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To: J.W. Bradbury
From: Susan K. Whatley

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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 occurring. 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).

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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.

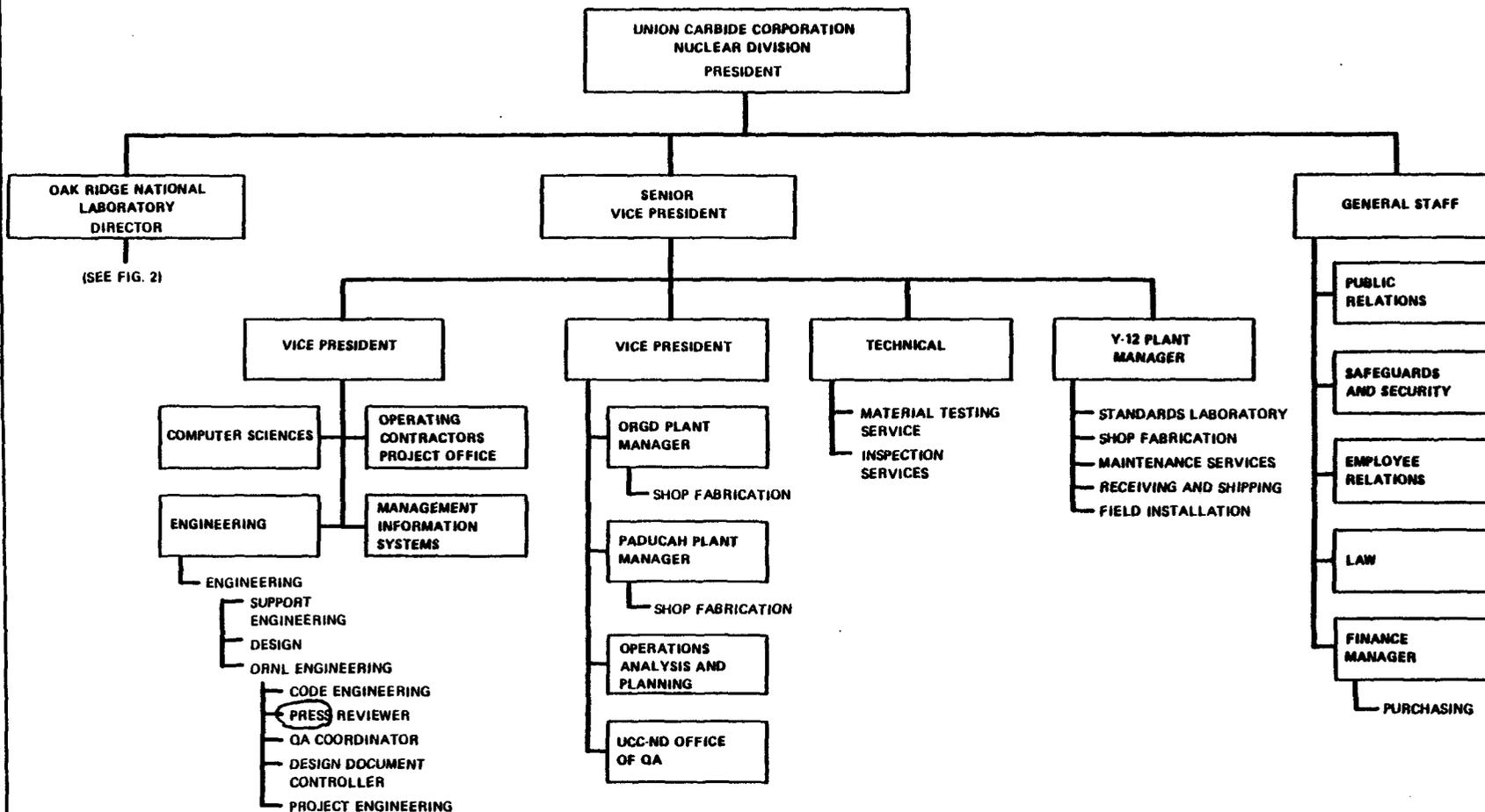
2.1 OAK RIDGE NATIONAL LABORATORY

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

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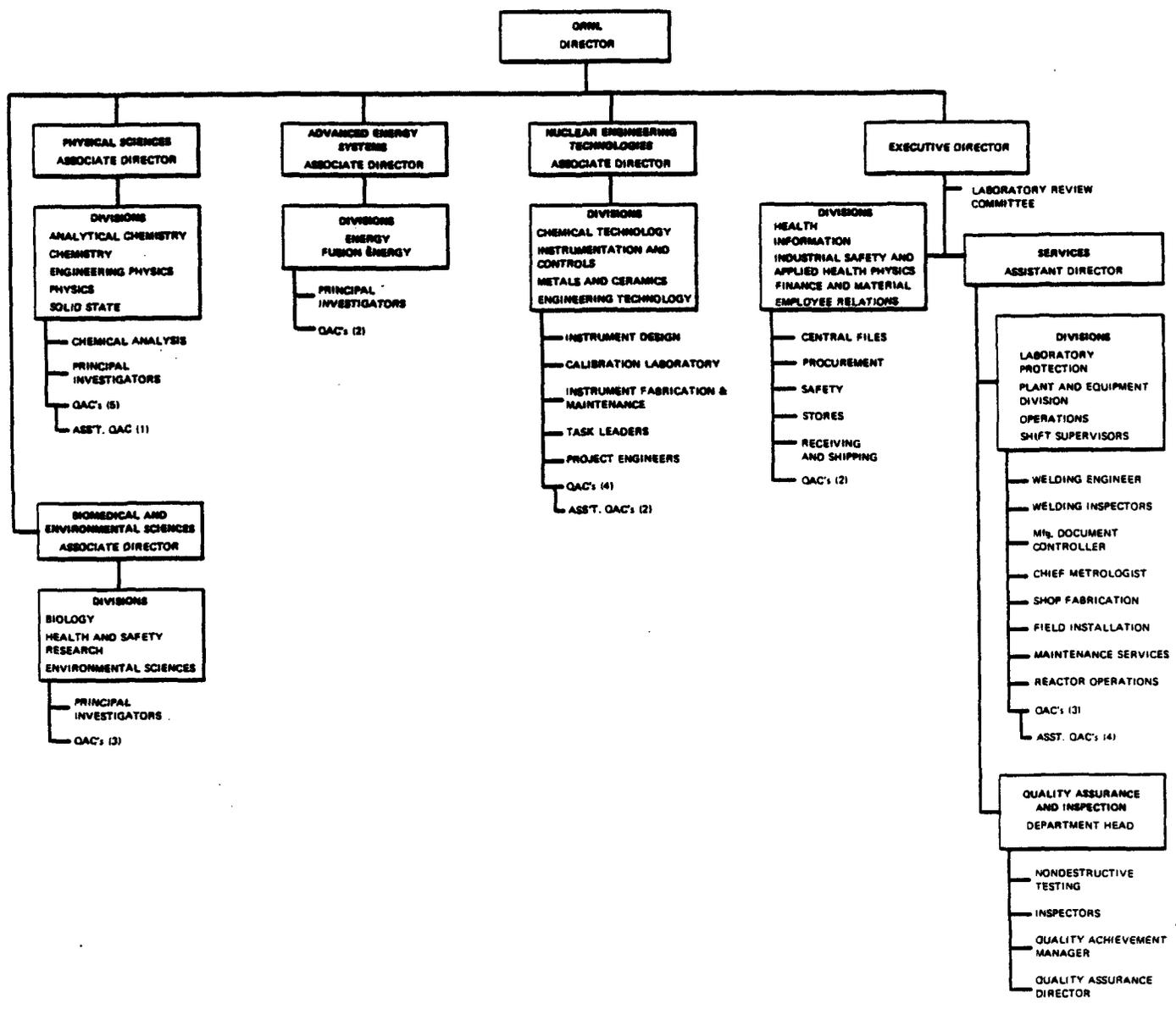


