

United States Government

Department of Energy

memorandum

DATE:
REPLY TO
ATTN OF:

NOV 19 1985

'85 NOV 25 P3:41

SUBJECT:

TO: Mr. Robert Browning, Director
Division of Waste Management
U.S. Nuclear Regulatory Commission
SS-623
Washington, D.C. 20555

Dear Mr. Browning:

This confirms the arrangements for our meeting with you to discuss the Quality Assurance Program for DOE's Office of Geologic Repositories and to receive a briefing from NRC on draft Branch Technical Positions on QA that are under development by NRC. We have reserved conference room 1E-245 in the DOE Forrestal Building, 1000 Independence Avenue. The meeting will be on December 4-5, 1985, from 8:30 a.m. to 5:00 p.m., with December 6 set aside for the drafting and signing of the meeting minutes.

Representatives from the States and affected Indian Tribes are being invited to attend. The meeting will also be open to members of the public.

The agenda we propose for the meeting is as follows:

December 4, 1985 (Room 1E-245)

8:30 a.m. - 9:15 a.m.	Welcome and Introductory Remarks.....DOE	
9:15 a.m. - 9:30 a.m.	NRC Introductions and Overview.....NRC	
9:30 a.m. - 10:00 a.m.	Status of DOE QA Program and Response to NRC Site Visit CommentsCarl Newton	<i>Healy/Davis</i>
10:15 a.m. - 10:30 p.m.	Break	
10:30 a.m. - Noon	Continuation	
Noon - 1:00 p.m.	Lunch	
1:00 p.m. - 1:30 p.m.	Update on status of NRC Programs.....NRC	<i>Jim</i>
1:30 p.m. - 2:00 p.m.	NRC Experience in DOE Audits to DateNRC	<i>Dee</i>
2:00 p.m. - 2:30 p.m.	NRC Branch Technical Positions:	
	(1) Configuration management.....	
	...J. Kennedy, NRC	
	(2) Qualification of Existing Data...	
	...Bill Altman, NRC	

WM Record File

405

WM Project

Docket No.

PDR

LPDR

Distribution:

PEB MIB JOB

RDM DEM

(Return to WM, 623-SS)

QA people with full enclosures.

J. Gorn

DeMiguel / Kennedy

CER HJM G.W. KEE

Linehan / Bilhorn

Hedges G.D.R.N. J.

Ricketts, Lg. III

B. Trojanowski, Lg. II

S. Sanborn, Lg. I

D. Kunihiro, Lg. I

- 2 -

- (3) QA for Research & Exploratory Activities....Bill Altman, NRC
- (4) Peer Review...Bill Altman, NRC

2:30 p.m. - 2:45 p.m. Break
2:45 p.m. - 5:00 p.m. Continuation

December 5, 1985 (Room 1E-245)

8:30 a.m. - 9:00 a.m. Update on Q-List Generic Technical Position.....Susan Billhorn, NRC
9:00 a.m. - 10:00 a.m. DOE Configuration Management (SEMP).....
.....Charles Brooks, DOE *Jim*
10:00 a.m. - 10:15 a.m. Break
10:15 a.m. - Noon DOE QA Plan Supplements...Carl Newton, DOE
(1) Qualification of Personnel *Dale*
(2) Overview of QA Activities *Dale*
(3) Control of Measuring & Test Equipment *Dale*
(4) Quality Assurance Records *Dale*
(5) QA on R&D (Experiments) *Bill*
(6) Computer Software Control *Craig*
Noon - 1:00 p.m. Lunch
1:00 p.m. - 2:30 p.m. Continuation of DOE QA Plan Supplements...
..... Carl Newton, DOE
2:30 p.m. - 2:45 p.m. Break
2:45 p.m. - 3:45 p.m. Status of Q-List Methodology.....
.....Carl Newton, DOE *Seamus*
3:45 p.m. - 5:00 p.m. Status of Graded Approach to QA.....
.....Carl Newton, DOE

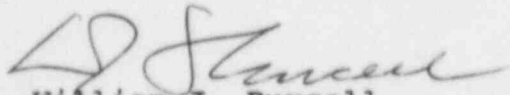
December 6, 1985 (Room 4F-056 for NRC, Room 7F-070 for DOE)

8:30 a.m. - noon Caucus of DOE/NRC Staffs (Independent)
Noon - 1:00 p.m. Lunch
1:00 p.m. - 5:00 p.m. Write-up of Joint Meeting Minutes

Enclosed are copies of the six DOE QA Plan Supplements that we propose discussing with you on December 5, 1985, a copy of DOE's System Engineering Management Plan, and a paper titled "DOE's Response to NRC's concerns about DOE's Quality Assurance Program". We trust you will find these helpful in understanding DOE's positions on various QA issues. We have enclosed a list of

"Questions for NRC on Implementation of Q-List Methodology". We would appreciate your response to these (at the meeting, if possible).

Please contact Carl Newton at (252-1248) if you have any questions or desired changes to the meeting agenda. We look forward to this meeting with you.



