Attachment 5

ORNL QUALITY ASSURANCE PROGRAM

Policy Statement

In order to continue the Laboratory's goals of excellence in all aspects of its work and quality performance in carrying out its urgent commitments, it is the policy of the Laboratory to maintain and enforce a quality assurance program. This program is designed to aid in assuring reliable, efficient, and safe operation of all pertinent experimental, conventional, operational, and test facilities and systems. More specifically, the objective of the quality assurance program is to provide a means for the establishment, control, and verification of the required quality of design, development, procurement, fabrication, construction, inspection, installation, operation, and maintenance of these facilities and systems.

Because of the wide variety of work at the Laboratory, responsibility for the quality of all phases of the work must be accepted and discharged by the line organization, and it is requested that all personnel participate, as necessary, in the quality assurance program. The ORNL quality assurance staff is available to provide advice and service to aid the line organization in performance of this important responsibility as well as to assure me that the objectives of the program are being carried out in an effective and efficient manner.

Herman Postma

Herman Postma, Director
Oak Ridge National Laboratory

CHEMICAL TECHNOLOGY DIVISION

Policy Statement

It is the policy of the Chemical Technology Division to maintain and enforce an effective quality assurance program. The program is formulated to assist in assuring reliable, efficient, and safe operation of all significant activities and facilities. Specifically, a primary objective of the quality assurance program is to provide a system for the establishment, control, and verification of the required quality of design, procurement, fabrication, installation, inspection, operation, and maintenance.

Procedures that implement this policy are set forth in this Division's Quality Assurance Manual and are responsive to the ORNL Quality Assurance Manual and Standard Practice Procedure D-2-16, Quality Assurance Program.

All Division personnel shall actively support the quality assurance program and assist Division management in QA program improvements.

The Division's Quality Assurance Coordinator has the responsibility for coordinating all quality assurance activities and preparing, issuing, and maintaining the Division's quality assurance procedures. He also has the responsibility for performing QA audits, personnel QA training, and serves as the primary contact with the Laboratory's quality assurance organization.

Any unresolved conflicts that occur on quality assurance matters should be brought to the attention of the Division Director for resolution.

R. G. Wymer

R. G. Wymer, Director
Chemical Technology Division

INTRODUCTION

This manual sets forth quality assurance (QA) procedures and policy of the Oak Ridge National Laboratory (ORNL), including those quality-related activities that are an integral part of Division operating procedures. These Division quality-related activities are frequently not isolated and identified specifically as QA activities; however, they do represent a substantial part of the total ORNL QA program. The Nuclear Division of Union Carbide Corporation (UCC-ND) has placed full responsibility on the line organization both for the quality of items and services and for the assurance of that quality. Therefore, the application of QA to experiments, projects, and programs is determined by the project and line-organization personnel in consultation with the Division QA Coordinators (QAC's) in such a way that each application is consistent with the ORNL QA policy. No single set of QA requirements can be imposed satisfactorily on all experimental programs because of the wide variety of individual experiments and of experimental facilities operated by the research and development (R&D) divisions. These range from bench-scale experimental facilities designed for investigations associated with basic research to large engineering-scale facilities, including the operation of the several research reactors, the accelerators, and the cyclotron facility. The intensity of the QA effort that is applied to a given experiment or project, therefore, must be commensurate with the scope, complexity, duration, and importance of each undertaking; with the potential impact on health, safety, and the environment; and with requirements for reliability and continuity of operation.

This QA manual is divided into four sections:

Section 1 describes how the ORNL QA program implements 18 selected QA elements, including those QA activities taken by the line organization.

Section 2 tabulates the procedures used to implement the ORNL QA program. Part 1 of the tabulation lists ORNL QA procedures, Standard Practice Procedures (SPP), Controlled Manufacturing Manual

(CMM) Procedures, and Service Division Procedures that implement the QA program. Part 2 of the tabulation lists QA procedures prepared by the R&D divisions that implement the QA program within the division and procedures that complement the procedures listed in Part 1 of the tabulation. Section 2 also contains a chart that cross-references the ORNL QA program practices with the standards of the Energy Research and Development Administration (ERDA) and the Nuclear Regulatory Commission (NRC) (i.e., ERDA Manual Chapter 0820; RDT Standard F 2-2; and 10 CFR 50, Appendix B).

Section 3 lists QA procedures prepared by the QA program organization. These procedures are applicable to all divisions.

Section 4 is a glossary of terms used in the QA policy, procedures, and program description. The table lists those terms that are used in a more restrictive sense than the definition given in the dictionary.

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SECTION 3: ORNL QA PROGRAM PROCEDURES

1.0 QA PROGRAM

The ORNL QA Program is developed to meet QA requirements contained in DOE-ORO Order OR 5700.6, Quality Assurance. In addition, the QA program is responsive to specific sponsor QA standards (such as RDT F2-2, Quality Assurance Program Requirements, for certain projects funded by the DOE Office of Nuclear Energy (NE); 10 CFR 50, Appendix B and NQA-1, for the operation and maintenance of the ORNL reactors; and ASME Code, Sections III and VIII, for pressure systems that are subject to the Code).

1.1 QA PROCEDURES

The ORNL QA Program is implemented through a series of QA procedures and other quality-related requirements. QA procedures prepared by the Laboratory QA Program staff apply to all ORNL divisions and are contained in the third section of this manual. In addition, service divisions and R&D divisions have QA manuals for the operation of their QA programs. These procedures are referenced in the second section of this QA manual. The numbering system used for ORNL procedures is in the form, QA-L-X-XXX. Division QA procedures follow a similar system with the "L" (for "Laboratory") being replaced with division code letters (see ORNL QA procedure QA-L-1-105).

1.2 QA PLANNING

A QA Assessment (QAA) is prepared for all projects and activities (see QA-L-1-103). The QAA identifies and evaluates the risk of potentially significant quality problems and identifies those for which special QA activities are necessary to provide adequate confidence that these problems will be prevented or the impact reduced if failure occurs. The QAA contains, in addition, a brief description of the project, a list of all standard QA related procedures used in risk determinations, and rationale for acceptable risk determinations. When potential quality problems with an unacceptable risk are identified, a QA Plan (QAP) is prepared (see QA-L-1-104). The QAP lists the potential quality problems with an unacceptable risk, and the special QA actions to be taken to minimize the probability of the problem occuring. The QAP contains, in addition, a brief description of the project, an organization chart, a listing of the individuals responsible to implement the QA actions, and a schedule for implementing QA actions. QAAs and QAPs are normally approved by management, QA Coordinator, (QAC), and the QA Program Director (QAD). QA Planning for capital construction and line-item projects is processed in accordance with QA-L-1-108. Distribution is made to sponsoring organizations for review and/or approval, when requested.

The UCC-ND Engineering organization participates in the QA management of line-item projects, general plant projects, and all directive projects. When requested by the program organization, UCC-ND Engineering will also participate in QA management of nondirective capital-equipment and expense-funded projects. In such cases, UCC-ND Engineering is delegated to administer the QA during design, procurement, construction, and installation of such projects. UCC-ND Engineering prepares QAAs and QAPs in accordance with the requirements of QA procedure EQA-7.

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1.3 TRAINING AND MOTIVATION

A broad range of training and indoctrination programs are incorporated in the ORNL QA Program. Quality assurance training sessions are periodically scheduled for all QACs, and continuing QA group discussions are conducted at staff meetings by the ORNL QA staff for division supervisory personnel. These discussions are supplemented, when deemed appropriate by division management, by periodic QA seminars by the QACs in their own divisions. QA consultants are invited to ORNL to present QA training sessions for both QA personnel and line management. Quality assurance personnel are also sent to continuing-education courses on QA-related subjects.

Each service division is responsible for the indoctrination, training, and qualification of its personnel. In general, personnel are trained on-the-job and are qualified by their supervisor for each specific job. Training courses in a large number of specific fields have been and continue to be developed and presented when analysis of performance indicates a need or when DOE directives require it. These training programs include training in welding and inspection leading to certification of compliance in accordance with the requirements of National Codes and Standards.

Posters on QA-related matters are periodically displayed on bulletin boards throughout ORNL and in the ORNL divisions at the Y-12 Plant as a constant reminder to personnel of good QA practices and policies. Also, QA bulletins are issued to supervisory personnel to call attention to quality deficiencies that have resulted in significant delays or that have been costly.

1.4 REPORTS

Internal monthly QA progress reports that describe activities of the QACs and activities of the QA staff are issued to QA personnel. Input to the monthly reports is provided by monthly QA progress reports prepared by the QACs for their division management and the QAD. In addition, a monthly report that describes the status of QA activities is prepared for ORNL management (see QA-L-1-109).

The status of significant quality related documents and actions are tracked, with the aid of a computer, to provide information to line management and QA personnel for timely and effective management of their QA programs. These reports are issued on a periodic basis (see QA-L-1-110).

Quality problems are investigated and reported. Corrective action is taken through a quality investigation and corrective action procedure (QA-L-6-103). Unusual occurrences, as defined by DOE Order OR 5484.2 are reported to ORNL management and to DOE-ORO through a UCC-ND unusual occurrence reporting system (Standard Practice Procedure D-5-16).

2.0 ORGANIZATION AND RESPONSIBILITIES

ORNL is operated for DOE by UCC-ND, UCC-ND provides ORNL with Engineering Design, Project Engineering, and Purchasing services. For ORNL projects fabricated and installed in the Y-12 area, UCC-ND provides inspection services by the Technical Division and fabrication, installation, and calibration services by the Y-12 Maintenance Division and the Y-12 Fabrication Division.

The UCC-ND Office of Quality Assurance, see Figure 1, establishes and interprets the overall Nuclear Division QA program and coordinates its implementation. The Office also serves as a focal point for Nuclear Division communication with the DOE-ORO Standards and Quality Assurance Division.

2.1 OAK RIDGE NATIONAL LABORATORY

Quality-assurance activities at ORNL are coordinated by the QAD, who reports to the Director for Quality Assurance and Inspection. Quality Assurance and Inspection is under the Director for Administrative Services. The QADs staff consists of two QA specialists who are principally responsible for QA audits, QA training and motivation, and QA procedures; and a Reports and Data Assistant. Each research and development (R&D) division and each service division supporting such programs has one or more QACs appointed by its respective division director to coordinate the QA activities within the division. The QACs are responsible to their division directors for the QA activities within their divisions and for keeping the QAD informed of division QA activities. The ORNL organization is shown in Figure 2 and the QA organization in Figure 3.

2.1.1 QA Program Organization

The QA Director is responsible for:

1. Administering the QA Program in a manner that is consistent with the requirements of UCC-ND Standard Practice Procedures (SPP), other applicable ORNL procedures and practices, DOE, and other sponsoring organizations;

2. Interpreting QA requirements for ORNL personnel;

3. Providing general guidance to the ORNL division in preparation of QA assessments and plans;

4. Reviewing and approving QA-related material prepared by the various divisions and programs;

5. Arranging for audits of all ORNL QA activities;

6. Keeping ORNL management advised periodically of QA activities and recommending changes to the QA program as necessary.

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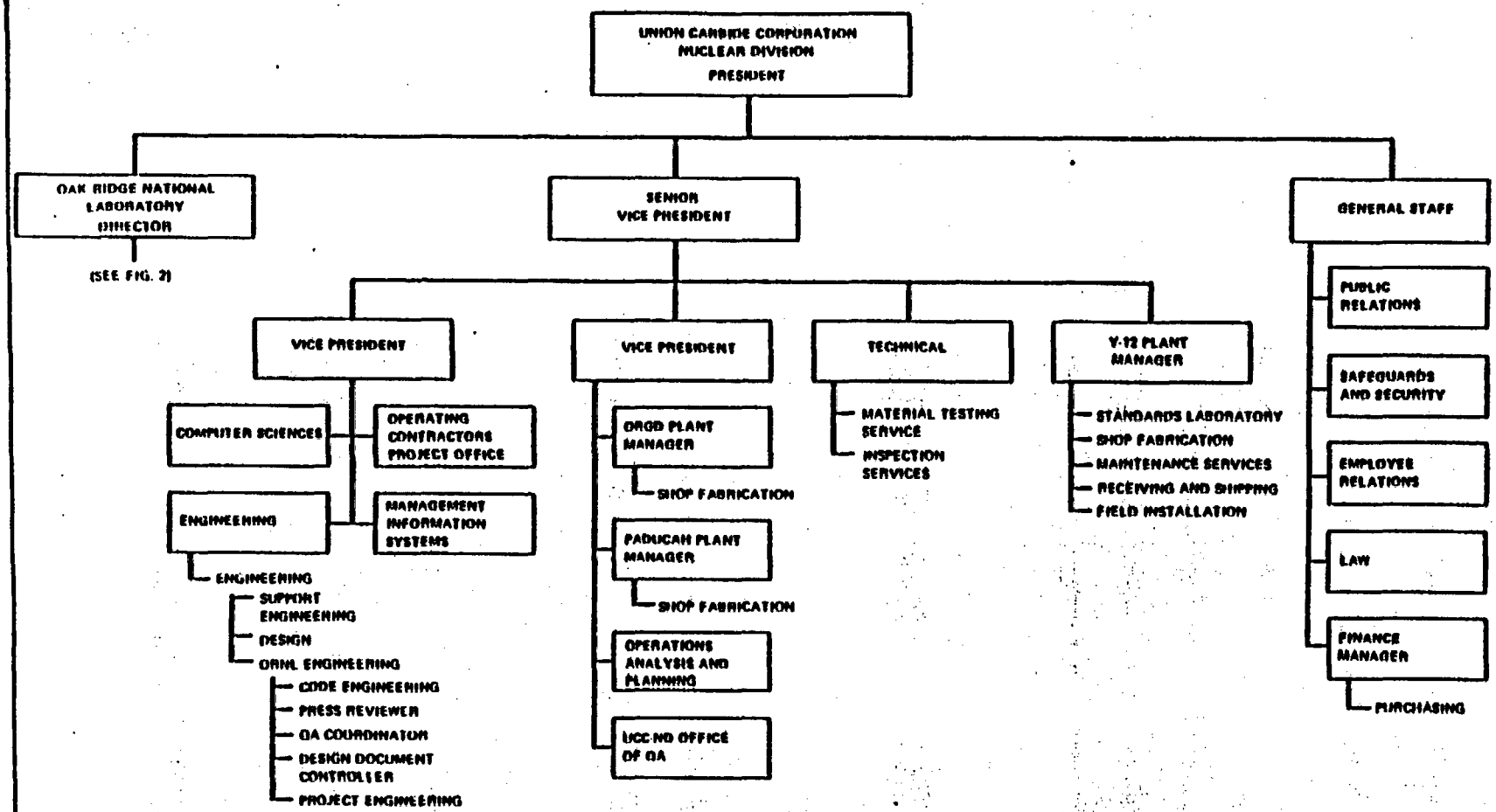

Figure 1. Union Carbide Corporation, Nuclear Division Organization Chart

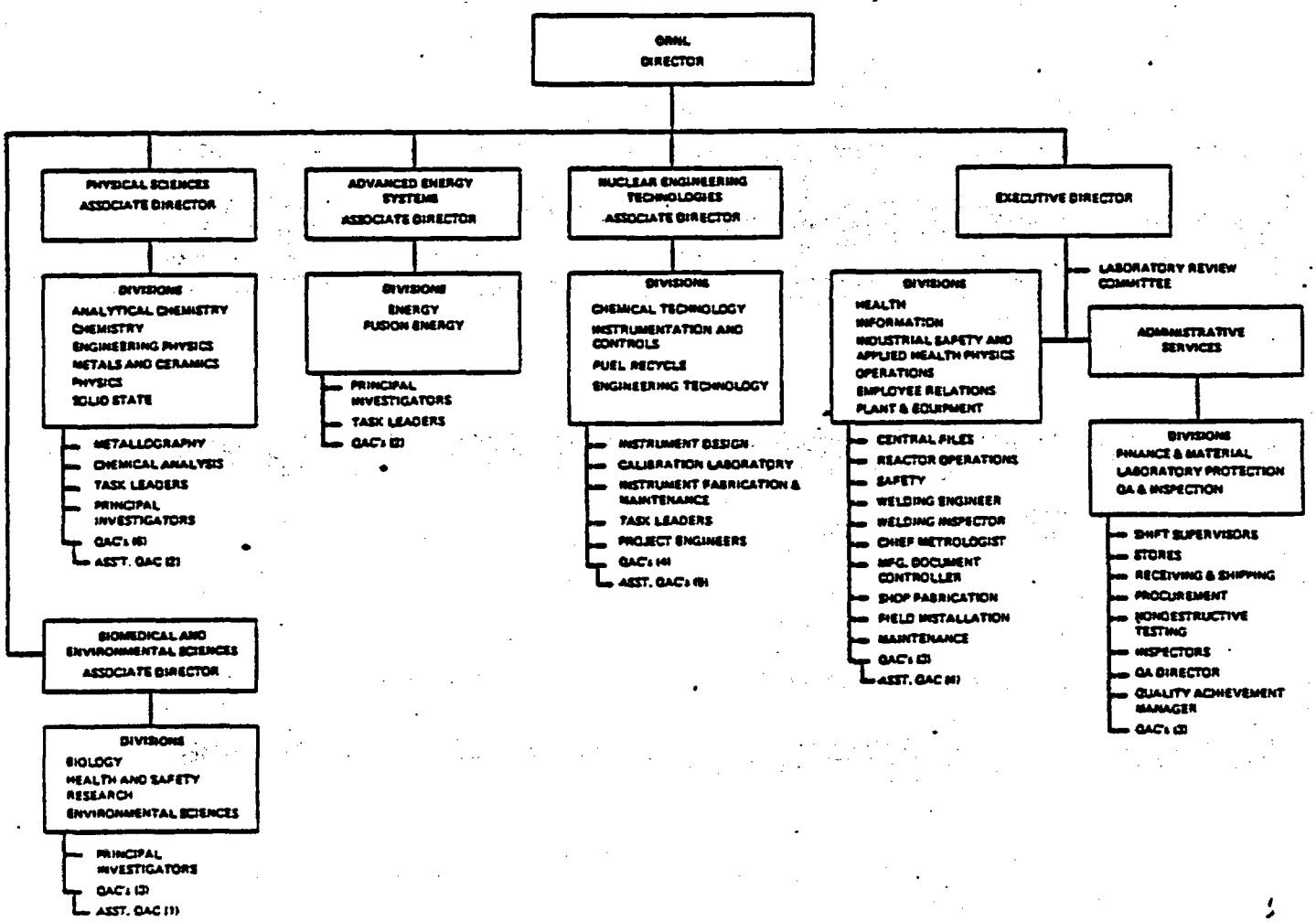

Figure 2. Oak Ridge National Laboratory Organization Chart

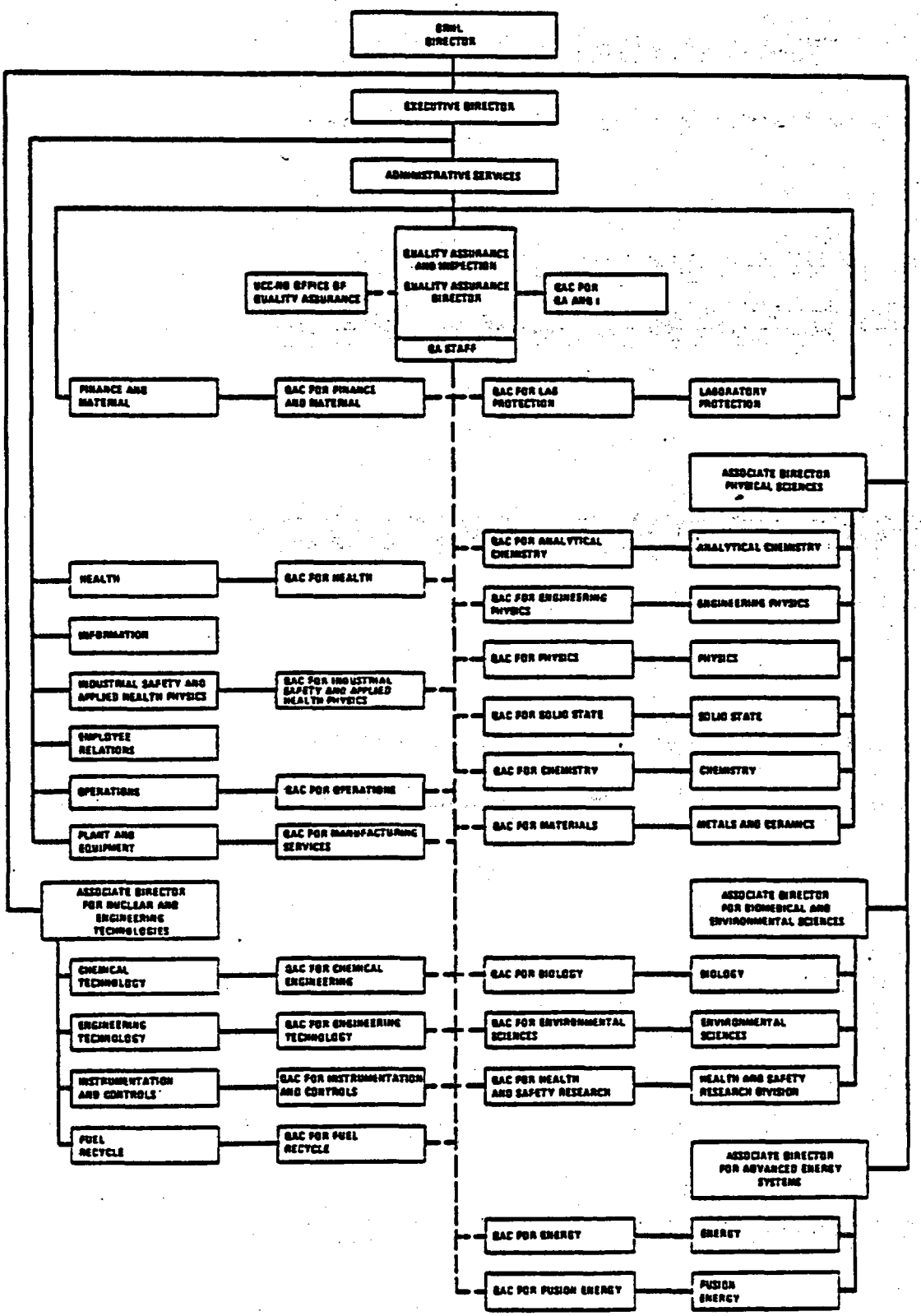

Figure 3. Quality Assurance Program Organization Chart

7. Maintaining close liaison with QACs to achieve a satisfactory QA effort throughout ORNL;

8. Maintaining a liaison with the appropriate outside organizations in promoting and improving QA standards and applications;

9. Establishing and maintaining programs for strengthening the needed activities of QACs and arranging for training in specialized areas as necessary.

