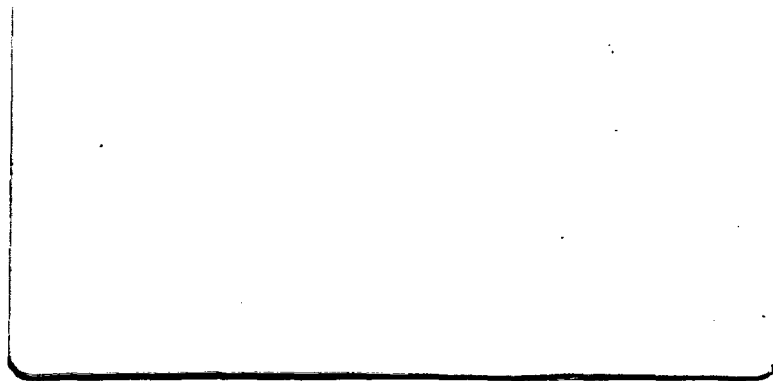


SEE D1021 6/5/86 J. Pohle
Communication NO. 01



NUCLEAR WASTE CONSULTANTS INC.

DRAFT

**QUALITY
ASSURANCE
MANUAL
Issue I**

NUCLEAR WASTE CONSULTANTS

MAY 9, 1986

DISTRIBUTION:

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Number i
Page 1 of 1
Effective Date
Revision 0
Approved

DRAFT

INDEX
QUALITY ASSURANCE MANUAL
ISSUE I

- i Index
- ii NWC Quality Assurance Policy
- iii Custody Assignment
- iv Manual Revisions and Control
- v Record of Revisions
- 1.0 Introduction
- 2.0 Project Description
- 3.0 Quality Assurance Management
- 4.0 Quality Assurance Task Plans
- 5.0 System Audits
- 6.0 Corrective Action
- 7.0 Quality Assurance Records
- 8.0 Reports to Management

DRAFT

Number iii
Page 1 of 1
Effective Date
Revision 0
Approved

CUSTODY ASSIGNMENT

This copy, No _____ is issued by Nuclear Waste Consultants, Inc. to

_____ on _____.

MAY 1986
DRAFT

Number ii
Page 1 of 1
Effective Date
Revision 0
Approved

ii QUALITY ASSURANCE POLICY

It is the policy of Nuclear Waste Consultants, Inc. (NWC) to perform all technical work under U.S. Nuclear Regulatory Commission Contract No. RS-NMS-85-009 in accordance with quality assurance programs and procedures established by NWC. The programs and procedures include provisions for the conduct of work related to nuclear safety and other work.

The nuclear-safety-related work will be performed using 10CFR 60 Subpart G and 10CFR 50 Appendix B as references to an extent consistent with its importance to safety.

The President of NWC is responsible for the implementation of the above objectives. The President has designated a Quality Assurance Director to develop, implement, and monitor the Quality Assurance Program.

DRAFT
MAY 1986

Number iv
Page 1 of 1
Effective Date
Revision 0
Approval

QA MANUAL REVISIONS AND CONTROL

- 1.0 Manual revisions and control.
- 1.1 Nuclear Waste Consultants, Inc., (NWC) Quality Assurance Manual is under the general administration of the NWC QA Director, who is responsible for its maintenance and periodic revision. The manual and its revisions require the approval of the President of NWC. The QA Director controls the distribution of the manual and maintains a record of custody of all copies.
- 1.2 All copies of the manual are serialized and remain the property of NWC.
- 1.3 Recipients agree to return the manual to NWC upon request.
- 1.4 The manual is subject to periodic review and updating. The proposed manual revisions are subject to approval by the President of NWC.
- 1.5 Manual revisions are documented on the Record of Revisions page, a revised copy of which is transmitted along with the changed or added pages.

QUALITY ASSURANCE MANUAL - ISSUE 1

DRAFT
MAY 1986

Number v
Page 1 of 1
Effective Date
Revision 0
Approval

RECORD OF REVISIONS

<u>Section</u>	<u>Revision</u>	<u>Date</u>	<u>Pages</u>	<u>Changes certified</u>
i				
ii				
iii				
iv				
v				
1.0				
2.0				
3.0				
4.0				
5.0				
6.0				
7.0				
8.0				

DRAFT

Number 1.0
Page 1 of 6
Effective Date
Revision 0
Approval

1.0 INTRODUCTION

1.1 BACKGROUND

As part of the regulatory requirements of 10CFR Part 60, the DOE must implement a quality assurance (QA) program to provide confidence in the studies performed to support license applications for construction and operation of geologic repositories for permanent disposal of high-level nuclear wastes. The role of the NRC in licensing is to exercise sufficient, but limited, oversight to provide reasonable assurance that a license applicant meets all of the applicable requirements.

