OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-L-1-103 (Rev. 10)

DATE February 16, 1985

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SUPERSEDES ISSUE DATED October 20, 1983

TITLE: QUALITY ASSURANCE ASSESSMENT/PLAN

Purpose: (R)

To define requirements for Quality Assurance Assessments and Plans (QAA/P).

Scope: (R)

This procedure is applicable to all projects* during (a) start-up and routine operation, (b) manufacture of items (products), and (c) design and construction phases of expense funded and capital equipment funded projects. For QAA/P requirements on capital projects, see Ref. 1.

References:

1. QA Planning for Capital Projects, ORNL QA-L-1-108.
2. Tracking of QA Documents and Actions, ORNL QA-L-1-110.

Requirements: (R)

All projects* are subject to the requirements of the ORNL Quality Assurance Program. The program Quality Assurance (QA) elements shall routinely be applied on a selective basis, depending on the complexity, consequences of failure, and significance to the program success. Additionally, an Assessment Checklist shall be completed for each project to determine if a QAA/P is required. The QAA/P is used to identify and evaluate the risk of potentially significant quality problems (failure modes), and to plan for this prevention or to minimize the consequences should they occur.

Procedure: (R)

100.1 Project Selection – The task leader, with advice of the division quality assurance coordinator (QAC), shall review all projects under his/her responsibility, using the Assessment Checklist (Appendix A), to determine which projects require the preparation of a QAA/P (Appendix B).

100.2 Computer Generated Checklist – For projects covered by Field Task Proposal/Agreements, a computerized Assessment Checklist form will be generated by the QA Director's Office which will contain the project description. For other projects, blank forms (UCN-15503) are available. (N)

*Includes tasks, experiments, tests, job, activities, analytical studies and programs, and management activities.

OAK RIDGE NATIONAL LABORATORY
OPERATED BY
MARTIN MARIETTA ENERGY SYSTEMS, INC.

Approved By: F. H. Neill, QA Program Director

Approved By: R. D. Wiltshire, Executive Director for Support and Services

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100.3 Assessment Schedule – A QAA/P shall be completed when indicated by the checklist, for the operation and maintenance of a project and shall be prepared prior to pre-operational testing. The QAA/P for the design and construction will normally be assigned to Energy Systems Engineering to prepare and it shall be completed during the conceptual design phase of the project. (See Ref. 1.) (N)

100.4 QAA/P Planning – For projects requiring the participation of several ORNL divisions, a single QAA/P shall be prepared by the division with the overall QA management responsibility, with input from participating divisions. Each division shall use its division QA implementing procedures for the phase of the project for which it is responsible, unless directed otherwise by the managing division.

For assessment purposes, large projects may be subdivided into systems, subassemblies, components, and parts (phases for analytical studies and programs and management activities) to improve QA. Likewise, similar small projects may be combined to enhance cost-effective QA.

100.5 Chairperson - Division management shall appoint a chairperson (normally the task leader) for the QAA/P team.

100.6 Assessment/Plan – The chairperson, with QAC assistance, shall prepare a draft QAA/P (Forms UCN-15006 and -15007), using the instructions shown on the attached forms, Appendices B and C. Figure 1 illustrates the steps to be followed in conducting the QAA/P.

100.7 Assessment/Plan Team Meeting – The chairperson shall schedule and conduct a QAA/P team meeting. Project personnel, QACs from organizations participating in the project, and a member of the ORNL QA staff shall be invited to attend the meeting to critique and provide input to the draft QAA/P. Knowledgeable personnel from participating groups shall be requested to attend the meeting to provide additional input. The following should be considered: maintenance, fabrication, engineering, safety environmental protection, health physics, and laboratory protection.

The chairperson shall distribute a copy of the draft QAA/P document to each member of the team prior to the meeting.

100.8 QAA/P Document Format – The QAA/P document shall consist of the following sections:

A. The completed QAA/P form, including work sheets.

B. A list of quality-related standard practices, procedures, and instructions that have been reviewed and evaluated for use as the Basic QA Program on this project. Indicate title and document number. List specific paragraphs in the procedures, when applicable.