10. Maintaining close liaison with the service divisions to assure that the design, procurement, fabrication, construction, inspection, installation, operation, and maintenance procedures being used conform with the latest codes, standards, and other ORNL QA requirements;

11. Preparing and maintaining an ORNL QA manual;

12. Monitoring QA activities on ORNL projects for which UCC-ND Engineering has QA cognizance; and

13. Arranging for educational and motivation programs on QA activities for ORNL personnel.

2.1.2 QA Coordinators

The division QACs are responsible for:

1. Coordinating and assisting in the preparation of division QA-related documents and arranging for review and approval, when appropriate, by the division director and review by the QAD;

2. Keeping the QAD informed of QA activities within the division or program;

3. Being responsible to the director for QA activities within the division or program;

4. Cooperating with other QACs in coordinating mutual QA activities.

5. Assisting management in implementation of QA objectives within their division;

6. Performing division audits and assisting the QAD in performing ORNL audits;

7. Interpreting QA procedures, instructions, and policies for the division;

8. Reviewing and approving division QA assessments and plans;

9. Reviewing and approving division QA requirements on engineering documents; and

10. Seeking out and reporting potential quality problems.

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2.1.3 Quality Assurance and Inspection

Quality Assurance and Inspection (QA&I) provides inspection services in the areas of (1) periodic safety inspections, (2) nondestructive examinations, (3) manufacturing surveillance, and (4) receiving inspection. Periodic safety inspections are performed on pressure-containing equipment, air-filtration systems, material-handling equipment, and nuclear-reactor containment systems at the direction of ORNL management. Nondestructive examination is performed routinely on raw materials and applied to special problem situations on request. Manufacturing surveillance is applied to materials and fabrications made in the ORNL shops and by on-site subcontractors, as required. A variety of special projects in related areas are also carried out.

The director of QA&I acts at the Quality Achievement Manager when fulfilling the requirements of the Controlled Manufacturing Procedure Manual (CMM) for ASME-Code design and manufacture in ORNL.

2.1.4 Controls Systems, Instrumentation, and Instrumentation Calibration

The Instrumentation and Controls (I&C) Division provides ORNL with development, design, and mathematical modeling of a full range of measurement and control systems. Areas covered are process variables, time standards, digital electronics, computer interfacing, mini-computers, microprocessors, telemetering, reactor instrumentation, radiation monitoring, spectrometry, pollution monitoring, robotics, electro-optics, biomedical electronics noise signature analysis, vacuum-system instrumentation, and allied categories.

Besides these services, the division maintains a vigorous research program in applied temperature measurements, with calibration support by the division's Metrology Research and Development Laboratory (MRDL). The MRDL also carries out research to improve the accuracy and reliability of physical measurements at ORNL and provides highly accurate and precise instruments and measurement standards for special calibration services.

Normal instrument calibration and maintenance, by request or as scheduled by the Maintenance Information System (MIS, a computer-oriented scheduling system), are part of the division's services to ORNL.

2.1.5 Chemical Analyses

The Analytical Chemistry Division, reporting to the Associate Laboratory Director for Physical Sciences, in addition to carrying out an extensive basic research program, also provides typical analytical-chemistry services for all other ORNL divisions. Typically, this service performs more than 270,000 analyses per year.

2.1.6 Special Nondestructive-Examination and Welding Techniques

The Metals and Ceramics Division, reporting to the Associate Laboratory Director for Physical Sciences has sections devoted to developing special techniques in nondestructive examinations and in welding. These services are available to all ORNL Divisions in solving difficult welding-inspection problems.

2.1.7 Metrology

The Dimensional Inspection Facility is in the Fabrication Department of the Plant and Equipment Division (see Figure 3). This facility is responsible for providing inspection services on items fabricated by the Fabrication Department and on items fabricated for the department by outside suppliers. Other services provided by this group include calibrating departmental dimensional-measuring tools and working standards; maintaining calibration files and computer recall systems, providing calibration services to other ORNL divisions; and servicing and calibrating accountability balances, scales, and working mass standards.

2.1.8 Welding Engineering and Inspection

Welding engineering services are provided to the Fabrication Department of the Plant and Equipment Division. Welding inspection of in-house and field-fabricated and installed components is provided through a group of welding technologists (see Figure 2). It is the responsibility of this group to develop new welding techniques, to prepare ORNL welding procedures, to maintain the ORNL Welding Procedures Manual, and to inspect welding performed by ORNL craftsmen.

When third-party inspection is required, this service is provided by QA&I.

2.1.9 Fabrication Department Metallurgical Support

Two staff metallurgists review and provide professional services on metallurgical problems related to fabrication. In particular, they review fabrication problems related to welding, materials, and heat treatment.

2.1.10 Laboratory Director's Review Committees

The Laboratory Director's Review Committees are responsible for an independent evaluation of ORNL's operational safety programs and for reporting their conclusions and recommendations directly to the Laboratory Director. Members are appointed to the Laboratory Review Committees by the Laboratory Director, and the activities of the Committees are coordinated through the Office of the Executive Director as shown in Figure 2. The following committees have been established: Accelerators and Radiation Sources Review Committee, Criticality Committee, Electrical Safety Committee, Radioactive Operations Committee, Reactor Experimental Review Committee, Reactor Operations Review Committee, Transportation Committee, Biohazards Committee, and High Pressure Equipment Review Committee (see Section 2.1.12).

2.1.11 Designated Pressure Reviewers

Designated Pressure Reviewers are a group of engineers registered as professional engineers in the State of Tennessee who are experienced in the design of pressure-containing equipment and in the requirements of the ASME Pressure Vessel Code. They

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are appointed by the Associate Laboratory Director for Nuclear and Engineering Technologies to review and approve new pressure-system designs before such systems are placed in service (see ORNL Standard Practice Procedure 12). The Pressure Reviewer selected to review a specific design will be one who has not been involved in the design of that specific component. Upon completion of each review, the Reviewer files a report of his or her findings with the user, the Pressure Reviewees, the QAD, and the Director of the Office of Operational Safety.

2.1.12 High Pressure Review Committee

This is a standing committee designated to review the design and operation of pressure systems that will operate at pressures above 20.8 MPa (3000 psig). The committee, appointed by the Laboratory Director, reviews high-pressure systems and reports its findings to the Executive Director, the QAD, the Director of the Office of Operational Safety and the user. This committee is composed of representatives from ORNL Engineering, Metals and Ceramics Division, Safety, and ORNL management.

2.2 UCC-ND ENGINEERING

The UCC-ND Engineering organization provides design-engineering, project-engineering, and support- (construction-) engineering services to ORNL and reports to the Nuclear Division Vice President for Engineering and Computer Sciences as shown in Figure 1. QA interfacing activities between ORNL and Engineering, during construction, is in accordance with QA-L-17-100. The UCC-ND Engineering Quality Assurance Engineer coordinates the QA activities within UCC-ND Engineering and interacts with production plants and ORNL's QA organizations. Those groups of UCC-ND Engineering assigned to specific plant sites each have Quality Assurance Engineers who are designated by the respective UCC-ND Engineering Site Manager to coordinate the Engineering QA activities of that installation. The QA Engineers have the responsibility and organizational freedom for developing new or revised procedures, for assisting the line-organization and project-team members,* for setting up indoctrination and training activities within their respective organizations, for participating in quality problem investigations and reporting, for verifying compliance, and for initiation audits.

2.3 UCC-ND Y-12 PLANT

The UCC-ND Y-12 Plant organization provides support services to those ORNL Divisions located in the Y-12 area, which includes Engineering Technology Division, Fusion Energy Division, Biology Division, Stable Isotope Department of Operations Division, and the Spectrometry Department of the Analytical Chemistry Division. The Y-12 organization and the services provided to ORNL are shown in Figure 1. In addition, Y-12 shops provide fabrication services to all ORNL divisions.

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*Individuals assigned specific responsibilities for a specific project. (See "Guide for Contractors Participating in ORO Construction Program, Part 1-F-1, 2 and Part IV. Also see UCC-ND Engineering Procedure EP-A-06, "The Project Team Concept.")

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The Y-12 Plant QA organization consists of a Plant Operations QA Coordinator (appointed by the Plant Manager) who chairs the Plant Operations QA Committee. This committee is composed of the Y-12 Plant Division QA Coordinators who act to coordinate the QA activities in the plant operations.

3.0 DESIGN CONTROL

3.1 ORNL ENGINEERING RESPONSIBILITIES

During the design of a project, UCC-ND Engineering provides engineering services to ORNL through its ORNL Engineering organization (see QA-L-2-100). ORNL Engineering secures specialized skills from other organizations to design groups in UCC-ND Engineering or from architectural-engineering (A-E) firms, as necessary. Guidance to A-Es for the application of QA to capital construction projects is provided by the document, "Application of QA Guidelines for A-Es Participating in the DOE-ORO Construction Program." Engineering will conduct the initial QAA, and if required by the QAA prepare the QAP. Engineering will serve as the "QA Secretarial" and in this capacity and maintain the "master" QAA and QAP.

Design control is provided in accordance with UCC-ND Engineering QA procedures.

During the design phase, ORNL Engineering in concert with other project team members is responsible for performing the following activities:

Design Planning - Design planning includes determining project requirements and objectives, discipline responsibility, design schedule, number and type of design documents required, and design criteria.

Design Coordination - Engineering coordinates the project design effort, including the activities that are carried out with other organizations and other design disciplines with the purpose of maximizing the mutual flow of design information.

Evaluation of Design - It generates technical and engineering data to evaluate the adequacy of prospective designs for satisfying the design criteria and operational requirements and incorporates this information into design documents.

Design Organization Practices - Engineering prepares engineering documents that contain the design details necessary for the project adequately referencing specifications for materials, fabrication, storage, handling, shipping, inspection and testing, and acceptance criteria and adequately identifying required codes, standards, and practices. It also prepares special specifications and procedures when necessary to attain design requirements. Preoperational, operational, and maintenance design features are included in engineering documents when necessary to meet the design criteria. Item-traceability information is also included in design documents when required. Engineering procedures are specified to ensure a uniform system of identification on engineering drawings, specifications, and related design documents for materials, parts, systems, manufacturing and construction procedures, and inspection processes.

Engineering participates in the resolution of technical problems during procurement, fabrication, construction, and initial operating phases of a project and provides a mechanism of feedback to the customer of important information from fabrication, construction, and start-up operations as an integral part of the design functions.

Design Reviews - Engineering performs design reviews of design documents at appropriate stages of design to substantiate conformance with design requirements in areas such as mechanical features, dimensions, electrical, electronic, instrumentation, material acceptability, codes and standards, welding and inspection, cleanliness, fabricability, operability, operational safety, radiation hazards, and other QA considerations. It also reviews documentation and engineering studies supporting the design.

Engineering-Document Identification - Engineering maintains an identification system for design documents that identifies each document with a specific project.

Design Document Approval for Release - Engineering reviews completed design documents with personnel that had requested the work or others designated by the project team for review, and it revises documents as required and obtains the necessary approvals. Prior to the release of design documents, the division reviews them to ensure that all requirements for project design have been met and that all the necessary approvals have been obtained.

Document-Release and Change Control - Engineering utilizes a release system for design documents to ensure that such documents are released only by authorized persons, distributed to prescribed parties, and kept updated. Its change-control system provides a method to be incorporated into previously released design documents and includes proper notification and reissue steps. Significant design changes to approved documents will be made only with approval of the design organization.

Design-Records Storage and Maintenance - During the design stage of a project, documents will be maintained by Engineering in a secure place where they are readily retrievable on request. A design job file will be maintained by the design organization for each project.

Audits - Engineering conducts periodic internal design audits to evaluate adequacy and implementation of QA activities related to the design phase of a project.

3.2 ORNL INSTRUMENTATION AND CONTROLS DIVISION RESPONSIBILITY

Design control for instrument and control systems is provided in accordance with the I&C Division's QA Procedures and the Division's Drafting Manual.

3.3 INDEPENDENT REVIEWS

ORNL uses many different methods for performing independent reviews of designs prepared by ORNL Engineering. The reviews vary in intensity depending upon the intended use, importance, and complexity of the design being reviewed; the degree of standardization; the state of the art; and the design's similarity to previously proven designs.

3.3.1 ORNL User Reviews

A representative from the ORNL user division reviews and approves all design documents. On selected projects the division QAC also reviews and approves the QA requirements.

3.3.2 Routine Design Reviews

Preliminary drawings and specifications of proposed projects to be located in ORNL are routinely reviewed by the ORNL Fire Protection Department, Industrial Safety, and the Office of Operational Safety to ensure safe operation. Drawings and specifications may also be reviewed by one or more of the following ORNL speciality groups: Health Physics, Industrial Hygiene, Environmental Protection, Utilities, Test and Inspection, Security, and Maintenance (see Paragraph 3.3.6 for ORNL projects located in the Y-12 Plant).

3.3.3 Special Design Review

Independent design reviews of projects of high complexity or of major importance are conducted by personnel appointed by the ORNL division in charge of a project. Such personnel are chosen from those not directly responsible for technical or administrative aspects of the particular design. The composition of a design review committee or design, materials, engineering, manufacturing, testing and inspection, QA, operation, and maintenance. This design review is conducted in accordance with ORNL Procedure QA-L-4-100.

3.3.4 Pressure-Vessel-Equipment Reviewers

Reviewers of pressure-vessel equipment act at the request of the user division and check the design of pressure vessels and piping for compliance with ASME pressure-vessel codes to assure safe operation (see paragraph 2.1.11).

3.3.5 Laboratory Director's Review Committees

Certain design-review functions are performed by the following committees appointed by the Laboratory Director. These reviews are performed to assure safe operation. In general, these committees only review projects located and operated in ORNL or shipments of radioactive or fissile materials from the ORNL area. For ORNL projects located and operated in the Y-12 Plant area, refer to paragraph 3.3.6 for information about independent design reviews.

Radioactive-Operations Committee - This committee reviews the design and operation of ORNL facilities handling or processing significant quantities of radioactive materials and the practices used in the disposal of radioactive solid, liquid, and gaseous waste. All new radiochemical facilities or processes are reviewed prior to operation; existing facilities are reviewed periodically and whenever changes in purpose or scope are proposed.

Reactor-Operations Review Committee - This committee performs an independent annual safety review of all ORNL reactors. The committee also performs ad-hoc reactor reviews of safety-analysis documents, evaluation of significant changes in reactor-operating policy and joint reviews, when appropriate, with the Reactor-Experiment Review Committee.

Accelerators and Radiation-Sources Review Committee - This committee is concerned with all safety aspects involved in the operation of devices classified as accelerators and radiation sources; specifically, it inspects and reviews radiation shielding, interlock systems and lockout devices, radiation-monitoring and warning devices, electrical safety, hazard evaluation, operational protocols, and record keeping.

Reactor-Experiments Review Committee - This committee reviews all new or unusual experiments proposed for insertion in ORNL reactors.

Criticality Committee - This committee has review and approval jurisdiction over operations that involve the handling, storage, transportation, and disposal of significant quantities of fissile material.

Electrical-Safety Committee - This committee has responsibility for review of electrical safety concerns in ORNL facilities and operations, and to maintain a set of electrical-safety guides, which represent minimum safety standards to be met by ORNL divisions.

Transportation Committee - This committee, on its own initiative or at the request of management, reviews safety aspects of all phases of operations involved in the transfer of radioactive or fissile materials from one ORNL facility to another or from one ORNL group to another as well as reviewing shipments made off-site. The committee is responsible for review and approval of information prepared for submission to DOE for approval of casks for off-site shipments.

High-Pressure-Equipment Review Committee - This committee, on its own initiative or at the request of management, reviews all safety aspects of proposed or operating high-pressure equipment (see Paragraph 2.1.12).

Biohazards Committee - This committee reviews and evaluates the hazard to humans of infectious carcinogenic, toxic, and genetic agents employed or generated in ORNL research projects.

3.3.6 Design Review in Y-12 Plant

Preliminary drawings and specifications of proposed ORNL projects to be located in the Y-12 Plant are routinely reviewed by the Y-12 Plant Health and Safety Coordinating Committee to assure safe operation. This committee consists of representatives from the Fire Protection Engineering Department, the Industrial Hygiene Department, the Mechanical Inspection Department, the Radiation Safety Department (including Health Physics), and the Safety Department. On significant projects, a safety-analysis report is prepared and forwarded to the Y-12 Safety, Documentation Coordinator, and Plant Manager.

The Y-12 Plant Laser Committee provides guidance to UCC-ND Engineering and reviews laser installations for safety and compliance with Y-12 Plant Procedures on Laser Installations (see Y-12 Plant Health and Safety Procedure No. 70-625).

The Y-12 Plant Radiation Safety Feature Committee reviews proposals and completed installations of routine x-ray equipment and radioactive sources (see Y-12 Plant Health and Safety Procedure No. 70-102). Special installations are also reviewed by the appropriate ORNL review group.

4.0 PROCUREMENT-DOCUMENT CONTROL

ORNL ordering divisions are responsible for ensuring that documents necessary for a procurement, such as plans, specifications, engineering drawings, instructions, procedures, codes, standards, requisitions, and purchase orders are prepared for a procurement and are made a part of the contract. Quality-related subjects that are covered by such above documents are source selection and evaluation, supplier's QA program, material inspections, nondestructive examination, fabrication, processing, documented supplier reports and due dates, supplier data packages, supplier certifications, supplier nonconformances, supplier deviations, QA audits, source surveillance and inspection, shipping, operating manuals, equipment acceptance tests, and quality records (see QA-L-9-100).

For research and development subcontracts, measures are established to: (a) select and invoke appropriate QA requirements in procurement documents, (b) evaluate and select subcontracts, (c) monitor implementation of QA requirements and (d) measure results of R&D contractor's QA program. The measures apply to R&D contracts involving operation or testing of experimental equipment and systems. Guidelines are provided for R&D contracts involving studies, and the development and use of computer programs and mathematical models (see QA-L-9-101).

