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Chemical Technology Division

PROJECT QUALITY ASSURANCE PLAN FOR RESEARCH AND DEVELOPMENT SERVICES PROVIDED BY OAK RIDGE NATIONAL LABORATORY IN SUPPORT OF THE HANFORD GROUT DISPOSAL PROGRAM

R. D. Spence
T. M. Gilliam

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Prepared for
Westinghouse Hanford Company
EW 10 10 03 0

Prepared by the
OAK RIDGE NATIONAL LABORATORY
Oak Ridge, Tennessee 37831-7273
managed by
MARTIN MARIETTA ENERGY SYSTEMS, INC.
for the
U.S. DEPARTMENT OF ENERGY
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PREFACE

The draft of this report met requirements for Milestone 3.1, "Update of Quality Assurance Project Plan," as described in Statement of Work TMG-SOW-H-91, Revision No. 0, in support of the Westinghouse Hanford Company (WHC) Grout Disposal Program. The draft was revised based on comments from WHC, the program manager, and ORNL QA specialists and is now being issued as this report.

This Project Quality Assurance Plan (PQAP) is being published to provide the sponsor with referenceable documentation for work conducted in support of the WHC Grout Disposal Program. This plan, which meets NQA-1 requirements, is being applied to work performed at ORNL during FY 1991 in support of this program. It should also be noted that with minor revisions, this plan should be applicable to other projects involving research and development that must comply with NQA-1 requirements.

PROJECT QUALITY ASSURANCE PLAN FOR RESEARCH AND DEVELOPMENT SERVICES PROVIDED BY OAK RIDGE NATIONAL LABORATORY IN SUPPORT OF THE WESTINGHOUSE HANFORD COMPANY GROUT DISPOSAL PROGRAM

Project title: Hanford Grout Disposal Program Support at Oak Ridge National Laboratory

Approved: Roger D. Spence 8-6-91
ORNL Project Leader

Approved: Thomas M Gilliam 8-6-91
Group Leader
Waste Solidification Technology

Approved: Earl W. McDaniel
Project Manager
Hanford Grout Disposal Program Support at ORNL

Approved: C.H. Brown, Jr. 8-14-91
Engineering Development Section (EDS) Head,
Chemical Technology Division

Approved: T K Baylor 8-17-91
Chemical Technology Division Quality Assurance Specialist

Approved: P.B. Hoke 8/28/91
Oak Ridge National Laboratory Quality Assurance Manager

Approved: J. A. Voogd 10-28-91
Sponsor Representative

STATEMENT OF POLICY

The research divisions of the Oak Ridge National Laboratory (ORNL) have established and shall maintain Quality Assurance (QA) Programs as required for all services commensurate with the needs and resources of our sponsors. The Engineering Development Section (EDS) of the Chemical Technology Division at Oak Ridge National Laboratory (ORNL) conducts research and development activities covering a vast range of engineering applications.

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

It is the policy of EDS to maintain and implement a documented QA program. The program is designed to meet the requirements of:

1. ANSI/ASME NQA-1 QA Program Requirements for Nuclear Facilities,
2. Department of Energy Order 5700.6B QA, and
3. ORNL QA Procedures Manual.

This Project Quality Assurance Plan (PQAP) will be applied to those elements of this project involving research and development (R&D) performed at ORNL. Compliance with the requirements of this PQAP, corresponding statement of work, and documents required by the plan are mandatory for all employees performing project quality-related activities for this project.

Approved: _____
EDS Head

PROJECT QUALITY ASSURANCE PLAN FOR RESEARCH AND DEVELOPMENT SERVICES PROVIDED BY OAK RIDGE NATIONAL LABORATORY IN SUPPORT OF THE HANFORD GROUT DISPOSAL PROGRAM

R. D. Spence
T. M. Gilliam

ABSTRACT

The Project Quality Assurance Plan is being applied to work performed at Oak Ridge National Laboratory during FY 1991 in support of the Westinghouse Hanford Company Grout Disposal Program. The plan is consistent with NQA-1 requirements.

1. INTRODUCTION

This Project Quality Assurance Plan (PQAP) sets forth the quality assurance (QA) requirements that are applied to those elements of the Hanford Grout Disposal Program (HGDP) support at Oak Ridge National Laboratory (ORNL) project (hereafter referred to as project) that involve research and development (R&D) performed at ORNL. This is in compliance with the applicable criteria of 10 CFR Part 50, Appendix B, ANSI/ASME NQA-1, as specified by Department of Energy Field Office, Oak Ridge (DOE-OR) Order 5700.6B. For this application, NQA-1 is the core QA Program requirements document. QA policy, normally found in the requirements document, is contained herein.

The requirements of this PQAP apply to project activities that affect the quality and reliability/credibility of research, development, and investigative data and documentation. These activities include the functions of attaining quality objectives and assuring that an appropriate QA program scope is established. The scope of activities affecting quality includes organization; personnel training and qualifications; design control; procurement; material handling and storage; operating procedures; testing, surveillance, and auditing; R&D investigative activities and documentation; deficiencies; corrective actions; and QA record keeping. The basic elements of NQA-1 are listed in Table 1.

2. ORGANIZATION

The Engineering Development Section (EDS) is made up of groups engaged in various waste management R&D-related activities. These groups are supervised by group leaders who

Table 1. NQA-1 quality assurance elements

NQA-1 basic element	Reference ORNL/Energy Systems[a] QA procedure(s)	See indicated QA plan section
1. Organization	QA-L-1-100	Sect. 2
2. Quality assurance program	QA-L-2-100 QA-L-2-101 QA-L-2-103 QA-L-2-105 QA-L-2-106	Sect. 3
3. Design control	QA-L-3-100 QA-L-3-101 QA-L-3-102	Sect. 4
4. Procurement document control	QA-L-4-100 QA-L-4-101	Sect. 5
5. Instructions, procedures, and drawings	QA-L-5-100	Sect. 6
6. Document control	QA-L-6-100	Sect. 7
7. Control of purchased items and services	QA-L-7-100 QA-L-7-101 QA-L-7-102	Sect. 8
8. Identification and control of items	QA-L-8-100	Sect. 9
9. Control of processes	QA-L-9-100	Sect. 10
10. Inspection	QA-L-10-100	Sect. 11
11. Test control	QA-L-11-100	Sect. 12
12. Control of measuring and test equipment	QA-L-12-100	Sect. 13
13. Handling, storage, and shipping	QA-L-13-100	Sect. 14
14. Inspection, test, and operating status	QA-L-14-100	Sect. 15
15. Control of nonconforming items	QA-L-15-100	Sect. 16
16. Corrective action	QA-L-16-100, Rev. 2 QA-L-16-102	Sect. 17
17. Quality assurance records	QA-L-17-100	Sect. 18
18. Audits and surveillances	QA-L-18-100 QA-L-18-101 QA-L-18-102	Sect. 19

[a]Energy Systems = Martin Marietta Energy Systems, Inc.

report to the section head. In addition, personnel may be on special assignment and report directly to the section head.

A PQAP is required for each project in order to meet the specifications of individual projects and sponsors. The need for (and level of) detail required using this plan is jointly determined by the project leader, group leader, EDS Head, and division QA specialist (QAS) prior to initiating the project. The decision and rationale for use of this plan are documented by the ORNL QA mini-assessment (Figs. 1 and 2).

2.1 FUNCTIONAL ORGANIZATION

The responsibilities for implementing the QA program for a specific project lie with the EDS Head. The EDS Head is responsible to the Chemical Technology Division (CTD) Director and associate division director, who are responsible to the ORNL Director through the appropriate associate laboratory director. Functional organizational charts are provided in Figs. 3 and 4, respectively, delineating the lines of reporting for the EDS Head upward to the laboratory director and downward for the EDS Head to the key personnel performing the project work assignments. QA responsibilities are established in Fig. 5.

2.2 ORGANIZATIONAL RESPONSIBILITIES

This section delineates project organizational authorities and responsibilities for key personnel.