Licensing of a geologic repository for high-level waste involves assessing whether the geologic setting and the engineered system will perform in a manner which will meet the performance objectives and requirements of 10CFR Part 60. The quality and assurance of quality of data and analyses used in support of the license application for proposed sites will be of great importance. In addition to questioning the relevance and completeness of data

DRAFT
MAY 1986

Number 1.0
Page 2 Of 6
Effective date
Revision 0
Approval

supplied in the license application, the licensing process will address the question of whether data and analyses are of adequate and known quality so that there will be reasonable assurance that operation and long-term disposal of high-level waste in the geologic repository will not provide an unreasonable risk to the health and safety of the public. A quality assurance program is therefore necessary to provide confidence in the work performed in development of the repository.

Within the broad content of site characterization at each of the three sites nominated by DOE and review by NRC and its technical assistance contractors of DOE site characterization plans, hydrogeology is of particular importance. The only probable medium for post-closure radionuclide transport to the accessible environment is groundwater and the hydrogeologic system is of critical importance in evaluating programs and plans for the design of engineered systems in the geologic repository.

Nuclear Waste Consultants (NWC) intends to conduct sufficient Quality Assurance (QA) activities to demonstrate that data generated or utilized in conducting technical reviews will be scientifically valid, defensible, and of

DRAFT
MAY 1986

Number 1.0
Page 3 of 6
Effective Date
Revision 0
Approval

known quality. Documents produced by NWC must be complete, representative, and meet the QA requirements established by NWC.

The program will provide assurance that activities affecting quality are documented with a document control system and accomplished in accordance with written instructions or procedures. The program will provide for the regular review by NWC management of the status and adequacy of the QA program.

1.2 QUALITY ASSURANCE PROGRAM CONCEPTS

Quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given needs. The NWC QA program for work under NRC Contract No. RS-NMS-85-009 incorporates the following concepts:

Level 1 - This concept applies to those studies and analyses of nuclear sites that provide input (data and/or analyses) to the design of repository systems and components that are regulated by the NRC in order to ensure the radiological health and safety of the public. The

DRAFT
MAY 1986

Number 1.0
Page 4 Of 6
Effective Date
Revision 0
Approval

level of review and documentation is governed by 10CFR 60 Subpart G and 10CFR 50 Appendix B. These studies are subject to NWC internal audit.

Level 2 - This concept applies to those studies, reports, and evaluations that are not directly related to health and safety, but that for project complexity or liability are subject to systematic control of project records, calculations, reviews, or final work products. These studies are subject to NWC internal audit.

Level 3 - This concept includes work which is not otherwise controlled by levels 1 and 2. Level 3 allows less comprehensive controls on record-keeping, or reviews. This level requires minimum management review and no NWC audit.

Common to Level 1, Level 2, and Level 3 studies is a set of QA procedures for the systematic review of analyses, studies, and reports prepared for NRC. These procedures are instituted to provide technical review of professional work that will better ensure the maintenance of the highest professional quality of work. The major difference between Level 1, Level 2, and Level 3 studies is the level of review and the degree of documentation of the quality assurance review process.

DRAFT
MAY 1986

Number 1.0
Page 5 of 6
Effective Date
Revision 0
Approval

The NWC Quality Assurance Manual is established and maintained as the documented basis for compliance of NWC Level 1 and Level 2 work. The NWC QA Director is responsible for the maintenance and periodic revision of the NWC QA Manual. The President of NWC is responsible for approving the manual and its revisions prior to their issuance. To ensure manual validity, it shall be routinely reviewed by NWC management 12 months after its last revision date. Distribution will be controlled by current distribution lists.

1.3 ORGANIZATION AND OPERATORS

The President of NWC has the overall responsibility for the development, implementation, and continued operation of the Quality Assurance Program. To ensure that the NWC QA policy is carried out, a Quality Assurance Director serves under the direction of the President. The QA Director has the responsibility for development of the program and determining that QA requirements are met.