The plant procurement organization (Materials Department of the F&M Division for ORNL divisions located at the X-10 site) reviews the procurement package, ensures that it contains all necessary ORNL reporting forms needed by the supplier, makes lists of items to be furnished under the contract, and adds any supplementary requirements regarding UCC-ND Purchasing Division actions relating to administrative matters.

The UCC-ND Purchasing Division upon receiving a procurement bid package, coordinates all procurement-document control for a procurement, ensures that Supplier Bids on alternate proposals are communicated to the ordering division, and that final Purchase Orders are prepared.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality are controlled by procedures that are contained in the ORNL QA Manual or in division or program procedures manuals, which are approved by division or program directors. The Standard Practice Procedure (SPP) Manual contains instructions and procedures that also are applicable to a QA program.

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5.1 DESIGN, PROCUREMENT, MANUFACTURING, AND CONSTRUCTION PHASES

The ORNL and other UCC-ND plant and division manuals contain requirements for instructions, procedures, and drawings that are used, as applicable, in the ORNL QA Program; for example, these are the Engineering Procedures Manual, the Engineering Standards Manual, and the Welding Manual. These procedures control the application of the QA elements listed in Section 2 of this manual during the various phases of the ORNL QA program. Documents and forms used include program check lists, planning documents, quality verification decals, work-authorizing documents, procurement documents, engineering drawings, manufacturing plans, inspection and test plans, equipment test instructions, nonconformance reports, deviation requests, unusual-occurrence reports, quality investigation reports, data certification, inspection and test reports, QA auditing reports, and QA program reports. These documents affect control of quality from the planning stage through acceptance and pre-operational testing of components and systems. Test procedures and acceptance criteria are detailed in these documents.

Design criteria are formalized, when deemed necessary by line-management, by preparation of engineering drawings and specifications with all applicable engineering, technical, and QA procedures or instructions included to ensure that quality expectations will be attained.

5.2 OPERATIONS PHASE

Planning for operation of R&D projects includes schedules, the start-up check-outs, tests, and inspections required to place the project into operation, and determination of operational modes and the essential testing and in-service inspections required to sustain operation in accordance with project objectives.

Pre-operational check-out and evaluation procedures and/or instructions are prepared for checking systems and their interaction with other systems for completeness and operational worthiness. Operating procedures and/or work instructions are prepared, when deemed necessary by the line-organization, for predetermined conditions of start-up, normal, shutdown, and emergency operations. Technical specifications are prepared separately or with operating procedures that define the operating capabilities of the project. Operating logs and check lists are used to record actual operating events. Operational reviews are conducted periodically to evaluate the readiness and safety; the results of inspections and tests, including failure investigations; the methods and procedures that are employed in operating the project; and whether the system meets its operating objectives.

5.3 MAINTENANCE PHASE

Maintenance-work requests are originated by the user group. The work request describes work to be performed and includes requirements for each job, such as drawings, specifications, procedures, manuals, and other pertinent data, including safety work permits. Maintenance activities are planned and performed by plant maintenance groups in accordance with procedures prepared be the applicable maintenance division. Computer recall systems are used in both Instrumentation and Controls Division and in the Plant and Equipment Division to assure instrumentation calibration is current.

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6.0 DOCUMENT CONTROL

Documents, such as plans, drawings, specifications, procedures, and instructions that establish the item description and quality requirements or that prescribe inspections and test to determine compliance of the completed item with technical requirements are defined as quality-related documents.

Quality-related documents are reviewed prior to their release by designated individuals or groups that are cognizant of the QA requirements to assure that the documents are clear, accurate, and authorized. Changes to these documents are normally reviewed and approved by the same organization that performed the original review and approval (see QA-L-3-100).

Quality-related documents are approved by a designated individual and normally by the QAC. These approvals verify that particular control requirements applicable to the document have been satisfied and that the designated individual certifies that the document is acceptable for its intended use. Understanding and acceptance is indicated by the signature and the date on the document.

The initial release and distribution of documents and changes thereto are the responsibility of a designated releasing authority; who has or constitutes that authority depends on the document type. The releasing authority is also responsible for directing the user how to dispose of obsolete quality-related documents previously issued and for obtaining any necessary verification that such action has been taken, when required by the complexity of the project.

Controlled quality-related documents are uniquely numbered, and they are identified on a controlled master list so that the letter or number used to designate the current issue can be quickly and easily checked to ensure that the most up-to-date version of a document is used. This list is updated on a periodic basis as documents are changed and reissued. Between updatings of the master list, document changes are permitted when supported by approved Deviation Notices (UCN Form 5458A). Documents* that may be changed with such notices are Controlled Manufacturing Manual (CMM); Controlled Manufacturing Procedures (CMP); drawings, specifications, and procedures; and manufacturing and inspection plans.

Work-authorizing documents are the instructions prepared by the ORNL R&D divisions and service divisions that authorize service divisions to perform work. They include Engineering Service Orders' Work Orders and Cross Orders for items manufactured, installed, and maintained by ORNL: and Purchase Requisitions. Other documentation that might be required for installation, construction, operation, and maintenance work includes Radiation Work Permits, Safety Work Permits, Construction Work Permits, and Operations Safety Work Permits.

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*All of these documents concern design, manufacturing, and installation activities by ORNL service groups in accordance with requirements of the ASME Boiler and Pressure Vessel Code, Section III and VIII.

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7.0 CONTROL OF PURCHASED MATERIALS, EQUIPMENT, AND SERVICES

When requested by project management, source surveillance of suppliers and manufacturers is performed during the course of a procurement by designated ORNL personnel. In such events, inspection personnel are periodically sent to a supplier's plant or provided to project management. Inspection personnel includes in their reports recommendations for any required corrective action (see QA-L-9-100).

Any proposed changes to design documents, standards, specifications, manufacturing procedures, inspection and test procedures, QA programs, or other documents forming a part of procurement contacts require approval of the item user, and Engineering, when appropriate.

Data packages on completed items are submitted to the using division after being reviewed for compliance with technical and quality-related requirements. The Materials Department in the receiving plant performs routine receiving inspection and ensures that the agency designated to perform special inspections, as indicated on the Purchase Requisition, is notified. Receiving-inspection results and all quality-verification documentation submitted by the supplier are transmitted to the ordering division. Nonconformances are transmitted to the UCC-ND Purchasing Division Contract Administrator so that contracts will not be closed out until corrective measures are taken and the item is fit for intended use.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Reactor-safety-related items, ASME-Code items, and other special high-quality items (including instruments, materials, parts, componenrs, and subassemblies) are identified in a manner that provides direct traceability to the documentation that verifies the acceptability of the items. This means of control was established to ensure that nonconforming materials, parts, and components that have been rejected will not be used. The methods of identification used does not adversely affect the functional quality of the item identified.

Supplier-provided items are identified and documented by the supplier in a manner consistent with applicable codes or in the manner specified in the procurement documents. When several parts of high-quality items are joined in fabrication, a list of parts and the corresponding identification documents will accompany the assembly. This documentation will normally include any model numbers, heat numbers, part numbers, serial numbers, material certifications, and weld qualifications.

Upon the user division's receipt of materials, parts, and components, inspections are made according to procedures and specifications that contain preplanned inspection and test requirements. If the items are incorrectly identified or incorrectly documented, they are not accepted until the condition is resolved.

Incorrect or defective material, parts, and components are identified with "Hold Tags" and handled in accordance with Section 15 of this manual, "Nonconforming Items" (QA-L-6-100).

Materials, parts, and components manufactured, modified, or installed by ORNL service groups or other UCC-ND service groups, including construction contractors, are identified, documented and controlled in the same manner as described above, when required by project management.

9.0 CONTROL OF SPECIAL PROCESSES

Special processes are controlled to ensure that their objectives are accomplished in a satisfactory manner. Some examples of special processes include: metal joining (such as welding and brazing), heat treating, plating, cleaning, and nondestructive examination (NDE).

Special processes are controlled by ASME Code Section III, VIII, or IX or by other requirements determined during the design phase. The application of a special process is specified on the applicable component, system, or structure drawing. Special processes are performed in accordance with written procedures or instructions, and means are provided for recording evidence of verification of the processes.

Personnel, procedures, and equipment associated with metal joining and NDE are qualified, and the results are documented in accordance with the requirements of ASME Code, Section IX, ASNT SNT-TC-1A; or specially developed procedures. Qualification of other procedures and equipment is based on previous successful operation.

The supervisor of special processes is responsible for ensuring that personnel under his or her supervision are qualified to perform a particular process. When qualification records are required, they are maintained by the cognizant supervisor of the particular special process.

Welder qualification records are stored in a computer data base which is accessible to inspectors and welding supervisors for immediate response. Records include, welders name, weld procedure, position, date of last weld, and expiration date.

10.0 INSPECTION

10.1 PROCUREMENT, MANUFACTURING, AND CONSTRUCTION PHASES

Inspection verifying the quality of work by Service Divisions is performed by personnel other than those who perform the activity being inspected. As a minimum, inspectors must be personnel who report to supervisors other than to the supervisors directly responsible for the work.

Quality Assurance and Inspection (QA&I) is an independent inspection group. QA&I performs source surveillance, special receiving inspections, and ASME-Code-Inspection activities.

When requested by the user, QA&I also monitors inspection activities in supplier's facilities.

All material received from suppliers is routinely inspected by ORNL Materials Department personnel for damage, quality, and item descriptions. Special inspections are performed, when required, in accordance with requirements contained on purchase requisitions.

Inspections are performed by QA&I personnel on all material received at ORNL for ASME-Code fabrication and installation. QA&I also performs mechanical inspections when requested by the Materials Department of the user; electronic equipment inspection is performed by the Instrumentation and Controls Division.

Manufacturing plans, work plans, and/or inspection plans, when requested by design documents or the user, are prepared by the manufacturing or the installation groups and approved by the user and the QAC. These manufacturing and work plans are used to integrate inspection operations with manufacturing or installation operations and to provide the necessary in-process inspections with appropraite sign-off for each. The Inspection Plan and Dimensional Certification Report is used to plan and record dimensional inspections.

Mandatory hold points are identified on the manufacturing plan by QA&I to satisfy the requirements of the user, the ASME-Code Inspector, and the QAC.

When requested by R&D Divisions, specialists in the ORNL Metals and Ceramics Division develop new techniques and perform NDE on special materials and components. Analytical Chemistry Division performs chemical analyses on materials in support of procurement, manufacturing, and construction activities. These analyses are normally performed to verify the chemical composition of various metal products.

10.2 OPERATION AND MAINTENANCE PHASE

On a scheduled basis in-service inspection of various components of operating research reactors is performed, and the results are evaluated.

Selected instruments and mechanical equipment are placed in the preventive maintenance program for routine inspection and maintenance. These inspections and maintenance activities are computer programmed and scheduled. Other inspections are performed as called for by project management (see Paragraph 11.2 for in-serving testing activities).

The Analytical Chemistry Division performs routine chemical analysis for process control and operation of projects and facilities. In addition, specialists develop new techniques for performing chemical analyses on new and special materials and compounds in support of project operation.

11.0 TEST CONTROL

11.1 MANUFACTURING AND CONSTRUCTION PHASES

When required by the complexity of the operation, detailed test procedures are prepared for evaluating the performance of items prior to their use. Written test procedures are prepared by organizations having expertise in the particular area being evaluated.

Test criteria are developed either by engineering, inspection, or qualified technical and QA personnel of the user division. Testing is performed by qualified personnel and may include prototype qualification tests, system testing, component testing, proof testing of an installation, operation shakedown testing of an installation, and post-operation NDE of various components. Testing results are documented and evaluated for conformance with criteria.

The test program and the test results are reviewed under the direction of the user organization to ensure that the tests were performed according to requirements and that the results are valid. The review includes adequacy of instrumentation, sufficiency of testing apparatus, adequacy of data gathered and monitored, and use of qualified personnel. Testing of individual items and subsystems is normally performed by UCC-ND service groups with assistance from the user. Test control of capital construction is under control of UCC-ND Engineering. Each contract for capital construction outlines the various tests to be applied by the contractor, the control to be exerted, and the documentation and certifications to be furnished UCC-ND or DOE before acceptance of the work. Testing of completed systems under normal or simulated process conditions is ordinarily performed by the operating group in the user division.

11.2 OPERATION AND MAINTENANCE PHASE

In-service tests are performed to verify that components, systems, and structures are being maintained and are performing at the capability levels specified as necessary for safe operation and for achievement of project objectives. Routine tests are performed on pressure vessels, hoists and related lifting equipment, air-filtering systems, and water-backflow preventers. Special tests are performed when the operating group determines that they are required.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

For a systematic approach to proper calibration, all M&TE in ORNL is categorized according to one of the following application categories: (see QA-L-14-100) (A) "Casual" devices and systems that are not to be calibrated in service, (B) "Routine" devices and systems that are to be included in a calibration recall program on a regular cycle, and (C) "Experimental" devices and systems that are to be calibrated by, or at the direction of the user.

12.1 MANUFACTURING, CONSTRUCTION, AND MAINTENANCE PHASES

Calibration control is achieved by specific procedures that describe calibration techniques and requirements for frequency of calibration of the instruments and standards. This control is utilized to ensure that all tools, gages, instruments, and other measuring and test devices are calibrated to acceptable accuracies. The supervisor responsible for testing material parts, assemblies, and end products has the responsibility for ensuring the calibration controls. Calibrations are performed by gage- and instrument-calibration groups against certified measurement standards that are traceable

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to the National Bureau of Standards where possible. Each device is assigned an identifying number and is marked with that number. Calibration frequency is based on the usage of the device and the accuracy required, giving consideration to the supplier's recommendations and to experience with each particular device. Frequently used inspection instruments are checked for accuracy on a specified routine basis. Inspection instruments used only on an infrequent basis are checked before use.

Inspection instruments are stored in suitable environments and are used only by personnel trained in their proper use and care. The calibration-control documentation indicates the source and traceability of calibration, including the date of last calibration. The records also provide identification and traceability for all measuring equipment by a serial number of other suitable means.

12.2 OPERATIONS PHASE

Calibration control is achieved by procedures that describe calibration techniques and requirements for the frequency of calibration of the operating instruments. This control is utilized to ensure that all instruments, gages, and other measuring and test devices are calibrated to the required accuracies. The supervisor responsible for operations ensures enforcement of the calibration controls.

Calibrations are normally performed by gage- and instrument-calibration groups against certified measurement standards that are traceable to nationally recognized standards, where possible. Each device is assigned an identifying number and is marked with that number. Calibration frequency is based on predicted drift or other inaccuracies introduced within the device with time, on supplier's recommendations, and on experience with each device.

Frequently used operating instruments are checked for accuracy on a specified routine basis and controlled by computer print-out. Operating instruments used on an infrequent basis are checked before use.

Calibration standards are prepared when nationally recognized standards do not exist. These special standards are used either by operating personnel and/or gage- and instrument-calibration groups to calibrate special operating instruments.

Duplicate instruments may be used for certain safety and data-collecting instrument applications to ensure the accuracy and reliability of measurements. The results of each instrument are checked against the other at specified, regular intervals.

The calibration-control documentation indicates the source and traceability of calibration, including date of last calibration. The records also provide identification and traceability for all measuring equipment by a serial number or other suitable means.

13.0 HANDLING, STORAGE, AND SHIPPING

Routine material handling is accomplished in accordance with the requirements of national codes and standards, industry standards, regulations, federal specifications, OSHA rules and regulations, and the ORNL Material Handling Manual.

Special requirements for handling, storage, shipping, cleaning, and preservation are specified on drawings, specifications, instructions, and work-authorizing documents. These documents are verified by review and approval by qualified design, project, and QA personnel. Implementation of special requirements includes the use of manufacturing plans and work plans, installation plans, and a "Check List and Work Plan for Handling, Packing, and Shipping Critical Components and Equipment" (UCN Form 10637).

Hoisting equipment and accessories are routinely inspected and tested in accordance with written procedures (Section 14, Quality Assurance and Inspection Manual) and at specified intervals. Special handling tools and equipment are inspected and tested in accordance with requirements on drawings, specifications and work-authorizing documents.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 MANUFACTURING AND CONSTRUCTION PHASES

Only items that are acceptable for use are permitted into the flow of work during manufacturing and construction activities. Nonconforming items are identified as such and removed from the work area, or clearly segregated within the work area, until final disposition on their future use is completed. Nonconforming items are tagged with a yellow HOLD tag (UCN-10858). The HOLD tag is removed only by authorized personnel and only after the technical review board has decided to use the item uncorrected or after the repair or rework is completed. If the item is rejected, the HOLD tag is replaced with a red REJECT tag (UCN-10859) (see QA-L-6-100).

The inspection and test status of items is given on inspection and test reports, inspection plans, and manufacturing and construction plans. Inspector(s) indicate by dated signature on these reports and plans status and results of inspections and tests.

14.2 OPERATION AND MAINTENANCE PHASE

The status of inspections and test performed during the operation and maintenance phase is recorded in the operating log and/or on inspection and test reports. Tags or locks may be attached to critical valves and switches to prevent inadvertent operation. Decals or tags are used to record the status of in-service inspection and tests of pressure vessels, absolute filters, and lifting equipment and to note the calibration status of operating instruments and gages.

Work permits are required and issued by operating groups prior to start of maintenance work to assure controlled working conditions and to prevent inadvertent operations.

15.0 NONCONFORMING ITEMS

Written procedures govern the action upon discovery, control, identification, reporting, and disposition of nonconforming items. The control actions specified in these procedures are applied through tests and inspections during in-paint or vendor manufacture, receiving of purchased items, installation, construction, and preoperational evaluation (see QA-L-6-100).

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When the application of inspection, testing, analyses, or other QA actions indicates a nonconforming item a HOLD tag or REJECT tag is attached to the item, and the questionable piece is physically segregated from other like items where possible. The condition causing the item to be unacceptable is reviewed by design, inspection, technical, and management personnel, as appropriate, and its disposition is determined and justified. A nonconformance report (UCN-10077) is initiated by those personnel discovering the nonconformance; this report describes the nonconformance and recommends a disposition. The reviewer's determinations are documented on the nonconformance report and approved by the QAC and higher management. Final disposition is also documented on the report.

The possible dispositions of nonconforming items are "use uncorrected," "repair" (reprocess so that the item is usable although all characteristics will not meet all requirements), "rework" (reprocess item to return it to within specification), or "reject" (scrap or apply to some alternate use). The HOLD or REJECT tags remain on the items until the final authorized disposition. Nonconformance reports are maintained as quality records by the item user division.

Nonconformances occurring on items at suppliers' plants are documented on Supplier Nonconformance Reports (UCN-10816) initiated by the supplier; these SNR's are reviewed by the Project Engineer and QA personnel for acceptance and approval of the supplier's proposed disposition. Such review and action is documented, and the SNR's are retained by user divisions as quality records.

16.0 QUALITY PROBLEMS AND CORRECTIVE ACTION

Unusual or unplanned events having an adverse effect on quality, such as failures, malfunctions, deficiencies, defective material and equipment, unapproved deviations, and other quality problems are noted in nonconformance reports, unusual occurrence reports, and quality investigation reports. Where such conditions indicate that the quality system required improvement or modification, actions are taken to identify the particular problem and to determine appropriate measures required to correct the condition (see QA-L-6-101).

Corrective actions are a documented part of unusual occurrence reports, quality investigation reports, and QA audit reports.

Corrective action reports relate the specific condition that indicates a quality problem, what the quality problem is, what actions will be taken to eliminate it, by whom and when they will be accomplished, and their actual accomplishment. These documented reports are distributed to various levels of management of ORNL.

17.0 QUALITY RECORDS

17.1 PROCUREMENT, MANUFACTURING, AND CONSTRUCTION PHASES

Quality records desired by the user can be identified and specified: (1) on drawings by use of notes and "Quality Verification" decals (Form UCN-10490A), (2) in specifications and procedures, (3) on purchase requisitions, and (4) on work-authorizing documents.

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Quality records are normally collected and retained during manufacture and construction by the UCC-ND service division or contractor that generates the records (see QA-L-16-100). These records are normally transmitted by the service divisions to the user for review, approval, and storage when the manufacturing and/or construction work is completed. Quality records generated by suppliers which are transmitted to the UCC-ND Purchasing Division are forwarded via the Materials Department to the user.

