit findings classified as nonconformances shall be governed by procedures QAP-15.1 and QAP-16.1.
- 4.14.2 The response to the audit report shall include the following, as a minimum:

Identification as an audit report response

Name, position title, organizational affiliation, and dated signature of the Responsible Individual or Designee

On each page of the response:

Identification of audit report and audit report revision to which response is being made

Date of response to the audit report

Page number and total number of pages (e.g., Page 2 of 3)

For any audit findings classified as nonconformances:

A listing and brief summary of the nonconformances with NCR/CAR number, as applicable, per procedures QAP-15.1 and QAP-16.1 (these items to be filled in by the QA Manager)

For any audit observations or for audit findings not classified as nonconformances:

Determination of the root cause of the observation/finding

Action to be taken to correct the observation/finding

Corrective action to be taken to prevent recurrence

A schedule for completion of all proposed corrective action

Verification of Corrective Action

- 4.15 The QA Manager and technical personnel, as needed, shall verify and document that corrective action has been satisfactorily and effectively implemented. Verification may be accomplished by a special follow-up audit in accordance with Subsections 4.1 through 4.12 and 4.16, herein.
- 4.15.1 If all corrective action for the audit has been satisfactorily and effectively implemented, the QA Manager shall so indicate this by his/her dated signature on the audit report response of Subsection 4.14, closing out the audit. He/she shall then attach the audit report response to the audit report and process both documents per Section 5.0.
- 4.15.2 If all corrective action has not been satisfactorily and effectively implemented, the QA Manager shall request whatever action may be necessary to secure implementation. If required, the QA Manager may issue a written request to the Executive Director, Administrator of Technical Programs, or Principal Investigator for suitable action.

Special Audits

- 4.16 When necessary, regularly scheduled audits shall be supplemented by special audits. Special audits shall be planned, performed, and documented as indicated by Subsections 4.1 through 4.14, herein.
- 4.16.1 The QA Manager shall perform special audits as follows:
- To verify (follow-up) implementation of corrective action arising from significant conditions adverse to quality (see procedures QAP-16.1, "Corrective Action" and QAP-15.1, "Nonconformances").
- When requested to do so by the Executive Director, the Administrator of Technical Programs, the Project Manager, the Principal Investigators, or other responsible persons.
- 4.16.2 The QA Manager may initiate special audits as follows depending on circumstances:
- To verify implementation of corrective action arising from nonconformances, audit findings, or audit observations.
- In response to a notification(s) of an apparent nonconformance(s) from NWPO, contractor, subcontractor or vendor/supplier staff (in accordance with procedure QAP-15.1).
- When significant changes are made in functional areas of the QA program, such as significant reorganization or procedure revisions.

When it is suspected that the quality of an item or service is in jeopardy.

When a systematic, independent assessment of the QA program or procedures is considered necessary.

For any other reason the QA Manager deems sufficient.

- 4.16.3 Follow-up audits shall be specifically identified on the audit schedule.

Tracking of Audit Findings and Observations

- 4.17 The QA Manager shall maintain a tracking system for audit findings and audit observations to ensure that all audit findings/observations are promptly addressed. The tracking system may be modeled on the NCR tracking log of procedure QAP-15.1 or the CAR tracking log of procedure QAP-16.1. Audit findings classified as nonconformances shall be tracked in accordance with procedures QAP-15.1 and QAP-16.1, as appropriate.

Trend Analysis

- 4.18 The QA Manager shall perform a trend analysis of all audit findings and observations to determine any adverse trends. Trend analysis shall be performed, at a minimum, semiannually and any adverse trends shall be reported to the Executive Director and, as appropriate, to others.
- 4.18.1 Trend analysis of audit findings classified as nonconformances shall be included with the NCR/CAR trend analysis of procedure QAP-16.1. Trend analyses of other audit findings and of audit observations may also be included. All trend analyses shall be documented and the documentation processed as indicated in Section 5.0, herein.

5.0 OUTPUT DOCUMENTS

- 5.1 The QA Manager shall ensure marking of the following documents with the category file index designation, per QAP-6.1, and transmittal to and processing of the documents in the NWPO Records Center in accordance with procedure QAP-17.1, "Quality Assurance Records."
- 5.1.1 Audit checklists
- 5.1.2 Audit plans
- 5.1.3 Audit reports
- 5.1.4 Closed out audit report responses

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- 5.1.5 Audit schedules
- 5.1.6 Trend analysis and tracking documentation
- 5.1.7 Other audit documentation

5.2 The QA Manager shall ensure distribution of the audit schedule, audit reports and closed-out audit report responses to the Executive Director, QA Manager, Administrator of Technical Programs, and Responsible Individuals audited and, as applicable, to the Project Manager, Principal Investigator, and others identified on the Document Distribution List (DDL) of procedure QAP-6.1. He/she shall also ensure distribution of reports of adverse trends to the Executive Director and others on the DDL and distribution of other documents as indicated on the DDL.