The QA Director will review and approve Quality Assurance plans of subcontractors, provide QA assistance to subcontractors, conduct periodic audits of the QA program and plans of NWC and subcontractors, prepare formal

DRAFT
MAY 1986

Number 1.0
Page 6 of 6
Effective Date
Revision 0
Approval

reports and other communications related to the status of the NWC and subcontractor QA program and plans, provide QA assistance as required to improve the program and ensure its continuity, and serve as the clearinghouse in the preparation, implementating and revisions of all QA program plans.

In implementing the NWC QA program, the QA Director will be assisted by QA Coordinators of NWC subcontractors and by the NWC Project Manager. The NWC Project Manager and subcontractor management will establish the level of QA applicable to each subcontractor task and the subcontractor QA Coordinator will then assist in the implementation and monitoring of task QA plans.

DRAFT

Number 2.0
Page 1 of 2
Effective Date
Revision 0
Approval

2.0 PROJECT DESIGN

2.1 PROJECT OBJECTIVES

Nuclear Waste Consultants and its subcontractors under Nuclear Regulatory Commission (NRC) Contract No. RS-NMS-85-009 are currently providing technical assistance in hydrogeology to NRC. The major role of the NWC and its subcontractors is preparing for and evaluating the hydrogeologic aspects of DOE site characterization plans for potential sites for geologic repositories for high-level nuclear waste disposal. The elements of this NWC effort include: site familiarization; data inventory and management; reviews of site activities and documents; conceptual model evaluation; possible numerical evaluation of conceptual models; identification and assessment of hydrogeologic issues for each proposed DOE site; and preparation of technical reports to support the development of NRC staff technical positions. The overall objective of NWC in this program is to provide timely, accurate, and complete technical consulting assistance to NRC.

DRAFT

Number 2.0
Page 2 of 2
Effective Date
Revision 0
Approval

2.2 QUALITY ASSSURANCE OBJECTIVES

Quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given needs. QA includes internal quality control but also includes external elements such as independent performance audits, and periodic evaluation of internal quality control documentation. QA as defined by 10CFR 60 Subpart G is "all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its subsystems or components will perform satisfactorily in service."

The overall objective of the NWC QA program is to provide control over activities affecting the quality of the assessment of hydrogeologic systems to an extent consistent with their importance to safety. Within this context further objectives of the NWC QA program are: the generation of data/reports of known quality and integrity; operation of a system to ensure quality in data review, validation, and reporting; and operation of a quality assurance management system which provides both quality and task-oriented flexibility.

DRAFT
MAY 1986

Number 3.0
Page 1 of 5
Effective Date
Revision 0
Approval

3.0 QUALITY ASSURANCE MANAGEMENT

3.1 ASSIGNMENT OF RESPONSIBILITIES

In order to properly manage the QA activities of NWC and its subcontractors, all QA management responsibilities are assigned by the President of NWC to a Quality Assurance Director. The success of the QA program depends upon the QA Director being organizationally independent of all functions involved in the generation, processing, or use of technical data. The QA Director will: develop and implement the NWC QA program; identify and respond to QA needs; review and approve all QA program and task plans for the NRC project; serve as the clearinghouse in the preparation, implementation, and revision of QA program plans; be responsible for audits; and submit periodic reports to management.

3.1.2 Subcontractors

Each subcontractor to NWC will designate a QA Coordinator to assist the NWC QA Director and subcontractor management with development and operation of

Number 3.0
Page 2 of 5
Effective Date
Revision 0
Approved

task-specific QA plans. The QA Coordinator will have the responsibility to: be the subcontractor contact for all QA matters from the development of task-specific QA plans to the use of data; overview QA activities within his organization; review, revise, and approve task-specific QA plans; identify and respond to QA needs; serve as the subcontractor clearinghouse in the preparation, implementation, and revision of all QA task plans; conduct periodic performance audits; coordinates and conducts quality problem investigations; and provides periodic QA status reports to management and to the NWC QA Director.

3.2 COMMUNICATION

For the QA program to be effective, communication between NWC management, subcontractor management and NWC and subcontractor QA personnel must be routine and open regarding the overall QA program, task plans, QA audits, problem areas and other QA matters.

