

W/ltc lth 4/28/88
To: Jeff Pohle
From: Thomas M. Ivory

D.1021

QUALITY
ASSURANCE
MANUAL
Issue I
Revision 1.0

NUCLEAR WASTE CONSULTANTS

APRIL, 1988

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RECORD OF REVISIONS

<u>Section</u>	<u>Revision</u>	<u>Date</u>	<u>Pages</u>	<u>Changes certified</u>
i	1.0	9/87	i.1	
ii				
iii				
iv				
v	1.0	9/87	v.1	
1.0				
2.0				
3.0	1.0	9/87	3.3-5	
4.0	1.0	9/87	4.2-10	
5.0				
6.0	1.0	9/87	6.2	
7.0	1.0	9/87	7.3-7	
8.0				
9.0	1.0	9/87	9.1-9.10	
		4/88	9.2, 9.5-6	
Appendix I	1.0	9/87		
Appendix II	1.0	9/87		
Appendix III	1.0	9/87		
Appendix IV	1.0	9/87		
Appendix V	1.0	9/87		
Appendix VI	1.0	9/87		

4. Results of performance audits.
5. Other relevant information.

The QA Director will communicate directly with subcontractor QA Coordinators to provide assistance and recommendations related to all aspects of Quality Assurance. In addition, subcontractors will submit copies of all task plans, all report and computer software reviews, and all QA status assessments to the NWC QA Director. The QA Director will provide copies of his monthly status reports and his audit reports to subcontractor management and QA Coordinators.

A copy of the monthly QA report to NWC management will be attached to the project's monthly status report to NRC, or incorporated into the project monthly status report.

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 management commitment to appropriate level of product quality and provides for the preparation of QA task plans. Specifically, the QA task plan must insure that:

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 1-A 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 1-A plans during the performance of each task. A written assessment (Appendix I) will be prepared by the QA Coordinator at the time of completion of the first draft report or analysis and at the completion of each Level 1 and 1-A subcontractor task. The assessment will be sent to the NWC QA Director for his review. Work performed as QA Level 1-B requires verification of mathematical calculations and review and approval by subcontractor and NWC management and completion of Appendix I.

3.3.2 Audits

As part of the QA Coordinators' responsibility for QA (Levels 1 and 1-A) program overview, all QA task plans will be reviewed initially and after the completion of a first report draft or written analysis for adequacy and modified as necessary. Periodic internal audits of QA task implementation will be 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. The QA Director will submit an audit checklist to the subcontractor at least two weeks prior to an audit. In addition, the NWC QA Director will receive monthly QA status reports from subcontractor QA Coordinators and will communicate monthly with the Coordinators.

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 II is an outline of a QA task plan the format of which should generally be followed in preparing Task Plans for Level 1 and 1-A tasks.

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.

4.3 INTERNAL QUALITY ASSURANCE AUDITS

Each subcontractor Quality Assurance Coordinator will monthly 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 in writing 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; and maintenance of distribution records for task plans.

Standard procedures for quality verification of NWC and subcontractor reports and analyses include the following:

1. The task manager will be responsible for final review and approval of all final reports/analyses for his task. It will be the responsibility of the author to assure the quality of his work product. The author should utilize Appendix III, Technical Report Author Review Checklist and Appendix IV, Review of Equations, for this purpose. Final approval will imply the task manager's certification that all mathematical computations have been checked by a competent reviewer who was not the original author of the computations (Appendices IV, V, and VI should be used for such reviews); where a computer program has been used to perform calculations, the final approval will imply the task manager's certification that the software has met the NWC software QA standards and that documentation of this is included in the report or already on file with NWC.
2. A NWC/Subcontractor Review Board will be responsible for review and comment on all reports/analyses, technical memoranda, etc., resulting

from Level 1 work. The task manager is responsible for documenting responses to all comments received from the Review Board.

The NWC/Subcontractor Review Board will include the President of NWC, the NWC Project Manager, the subcontractor Task Manager, and one or more technical reviewers who have not worked on the task under review. The meeting of the Review Board may be conducted by phone and documented by completion of the NWC Record of Report/Analysis Review.

3. Level 1-A and 1-B final work products require NWC/subcontractor management review and approval, and Level 1-A work may be submitted to outside technical review by one or more members of the NWC Technical Pool at the option of the NWC Project Manager. Review comments may be submitted by phone and documented by completion of the NWC Record of Report/Analysis Review. The task manager is responsible for documenting responses to all comments, technical or managerial, that are submitted.