A. EDS Head

The EDS Head, hereafter referred to as the section head, has overall management responsibility and authority for cost, schedule, QA, and technical performance of all activities performed within the section. The section head reports to the division director through the associate division director. The section head shall approve project QA plans, purchase requisitions, travel authorizations, and any subsequent revisions as necessary. He/she may delegate direct management responsibility and authority for cost, schedule, QA, and technical performance to the group leader.

B. Group Leader

The group leader reports directly to the section head. The group leader has direct management responsibility for cost, schedule, QA, and technical performance associated with projects performed within the group. He/she serves as the interface between (1) the project for

Chemical Technology Division

QUALITY ASSURANCE ASSESSMENT CHECKLIST
OAK RIDGE NATIONAL LABORATORY

PROJECT TITLE

PROGRAM

DOCUMENT NO.	REV	DATE	DIVISION

PROJECT DESCRIPTION:

CHECKLIST OF SIGNIFICANT ITEMS:
Task Leader should complete a checklist on reverse side.

RISK DETERMINATION:
QA Representative should review the checklist and determine (after consultation with specialists and Task Leader as needed) that if a failure occurs, then the consequences on meeting technical and program objectives, funding, schedule, public and DOE reaction, human health and safety, or the environment will be:

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

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

☐ No 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-15008)

☐ Training program and/or operating procedures, which will be reviewed and evaluated on a periodic basis, provide reasonable confidence that personnel and equipment will be operated in a satisfactory manner.

☐ Equipment will be easily maintainable so project can resume operations within an acceptable time period. Vital spare parts are readily available.

☐ Redundancy and/or back systems will be provided.

☐ Items have a history of reliable operation in a similar application.

☐ Reasonable confidence that standard quality control actions (inspections, tests, etc.) will be adequate to mitigate failure.

☐ Other _____

CHECKLIST FOLLOW-UP REVIEW NEEDED: ☐ YES ☐ NO
If Yes, Review Date: _____; Responsible Person: _____

APPROVAL

TASK LEADER	DATE	QA COORDINATOR	DATE
QA REPRESENTATIVE	DATE		DATE

DISTRIBUTION: Task Leader, QA Coordinator, ORNL QA Program Director, Section/Department Head, Division Safety Officer, Others.
(See ORNL PQ Procedure QA-L-1-103 for applicability of form)

UCN-15983 (3 3-88)

Fig. 1. Front of CTD QA mini-assessment checklist form.

CHECKLISTS

Indicate conditions, materials, and circumstances as applicable.
Enter "N/A" if not applicable.

SAFETY

Pressure range (Pa): _____
Temperature range (°C): _____
Electric power needs: _____ volts _____ amps
Does this project involve:

Fissile materials	Yes ____;	No ____;	Unknown ____
Radioactive isotopes	Yes ____;	No ____;	Unknown ____
Hazardous chemicals (i.e., carcinogens, flammables, oxidizing or biological agents, proprietary formulations, etc.)	Yes ____;	No ____;	Unknown ____
Hazardous equipment (i.e., glass components, machinery, intense energy generators, etc.)	Yes ____;	No ____;	Unknown ____

COST AND SCHEDULE

Total or annual (indicate which) cost of task $_____

Is the success of this project dependent upon:

Other Divisions (and their facilities)	Yes ____;	No ____;	Unknown ____
Outside contractors/consultants	Yes ____;	No ____;	Unknown ____
Craft work (and any special equipment such as cranes, core drillers, large saws, etc.)	Yes ____;	No ____;	Unknown ____

Due date for completion of project: _____

Is the project dependent upon facility availability or equipment repair or replacement such that it could jeopardize the above date?	Yes ____;	No ____;	Unknown ____
Is this task necessary to (help) meet a major milestone?	Yes ____;	No ____;	Unknown ____

PROJECT CHARACTERISTICS

Is security classification applied to this project?	Yes ____;	No ____;	Unknown ____
Are accountable amounts of nuclear or precious materials involved?	Yes ____;	No ____;	Unknown ____
Is collection of measurement data involved?	Yes ____;	No ____;	Unknown ____
Is computer software development involved?	Yes ____;	No ____;	Unknown ____
Are the project characteristics expected to remain as defined in the Problem Safety Summary or work plan until the end of the project?	Yes ____;	No ____;	Unknown ____

What organization(s) needs (or has paid for) the results? _____

_____

APPLICABLE QA PROCEDURES
(Consult the CTD QA Manual)

Procedure No.	Procedure Name
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Fig. 2. Back of CTD QA mini-assessment checklist form.

ORNL DWG 90A-1428R

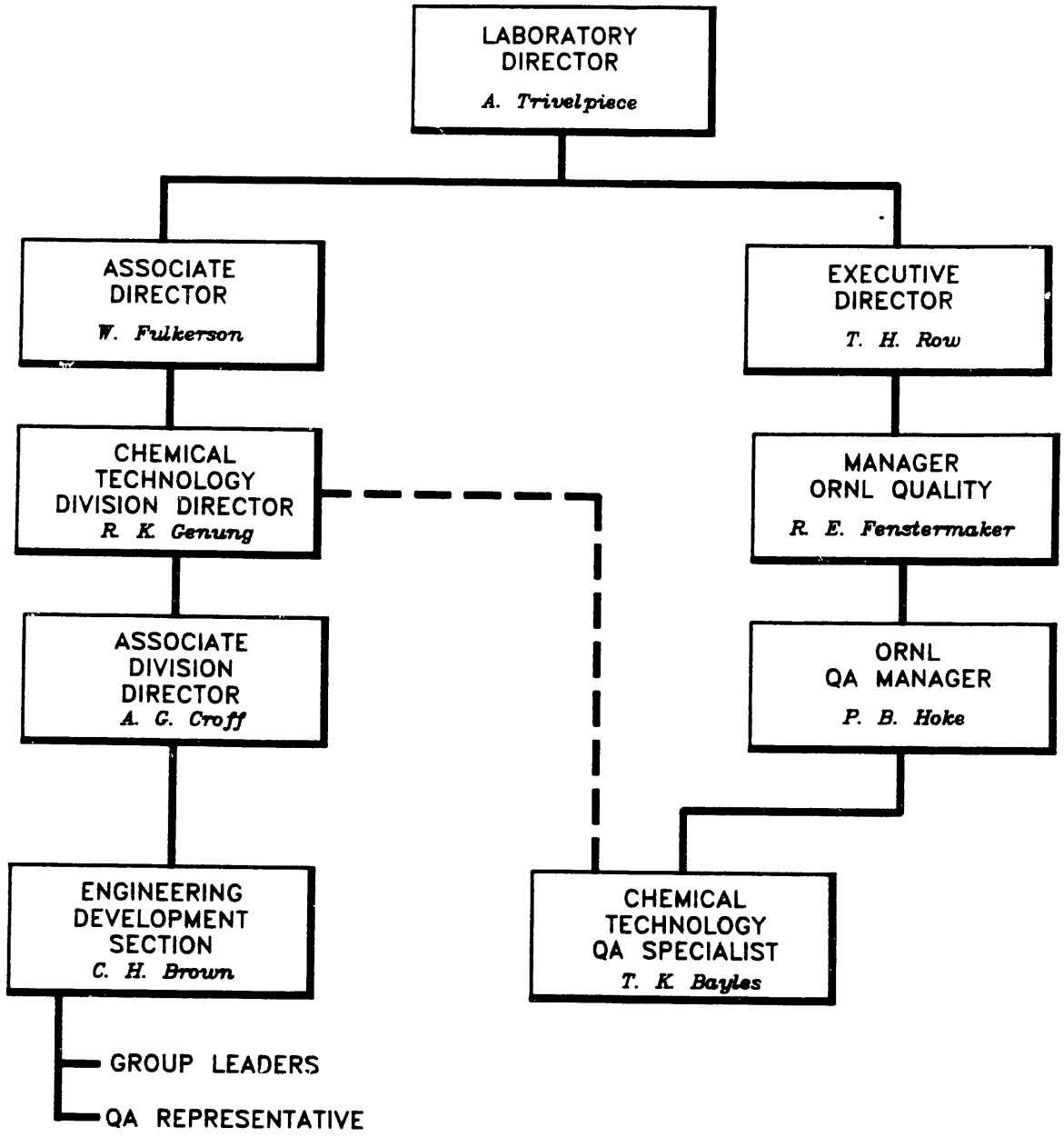

Fig. 3. Organization chart for ORNL R&D Project QA plan.