Formal QA reports will be submitted annually by subcontractors to the NWC QA Director. The NWC QA Director will in turn, submit an annual QA report to

DRAFT
MAY 1986

Number 3.0
Page 3 of 5
Effective Date
Revision 0
Approved

NWC management. Subcontractor reports must contain the following types of information:

1. Status of QA task plans.
2. Significant QA problems, corrective actions, progress, plans, and recommendations.
3. Results of performance audits.
4. Other relevant information.

3.3 PROGRAM ASSESSMENT AND AUDITS

3.3.1 Assessment

Effective management of a QA program requires periodic assessment to determine the need for revision or corrective action. The QA program of NWC insures appropriate management commitment to an acceptable QA program and provides for the preparation of QA task plans. Specifically, the QA task plan must insure that:

DRAFT
MAY 1986

Number 3.0
Page 4 of 5
Effective Date
Revision 0
Approved

1. The level of QA and required data/report quality is determined and stated before the task begins, and
2. All data/reports generated are of the quality established by the QA task plan.

The NWC QA Director will review the QA task plans for QA Levels 1 and 2 as they are developed; the Director will then periodically review and evaluate the implementation of these plans. In addition, the subcontractor QA Coordinators will review and evaluate the implementation of these Level 1 and 2 plans during the performance of each task. A written assessment will be prepared by the QA Coordinator at the completion of each Level 1 and 2 subcontractor task. The assessment will be sent to the NWC QA Director for his review.

3.3.2 Audits

As part of the QA Coordinators' responsibility for QA (Levels 1 and 2) program overview, all QA task plans will be reviewed for adequacy and modified as necessary. Periodic internal audits of QA task implementations will be

DRAFT
MAY 1986

Number 3.0
Page 5 of 5
Effective Date
Revision 0
Approved

conducted by the Coordinator to determine QA acceptability and the requirement for any corrective actions. The results of such internal audits will be submitted in writing to subcontractor management and to the NWC QA Director.

Periodically (at least annually) an external review of each subcontractor's QA activities will be conducted by the NWC QA Director and written results of such audits will be submitted to subcontractor and NWC management.

DRAFT

Number 4.0
Page 1 of 7
Effective Date
Revision 0
Approved

4.0 QUALITY ASSURANCE TASK PLANS

4.1 DEVELOPMENT OF TASK PLANS

The assignment of any Nuclear Regulatory Commission task by NWC to its subcontractors will trigger the development of a task-specific QA plan consistent with the overall QA program. Each plan, from those covering the very simple, single-person consulting assignments to those covering more complex multi-faceted tasks, will consist of an orderly set of specific procedures by which the subcontractor delineates how it produces and documents quality data for that specific task. The type and level of documentation will vary with each QA task plan and its potential to affect safety-related systems.

4.2 OPERATING PROCEDURES

The development of task-specific QA plans by each subcontractor will require that the NWC Project Manager and the subcontractor management agree on the QA

DRAFT
MAY 1986

Number 4.0
Page 2 of 7
Effective Date
Revision 0
Approved

level required for each task prior to its initiation. The level of documentation will range from a basic management review of small, simple tasks to an extensive QA review and documentation effort for the major, complex tasks. Once a task QA plan has been prepared by a subcontractor, it will be reviewed and approved by NWC management and by the NWC QA Director.

In determining which QA elements should be included as part of a QA task plan the following questions should be answered: What activities should be considered? What of these activities are most crucial? What acceptance (control) limits for these activities should be checked? What action should be taken if acceptable limits are not met? Appendix 1 is an example outline of a QA task plan.

Task plans will be subject to change during the life of the project. Any changes which affect the established quality provisions will be reflected in a revision to the task plan. Revisions to task plans will be subjected to the same level of review and approval as was the original document. Distribution of revised task plans will include all holders of the original document.

DRAFT

Number 4.0
Page 3 of 7
Effective Date
Revision 0
Approved

4.3 INTERNAL QUALITY ASSURANCE AUDITS

Each subcontractor Quality Assurance Coordinator will periodically review and assess the status of QA task plans and their implementation. Results of these periodic audits and any recommendations for corrective action will be documented and submitted to subcontractor management and to the NWC QA Director.