Quality records are stored by the user in accordance with project or user-division procedures for storing quality records. Certain service divisions retain duplicate quality records for definite periods of time; however, normally service divisions do not store records. Certain quality records may be stored by the Records Storage Center of the ORNL Information Division, when requested by the user division. This records Storage Center is a fully enclosed facility especially equipped to store and retrieve large collections of noncurrent records (see QA/ID/LRD-509/A).

17.2 OPERATION AND MAINTENANCE PHASES

Quality records that are related to preoperational testing, operation, and maintenance phases of the project or facility are normally retained by the user division responsible for operation. Typical records include as-built drawings, operating logs, operating personnel certifications, calibration history, operational reviews, maintenance data, inspection and test results, quality investigation reports, and quality audits. These records are retained in accordance with procedures for quality records prepared by the user division responsible for operation and consistent with UCC-ND and DOE requirements for record retention (see QA-L-16-100).

Provisions have been made within the Computer Services Center to duplicate and store vital and important computer magnetic tapes, when requested by the user.

18.0 AUDITS, REVIEWS, AND APPRAISALS

A series of internal audits and reviews are performed by the ORNL QA Lead Auditor, the QACs, the Quality Achievement Manager, the Reactor Operations Review Committee, and the Radioactive Operations Committee to verify compliance with all aspects of the ORNL QA Program and Safety Program. External audit functions are performed by the ORNL QA Auditor and by QA&I.

DOE-ORO performs annual QA Appraisals of the ORNL QA Program.

18.1 ORNL INTERNAL AUDITS

The ORNL QA Lead Auditor performs regular QA Audits of ORNL research and development divisions, service divisions supporting the research of ORNL Programs, and other UCC-ND service divisions that provide services for ORNL in order to verify that the ORNL QA Program is effective and in order to ensure compliance with the ORNL QA Program and applicable procedures. Normally one audit is conducted each month in a division, project, or facility selected by the ORNL QAD.

Audits are conducted in accordance with an announced audit plan and check list by the ORNL QA Lead Auditor (Chairman) with a team composed of UCC-ND staff members. The audit team members are chosen by the Lead Auditor for their experience and/or knowledge in QA and/or in the activity being audited. Normally a member of ORNL Management is a member of the Audit Team. Audits are conducted in accordance with ORNL QA Procedure QA-L-8-100.

Audit findings and recommendations of the audit team, as well as agreements and commitments for correction of any deficiencies, are documented by the audit team. The reports are distributed to ORNL and division management.

Audit corrective actions are placed on a computer tracking system for appropriate follow-up.

18.2 DIVISION INTERNAL AUDITS

The division and program QAC performs QA audits of activities within the division or program to verify for the director that the QA program is effective and to assure that the staff is complying with appropriate aspects of the division's QA program.

Audits may be formal or informal. During formal audits, the following activities are normally documented: notification of audit, audit plan, audit check list, audit findings, corrective action recommendations, and final summary report to division management.

Formal audits are normally conducted by an audit team chaired by the division/program QAC. The QAC reports to division/program management and is independent of activities being audited.

Informal audits are conducted more frequently than formal audits. They are normally conducted by the QAC on an individual basis with the responsible individual(s) in the group being audited. These informal audit activities may or may not be formally documented.

Audits are conducted when scheduled by the QAC or when scheduled by responsible division management.

18.3 CONTROLLED-MANUFACTURING-PROGRAM AUDITS

The Quality Achievement Manager performs audits to determine the effectiveness of and to ensure compliance with the Controlled-Manufacturing Program (which implements ASME-Code requirements) and to initiate corrective action, when appropriate. The audit procedure is contained in the CMP Manual.

Each audit is performed by knowledgeable personnel not directly involved in the area being audited. Each audit is conducted using a written check list prepared specifically for the occasion. This check list gives due consideration to the nature of the activity being audited and the requirements of the Controlled-Manufacturing Program and the ASME Code. Deficient areas are reaudited to make sure that effective corrective action has been taken.

Each audit is conducted, in accordance with a written procedure, by a team designated by the Quality Achievement Manager. The results of each audit are documented in a written report, which is reviewed by the supervisor having responsibility for the area audited. The supervisor then issues a memorandum describing the corrective action that will be implemented to correct any observed deficiencies. The audit report, with the supervisor's response, is distributed to the Director of Administrative Services, the ORNL QAD, the QAC for Manufacturing Services, the Quality Achievement Manager, and the Superintendnet of the Fabrication Department.

18.4 AUDITS OF NUCLEAR REACTOR OPERATIONS

The Reactor-Operations Review Committee (RORC) performs an independent annual safety review of ORNL's operating reactors. During the review, consideration is given by the committee to the condition and usage of operating procedures; facility-maintenance program; operating-personnel changes; operator training programs; and mechanical, electrical, and instrument changes to the reactor system. Each member of the committee is assigned a continuing responsibility for keeping up to date on operating history, major design changes, and safety status of a particular ORNL reactor. When an annual inspection is made, the cognizant committee member and two other staff members, who are not associated with RORC or the reactor-operating organization, constitute a subcommittee that inspects the reactor facility. The subcommittee will observe startup, reloading, and shutdown procedures, as well as examine facility logbooks, operating reports, facility drawings, etc. The subcommittee submits a written report to the full RORC presenting its findings and suggesting areas for discussion at the annual review with the reactor operators. As a result of the review, specific recommendations may be made to ORNL management by the committee.

18.5 SUPPLIER AUDITS

Quality assurance and quality control audits of suppliers are normally conducted by Quality Assurance and Inspection and/or by qualified personnel from the ORNL user divisions and/or by other experts selected by the user divisions. These audits are scheduled by the user divisions on the basis of quality requirements.

18.6 DOE-ORO APPRAISALS

The Quality and Reliability Division of DOE-ORO conducts annual appraisals of the policies, activities, and procedures of the ORNL QA program for compliance with DOE QA policies. The findings and recommendations are documented, and a report distributed to the Laboratory Director.

OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE	
PROCEDURE NO.	QA-L-1-100 (Rev. 3)
DATE	January 29, 1983
PAGE	1 OF 1
SUPERSEDES ISSUE DATED	December 22, 1982

TITLE: QUALITY ASSURANCE PROGRAM

Purpose:

To define the Quality Assurance Program requirements that shall be implemented by the ORNL QA Program and by division and program QA Programs.

References:

A. Quality Assurance, DOE-ORO, OR 5700.6.
B. Quality Assurance Program, UCC-ND Standard Practice Procedure D-2-16.
C. Quality Assurance Program, ORNL Standard Practice Procedure Supplement, D-2-16S.
D. QA Program Requirements, Nuclear Energy Programs, DOE, RDT F2-2.
E. QA Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, Nuclear Regulatory Commission, 10 CFR 50, Appendix B.
F. QA Program Requirements for Nuclear Power Plants, American National Standard, ANSI/ASME NQA-1 1979.

Requirements:

On all programs, the Laboratory shall implement those QA requirements established by the Department of Energy (Reference A) and by UCC-ND (References B and C). The Laboratory shall also implement on specific programs and projects QA Standards specified by the sponsoring organization (e.g., References D, E, and F).

Procedures:

100.1 The Quality Assurance Director (QAD) will develop and administer a Laboratory-wide QA Program which is responsive to the requirements of DOE and of UCC-ND (References A, B, and C) and will coordinate development of other QA procedures, as necessary, to implement special QA requirements of sponsoring organizations for specific programs (References D, E, and F).

100.2 Division and program management shall ensure that divisions and programs establish QA programs. The division/program QA Program shall be responsive to the QA requirements of ORNL QA Program and DOE-ORO (Reference A), plus any additional QA requirements (e.g., References D, E, and F) of sponsoring organizations, including other DOE organizations.

OAK RIDGE NATIONAL LABORATORY
OPERATED BY
UNION CARBIDE CORPORATION
NUCLEAR DIVISION

Submitted by: F. H. Neill Director
Quality Assurance Program

Approved by: [signature]
Executive Director for Support and Services

UCN-9938

OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA- L-1-101 (Rev. 1)

DATE July 31, 1981

PAGE 1 OF 3

SUPERSEDES ISSUE DATED March 1, 1979

TITLE: QA PLANNING

Purpose:

To delineate the QA planning procedures applicable to various types of projects and activities to ensure a systematic approach to quality assurance.

References:

A. Quality Assurance Assessments, ORNL QA Procedure QA-L-1-103.
B. Quality Assurance Plan, ORNL QA Procedure QA-L-1-104.
C. Quality Assurance Planning For Capital Projects, ORNL QA Procedure QA-L-1-108.
D. Quality Assurance Requirements, DOE Standard RDT F2-2.

Requirements:

Each project/activity shall be classified as to its type and the appropriate QA assessment and planning procedure shall be invoked.

Procedures:

100.1 Upon initiation of a project/activity, the task leader shall consult the guidelines contained in Figure 1 of this procedure and implement the QA assessment and planning procedures as shown.

100.2 On projects that require the participation of several Laboratory divisions, the establishment of overall QA requirements for the project shall be the responsibility of program management. For such projects, the overall QA coordination of the project shall be the responsibility of the QA Coordinator (QAC) whose division has overall management responsibility or the QAC designated by program management.

100.3 The task leader shall not authorize the release of "Approved for Construction" drawings or specifications on any project requiring a QA Plan until such drawings or specifications have final approval. However, long lead items may be procured if the appropriate QA actions can be identified, approved, and incorporated into the procurement documents.

ADDITIONAL CONSIDERATIONS FOR REFERENCE D COMPLIANCE

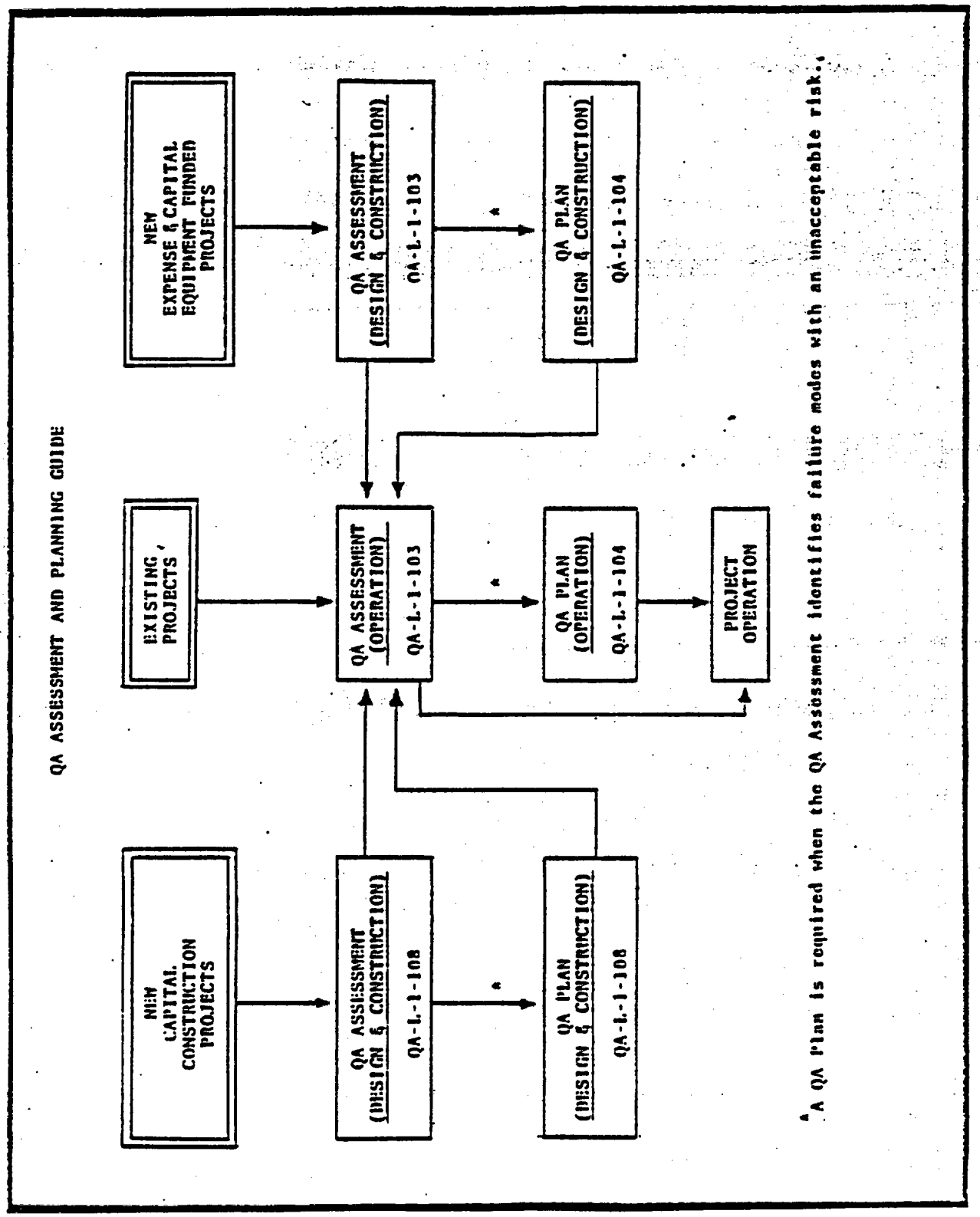
200.1 On ASNE funded project a QA Program Index (Ref. D, paragraph 2.2.2) shall be prepared in accordance with specific requirements of ASNE. When preparing a QA Program Index use the format in Appendix A.

OAK RIDGE NATIONAL LABORATORY
OPERATED BY
UNION CARBIDE CORPORATION
NUCLEAR DIVISION

Prepared by: F. H. Neill
QA Program Director

Approved By: C. C. Hopkins
Executive Director, Support & Services

TITLE: QA PLANNING



TITLE: QA PLANNING

APPENDIX A

QA PROGRAM INDEX

NOTE: Completion of this section is optional unless Paragraph 2.2.2 of RDT Standard F 2-2 has been invoked on the project.

1. List below those paragraphs of RDT Standard F 2-2 that are to be implemented on this project.
2. Indicate the corresponding UCC-ND division and ORNL QA procedures that will be applied to implement the paragraphs of F 2-2 listed.
3. If the implementing procedure is to be prepared at a later date, assign the procedure a number and indicate the number and date at which it will be prepared.

F 2-2 Paragraph Number	UCC-ND, ORNL, or Division Procedure No. and Revision No.	Procedure Title

OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-L-1-102

DATE May 3, 1983

PAGE 1 OF 4

SUPERSEDES ISSUE DATED

TITLE: QA TRAINING AND QUALITY AWARENESS

Purpose:

To delineate the means for each employee to understand his/her role in assuring quality.

References:

A. Quality Assurance, DOE Order OR 5700.6.
B. Quality Assurance Program, SPP D-2-16 and ORNL Supplement.
C. ASME Controlled Manufacturing Manual, ORNL.
D. ASME Fabrication and Inspection Procedure Manual, ORNL.
E. Quality Perspectives, UCC-ND Office of QA.

Requirements:

ORNL shall provide a means for each employee to clearly understand his/her role in providing assurance of quality (Reference A).

Procedure:

ORNL QA OFFICE

100.1 The Quality Assurance Director (QAD) shall define and assure that adequate training and quality awareness programs are provided for ORNL personnel to understand the ORNL QA program and their responsibilities for its implementation (Ref. B).

Training and quality awareness programs vary and are provided in three different ways: those sponsored by the UCC-ND Office of QA, the ORNL QA staff, and the ORNL in-house continuing education program. A description of the ORNL training and quality awareness training programs is provided in Appendix A. These training programs are offered as demand requires. Programs are periodically reviewed and revised when the need arises. In addition, quality control and quality engineering courses are offered by local colleges and universities.

100.2 The QAD shall monitor the ORNL in-house continuing education programs and make recommendations, as required, to assure that adequate courses in QA and other quality-related subjects are provided for staff personnel.

DIVISIONS AND PROGRAMS

200.1 Management shall assure that subordinates understand, accept, and implement the QA program (Reference B). Management shall encourage all appropriate personnel to attend training and quality awareness programs listed in Appendix A or available from other sources.

OAK RIDGE NATIONAL LABORATORY
OPERATED BY
UNION CARBIDE CORPORATION
NUCLEAR DIVISION

Submitted by: [signature]

Approved By: [signature]
Executive Director for Support and Services

TITLE: QA TRAINING AND QUALITY AWARENESS

The extent of training and quality awareness for personnel may vary, depending on the division's mission. As a minimum, all personnel should attend Division QA Week presentations each year.

200.2 Division QA Coordinators (QACs) shall conduct or assist in training and quality awareness programs (Ref. B). QACs shall work in collaboration with management to develop appropriate programs for their division's needs. Through these programs, personnel shall periodically be informed of changes in the ORNL QA Program.

200.3 As a minimum, all QACs shall attend the "QA and Auditing Course" described in Appendix A and courses on QA Assessments, QA Plans, and Quality Problem Investigations.

200.4 QACs shall periodically report to the division director the status of the QA training and quality awareness programs in their divisions and make recommendations for improvements to the programs (Reference B).

ASME CODE COMPLIANCE

300.1 Training and qualification of ORNL welders shall be in accordance with the "Welding" procedure in Section 7, of Reference C.

300.2 Training, examination, and qualification of ORNL inspectors and nondestructive examination (NDE) personnel shall be in accordance with the "Certification of Inspection and NDE Personnel" procedure, ORNL NDE 10, in Reference D.

TITLE: QA TRAINING AND QUALITY AWARENESS

APPENDIX A
TRAINING AND QUALITY AWARENESS PROGRAMS

UCC-ND SPONSORED PROGRAMS

A. Quality Assurance Week - This QA awareness program is presented during one week each year for all employees in the Nuclear Division. At ORNL this program typically consists of statements by division management on division QA policy; a UCC-ND/ORNL produced videotape presentation on current QA-related activities in UCC-ND and ORNL; and may include posters, contests, articles in UCC-ND, ORNL, and local newspapers, and local TV talk shows. ORNL staff members supply the ORNL part of the videotape and meeting messages.

B. QA Seminars - A variety of seminars is presented periodically each year, for management, QA, and staff personnel. Normally, they are conducted by invited QA specialists and are offered at on-site as well as off-site locations. Seminar subjects are of current interest.

C. Four-Plant QA Coordinators Meeting - These meetings are conducted every 2 months for plant QA Coordinators of the 4 UCC-ND Plants, Engineering, Purchasing, and the Operating Contractors Project Office. In these meetings plant QACs are (1) made aware of the latest DOE and UCC-ND quality-related developments that may affect their plant QA program, and (2) given an opportunity to exchange information and ideas with other plant QACs.

ORNL QA STAFF SPONSORED PROGRAMS

A. QA and Auditing Course - This three-day course is normally conducted once a year for QACs, managers, supervisors, and other staff personnel.

The QA part of the course is based on QA Standard ANSI NQA-1. It covers basic elements of QA (Organization; QA Program; Design Control; Procurement Document Control; Instructions, Procedures, and Drawings; Document Control; Control of Purchased Items and Services; Identification and Control of Items; Control of Processes; Inspection; Test Control; Control of Measuring and Test Equipment; Handling, Storage, and Shipping; Inspection, Test, and Operating Status; Control of Nonconforming Items; Corrective Action; QA Records; and Audits).

The auditing part of the course covers fundamentals of QA auditing and includes an actual practice audit.

B. QA Orientation for New Employees - The ORNL QA Program is presented to all new employees as part of the ORNL Orientation Program.

C. QA Seminar for ORNL Managers - This seminar, for the ORNL Associate Laboratory Directors, and division and program directors, is offered periodically. It covers subjects such as intent of the ORNL QA program, ORNL QA procedures, legal aspects of QA, QA in procurement, QA interactions with Engineering, Computer Sciences QA, QA through Inspection Engineering, QA in instrumentation, and Analytical Chemistry QA.

D. QA Segment of the Basic Management and Supervisory Development Course - This course is presented quarterly for experienced managers and supervisors. The QA segment of the course includes ORNL QA policy and implementation of ORNL QA procedures.

E. QAC Staff Meetings - These meetings are conducted each month for QACs. In these meetings QACs are (1) made aware of the latest ORNL quality-related developments that may affect their division/program QA program, (2) given an opportunity to exchange information and ideas with other QACs, and (3) advised of new techniques and developments on quality-related subjects from guest speakers.

F. QA Videotape Training Course - A variety of videotapes on current QA-related subjects are available for loan through the ORNL QA Program Office.

G. Awards of Recognition - This award, normally presented quarterly, is available to all employees except QACs. It is awarded for identifying potential significant quality problems (see Reference E, Section 4). The award normally consists of personal recognition by top Laboratory management, a certificate of appreciation, and an article and photograph in the UCC-ND paper.