C. A functional responsiblity chart (Appendix D) indicating who will be responsible for implementing the quality-related standard practices, procedures, instructions, and actions. Titles shown on this chart should agree with titles shown on the organization chart.

D. An organization chart showing organizational structure, levels of authority, and line of internal and external communication for management and for the direction and execution of activities effecting quality.

100.9 Rationale Statements – Rationale statements shall be provided for each acceptable risk determination on the QAA/P. For potential quality problems that have been judged to have insignificant consequences, state why the consequences of failure will be insignificant (acceptable risk). Select rationale statements from Appendix E (modified for the project) or provide rational statements that are more appropriate for this project.

For potential quality problems that have been judged to have a significant consequence of failure, with a low probability of failure (acceptable risk), state why the probability* of failure is judged to be low. Select rational statements from Appendix E (modified for the project) or provide other rationale statements that are more appropriate for this project.

100.10 Preventive QA Actions – Planned preventive QA actions shall be provided for each unacceptable risk determination. The planned actions, when implemented, should provide reasonable confidence that the failure will not occur, or that the impact will be mitigated, if the failure does occur. Examples of preventive QA actions are provided in Appendix F. All QA actions taken collectively are the QA Plan. (R)

100.11 Risk Assessment by Others – Any risk assessment(s) by Laboratory Director's Review Committee(s), or equivalent Y-12 Plant review committee(s), including safety analysis reports and environmental impact statements, shall be reviewed to determine if there are significant potential quality problems (failure modes) identified that will require preventive QA actions. Such significant potential quality problems shall be identified or referenced on the QAA/P form.

*When determining probability, evaluate the adequacy of existing standard QA practices and procedures, state-of-the-art, number and types of organizations involved and their experience. In considering the adequacy of standard QA practices and procedures, it must be assumed that they may not be current and that they may not be fully implemented unless they receive special attention.

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100.12 Documentation — Following the QAA/P meeting, the chairperson shall resolve comments, complete the QAA/P document, and obtain necessary approvals.* The chairperson shall distribute copies of the approved QAA/P document to, as a minimum, all persons signing the QAA/P document, project members, division/program management, the ORNL Quality Assurance Director (QAD), and the QACs of participating organizations.

100.13 Tracking Preventive QA Actions — The QAC shall monitor and track all preventive QA actions in each QAA/P. A log or equivalent shall be used. The log shall indicate the current status of each QA action, title of person(s) responsible for implementing the action, and schedule for completion. The QAC shall promptly notify the task leader and management, as appropriate, of deficiencies in implementing the QA actions. The ORNL computerized QA document and action tracking system may be used by the QAC to track the status of QA actions (see Reference 2).

100.14 Review — Each QAA/P shall be reviewed by the task leader and the QAC, at least every 12 months, to determine if reassessment is required. When the project reaches stable long-term operation, a 24-month review may be adequate.

100.15 Reassessment — Reassessment may be required by project scope changes, evidence that quality problems are developing, the occurrence of significant quality failures or satisfactory completion of planned preventive (special) QA actions.

When a planned preventive QA action has been completed and proven adequate during actual use, such that the corresponding unacceptable risk has been reduced to an acceptable risk, then the preventive QA actions, responsibility, and schedule shall be deleted from the QAA/P. The rationale for the acceptable risk determination shall then be stated in place of the preventative QA action. Normally, the rationale statement should indicate that the former preventive QA action has been implemented and provides the necessary confidence that the risk of failure is acceptable.

Reassessments shall be reviewed, approved, and distributed in the same manner as the initial QAA/P. A QAA/P team review is normally not necessary for reassessments.