ORNL DWG 90A-1402

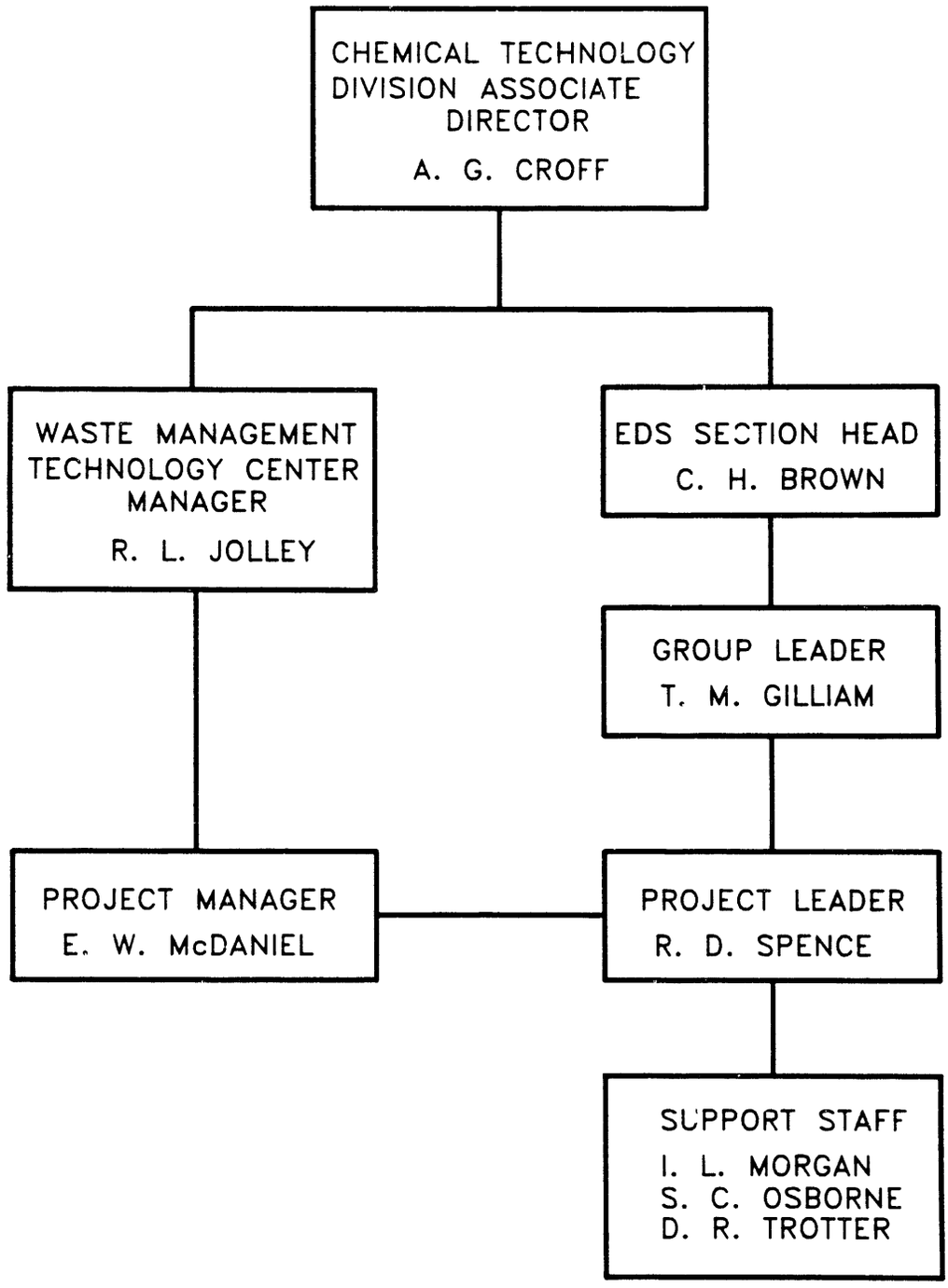

Fig. 4. Program organization chart for EDS Project personnel.

Documents/action[a]	Project leader	Group leader	Project manager	Engineering Development section head	Chemical Technology Division director	Chemical Technology Division associate director	Chemical Technology Division QA specialist
Scope of work	P[b], A[c]	P, A	I[d], R[e], A	R, A	R	R	
Project QA plan	P, A	I, R, A	R, A	R, A		R	R, A
Project records and documents	P, A	R, A		R, A		R	
Publications	P	R, A		R, A	R, A		
QA audits/surveillance (internal)	I[e]	I	I	I	R	R	P
QA audits (external)	I	I	I	I	R	R	I
Corrective action report and status	P	P	R	P, R	R	R	R, A

[a]Blank = not required.
[b]P = prepare/perform.
[c]A = approve.
[d]I = input.
[e]R = review.

Fig. 5. Functional responsibility matrix for QA.

which he/she has management responsibility, (2) the QA representative (QAR), and (3) the division QAS.

D. Project Manager

The project manager reports directly to the Waste Management Technology Center (WMTC) manager and through him to the associate division director. He/she serves as the interface among (1) the project for which he/she has management responsibility, (2) the QAR, and (3) the division QAS. His/her primary functions and responsibilities are to ensure that the quality program requirements are satisfactorily implemented. As appropriate, the project manager will approve the PQAP, project procedures (PPs), and work plans.

E. Project Leader

The project leader may report directly to the section head or through the group leader. For this particular project, the project leader reports through the group leader.

The project leader prepares the PQAP and has the primary responsibility for and authority to ensure that all aspects of the project activities are conducted in accordance with the written and approved work plans, the PQAP, and project procedures (PPs), and that appropriate data and documentation are maintained. The project leader shall approve work plans, laboratory notebooks, purchase requisitions, and receiving reports. The project leader will also secure PQAP approval by the project sponsor, as necessary.

F. EDS QA Representative

The EDS QAR shall serve as the section interface to the division QAS. He/she shall consult with and advise EDS personnel, when called upon, concerning the completion of the QA Assessment Check List and the initiation of occurrence reports. He/she shall also maintain section QA records and a QA notebook, ensuring that both are complete and current. The QAR shall serve as a member of the division QA review committee, whose function is to advise the division director of needs or requirements pertaining to QA.

G. Division QA Specialist

The division QAS shall consult with and advise the EDS QAR and/or the project leader on all QA-related activities and, upon request, any work activity conflicting with QA program commitments. He/she shall maintain and store QA records, as appropriate, in a separate building. He/she reports functionally to the division director and administratively to the ORNL QA manager.

2.3 REFERENCE

The following ORNL QA procedure is referenced:

QA-L-1-100.

3. QA PROGRAM

The PQAP shall ensure that all data and research documentation generated under the project is traceable and in accordance with project requirements through utilization of this document, laboratory notebooks, and applicable PPs and work plans. Control shall be asserted through routine surveillance and internal audits as requested by the section head or the division director. Corrective actions shall be implemented on a timely basis to correct any nonconforming item or data and to satisfy findings issued during each audit. External audits by ORNL Quality Department can be requested. The ORNL Quality Department annually reviews such audit results and deficiencies by trend analysis to assess the effectiveness of QA program implementation. When the PQAP cannot be implemented or maintained, the sponsor's representative shall be notified.