H. QA Auditing - Service by top management on ORNL QA audit teams provides "hands-on" experience in practical application of QA elements.

ORNL IN-HOUSE CONTINUING EDUCATION PROGRAM

In-house continuing education programs are of two general types — the In-Hours Continuing Education Program and the Management Resource Development Program. The In-Hours Continuing Education Program normally offers courses in statistics, risk analysis, computer programming, reliability engineering, technical writing, and similar courses. The Management Resource Development Program normally offers courses in project management, human relations, oral technical presentations, and interpersonal effectiveness.

FOR TRIAL USE

OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-L-1-103 (Rev. 8)

DATE August 10, 1983

PAGE 1 of 16

SUPERSEDES ISSUE DATED December 22, 1982

TITLE: QUALITY ASSURANCE ASSESSMENT/PLAN

Purpose:

To define requirements for Quality Assurance Assessments and Quality Assurance Plans.

Scope:

This two part procedure is applicable to all projects*, including small projects, during (a) start-up and routine operation, (b) manufacture of items (products) and (c) design and construction phases of expense funded and capital equipment funded projects. For QA Assessments and Plans on capital projects see Reference A.

References:

A. QA Planning for Capital Projects, ORNL QA-L-1-108.
B. QA Planning, ORNL QA-L-1-101.
C. Tracking of QA Documents and Actions, ORNL QA-L-1-110.

Requirements:

A QA Assessment (QAA) shall be completed for all projects to identify and evaluate the risk of potential significant quality problems (failure modes), and for each quality problem with an acceptable risk provide a rationale for the determination. For each potential quality problem with an unacceptable risk, define the planned preventative action(s) required to provide confidence that the problem is unlikely to occur, or to minimize the consequence of the problem if it does occur, and to specify the responsibility and schedule for carrying out preventative action(s).

Procedure:

100.1 Project Selection - All projects shall be assessed. Division management, with advice of the division Quality Assurance Coordinator (QAC), shall review all projects within the division to determine which projects are likely to be considered small for QA mini assessment purposes. See guidelines for selecting small projects in Appendix A. Those projects identified as small may follow Part I of this procedure. All other projects shall follow Part II of this procedure (Reference B).

---

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

TITLE: QUALITY ASSURANCE ASSESSMENT/PLAN

PART I

OA Mini Assessment for Small Projects

200.1 QAA Schedule - A QAA shall be completed for all existing projects and all new projects early in the planning stage.

200.2 Assessment - The task leader, with assistance of the QAC, shall conduct the QAA. The QAA shall be documented on the QA Mini Assessment form for small projects, using the instructions on the form (see Appendix B).

200.3 Review and Reassessment - Reassessment may be required by project scope changes, evidence that quality problems are developing, or the occurrence of significant quality failures. Each QAA shall be reviewed by the task leader and the QAC every 12 months (24 months after routine operation is established) to determine if the QAA is adequate or if reassessment is required. The QAC shall notify the ORNL QA Office when the project is complete. This QAA status information shall be documented on the QAA computer status report provided periodically by the ORNL office of QA.

PART II

OA Assessment/Plan (QAA/P) for all Projects Except Small Projects

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

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

300.2 QAA/P Schedule - The initial QAA/P shall be completed early in the planning phase* of new projects. A QAA/P shall be completed for all existing projects and for all new projects entering the operating phase. A schedule for conducting initial QAA/Ps shall be prepared.

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

300.4 Assessment/Plan - The chairperson, with QAC assistance, shall prepare a draft QAA/P (Forms UCN-15006 and UCN-15007), using the instructions shown on the attached forms, Appendices C, D, and E. Ground rules and limitations of the QAA/P shall be listed at the top of page 1 of the QAA/P (Form 15007). Figure 1 illustrates the steps to be followed in conducting the QAA/P.

*Preparation of the QAA/P during design and construction may be delegated to Engineering.

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

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

300.6 QAA/P Document Format - The QAA/P document shall consist of the following sections:

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

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

C. A functional responsibility chart indicating who will be responsible for implementing the quality related standard practices, procedures, instructions, and actions.

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

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

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

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

TITLE: QUALITY ASSURANCE ASSESSMENT/PLAN

300.8 Preventative QA Actions - Planned preventative QA actions shall be provided for each unacceptable risk determination. The planned actions, when implemented, should provide reasonable confidence why the failure will not occur or the impact mitigated, if the failure does occur. Examples of preventative QA actions are provided in Appendix G.

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

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

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

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

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

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

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

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

300.15 Records and Status - The QAC shall maintain a copy of all QAA/P documentation. The QAC shall maintain a log which lists the projects to be assessed/reassessed, schedule, and current status. The ORNL QA document computer tracking system may be used by the QAC to track the status of QAA/Ps (see Reference C).

OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-L-1-103 (Rev. 8)

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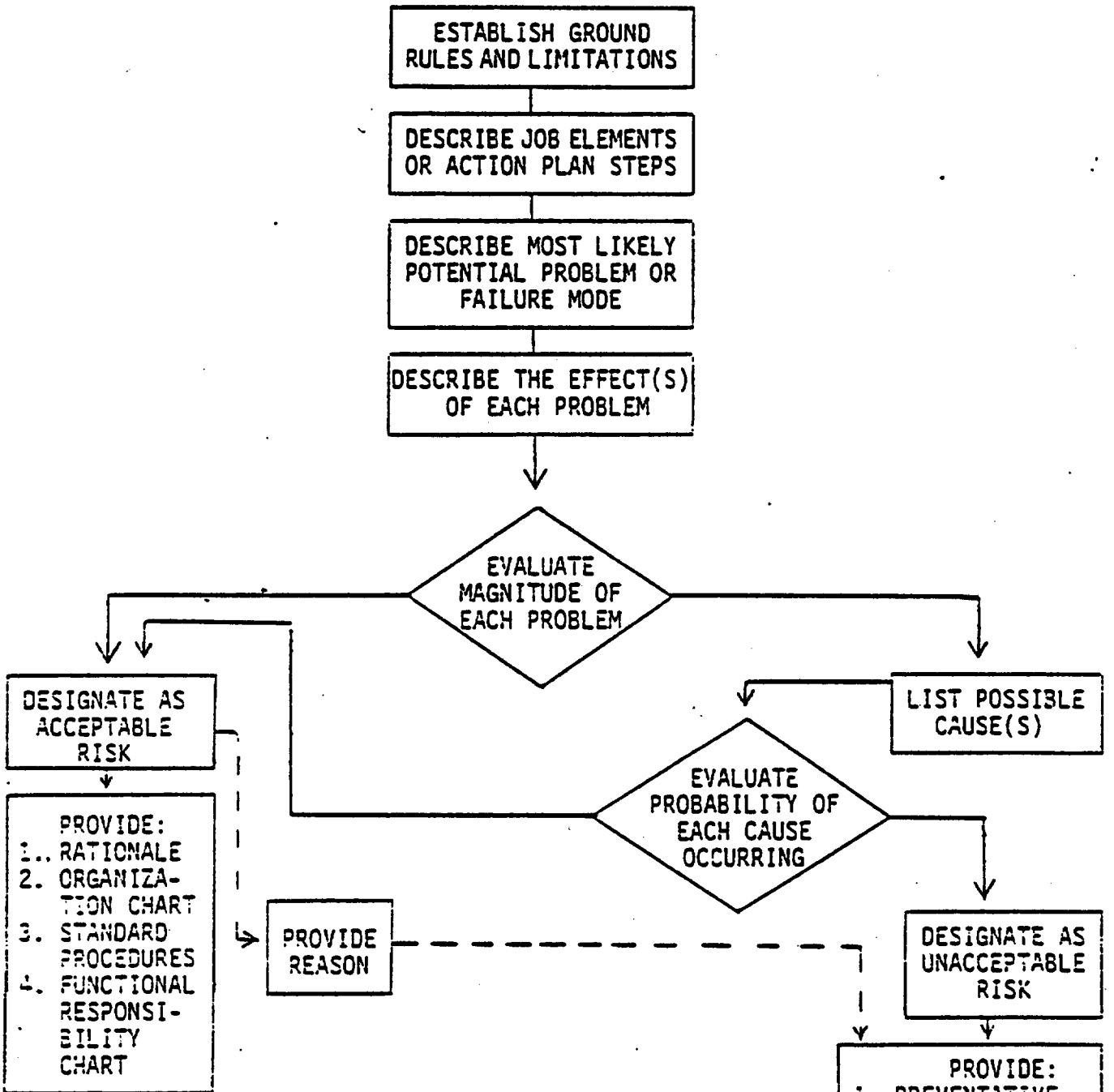
TITLE: QUALITY ASSURANCE ASSESSMENT/PLAN



*For problems with an extremely significant consequence, requiring preventative action, even though probability is low.

QAA/P LOGIC CHART

FIGURE 1

APPENDIX A

GUIDELINES FOR USE IN IDENTIFYING SMALL PROJECTS AND USE OF THE QA MINI ASSESSMENT FORM

(Reference Paragraph 100.1)

The QA mini assessment form may be used on small, non-complex projects where the risk of failure for all potential quality problems or failure modes in the project is judged to be acceptable. An acceptable risk is when the consequence* of failure is not significant; or when the consequence of failure is significant, but the probability of failure is low.

In addition, the mini QA assessment form may not be used if one or more of the following criteria apply to a project:

1. Projects with a high visibility to DOE and/or others.
2. Nuclear reactors and nuclear processing facilities.
3. Large complex (nonnuclear) facilities where the replacement cost of hardware, in case of failure, will exceed $150,000.

*When determining consequence, evaluate the impact of failure on meeting technical and program objectives, funding, schedule delays, public and DOE reaction, human health and safety, and the environment.

OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-L-1-103 (Rev. 8)

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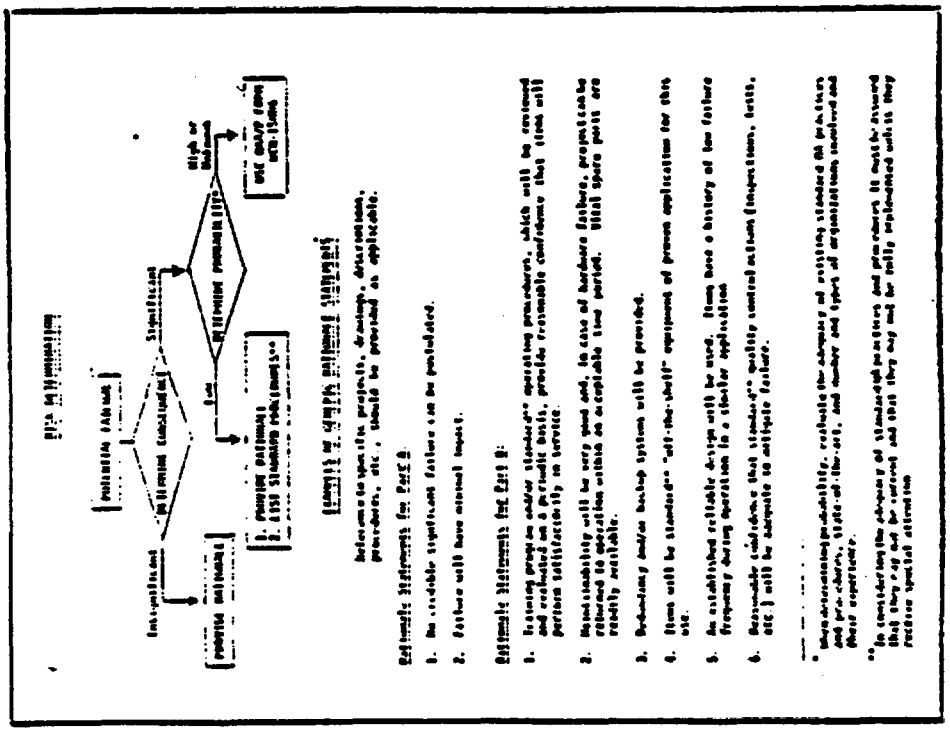
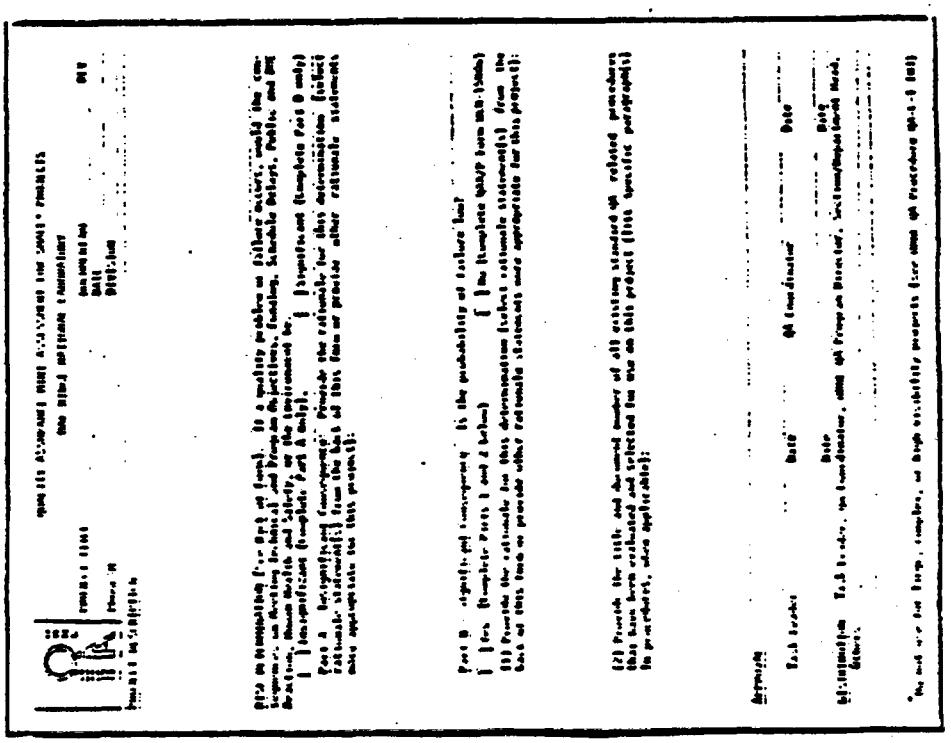
TITLE: QUALITY ASSURANCE ASSESSMENT/PLAN

APPENDIX B





OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-L-1-103 (Rev. 8)

TITLE: QUALITY ASSURANCE ASSESSMENT/PLAN

APPENDIX C

QUALITY ASSURANCE ASSESSMENT/PLAN

UNION CARBIDE CORPORATION
NUCLEAR DIVISION

PLANT | DIVISION/FACILITY | ASSESSMENT PLAN NO. | ORIGINAL ISSUE DATE | REV. (NO.) DATE

PROJECT TITLE = BUILDING OR ACTIVITY | PROJECT NO. (ENGR.) | SRO NO. (ENGR.)

JOB (Subproject, Subsystem, Program, Phase, etc.) TITLE = BUILDING | WBS NO. (ENGR.) | PAGE : OF

PROJECT PHASE: ☐ DESIGN/CONSTRUCTION ☐ MANUFACTURE ☐ OPERATION | ASF Engineering QAA No.

I. PROJECT (SUBPROJECT) DESCRIPTION

II. ASSESSMENT STATUS
☐ INITIAL ☐ INTERIM ☐ FINAL

III. ASSESSMENT CONCLUSION (See Worksheets UCN-15007)
QA PLAN REQUIRED? ☐ YES ☐ NO QA PLAN REVISION REQUIRED? ☐ YES ☐ NO

IV. INDIVIDUALS RESPONSIBLE FOR PERFORMING THIS ASSESSMENT

CHAIRPERSON	

V. APPROVALS (NAME AND DATE)

SITE	ENGINEERING	OTHERS
PLANT DIVISION REPRESENTATIVE	PROJECT MANAGER/ENGINEER	DOE-ORO
DIVISION QA COORDINATOR	PROJECT QA ENGINEER	
PLANT QA COORDINATOR	PRINCIPAL ENGINEER	

VI. ASSESSMENT REVIEW

REVIEW	SCHEDULED REVIEW DATE	DATE REVIEWED	REASSESSMENT REQUIRED NO	REASSESSMENT REQUIRED YES	APPROVAL SIGNATURES
1					
2					
3					
4					

TITLE: QUALITY ASSURANCE ASSESSMENT/PLAN

APPENDIX D

QUALITY ASSURANCE ASSESSMENT AND PLAN

Page ____ of ____
Document Number
Revision (No.) Date

Ground Rules and Limitations

JOB ELEMENTS OR ACTION PLAN STEPS		POTENTIAL PROBLEMS OR FAILURE MODES	EFFECT(S)	CONSEQUENCE[1]
NO.	DESCRIPTION			
	List ground rules and limitations for this project			

[1] [illegible]

APPENDIX E

QUALITY ASSURANCE ASSESSMENT AND PLAN
(CONTINUED)

Page ____ of ____
Document Number
Revision (No.) Date

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

[2] [illegible]
[3] [illegible]
[4] [illegible]
[5] [illegible]

APPENDIX F

EXAMPLES OF GENERIC RATIONALE STATEMENTS

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

For Quality Problems with an Insignificant Consequence of Failure:

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

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

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

APPENDIX G
PREVENTATIVE QA ACTIONS* TO BE CONSIDERED IN QUALITY ASSURANCE ASSESSMENTS/PLANS
(Reference paragraph 300.8)

Design Phase:

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

Procurement Phase:

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

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

TITLE: QUALITY ASSURANCE ASSESSMENT/PLAN

UCC-ND Shop Fabrication Phase:

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

Installation and Pre-Operational Test Phase:

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

Miscellaneous:

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

Operational Phase:

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

8. Identify measuring and test equipment (including safety related instruments) requiring calibration and establish a recalibration schedule.

Experimental and Developmental Testing Phase:

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

Maintenance Phase:

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

QUALITY ASSURANCE MINI ASSESSMENT FOR SMALL* PROJECTS

OAK RIDGE NATIONAL LABORATORY

PROJECT TITLE _____ DOCUMENT NO. _____ REV__

DATE _____

PROGRAM _____ DIVISION _____

ROJECT DESCRIPTION:

ISK DETERMINATION (See Back of Form): If a quality problem or failure occurs, would the consequences on Meeting Technical and Program Objectives, Funding, Schedule Delays, Public and DOE eaction, Human Health and Safety, or the Environment be:

☐ Insignificant (Complete Part A only); ☐ Significant (Complete Part B only)

Part A - Insignificant Consequence: Provide the rationale for this determination (select rationale statement(s) from the back of this form or provide other rationale statements more appropriate for this project):

Part B - Significant Consequence: Is the probability of failure low?

☐ Yes (Complete Parts 1 and 2 below) ☐ No (Complete QAA/P Form UCN-15006)

(1) Provide the rationale for this determination (select rationale statement(s) from the back of this form or provide other rationale statements more appropriate for this project):

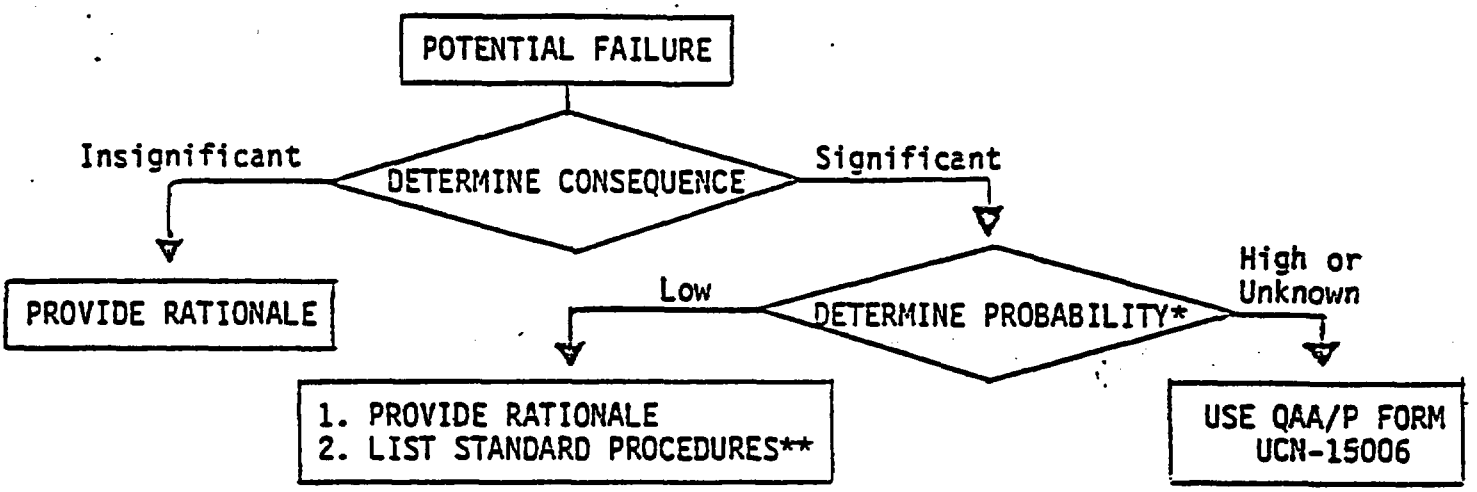
(2) Provide the title and document number of all existing standard QA related procedures that have been evaluated and selected for use on this project (list specific paragraph(s) in procedures, when applicable):

PPROVAL:

Task Leader	Date	QA Coordinator	Date
	Date		Date

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

RISK DETERMINATION



EXAMPLES OF GENERIC RATIONALE STATEMENTS

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

Rationale Statements for Part A:

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

Rationale Statements for Part B:

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

---

* When determining probability, evaluate the adequacy of existing standard QA practices and procedures, state-of-the-art, and number and types of organizations involved and their experience.

