Title

A NATIONAL RESEARCH LABORATORY GENERIC PROJECT QUALITY ASSURANCE PLAN FOR RESEARCH AND DEVELOPMENT

Authors

Bain, E.E.
Hinckley, R.L.

Publication Date

1986-09-01

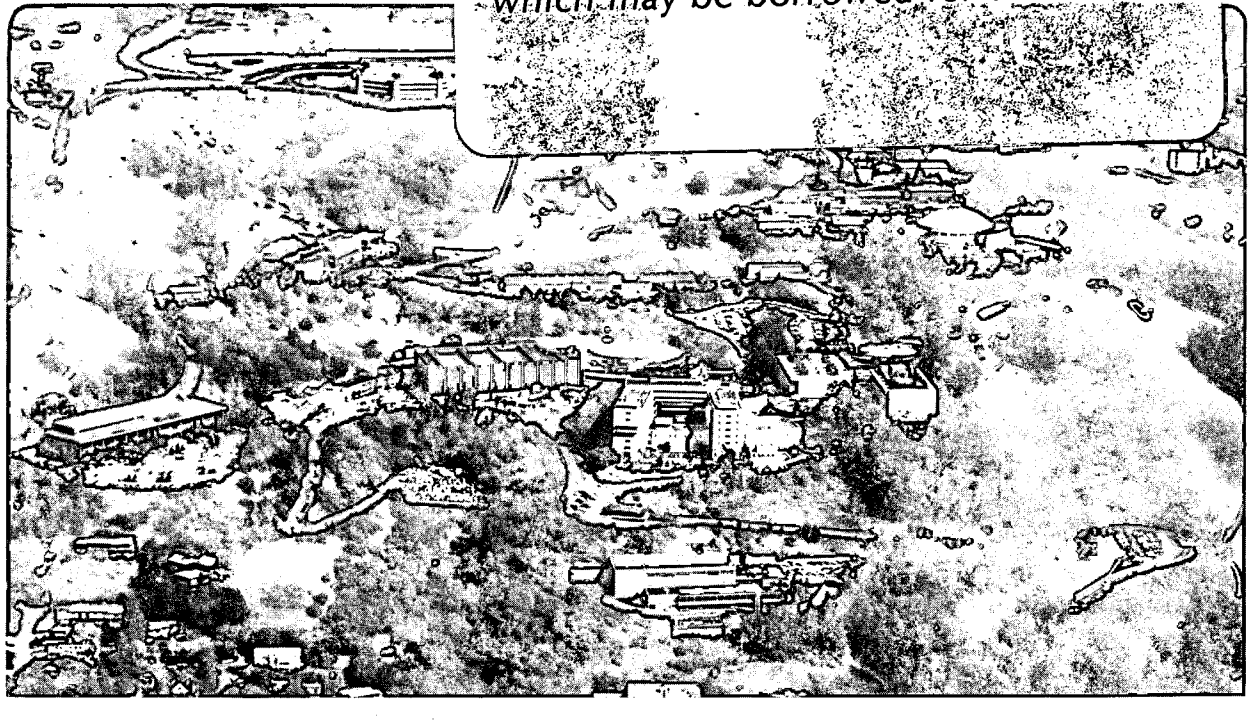
Lawrence Berkeley Laboratory
UNIVERSITY OF CALIFORNIA
Engineering Division

To be presented at the Thirteenth Annual
National Energy Division Conference,
Ft. Lauderdale, FL, September 21-24, 1986

A NATIONAL RESEARCH LABORATORY GENERIC PROJECT QUALITY ASSURANCE PLAN FOR RESEARCH AND DEVELOPMENT

E.E. Bain and R.L. Hinckley

September 1986



Prepared for the U.S. Department of Energy under Contract DE-AC03-76SF00098

DISCLAIMER

LBL-22157

A National Research Laboratory Generic Project Quality Assurance Plan for Research and Development

Elmer E. Bain
Science Applications International Corporation
Erwin, TN 37650

and

Robert L. Hinckley
Lawrence Berkeley Laboratory
University of California
Berkeley, CA 94720

September 1986

This work was supported by the U.S. Department of Energy under Contract Number DE-AC03-76SF00098.

PREFACE

By Robert L. Hinckley 9/10/86

Quality is that goal of excellence which scientists, engineers and other professionals strive to attain in carrying out their work. Quality Assurance (QA) is a management tool to assure that activities are conducted in a planned and controlled manner, and that there is a written, signed and dated set of records to support each activity.

There are legitimate requirements for formal Quality Assurance Plans in the Research and Development area. These are QA requirements imposed because of high risk to life or health, risk to national security, traceability, or in view of long term cost benefits, so determined by those who have the responsibility for the research being undertaken. In some cases decisions for requiring formal QA Plans are driven by need for the type of "objective evidence" which will meet the legal requirements imposed on the agency responsible for having the research accomplished.

This generic plan was written to reference or provide the required formal documents, controls and information structure for verification of quality control during the life of any project which has a mandatory specified QA requirement. It is based on the NQA-1 Standard which is the reference document for DOE QA Order 5700.6A. The prototype of this QA plan which we have previously developed, is being used by Dr. Norman Edelstein of The University of California Lawrence Berkeley Laboratory for the study: Solubilities and Speciation of Radionuclides in Brine. For this research in the extension of actinide chemistry to define some of the long term chemical processes in the containment of nuclear waste material, QA which conforms to NQA-1 is a specified requirement.

The quality control of research in science and engineering is monitored by the very competitive world research arena itself, in which rather objective peer review and the self determining interest of the researcher are the driving forces for quality. The "objective evidence" of basic research is the degree of acceptance that each increment of completed research work receives in the light of peer review.

From the authors' perspective, a formal Q A is not helpful in attaining the goal of quality in most research and development (R&D). Such formal QA is not cost effective and is likely to be detrimental to the goals of attaining quality. The best research people will not be willing to put up with the accounting type discipline required by a Quality Assurance Plan, except where employee safety is involved. As documented in the Quality Assurance Institutional Program Plan for the University of California Lawrence Berkeley Laboratory, which I helped develop, some elements of QA are generally applicable to R&D in that they are good management practices which can help the researcher reconstruct the process of an experiment, but formal QA is not required to do this. QA is a distraction from the purpose of research and is by nature antithetical to it. QA will also add significant unnecessary cost. Research probes the unknown, and to a great extent, success is dependent on maximum freedom from any rules not imposed by the basic laws of Nature. If QA is required, it would be more cost effective to select the specific research after it is complete, and re-do that research with QA controls in place a second time through.

In over forty years of cumulative experience of working in management roles with Nobel laureates and other "world class" senior research persons in science and engineering, it is evident to the authors that the primary method of obtaining quality in research is by hiring the most qualified persons available to accomplish the specific research. Formal QA should be used only where it can be fully justified.