3.1 PROJECT QUALITY ASSURANCE PLAN (PQAP)

This PQAP is a concise statement of the applicable NQA-1 elements required to ensure appropriate project QA.

3.2 TRAINING

Indoctrination and training of personnel performing quality-related activities shall be provided, as necessary, by a qualified staff member at the direction of the section head. Records of the training will be made and maintained by the section head as part of EDS quality records.

3.3 PERSONNEL QUALIFICATIONS

Qualification requirements for personnel will be established, and personnel records will be maintained on file as evidence of compliance with the requirements.

3.4 PROGRAM STATUS SUMMARY

The division QAS is responsible for preparing and issuing a monthly summary of QA activities as deemed appropriate. The summary may include such items as:

1. changes in organization structure or responsibilities,
2. changes in the QA plan or procedures,
3. changes in audit and surveillance schedules,

4. results of internal audits and surveillances,
5. status of corrective actions, and
6. occurrence reports.

3.5 REFERENCES

The following ORNL QA procedures are referenced:

QA-L-2-100,
QA-L-2-101,
QA-L-2-103,
QA-L-2-105, and
QA-L-2-106.

4. DESIGN CONTROL

This section describes the requirements for design control activities related to R&D experiments.

4.1 ROUTINE ITEMS

Routine items are those typically applicable in R&D activities. These items only require rough sketches for their construction. Verification of the design and subsequent modifications are to be performed as part of the experiments in support of the project objectives. The project leader will initial the sketches. The initialed sketch will be placed in appropriate files or laboratory notebooks.

4.2 NONROUTINE ITEMS

Nonroutine items are those that are submitted to Martin Marietta Energy Systems (Energy Systems) Engineering for detailed drawings prior to construction. For these items, procedures governing design definition and control are QA-L-3-100, QA-L-3-101, QA-L-3-102, and QA-CT-3-110. Copies of the manual containing these procedures are kept by the QAR and section head. Unless otherwise specified, the interface between the project and engineering will be the project leader. Quality control (QC) related to documentation is the responsibility of engineering.

4.3 CONFIGURATION CONTROL

Any activity that involves changes in a safety system requires a documented, approved change order. Laboratory and pilot experiments require a safety summary. The safety summary is to be initiated by the project leader and will contain a brief description of the experiment to be performed, the equipment and materials to be utilized, an identification of the known safety concerns associated with the experiment, and the mechanical and administrative controls to be used to minimize the risks associated with these safety concerns. The safety summary will by approved by the project leader, section safety officer, section head, division safety officer, and site Health, Safety, and Environmental (HS&E) personnel as appropriate. This safety summary approval is a form of QA design control.

4.4 REFERENCES

The following ORNL QA procedures are referenced:

QA-L-3-100,

QA-L-3-101, and

QA-L-3-102.

5. PROCUREMENT DOCUMENT CONTROL

This section describes the control measures designed to ensure that applicable design bases and other technical requirements necessary to obtain adequate quality are included or referenced in documents for procurement of items and services from vendors.

5.1 DEFINITIONS

Standard Items. These are items or services procured according to the seller's description or national consensus standards and normally delivered from the seller's stock (off-the-shelf items) or purchases made using the Accelerated Vendor Inventory Delivery (AVID) computerized purchasing system. Procurement document control is not required for standard items.

Special Items. These are items or services procured according to special descriptions and requirements provided by Energy Systems (the company). They are normally based on

performance specifications or detailed design drawings and/or specifications provided by the company. Procurement document control is required for special items.

5.2 PROCUREMENT DOCUMENTATION

Purchase requisitions shall be initiated by the project leader or his/her designee for all procured items except for those purchased using the AVID system. These requisitions shall be reviewed and initialed by the project leader and the group leader and approved by the section head or designee. Purchase requisitions involving special items are to be reviewed and initialed by the QAR.

The purchase requisition shall contain specific identification and technical requirements to ensure that the proper item is ordered. In the case of standard items, the manufacturer's model/catalog number and a brief description is sufficient. For special items, the purchase requisition shall contain, as appropriate, a scope of work, technical requirements, QA program requirements, right-of-access, and documentation requirements.

Changes to purchase requisitions shall be reviewed and approved by the same organizational positions that approved the original purchase requisition. The requisitioner will verify that the contents of the purchase requisition and subsequent changes are accurately and correctly transferred to the purchase order.

5.3 INSPECTION

Special inspection requirements exceeding those routinely performed by the item recipient and receiving (as defined in Sect. 8) are to be specified on the purchase requisition. Documentation certifying these special inspections are to provided by the inspector and reviewed by the item recipient.

5.4 DOCUMENTATION

A copy of the purchase requisition and all changes pertaining to it shall be kept by the project leader. For standard items, copies of the purchase requisition, purchase order, change notices, and inspection reports will be kept until the purchased item has been put into successful use. For special items, such documents will be kept for the lifetime of the project.

5.5 CHEMICALS

Upon initiating a requisition for the purchase of any chemical, the requestor will notify the Site Hazardous Chemical Coordinator of the intended purchase. The coordinator will then determine the proper Occupational Safety & Health Administration (OSHA) labeling requirements.

5.6 REFERENCES

The following ORNL QA procedures are referenced:

QA-L-4-100 and

QA-L-4-101.

6. PLANS, PROCEDURES, AND RECORD DOCUMENTS

This section describes the requirements for issuance of approved procedures, work plans, and record documents for use in implementing activities affecting quality performed by EDS personnel for this project.

6.1 PROJECT PROCEDURES (PPs)

PPs will be issued for the elements of this PQAP that require additional detail, clarification, or documentation. All PPs shall be prepared by the project leader or his/her designee; reviewed for technical content by an individual(s) selected by the section head; and then approved by the project leader, the group leader, and the section head. These PPs may be referenced as appendixes to this section.

6.2 WORK PLANS

A work plan or statement of work (SOW) will be prepared by the project leader. The work plan will describe the work to be performed and all deliverables to the sponsor. The work plan shall be approved by the project leader, the group leader, section head, and sponsor representative. Changes to the work plan will be approved by the same personnel in accordance with SOW No. TMG-SOW-H-91.

6.3 RECORD DOCUMENTS

Record documents for activities associated with the project include appropriate data files and/or laboratory notebooks at the discretion of the project leader. Data files may be used for data too bulky for inclusion in laboratory notebooks (e.g., computer printouts, mass spectra, etc.). Data files will be clearly identified and labeled.

Project laboratory notebooks will be identified by number and assigned to specific project personnel on a controlled basis by Laboratory Records for purposes of recording data and results. These notebooks are bound and are identified by a specific number referenced to the individual using each book. Each page shall be numbered, dated, and signed upon completion of documentation on each page. The project leader or appropriate reviewer shall review, evaluate, sign, and date his/her comments as deemed appropriate by writing in the notebook the pages covered in the review and the general topic in these pages.

6.4 REFERENCE

The following ORNL QA procedure is referenced:

QA-L-5-100.

7. DOCUMENT CONTROL

This section describes the methods and policies for issuance and distribution control of the PQAP, PPs, record documents, and work plan associated with this project.

A copy of the most current revisions to each of the above documents shall be maintained by the project leader in an appropriate document file. A master index listing for each category of controlled document should be maintained current with the latest revision number for each document at the same location. Obsolete copies of documents shall be removed by the project leader when inserting the most current revision. It is 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 most up-to-date version.

Review and approval requirements for these documents have been assigned under Sects. 2 and 6 of this plan.

7.1 REFERENCE

The following ORNL QA procedure is referenced:

QA-L-6-100.

8. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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

8.1 APPROVED VENDORS

As stated in Sect. 5 of this document, "Procurement Document Control," most items will be categorized as standard. All requisitions involving standard items shall have a recommended vendor by the requisitioner for cost reference. As a standard item, there will be significant historical evidence available to the requisitioner as to the quality of the product and the vendor. Based on his/her experience with purchasing similar items, the purchasing agent may utilize another vendor to meet schedule and cost constraints. When another vendor is used, the purchasing agent will notify the requestor by telephone and receive his/her approval prior to purchasing the item. The requestor will note his/her approval and date it either by notation on the original purchase requisition or a memo to file.