100.16 Deviation — Temporary deviations from approved QAA/Ps shall be prepared by the task leader and documented on ORNL Deviation Request (Form UCN-5458A). The deviation request shall be approved by the QAC and division management before changes are implemented. Distribution of approved deviations shall be the same as approved QAA/Ps. (R)

*As a minimum, the QAA/P shall be approved by project management, Division QAC, and QAD. ORO approval is only required if they request it.

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100.17 Records and Status — The QAC shall maintain a copy of all QAA/P documentation. The QAC shall maintain a log which lists the projects to be assessed/reassessed, schedule, and current status. The QAC shall notify the ORNL QA Office when the project is complete so that the QAA/P can be closed out. The ORNL QA document computer tracking system may be used by the QAC to document and track the status of QAA/Ps (see Ref. 2).

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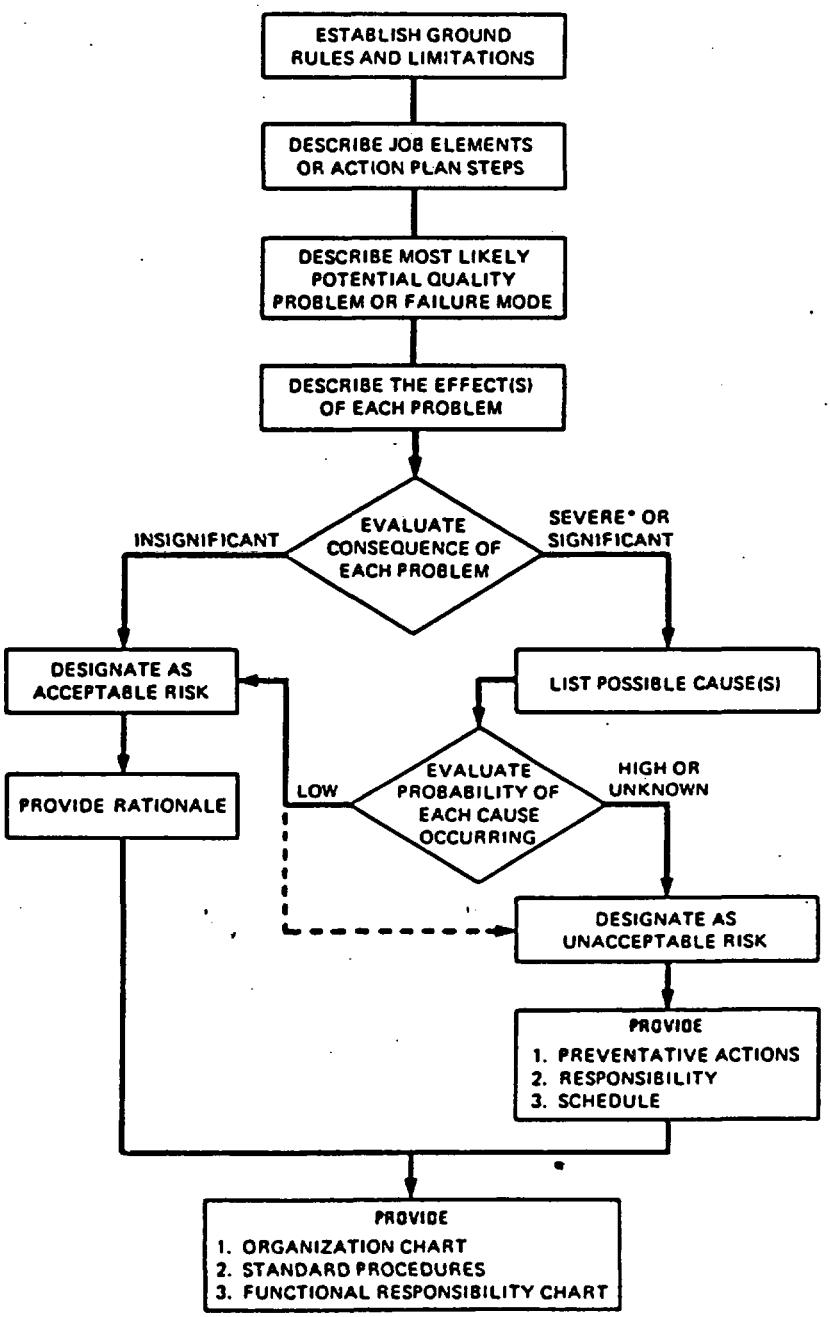
ORNL-DWG 84-14002

QAA/P FLOW CHART



*PROBLEMS WITH AN EXTREMELY SEVERE CONSEQUENCE, REQUIRING PREVENTATIVE ACTION, EVEN THOUGH PROBABILITY IS LOW.