A National Research Laboratory
Generic
Project Quality Assurance Plan
For
Research And Development

Manual No: _____

Issued To: _____

Approved: _____ Approved: _____
Project Manager Research Division Head

Approved: _____
Project QA Coordinator

STATEMENT OF POLICY

The Research Divisions of the National Research Laboratory have established and shall maintain Quality Assurance Programs as required for all services of the highest quality commensurate with the needs and resources of our sponsors.

Quality Assurance is a management tool to assure that activities are conducted in a planned and controlled manner and that there is a written, signed record to support each activity. Performing quality work and implementing a quality assurance program can be achieved only through a cooperative effort and commitment to quality by all project personnel.

The Project Quality Assurance Plan will be applied to selected R&D projects. Compliance with the requirements of this Project Quality Assurance Plan (PQAP), Project Quality Procedures (PQPs), Work Instructions (WIs), and documents required for the plan, procedures, or instructions is mandatory for all employees performing project quality-related activities for the selected project.

Approved _____

Research Division Head

TABLE OF CONTENTS

INTRODUCTION

Purpose and Scope

This Project Quality Assurance Plan (PQAP) sets forth the requirements for the National Research Laboratory's Research Divisions' quality assurance programs to comply with the applicable criteria of 10CFR Part 50, Appendix B, ANSI/ASME NQA-1 and to meet the requirements of the Funding Agency's Quality Assurance Specification and the National Research Laboratory's QA Program for the projects that require a formal Quality Assurance plan.

The requirements of this plan apply to project activities that affect the quality and reliability/creditability of research, development, and investigative data and documentation. These activities include the functions of attaining quality objectives and assuring that an appropriate quality assurance program scope is established. The scope of activities affecting quality include personnel training and qualifications; designing; purchasing; material handling and storage; surveillance, testing, and auditing; R&D investigative activities and documentation; deficiencies; corrective actions; and QA recordkeeping.

1.0 ORGANIZATION

This National Research Laboratory is made up of divisions engaged in various research-related activities. Quality Assurance Programs are issued on a project basis to meet the specifications of individual project ordering requirements. These Project QA commitments are contained in a Project QA Plan.

1.1 FUNCTIONAL ORGANIZATION

The responsibilities for implementing the quality assurance program for a specific project lies with the Project Manager. The Project Manager is responsible to his Division Head, who is responsible to the National Research Laboratory Director through the appropriate Laboratory Deputy Director. Functional organizational charts are provided under Figures 1-1 and 1-2, respectively; delineating the lines of reporting for the Project Manager upward to the Laboratory Director and downward for the Project Manager for the key personnel performing the project work assignments.

1.2 ORGANIZATIONAL RESPONSIBILITIES

The following delineates project organizational authorities and responsibilities for key personnel:

a. Project Manager

The Project Manager has direct overall management responsibility and authority for cost, schedule, quality assurance, and technical performance of all activities performed under this project. He reports directly to the Division Head. The Project Manager shall approve the Project QA Plan, Project Quality Procedures, Work Instructions, Purchase Requisitions, and subsequent revisions thereto.

SAMPLE
ORGANIZATION CHART
FOR
A National Research Laboratory
Research And Development
Project Quality Assurance Plan

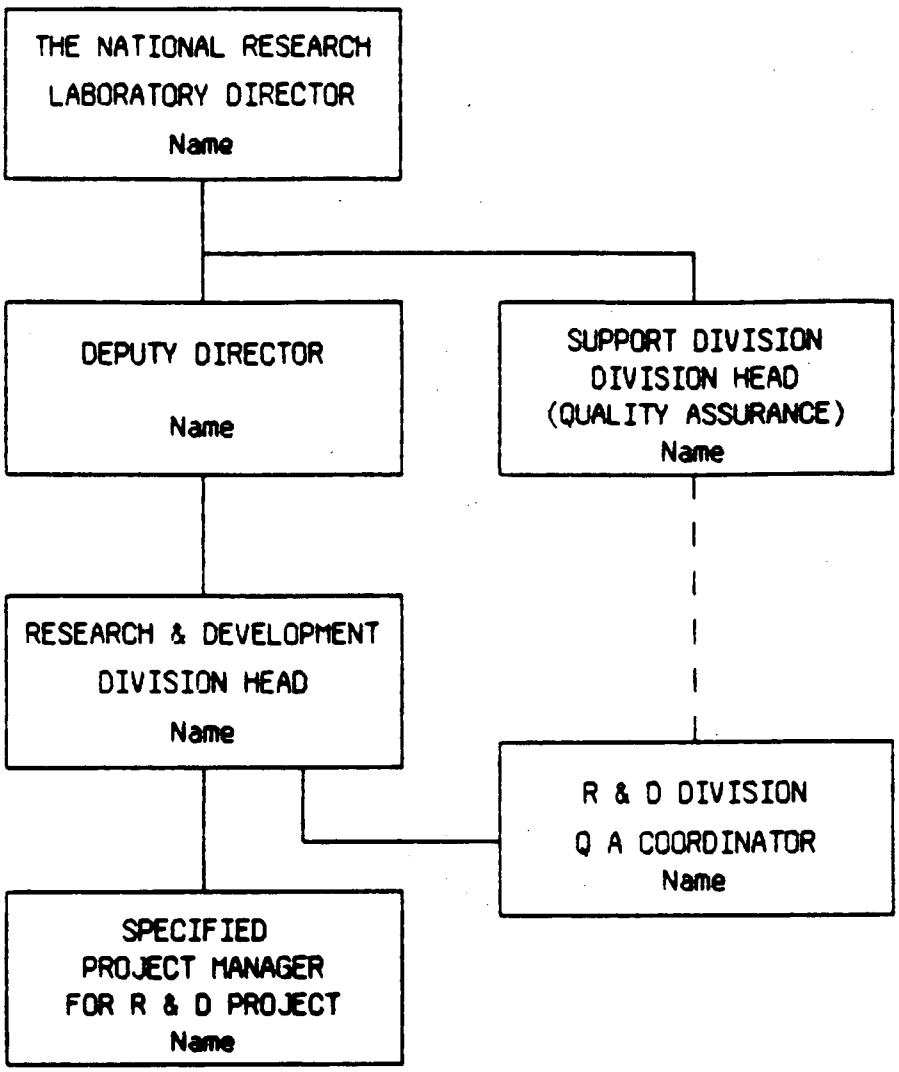


FIGURE 1-1

TYPICAL
PROJECT ORGANIZATION CHART
FOR
A Specified Research & Development Project