** In considering the adequacy of standard QA practices and procedures it must be assumed that they may not be current and that they may not be fully implemented unless they

OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO.	QA- L-1-104 (Rev. 6)
DATE	December 22, 1982
PAGE	1 OF 7
SUPERSEDES ISSUE DATED	February 13, 1981

TITLE: QUALITY ASSURANCE PLAN

Purpose:

To define requirements for preparing Quality Assurance Plans (QAP).

Scope:

This procedure is applicable when it has been determined in a quality assurance assessment (QAA) that a project/activity has potentially significant quality problems with an unacceptable risk (Reference A).

For QAPs on capital construction projects see Reference B.

References:

A. Quality Assurance Assessments, ORNL QA Procedure QA-L-1-103.
B. Quality Assurance Planning for Capital Projects, ORNL QA Procedure QA-L-1-108.
C. Tracking of QA Documents and Actions, ORNL QA-L-1-110.

Requirements:

A QAP shall be prepared which describes potentially significant quality problems (failure modes or concerns), defines the QA actions required to provide confidence that these problems are unlikely to occur, and specifies the responsibility and schedule for carrying out the QA actions. The plan shall be comprehensive and shall include input from all participants for their portion of the work.

Procedure:

100.1 A QAP shall be prepared for each project/activity covered in the scope.

100.2 The QAP shall be prepared early in the planning phase for design, operation or manufacture, as appropriate.

100.3 The task leader shall be responsible for preparation of the QAP, for selecting the appropriate QA actions, and for assuring implementation of the QAP. The task leader shall seek the advice and/or assistance of the division and program Quality Assurance Coordinator (QAC), service division personnel, and others as appropriate.

100.4 For projects that require the participation of several ORNL divisions, a single QAP shall be prepared by the division with overall QA management responsibility,

with input from participating divisions. Each division shall use its division QA implementing procedures for the project phase for which it is responsible unless directed otherwise by the managing division.

100.5 QAP Format - Each QAP shall include the following elements:

A. Title, Approval, Distribution, and Document Number.

B. Scope of Plan - Define the limits of applicability of the plan and to the organizations to which it applies. Include a reference to the QAA on which the plan is based.

C. Brief Description and Function of the Project

D. Organization and Responsibilities - Provide an organization chart showing organizational structure, levels of authority and lines of internal and external communication for management and for the direction and execution of activities affecting quality.

E. Special Quality Assurance Actions

(1) State all potentially significant quality problems (failure modes or concerns) with an unacceptable risk that were identified in the QAA, and state the most likely cause(s) of such failures.

(2) State those special QA actions required to provide confidence that identified failures or concerns will be prevented or the impact reduced if failure occurs. Select special QA actions from Appendix A or other sources. The title and document number of instructions, plans, studies, procedures, etc., that will be used to implement the special QA actions should be identified (special QA actions are those QA actions required in addition to standard QA practices).*

(3) Provide the schedule for implementing each of the special QA actions.

(4) Identify the organizational unit responsible for performing special QA actions.

An example QAP is included in Section 1 of the QAC Source Manual.

---

*It should not be assumed that necessary standard design procedures will be followed all the time or standard inspection or tests will be made. The probability that such events will occur is uncertain. When assurance is required that such events have been performed then QAPs should identify the applicable procedures, including means for assuring that actions in the procedures have been completed. (It is recognized that some standard procedures contain means for verifying that actions have been accomplished.)

TITLE: QUALITY ASSURANCE PLAN

100.6 The QAP shall be reviewed if required by reassessment or when a quality investigation or audit indicates that the QAP is inadequate or incomplete.

100.7 Procedures, plans, forms, and other quality related documents referenced in the QAP should be organized and readily available for use, review, and audit.

100.8 QAPs shall be approved by division/program management, the QAC, and the ORNL Quality Assurance Director (QAD). In addition, others as determined by the task leader should review and/or approve QAPs.

100.9 The task leader shall establish adequate distribution for the QAP, which, as a minimum, shall include all persons signing it and the QACs of all divisions involved.

100.10 The QAC shall monitor and track all special QA actions in each QAP. A log or equivalent shall be used. The log shall indicate the current status of each special QA action, title of person(s) responsible for implementing the special QA action and schedule for completion. The QAC shall promptly notify the task leader and management, as appropriate, of deficiencies in implementing the special QA actions. The ORNL QA document and action tracking system may be used by the QAC to track the status of special QA actions (See Reference C).

100.11 The QAC shall maintain a copy of all QAPs.

100.12 Temporary deviations from approved QAPs shall be prepared by the task leader and documented on ORNL Deviation Request UCN-5458A. The deviation request shall be approved by the QAC and division/program management before changes are implemented. Distribution of approved deviations shall be the same as approved QAPs.

TITLE: QUALITY ASSURANCE PLAN

APPENDIX A
SPECIAL QA ACTIONS* TO BE CONSIDERED IN QUALITY ASSURANCE PLANS
(Reference paragraph 100.6, E)

Design Phase:

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

Procurement Phase:

1. Review of procurement documents by QAC for specification of QA requirements.

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

2. ASME Code shop required.

3. Evaluate potential sellers.

4. Conduct source surveillance and inspection.

5. Conduct receiving inspection.

6. Review seller's QA program.

7. Review seller's bid proposal by appropriate project participants.

8. Conduct pre- and post-award meeting with sellers.

9. Prepare procurement plans.

10. Prepare and store archive samples of raw materials.

11. Define method for accepting items.

12. Require item verification, certification, test, and/or traceability.

UCC-ND Shop Fabrication Phase

1. Provide manufacturing inspection and test plan with hold points.

2. Specify requirement for QA data package (inspection and test reports) and/or letter of compliance.

3. ASME Code shop required.

4. Provide system and facilities for controlling nonconforming items.

5. Review shop QA program.

6. Use independent inspection agency (such as QA&I) to monitor material control and inspection activities.

7. Provide procedure for preparation and approval of shop drawings and as-built drawings.

8. Verify identity of raw material to a known specification.

Installation and Pre-Operational Test Phase:

1. Provide installation, inspection, and test plan with hold points.

2. Provide inspection, test, and cleanliness control procedures.

3. Conduct pre-operation/functional tests.

4. Conduct training and certification of personnel.

5. Use mock-ups during installation.

6. Describe unusual safety considerations.

7. Provide field change procedure.

8. Provide procedures for preparation and approval of field sketches and as-built drawings.

9. Describe final acceptance inspections and tests.

10. Use independent inspection agency (such as QA&I) to monitor material control and inspection activities.

Miscellaneous:

1. Transmit documents by a controlled document release system.

2. Identify "lifetime" and "non-permanent" QA-related type records. Identify custodians and file location for such records.

3. Provide interface controls between project participants.

Operational Phase:

1. Identify any Laboratory Director's Review Committees that will review project for safe operation.

2. Prepare operating procedures including start-up, routine, and shutdown operation.

3. Provide emergency shutdown procedure.

4. Describe unusual safety considerations.

5. Establish method for disposing of contaminated material.

6. Prepare and implement method (such as tags and logs) for indicating operating or maintenance status of systems and components.

7. Provide training of operators, and certification when required.

8. Identify measuring and test equipment (including safety related instruments) requiring calibration and establish a recalibration schedule.

Experimental and Developmental Testing Phase:

1. Prepare experimental test plan including definition of test requirements.

2. Conduct Readiness Review to assure that test rig or apparatus is ready to begin operation.

3. Prepare special detailed test or operating procedures.

4. Define method for calibrating data collecting measuring and test equipment.

5. Define method for documenting data (technical notebooks or other).

6. Establish requirements for archive samples.

7. Define method for assuring that computer program designs are appropriate, and current.

8. Define method for assuring traceability of data (show how published data can be traced to raw data).

9. Define method of review (peer or other) to verify that test results are correct and meet test requirements and criteria.

10. Define method for identifying and storing test records including the use of computers to allow repeatability of tests.

Maintenance Phase:

1. Conduct special training of maintenance personnel.

2. Implement programmed mechanical maintenance program for routine maintenance activities.

3. Prepare special maintenance procedures.

4. Prepare special maintenance plans.

5. Identify requirements for spare parts including quantity and storage requirements.

6. Conduct inservice inspections and tests to verify integrity of systems and components.

7. Identify and store special repair and maintenance records.

ORNL

OAK
RIDGE
NATIONAL
LABORATORY

UNION
CARBIDE

ENVIRONMENTAL [illegible] DOCUMENTATION
QUALITY [illegible] PROGRAM

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OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-ES-1-100

DATE December 30, 1981

PAGE 1 of 9

SUPERSEDES ISSUE DATED August 28, 1979

TITLE: ENVIRONMENTAL SCIENCES DIVISION'S QUALITY ASSURANCE PROGRAM

I. Mission of the Division

The primary mission of the Environmental Sciences Division is to conduct strong fundamental and applied research and assessment programs in the environmental sciences that contribute to the goals of the Laboratory, UCC-ND, DOE, and other sponsoring agencies and to assist other divisions of the Laboratory in the successful accomplishments of research projects assigned to them.

state

III. Conduct of Research

Research in ESD is conducted by individual scientists. The scientists carefully plan their research, obtain the most suitable equipment for the experiments, studies, or sample analyses; perform appropriate calibration procedures, collect the necessary data; critically analyze the data; and compare them with other experimental results and theoretical calculations. A great deal of the laboratory research involves testing the responses of organisms to a variety of materials under various conditions. Often, the most critical aspect of these experiments is the maintenance of biological materials, so that damage is minimal due to causes other than those that are the subject of the experiments per se. Loss of plants or animals can result in a serious loss of time, whereas loss or damage of equipment may not be that serious because it can be replaced readily. The key to these kinds of studies in many cases is that they are done as a function of time. Most of the research equipment is relatively inexpensive and usually the scientists are involved in the design and construction, the purchase, and the testing of new equipment. Results of the investigation are presented promptly at scientific meetings and published promptly in scientific journals.

Research activities do not deal in large H&Ev. not Dg subcontract Large fabrication

6. Interpret Quality Assurance procedures for the Division.

7. Review and approve QA Program plans with the Division Director.

8. Maintain a list of locations of permanent files on Quality Assurance kept by each section of the Division.

9. Maintain a log or file of significant failures due to quality deficiencies occurring within the Division and the corrective actions that are taken.

10. Approve work orders, subcontracts, capital equipment requisitions, purchase requisitions (greater than or equal to $1,000) for outside fabrication, and instrumentation.

11. Review Field Task Proposal Agreement (FTPA) for Quality Assurance Assessment.

12. Inform each employee of ESD of the purpose, need, and scope of this Quality Assurance Program through orientation sessions.

C. Principal Investigator (supervisor)

1. Plans the research program for his group in concert with scientists involved and outlines these plans on Form FTPA. Deviations from these plans will be discussed with the Section Head and Division Director and then cleared with the program office of DOE.

2. Ensures that equipment and instrumentation used in an experiment or test is checked and calibrated such that data obtained from an experiment are accurate and within the required limits.

3. Consults the Division QAC for consideration of Quality Assurance application to all projects for which he is directly responsible. QA Assessment form UCN 12972 and QA Plan for Small Research & Development Projects (when applicable) shall be prepared for all FTPA's.

4. Notifies the Division Director and the QAC of any significant failure occurring during the operation of a project.

Ann Wilson: To impose top down enforcement only when necessary more important to instill in all the understanding and appreciation of QA so they will implement themselves.

H. Procurement control - procurement control provides assurance that each investigator receives equipment that is fit for its intended use. The PI has responsibility for ensuring that procurement control procedures are implemented:

1. Capital equipment

   a. The PI should consult with the ORNL servicing Division prior to preparation of requisition.

   b. Technical Specification for Procurement -- A technical specification shall be prepared by the PI or his designee and included on the purchase requisition for special items from outside sources. The technical specifications shall contain QA program requirements such as testing and inspection, acceptance criteria, and manufacturer's data. A copy of all purchase requisitions for special items shall be supplied to the QAC for review of quality requirements.

   c. Special Inspection. All items will receive a special inspection that shall be at a minimum conducted by the requisitioner (see appendix H). The requisitioner is required to determine the appropriate individual or organization for the special inspection.

   d. Loaned demonstrational equipment --Personnel accepting loaned demonstrational equipment shall prepare a "No Charge" requisition to cover liability while the equipment is on loan. The "No Charge Requisition" shall include: date received, who delivered, length of loan, reason for loan, and the equipment's serial number and model number.

   e. The requisitioner should request 3 sets of operating manuals, maintenance manuals, and schematics as an item on the purchase requisition (PR).

   f. Tests performed on equipment by ESD should verify specification compliance by vendor.

c. Serve as a source of information for reports and technical talks.

d. Provide records for patent purposes. The notebook should be registered with Laboratory Records.

7. Reports failures of operational apparatus.

8. Assigns an individual the responsibility for each apparatus to ensure reliability of operation.

The above procedure is applicable to "on going" R&D projects, to modifications thereof, and to new R&D projects.

J. Fabrication, construction, and installation control - the following procedures are intended to ensure that fabricated materials will perform in a satisfactory manner: I will give you more specific examples of which

1. Fabrication and construction.

a. Review of design and estimation.

b. Verification of design specifications.

c. Approval of final engineering design drawings.

d. Performance of inspections and tests to assure compliance with specifications and drawings.

e. Use of inspection hold points when necessary.

f. Provision for training and certification of personnel.

2. Installation

a. Evaluation of work order progress.

b. Tests of equipment.

c. Assessment of equipment performance by the use of a prototype .

d. Review of design prior to the initiation of installation.

2. Are specifications clearly spelled out on requisition?

3. Have 3 sets of operating manuals, procedure manuals, and schematics been requested for the equipment?

D. Requisitions - noncapital equipment:

1. Have implementation guidelines (Section V, H2) for special inspections been considered?

2. When "NO SUBSTITUTE ACCEPTABLE" appears on the body of a requisition, is sole source documentation necessary?

3. Would a "REQUEST REVIEW OF BIDS" be beneficial?

4. Are items not considered "Off-The-Shelf" available as specified?

E. Fabrication (outside):

1. Are blueprints and/or specifications included?

2. Is a design review by customer necessary?

3. Should there be a review of bids? Should vendor be visited before bid is accepted?

F. Instrumentation:

1. Are specifications needed?

2. Has there been consultation with servicing division prior to requisition preparation?

Procurement examples

TITLE: QUALITY ASSURANCE ASSESSMENTS

Procedures:

A. Project Selection - All Projects* shall be assessed. Division/program management (or designee) with advice of the QAC shall review all projects within the division/program and determine which projects are to be defined as major and minor for assessment purposes.

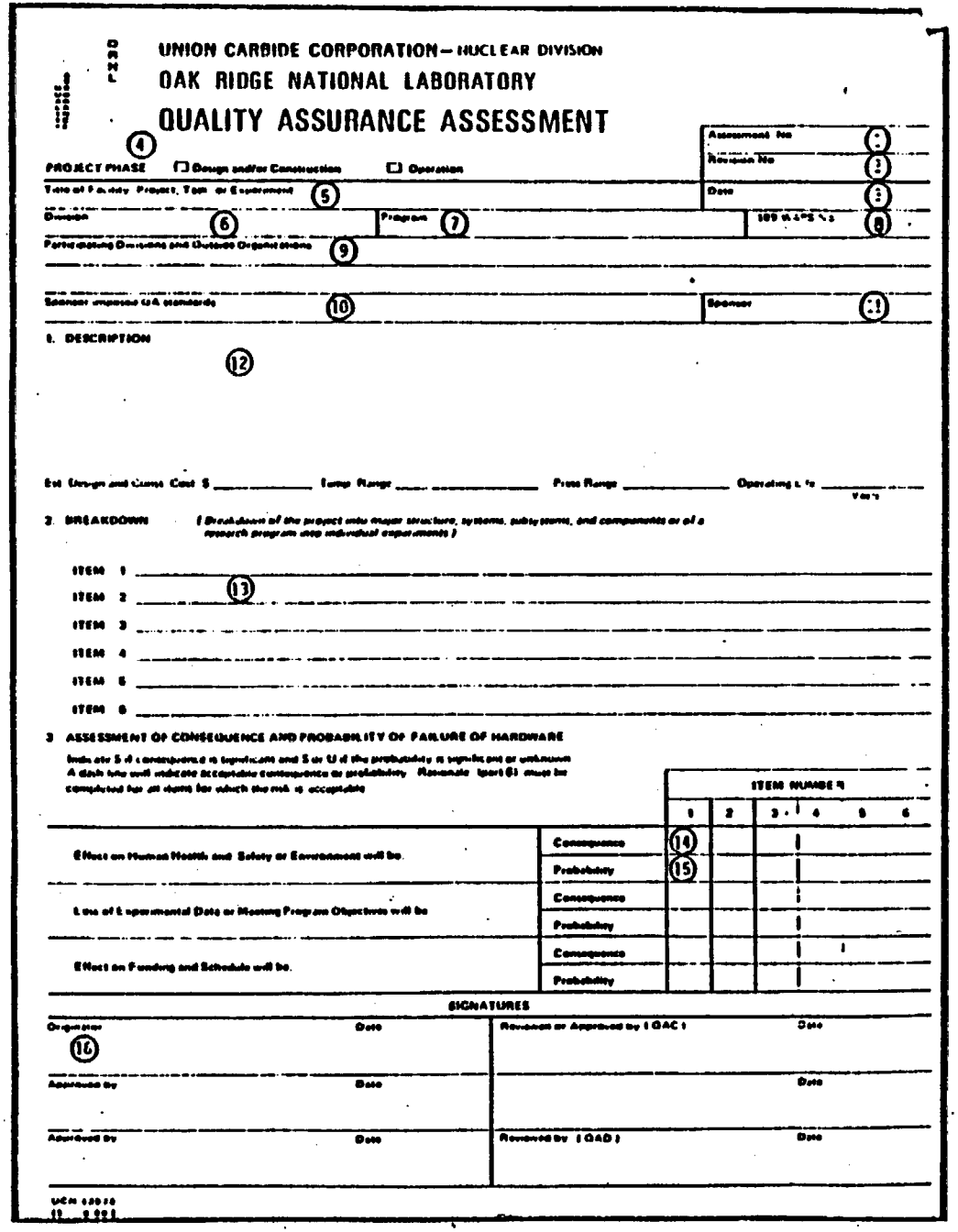
B. Assessment Schedule - The initial QAA shall be completed early in the design planning phase of the project. A QAA shall be completed for all existing projects and new projects entering the operating phase. A schedule for conducting assessments shall be prepared.

C. Review and Reassessment - Reassessment may be required by project scope changes, evidence that quality problems are developing, or the occurrence of significant quality failures. Each QAA shall be reviewed by division/program management (or designee) and the QAC at least every 12 months to determine if reassessment is required. When projects reach stable long-term operations, a 24-month review may be adequate. Reassessments shall be reviewed, approved and distributed in the same manner as QAAs. A copy of all reviews shall be sent to the QAD.