5.3 Recipients shall maintain documents in file as needed.

#### 6.0 REVISIONS

- 6.1 Revisions to documents shall be processed in the same manner as for the original issue. Revised documents shall be issued in their entirety.
- 6.2 Each revised portion shall be identified by bold face type or by other means as necessary. Previous revision identification shall be deleted.
- 6.3 Recipients of revised documents shall promptly destroy the superseded copies or promptly mark them "Void" or "Superseded."

#### 7.0 REFERENCES

- 7.1 NWPO QA Program, Section 15, Nonconformances
- 7.2 NWPO QA Program, Section 16, Corrective Action
- 7.3 NWPO QA Program, Section 18, Audits
- 7.4 10CFR Part 50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants - 1975
- 7.5 10CFR Part 60, Subpart G - Disposal of High Level Radioactive Wastes in Geologic Repositories, Quality Assurance - 1983
- 7.6 ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities - 1986
- 7.7 U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984

#### 8.0 FLOW CHART

None.

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TITLE: GLOSSARY OF DEFINITIONS

APPROVED:

  
Quality Assurance Manager

  
Executive Director

NOTE: The acronym NWPO stands for Agency for Nuclear Projects/Nuclear Waste Project Office and the acronym DOE stands for United States Department of Energy.

Acceptance/Rejection Criteria	Specified limits placed on a physical property of an equipment item or service to determine its acceptability or unacceptability according to the requirements of procurement documents or technical procedure procedures.
Approval	The act of releasing an output document by an authorized individual for final issue and use. Approval is shown by signature and date. See definition of Output Document.
Approver	The authorized individual responsible for approval. The preparer of a document may perform the approval function if he/she has been duly authorized to do so.
Audit	A planned and documented activity, performed with written procedures or checklists, to determine by examination and evaluation of objective evidence, the adequacy of and status of compliance with the NWPO QA Program and implementing quality assurance and technical procedures. Quality of work audited is a major audit goal.
Audit Comment	A statement of opinion or suggestion, favorable or unfavorable, that the QA Manager (Lead Auditor) wishes to express to the Responsible Person audited. An audit comment is not an audit observation or audit finding and does not require corrective action.

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<b>Audit Finding</b>	An item, activity, or condition determined to be in non-compliance with the QA program, implementing procedures, or procurement documents as a result of an audit. Audit findings satisfying the definition of nonconformance are identified and processed as such. See the definition of Nonconformance.
<b>Audit Observation</b>	An observed program weakness or practice which could lead to a more serious deficiency if not corrected.
<b>Auditor</b>	Any individual who performs any portion of an audit, including Lead Auditors, Technical Auditors, and others, such as management representatives. See definitions of Lead Auditor and Technical Auditor.
<b>Authorized Nonconformance</b>	A proposed deviation from requirements of procurement documents, submitted by a contractor, subcontractor, or, as appropriate, a vendor/supplier, that has been reviewed and approved (found acceptable), in writing, by the Administrator of Technical Programs/QA Manager, and as appropriate, by the Project Manager/Principal Investigator.
<b>Category File Index Designation</b>	A distinguishing number and/or letter(s) which uniquely identifies a document by category and generating organization. See definition of NWPO File Index.
<b>Certificate of Conformance</b>	A signed document generated by a contractor or subcontractor certifying the degree to which materials, equipment, or services meet specified procurement document requirements.
<b>Comment</b>	A written and/or pictorial evaluation and judgment of an NWPO, contractor, or subcontractor document, which is subject to subsequent resolution.
<b>Component Model</b>	A logically distinct subset of a model.
<b>Computer Code</b>	A set of computer instructions for performing the operations specified in a numerical model.