Items classified as special in Sect. 5 are typically purchased on a competitive bid basis. In this instance, bids will be solicited by the purchasing agent from his/her approved vendor list and vendors supplied by the requisitioner. The bids received will be evaluated by the requisitioner against the technical and quality criteria as specified in the purchase request. The results of the evaluation will be approved by the line organization personnel that approved the original purchase requisition. The section head may appoint a team to evaluate the bids.

8.2 RECEIPT INSPECTION

Upon receipt of the items, Receiving will inspect the items in order to verify that the number of items received corresponds to the number ordered. Verification will be in the form of a receiving report, which is a record of inspection, and will accompany the item as it is distributed to the requestor. The receiving report will contain the date of inspection and the name of the inspector. Upon receipt of the item, the requestor will verify the accuracy of the information in the receiving report and the items received with the purchase requisition. If

either is in error, corrective action will be taken by the requestor. In most cases, this will require returning the item in question to Receiving, which will, in turn, return the item to the vendor for replacement. It is the responsibility of the requestor to verify within 30 d after receipt that the items function as specified on the purchase requisition. The requestor will sign and date the receiving report, signifying his/her acceptance of the item.

Special inspections of the item may be required and performed by groups designated on the purchase requisition. Certificates of conformance or inspection reports will be issued to the requestor by the inspector(s). If the special inspections involve the surveillance and inspection of the vendor, the certificate of conformance may be in the form of a memo to file.

8.3 DOCUMENTATION

For standard items, a copy of the purchase order, receiving report, and all related certificates of conformance are to be retained by the project leader until the purchased item has been put into successful use. For special items, these documents are to be kept for the lifetime of the project.

8.4 NONCONFORMANCE

Upon verification of a nonconformance, the project leader is to be notified so that he/she can investigate the nonconformance. A nonconformance report (NCR) (see Sect. 16) can be initiated by anyone who discovers a nonconformance, but the project leader is to be notified in all cases. It is the responsibility of the project leader to make certain that the NCR is initiated, if required. The NCR is processed by the QAR who sends it to the division QAS. The QAS will enter the NCR into the Energy Systems Quality Information System (ESQIS) and obtain an appropriate identification number. The NCR will then be processed in accordance with QA-L-15-100 and QA-L-16-102.

8.5 REFERENCES

The following ORNL QA procedures are referenced:

QA-L-7-100,
QA-L-7-101,
QA-L-7-102,
QA-L-15-100, and
QA-L-16-102.

9. IDENTIFICATION AND CONTROL OF MATERIALS

This section describes the requirements designed to ensure that only correct and accepted items are utilized. These requirements will apply to quality-related items, including test specimens, materials, and samples used for R&D.

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 used shall be clearly identified and labeled. Resulting sample evaluation and analytical data will be appropriately recorded. The person performing the activity shall be responsible for ensuring the intended use of the sample and recording the sample identification and evaluation data. Samples generated that are submitted to Analytical Chemistry will be accompanied by a chain-of-custody form (see Sect. 14.2). Any items to be shipped will require the development of appropriate QA record control. In general, "Shipping" denotes any QA record control related to shipment.

9.1 REFERENCE

The following ORNL QA procedure is referenced:

QA-L-8-100.

10. CONTROL OF SPECIAL PROCESS

This QA program element is not applicable under the scope of work established for this project. Only laboratory data and documentation of results will be routinely generated as a deliverable.

11. INSPECTION

Process and product inspections, as normally defined for manufactured items, will not be applicable under the scope of work established for this project. Only data and documentation from technical analyses will be routinely generated.

Receiving inspections will be performed and documented as delineated in Sect. 8 of this document.

11.1 REFERENCE

The following ORNL QA procedure is referenced:

QA-L-10-100.

12. TEST CONTROL

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

12.1 PROGRAM REQUIREMENTS

Test programs, including specific work plans and/or project procedures, if necessary, shall be prepared in accordance with Sect. 6 of this document. Instrument calibration shall be defined and performed in accordance with Sect. 13 of this document. Personnel training will be performed in accordance with Sect. 3 of this document.

12.2 RECORD DOCUMENT

Tests required to verify or evaluate conformance of an item to specified requirements will be documented in a records document (e.g., laboratory notebook) in accordance with Sect. 6 of this document. Although document entries are not rigid, entries will supply sufficient information to permit the project leader to document the following: items tested, date of test, characteristics to be tested, test method employed, person performing test or recording data, observations, test results, and acceptability.

12.3 INDEPENDENT TECHNICAL REVIEW

The requirements addressed in this section, including characteristics tested, test methods employed, and evaluation of test results against acceptance criteria, will be documented in a draft report to the sponsor. Preparation of this report is the responsibility of the project leader.

The report may also be issued as an external publication (e.g., TM, journal article). The external report is to be approved by the section head with approval documented by initials or signature on the document clearance form. Prior to publication, it is required that each report receive at least two technical reviews by personnel who are independent of the work performed and qualified to judge its technical merits. It is the responsibility of the section head to identify

reviewers and document the review comments on a technical review form (Fig. 6). These reviews are to be treated as QA records until publication of the document and will be maintained by the section head. It is the responsibility of the project leader to resolve all technical comments received. The section head or designee shall resolve any disputed comments.

12.4 REFERENCE

The following ORNL QA procedure is referenced:

QA-L-11-100.

13. CONTROL OF MEASURING AND TEST EQUIPMENT

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

Under the scope of work for this project, only instruments that have documented calibration by the manufacturer and/or instruments subject to internal calibration may be utilized for reportable data. Where possible, M&TE calibration will be performed by instrumentation & control specialists utilizing industry standards. Where industry standards are not available, standards will be prepared by EDS personnel for use in verifying that the items and instrumentation affecting quality will yield the known data for each standard utilized. The standard to be used, calibration frequency, and acceptance criteria will be stated in a record document (e.g., laboratory notebook), providing directions for analyzing the standard. Results are to be recorded in a record document.

All M&TE subject to calibration, as determined by project management, shall be labeled to indicate the M&TE status and unique serial number. M&TE used for nondata purposes are not required to be calibrated. Where possible, the reference standards utilized shall be traceable to the National Institute of Standards and Technology or to other nationally recognized standards. At a minimum, M&TE labels shall state calibration date, due date, identification number, and calibrator's initials. When the performance of M&TE is suspect, it shall be

File No._____

EDS DOCUMENT REVIEW

TO:

FROM:

SUBJECT:

NATURE OF REPORT:

Please review the attached document for clarity, technical accuracy, general knowledge, and objectivity. Feel free to comment on the makeup and mode of presentation, but you need not be concerned with minor grammatical errors (and the like) since the document will be submitted for editorial review.

I would appreciate it greatly if you would complete your review within two weeks if possible and return the completed form to me. Thank you.

REVIEWER'S RECOMMENDATIONS:

IF YOU HAVE ALSO MADE NOTES ON THE MANUSCRIPT, PLEASE CHECK HERE ___

Comments (use additional pages if necessary): Please indicate if comments are optional suggestions versus mandatory.

Comment#	Page#, Line#	Suggestions:	Optional or Mandatory

Fig. 6. EDS document review form.

REVIEWER'S RECOMMENDATIONS: (CONT.)

Comments (use additional pages if necessary): Please indicate if comments are optional suggestions versus mandatory.

Comment#	Page#, Line#	Suggestions:	Optional or Mandatory

This report should be submitted for publication

_____ Unchanged

_____ After minor revision (as indicated on returned document)

_____ After major revision (see comments)

_____ _____

Date

Fig. 6. EDS document review form (continued).

RESPONSE TO REVIEWERS

Please indicate your response to each of the mandatory reviewer's comments. Use additional sheets if necessary.