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Appendix A

QUALITY ASSURANCE ASSESSMENT CHECKLIST
OAK RIDGE NATIONAL LABORATORY

PROJECT TITLE

PROGRAM

DOCUMENT NO.	REV.	DATE	DIVISION

PROJECT DESCRIPTION:

RISK DETERMINATION: IF A QUALITY PROBLEM OR FAILURE OCCURS, WOULD THE CONSEQUENCES ON MEETING TECHNICAL AND PROGRAM OBJECTIVES, FUNDING, SCHEDULE DELAYS, PUBLIC AND DOE REACTION, HUMAN HEALTH AND SAFETY, OR THE ENVIRONMENT BE:

☐ INSIGNIFICANT (COMPLETE PART A ONLY): ☐ SIGNIFICANT (COMPLETE PART B ONLY)

PART A - INSIGNIFICANT CONSEQUENCE: PROVIDE THE RATIONALE FOR THIS DETERMINATION

☐ No credible significant failure can be postulated.
☐ Failure will have a minimal impact
☐ Other: _____

PART B - SIGNIFICANT CONSEQUENCE: IS THE PROBABILITY OF FAILURE LOW?

☐ YES (CHECK RATIONALE BELOW) ☐ NO (COMPLETE QAA/P UCN-15006)

☐ Training program and/or standard operating procedures, which will be reviewed and evaluated on a periodic basis, provide reasonable confidence that items will perform satisfactorily in service.
☐ Maintainability will be very good and, in case of hardware failure, project can be returned to operation within an acceptable time period. Vital spare parts are readily available.
☐ Redundancy and/or backup systems will be provided.
☐ Items will be standard** "off-the-self" equipment of proven application for the use.
☐ An established reliable design will be used. Items have a history of low failure frequency during operation in a similar application.
☐ Reasonable confidence that standard** quality control actions (inspections, tests, etc.) will be adequate to mitigate failure.
☐ Other: _____

APPROVAL

TASK LEADER	DATE	QA COORDINATOR	DATE
	DATE		DATE

DISTRIBUTION: Task Leader, QA Coordinator, ORNL QA Program Director, Section/Department Head, Others:

(See ORNL QA Procedure QA-L-1-103 for applicability of form)

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Appendix B

MARTIN MARIETTA

MARTIN MARIETTA ENERGY SYSTEMS, INC.

UCN-15006
(2 6-84)

QUALITY ASSURANCE ASSESSMENT/PLAN

PLANT	DIVISION/FACILITY	ASSESSMENT/PLAN NO.	ORIGINAL ISSUE DATE	REV. (NO.) DATE
PROJECT TITLE – BUILDING OR ACTIVITY			PROJECT NO. (ENGRG.)	ESO NO. (ENGRG.)
JOB (Subproject, Subsystem, Program, Facility, etc.) TITLE – BUILDING			WBS NO. (ENGRG.)	PAGE 1 of
PROJECT PHASE: ☐ DESIGN/CONSTRUCTION ☐ MANUFACTURE/INSTALLATION ☐ OPERATION				REF. Engineering QAA No.