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 (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 or cases for complex multi-function codes (provide standard case or cases 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 1-A 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) Demonstrate that the computer program solutions to a series of test problems are in substantial agreement with those obtained by a similar independently written, verified program in the public domain.

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

Each subcontractor will be required to implement a Computer Software Management System (CSMS) as part of the QA program. The subcontractor QA Coordinator will be responsible for design and implementation of this system.

The CSMS will function to ensure documentation and traceability of software used under NRC contract. The CSMS will serve as a repository for current and previously-utilized versions of computer software. An archiving system will maintain current versions of the software in an immediately accessible form and previous versions in less accessible archived form. The archiving system must be sufficient to permit traceability and retrievability. The CSMS will also serve as a repository for documentation for software, including original reports, documentation of errors, modifications, and enhancements, results of verification test simulations, and other related materials.

Any system command procedures and libraries of data required to utilize the programs should be available in the CSMS. The QA Coordinator must ensure that the CSMS adapts to changing hardware and system hardware.

Subcontractors will utilize NUREG/CR-4369 Quality Assurance (QA) Plan for Computer Software Supporting the U.S. Nuclear Regulatory Commission's High-Level Waste Management Program for guidance in establishing their Computer Software Management System (CSMS).

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.
- (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.

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.

The purpose of a QA audit and surveillance program is to provide management with documentation of the quality of work performed; combined with an effective corrective action program, the QA program provides NWC and subcontractor management an excellent mechanism to ensure a consistently high quality technical product.