REVIEWER 1

Comment No.	M/S No.	Page	Response

REVIEWER 2

Comment No.	M/S No.	Page	Response

Fig. 6. EDS document review form (continued).

removed immediately from service, repaired, and/or recalibrated. Inspection of suspect equipment shall include documentation of "as found" conditions so that the degree of error can be assessed. When M&TE is found to be out of calibration, it shall be documented; and, where applicable, an immediate investigation shall be performed by the project leader and section head or his/her designee to determine the validity of measurements taken since the previous acceptable standardization was completed. Data obtained during this time interval shall be accepted or rejected by the project leader based on the investigation. The project leader shall issue a quality event report described under Sect. 16 of this document if the validity of measurements taken since the previous acceptable standardization was completed cannot be established as acceptable.

13.1 REFERENCE

The following ORNL QA procedure is referenced:

QA-L-12-100.

14. HANDLING STORAGE AND SHIPPING

This section describes the methods and policies designed to ensure proper physical care of materials, test samples, and samples used for R&D whose loss or damage could compromise program quality objectives.

14.1 HANDLING AND STORAGE

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 and humidity, as well as safety considerations for standards and internally prepared samples to be analyzed, will be established by the project leader.

Samples that present a possible radioactive and/or chemical hazard to personnel or the environment will be identified in the project safety summary for special handling and storage. A description of the project safety summary and the approvals required is described in Sect. 4.3.

14.2 SAMPLE CHAIN-OF-CUSTODY AND ANALYTICAL SERVICES

As described in Sect. 9, samples submitted to Analytical Chemistry for analysis shall be accompanied by a chain-of-custody form (Figs. 7 and 8). Additional traveler documents, prescribed by the personnel receiving the samples, will also accompany the samples. Analytical services will be performed and documented by the personnel performing the analytical service.

K-25 SITE CHAIN OF CUSTODY FORM

SAMPLER (signature)		Dept.	Building phone		SAMPLE TYPE	REMARKS
CUSTOMER SAMPLER NUMBER	Sampling date	Sampling time	SAMPLE LOCATION	Total No. of containers		

UCN-15487A Signature required on back

Fig. 7. Front of chain-of-custody card.

Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Date/Time	Phone
Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Date/Time	Phone
Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Date/Time	Phone
Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Date/Time	Phone
Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Date/Time	Phone
Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Date/Time	Phone

REMARKS:

RETURN TO (check one):

|___| ENVIRONMENTAL MANAGEMENT, K-1020, MS 402, 6-2510

|___| SAMPLING MANAGEMENT, K-1004C, MS 440, 4-9609

Back UCN-15487A

Fig. 8. Back of chain-of-custody card.

14.3 WASTE DISPOSAL

Samples will be prepared for shipment in accordance with guidelines from Shipping. Samples and materials will be disposed of in accordance with the ORNL Environmental Protection Manual.

14.4 REFERENCE

The following ORNL QA procedure is referenced:

QA-L-13-100.

15. INSPECTION, TEST, AND OPERATING STATUS

There are no "manufacturing and installation" activities applicable to "structures, systems, and components" being performed under the scope of this project. Thus, this QA program element is not applicable to this project.

16. QUALITY EVENTS

This section describes the methods and policies to be used to document, evaluate, and perform corrective action and closeout activities when a quality event is detected. A quality event is a real-time occurrence that may involve safety, health, quality, security, operational, or environmental considerations. An occurrence is defined as any of the following:

1. reportable problems, concerns, and adverse conditions or events that have or could have an adverse or negative impact on safety, environment, health, quality, security or operations;
2. failure, malfunction, deficiency, deviation, defective item or nonconformance in material, equipment, process, procedure, or program within Energy Systems;
3. deviations from standard requirements, procedures, or operations, including all safety, quality, environmental, and operational activities; or
4. occurrences as defined in this section (do not include routine maintenance items, personnel concerns, or other similar issues that are already covered by existing administrative programs).

All quality events will be investigated by the project leader and reported to the section head. All events determined by the section head to be reportable as an event/occurrence will be processed on either a NCR form (Fig. 9) or an Occurrence Reporting System (ORS) Report form (Fig. 10).

16.1 NONCONFORMANCE REPORT

Events related to receipt of purchased items as described in Sects. 5 and 8 are reported using an NCR. The corrective action will be the immediate return of the item to the manufacturer for repair or replacement.

16.2 OCCURRENCE REPORTING SYSTEM REPORT

All events not reported using an NCR will be reported by an ORS Report (Fig. 10). The section head will make a preliminary determination as to the category (I, II, III, or IV) of the occurrence. Occurrence reporting requirements and criteria for category designation are defined below.

Category I - Emergency. These are events that require an increased alert or activation status of the plant and possible off-site agencies. Emergency occurrences include those that could potentially impact the health and safety of employees or the public. Typically, emergencies involve a release to the environment. These events require immediate (15 min) verbal notification to the plant shift superintendent, and a written ORS notification report using items 1-14 of Fig. 10 shall follow as soon as practical, but no later than 24 h after categorization.

Category II - Unusual Occurrence. An unusual occurrence is a non-emergency problem that has impact or potential for impact on safety, quality, environment, health, security, or operations. Unusual occurrences must be verbally reported to the plant shift superintendent as soon as practical within 2 h after being categorized, and a written ORS notification report, using items 1-14 of Fig. 10, shall follow within 24 h.

Category III - Off-Normal Occurrence. Off-normal occurrences are abnormal or unplanned events or conditions that adversely affect, potentially affect, or are indicative of degradation in the safety, security, quality, environmental, health protection, or operation of a facility. A written ORS notification report, using items 1-14 of Fig. 10, shall be made to the plant shift superintendent no later than 24 h after categorization.

NONCONFORMANCE REPORT (NCR)

MARTIN MARIETTA

Sheet ____ of ____

This form should be completed when one or more distinct, describable, and measurable properties or characteristics of an item (hardware or software) do not conform to documented technical requirements.

1. NONCONFORMANCE REPORT NO. NCR-

2. OCCURRENCE DATE	3. ORIGINATOR	4. PLANT/ORGANIZATION	5. DIVISION	6. ADDRESS	7. PHONE NUMBER

8. PURCHASE ORDER/WORK ORDER OR CONTRACT/ STORES NO.	9. ITEM NO.	10. REC. REPORT NO.	11. DWG/SPEC/DOC. NO.	12. REV. NO.	13. QTY REC'D. OR PRODUCED	14. QTY. NONCONFORM.

15. DESCRIPTION

15A. SPECIFIED REQUIREMENT(S)	15B. NONCONFORMANCE(S)

16A. NONCONFORMANCE DISPOSITION	16B. REMEDIAL ACTION(S) AND JUSTIFICATION
☐ ACCEPT; USE-AS-IS ☐ REWORK (TO SPEC.) ☐ REPAIR (TO USABLE COND.) ☐ RETURN TO VENDOR / SHOP ☐ REJECT/SCRAP	

17. DISPOSITION APPROVALS

17A. ENGINEER/REQUISITIONER	DATE	17B. CUSTOMER/USER	DATE	17C. QA SPECIALIST	17D. DATE

18. CORRECTIVE ACTION(S) TO PREVENT RECURRENCE

18A. ACTION	18B. TECHNICAL OR SYSTEM	18C. RESPONSIBILITY	18D. SCHEDULED COMPLETION DATE

19. CORRECTIVE ACTION APPROVALS

19A. ENGINEER/REQUISITIONER	DATE	19B. RESPONSIBLE MGR. OR BUYER	DATE	19C. QA SPECIALIST	19D. DATE

20. COST/SCHEDULE DELAY SUMMARY

COST ITEM	TOTAL
· COST OF REPAIR REWORK - the cost of correcting failed and defective items to make them fit for intended use.	
· COST OF REPLACEMENT - the cost of procuring and installing a fit substitute for failed and defective items.	
· COST OF DELAY - the cost occurring as a result of delays caused by the nonconformance.	
· COST OF REDESIGN - the cost of revising, deviating, eliminating or approving the design of items due to nonconformance.	
· COST OF CONSEQUENTIAL DAMAGE - the cost of actual, nominal, tangible, or intangible damage directly related to nonconformance.	