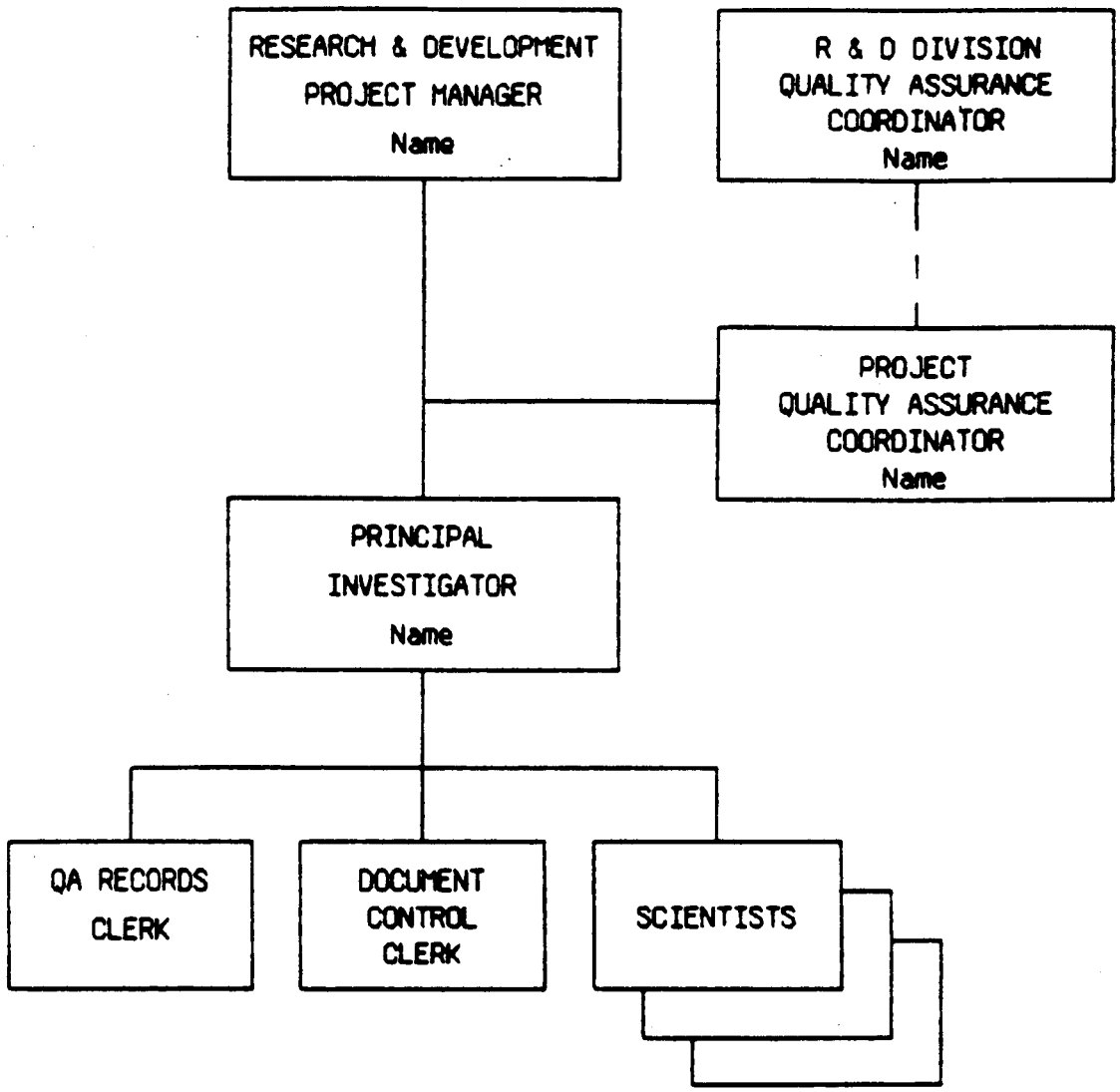


FIGURE 1-2

b. Project QA Coordinator

The Project QA Coordinator reports administratively to the Project Manager and functionally to the Division QA Coordinator. This allows freedom from cost and schedule responsibilities in complying with requirements of QA specifications required for this project. His primary functions and responsibilities are to prepare, implement, and maintain the Project QA Plan and ensure through the authority of the Project Manager that the quality program requirements are satisfactorily implemented.

The Project QA Coordinator shall approve the Project QA Plan, Project Quality Procedures, Work Instructions, Purchase Requisitions, and a copy of the Purchase Orders signifying acceptance and release of purchase items upon receipt inspection.

c. Principal Investigator

The Principal Investigator reports to the Project Manager and has the primary responsibilities and authorities to ensure that all aspects of the project activities are conducted in accordance with written and approved Work Instructions, the Project QA Plan, and Project Quality Procedures and that data and documentation are maintained as QA records.

The Principal Investigator shall approve Work Instructions, Laboratory Book individual pages, and Purchase Requisitions.

d. Division QA Coordinator

The Division QA Coordinator shall consult with and advise the Project QA Coordinator upon request concerning any work activity conflicting with QA Program commitments. In addition, he shall maintain and store a second copy of QA records provided to him by the Project QA Coordinator in a separate building.

2.0 QUALITY ASSURANCE PROGRAM

The Project Quality Assurance Plan shall ensure that all data and research documentation generated under the project is valid, traceable, and in accordance with Project requirements through utilization of the Project Quality Assurance Plan (PQAP), Project Quality Procedures (PQPs) as applicable, Laboratory Notebooks, and Work Instructions (WIs). Control shall be asserted through periodic audits to be conducted no less frequently than annually with audit results to be reported to the Division Head and the Project Manager. Corrective actions shall be implemented on a timely basis to correct any nonconforming item or data and to satisfy findings issued during each audit. The National Research Laboratory shall annually review audit results and deficiencies for trend analysis and to assess the effectiveness of the Project QA Program implementation. The Funding Agency's Project Office QA Manager shall be notified when the Project QA Plan cannot be implemented or maintained. Revision to the Project QA Plan and procedures (technical and QA) shall be submitted to the Funding Agency's Project office for acceptance.

2.1 TRAINING

Indoctrination and training of personnel performing quality-related activities shall be provided by a qualified instructor, as necessary, to ensure that suitable proficiency is achieved and maintained. The Training Instructor shall provide documentation, as provided for under Figure 2-1, for the scope of training provided, the list of personnel trained, and the date of such training.

2.2 PERSONNEL QUALIFICATION

Management shall attest to personnel qualifications in writing. Personnel records shall be maintained to include resume, training, and qualification statement for the assigned task.