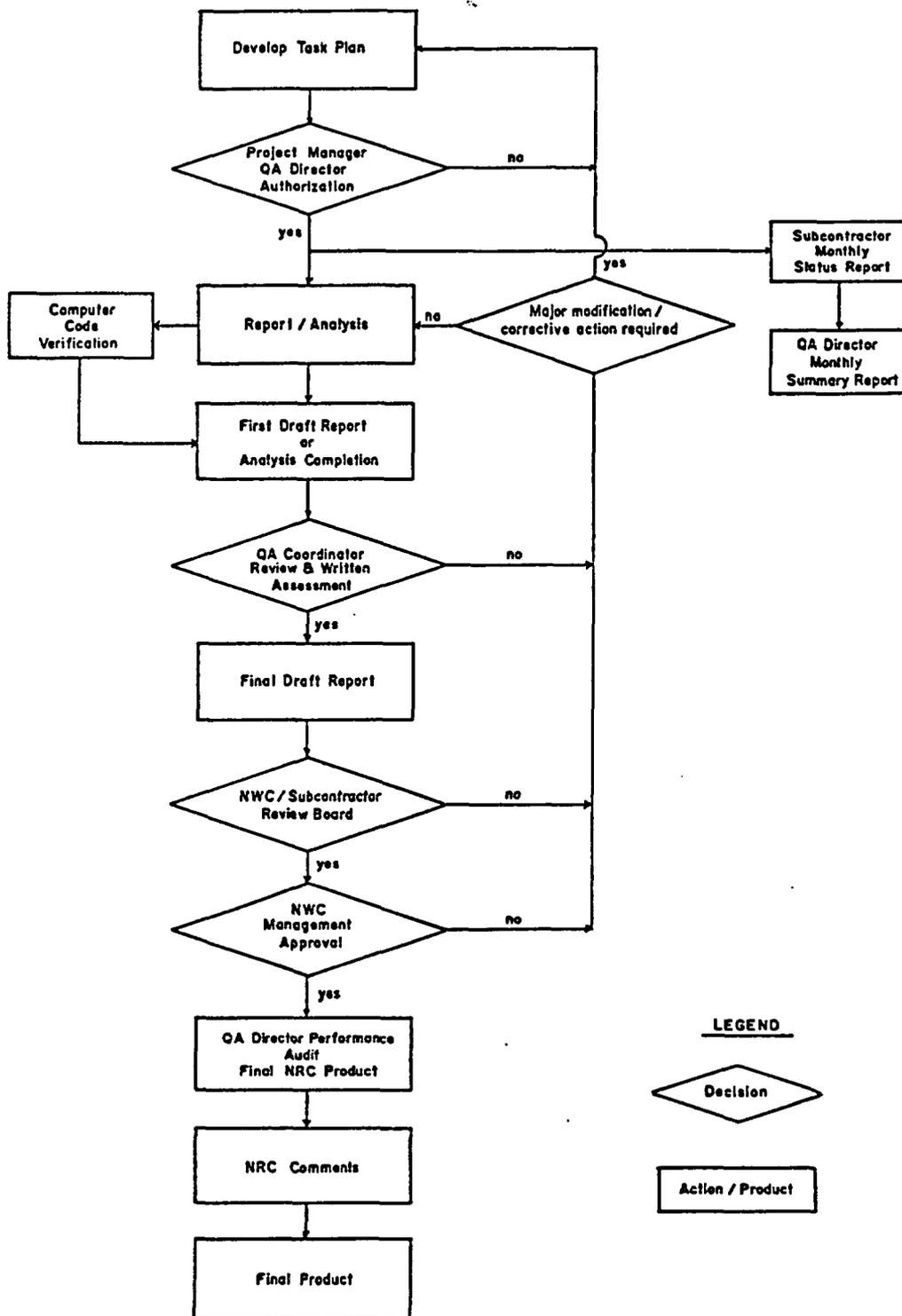
9.0 Flow Chart for Quality Assurance

9.1 QA Level 1

1. QA Task Plan written and QA Coordinator assigned by subcontractor.
2. Project manager gives authorization to proceed with Task (Project Manager and Subcontractor agree on QA Level for the Task).
3. Task Plan approved by Nuclear Waste Consultants (QA Director and Project Manager) and returned to subcontractor.
 - a. Each month the subcontractor Task manager will submit a QA status report to NWC providing a summary of QA activities, problems, and other relevant items.
 - b. Each month the NWC QA Director will submit a QA report to NWC management. This report will summarize QA activities for the past month by NWC and its subcontractors.
4. Task Plans are reviewed after completion of first draft analysis or report to determine adequacy of plan and need for modification. Any modifications require written modification of plan and subsequent approvals.
5. Computer codes, whether developed internally or acquired from an outside source, must have adequate documentation, and must be verified (QA Manual 4.4 and 4.5).

6. Internal written QA assessment should be made by subcontractor QA coordinator at the time of completion of the first draft of report or analysis.
7. Reports, analyses, and technical work products which are level 1, and are to be submitted to NRC must be reviewed by an NWC/Subcontractor Review Board and Board comments resolved by NWC management prior to submittal of the final report to NRC.
8. Where necessary, corrective actions should be proposed to subcontractor management by the QA Coordinator, and agreement by subcontractor and NWC management obtained. Actions are taken and subsequent performance audits should verify effectiveness.