I. PROJECT (SUBPROJECT) DESCRIPTION

II. ASSESSMENT STATUS

☐ INITIAL ☐ INTERIM ☐ FINAL

III. ASSESSMENT CONCLUSION (See Worksheets UCN-15007)

QA PLAN ACTION(S) REQUIRED? ☐ YES ☐ NO

IV. INDIVIDUALS ATTENDING ASSESSMENT MEETING DATE:

CHAIRPERSON	

V. APPROVALS (NAME AND DATE)

SITE	ENGINEERING	DOE OR OTHER

VI. ASSESSMENT REVIEW

REVIEW	SCHEDULED REVIEW DATE	DATE REVIEWED	QA PLAN ACTION REVISION? NO	QA PLAN ACTION REVISION? YES	APPROVAL SIGNATURES CHAIRPERSON	QAC			
1									
2									
3									
4									

(Stores Item No. 10-997-5030)

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Appendix C

QUALITY ASSURANCE ASSESSMENT/PLAN

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DOCUMENT NUMBER
ISSUE/REV. NO. / DATE

GROUND RULES

JOB ELEMENTS OR ACTION PLAN STEPS		POTENTIAL PROBLEMS OR FAILURE MODES	EFFECT(S)	CONSEQUENCE[1]
NO.	DESCRIPTION			

[1] Evaluate the consequences of each potential problem in terms of its effect on monetary loss; programmatic loss and delay; and health, safety, and environmental injuries and events. Designate each potential problem as I-Insignificant or S-Significant. If the consequence is insignificant, include a rationale statement and designate the risk as A-Acceptable on columns on second page of form. If the consequence is significant, list the possible causes in the columns on the second page of form.

(Stores No. 10-997-5035)

QUALITY ASSURANCE ASSESSMENT/PLAN
(CONTINUED)

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NO.[2]	POSSIBLE CAUSES	PROBABILITY[3]	RISK[4]	PREVENTATIVE ACTION[5] OR RATIONALE STATEMENT	RESPONSIBILITY (Organization and Person)	SCHEDULE

[2] Repeat Job Element or Action Plan Step number from previous page.

[3] Evaluate the probability of each possible cause occurring as H-High, L-Low, or U-Unknown. If the probability is Low, include a rationale statement and designate the risk as A-Acceptable (Risk). The consequences of some problems may be extremely severe, requiring preventative action, even though probability is low. If the probability is high or unknown, designate the risk as U-Unacceptable and include preventative actions in the next column.

[4] Risk is the combination of consequences and probability and should be designated as A-Acceptable or U-Unacceptable, in accordance with the above instructions.

[5] For each preventative action, include responsibility (organization and person) and schedule (month and year).

(Stores No. 10-997-5036)

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Appendix D

TABLE 1

Functional Responsibility

P - Prepare/Perform A - Approach
I - Input R - Review
Blank - Not Required

Document/Action	Task Leader	Lead Designers [2]	Section Head	Division Director	Program Director	Division QAC	Div. Eng. Service	Seller			Installation Group	UCC-ND Shops	Inspection (QARI)	QA Director			
Documents																	
QA Plan																	
Design Criteria & Requirements																	
Design Drawings & Specifications																	
Design Change Requests																	
Deviation Requests																	
QA Document Decal on Drawings																	
Purchase Requisition																	
Seller QA Plans																	
Seller Surveillance Plans																	
Receiving Inspection Plans																	
UCC-ND Shop Manufacturing Plans [1]																	
Nonconformance Requests																	
Installation Plans [1]																	
Functional & Pre-Op Test Plans [1]																	
Record Storage Requirements																	
QA Data Pkg. & Letter of Compliance																	
Failure Analysis Reports																	
Actions																	
Source Inspection & Surveillance																	
Receiving Inspection																	
Functional & Pre-Op Testing																	
Collect & File Quality Records																	

1) When applicable 2) Engineering and I&C as appropriate

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Appendix E

EXAMPLES OF GENERIC RATIONALE STATEMENTS

Reference to specific projects, drawings, descriptions, procedures, etc., should be provided as applicable.