William J. Purcell
Associate Director for
Geologic Repositories
Office of Civilian Radioactive
Waste Management

Enclosures

1. Supplement #1, "Qualification of Personnel"
2. Supplement #2, "Overview of QA Activities"
3. Supplement #3, "Control of Measuring & Test Equipment"
4. Supplement #4, "Quality Assurance Records"
5. Supplement #5, "QA on R&D (Experiments)"
6. Supplement #6, "Computer Software Control"
7. Systems Engineering Management Plan
8. "DOE Response to NRC's Concerns about DOE's QA Program"
9. "Questions for NRC on Implementation of Q-List Methodology"

SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

QUALIFICATION OF PERSONNEL PERFORMING AND VERIFYING ACTIVITIES AFFECTING QUALITY

1.0 SCOPE

These HQ/OGR requirements apply to all personnel who are assigned to perform and verify activities affecting quality.

1.1 QUALIFICATION REQUIREMENTS

Each OGR participating organization shall establish written procedures for the qualification of personnel and ensure that only those personnel who meet the minimum established qualification requirements are permitted to perform or verify activities that affect quality.

Minimum education and experience requirements shall be established and documented in job specific position descriptions or other suitable means as appropriate for the job to be performed.

In addition, personnel who verify the quality of items and activities through audits, inspections, tests, and nondestructive examinations shall be certified in accordance with the applicable supplementary requirements of NQA-1.

1.2 PERSONNEL SELECTION

Personnel selected for performing or verifying activities shall have education and experience commensurate with the minimum requirements specified for the job. The capabilities of an individual shall be based upon an evaluation of the candidate's education, experience, and training and compared to those established for the position.

1.3 INDOCTRINATION

Provisions shall be established for the indoctrination of personnel prior to assigning them to perform activities affecting quality. Emphasis shall be placed on the purpose, scope, and implementation requirements of the related manuals, procedures, and instructions. Those who verify activities affecting quality shall be instructed in the principles, techniques, technical objectives, and requirements of the activity being performed. Records of indoctrination shall be maintained and will include as a minimum, the objective and content of the session, instructor, attendees, and dates of attendance.

1.4 TRAINING

Suitable proficiency shall be maintained by establishing a formal training program. For those areas which require training, determination will be

made of: personnel required to attend; description of course content, instructor qualifications and frequency. The trainee's assimilation of the subject matter shall be determined through either examination or performance evaluation. Training records shall include the names of attendees, date of training, type of training, instructor's name and results of examination or performance evaluation.

On-the-job training may also be included in the program, with emphasis on hands-on experience gained through actual performance of activities.

1.5 PERFORMANCE EVALUATION

The job performance of personnel who perform or verify activities important to quality shall be evaluated at least annually. The evaluation shall determine whether adequate proficiency has been maintained. The evaluation shall also determine the need for retraining or replacement.

1.6 DOCUMENTATION OF QUALIFICATION

The qualification of personnel shall be documented on appropriate forms and include the following information:

- (a) Employer's name;
- (b) Name of person being qualified;
- (c) Activities qualified to perform;
- (d) Basis used for qualification, including such factors as:
 - (1) Education, experience, and training;
 - (2) Test results, where applicable;
 - (3) Results of capability demonstration;
- (e) Results of periodic evaluation;
- (f) Results of physical examination, when required;
- (g) Signature of employer's designated representative who is responsible for evaluation;
- (h) Date of qualification and date of expiration (where applicable).

The documentation of qualification shall be retained as permanent QA records.

SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

Overview of Quality Assurance Activities

1.0 INTRODUCTION

Each OCR project office is to develop and implement written procedures for the overview of the quality assurance activities of all project participants under its purview including contractors, subcontractors, national laboratories, and other government agencies doing supportive work.

This overview is to include, as a minimum, the review and approval of participant's quality plans/manuals/procedures; surveillance of participant's activities affecting quality to assure compliance with requirements; performance of quality audits to verify the adequacy and effectiveness of the participant's program, and management assessments of the program. The overview function is to be applied to activities important to safety and to waste isolation, as well as to other activities important to program success, including quality evaluation of structures, systems, and components.

1.1 SCOPE

This procedures applies to HQ-OCR QA overview of the activities of the project offices, the project offices QA overview of the activity of their contractors, national laboratories and other project participants, and contractor overview of subcontractor activities to the extent necessary to cover all QA related activities.

1.2 REVIEW AND APPROVAL OF PARTICIPANT'S QA PROGRAMS

Procedures are to be established for the review of the participant's QA program documentation for adequacy, completeness and relevance. This includes review of their QA program plans/manuals and procedures. The overview procedures shall identify the types of documents to be submitted by the participants for review and/or approval, assign project responsibility for review, and identify the methods for documenting review and approval action.