TRAINING SESSION RECORD

Date of Session: _____ Name of Instructor _____

(signed)

Scope (including specific document references): _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

List of Attendees (signed by each individual):

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____
16. _____

Approved: _____

Project Manager

FIGURE 2-1

2.3 PROGRAM STATUS SUMMARY

The Research Division Management will issue a quarterly summary of quality assurance activities. The summary shall include:

a. Changes in organization structure or responsibilities
b. Changes in the Project QA Plan or procedures
c. Changes in audit/surveillance schedules
d. Results of internal audits/surveillances
e. Status of corrective actions

SAMPLE QA PLAN REQUIREMENTS MATRIX

NQA-1 Basic Requirement	NQA-1 Supplemental Requirement	QA Specification Qualifier	The National Research Laboratory QA Plan
1			1.0
	1S-1		1.2, 15.0
2			2.0
	2S-1		2.1
	2S-3		18.0
		2.0	2.0, 2.1, Figure 5.1
3			3.0
		3.0	3.1, 3.2
4			4.0
5			5.0
6			6.0
	6S-1		6.0
7			7.0
		7.0	7.3
8			8.0
		8.0	8.0
11			11.0
	11S-1		5.2

SAMPLE QA PLAN REQUIREMENTS MATRIX (CONTINUED)

NQA-1 Basic Requirement	NQA-1 Supplemental Requirement	QA Specification Qualifier	The National Research Laboratory QA Plan
12			12.0
	12S-1		12.0
		12.0	12.0
13			13.0
		13.0	13.0
15			15.0
	15S-1		15.0
		15.0	15.0, 16.2
16			16.0
		16.0	15.0
17			17.0
	17S-1		17.0
		17.0	Figure 17.1, 1.2d
18			18.0
	18S-1		18.0
		18.0	10.0, 18.0
		A.3.2	2.3
		A.3.3	16.2
		A.3.4	2.0

3.0 DESIGN CONTROL

This section describes the requirements for the National Research Laboratory's interface and design control activities.

3.1 COMPUTER CODES

Computer codes may be utilized, either developed or modified by the National Research Laboratory, in order to control and obtain data under this project. Upon completion of the development, modification, or change to a computer code, a verification and validation review shall be completed, documented, and signed by an individual with equivalent capabilities who did not generate the original work. Alternate techniques (e.g., expert estimates of input data and evaluation of model test results, or comparison with results of other known code analyses with the use of a known computer code program version results) shall be utilized.

Acceptance validation testing shall be performed to (1) evaluate function, performance, and/or interfaces, and (2) assure that results obtained with the installed computer code are consistent with results obtained with the computer on which the computer code was developed. Documentation of acceptance testing for computer codes shall include:

a. Computer code name (title) and version
b. Computer type and operating system
c. Test problems, data sets, evaluation methods, and/or known code
d. Acceptance criteria range (maximum and minimum)
e. Documentation of test results
f. Review and approval by PM and PQAC

The Project QA Coordinator shall have responsibility as Code Custodian and shall approve, along with the Project Manager, all validated codes utilized in this project. The code validation documentation shall be

maintained current by the Project QA Coordinator. Any changes or modifications thereto will be subjected to the same validation and acceptance testing as stated above with approvals by the Project QA Coordinator and the Project Manager, prior to use.

3.2 INDEPENDENT TECHNICAL REVIEW

Independent technical reviews are documented reviews performed by personnel independent of the work performed and at least equally qualified to those who performed the work. Review comments shall be recorded on the Technical Review Form (Figure 3-1). The document originator shall resolve all comments received. The Division QA Coordinator shall resolve any disputed comments.

Technical reviews shall be performed for:

a. Work Instructions
b. Calculations
c. Computer Programs
d. Technical Reports

The National Research Laboratory QA auditor shall audit this function annually to assure compliance.

TECHNICAL REVIEW COMMENT FORM

1. Originator: _____ Date _____
2. Identification of Documentation Reviewed:(List Document No., Date, and Title)
   a. Document No.: _____
   b. Revision No.: _____
   c. Date of Issue: _____
   d. Title: _____
3. Personnel Performing Review: (Name and Title)
   a. _____
   b. _____
   c. _____
4. Comments:
   a. _____
   _____
   _____
   b. _____
   _____
   _____
   c. _____
   _____
   _____
   d. _____
   _____
   _____
   e. Continued: (Note Attached Page Nos.) _____
5. Comment Resolutions Incorporated into document:
   Project QA Coordinator: _____
   Project Manager: _____

Page No. _____

FIGURE 3-1

4.0 PROCUREMENT DOCUMENT CONTROL

This section describes the control measures to assure that applicable design bases and other technical and quality requirements necessary to obtain adequate quality are included or referenced in procurement documents for procurement of items and services from vendors. Procurement of finished items for use in generating data under this project will be restricted to standard catalog and vendor standard-model items supplied as off-the-shelf items. These items are generally purchased from distribution warehouses but may be purchased direct from the manufacturers.

Purchase Requisitions shall be generated for purchase of such items that will contain specific identification of the manufacturer's model/catalog number to ensure quality and technical requirements are included, as applicable.

Purchase requisitions shall be reviewed and approved by the Project QA Coordinator and the Principal Investigator to ensure correct identification of items in the Purchase Requisition for conformance to the required technical and quality specifications.

Changes to Purchase Requisitions shall be reviewed and approved by the same organizational positions that approved the original Purchase Requisition. Purchasing shall ensure that the contents of the Purchase Requisitions are accurately and correctly transferred to the Purchase Order.

Catalog items generally available through local distribution warehouses and standard model equipment such as calibrated glassware and instruments to be purchased as off-the-shelf items that will be required under this project shall be identified under separate memorandum by the Project Manager.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

This section describes the requirements for issuance of approved Project Quality Procedures (PQPs), Work Instructions (WIs), and Laboratory Notebooks for use in implementing activities affecting quality performed by the National Research Laboratory under this project. All Project Quality Plans, Procedures, and Work Instructions shall be approved by the Project Manager and the Project QA Coordinator. Changes shall be approved by the same personnel. A list of all proposed procedures shall be issued by the Project Manager prior to start of the affected activity.

5.1 PROJECT QUALITY PROCEDURES (PQPs)

PQPs will be issued for the Project Quality Program criteria elements which require additional detail and clarification of commitments and documentation other than that provided in the PQAP, as deemed appropriate by project management. Such PQPs will be referenced to the applicable PQAP criteria by plan section number.

5.2 WORK INSTRUCTIONS (WIs)

WIs will be prepared, approved, and issued prior to the performance of the research and development laboratory analyses being performed. WIs will be of a generic nature with as many specifics provided as possible, realizing this project is an R&D effort and methodology will be developed in the area of procedures as well as generating and recording data. The Work Instruction format to be followed for content is shown under Figure 5-1. If changes or additional General Instruction Sequences are added, these modifications will be initialed and dated by the same organizational personnel approving the original document.

The information to be included in the WIs at original issuance will include generally known information as follows:

a. Resource References
b. Equipment (specific model identification)
c. Materials (specify)
d. Standards (specific identification)
e. Instruction Sequences
f. Record Requirements

5.3 LABORATORY NOTEBOOKS

Project Laboratory Notebooks will be identified by number and signed out to specific project personnel on a controlled basis by the PQAC for purposes of recording data and results. These notebooks are bound and identified by individual number referenced to the individual utilizing each book. The PQAC will maintain a master list recording the book number and the individual responsible for each book. Each page shall be numbered, dated, and initialed by the laboratory scientist upon completion of documentation on each page. The PI shall review, evaluate, and sign/date each page or day's work in ink upon completion of data recording for that page or work on a monthly basis, minimum.