D. Records - The QAC shall maintain the record copy of all QAA documentation. The QAC shall maintain a log which lists the projects to be assessed/reassessed; schedule and current status. The log shall indicate if a PA Plan is required, its scheduled issue date and status.

E. Minor Projects Assessment - The task leader (originator), with QAC assistance, shall conduct the QAA meeting using Fig. 1 as guidance in steps to be followed. QAA form, UCN-12972, shall be completed to document results of the QAA meeting (see instructions in Appendix C for completing the form).

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



UNION CARBIDE CORPORATION—NUCLEAR DIVISION
OAK RIDGE NATIONAL LABORATORY
QUALITY ASSURANCE ASSESSMENT

(4) PROJECT PHASE ☐ Design and/or Construction ☐ Operation

Assessment No (1)
Revision No (2)
Date (3)

Title of Facility, Project, Task or Experiment (5)

Division (6) Program (7) 189 WAPS No. (8)

Participating Divisions and Outside Organizations (9)

Sponsor imposed QA standards (10) Sponsor (11)

I. DESCRIPTION (12)

Est. Design and Const. Cost $ _____ Temp. Range _____ Press. Range _____ Operating Life _____ Years

II. BREAKDOWN (Breakdown of the project into major structures, systems, subsystems, and components or of a research program into individual experiments) (13)

ITEM 1
ITEM 2
ITEM 3
ITEM 4
ITEM 5
ITEM 6

III. ASSESSMENT OF CONSEQUENCE AND PROBABILITY OF FAILURE OF HARDWARE

Indicate S if consequence is significant and S or U if the probability is significant or unknown. A dash line will indicate acceptable consequence or probability. Remainder (part B) must be completed for all items for which the risk is acceptable

		ITEM NUMBER					
		1	2	3	4	5	6
Effect on Human Health and Safety or Environment will be.	Consequence (14)						
	Probability (15)						
Loss of Experimental Data or Meeting Program Objectives will be	Consequence						
	Probability						
Effect on Funding and Schedule will be.	Consequence						
	Probability						

SIGNATURES

Originator (16)	Date	Reviewed or Approved by (QAC)	Date
Approved by	Date		Date
Approved by	Date	Reviewed by (QAD)	Date

UCN 12972 (1 9 81)

INSTRUCTIONS FOR COMPLETING QA ASSESSMENT FORM (UCN-12972)
(See Figure 1)

1. Enter number assigned by division or program.
2. If reassessment, enter revision number.
3. Enter date of initial assessment or reassessment.
4. Indicate project phase.
5. Enter name or title of project, facility, task or experiment.
6. Enter name of division/program preparing assessment.
7. Enter name of program, if applicable.
8. Enter 189/WAPS number, if applicable.
9. Enter name(s) of participating ORNL divisions and outside organizations, if applicable.
10. List sponsor imposed QA standard such as IMD 02XX.
11. List sponsor such as DOE-ORO.
12. Provide brief description of project and state its function or intended use. Define ground rules and assumptions that are used to limit assessment. Provide a measure of magnitude of project (i.e. estimated design and construction cost, temperature range, pressure range and operating life.)
13. List all principal items of project. Break down project into identifiable units which are reasonable and can be readily and adequately assessed.
14. Determine consequences of failure for each item and identify as acceptable(-) or significant(S). In determining consequences of failure consider all hardware related significant potential failure modes. Consider consequences of each failure on human health and safety and environment; loss of experimental data or meeting program objectives; and effect on funding and schedule. (Refer to Fig. 1)
15. Estimate probability of each failure and identify as acceptable (-), significant (S) or unknown(U), for each item whose consequence of failure is determined to be significant. (Refer to Fig. 1) When estimating probability of failure, take into account state-of-the-art, experience, normal application of procedures, human error, function interface and organizations involved.
16. a. Signature of originator and date.
    b. Signature of QAC and date.
    c. Signature of division/program manager and date.
    d. Signature of any additional person(s) as may be required by division/program procedures and date.
    e. Signature of QAD and date, if required (see paragraph 200.2).

General: Entries on form should be typed.

TITLE: QUALITY ASSURANCE ASSESSMENTS

EXAMPLES OF RATIONALE STATEMENTS

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

1. Training program and/or standard operating procedures provide adequate confidence that the item will perform satisfactorily in service. (The project must indicate that the training program and/or operating procedures are reviewed and evaluated on a periodic basis.)

2. Maintainability is very good.

3. Redundancy and/or backup systems are provided.

4. Item is standard "off-the-shelf" equipment of proven application for this use.

5. An established reliable design has been used. Item has a history of low failure frequency in a similar application.

6. Design, test and operational experience of item provide design maturity.

7. High confidence that standard quality control actions (inspection, test, procedure, etc.) are adequate to mitigate failure.

UNION CARBIDE CORPORATION — NUCLEAR DIVISION

OAK RIDGE NATIONAL LABORATORY

QUALITY ASSURANCE ASSESSMENT

APPENDIX C

Assessment No. OA-ES-1-100-36

Revision No.

PROJECT PHASE: ☐ Design and/or Construction ☒ Operation

Title of Facility, Project, Task, or Experiment: Engineered Test Facility

Date: 3/10/81

Division: Environmental Sciences

Program: Low Level Radwaste Management

189/WAPS No.: OR 3.5.4 AR

Participating Divisions and Outside Organizations: Subcontracts with University of Arizona and Indiana University

Sponsor imposed QA standards: 1MD02XX

Sponsor:

1. DESCRIPTION The Engineered Test Facility is devoted to a 5-year experimentation and evaluation of advanced LLW disposal techniques in a humid environment. Several waste disposal methodologies will be evaluated concurrently. Nine trenches with tracer-tagged synthetic waste will be used, 1 set of 3 controls, 1 set with liner treatment and 1 set with a fill treatment. Prior, during and after environmental monitoring will be performed.

Est. Design and Const. Cost $ 3.7M Temp. Range _____ Press Range _____ Operating Life 6 Years

2. BREAKDOWN *(Breakdown of the project into major structure, systems, subsystems, and components or of a research program into individual experiments)*

ITEM 1 Site Characterization

ITEM 2 Waste Emplacement

ITEM 3 Monitoring

ITEM 4

ITEM 5

ITEM 6

3. ASSESSMENT OF CONSEQUENCE AND PROBABILITY OF FAILURE OF HARDWARE

Indicate S if consequence is significant and S or U if the probability is significant or unknown. A dash line will indicate acceptable consequence or probability. Rationale (part 6) must be completed for all items for which the risk is acceptable.

		ITEM NUMBER					
		1	2	3	4	5	6
Effect on Human Health and Safety or Environment will be:	Consequence	-	-	-			
	Probability	-	-	-			
Loss of Experimental Data or Meeting Program Objectives will be:	Consequence	-	-	S			
	Probability	S	-	U			
Effect on Funding and Schedule will be:	Consequence	-	-	-			
	Probability	-	-	-			

SIGNATURES

Originator: Nancy D. Vaughan	Date: 3/10/81	Reviewed or Approved by (QAC): M. H. Shanks	Date: 5-14-81
Approved by: Norman Cutshall	Date: 3/10/81		Date:
Approved by: DOE	Date: 5/19/81	Reviewed by (QAD):	Date: 8/28/81

UCN-12972
(3 8-80)

Document No.: ES-20-QAP-1
Issue Date: July 28, 1981
Revision: 0

APPENDIX D

Quality Assurance Plan for Engineered Test Facility located in Solid Waste Disposal Area 6 Oak Ridge, Tennessee

Environmental Sciences Division
Oak Ridge National Laboratory

Prepared By

Nancy D Vaughan — Task Leader — July 29, 1981 — Date

Approvals

Marvin H. Shanks — QA Coordinator — July 30, 1981 — Date

T. Tamura — Section Head — July 30, 1981 — Date

D C D Uberbacher — Division Director — 4 Aug 81 — Date

Norman Cutshall — Program Manager — July 29, 1981 — Date

ORNL QA Director — 8/28/81 — Date

Distribution

Task Leader
Section Head
Division Director
Program Manager
QAC
QA Director

Title: Quality Assurance Plan for Engineered Test Facility located in Solid Waste Storage Area 6, Oak Ridge, Tennessee

1.0 Scope

This document describes the quality assurance plan for the Engineered Test Facility in SWSA 6. The plan defines the actions that will be taken and designates responsibility for specific project participants for each action to ensure that the potential significant quality failures cited in the Project Quality Assurance Assessment are unlikely to occur.

This Project Quality Assurance Plan is intended for use in the management and implementation of the quality assurance requirements to be applied to the project. The requirements pertain to the following activities: site characterization, waste emplacement, monitoring.

2.0 Description of Project

The Engineered Test Facility site is to be used for a five-year period of experimentation and evaluation of advanced LLW disposal techniques in a humid environment. After site characterization nine pilot-scale (3 x 3 x 4.5 m) trenches will be emplaced with tracer-tagged waste. One set of three trenches will be preserved as controls, another set will have a liner, and the third set will have grout. Total open time should be 6 months to simulate actual burial practice. Hydrologic monitoring of the site will begin at the site characterization stage and continue for the life of the project to establish the success or failure of each treatment method.

QA PROGRAM

Individual/Organization

A-Approve
P-Perform
R-Review
C-Copy
I-Inform

Activity	Task Leader	Section Head	Division Director	Program Manager	Division QAC	I & C	QA Director
1. Perform Project QA Assessment	P		A	A	A		
2. Prepare Project QA Plan	P		A	A	A		
3. Select Site Characterization Parameters	P	I		I			
4. Assemble Instruments for Site Characterization (Field Ready)	R					I	
5. Monitor Field Equipment	R					I	
6. Prepare Purchase Requisitions	P/R		A	A			
7. Prepare Emplacement Design & Requirements	P	I		I			
8. Prepare Purchase Orders	P/R		A	A			
9. Conduct Receipt Inspections	C					A	
10. Conduct QA Activity Audit	C			C	P		
11. Update PQAP as Required	P/A			A	A		

TABLE 1

Special QA Actions

Potential Significant Failure Modes of Concerns and Causes	Special QA Action	Schedule	Responsibility
1. Improper operation or total failure of field instrumentation causing loss of data* Cause: (a) Malfunction of data collecting equipment. (b) Operation error	(a) Establish a maintenance system which includes calibration of new instruments, recalibration of old instruments, and weekly check when charts are changed.** (b) Operators are trained in use of equipment	(a) System is instituted by 7/1/81. All instrumentation is checked weekly.*** (b) Operator training completed by 6/1/81	Task Leader: N. D. Vaughan Technicians: O. M. Sealand, N. D. Farrow Task Leader: N. D. Vaughan

* This potential significant failure mode and the special QA action is the same for both Site Characterization and Monitoring (as identified on the QAA).

** Instrumentation includes water level recorders, rain gauge, dipper-flow meters and samplers and tensiometers.

*** When instrumentation is found to be malfunctioning during the weekly check, an in-house check is performed by responsible party. Backup instrumentation or parts are available for replacement and/or repair, and are obtained by procurement. Aid from Instrumentation and Controls Division sought when deemed necessary by responsible party.

TITLE: QUALITY INVESTIGATION AND CORRECTIVE ACTION

A. Purpose:

To define requirements for investigating and reporting quality problems; and for planning and tracking corrective action.

B. Scope:

This procedure applies to internal reporting of quality problems. When reporting unusual occurrences to DOE see Refs. 1 and 2. This procedure applies to all projects* and activities during design, procurement, manufacturing, fabrication, installation, acceptance testing, preoperational testing, and operation.

C. References:

1. Quality problems, ORNL QA-L-6-101.
2. Unusual Occurrences Notification, Investigation, and Reporting, UCC-ND Standard Practice Procedure D-5-16.
3. Quality Failure Investigation and Reporting, UCC-ND Engineering EQA-19.

D. Requirements:

When a quality problem occurs and when the problem has or could have a significant impact on the project/program/activity, an investigation shall be undertaken to: (1) determine the cause of the problem, (2) evaluate QA measures which were taken and (3) define appropriate technical and QA coorective actions and follow-up.

*When UCC-ND Engineering has been assigned management responsibility, Quality Problems will normally be reported by Engineering in accordance with Ref. C.

TITLE: QUALITY INVESTIGATION AND CORRECTIVE ACTION

EXAMPLES OF QUALITY PROBLEMS TO BE INVESTIGATED

The following problems should be considered for a quality investigation when they have or could have a significant impact on a project or activity:

1. Failure of a system or component to meet performance requirements during acceptance testing, preoperational testing and operation including in-service inspection.
2. Unexpected leakage, rupture or degradation of integrity of equipment.
3. Detection of the inability of a safety or emergency system to function as intended.
4. Equipment or personnel actions which adversely affect project operation.
5. Unplanned or uncontrolled releases of radioactivity from a project.
6. Discovery of foreign objects or material in project equipment or system.
7. Deviations from approved procedures which cause malfunction of the equipment.
8. Discovery of a design deficiency, such as an overstress condition.
9. Unexpected operational interruption other than scheduled shutdown, those caused by normal wear and tear or those "test to failure" type experiments.
10. Errors which result in program delays or create safety hazards.
11. Latent defects or rejections of material or equipment recognized subsequently in inspection.
12. Significant nonconformances.
13. Nonexistent or deficiency in the QA assessment.
14. Deficiency or unapproved deviation from the approved QA plan.

TITLE: QA AUDITS

A. Laboratory

1. Purpose

To define Laboratory requirements for quality assurance (QA) audits at ORNL and at support facilities.

2. Requirements:

Adequacy and effectiveness of the ORNL QA program are monitored through audits. These ORNL QA audits include appraisal of planning, management, and implementation of QA in:

Research and Development,
Design,
Procurement,
Fabrication, Construction, and Installation,
Inspection and Testing, and Operation, Maintenance, and Modification.

Audits and re-audits will be performed periodically, or as deemed necessary for purposes of the ORNL QA Program. They will be scheduled and conducted so as to minimize disruption of work in progress.

3. Responsibilities:

The ORNL QA Director (QAD) is responsible for providing an effective ORNL QA audit program.

The ORNL QA Lead Auditor (QALA) has responsibility for scheduling and conducting the audits in the program.

Divisional or programmatic QA Coordinators (QACs) are responsible for conducting audits internal to their organizations. They are also responsible for maintaining audit logs for the organizations, and for follow-up on any required corrective actions concerning their organizations.

f. The audit report, including introductory statement as to the audit scope and criteria, observations, findings and commitments (if any), attendance lists and agreement and commitments, will be signed by every member of the audit team, and distributed by the QAD, to the auditee, the responsible ORNL Associate Director, the Head of the Department of Quality Assurance and Inspection, and the audit team.

g. All provisions of the above procedures apply to any required re-audits.

B. Division/Program Internal Audits

1. Procedures

a. Internal audits shall be conducted by ORNL Divisions or Programs on a periodic or random, unscheduled basis. The Division or Program QAC has audit responsibility within his organization paralleling that assigned to the QALA as regards the Laboratory, and may choose to operate in the manner shown for the QALA or in a more informal fashion in the internal audits.

b. On completion of an internal audit, the QAC and his audit team shall meet with appropriate personnel of the audited department, group, or task to agree upon any commitments that will become part of the audit report. The audit report should be signed by the QAC, the auditee, and audit team members.

c. The QAC shall distribute the audit report to Division or Program Management, and maintain a copy in his files.

SECTION

DATE
April 23, 1981

GLOSSARY OF SELECTED TERMS

ACCEPT - To certify that item(s), or specific characteristics of the item(s), conform to the criteria, requirements, standards, or limits established by the specified QA documents.

ACCEPT "AS-IS" - To certify that specific discrepancies will not adversely affect the function of an item or degrade the reliability of the item or any portion of the system of which it is a part.

ACCEPTANCE CRITERIA - Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents. (Ref: ANSI/ASME NQA-1). (R)

AUDIT - A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance (Ref: ANSI/ASME NQA-1). (N)

CALIBRATION - The act of determining the accuracy of a measuring instrument by comparing it to a standard.

CALIBRATION STANDARD - A standard maintained at the National Bureau of Standards (NBS) or other institutions as designated by Congressional statute is a National Reference Standard. A standard maintained at other standards laboratories calibrated against a Primary Standard is a Working Standard. A standard of the highest accuracy order in a calibration system which establishes the basic accuracy values for that system is a Reference Standard. A standard which has been calibrated against a standard of higher order of accuracy is a Transfer Standard.

CAPITAL CONSTRUCTION - A capital construction project involves design, procurement, construction, fabrication, installation, or combinations thereof associated with the addition or improvement of a plant, building, structure, system, process, etc. For general guidance a 10% increase in asset value or a minimum increase of $25,000 can be used to represent an improvement (Ref. UCC-ND Engineering EP-8-06).

1. Line Item: A line item is a capital construction project that normally has a total estimated cost in excess of $1,000,000.

2. General Plant Project (GPP): A general plant project is a capital construction sub-project that has a total estimated cost of less than $1,000,000. All GPPs within a given program are budgeted as a single unit and receive an annual appropriation of funds.

3. Contingency-Type Project: A contingency type project is a capital construction project for which firm detailed plans cannot reasonably be determined at the time the estimates are prepared. These projects are of sufficient urgency that they cannot be defined and included as line items for routine Congressional approval. They are funded by DOE from an allowance granted by Congress to cover such urgent major projects.

SECTION	
DATE	April 23, 1981

GLOSSARY OF SELECTED TERMS

GENERAL PLANT PROJECT (GPP) - See Capital Construction.

HOLD POINT - Stages of the work at which witnessing or objective examination is required before further processing (UDD-ND Office of QA). (R)

IR NUMBER - An Inspection Request number, assigned by the Department of Quality Assurance and Inspection, used within ORNL to identify material with inspection files.

INSPECTION - That phase of quality control which, by means of examination or test, determines the conformance of supplies, materials, services, processes, or items to establish requirements (Ref. ANSI N45.2.10).

INTERFACE - The identifiable point of connection or coordination between two or more defined physical, performance, or organizational entities leading to the intended end result.

ITEM - An all-inclusive term used in place of any of the following: apportenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, unit, or facility (Ref. UCC-ND SPP-D-2-16 and ANSI/ASME NQA-1).

LEAD DESIGNER (PRINCIPAL ENGINEER) - A qualified person who is responsible for the accomplishment of design, specification, or engineering actions, functions, or requirements necessary for attainment of the technical objectives of the design phase.

LINE ITEM - See Capital Construction.

MANUFACTURING AND INSPECTION PLAN - A document normally prepared by the controlling manufacturing shop and the Inspection Agency that details the sequential process through which a part, subassembly, or assembly is routed in all stages of machining, welding, heat treating, inspection, etc, and the respective inspection, hold, and sign off points.

MATERIAL MILL CERTIFICATE (MILL TEST REPORT) - A form furnished by a material manufacturer or supplier certifying the compliance of specific manufacturing processes, tests, examination, identifications, or other specified requirements to the purchase specifications.

MATERIAL REVIEW BOARD (MRB) - A formal board established for the purpose of reviewing, evaluating, and disposing of nonconforming items (Ref. UCC-ND Office of QA). (N)

NONCONFORMANCE - (A) A deficiency in characteristic, documentation, or procedures that renders the quality of an item or activity unacceptable or indeterminate (Ref. ANSI/ASME NQA-1). (B) The failure of a characteristic of an item to conform to specific requirements (UCC-ND Office of QA). (R)

OBJECTIVE EVIDENCE - Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified (Ref. ANSI/ASME NQA-1). (N)

PROJECT - A planned undertaking such as a definitely formulated piece of research or a large government supported undertaking (Ref. Webster's Dictionary). Note: A generic term for experiments, tasks, tests, jobs, programs, etc.

SECTION	
DATE	April 23, 1981

GLOSSARY OF SELECTED TERMS

QUALITY INVESTIGATION - The actions taken as the result of a quality problem to: (1) determine the cause of the problem (2) evaluate the QA measures which were taken, and (3) define any appropriate corrective action and follow-up (Ref. UCC-ND Office of QA). (R)

QUALITY PROBLEM - A difficulty (existing or with potential) which has resulted in or is judged to be likely to lead to a significant quality failure, or which would have a prolonged detrimental effect on the quality level of a product or major item (Ref. UCC-ND Office of QA).

QUALITY RECORDS - Documented information that indicates the extent of conformance of articles or quality characteristics to contractual requirements, applicable specifications, or drawing requirements.