1.3 SURVEILLANCE

Procedures are to be established for planning, scheduling, performing, and documenting surveillance of participant's activities affecting quality. The surveillances are to be performed by trained and qualified surveillance personnel who are not directly responsible for performing the work being monitored. Surveillances are to be performed to written check lists, or surveillance plans whenever practicable and the results of all surveillances are to be documented in the form of surveillance reports. All deficiencies, non-conformances, and potential quality problems identified during the surveillance are to be documented and followed until verification of implementation of effective corrective actions is made.

1.4 QUALITY AUDITS

Procedures are to be implemented for the planning, scheduling, performing and reporting of quality assurance audits. Audit schedules are to be developed annually and updated as changes occur. Audits of organizations common to more than one project are to be coordinated whenever practicable to conserve resources and maintain consistency. Audit results are to be documented, deficiencies identified during the audit are to be monitored to verify that prompt and effective corrective actions have been taken, and that root causes of deficiencies have been determined. An analysis of audit results and surveillance findings is to be performed to identify quality trends.

Audits will be performed by trained, qualified and certified personnel not directly responsible for the activity being audited.

1.5 VERIFICATION BY HQ-OGR

HQ/OGR is to assess the status and adequacy of the project's QA overview program by review and approval of the project's QA plan and procedures and by regularly scheduled audits of project office QA activities.

SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

Control of Measuring and Test Equipment

1.0 Scope

This procedure shall apply to all project participants to assure that measuring and test equipment, both installed and portable used in activities affecting quality are controlled and calibrated.

1.1 General

A program for the calibration of M&TE shall be established and maintained. The program shall be designed to measure and assure the accuracy of controlled M&TE. It shall provide for the timely detection of inaccuracies and for prompt, effective action for their correction.

1.2 Calibration Control

The calibration program shall include the following elements of control:

- A. Program Description. A list of M&TE shall be prepared and maintained to identify those items included in the calibration program covered by the scope of this document. Written procedures shall be provided describing controls over M&TE.
- B. Adequacy of Standards. Standards used for calibrating M&TE shall have an accuracy level, history of stability and acceptable calibration range that are adequate for the programmatic requirements for the M&TE. M&TE shall be calibrated against standards having tolerances of at least four times better than those of the M&TE being calibrated unless limited by state-of-the-art.
- C. Environmental Control. M&TE shall be stored and calibrated in environments which will not adversely affect their accuracy. Environmental factors which shall be considered include, but shall not be limited to; temperature, humidity, vibration, radio frequency interference, electromagnetic interference, dust cleanliness, fumes and voltage stability. When inaccuracy due to environmental effects cannot be avoided, compensating corrections shall be determined, recorded, and applied to the calibration made.
- D. Intervals of Calibration. Written methods or procedures shall be provided to assure recall of all controlled M&TE for recalibration at prescribed intervals to verify the required accuracy. Such intervals may be in calendar time or relate to usage. Interval selection should consider experience, inherent stability, purpose or use, accuracy required, and manufacturer's recommendations. Historical records shall be maintained which contain sufficient experience data for evaluating calibration intervals.

1.3 Definitions

- A. Accuracy. A measure of the degree by which the actual output of a device approximates the output of an ideal device nominally performing the same functions.
- B. Calibration. Comparison of items of measuring and test equipment with reference standards or with items of measuring and test equipment of equal or closer tolerance to detect and quantify inaccuracies and to report or eliminate those inaccuracies.
- C. Measuring and Test Equipment. Devices or systems used to calibrate, measure, gage, test, inspect, or control in order to acquire research, development, test or operational data or to determine compliance with design, specifications, or other technical requirements.
- D. Precision. The degree of resolution of a measurement, for example, readability.
- E. Reference Standards. Standards (that is, primary, secondary, and working standards, where appropriate) used in a calibration program. These standards establish the basic accuracy limits for that program.
- F. Tolerance. The allowable deviation from a specified or true value.

1.4 Calibration Procedures

Written methods or procedures for calibrating M&TE shall be provided to assure calibration technique uniformity. Maximum use shall be made of existing methods, practices or procedures that comply with these requirements. Calibration Procedures shall include the following information as a minimum:

- A. Identify of the item or system to be calibrated.
- B. Calibration equipment and standards.
- C. Sequence of operations.
- D. Checks, tests, measurements and acceptance tolerances.
- E. Method of presenting calibration data.
- F. Special instructions when necessary.

1.5 Traceability

M&TE shall be calibrated utilizing standards whose calibration is traceable to nationally recognized standards, accepted values of natural physical constants, or derived by the ratio type of self-calibration techniques.