20A. TOTAL COST IMPACT _____

WAS SCHEDULE IMPACTED? ☐ YES ☐ NO 20B. SCHEDULE DELAY (DAYS) _____

ENERGY SYSTEMS QUALITY INFORMATION SYSTEM ATTRIBUTES

21. REP. QER NO. (IF APPLICABLE): _____ 22. OTHER APPLICABLE QIRS, UQRS, OR NCRS: _____

23. ☐ HARDWARE ☐ SOFTWARE	24. ITEM	25. DEFECT

26. QUALITY INDICATOR CATEGORY	27. PROJECT NO. (IF APPLICABLE)

28. ☐ VENDOR SUPPLIED ☐ MMES/MMC FABRICATED/ DEVELOPED/CONSTRUCTED ☐ AE/SUBCONTRACTOR SUPPLIED/CONSTRUCTED	29. NAME OF VENDOR, SHOP/ORGANIZATION, CONTRACTOR/AE, ETC.

30. KEYWORD	31. PRIMARY PROBLEM CAUSE CATEGORY:	32. PROBLEM DISCIPLINE CATEGORY:
	☐☐	☐☐

NOTE: SHADED AREAS INDICATED ENERGY DATA BASE ENTRIES

UCN-11457 (2 3-87)

Fig. 9. Nonconformance Report (NCR).

ATTACHMENT 2. GS-13.1.
OCCURRENCE REPORTING SYSTEM (ORS)
REPORT FORM

24-Hour
Notification Report
Page 1 of ___

FORMAT *Spacing of items in the following example may be altered as necessary to provide adequate space for full exposition of items).*

_____
(Name of Facility)

_____
(Name of Laboratory Site or Organization)

Name: Title: Telephone No.:
Facility Manager

Name: Title: Telephone No.:
(Originator)

1. OCCURRENCE REPORT NUMBER _____

2. STATUS REPORT DATE *(Check One)* Date
[ ] Notification _____
[ ] 10-Day _____
[ ] Final _____

3. OCCURRENCE CATEGORY
[ ] Emergency
[ ] Unusual Occurrence
[ ] Off-Normal

4. DIVISION OR PROJECT *(check one)* [ ] CE [ ] DP [ ] ER [ ] NE [ ] FE [ ] RW [ ] EM

5. FACILITY, SYSTEM, BLDG., OR EQUIPMENT:	6. PLANT AREA:	7. DATE AND TIME OCCURRENCE DISCOVERED:
8. DATE AND TIME OCCURRENCE CATEGORIZED:	9. DATE AND TIME OF DOE PROGRAM NOTIFICATION:	10. DATE AND TIME OF OTHER NOTIFICATIONS

11. SUBJECT OR TITLE OF OCCURRENCE:

12. DESCRIPTION OF OCCURRENCE:

13. OPERATING CONDITIONS OF FACILITY AT TIME OF OCCURRENCE:

14. IMMEDIATE ACTIONS TAKEN AND RESULTS:

Fig. 10. Occurrence Reporting System (ORS) report form.

ATTACHMENT 2. GS-13.1 (continued)
OCCURRENCE REPORTING SYSTEM (ORS)
REPORT FORM

OCCURRENCE
REPORT NUMBER: _____

Report Date: _____

15. CAUSE:

Direct Cause: *(mark only one)*

Design _____ Material _____ Personnel _____ Procedure _____ Other_____

EXPLAIN:

Contributing Cause(s): Design _____ Material _____ Personnel _____

Procedure _____ Other_____

EXPLAIN:

Root Cause: Procedure _____ Training _____ Management _____ Personnel _____

Design _____ Material _____

EXPLAIN:

16. DESCRIPTION OF CAUSE:

17. EVALUATION: (by Facility Manager)

18. IS FURTHER EVALUATION REQUIRED? *Yes* _____ *No* _____

IF YES, BEFORE FURTHER OPERATION: *Yes* _____ *No* _____

IF YES, BY WHOM? _____

WHEN? _____

Fig. 10. Occurrence Reporting System (ORS) report form (continued).

ATTACHMENT 2. GS-13.1 (continued)
OCCURRENCE REPORTING SYSTEM (ORS)
REPORT FORM

Occurrence Report
Page 3 of ___

OCCURRENCE
REPORT NUMBER: _____

Report Date: _____

19. CORRECTIVE ACTION:

Taken: _____ Recommended: _____ To Be Supplied: _____

20. IMPACT ON ENVIRONMENT, SAFETY, AND HEALTH:

21. PROGRAMMATIC IMPACT:

22. IMPACT UPON CODES AND STANDARDS:

23. FINAL EVALUATION AND LESSONS LEARNED:

24. SIMILAR OCCURRENCE REPORT NUMBERS:

25. SIGNATURES:

Approved by: _____ Date: _____
Facility Manager *(Name, Position)*

Reviewed by: _____ Date: _____
DOE Facility Representative *(Name, Position)*

Approved by: _____ Date: _____
DOE Program Manager *(Name, Position)*

Fig. 10. Occurrence Reporting System (ORS) report form (continued).

ATTACHMENT 2. GS-13.1 (continued)
OCCURRENCE REPORTING SYSTEM (ORS)
REPORT FORM

Occurrence Report
Page 4 of ___

OCCURRENCE
REPORT NUMBER: _____

Repon Date: _____

DOE FACILITY REPRESENTATIVE INPUT

26. DOE FACILITY REPRESENTATIVE INPUT:

27. Entered by: _____ Date: _____
Name of DOE Facility Representative

Fig. 10. Occurrence Reporting System (ORS) report form (continued).

Category IV - Non-Routine Occurrence. If an occurrence does not meet the criteria of any of the previous categories but meets the definition of an occurrence, then it is considered a Non-Routine Occurrence, category IV. Non-Routine Occurrences typically do not require a detailed evaluation, and the corrective action, if required, is apparent without further investigations. A written ORS notification report, using items 1-14 of Fig. 10, shall be made to the division QAS as soon as practical.

16.3 INVESTIGATION REPORT

A follow-up investigation report shall be submitted to the facility representative within 7 d of reporting the occurrence for all category I, II and III occurrences. This report shall include completed items 1-24 of Fig. 10. This report will be completed by the responsible line organization as determined by the plant shift superintendent. Where CTD is determined to be the responsible line organization, the report is to be prepared by the section head or his/her designee and the project leader.

16.4 REFERENCES

The following ORNL QA procedures are referenced:

QA-L-15-100,

QA-L-16-100, and

QA-L-16-102.

17. CORRECTIVE ACTION

This section describes the methods and policies for documentation and implementation of corrective actions for conditions adverse to quality. These conditions shall be those documented on a QA form. The process for initiating a QA form, processing the form, and performing the investigation necessary to determine the appropriate corrective action, if any, is described in Sect. 16 of this document.

17.1 QA FORM REVIEW

The division QAS and/or ORNL QA periodically reviews NCRs and ORS reports (at least annually) to analyze for quality trends and root causes of deficiencies. The trend analyses are reported to the division director and ORNL management for review and assessment.

17.2 CORRECTIVE ACTION REPORT AND STATUS (CARS)

The section head shall evaluate each reported nonconformance and category I, II, or III quality event relevant to this project and make a documented appraisal for impact on cost, schedule, safety, health, environment, or reliability/credibility of data. The results of the section head's evaluation shall be documented in a letter, transmitted with a copy of each quality event report to the sponsor's representative within 14 d of the quality event occurrence. Verbal notification shall be made to that representative within 48 h of the event's occurrence if the section head determines that the results are significant. The CARS form (Fig. 11) will be used for reporting evaluations, corrective actions, and corrective action status.