For Quality Problems with an Insignificant Consequence of Failure:

1. No credible failure can be postulated.
2. Failure will have minimal impact.

For Quality Problems with a Significant Consequence and a Low Probability of Failure

1. Training problem and/or standard operating procedures, which will be reviewed and evaluated on a periodic basis, provide reasonable confidence that the items will perform satisfactorily in service.
2. Maintainability will be very good and, in case of hardware failure, project can be returned to operation within an acceptable time period. Vital spare parts are readily available.
3. Redundancy and/or backup systems will be provided.
4. Items will be standard "off-the-shelf" equipment or proven application for this use.
5. An established reliable design will be used. Items have a history of low failure frequency during operation in a similar application.
6. Reasonable confidence that standard quality control actions (inspections, tests, etc.) will be adequate to mitigate failure.

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Appendix F

PREVENTATIVE QA ACTIONS* TO BE CONSIDERED IN QUALITY ASSURANCE ASSESSMENTS/PLANS
(Reference Paragraph 100.11)

Design Phase

1. Conduct special design review by Engineering (Reference Engineering Procedure EP-C-17).
2. Conduct project technical review (Reference ORNL QA Procedure QA-L-4-100).
3. Construct prototypes to verify design.
4. Use redundant or backup items or derate items.
5. Specify special inspections and tests, including hold points and acceptance criteria, during procurement and shop and field fabrication.
6. Conduct special reviews, analyses and studies such as safety, pressure vessel equipment, the Laboratory Director's Review Committee, Failure Mode and Effect Analyses, and Fault Tree Analyses.
7. Request traceability of material and/or hardware.
8. Specify quality systems or inspection system requirements for sellers.
9. Identify quality verification requirements for procurement, fabrication, and installation activities (Reference ORNL QA Procedure QA-L-2-107).
10. Identify requirements for controlling special processes such as welding, heat treating, cleaning, and nondestructive testing.
11. Identify requirements for protecting items against deterioration and damage during handling, shipping, and storage. Consider use of a special plan.
12. Conduct review of drawings and specifications for inspectability, fabricability, maintainability, and operability by inspection, shop, maintenance, and operations personnel, as appropriate.
13. Prepare "as-built" drawings and specifications.
14. Prepare and maintain current an engineering drawings list.

Procurement Phase

1. Review of procurement documents by QAC for specification of QA requirements.
2. ASME Code shop required.
3. Evaluate potential sellers.
4. Conduct source surveillance and inspection.
5. Conduct receiving inspection.
6. Review seller's QA program.
7. Review seller's bid proposal by appropriate project participants.
8. Conduct pre- and post-award meeting with sellers.
9. Prepare procurement plans.
10. Prepare and store archive samples of raw materials.
11. Define method for accepting items.
12. Require item verification, certification, test, and/or traceability.

*These actions are typical. Others actions should be designated as needed. Some of these preventative QA actions may be standard practice in some organizations.

Appendix F
(cont'd)

Energy Systems Shop Fabrication Phase

1. Provide manufacturing inspection and test plan with hold points.
2. Specify requirement for QA data package (inspection and test reports) and/or letter of compliance.
3. ASME Code shop required.
4. Provide system and facilities for controlling nonconforming items.
5. Review shop QA program.
6. Use independent inspection agency (such as QA&I) to monitor material control and inspection activities.
7. Provide procedure for preparation and approval of shop drawings and as-built drawings.
8. Verify identity of raw material to a known specification.

Installation and Pre-Operational Test Phase

1. Provide installation, inspection, and test plan with hold points.
2. Provide inspection, test, and cleanliness control procedures.
3. Conduct pre-operation/functional tests.
4. Conduct training and certification of personnel.
5. Use mock-ups during installation.
6. Describe unusual safety considerations.
7. Provide field change procedure.
8. Provide procedures for preparation and approval of field sketches and as-built drawings.
9. Describe final acceptance inspections and tests.
10. Use independent inspection agency (such as QA&I) to monitor material control and inspection activities.