1.6 Records

The validity of all measuring and test equipment shall be supported by certificates, reports, or data sheets which indicate:

- A. Identification of calibrating agency.
- B. Identification of item tested/calibrated (name, manufacturer, serial number, range).
- C. Tolerance data.
- D. Date of test/calibration; next calibration due.
- E. Identification of calibration standard.
- F. Record of calibration standard calibration due date.
- G. As found reading.*
- H. As completed (final) readings.*
- I. Calibration results and acceptability of readings.
- J. Calibration points that were verified.
- K. Documentation of action taken in connection with any deviations including modification, repair or adjustment.
- L. Signature or stamp impression of person performing the test (calibration).
- M. Statement of traceability to nationally recognized standards: where no known standards exist, document the acceptability of the standard.
- N. Procedure used with revision number or effective date.
- O. Compensating correction for environmental effects.
- P. Limitations of use (when applicable).
- Q. Standards Laboratory personnel who were not directly involved in the calibration activities shall evaluate the calibration results and verify, through review, that the calibration record accurately and completely identifies the items listed above. The reviewer shall sign the calibration signifying approval.

*Ability to report as found and final readings is dependent on the type of measuring and test equipment being calibrated and method of calibration.

Records shall be maintained to show that established schedules and procedures for the calibration of standards and M&TE have been followed. The records for M&TE shall contain a history of calibration of other means of control for each item or system of M&TE showing calibration interval, date of last calibration, and conformance or nonconformance to require tolerances before adjustments.

1.7 Labeling

Each item or system of M&TE shall be labeled to indicate its calibration status. Systems shall show a listing of components. The label shall indicate by whom the M&TE was calibrated and when the next calibration is due. When size or functional characteristics of M&TE prevent the application of a label, an identifying code shall be applied to reflect status. When neither labeling nor coding is practical, the procedures shall provide for monitoring of records to assure control. Labels, codes, or recall records shall be used to identify and control any M&TE whose use must be limited due to imprecision or bias.

1.8 Use of M&TE

Controls shall be established and implemented to assure that M&TE consistently produces results of acceptable accuracy. Such measures shall include, as appropriate:

- A. Environmental and handling controls.
- B. Training and qualifications of personnel who use and calibrate M&TE (in accordance with OGR QA Plan Supplement #1).
- C. Checking calibration status before use.
- D. Interim checks between calibrations.
- E. Reporting and recalibrating potentially damaged M&TE.

M&TE which has not been properly maintained or calibrated shall be identified as nonconforming, appropriately tagged and removed from service.

1.9 Nonconformances

If an M&TE item or system is found to be outside of required tolerances, it shall be identified as nonconforming and the using organization shall be notified that all items inspected or tested with the nonconforming device since its last calibration are suspect and should be considered nonconforming until proven otherwise.

SUPPLEMENTAL QA REQUIREMENTS

QUALITY ASSURANCE RECORDS

1.0 General

This document provides amplified guidance for the control of quality assurance records on geologic repository programs. The provisions presented in this guidance document should be used in addition to the provisions of ANSI/ASME NQA-1-1983 Basic Requirement 17 and Supplement 17S-1, and applicable provisions of the NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories.

For a geologic repository, records may be of two types:

- (a) Document records which consist of all written, photographic and magnetic-media scribed, records including geotechnical and environmental data.
- (b) Nondocument records which consist of physical samples taken during geotechnical and environmental activities. Nondocument records include descriptive documentary material which describes the samples which are being retained.

2.0 Definitions

- 2.1 Document - Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined below.
- 2.2 Record - An individual document or other item that has been executed, completed, and approved within the context of the requirements for each type of document. A completed record is a document or other item which will receive no more entries, one whose revisions would normally consist of a reissue of the document, and one which is signed and dated by the originator and, as applicable, by approval personnel.
- 2.3 Quality Assurance Record - A document or other item that furnishes evidence of the quality and completeness of data (including raw data), items, and activities affecting quality; documents prepared and maintained to demonstrate implementation of the quality assurance programs (e.g., audit, surveillance, and inspection reports); procurement documents; and other documents such as plans, correspondence, telecons, specifications, technical data, books, maps, papers, photographs, data sheets, magnetic media, physical samples (such as rock, core, and water), and other materials that provide data and document quality regardless of the physical form or characteristic.

3.0 Records Management Plan

Organizations participating in any phase of the geologic repository program shall prepare a records management plan and shall submit it to the same authority that approves their QA Plan (hereafter called Purchaser) for review and approval. The plan shall identify the methods to be used by the submitting organization to comply with the requirements of ANSI-ASME NQA-1-1983 Basic Requirement 17, Supplement 17S-1, the guidance provided in this document, and any other applicable contractual requirements related to records. The records management plan shall also identify and define the responsibility of the QA organization and other organizations for the definition and implementation of activities related to QA records. The records management plan will also describe the requirements for storage of records, and the methods to be used to achieve retrievability (i.e., keywording of record identifiers, manual searches, computerized searches, etc.).

4.0 Record Identification and Cross Referencing

Provisions shall be made for documents generated or purchased, for use as a record in any phase of a geologic repository, to be clearly identified by a unique number or other designation which is directly traceable to controlling programmatic information (e.g., project, contract number, task number, WBS number, preparing organization, author, date, title, subject, etc.).

Final reports shall contain a listing, by unique number or other designation, of all documents used to compile or evaluate the report.