A CARS form is required for all reported quality events requiring corrective action. The section head or his/her designee shall initiate the CARS form and transmit it to the division QAS, who is responsible for logging and tracking the form until successful resolution of the event. The section head or his/her designee will verify that satisfactory corrective action has been completed, sign, and date the form. Final distribution shall only be made after the final acceptance lines are signed and dated by the division QAS and project sponsor's representative, as necessary. A copy of the approved and signed reports will be maintained by the project leader.

17.3 REFERENCES

The following ORNL QA procedures are referenced:

QA-L-16-100, Rev. 2 and

QA-L-16-102.

18. QA RECORDS

This section describes the methods and policies used for identification and maintenance of QA records. It applies to completed records required to furnish objective evidence of the quality of data and documentation to be furnished under this project.

18.1 RECORDS INDEX

The project leader shall issue and maintain a master QA records/file list identifying each category of records to be maintained as a QA record for this project. The section head or designee will approve the list. Each category of records on this list will be assigned a unique index file number that will be cross-referenced to the QA record category. An example of this list and the appropriate form is shown in Fig. 12.

MMES/ORNL/CTD

CORRECTIVE ACTION REPORT AND STATUS

CORRECTIVE ACTION SOURCE Initiation Date: _____

(Specify): _____
(Audit #, NCR #, Surveillance #, Occurrence Report #, or Other)

FINDING AND/OR RECOMMENDATION:

Applicable to Other Areas? (Y/N) ___ _____ _____
Section Head QAS

CORRECTIVE ACTION OR ACTION TO PREVENT RECURRENCE:

RESPONSIBLE PERSON(S): _____

SCHED. COMPLETION DATE: _____ REVISED COMPLETION DATE: _____

Commit to Corrective Action: _____ _____ Distribution:
Responsible Manager Date

Accept and Understand Task: _____ _____
Responsible Person Date

Concurrence: _____ _____ _____
Division/Program QAS Date Data Base, Date Entered Tracking Number

STATUS:

Distribution:

CORRECTIVE ACTION COMPLETED: _____ _____
Responsible Person Date

Verified ___ Acknowledged ___ _____ _____
QAS Date

Closed in: _____ _____
Data Base, Date By Whom

Fig. 11. Corrective Action Report and Status (CARS) form.

		QAP Number: Date:	
Project Title:			
Project Manager		QAS:	
Name of Record	Retention Period	Master File Point[a]	Duplicate File Point[b]
Project QA plan	lifetime[c]	section office	QAS
Problem safety summary	lifetime	section office	safety officer
Experimental parameters and instrumentation record	lifetime	project investigator	
Nonconformance reports (NCRs)	lifetime	project investigator	QAS
Occurrence report	lifetime	project investigator	QAS
Master QA records file index list	lifetime	project investigator	
Laboratory notebooks	permanent	project investigator	
Experimental data sheets	lifetime	project investigator	
Audit reports	lifetime	project investigator	QAS
Surveillance reports	lifetime	project investigator	QAS
Corrective action report and status sheets	lifetime	project investigator	QAS
Process and control diagram	lifetime	project investigator	
Review documentation	lifetime	project investigator	
Purchase requisition	lifetime	project investigator	
Equipment calibrations	lifetime	project investigator	
Personnel training	permanent	project investigator	
Monthly status reports	lifetime	project investigator	
Sample chain of custody	lifetime	project investigator	

[a]Master file point - give name of person to keep records.
[b]Duplicate file point - state location of duplicate records.
[c]Lifetime = lifetime of project.

Fig. 12. Quality assurance records list.

18.2 RECORDS CONTROL

The project leader shall provide a copy of the designated records on the list within 30 d after record completion to the division QAS for controlled access, maintenance, and storage in a separate building. A sign-out log shall be maintained by the QAS for records released from his/her area.

18.3 FINAL DISPOSITION OF RECORDS

The records on the master QA records/file list will be stored for a period of 90 d after project completion. For this project, project completion is defined by the delivery of Milestone 9.3, "Letter Report Describing Preliminary Identification of Dry-Solid Blend Components Which Merit Additional Study" (TMG-91-017, Appendage to TMG-SOW-H-91, Rev. No. 0 for FY 1991).

Upon completion of the project, the project leader will transmit a letter to the project sponsor concerning retention of the QA Records. The sponsor representative will respond to this letter within 30 d. If the sponsor requires longer record retention, the project leader will transmit copies of the records to the sponsor for storage. The sponsor's representative will transmit documentation verifying receipt of these records to the project leader within 30 d after receipt of the records. This documentation is to be placed in the laboratory notebook assigned to the project. After receipt of these records has been documented (or the 90-d period expires), copies maintained by ORNL staff will be discarded.

18.4 LABORATORY NOTEBOOKS

It is the responsibility of the project leader to ensure the safe, temporary storage of laboratory notebooks assigned to this project, while they are in use. While in use, laboratory notebooks are working documents; when no longer in active use, they become completed QA records. At that time, these notebooks will be returned to Laboratory Records to be stored for a period of 25 years. Prior to the transfer of the notebooks to Laboratory Records, the project leader will transmit a letter to the sponsor representative indicating the notebook numbers. The sponsor will provide documentation verifying receipt of this letter, within 30 d, to the project leader. This documentation is to be placed in the laboratory notebook and the notebook(s) transferred to Laboratory Records.

18.5 REFERENCE

The following ORNL QA procedure is referenced:

QA-L-17-100.

19. AUDITS AND SURVEILLANCE

This section describes the methods and policies designed for planning, performing, and reporting audits and surveillance activities to verify compliance with all aspects of the QA program and to determine program effectiveness. The requirements of this section apply to internal audits and surveillance activities initiated by the CTD. Audits and surveillances will be required when deemed necessary by line management or by the QAS.

19.1 INTERNAL AUDITS

Audits shall be performed as needed by using project/program documents and highlighting the items to be verified and/or compiling checklist questions. Audit results shall be documented in a report that will be issued on a timely basis by the QAS. This report will provide the status of items that were verified during the audits. Copies to the audit reports shall be distributed to the project leader, group leader, section head, associate division director, division director, and sponsor representative.

19.2 SURVEILLANCE

The section head is responsible for establishing a surveillance program for this project in consultation with the QAS, QAR, and project leader. Surveillances will be conducted by the section head or individuals designated by the section head.

The project leader shall provide a technical progress summary of this project on a monthly basis. The section head shall review the progress report and document the results in the EDS monthly progress report. At a minimum, quarterly surveillance of work activities shall be conducted by the group leader or his/her designee and documented in a laboratory notebook. The group leader or his/her designee shall sign and date the documented results. The group leader or his/her designee shall supply documentation of the surveillance to the section head in the form of a memo.

19.3 REFERENCES

The following ORNL QA procedures are referenced:

QA-L-18-100,

QA-L-18-101, and

QA-L-18-102.

INTERNAL DISTRIBUTION

1. T. K. Bayles
2. C. H. Brown
3. A. G. Croff
4. T. M. Gilliam
5. P. B. Hoke
6 K. H. King-Jones
7. E. W McDaniel
8-17. R. D. Spence
18. M. G. Stewart
19. Central Research Library
20. ORNL Y-12 Technical Library, Document Reference Section
21-22. Laboratory Records
23. Laboratory Record (RC)
24. ORNL Patent Section

EXTERNAL DISTRIBUTION

25. Office of Assistant Manager, Energy Research and Development, DOE Field Office, Oak Ridge, P. O. Box 2001, Oak Ridge, Tennessee 37831.

26-35. Office of Scientific and Technical Information, Oak Ridge, TN 37831.

36-41. J. A. Voogd, Manager, Waste Processing Technology Unit, Westinghouse Hanford Company, Post Office Box 1970 MO-248/1/R4-03, Richland, Washington.

END

DATE
FILMED
2/25/92