A copy of the approved current Work Instruction shall be attached to the left side page of the Laboratory Notebook identifying the activities to be performed. Project Laboratory Notebooks shall not be used in lieu of written and approved work instructions.

WORK INSTRUCTION FORMAT

1. Purpose
2. Scope
3. Reference Resources (if available)
4. Equipment Identification
5. Materials Identification
6. Standards (specific identification)
7. General Instruction Sequences:

    7.1
    7.2
    7.3
    7.4

8. Additional Sequence (if needed)
9. Record Requirements

FIGURE 5-1

LIST OF PROCEDURES

1. Equipment Calibration
2. Preparation of Materials
3. Measurements

FIGURE 5-2

6.0 DOCUMENT CONTROL

This section describes the methods and policies for issuance and distribution control of the Project QA Plan, Project Quality Procedures, and Work Instructions.

A copy of the most current revisions to each of the above documents shall be maintained by the Document Control Clerk in an appropriately accessible location to the work and office areas and designated as Controlled Document Station No. 1. A Master Index Listing for each category of controlled document shall be maintained current with the latest revision number for each document at the Controlled Document Station. Obsolete copies of documents shall be removed by the clerk when inserting the most current revision. It shall be the responsibility of each individual utilizing a document to check for the most current revision against the Master Index List before utilizing the document to ensure the use of the current document revision.

Review and approval requirements for these documents have been assigned under Section 1 of this plan.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

This section describes the methods and policies to assure that items are procured from approved sources and conform to specified purchase order requirements.

7.1 APPROVED VENDOR LISTING (AVL)

As already stated under Section 4 of this plan, the items that are to be purchased under this project are standard catalog and/or off-the-shelf materials and instruments generally purchased from local warehouse distributors. In fact, the vast majority of the equipment and materials to be utilized under this project are already available in the laboratory. The PQAC will provide Purchasing an Approved Vendor Listing (AVL). The evaluation and selection of vendors shall be based on utilization of historical performance data for each vendor supplying items of a similar nature. The Project Manager shall approve and date the AVL and each revision thereto. Distribution warehouse firms will not be included on the Approved Vendor List for purposes of purchasing stock or off-the-shelf items.

7.2 RECEIPT INSPECTION

Upon receipt of items, the PQAC will document his verification that the received items, as labeled or identified, are in accordance with the Purchase Order requirements by initialing and dating a copy of the applicable P.O. signifying acceptance and release of the items for use under the project.

Certificates of Conformance will not be required of stock items either purchased directly from a distribution warehouse or direct from a manufacturer. Certificates of conformance shall be required for quality related items purchased to specifications originated by project personnel. Vendor surveillance and inspection at the manufacturer's facility will be accomplished where applicable. This

is not required for any procured items that are stock or off-the-shelf materials which can be verified upon receipt. Any items not meeting the P.O. requirements will be marked rejected and placed in a locked area by the PQAC until returned to the vendor.

7.3 NON-QA DERIVED MATERIALS

Items such as literature, data, items, or services obtained from sources for which no QA/QC program is in evidence shall be validated (documented approval memo) for both technical adequacy and correct application by the PM and the PQAC.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

This section describes the requirements to assure that only correct and accepted items are utilized. These requirements will apply to quality-related items including test specimens, materials, and samples used for research and development.

Stock materials and laboratory equipment that are adequately labeled or identified by the supplier and stored such that item identity and status are maintained do not require any additional identification controls or markings.

Sample specimens to be utilized shall be identified in the Work Instruction and the Laboratory Notebook. The individual scientists performing the activity shall be responsible for ensuring the use of the sample as identified in the Work Instruction and for logging the sample identification in the Laboratory Notebook as it is utilized. Any items to be shipped under this project will require the development of appropriate QA Record control.

9.0 CONTROL OF SPECIAL PROCESSES

This QA program criteria element is not applicable under the scope of work to be performed for this project. Only laboratory data and documentation of results will be generated as a deliverable. Any special process development that evolved out of the research would require the development of a documented controlled process.

10.0 INSPECTION

This section describes the surveillance and inspection requirements under this project. Process and product inspections, as normally defined for manufactured items, will not be applicable for the scope of work under this project. Only laboratory data and documentation from analyses will be generated. If products are developed, appropriate QA inspection procedures must be defined and applied to those products.

Receiving inspection will be performed and documented by the PQAC as delineated under Section 7.0 of the PQAP.

Quarterly surveillance of work activities, as a minimum, shall be conducted by the PQAC and documented in the Laboratory Notebooks for the activity surveilled. The PQAC shall sign and date the results of surveillance activity in the Laboratory Notebooks for the activities surveilled.

11.0 TEST CONTROL

This section describes the requirements for executing, documenting, and evaluating tests performed during the acquisition of reportable data under this project.

This section applies to validation of computer codes developed and/or modified for use under this project. Verification (design review) and validation (performance testing) of computer codes generated under this project will be performed and documented as delineated under Section 3.0 of the PQAP.

Test programs, including specific work instructions, shall be prepared in accordance with Section 5.0: Instruction, Procedures, and Drawings. Test work instructions shall be reviewed in accordance with Section 3.0: Design Control, Paragraph 3.2 and approved as stated under Section 5.0.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

This section describes the methods and policies to assure that instruments and other measuring and test equipment used for activities affecting quality are calibrated and adjusted at specified frequencies to maintain accuracy within necessary limits. Measuring and test equipment (M&TE) used to obtain reportable data shall be calibrated. M&TE includes devices or systems used to calibrate, measure, gauge, and test in order to acquire research, developmental, or operational data as applicable.

Under the scope of work of this project, instruments that have been calibrated by the manufacturer will be utilized. Standards will be prepared by the National Research Laboratory, where industry standards are not available, for use in verifying that the laboratory items and instrumentation affecting quality will yield the known data for each standard utilized. The standard to be used, frequency, and acceptance criteria (maximum and minimum range) will be stated in the applicable Work Instructions, providing directions for analyzing the standard. Results shall be recorded in the Laboratory Notebooks. The PQAC shall initial and date each standard analysis result in the Laboratory Notebook signifying the M&TE is calibrated and will yield results meeting the acceptance criteria in the Work Instructions.

Where feasible, M&TE shall be labeled to indicate the M&TE status and unique serial number. M&TE used for non-data purposes is not required to be calibrated. Where possible, the reference standards utilized shall be traceable to the National Bureau of Standards or to other nationally recognized standards. Use of employee-owned M&TE is not permitted. M&TE labels shall state, as a minimum: calibration date, due date, ID number, and calibrator's initials.