This listing shall include, as a minimum, all referenced documents, peer review or other review documents, computer codes, data sheets, procedures, test plans, etc. Each final report, when issued, must provide a listing of all reference documents. In addition, the Records Management System must contain all supporting material for the entire report and all supporting material. Also, the final report must identify all reference documents in a manner that enables prompt retrieval from the Records Management System.

5.0 Temporary Record Storage

Provisions shall be made to control records from the time a record is complete until the time the record is stored in the permanent records storage facility. Also, provisions shall be made to insure retrievability and to control the withdrawal of records from the temporary storage facility during this interim storage period.

6.0 Classification

Quality Assurance Records for geologic repositories should be classified as lifetime, or nonpermanent in accordance with criteria given in 6.1, and 6.2 below.

6.1 Lifetime Records - Lifetime records are those that are required to be retained and preserved in an acceptable condition for the operating life of the repository, i.e., until termination of the repository license. Any records that meet one or more of the following criteria are required to be maintained as lifetime records until the completion of all activities (siting, site characterization, and repository construction, operation, and decommissioning) at a particular site:

- o Those which may be used for repository licensing.
- o Those geologic repository records and data which were used in support of site selection, site nomination, site characterization, and repository location recommendations.
- o Those geologic repository records and data which were used to identify and assess the performance capabilities of those engineered and natural barriers important to waste isolation.
- o Those computer programs and mathematical models needed to perform ongoing correlations between performance assessment predictions and actual test results and data collection and analysis.
- o Those records which would be of significant value in demonstrating capability for safe operation of a repository.
- o Those records which would be of significant value in maintaining, reworking, repairing, replacing, or modifying repository systems, components, or structures.
- o Those records which provide required baseline data for in-service inspections and tests.
- o Those records which would be of significant value in exercising of the retrieval option for the waste package.

6.2 Nonpermanent Records

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the length of time required for lifetime records.

For a geologic repository, nonpermanent records should be retained for at least 3 years after initiation of repository operation or until the sites to which they relate are dropped from consideration as a repository site. The Records Management Plan will specify a requirement for periodic, mandatory purges of all nonpermanent records and will specify the maximum allowable time that nonpermanent records may be retained.

7.0 List of Typical Lifetime Records

Listed below are typical types of lifetime records for geologic repositories. Records of a type other than those identified on these lists are normally considered to be nonpermanent. Records initially identified as nonpermanent may at any time be reclassified as lifetime.

7.1 General Records

- Maps which identify site boundaries
- Location of site markers
- Underground facility configuration
- Stored waste inventory and location
- Repository environment monitoring records
- Waste package design, fabrication, testing and inspection records
- Other records having long term archival and historical interest
- Safety analysis reports
- Site Characterization Reports
- Licensing Reports
- Long Term Performance Assessment Records

7.2 Other Lifetime Records

7.2.1 Siting and Site Characterization Records

- Drill hole testing procedures
- Drill hole drilling procedures
- Drill hole location surveys or maps
- Drill hole logs and samples
- Drill hole test results (including evaluations and interpretations.)
- Geophysical logs and data
- Geophysical test results
- Self-potential logs and data
- Caliper logs and data
- Radioactive logs and data (gamma, spectral-gamma, neutron-gamma)
- Lithologic logs and data
- Seismic and resistivity survey procedures
- Seismic and resistivity location surveys or location maps
- Seismic and resistivity logs and data
- Seismic and resistivity test results (including evaluations)
- Laboratory testing procedures
- Laboratory record books
- Laboratory testing data and data processing
- Geologic maps and supporting data
- Geologic library samples
- Geologic and soil sampling procedures
- Geologic test results
- In-situ test results
- Logs, maps, and geophysical data in support of subsurface correlation
- Trench logs and data (including location surveys, maps, and results)

- Aerial mapping records (photographs and interpreted overlays)
- Microseismic records (paper or magnetic tape)
- Remote imagery reports and results
- Groundwater and hydrologic regime maps and data (including results)
- Seismicity maps and supporting data
- Fault maps and supporting data
- Epicenter maps and supporting data
- Isopach maps and supporting data
- Model definition and development reports
- Model acceptance criteria reports
- Model verification reports
- Model exercise reports and results
- Hydrogeologic test procedures
- Hydrogeologic test results and data
- Atmospheric test procedures
- Atmospheric test results and data
- Environmental study evaluations and results
- Site characteristics reference documents
- Test deviation records
- Unusual occurrence reports

7.2.2 Design Records

- Procedures and reports
- Design deviation records
- Performance specifications
- Peer review reports and comment resolution
- Design criteria records
- Design criteria change records
- Technical analyses, evaluations, and reports in support of project preparation
- Design review records and comment resolution
- Calculations and records of checks
- Applicable codes and standards used in design
- Configuration control records
- As-built drawings and records
- Design classification system
- Conceptual design reports
- Design verification testing reports and data
- Baseline document index
- Technical computer codes and models
- Original tracings of drawings, specifications, and photographs of repository systems, components, and structures
- Summary design data and/or records reflecting significant findings or containing significant findings or containing significant scientific data not duplicated elsewhere which serve as backup for notebook entries and/or reports.