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Computer Output	The results generated by a computer program, describing any normalizations of results and listing associated dimensional units.
Contract Award	An expression of the intent of the Executive Director or contractor's Responsible Individual to execute a contract with a contractor, subcontractor, or vendor/supplier.
Contractor	An organization under contract with NWPO to furnish specialized technical or scientific services to NWPO under the control of NWPO and NWPO's QA Program. See definition of Vendor.
Controlled Copy	A copy of a volume of the NWPO QA Manual that has been assigned to an individual and marked with a controlled copy number. Only holders of controlled copies receive revisions to the QA manual.
Corrective Action	Measures taken to rectify audit observations, audit findings, nonconformances, and significant conditions adverse to quality, and to preclude their repetition.
Corrective Action Report	Documentation of a significant condition adverse to quality and of verification that corrective action and action to prevent its recurrence have been completed.
Data Acquisition; Data Analyses	Same as Design Activity; Design Information.
Design Activity; Design Information	For purposes of the NWPO QA Program refers to acquisition and analyses of data that DOE may or should use as a basis for any repository design or feasibility determination it may choose to propose at Yucca Mountain, Nevada. NWPO, or its contractors, or subcontractors may monitor collection of or analyze data acquired by DOE or others, or may acquire and analyze their own data. Same as Data Acquisition; Data Analysis.

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- Document** Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. Examples of documents include audit reports, nonconformance reports, calculations, computer tapes, chips, cassettes, or mag cards, computer code documentation, or geologic maps, but not soil or rock samples. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record in this Glossary. See definitions of Input/Support Document and Output Document.
- Document Distribution List** A listing of documents which controls the distribution of NWPO, contractor, subcontractor, and vendor/supplier documents and revisions thereto.
- Drawing** A document, such as a geologic map, that pictorially displays data acquisition and/or analysis. Drawings are issued as parts of Technical Reports. See definition of Design Analysis; Design Information.
- Input Data** Information upon which data information or analysis output documents are based. For example, laboratory test results could be used as input data for calculations. See definition of Output Document.
- Input/Support Document** A document, such as a field or laboratory notebook, for which formal review and approval is unfeasible or disadvantageous but which is subject to some form of verification prior to issue. See definitions of Output Document and Verification.
- Inspection** Documented examination or measurement of an item or activity by a qualified and independent non-supervisory person, for compliance to specified requirements.

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Lead Auditor

An individual who is certified by NWPO and qualified to organize and direct an audit, to report audit findings and observations, to initiate and evaluate corrective action, and to close-out said findings and observations. The QA Manager is a certified Lead Auditor.

Master Document List (MDL)

An MDL is a listing of current revisions of approved data acquisition/analysis output documents by document type incorporating information from progress reports and/or from other sources. MDLs are issued to prevent inadvertent use of superseded, obsolete, or withdrawn documents. Documents such as technical reports, or procurement contracts are included on MDLs. Documents such as field or laboratory notes or QA procedures are not.

Mathematical Model

A mathematical representation of a process or system.

May

A word used to permit an activity on an optional basis. Refer to the definitions of Shall, Should, and Will.

Model

A representation of a process or system.

Monitor

Refer to the definition of Surveillance.

Nonconformance

A deficiency in a service, activity, or procedure, or of an in-service or installed material, item of equipment, apparatus, or instrument that renders the quality of an item or activity unacceptable or indeterminate.

Nonconformance Report (NCR)

Documentation of a nonconformance and of verification that corrective action and action to prevent its recurrence have been taken.

NWPO File Index

A unified listing by category titles and category file index designations of NWPO, contractor, subcontractor, and vendor/supplier documents.

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- NWPO Quality Assurance Manual A controlled document in six volumes consisting of NWPO's Quality Assurance (QA) Program, QA Policy Statement, implementing QA and technical procedures, a glossary of definitions, tables of contents, and appurtenant items. See entry for Controlled Copy.
- NWPO Records Center A location, under the control of the QA Manager, where NWPO, contractor, subcontractor, and vendor/supplier QA records are processed and stored.
- Numerical Method A procedure for solving a problem primarily by a sequence of arithmetic operations.
- Numerical Model A representation of a process or system using numerical methods.
- Objective Evidence Any written, pictorial, or observed evidence, either quantitative or qualitative, obtained by an auditor, that relates to implementation of QA requirements.
- Output Document A document, such as a technical report or QA procedure, that is subject to formal review and approval prior to issue. For purposes of Section 5.0 of the quality assurance and technical procedures, governing disposition of documents resulting from procedure activities, input/support documents are processed as output documents. See definition of Input/Support Document.
- Peer Review An in-depth critique of data, assumptions, extrapolations, activities, procedures, or results that involve untried or beyond the state-of-the-art investigation or analysis methods for which established technical criteria are nonexistent or under development. Peer reviews are performed by persons (peers) of high technical qualifications who are administratively, technically, and financially independent of the work under review. Peer review is distinct from technical review, which verifies compliance with established requirements. For example, technical review

of an age-dating calculation would emphasize correct performance of the calculation whereas peer review would consider whether the calculation, however well performed, will yield the expected results.