Figure 1. QA Level 1 Flow Chart

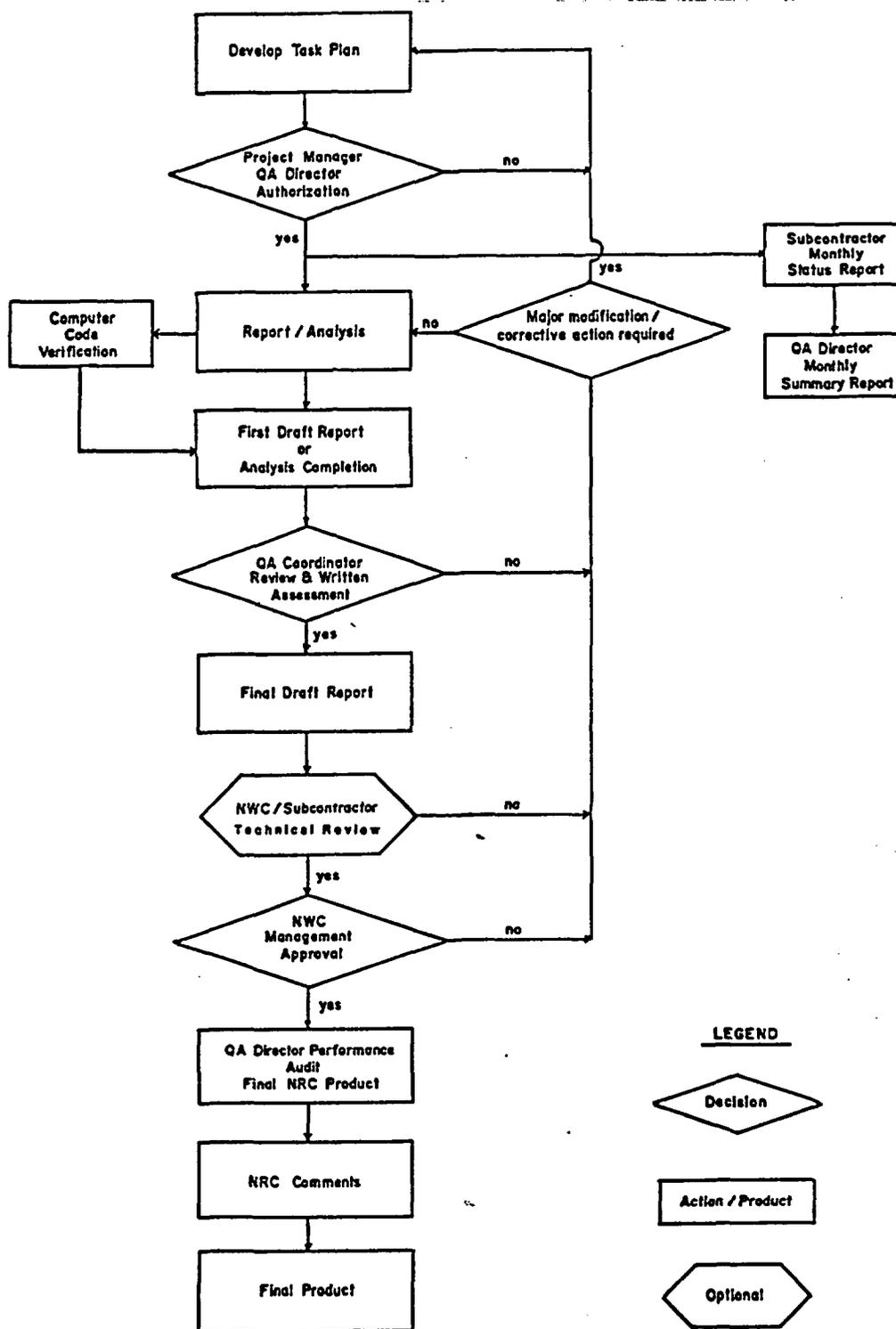


9.2 QA Level 1-A

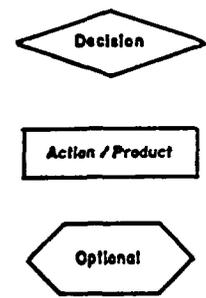
1. QA Task Plan written and QA Coordinator assigned by subcontractor.
2. Project manager gives authorization to proceed with Task (Project Manager and Subcontractor agree on QA Level for the Task).
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 - b. Each month the NWC QA Director will submit a QA report to NWC management. This report will summarize QA activities for the past month by NWC and its subcontractors.
4. Task Plans are reviewed after completion of first draft analysis or report to determine adequacy of plan and need for modification. Any modifications require written modification of plan and subsequent approvals.
5. Computer codes, whether developed internally or acquired from an outside source, must have adequate documentation, and must be verified (QA Manual 4.4 and 4.5).
6. Internal written QA assessment should be made by subcontractor QA coordinator at the time of completion of the first draft of report or analysis.

7. Level 1-A final work products require NWC/Subcontractor management review and approval. In addition, Level 1-A work may be submitted to outside technical review at the option of the NWC Project Manager. Work products must be submitted to NWC for final management review and approval prior to submittal to NRC. Document all management and reviewer comments on the NWC Record of Report/Analysis Review form (Appendix I).
8. Where necessary, corrective actions should be proposed to subcontractor management by the QA Coordinator, and agreement by subcontractor and NWC management obtained. Actions are taken and subsequent performance audits should verify effectiveness.