7.2.3 Procurement Records

- Contract requisitions
- Statements of work with amendments
- Acceptance records
- Equipment manuals
- Operating manuals
- Maintenance manuals

7.2.4 Manufacturing Records

- Applicable code data reports
- As-built drawings and records
- Certificate of compliance
- Electrical control verification test results
- Heat treatment records
- Liquid penetrant examination final results
- Location of weld filler material
- Magnetic particle examination final results
- Major defect repair records
- Material properties records
- Nonconformance reports
- Performance test procedures and results records
- Pressure test results (hydrostatic or pneumatic)
- Radiograph review records
- Ultrasonic examination final results
- Welding procedures

7.2.5 Installation Construction Records

Receiving and Storage - Nonconformance Reports

CIVIL

- Concrete cylinder test reports and charts
- Concrete design mix reports
- Grout design mix reports
- Material property reports on liner and seal materials
- Material property reports on reinforcing steel
- Material property reports on reinforcing steel splice sleeve material
- Material property reports on steel embedments in concrete
- Material property reports on structural steel and bolting
- Material property reports on waste package material
- Material property reports on rock bolt materials
- Pile loading test reports
- Rock bolt installation test reports
- Reports on high strength bolt torque testing
- Soil compaction test reports
- Seal installation records and test reports
- Shaft alignment measurements

WELDING

- Heat treatment records
- Liquid penetrant test final results
- Material property records
- Magnetic particle test final results
- Major weld repair procedures and results
- Radiograph review records
- Ultrasonic test final results
- Weld location diagrams
- Weld procedures

MECHANICAL

- Code data reports
- Installed lifting and handling equipment
procedures, inspection, and test data
- Lubrication procedure
- Material properties records
- Pressure test results (hydrostatic or pneumatic)

ELECTRICAL AND I&C

- Cable separation data
- Cable splicing procedures
- Cable terminating procedures
- Certified cable test reports
- Relay test procedures
- Voltage breakdown test results on liquid insulation

GENERAL

- As-built drawings and records
- Final inspection reports and releases
- Nonconformance reports
- Specifications and drawings

7.2.6 Preoperational Test Records

- Automatic emergency power source transfer
procedures and results
- Final system adjustment data
- Main and auxiliary power transfer test procedures
and results
- Off-site power source energizing procedures and
test reports
- On-site emergency power source energizing procedures
and test reports
- Power transmission substation test procedures and results
- Preoperational test procedures and results
- Primary and secondary auxiliary power test procedures
and results

7.2.7 Operation Records

Records and drawing changes identifying facility design modifications made to systems and equipment described in the Final Safety Analysis Report
Facility radiation and contamination survey results
Radiation exposure records for individuals entering radiation control areas
Training and qualification records for current members of the plant operating staff
In-service inspection records
Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments
Meeting minutes of the plant nuclear safety committee and company nuclear review board
Surveillance activities, inspections, and calibrations required by the Technical Specifications records
Changes made to Operating Procedures
Records and logs of maintenance activities, inspections, repair, and replacement of principal items of structures, systems, and components
Licensee event reports
Fire protection records
Nonconformance reports
Plant equipment operations instructions
Security plan and procedures
Emergency plan and procedures
Records of activities required by the security plan and procedures
Records of activities required by the emergency plan and procedures
Applicable records noted in other sections of this Appendix for any modifications or new construction applicable to structures, systems, or components
Evaluation of results of reportable safety concerns as required by regulations
Annual environmental operating report
Annual plant operating report

Supplemental Quality Assurance Requirements

QA on (R & D) Experiments

1.0 Scope

OGR participating organizations will apply, as a minimum, the following requirements when conducting experiments. However, since the requirements set forth in this section are not, by themselves, sufficient to assure that data so obtained will be suitable for licensing, all experiments should also be analyzed in accordance with the graded QA methodology to determine what additional QA requirements may be applicable. Data obtained from experiments conducted solely under these provisions shall not be used as the basis for formulating decisions affecting public health and safety or waste isolation, nor shall such data be used to support a license application.

1.1 Documentation

Documentation used to control the experiments shall include logbooks or other suitable bound means to provide a written record of the experiment. Unless otherwise specified by other applicable QA requirements, documentation should be treated as non-permanent records and retained for a period of five years.

1.2 Initial Entries

Prior to initiation of the experiment, the following entries as a minimum, will be made.

- a. Title of the experiment.
- b. Name of the qualified individual(s) performing the experiment and any additional witnesses to the experiment.
- c. Description of experiment's objective.
- d. Equipment and materials to be employed during the experiment, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material.
- e. Record retention time, if longer than five years from the date of the last entry.
- f. A description of the procedures that will be followed, or sequence of steps in the conduct of the experiment.