When M&TE is suspect, it shall be removed immediately from service and repaired and/or recalibrated. When M&TE is found to be out of calibra-

tion, it shall be documented in the Laboratory Notebook and, where applicable, an immediate investigation shall be performed by the PQAC to determine the validity of measurements taken since the previous acceptable standardization was completed. Data obtained during this time interval shall be so noted on a Deficiency Report, described under Section 15.0 of the PQAP, and shall be accepted or rejected by the PQAC based on his investigation. Consideration of issuing a Deficiency Report shall be made by the PM.

13.0 HANDLING, STORAGE, AND SHIPPING

This section describes the methods and policies for assuring the proper physical care of test samples, materials, and samples used for research and development and equipment whose loss or damage could compromise program quality objectives.

Shelf life requirements for standard laboratory items will be adhered to in accordance with the manufacturer's printed instructions, as applicable. Shelf life and environmental storage controls, such as temperature, humidity, and safety considerations for standards and National Research Laboratory-prepared samples to be analyzed will be stated on the sample identification label by the Principal Investigator, as appropriate.

Samples that present a possible radioactive hazard to personnel will be identified for special handling and storage instructions to be contained in the Work Instructions. The Work Instructions shall specify special handling tools and equipment or special protective environments, as required for particular items.

14.0 INSPECTION, TEST, AND OPERATING STATUS

This QA Program criteria element is not applicable to the research and data collection being performed under the scope of the project. There are no "manufacturing and installation" activities applicable to "structures, systems, and components" for laboratory data being generated under this R&D project.

If special manufacturing were to be required, specific instructions would have to be written or program requirements and approvals by the National Laboratory would be issued in procurement documents to the vendor performing the manufacturing. This requirement would be waived if manufacturing was by the National Research Laboratory, and under the control of the PM.

15.0 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

This section describes the methods and policies for the documentation, evaluation, corrective action, and close out activities when an unplanned deviation from the PQAP or Work Instruction is detected or errors noted in data.

All DRs are to be evaluated as potential incidents. Control of incidents is maintained by processing each incident in accordance with this section as if each incident is a deviation. Deviations or discrepancies found during computer code usage shall be processed on a Deficiency Report. All deviations and incidents shall be processed on the National Research Laboratory Deficiency Report (DR), Figure 15-1. Copies of all DRs shall normally be transmitted by the Project Manager to the Funding Agency Program Office for review and concurrence, or as required by their QA instruction.

Project personnel shall document all project deviations as described above on a Deficiency Report. The PQAP shall maintain a separate status log listing of all DRs/IDRs/audit findings issued. The individual initiating the DR shall complete the form through Reply Requested line and obtain PQAC approval signature for issuance. The activity affected shall complete the Root Cause (if known and take action to prevent recurrence) through the Responsible Party for Implementation of Corrective Action Work line. The PQAC will verify satisfactory corrective action has been completed and sign and date the form. Distribution shall only be made after Final Acceptance Blocks are signed and dated by the PM and PQAC. Normally, Funding Agency Program Office approval shall be obtained by correspondence after disposition by the National Research Laboratory.

The Project Manager shall determine the deficiency's impact on previously collected data (if any) and take appropriate actions to replace data, if required.

A National Research Laboratory

PAGE _____ OF ___

IDR/DR NO. _____

PROJECT NO. _____

DEFICIENCY REPORT

DATE	ORIGINATOR
POAC SIGNATURE	
PROGRAM REFERENCE	
REQUIREMENT	
DEVIATION	
RESPONSIBLE PARTY FOR INDICATING CORRECTIVE ACTION	☐ P.M. ☐ P.I. ☐ POAC ☐ PURCHASING ☐ OTHER ----------
REPLY REQUESTED OF RESPONSIBLE PARTY BY (DATE):	
ROOT OF CAUSE (IF KNOWN):	
PROPOSED CORRECTIVE ACTION:	
SIGNATURE	DATE
RESPONAIBLE PARTY FOR IMPLEMENTATION OF CORRECTIVE ACTION	☐ P.M. ☐ P.I. ☐ POAC ☐ PURCHASING ☐ OTHER ----------
	DATE

DISTRIBUTION	FINAL ACCEPTANCE	
☐ P.M. _____ ☐ P.I. _____ ☐ POAC _____ ☐ SRPO _____	POAC	DATE
	P.M.	DATE

FIGURE 15-1

16.0 CORRECTIVE ACTION

This section describes the methods and policy for documentation and implementation of corrective actions for conditions adverse to quality. These conditions shall be documented on a Deficiency Report. The process for initiating a DR, processing, and closeout of satisfactory corrective action is described under Section 15.0 of the PQAP.

16.1 DRs

The Division QA Coordinator shall periodically analyze any Deficiency Reports (at least annually) to analyze for quality trends and root causes of deficiencies. The trending analyses shall be reported to the Division Manager for review and assessment. The results of these reviews and assessments shall be documented.

16.2 IDRs

Incidents that have significant programmatic impact or are adverse to quality shall be identified on a DR Form for purposes of identification, evaluation, and disposition. Incidents shall be identified on the DR Form as an IDR, and an IDR log separate from the DR log shall be maintained by the PQAC. The Project Manager shall evaluate each IDR, a deviation from planned or expected behavior of an activity or operation, and make a documented appraisal for impact on cost, schedule, safety, health, environment, or reliability/credibility of data. The PM's evaluation results shall be documented in a letter transmitting a copy of each IDR to the Funding Agency Program Office within 14 days. Verbal notification shall be made to that office within 48 hours if it is determined by the PM to be significant.

17.0 QUALITY ASSURANCE RECORDS

This section describes the methods and policies for identification, preparation, and maintenance of Quality Assurance (QA) Records. This section applies to completed QA records required to furnish objective evidence of the quality of data and documentation to be furnished under a project.

The PQAC shall issue and maintain a Master QA Records/File Index List identifying each category of records to be maintained as a QA Record for this project. Each category of records on this list will be assigned a unique index file number cross-referenced to the QA Record category. A preliminary master QA Records/File Index List is attached as Figure 17-1 of the PQAP. The Project Manager shall approve the Master QA Records/File Index List. The QA Records/File Index list shall be submitted to the Project Manager for review and acceptance.

The PQAC shall provide a copy of each completed record on the list in a timely manner to the Division QA Coordinator for controlled access, maintenance, and storage in a separate building. A sign-out log shall be maintained by the Division QA Coordinator for records released from his area. Normally, the original QA records shall be submitted to the Funding Agency Program Office at records turnover upon completion of the Research Project. The PQAC shall ensure that safe temporary storage is maintained until records are consigned to the Division QA Coordinator.