Peer reviews may include reviews of qualifications of personnel, and organizations performing tasks subject to peer review.

**Peer Review Group**

An assembly of peers, including a chairperson, representing an appropriate spectrum of knowledge and experience in the subject matter under review.

**Preparer**

In connection with output documents a qualified individual who assembles and organizes input data and who, with the aid of administrative guidelines and/or assumptions and/or technical/scientific judgment (as needed), produces a designated output document in a prescribed manner for a designated purpose. A preparer is distinct from the individual(s) who physically produce the document, i.e., a drafter does not necessarily prepare a drawing any more than a typist prepares a technical report.

**Procurement Contract**

A written agreement between NWPO and contractors or vendors/suppliers, or between contractors and subcontractors and/or vendors/suppliers for purchase of technical or scientific services, materials, equipment, apparatus, or instruments. All contracts include a procurement document indicating scope of work and technical requirements. All contracts must conform to the laws and regulations of the State of Nevada, and to the NWPO QA Program and Procedures. All contracts are reviewed by the QA Manager for adherence to QA requirements.

**Procurement Document**

See definition of Procurement Contract. Same as procurement contract document.

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- Progress Report** A report generated by NWPO or its contractors summarizing NWPO, contractor, and subcontractor activities and current status (e.g., in preparation, in review) of data acquisition/analysis (design information/activity) documents. See definition of Master Document List (MDL).
- Quality Assurance** All those planned and systematic actions necessary to provide adequate confidence that activities significant to NWPO's goals have been satisfactorily performed by qualified persons.
- Quality Assurance Manual** See definition of NWPO Quality Assurance Manual.
- Quality Assurance Policy Statement** A document, signed by NWPO's Executive Director, that (1) briefly summarizes the purpose, scope, and intent of NWPO's activities and of its QA program and (2) commits NWPO and its contractors, subcontractors, and vendors and suppliers to the policy statement, program, and its implementing procedures.
- Quality Assurance Procedure (QA Procedure)** A controlled document, part of the NWPO QA Manual, which implements the NWPO QA Program, and which assigns the detailed responsibilities and requirements for regulating quality related activities (i.e., activities significant to NWPO's goals) primarily of an administrative nature. See definition of Technical Procedure.
- Quality Assurance Program** A controlled document, part of the NWPO QA Manual, describing how NWPO will meet the relevant requirements of 10CFR50, Appendix B, and other documents listed in Section 00 of the program.
- Quality Assurance Records** Completed documents, accepted for the NWPO Records Center per stated requirements, that furnish evidence of quality of item and/or activities significant to NWPO's objectives.

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Examples of QA records include technical reports, calculations, computer tapes, and technical procedures but not samples of materials such as rock or water. A document is considered complete when it has been reviewed and approved for use or otherwise verified.

Quality Control

An aspect of quality assurance emphasizing physical properties and quality of materials, materials, equipment, apparatus, or instruments.

Readiness Review

A review of work in process which is planned and performed prior to the completion of a major work activity or event.

Responsible Individual

A designated individual who has been assigned the responsibility of performing a specific task or is in charge of a specific activity.

Responsible Person

Same as Responsible Individual.

Review

In general, an analysis to provide assurance that QA documents such as, but not limited to, technical reports, calculations, procurement documents, employee experience records, and QA procedures are correct, satisfactory, technically and/or administratively adequate, and conform to established quality requirements.

Supervisory Reviews are reviews performed by supervisors in the course of their normal supervisory duties but which do not substitute for technical reviews and which are not addressed by the NWPO QA Program.

Technical Reviews are reviews of data acquisition/analysis (design information/activity) output documents such as calculations, technical procedures, or technical reports, performed by technically qualified individuals to determine technical adequacy and conformance to established technical requirements. Technical review also includes technical review of input/support documents, such as field notes, or examination of such documents for evidence of another, previous, appropriate form of verification when these input/support documents are used as input for output documents.

Nontechnical Reviews are reviews of administrative documents, such as employee experience records or the NWPO File Index, for compliance with administrative and QA requirements indicated in the QA program and procedures. These reviews are performed by individuals indicated in the QA program and procedures.

See definitions of Peer Review, Readiness Review, and Verification.