1.3 Entries to be made during the experiment, daily or as appropriate, should be sufficiently detailed that another competent experimenter could repeat the experiment and should include:

- a. Date and name of individual making the entry.
- b. Description of the experiment attempted, including detailed step-by-step process followed.

- c. Description of any conditions which may adversely affect the experiment.
- d. Identification of samples used and any additional equipment and materials not described in Section 1.2.
- e. All data taken and a brief description of the results to include notation of any unaccepted results.
- f. Any deviations from the experiment.
- g. Any interim conclusions reached, as appropriate.
- h. Final results and a summary of the outcome of the experiment. Also a discussion of whether the experiment's objectives (see 1.2c above) were achieved.

1.4 The final entry in the record should be the signature of the experimenter, the signature of a competent technical reviewer, and if required, the signature of a QA representative to verify that necessary procedures were followed.

SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

COMPUTER SOFTWARE

1.0 PURPOSE

The purpose of this section of the OGR QA Plan is to specify acceptable methods meeting the "Supplementary Requirements for Design Control" of NQA-1, Supplement 3S-1 as they apply to computer software, and NUREG-0856 requirements for computer software documentation.

2.0 SCOPE

This attachment describes the controls to be applied to computer software during computer code design, development, verification, validation, transfer, and application and for changes or modifications to computer codes that are to be used to support licensing and that important to the health and safety of the public or to waste isolation. These requirements apply to OGR projects and contractors. Developmental and business management and wage/personnel applications are exempt.

3.0 REQUIREMENTS

3.1 Configuration Management

3.1.1 The Organization designing developing, verifying, validating, or transferring computer codes (hereafter called "contractor") shall develop and implement a software configuration management system that ensures an orderly development of software from initial design through verification/validation testing, resulting in an approved code and related documentation.

3.1.2 The configuration management system shall establish requirements for baselining software (placing software under configuration control) and provide for positive identification of software and control of all software baseline changes. Baselined software includes approved codes and supporting documentation such as design specifications, test plans and results, user instructions, and change reports.

3.1.2.1 Software shall be uniquely identified to assure positive control of all revisions to codes and related documentation. The Contractor shall develop written procedures which provide for identification of each code version and corresponding documentation set as an integral part of the software baseline. The procedures shall also establish a method for identifying and tracking baseline changes throughout the life of the software. The tracking system shall include a listing of all software under configuration control and the status of required changes.

3.1.2.2 Configuration change control shall consist of systematic evaluation, coordination, and approval or rejection of all proposed changes and the implementation of only approved changes to baseline software.

- (1) The impact of a change(s) is carefully evaluated, required action is documented, the resulting version is uniquely identified, and information concerning the change is transmitted to all affected personnel/organizations.
- (2) Changes to computer software shall be subjected to the same level of approval, verification, and validation as the original software.

3.1.3 The Contractor shall also develop written procedures describing requirements for reporting and documenting software discrepancies and determining the appropriate corrective action. The corrective action system shall provide for an independent evaluation of possible impacts upon previously reported applications and/or analysis using the affected version of the software.

This requirement may be met by an appropriate expansion/modification of the contractor's nonconformance reporting and corrective action program (ref. NQA-1 Basic Requirement 15 and 16).

3.2 Software Design Control

3.2.1 The Contractor shall develop written procedures describing the controls applied to the design of software and the verification of that design through independent technical review. Basic elements that shall be considered in these reviews include:

- o Design bases/technical requirements (design input and sources)
- o Methodology (mathematical model and correlations used)
- o Assumptions (descriptions, identification, and justification of assumptions which cannot be verified until a later date)
- o Algorithms (appropriateness of algorithms)
- o Approach (suitability of coding approach and program organization)
- o Standards (coding standards established)

- 3.2.2 The design control procedures shall provide for documentation of review activities including requirements for documenting comments and resolving disagreements.
- 3.2.3 Reviews of software design shall be subjected to a review by the Contractor's QA organization to assure that comments or recommendations and subsequent dispositions have been addressed.

3.3 Software Verification Testing

- 3.3.1 The Contractor shall test and verify computer software developed under this scope of work, or modifications to existing software by one or more of the following:
- o Comparison of results with those from other verified software or with results from previous test cases or sample problems.
 - o Comparison of results with results from alternate calculational methods, such as analytical solutions or alternate calculations.
- 3.3.2 For computer software developed for the OGR Program verification procedures or test plans shall be prepared identifying the test cases to be run, the input data to be used, and the expected results. The procedures or test plans shall be submitted to the contracting organization for acceptance prior to formal testing.
- 3.3.3 Testing of new software designs shall be performed for those inputs and conditions necessary to fully exercise the software, identify acceptable ranges of input values, and to provide a suitable benchmark or sample problem.
- 3.3.4 Modifications or updates to existing software or software being transferred into the system shall be verified to assure the software will provide correct results consistent with:
- o Assumptions in the underlying conceptual model
 - o Numerical techniques or algorithms selected for the solution
 - o Limitations of the computational scheme, range limits for each variable, parameters and constants employed.