Figure 2. QA Level 1A Flow Chart



LEGEND

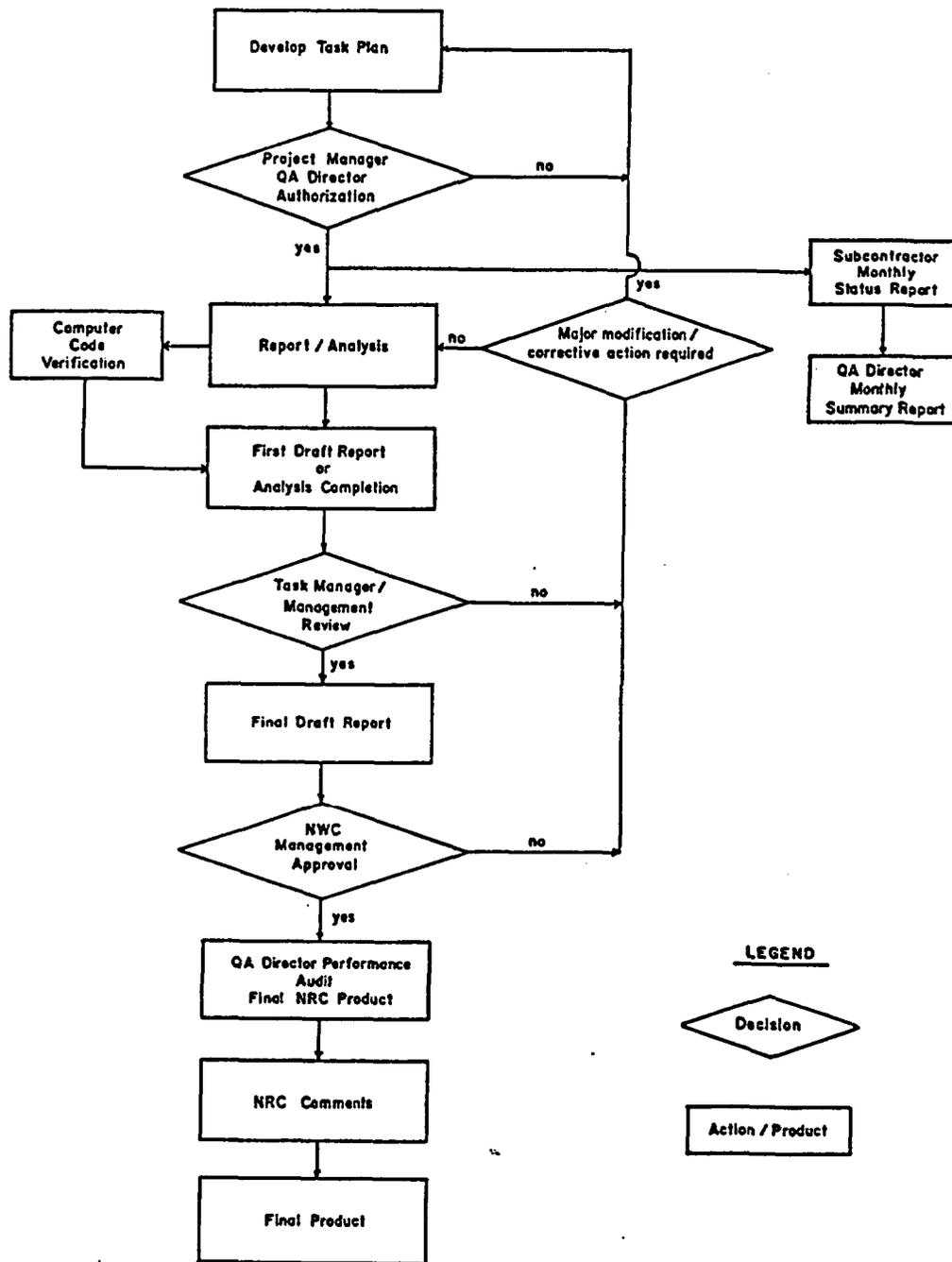


9.3 QA Level 1-B

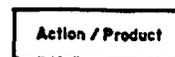
1. QA Task Plan written and QA Coordinator assigned by subcontractor.
2. Project manager gives authorization to proceed with Task (Project Manager and Subcontractor agree on QA Level for the Task).
3. Task Plan approved by Nuclear Waste Consultants (QA Director and Project Manager) and returned to subcontractor.
 - a. Each month the subcontractor Task manager will submit a QA status report to NWC providing a summary of QA activities, problems, and other relevant items.
 - b. Each month the NWC QA Director will submit a QA report to NWC management. This report will summarize QA activities for the past month by NWC and its subcontractors.
4. Task Plans are reviewed after completion of first draft analysis or report to determine adequacy of plan and need for modification. Any modifications require written modification of plan and subsequent approvals.
5. Computer codes, whether developed internally or acquired from an outside source, must have adequate documentation, and must be verified (QA Manual 4.4 and 4.5).
6. Level 1-B final work products require NWC/Subcontractor management review and approval. Review comments should be documented on NWC QA Appendix I.