Procedures will be established by NWC and subcontractors to control the issuance of documents, such as task plans, which describe activities affecting quality. The procedures will ensure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and are distributed to and used at the location where the described activity is performed. These procedures will include: identification of each task plan as to project and task number; maintenance of distribution records for task plans.

Standard procedures for quality verification of NWC and subcontractor reports and analyses include the following: the task manager will be responsible for final review and approval of all final reports/analyses for his task; a

DRAFT
MAY 1986

Number 4.0
Page 4 of 7
Effective Date
Revision 0
Approved

NWC/Subcontractor Review Board will be responsible for review and approval of all Level 1 reports/analyses, technical memoranda, etc., resulting from Level 1 work; Level 2 work requires NWC/subcontractor management review and approval as does Level 3 work.

Where computer codes are relied upon for results, each code will be validated and documented. Verification of codes will refer to development or acquisition of documentation that confirms that a software program correctly performs its intended function. Task-specific software will refer to an original software program or modified existing program developed by NWC or subcontractors to simulate for analysis or operation unique task analytical and/or decision processes. Public domain software will refer to a software program developed by others which is made available to NWC or subcontractors.

All software programs, whether developed internally or acquired from an outside source, will be provided with documentation so they can be understood and verified by an independent reviewer. The program documentation will contain the following: program identification; author; purpose; description of problem or function; programming languages used; restrictions

MAY 1986
DRAFT

Number 4.0
Page 5 of 7
Effective Date
Revision 0
Approved

(limitations); computers for program use; machine requirements; related material (any auxiliary program or external data files required for this program); references; method of solution (summarize mathematical techniques, procedures, assumptions, and numerical algorithms employed for solution); and standard test case (provide standard case for periodic validation).

Verification is the process of ensuring that the program does correctly what it was intended to do. Verification is required for all Level 1 and 2 computer programs. Verification will be accomplished by checking the mathematical modeling, numerical analysis, and program logic and then doing either of the following:

- (1) Demonstrate that the program's solutions to a test problem are in substantial agreement with those obtained by hand calculations or from accepted experimental or analytical results published in the technical literature.
- (2) Demonstrating that the computer program solutions to a series of test problems are in substantial agreement with those obtained by a similar independently written program in the public domain.

DRAFT
MAY 1986

Number 4.0
Page 6 of 7
Effective Date
Revision 0
Approved

The program verification should be documented including methods used, and details of the calculations used (manual or computer) and results and conclusions.

4.4 CORRECTIVE ACTION

A critical element of any QA program is the ability of the QA Coordinators, together with their management to define and take corrective action when necessary to resolve QA problems. Each task QA plan will identify control limits which will indicate the need for corrective action when they are exceeded, and will also describe procedures and requirements to ensure that early and effective action can be and is taken. The Task Manager will be responsible for evaluating non-conformances and recommending action to subcontractors or NWC management.

There are two types of corrective action:

- (1) Immediate, to correct non-conforming data or equipment.

DRAFT
MAY 1986

Number 4.0
Page 7 of 7
Effective Date
Revision 0
Approved

- (2) Long-term, to eliminate the causes of non-conformance.

The steps in the closed-loop corrective action system are: define the problem; assign responsibility for investigating the problem; investigate and determine the cause; determine a corrective action to eliminate the problem; assign responsibility for implementing the corrective action; confirm the effectiveness of the corrective action.

APPENDIX I

EXAMPLE

QUALITY ASSURANCE TASK PLAN

DRAFT

Task

Date Prepared

Prepared By

Revision No.

Page No.

1. Title Page

Title

Organization

Approval Blocks

2. Table of Contents

3. Task Description

Contract background with dates

General description

Intended use of data

4. Task Organization and responsibility

Task Organization and line authority

Identify key QA personnel

DRAFT
MAY 1986

5. QA Applicability

Identify Level 1, 2, or 3

Data quality objectives (precision, accuracy, completeness)

Final product form (report memo)

QA records (task plan, data base inputs, final report, documentation)

6. Data and documentation handling procedures

Chain-of-custody procedures (assignment of custodian; custody log)

Record keeping (forms, notebooks, and procedures to be used for recording)

7. Data reduction, validation, and reporting

Data reduction scheme

Data validation criteria

Identification and treatment of outliers

Flow chart, describing progress of data through the system

8. Performance audits

Schedule

9. Assessment procedures for data/report acceptability

10. Corrective action

Control limits

Procedures

Identification of responsible personnel

DRAFT
MM 1986

11. QA reports to management

12. Levels 1 and 2 task plans shall be reviewed and approved prior to issuance
by: Task Manager, Subcontractor Management, NWC QA Director, and NWC
Project Manager.