3.4 Software Validation Testing

If software being developed requires validation, this shall be noted in the statement of work or other technical directives.

3.4.1 Software validation shall consist of demonstrating the adequacy of the software and resultant data by comparing software results against fully verified and traceable data. Data used in the development process shall not be used in the validation process.

3.4.2 When data is not available from these sources, alternative approaches used shall be documented, including an evaluation of the degree of validity of the model. Alternate approaches may include peer review and comparisons with the results of a similar analysis.

3.5 Software Documentation

3.5.1 Computer software developed and/or modified shall be documented during development and testing in accordance with the applicable elements of NUREG-0856 as specified below. This requirement may be met in part by existing documentation if properly referenced and related to the NUREG-0856 requirements.

3.5.2 Documentation prepared during code design should include:

- o Performance Specifications - containing a general description of the model including a discussion of the intended purpose/use of results; physical and chemical phenomena; component models; mathematical models and numerical methods; equations, notations, and references or deviations; assumptions, limitations, and simplification; and input and output information requirements.
- o Solution Techniques - detailed descriptions of mathematical models and numerical methods employed, general numerical procedures to be used, component models, numerical method type, and numerical stability and accuracy.
- o Code Structure - an overview of program paths, internal data structures, common blocks and major arrays, and initialization and restart procedure.

3.5.3 Documentation prepared during testing should include:

- o Verification Tests and Results - purpose and limitations; model, support code and data-base assessments; reviews and tests performed; and assessments of results.
- o Benchmarking and Validation History - standard data set tests; code comparisons, mathematical models and numerical methods and code use experience, results of methods reviews, and code comparisons.

- o System Assessment and Integration - interaction with other codes, verification of the integrated package, and applicability to the scope of work.

3.5.4 Documentation prepared during software application should include:

- o Problem Definition - types of problems solved, data requirements, initial and boundary conditions and solutions strategy and options.
- o Data Files - organization rules; input, output, and workspace files; auxiliary processing and program use.
- o Input Data - general consideration and description of specific files, input records, data base instructions, and error processing.
- o Computer System Interface - computer-dependent features, compiler requirements, hardware requirements, and control cards or command files.
- o Output - general and output control.
- o Sample Problems - problem description, input and output listings, and a detailed description of listing contents.

3.6 Software Transfer

3.6.1 All requests for transfer of software developed by the Contractor for this scope of work shall be approved, in writing, by the contracting organization prior to transfer. Requests for transfer shall identify the code version to be transferred and provide an explanation of the intended use of the code. Updates to previously transferred codes shall be transferred in accordance with the requirements of 3.6.3 below.

3.6.2 Upon receipt of the written authorization the Contractor shall initiate a code transmittal letter; generate a tape copy of the code, reference data sets and applicable sample problems; compile the documentation set; verify the files were copied properly and retain a hard-copy of the code listing.

3.6.2.1 The transmittal letter shall identify the code by name, and code identification number; describe the applicability of the code for the intended use, if known; specify the tape read format; and provide a tape file index.

3.6.2.2 The tape copy shall also include and index of all files contained on the tape and include all pertinent input and output files required to run the sample problem.

3.6.3 Updates to previously transferred software shall be transferred to contracting organization when the new version is completed, verified, and the documentation prepared. Updated material may be submitted in lieu of a complete transfer of the tape copy or documentation, provided adequate instruction is given for revising the existing material (transmittal letter, tape copy and documentation).

3.6.4 The contracting organization shall be notified of any discrepancy or error discovered during the application or installation of transferred software. Errors identified during application shall be reported and affected analysis controlled as nonconformances. The Contractor shall evaluate errors identified during application for reporting as potential unusual occurrences.

3.7 Software Application

3.7.1 The Contractor shall establish requirements for controlling the application of computer software by technical calculations in support of the scope of work.

3.7.2 Technical calculations using software shall be performed with applicable computer codes and with software operating procedures defined sufficiently to allow independent repetition of the entire computation.

3.7.3 The Contractor shall develop written procedures that specify requirements for documenting and reviewing software applications and analyses and assuring that all results are accurate and reproducible. The procedures shall establish requirements for identifying or otherwise marking record copies of all analysis and supporting documentation. Supporting documentation includes computer output (results), code input data including data bases and original sources/references of and assumptions used to obtain such data, code design, user's and/or hand calculations.

3.7.3.1 The following information shall be referenced or included on each record (document, tape/disc) which contains the reported analysis or supports the analysis;

- o Project or analysis title/number
- o Objective of analysis/application
- o Personnel who performed or reviewed work reported
- o Date and time of computer run or date record was created

- o Code name (title) and version
- o Computer type, operating system, and applicable system libraries and compilers
- o Original sources/references of data used
- o Explicit statement of all assumptions and how they were developed or determined

3.7.3.2 All applications of computer software shall be independently reviewed and approved to assure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.