Reviewer; Technical Reviewer

A qualified individual responsible for performing a review. A Technical Reviewer is a technically qualified individual who performs technical reviews of data acquisition/analysis (design information/activity) output or input/support documents. A Technical Reviewer is independent of the work being reviewed and does not have immediate supervisory responsibility for the Preparer of the document under review except as indicated hereafter:

Technical Review may be performed by the Preparer's supervisor if either of the following conditions exists: (1) the supervisor is the only individual in the organization competent to perform the review, or (2) the supervisor did not specify a singular data acquisition/analysis (design information/activity) approach or rule out certain data acquisition/analysis (design information/activity) considerations and did not establish the inputs used in the data acquisition/analysis (design information/activity).

See definition of Verification.

Revision

A documented controlled update of a document which, as appropriate, is prepared, reviewed, approved, and distributed in a designated manner. Revisions, including additions to the QA manual, are reviewed for their effect on existing documents.

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- Right of Access** The right of NWPO auditors/monitors and contractor monitors to enter the premises of a contractor/subcontractor or vendor/supplier (e.g., testing laboratory, sample storage facility) for the purpose of inspection, surveillance, or audit.
- Service** The performance of technical/scientific activities by a contractor or subcontractor. See definitions of Vendor and Supplier.
- Shall** A word used to designate a mandatory requirement; synonymous with the word "must." See definitions of May, Should, and Will.
- Should** A word used to designate a recommendation, but not a mandatory requirement.
- Significant Activity** A technical or administrative activity which has important impact on NWPO's technical goals and objectives; synonymous with the words "important activity."
- Significant Condition Adverse to Quality (SCAQ)** A condition that has, has had, or could have a serious effect on the quality of the data or conclusions generated by NWPO-sponsored activities critical to the objectives of NWPO.
- Stop-Work Order** A document issued by the Executive Director to stop an activity because of the existence of a significant condition adverse to quality. A stop-work order remains in effect until lifted by the Executive Director when the adverse condition for which it was issued is substantially corrected.
- Stored Records Index** An index of QA records stored in the NWPO Records Center.
- Subcontractor** An organization under contract with an NWPO contractor to furnish specialized technical or scientific services under the control of NWPO and NWPO's QA Program.

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<b>Supervisory Review</b>	See definitions of Review and Reviewer; Technical Reviewer.
<b>Supplier</b>	Any individual or organization that furnishes materials, equipment, apparatus, or instruments to NWPO, its contractors, or its subcontractors in accordance with a procurement contract. Same as Vendor.
<b>Surveillance</b>	Observation and documentation of an activity by a qualified but nonparticipating observer. Same as monitor. See definition of Inspection.
<b>Technical Auditor</b>	A technically qualified individual who performs designated technical portions of an audit under the supervision of a Lead Auditor (QA Manager).
<b>Technical and Scientific Judgment</b>	A documented reasoning process, used in a data acquisition/analysis document in lieu of data, or of a more rigorous analysis, which can be understood by other individuals who may review or make reference to that document. Technical and scientific judgment may be based on experience or on other factors.
<b>Technical Procedure</b>	A controlled document governing NWPO technical activities, and prepared by NWPO, or a controlled document governing contractor or subcontractor activities, and prepared by a contractor or subcontractor and approved by NWPO. Technical procedures are part of the NWPO QA Manual. They assign detailed responsibilities and requirements for implementing technical aspects of the NWPO QA Program.
<b>Technical Reviewer</b>	See definition of Reviewer; Technical Reviewer.
<b>Validation</b>	The process of checking a computer program to provide assurance that a computer code correctly performs the operations specified in a numerical model and/or to document confirmation of the adequacy (suitability for its intended purpose) of the work or calculation under review.

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Vendor	Same as Supplier.
Verification	The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether materials, equipment, activities, services, or documents are satisfactory and conform to specified requirements and/or the act of providing assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended. Documents submitted to the NWPO Records Center must be verified in some specified manner before submittal.
Will	A word to indicate a predicted or customary activity rather than a mandatory activity. See definition of shall.

REFERENCES

1. ANSI/ASME NQA-1 - Quality Assurance Program Requirements for Nuclear Facilities -1986
2. U.S. NRC NUREG-1297 - Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories - February 1988
3. U.S. NRC NUREG-0856 - Final Technical Position on Documentation of Computer Codes for High-Level Waste Management - June 1983
4. ANSI/ASME N45.2.23 - Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants - 1978
5. U.S. DOE QA Management Policies and Requirements - October 1985
6. U.S. NRC - NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories - June 1984