MASTER QA RECORDS/FILE INDEX LIST

PROJECT RECORDS LIST

- Audit Reports
- Auditor Qualifications
- Project QA Plant (PQAP)
- Project Quality Procedures (PQPs)
- Work Instructions (WIs)
- Purchase Requisitions
- Purchase Orders
- Deficiency Reports
- Correspondence, External
- Correspondence, Internal
- Master QA Records/File Index List
- Equipment Calibration/Standardization
- Laboratory Notebooks
- Personnel Training
- Reports

Approved: _____

Project Manager

FIGURE 17-1

18.0 AUDITS

This section describes the methods and policies for planning, performing, and reporting audits to verify compliance with all aspects of the QA program and to determine program effectiveness. The requirements of this section apply to internal audits by the National Research Laboratory. Audits of suppliers and subcontractors may be applicable to a project.

Internal audits of all project QA criteria will be performed at least annuallly and scheduled by the PQAC. Audits will be performed by qualified auditors. In some cases, these will be required to be certified to the requirements of ANSI N45.2.23 and Supplement 2S-3 of ANSI NQA-1-1983 Edition or some other applicable standard to be determined by the Funding Agency. It is anticipated that each audit team will consist of a Certified Lead Auditor and a Technical Expert from the National Research Laboratory independent of the project activities.

Audits shall be performed utilizing project program documents, highlighting the items to be verified, and/or checklist questions. Audit results shall be documented in a report issued on a timely basis and providing the status of items verified during the audits. The audit team leader shall approve the audit report. Copies of audit reports shall be provided to the Project Manager, the Division Head, and the Funding Agency Program Office.

Audit findings shall be documented on a DR, Figure 15-1 under the PQAP, and shall be maintained on a separate log and processed in accordance with the requirements described under Section 15.0 of the PQAP. The DRs issued during an audit will be attached as a formal part of the audit report. Audit results will be discussed with the project management in an exit meeting at the close of the audit. Division Management of the National Research Laboratory shall include their analysis of audit results as input for their trending and effectiveness of quality program evaluation to be documented annually.

Resume

E. E. BAIN, JR.

East Tennessee State University: B.S., Chemistry

Mr. Bain joined SAIC in May, 1974, and is responsible for the SAIC nuclear quality assurance programs and for developing projects in the nuclear services area. Mr. Bain is a qualified quality assurance Lead Auditor in accordance with ANSI N45.2.23.

Mr. Bain has been providing quality assurance services to the utility industry since 1971. He has initiated and directed quality assurance audit programs for the following clients:

Alabama Power Company
Cincinnati Gas & Electric Company
Commonwealth Edison Company
Consolidated Edison Company
Consumers Power Company
Florida Power Corporation
Iowa Electric Light & Power Company
Maritime Administration
Niagara Mohawk Power Corporation
Pacific Gas & Electric Company
Portland General Electric Company
Power Authority of the State of New York
Public Service Colorado
Public Service Electric & Gas Company (NJ)
Public Service Indiana
Rochester Gas & Electric Company
Southern California Edison Company
Southern Services, Inc.
Southern Services, Inc./Georgia Power Company
Tennessee Valley Authority
Toledo Edison Company
Virginia Electric & Power Company
Washington Public Power Supply System
Wisconsin Electric Power Comapny
Wisconsin Public Service Company
Yankee Atomic Electric Power Company

Reference Attachment A.

204 Gay Street, Erwin, Tennessee 37650, (615) 743-4104

These quality assurance services have been performed at the following facilities:

* Babcock and Wilcox - Apollo, Pennsylvania
Babcock and Wilcox - Barberton, Ohio
* Babcock and Wilcox - Lynchburg, Virginia
Babcock and Wilcox - Mt. Vernon, Indiana
* Exxon Nuclear - Richland, Washington
General Electric - San Jose, California
General Electric - Vallecitos, California
**,* General Electric - Wilmington, North Carolina
General Atomics - La Jolla, California
* Kerr-McGee Corporation - Crescent, Oklahoma
** Sandvik Special Metals - Kennewick, Washington
** Teledyne Wah Chang - Albany, Oregon
* Westinghouse - Cheswick, Pennslyvania
* Westinghouse - Columbia, South Carolina
Westinghouse - Monroeville, Pennsylvania
** Westinghouse - Blairsville, Pennsylvania

Prior to 1971, he was Plant Manager of Nuclear Fuel Services' Nuclear Fuel Fabrication Facility in Erwin, Tennessee. In this capacity, he was responsible for managing and directing all activities at the Erwin Plant. His responsibilities included supervision and direction for manufacturing a wide variety of metallic and ceramic fuels for nuclear power reactors including uranium, thorium and plutonium fuels, and combinations thereof, as well as specialty chemicals and metals. Specific programs carried out under his direction included the following:

(a) Conversion of over 1,000,000 lb. of UF_6 (gas) to UO_2 ceramic grade powder suitable for fabrication into reactor fuel assemblies for various reactor fuel fabricators;

(b) Pelletizing and encapsulation of over 12,000 fuel pins consisting of $U^{233}O_2$ and mixtures of ThO_2-$U^{233}O_2$ pellets in Zircaloy rods. All of the analytical laboratory and physical testing requirements were carried out at the Erwin

---

* Denotes review and audit of fuel fabrication facilities.
** Denotes review and audit of facilities fabricating SS & Zr tubing for fuel fabrication.

facility. These fuel pins were for the Light Water Breeder (LWB) program meeting naval reactor quality requirements.

(c) Conversion, fabrication and encapsulation of the plutonium oxide fuel for the Southwest Experimental Fast Oxide Reactor (SEFOR) program. This fuel was produced at the Erwin facility and delivered directly to the reactor site for acceptance and loading.

(d) Production of highly enriched fuel particles for the Navy Nuclear program with the attendant strict quality assurance program. A complement of full-time government inspectors (DCAS) were assigned to the Erwin Plant during phases of this program.

(e) Various other types of fuel including NERVA fuel for the NASA space program, conversion of all enriched uranium metal for the Enrico Fermi initial core loading and thoria sol-gel high density particles used by the AEC as swaged fuel pin targets for U-233 production.

Prior to becoming Erwin Plant Manager in 1967, Mr. Bain was Process and Quality (P & Q) Engineer having responsibility for ceramic operations including production of all UO_2 powder from UF_6 gas and fabrication of pellets. Subsequently, Mr. Bain was Standard Product Manager having responsibility for production of a standard line of products including enriched and depleted uranium metal, low enriched UO_2 powder and pellets, low enriched and high enriched scrap recovery services, thoria and thorium metals, and the fuel pellet encapsulated facility.

Prior to joining NFS, he had been employed with Union Carbide Nuclear Company at the AEC owned Paducah, Kentucky gaseous diffusion plant form 1955 through 1958 as Supervisor of their Analytical and Development Laboratory.