7. The same Level 1 corrective action steps should be followed for Level 1-8.

Figure 3. QA Level 1B Flow Chart



LEGEND



9.4 Summary

The flow charts in each section represent the essential steps in the NWC Quality Assurance process for QA Levels 1, 1-A, and 1-B.

Steps 3a and 3b (monthly QA status reports) are completed by each subcontractor and the QA director regardless of QA Tasks in progress.

APPENDIX I

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

(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 _____

APPENDIX I

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 _____

B. To be completed by Task Manager

Verification scope

Sample problem Benchmark against existing program
 Mathematical modeling Benchmark against experimental results
 Numerical analysis Benchmark against hand calculations
 Standard test case libraries used 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:

- | | |
|---|--|
| <input type="checkbox"/> Program identification | <input type="checkbox"/> Related material |
| <input type="checkbox"/> Authors | <input type="checkbox"/> References |
| <input type="checkbox"/> Purpose | <input type="checkbox"/> Method of solution |
| <input type="checkbox"/> Programming languages | <input type="checkbox"/> Users manual |
| <input type="checkbox"/> Restrictions | <input type="checkbox"/> Listing |
| <input type="checkbox"/> Computer(s) | <input type="checkbox"/> Standard test case |
| <input type="checkbox"/> Operating systems | <input type="checkbox"/> 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:

APPENDIX II
EXAMPLE
QUALITY ASSURANCE TASK PLAN

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
5. QA Applicability
 - Identify Level 1, 1A, or 1B
 - 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 procedures
 - 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

11. QA reports to management

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

Approved	Date

MINI-REPORT AUTHOR REVIEW CHECKLIST

(1) Report No. _____ (2) Author _____

(3) Report Title

(4) Date of Review _____

(5) REVIEW CHECKLIST:

_____ All data referenced to source _____ Variables referenced to "previous" calculation

_____ Consistency of units _____ Check of Math

_____ Basic equations referenced (provide photocopy of referenced page)

PROJECT: _____ TASK _____ SUBTASK _____ PAGE _____ OF _____

SUBJECT: _____

BY _____ DATE _____ CHKD _____ DATE _____
(TASK MGR.)

REVIEW OF CALCULATIONS

PAGE _____ OF _____

<u>EQN</u>	<u>: FORM</u>	<u>: DEFS</u>	<u>: DIMS</u>	<u>: DATA</u>	<u>: SUBS</u>	<u>: COMPS</u>	<u>: UNITS</u>	<u>: COMMENT</u>	<u>: INITIALS</u>
1	:	:	:	:	:	:	:	:	:
2	:	:	:	:	:	:	:	:	:
3	:	:	:	:	:	:	:	:	:
4	:	:	:	:	:	:	:	:	:
5	:	:	:	:	:	:	:	:	:
6	:	:	:	:	:	:	:	:	:
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9	:	:	:	:	:	:	:	:	:
10	:	:	:	:	:	:	:	:	:

NOTES: 1. FORM - Form of equation (incl. symbols) checked; DEFS - Definition of terms; DIMS - Dimensions checked; DATA - Data checked; SUBS - Substitutions checked; COMPS - Computation checked; UNITS - Units of answer checked; COMMENT - Comment number, including attachments

2. AUTHORS SHALL FULLY REVIEW ALL EQUATIONS AND ATTACH THIS DOCUMENTATION TO ALL REVIEW DRAFTS. TASK MANAGERS INITIALS INDICATE THAT THE FORM HAS BEEN COMPLETED.

FOR QA-1, REVIEWERS SHALL FULLY CHECK FIRST 10 EQUATIONS AND 20% OF SUBSEQUENT EQUATIONS, WITH THE BALANCE CHECKED FOR FORM, DEFINITIONS AND DIMENSIONS.

FOR QA-1A, THE QA TASK PLAN SHALL IDENTIFY THE REVIEW REQUIREMENTS.

PROJECT: _____ TASK _____ SUBTASK _____ PAGE _____ OF _____

SUBJECT: _____

BY _____ DATE _____ CHKD _____ DATE _____

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____
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- 19 _____
- 20 _____

MATH REVIEW COMPLETED: _____

(QA COORDINATOR)

PROJECT: _____ TASK _____ SUBTASK _____ PAGE _____ OF _____

SUBJECT: _____

BY _____ DATE _____ CHKD _____ DATE _____