Approved

Date

Approved

Date

Approved

Date

Approved

Date

DRAFT
MAY 1986

Number 5.0
Page 1 of 2
Effective Date
Revision 0
Approved

5.0 SYSTEM AUDITS

5.1 BACKGROUND

The role of audits in the management of quality assurance is verification. Audits provide assurance that work prescribed has been conducted and documented properly. Audits conducted by individuals not responsible for day to day operations provide an assessment and control mechanism to management.

5.2 PROCEDURES

System audits will be conducted periodically (at least annually) on each subcontractor QA program by the NWC QA Director. The audits will be arranged by telephone and confirmed by letter. The purpose of these audits is to assess the adequacy of and adherence to the overall QA program and task plans. Appendix 2 is the audit checklist to be used by NWC in auditing subcontractors' QA programs.

DRAFT
MAY 1986

Number 5.0
Page 2 of 2
Effective Date
Revision 0
Approved

5.3 DOCUMENTATION

Results of system audits will be documented in writing and formally submitted to subcontractor and NWC management as soon as possible after completion of an audit.

DRAFT

Number 6.0
Page 1 of 2
Effective date
Revision 0
Approved

6.0 CORRECTIVE ACTION

The purpose of having a corrective action mechanism is to correct significant or repetitive unsatisfactory conditions relating to the quality of work in order to implement long-term actions which will eliminate the cause. The corrective action system, with good management support, ensures the step which closes the loop in problem resolution.

Quality Assurance Coordinators will identify deficiencies and non-conformances in writing to Task Managers and subcontractor management. The task and subcontractor management will be responsible for identifying and taking the required action to eliminate the cause. The Task Manager will assure that no further work dependent on the non-conforming item is performed until approval is obtained from subcontractor management.

The NWC QA Director and Project Manager will assist in evaluating disposition action taken, maintaining a log of non-conformances by task and subcontractor, and assure that a record of non-conformances is included as a part of the final task documentation package.

DRAFT

Number 6.0
Page 2 Of 2
Effective Date
Revision 0
Approved

The NWC QA Director will at least semi-annually analyze logged non-conformances to identify apparent unsatisfactory trends. Unsatisfactory trends will be reported to NWC management in writing.

In addition, the corrective action program covers the analysis of the cause(s) of any negative audit findings whether as a result of audits conducted by subcontractor QA Coordinators, the NWC QA Director, or by the NRC.

The results of audits performed by the NWC QA Director will be reviewed by NWC management within 30 days of receipt to determine the need for corrective action beyond the corrective action identified in the audit report. If this review determines that a need for a major or long-term corrective action exists, NWC will receive a commitment from subcontractor management to define and implement the necessary corrective actions to correct the cause(s) of the problem as well as remedy any immediate effects of the problem. Modifications to task work will be made, if necessary. The NWC QA Director and NWC management will subsequently review the results of major corrective action items to determine the effectiveness of the actions.

DRAFT

Number 7.0
Page 1 of 8
Effective Date
Revision 0
Approved

7.0 QUALITY ASSURANCE RECORDS

In order to document the quality assurance process, it is necessary to use and maintain sufficient records to furnish evidence of activities affecting quality. Such records must be identifiable and retrievable.

7.1 DEFINITIONS

The following definitions apply to quality assurance documentations:

- (1) **Quality Assurance Records** - These records which furnish documentation evidence of the quality of services or activities affecting quality. A document is considered a QA record when the document has been completed and approved by the responsible management personnel. (Examples included review forms for reports or records of computer software verification which have been reviewed and signed by management).

DRAFT
MAY 1986

Number 7.0
Page 2 of 8
Effective Date
Revision 0
Approved

- (2) Quality Assurance File - The file maintained by the Project or Task Manager or his designe(s) that will, by the termination of the task, include all QA documents generated in support of his assigned task.
- (3) Quality Assurance Records Index - A listing of the QA records identified in the task work plan.