Miscellaneous

1. Transmit documents by a controlled document release system.
2. Identify "Record" and "Non-Record" QA-related type records. Identify custodians and file location for such records.
3. Provide interface controls between project participants.

Operational Phase

1. Identify any Laboratory Director's Review Committees that will review project for safe operation.
2. Prepare procedures including start-up, routine, and shutdown operation.
3. Provide emergency shutdown procedure.
4. Describe unusual safety considerations.
5. Establish method for disposing of contaminated material.
6. Prepare and implement method (such as tags and logs) for indicating operating or maintenance status of systems and components.
7. Provide training of operators and certification, when required.
8. Identify measuring and test equipment (including safety-related instruments) requiring calibration and establish a recalibration schedule.

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Appendix F
(cont'd)

Experimental and Developmental Testing Phase

1. Prepare experimental test plan, including definition of test requirements.
2. Conduct Readiness Review to assure that test rig or apparatus is ready to begin operation.
3. Prepare special detailed test or operating procedures.
4. Define method for calibrating data collecting measuring and test equipment.
5. Define method for documenting data (technical notebooks or other).
6. Establish requirements for archive samples.
7. Define method for assuring that computer program designs are appropriate and current.
8. Define method for assuring traceability of data (show how published data can be traced to raw data).
9. Define method of review (peer or other) to verify that test results are correct and meet test requirements and criteria.
10. Define method for identifying and storing test records, including the use of computers to allow repeatability of tests.

Maintenance Phase

1. Conduct special training of maintenance personnel.
2. Implement programmed mechanical maintenance program for routine maintenance activities.
3. Prepare special maintenance procedures.
4. Prepare special maintenance plans.
5. Identify requirements for spare parts including quantity and storage requirements.
6. Conduct in-service inspections and tests to verify integrity of systems and components.
7. Identify and store special repair and maintenance records.

CHEMISTRY DIVISION

QUALITY ASSURANCE PROGRAM

Division Director's QA Policy Statement

The objective of the Chemistry Division is to produce innovative and high quality research relevant to the mission of Oak Ridge National Laboratory. This objective is reached by having highly qualified scientists conceive and carry out experimental or theoretical programs of short duration. Our work is generally then published in standard, refereed scientific journals in which the quality is assured by peer review.

Introduction

In view of the nature of the work, we base our quality assurance program on confidence in people performing the work and in knowing the manner in which they approach their work. The elements of quality assurance which apply to the Chemistry Division are: (1) Training and qualification of personnel, (2) Document review and approval, (3) Measuring and test equipment calibration and control, and (4) Audit planning, performance and reporting.

Training and Qualification of Personnel

The Division is staffed by people whose experience or academic degree attests to their qualifications. No one is hired for a permanent position without an interview and a review of their past performance. New employees may be given short training courses should their work require special or unusual techniques.

Document Review and Approval

Prior to the publication of papers and significant reports, security

and patent clearances and approval by the Division Director or designate are required. A file is maintained in the Division office of all publications.

Measuring and Test Equipment Calibration and Control

For a variety of standard instruments, calibrations are normally done by gauge and standard instrument control groups against certified standards which are traceable to nationally recognized standards. When nationally recognized standards do not exist or the work uses novel instruments or methods, duplicate experiments, comparisons with other experiments, and established theory will be used to ensure precision and accuracy.

Audit Planning, Performance, and Reporting

At least once a year, the performance of each person in the Division will be reviewed. The quality and quantity of work and the future plans will be discussed. A summary of this discussion will be maintained in the Division files.

When a research project is successfully completed, the results and conclusions are published. Prior to submission to the journal, these publications are reviewed by at least one person (generally a laboratory staff member) knowledgeable but not directly involved in the work.

At least once each year each program is appraised and reviewed for both content and direction. A Program and Budget Proposal is written which is reviewed by the Group Leader, Section Head, and Division Director prior to submission.

Approved: C. E. Haynes, Quality Assurance Coordinator — Date: June 14 1979

Approved: O. L. Keller, Division Director — Date: June 14 1979