ATTACHMENT A

REVIEW/SURVEILLANCE PROGRAMS CONDUCTED AT FUEL FABRICATION FACILITIES

Mr. Bain was or is presently an active participant in the following fuel fabrication surveillance programs:

A. Westinghouse - Columbia, South Carolina

(1) Alabama Power - Farley
(2) Commonwealth Edison - Zion
(3) Consolidated Edison - Indian Point
(4) Pacific Gas & Electric - Diablo Canyon
(5) Portland General Electric - Trojan
(6) Public Service Electric & Gas (N.J.) - Salem
(7) Rochester Gas & Electric - Ginna
(8) Southern California Edison - San Onofre
(9) Virginia Electric & Power - Surry
(10) Wisconsin Public Service - Kewaunee
(11) Wisconsin Electric Power - Point Beach
(12) Tennessee Valley Authority - Sequoyah

B. General Electric - Wilmington, North Carolina

(1) Georgia Power - Hatch
(2) Niagara Mohawk - Nine Mile Point
(3) Power Authority of the State of New York - Fitzpatrick
(4) Iowa Electric - Duane Arnold
(5) Yankee Atomic - Yankee Rowe
(6) TVA - Browns Ferry
(7) Toledo Edison - Davis-Besse (Vendor to B&W)

C. Babcock & Wilcox - Lynchburg, Virginia/Vendors

(1) Florida Power Corp. - Crystal River
(2) Toledo Edison - Davis Besse
(3) Washington Public Power Supply System - WNP-1

D. Exxon - Richland, Washington

(1) Rochester Gas & Electric - Ginna Reload

E. Kerr-McGee - Cresent, Oklahoma (Vendor to B&W)

(1) Toledo Edison - Davis-Besse
(2) Florida Power - Crystal River

UCLBL

University of California Lawrence Berkeley Laboratory

Resume

Robert L. Hinckley

Texas A & M University: B. S., Industrial Engineering with minors in Electrical Engineering and Mechanical Engineering (1948–1952)

Fuller Seminary, Pasadena, California: B. D. & M. Div. with graduate study in Philosophy, Theology, Psychology and Counseling (1952–1956)

US Air Force Personnel Officer's School, Lackland AFB, Texas, Graduate and Psychology Teacher (1959–1960)

Continued studies in Electronics, Computer Science, Nuclear Physics and Management (1957–1982)

Mr. Hinckley joined the Director's staff of Nobel laureate E. O. Lawrence in 1957 and has had a variety of management responsibilities at UCLBL. For the past fifteen years he has written substantially all of the UCLBL policy in the Quality Assurance (QA) area. He has a broad background in the management of science and engineering including the following:

First Program Manager at UCLBL as Managing Engineer for the Physics Division which then included Experimental Physics Research, Accelerator and Fusion Research, Special Projects Engineering, Technical Photography and The UCLBL Computer Center. He worked for four successive Associate Directors for Physics (1962–1973).

First Operations Engineer for UCLBL reporting to Nobel laureate Director E. M. McMillan with responsibility for improving UCLBL reports and management information and for priority planning and scheduling of all support effort (1969–1973).

First Deputy Division Head at UCLBL, Deputy Head of the Engineering and Technical Services Division which included all Engineering and Shops Support, Facilities Management, Site Maintenance, Environmental Health and Safety, Technical Information Services and the UCLBL Computer Center (1975–1984).

First Deputy Associate Director at UCLBL, Deputy Associate Director for the Engineering and Technical Services Division, with responsibility as alternate E&TS representative on the Director's Executive Committee (1975–1984).

Deputy for Applied Science and Engineering of the Engineering and Technical Services Division with specific line management responsibility for all E&TS engineering and research projects (1976–1985).

First Head of the Office of Project Management for UCLBL reporting to Director D. A. Shirley, with oversight management and QA responsibility for all UCLBL projects with budgets exceeding $500,000 (1981–1985).

Specific QA and Quality Control (QC) experience has included the following projects:

The development of QC in materials handling for an addition to the Imperial Oil Company refinery at IOCO, B.C., and QC in the Paraxylene Plant addition to the Standard Oil refinery at Richmond, California. He was a project and instrumentation design engineer with Bechtel Engineers, Refinery Division (1956–1957).

QA and QC as an OEM in the design, development and manufacture of computer interfaced mechanical–optical–electronic photogrammetric equipment. These were >$100,000 state of the art measuring equipment systems with reproducibility of + or – 5 microns. This was by The MicroMetric Corporation (later a division of Grass Valley Group Electronics), an engineering firm which he built and managed with Jack Franck. Jack holds the AEC patent on the Franckenstein Measuring Projector, the original being on display since 1975 at the Smithsonian National Museum of History and Technology. (1962–1968).

QA and QC in development of one of the earliest Management Information Systems. This was the first system to be designed as a fully interactive, remote terminal controlled MIS, on line to a time shared CDC 6600/7600 scientific computer installation. Many of the typical QA and information security problems in computer software and hardware design were involved. He was the Principal Investigator responsible for the project (LBL–MIS, A Computer Aided System For Management Of Research, By R. L. Hinckley, D. F. Kane, et. al., September 1974, LBL–3089, UC–2, TID–4500–R62), which was successfully used in research management by a majority of UCLBL research division managers through 1985 (1970–1974).

The Water Cooled Nuclear Reactor Emergency Breakdown Test Facility project at UCLBL which was part of the Emergency Core Cooling System Bypass Research Program, was his line management responsibility, including QA considerations (1976–1978).

Line management responsibility for the UCLBL Neutral Beams System Test Facility for development of the Princeton Plasma Laboratory prototype injector for their Tokamak Fusion Test Reactor and for the General Atomics International Company's Doublet III, a Fusion Reactor Development project . This included interfacing to each of their Fusion Energy QA requirements (1976–1981).

Line management responsibility, as Deputy Head of the Engineering and Technical Services Division, for Environmental Health and Safety's QA in transport of radioactive material (1977–1985).

The development of a QA plan for a conventional research laboratory facility, using the CMSL/CAM project as a prototype (1980–1985).

Member of the DOE Task Group on Enhancing Project Managers Quality Assurance Awareness/Acceptance (1985).

Working with E. E. Bain, V. P. for QA of Science Applications International Corporation, Developed the QA Plan for the SRPO/ONWI project The Solubilities and Speciation of Radionuclides in Brine, under NQA–1 regulations. This is the first UCLBL project which is essentially basic research (an extension of actinide chemistry) for which a workable QA Plan has had to be developed (1985–1986).

Chairman of the UCLBL Division QA Coordinators' Working Group, and currently in training to become the first certified QA Auditor at UCLBL (1985–1986).

LAWRENCE BERKELEY LABORATORY
TECHNICAL INFORMATION DEPARTMENT
UNIVERSITY OF CALIFORNIA
BERKELEY, CALIFORNIA 94720