QUALITY VERIFICATION - Those actions required to confirm, substantiate, and ensure that items or services (including subcontracted items) submitted to the purchaser for acceptance, conform to the specified quality requirements.

REMEDIAL ACTION - Those immediate actions taken following a quality failure, nonconformance, or unusual occurrence which will permit the item, system, facility or program to continue.

REJECT - Endorse authoritatively that items do not conform to specified requirements.

RELIABILITY - The probability that an item will perform its intended function for a specified period of time under stated conditions (Ref. UCC-ND Office of QA). (R)

REPAIR - The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirements (Ref. ANSI/ASME NQA-1).

REWORK - The process by which an item is made to conform to original requirements by completion or correction (Ref. ANSI/ASME NQA-1). (R)

RISK - The combined effects of the probability and consequences of a failure of an item expressed in qualitative or quantitative terms (Ref. UCC-ND SPP-D-2-16).

ROUTINE ITEM - An item whose risk of failure without special preventive actions is judged to be acceptable (Ref. UCC-ND Office of QA). (R)

SATISFACTORY PERFORMANCE - Performance which may not be perfect but which is safe and acceptable. A reasonable amount of maintenance may be required and operation is essentially as expected.

SPECIAL ITEM - An item whose failure would have a significant adverse impact on such factors as safety, environment, performance, costs, or schedules and for which the risk of failure without special preventive actions is judged to be unacceptable (Ref. UCC-ND Office of QA). (R)

SPECIAL TECHNICAL REQUIREMENTS - Those requirements or characteristics of a special item that are essential to the satisfactory performance of the item.

APPENDIX H

OAK RIDGE NATIONAL LABORATORY QUALITY ASSURANCE PROGRAM	QUALITY ASSURANCE PROCEDURE
	PROCEDURE NO. QA-FM-11-0805
	PAGE Exhibit "C" 1 of 1

TITLE: SPECIAL RECEIVING INSPECTION

UNION CARBIDE

UNION CARBIDE CORPORATION
NUCLEAR DIVISION

RECEIVING REPORT

Requisition No.	Deliver by	Wanted by	Attention	Plant	Order Number	Release No.	Procurement Date
M 9169	9-22-75	9-1-75	D. W. Brown	X-10	548-52774	Z03	7-17-75

ABOVE ORDER AND RELEASE NO. MUST APPEAR ON ALL PACKAGES, B/L, AND FREIGHT BILLS. SHIP TO PLANT INDICATED ABOVE:

Shipping Point: Plainview, NY

Vendor: V42871
Veeco Instruments, Inc.
Terminal Drive
Plainview, NY 11803

DNP

Attention: George F. Shinbrot

Suggested vendor:
Veeco Instruments, Inc.
Terminal Drive
Plainview, NY 11803

Item No.	Description	Ordered Quantity	Unit	Unit Price
1	L-59626-01 (Release Z03 against P. O. 548-52774). Control Unit, modular, for a high vacuum ionization gauge, in strict accordance with UCC-ORNL Specification SP-230A.	12	ea	500 96

INSPECTION REQUIRED

Special Inspection
Date of Inspection ____
Item(s) ____ Accepted
Item(s) ____ Rejected
Item(s) ____ Nonconforming
But Accepted (See Attachment)
Inspection Report
Attached ___Yes ___No
Inspector ____
Inspection Waived by ____

DWB;jcg

Inspection required: 2 — J.M. Groover

Requisitioner: H. L. Brant — Date: 7-14-75

Refer technical questions to: G. A. Holt — Phone: 3-1105

Deliver to: Brant/Holt — Building: 3500, Rm. 39

UCN-9834A
3 3-71

INTRA-LABORATORY CORRESPONDENCE

OAK RIDGE NATIONAL LABORATORY

June 4, 1984

To: N. H. Cutshall

From: I. L. Larsen

Subject: Quality Assurance-Quality Control for Radionuclide Analysis in the Environmental Sciences Division

Gamma-emitting radionuclides are analyzed by direct non-destructive photon counting. Samples are packed into appropriate containers and counted directly on Ge(Li) or intrinsic germanium detectors. Calibration has been described by Larsen and Cutshall (1981). A certified reference standard solution of mixed gamma emitters (Amersham, QCY.44 traceable to NBS) is quantitatively prepared in the appropriate sample geometry and counted for a sufficient time period to accumulate a smooth spectrum. After counting, a peak search program is used to locate peaks and to determine photopeak areas. From the photopeak counting rates and the known photon emission rates, the efficiencies for the particular sample container are calculated. The analyzer used in acquiring spectral data is a microprocessor-based system programmed to record gamma-spectra in 4096 channels (Nuclear Data Model 6700).

Accuracy of the efficiency calibration process is determined by analyzing certified Standard Reference Materials (National Bureau of Standards) and comparing the measured activities with the expected concentrations (Table 1).

For low-energy photon detection (i.e., ^{210}Pb, ^{241}Am), samples are counted using a 20 cm^2 by 16 cm thick planar intrinsic germanium (IG) detector having a thin beryllium window. The technique has been described by Larsen and Lee (1983). Corrections for sample self-absorption are made and activity units calculated (Larsen and Lee (1983). Performance checks of ^{241}Am photon counting were made by comparing the results of analysis of several NTS soils by radio-chemical separation and alpha counting to the direct photon counting procedure (Table 2). A similar comparison was also made with an IAEA marine sediment sample (Table 3). These results indicate excellent agreement between direct photon counting method and standard wet chemical separation and alpha spectrometry.

In addition to the above standardizations and intercomparisons, we participate routinely with the Environmental Protection Agency (Las Vegas, NV) Quality Control-Quality Assurance Program. A copy of the FY 1982 summary report is attached (attachment 1).

References

Larsen, Ingvar L. and Norman H. Cutshall. 1981. Direct determination of ^{7}Be in sediments. Earth and Planetary Science Letters 54:379-384.

Larsen, I. L. and S. Y. Lee. 1983. Nondestructive photon analysis of ^{241}Am in soils and sediment utilizing self-absorption corrections. Jour. Radioanalytical Chem 79(1):165-169.

Table 1. Comparison of measured values with expected values for NBS SRM 4353 Rocky Flats Soil #1, 15cc container, 13.85 grams

pCi/gram July, 1983

	Measured		Expected
	Detector No. 1	Detector No. 2	
Cs-137	0.45 ± 0.05	0.52 ± 0.05	0.45 ± 0.01
Ac-228	2.03 ± 0.17	1.92 ± 0.18	1.89 ± 0.03
Pb-214 (Ra-226)	1.21 ± 0.09	1.23 ± 0.09	1.16 ± 0.03
K-40	21.8 ± 0.9	20.00 ± 0.9	19.5 ± 0.6

Table 2
Comparison between photon counting and radiochemical separation-alpha spectrometry of ^{241}Am for Nevada Test Site soil samples (Area 201)

Sample code	Photon counting		Radiochemical-alpha counting	
	g	pCi/g	g	pCi/g
A	5.07	0.18 ± 0.04	0.1	0.6 ± 0.1
B	10.46	1.? ± 0.1	0.1	1.1 ± 0.2
C	5.42	7.2 ± 0.5	0.1	6.8 ± 0.2
D	8.74	20.9 ± 1.0	0.1	17.1 ± 2.0
E	5.40	36.0 ± 2.1	0.4	40.5 ± 3.0
F	9.00	146.0 ± 6.0	0.1	126.0 ± 2.0
G	4.92	446.0 ± 23	0.1	543.0 ± 22
H	10.38	2360.0 ± 93	0.1	2210.0 ± 22

±indicates one sigma. For photon counting this represents the pooled uncertainties based on counting statistics, transmission measurements, and precision and accuracy of the standard. For radiochemical separation and alpha counting of the Nevada Test Site soil samples this represents counting statistics and yield recovery uncertainties only.

Table 3

Comparison of ORNL photon counting results with U. S. Department of Energy round-robin intercomparison study.[10] IAEA marine sediment SD-B-3 pCi/g ^{241}Am

Laboratory	ORNL	ANL	SIO	WHOI	OSU	EML/IAEA
Method	*Photon counting	α	α	α	α	α
Results	0.192±0.021	0.142±0.003	0.194±0.009	0.188±0.018	0.162±0.018	0.168±0.025

*26.31 g

ORNL Oak Ridge National Lab., Environmental Sci. Div.
ANL Argonne National Lab., Ill.
SIO Scripps Inst. of Oceanog., Calif.
OSU Oregon State Univ. School of Oceanog., Oregon.
EML Environmental Measurement Lab., N. Y.
IAEA International Atomic Energy Agency, Monaco.
WHOI Woods Hole Oceanog. Inst. Mass.

ATTACHMENT 1

Quality Control-Quality Assurance Summary

October 1982 to September 1983

Environmental Science Division, Bldg. 3504, ORNL

Ingvar L. Larsen

During fiscal year 1983 the Environmental Sciences Division Low-Level Gamma Spectroscopy Laboratory participated in a nationally sponsored Quality Assurance-Quality Control radioanalytical program. This program, directed by the Environmental Protection Agency (EPA) at Las Vegas, Nevada, has over one-hundred participants which include national laboratories, federal health organizations, state surveillance and enforcement agencies, nuclear power plant facilities, universities, and military installations, as well as private industries including mining and processing facilities. Samples sent to the participants include: 1) cross-check solutions; 2) spiked liquid food samples (instant potato mix/powdered milk); 3) "Blind" solutions. A form specifying particular radionuclides to be reported is included with each sample. Results are submitted to EPA by a specified date. Approximately 30 days after the cutoff date, a preliminary report is received by each participant indicating the expected concentrations in the sample. A final report summarizing each laboratory's result (anonymously listed) along with a selected mean (outliers rejected) is also sent within 60 to 90 days after the cut-off date. This report allows comparisons to be made not only with the expected values, but also to the selected mean of the participating laboratories.

Results reported in the accompanying table are those performed by direct gamma-ray spectrometry and consequently do not include determinations requiring alpha or beta counting. All values lie within acceptable criteria ($\pm 3\sigma$), with the exception of one sample (^{137}Cs, 1 October 1982) which was considerably higher and outside the acceptable range of the expected value. This value was attributed to contaminations from use of "assumed clean" general usage laboratory glassware. The glassware apparently had been used in preparing highly contaminated waste pond water samples. This occurrence indicates the ease with which contamination can occur and demonstrates the care necessary in handling and preparing such samples for analysis.

In late September of 1982, the EPA in conjunction with the Nuclear Regulatory Commission (NRC) distributed a soil sample containing radium and daughter radionuclides. The sample was analyzed directly by gamma-ray spectrometry for ^{226}Ra and by low-energy photon analysis techniques developed in our laboratory (N. H. Cutshall, I. Larsen, and C. R. Olsen) for ^{210}Pb and ^{238}U determinations. The results presented in the accompanying table are in agreement within the expected results.

RESULTS OF QUALITY CONTROL - QUALITY ASSURANCE SAMPLES October 1982-September 1983 pCi/liter (± 1σ)*

Date	Sample Identification		Co-60	Cs-137	Cs-134	Cr-51	Zn-65	Ru-106	I-131	Ba-140
1 Oct 82	Liquid Cross-check	M	19±1	**67±1	16±1	43±5	25±3	27±2		
		E	20±5	20±5	18±5	51±5	24±5	30±5		
		A	20±3	21±3	18±3	51±15	24±4	31±8		
15 Oct 82	Liquid Blind	M	<1	20±1	2±0.2					
		E	0	20±5	2±5					
		A	3±7	20±3	6±11					
5 Nov 82	Liquid Food	M		28±3						
		E		27±5					24±1	<5
		A		29±4					25±6	0
									25±5	N.R.
4 Feb 83	Liquid Cross-check	M	21±1	18±1	17±1	44±1	22±2	45±1		
		E	22±5	19±5	20±5	45±5	21±5	40±5		
		A	23±3	19±3	20±3	48±10	22±5	47±10		
4 Mar 83	Liquid Food	M		30±2						
		E		31±5					33±3	<3
		A		33±3					37±6	0
									37±4	N.R.
9 May 83	Liquid Blind	M	28±1	26±1	27±1					
		E	30±5	27±5	33±5					
		A	31±4	27±4	31±4					
3 Jun 83	Liquid Cross-check	M	12±1	26±2	39±1	58±4	36±2	40±5		
		E	13±5	25±5	47±5	60±5	36±5	40±5		
		A	14±2	28±5	44±4	62±11	37±6	40±7		

N.R. - Not Reported

M - Measured Value; E - Expected Value; A - Selected Average of Participating Laboratories

* - based on two or more analysis, except when values were the same, the counting error was reported

** - high value resulted from use of contaminated glassware

< - "Less Than" values reported when requested radionuclide was not detected

RESULTS OF QUALITY CONTROL - QUALITY ASSURANCE SAMPLES October 1982-September 83 pCi/liter (± 1 σ) (con't)

Date	Sample Identification		Pb-210	Ra-226	U-238	Th-230
14 Sep 82	NRC Soil	M	5.3±0.2	3.3±0.9	2.2±0.2	N.A.
		E	5.2±1.3	5.2±1.8	2.4±0.3	5.7±0.9
		A	4.4±2.7	4.3±2.0	2.5±1.1	4.3±2.1

N.A. - Not Analyzed

SUBJECT: QUALITY ASSURANCE PROGRAM

2-16.1 POLICY: It is company policy to maintain a cost-effective quality assurance program which will provide adequate confidence that items in the company are fit for their intended use.

2-16.2 PROGRAM OBJECTIVES:

a. To enhance the success and reduce the cost of company activities by lowering the probability for occurrence of significant failures of items and by reducing the impact of failures which do occur.

b. To maintain a positive attitude for assuring all specifications are met and a commitment to excellence is pursued by all employees.

c. To ensure appropriate application of both special and routine assurance actions through effective planning for prevention of significant failures.

d. To provide compliance with contractual requirements for quality assurance activities.

2-16.3 DEFINITIONS:

a. Item: An all-inclusive term used in place of any of the following: assembly, component, equipment, material, module, part, structure, subassembly, subsystem, or facility.

b. Quality: Fitness for intended use.

c. Quality Assurance (QA): The planned and systematic actions necessary to provide adequate confidence that an item will perform satisfactorily in service.

d. Quality Failure: Occurs when an item is unfit for its intended use or when it fails to perform satisfactorily in service.

e. QA Assessment: A documented evaluation of a project or major item in which potential failures and uncertainties are identified and the associated risk is determined.

f. QA Plan: A document which describes potential significant quality failures, defines the QA actions required to provide confidence that these failures are unlikely to occur, and specifies the responsibility and schedule for carrying out the QA actions.

g. Risk: The combined effects of the probability and consequences of a failure of an item expressed in qualitative or quantitative terms.

2-16.4 QUALITY PHILOSOPHY: In order to accomplish the company Quality Assurance (QA) objectives, it is important for each employee to maintain a concern for efficient quality achievement. Each person should be alert for situations where special efforts might be needed to assure quality. Early identification of important quality requirements and implementation of appropriate assurance actions to prevent significant failures are the key elements of the company QA program, which includes two principal categories of quality-related activities.

a. Special QA Activities

On some items there are potential quality failures which would have significant adverse impact on such factors as safety, environment, performance, costs, or schedules. When the risk of such failures is unacceptable, it is prudent to plan special activities to lower the probability that they will occur and/or to reduce their impact if they do occur. These special activities could include special design review; prototype, first article and systems tests; special inspection requirements; special handling instructions; etc. When reliance on certain routine quality activities is necessary to assure the quality of an item which has unacceptable risk, special efforts must be made to ensure that these activities are completely implemented. It is important that the level of effort be consistent with the potential impact of failure so that the special activities are cost-effective.

b. Routine Activities

Activities specifically aimed at control of quality are routinely applied throughout the company. They include such actions as design verification, process control, inspection, material control, testing, personnel certification, equipment certification, audits, etc. For many items these routine activities provide adequate confidence that quality requirements will be met.

2-16.5 RESPONSIBILITIES:

a. Quality Director:

1. Establishes and interprets overall QA policy for the company; defines overall QA standards and goals.

2. Coordinates the implementation of the overall company QA program; provides guidance and assistance for QA program implementation to members of the QA Committee and managers.

2-16.5 a. RESPONSIBILITIES - cont.

3. Monitors the QA actions taken when significant quality failures occur or QA program deficiencies are detected. Initiates corrective action through appropriate channels when necessary. Assures management is aware of unusually significant quality failures.

4. Judges, through audits and regular contacts with other managers, the adequacy of the company QA activities for organizations and specific programs, and regularly reports the status to management.

5. Serves as focal point for company communication with the DOE-ORO Standards and Quality Assurance Division.

6. Ensures, in concert with company management, that appropriate QA committees are appointed for major projects and that the responsibilities of these special committees are defined.

7. Chairs the company QA Committee. (Committee typically includes the QA Coordinator for each plant, for Engineering, and for selected major projects.)

8. Suspends the flow of production or work when quality standards are threatened.

b. QA Coordinators for Installations, Engineering and Major Project Areas:

1. In concert with the appropriate manager and the Quality Director, define the QA program which is required within the organization and coordinate its implementation.

2. Assist organization personnel in implementing the QA program.

3. Define and conduct or coordinate training and quality awareness programs to assure that personnel understand the QA program and their responsibilities for its implementation.

4. Evaluate the effectiveness of QA activities and report QA program status to management and the Quality Director regularly. Schedule and conduct or coordinate QA audits of organization activities. Initiate corrective action through appropriate channels as necessary.

5. As appropriate, ensure utilization of organizations/personnel who are independent of those doing the work to verify item quality and for other assurance activities.

2-16.5 b. RESPONSIBILITIES - cont.

6. Seek out potential quality failures which have not been given adeq attention and ensure that preventive action is taken when needed.

7. Ensure that quality failure investigations adequately evaluate deficiencies in the QA program or its implementation.

8. Chair the QA committee for the installation, Engineering or major project area.

c. Division or Project QA Coordinators:

1. In concert with installation, Engineering or major project area QA Coordinators, coordinate the implementation of the required QA activities.

2. Conduct or assist in training and quality awareness programs.

3. Evaluate the effectiveness of QA activities in the organization and report the status to appropriate line and QA managers regularly. Schedule and conduct or coordinate QA audits of organization activities. Initiate or ensure the performance of corrective action through appropriate channels as necessary.

4. As appropriate, ensure utilization of organization/personnel who are independent of those doing the work to verify item quality and for other assurance activities.

5. Seek out potential quality failures which have not been given adequate attention and ensure that corrective action is taken when needed.

6. Ensure that quality failure investigations adequately evaluate deficiencies in the QA program or its implementation.

d. Managers:*

1. Are responsible for the quality of operations in their organization and for implementation of a QA program as required to assure that quality adequately.

2. Appoint a QA Coordinator for their organization.

*Refers to managers/directors of plants, divisions, and major projects or programs.

2-16.5 d. RESPONSIBILITIES - cont.

3. Assure subordinates understand, accept, and implement the QA program.

4. Assure routine and special quality-related activities in their organization are appropriate.

5. Regularly judge the effectiveness of QA in their organization, in concert with the Quality Director or Coordinator, and take corrective action as necessary.

6. Utilize independent organizations and/or personnel to verify item quality and for other assurance activities as appropriate.

e. Organization Personnel:

1. Maintain a concern for achieving good quality and take appropriate preventive measures when potential quality failures are recognized.

2. Understand, accept and implement the QA program.

3. With assistance from QA coordinator, perform QA assessments; develop and implement QA plans, as required.

4. Identify significant quality failures when they occur, initiate quality failure reports, participate in the investigation, and take required corrective action.

5. Include QA items in reports to management and provide information to the QA coordinator for inclusion in QA reports.

2-16.6 PROGRAM REQUIREMENTS:

a. Develop and implement procedures which provide compliance with this procedure and with approved supplements thereto for:

1. Performing QA assessments.

2. Preparing and implementing QA plans.

3. Conducting QA audits.

4. Investigating and following up on quality failures.

5. Reporting QA program status.

2-16.6 PROGRAM REQUIREMENTS - cont.

b. Apply the QA program to all company activities (R&D, design, procurement, construction, installation, production, operation, maintenance, etc). Tailor the level of effort to be consistent with the impact of potential failures.

c. Conduct programs to ensure general understanding and constant awareness of QA program responsibilities and requirements.

d. Ensure that routine assurance activities (e.g., equipment calibration, disposition of nonconformances, receiving inspection, process controls, material control, personnel certification, etc.) are appropriately employed.