7.2 RESPONSIBILITIES

The Task Managers will be responsible for identifying in the task plan those documents to be designated as QA records. The Task Managers will then be responsible for ensuring that records identified in task plans are being maintained.

The QA Coordinators will be responsible for maintaining a central QA Records Index for each task performed by that subcontractor. The QA Coordinator will maintain a record of external transmittal of all task QA records.

At the completion of the task, the Task Manager will be responsible for disposition of all task QA files as prescribed in the task plan.

DRAFT
MAY 1986

Number 7.0
Page 3 of 8
Effective Date
Revision 0
Approved

Forms for use in documentation of reports and analyses and for verification of computer software are presented in the following pages.

Number 7.0
Page 4 of 8
Effective Date
Revision 0
Approved

NUCLEAR WASTE CONSULTANTS
RECORD OF REPORT/ANALYSIS
REVIEW

(1) Report No. _____ (2) QA Level _____ (3) Task No. _____

(4) Report/Analysis Title _____

(5) Author(s) _____ (6) Total No. of pages _____

(7) Verification Scope (Check as applicable)

___ Method of Analysis ___ Computer Code Application

___ Reasonableness of results ___ Assumptions

___ Check of Sample Calculations ___ Complete check of Math

___ Input information ___ Spot check of Math

___ Partial independent analysis

DRAFT
MAY 1986

Number 7.0
Page 5 of 8
Effective Date
Revision 0
Approval

(8) Name of verifier _____

(9) Description of Verification (Activities, Findings, and Resolution)

(10) Verifier signature _____ Date _____

(11) Commentary reviewed and resolved (Author) _____ Date _____

(12) Report review checkoff Comments:

Assumptions approved

Report fulfills workscope

Report/analysis follows task plan

Applicable QA requirements met

(13) All applicable QA requirements have been met and report/analysis approved

Subcontractor Manager _____

Date _____

DRAFT
MAY 1986

Number 7.0
Page 6 of 8
Effective Date
Revision 0
Approval

NUCLEAR WASTE CONSULTANTS
RECORD OF REVIEW OF COMPUTER
SOFTWARE VERIFICATION

A. To be completed by programmer

(1) Software package name (unique definition, version, etc., on the documentation).

(2) Developer of program identification

(3) Programmer/Author

(4) Purpose of review

___ New Program ___ modification (new version)

___ periodic review ___ other _____

Number 7.0
Page 7 of 8
Effective Date
Revision 0
Approved

B. To be completed by Task Manager

Verification scope

- | | |
|---|---|
| <input type="checkbox"/> Sample problem | <input type="checkbox"/> Benchmark against existing program |
| <input type="checkbox"/> Mathematical modeling | <input type="checkbox"/> Benchmark against experimental results |
| <input type="checkbox"/> Numerical analysis | <input type="checkbox"/> Benchmark against hand calculations |
| <input type="checkbox"/> Standard test case
libraries used | <input type="checkbox"/> Other _____
_____ |

Comments:

C. To be completed by verifier

Description of verification activities and findings:

Verified By:

Date:

To be completed by Programmer Reviewer

Summary of review procedures and results:

Completed documentation checklist:

DRAFT
MAY 1986

Number 7.0
Page 8 of 8
Effective Date
Revision 0
Approved

___ Program identification

___ Related material

___ Authors

___ References

___ Purpose

___ Method of solution

___ Programming languages

___ Users manual

___ Restrictions

___ Listing

___ Computer(s)

___ Standard test case

___ Operating systems

___ Description of the verification

Reviewed by:

Date:

Comments reviewed and resolved (Author):

Date:

All applicable QA requirements have been met and approved by

Subcontractor Manager _____

Date:

DRAFT

Number 8.0
Page 1 of 1
Effective Date
Revision 0
Approved

8.0 Reports to Management

Periodic reports will be submitted to subcontractor management by QA Coordinators regarding the status of the QA program, any problem area, corrective actions, and any recommendations for programmatic changes. Copies of these reports will be submitted to the NWC QA Director. QA Coordinators will also submit an annual report to the NWC QA Director.

The NWC QA Director will submit periodic reports and audit reports to NWC management regarding the implementation and status of the QA program, problem areas, corrective actions, and recommendations for programmatic changes. In addition, the QA Director will submit an annual QA report to NWC management documenting the status of the NWC QA program for the NRC contract work.