Fig. 2. Oak Ridge National Laboratory Organization Chart

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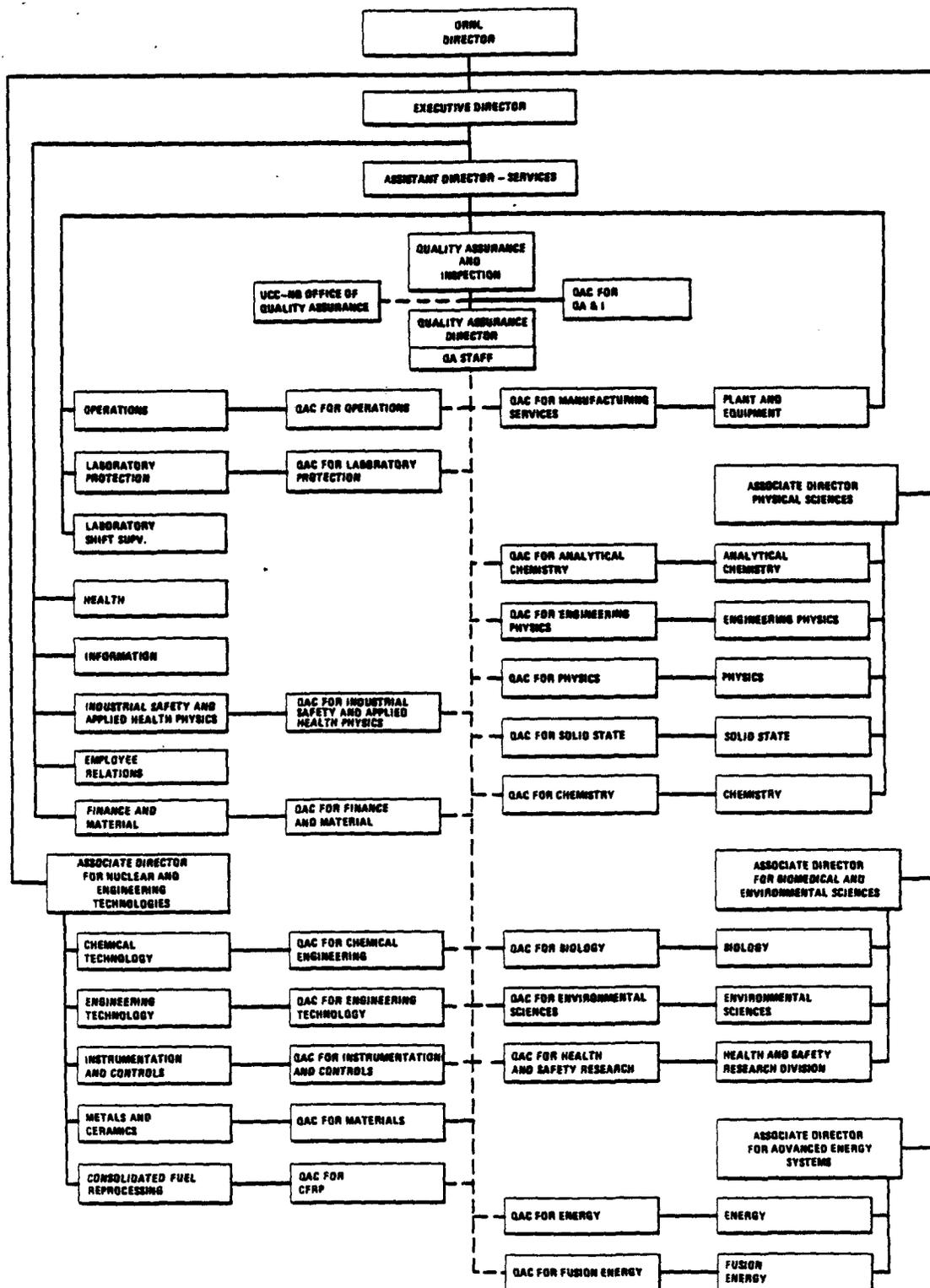


Fig. 3. Quality Assurance Program Organization Chart

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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 ^{MM-ES}~~UC-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: (also see Appendix A)

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. Non-destructive 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 as 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.

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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.

* 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.

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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.

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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.

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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.

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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 by 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.

* 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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QA PROGRAM DESCRIPTION

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, components, 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).

QA PROGRAM DESCRIPTION

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.

QA PROGRAM DESCRIPTION

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 appropriate 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.

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QA PROGRAM DESCRIPTION

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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QA PROGRAM DESCRIPTION

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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 or 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.

QA PROGRAM DESCRIPTION

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-palnt or vendor manufacture, receiving of purchased items, installation, construction, and preoperational evaluation (see QA-L-6-100).

QA PROGRAM DESCRIPTION

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.

QA PROGRAM DESCRIPTION

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.

QA PROGRAM DESCRIPTION

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.

QA PROGRAM DESCRIPTION

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 Superintendent 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

DATE March 15, 1978

PAGE 1 of 1

SUPERSEDES ISSUE DATED

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. ORO-DOE, OR IMD 02xx, "Quality Assurance"
- B. UCC-ND Standard Practice Procedure D 2-16, "Quality Assurance Program"
- C. ORNL Standard Practice Procedure 39, "Quality Assurance Program"
- D. Nuclear Energy Programs, DOE, RDT F 2-2, "QA Program Requirements"
- E. Nuclear Regulatory Commission, 10 CFR 50, Appendix B, "QA Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
- F. American National Standards Institute, ANSI N 45.2-1977, "QA Programs for Nuclear Facilities"

Requirements

On all programs, the Laboratory shall implement those QA requirements established by DOE (Ref. A) and by UCC-ND (Ref. B and C). The Laboratory shall also implement on specific programs and projects QA Standards specified by the sponsoring organization (e.g., Ref. 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 UCC-ND (Ref. A through F) and will coordinate development of other QA procedures, as necessary, to implement special QA requirements of sponsoring organizations for specific programs.
- 100.2 Division and program management shall ensure that divisions and programs establish QA Programs which are responsive to the QA requirements established by DOE, the Laboratory QA Program, and the sponsoring organization.

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OAK RIDGE NATIONAL LABORATORY

OPERATED BY
UNION CARBIDE CORPORATION
NUCLEAR DIVISION

Approved By: F. J. [Signature], Director
Quality Assurance Program

OAK RIDGE NATIONAL LABORATORY
QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-L-1-101

DATE March 1, 1979

PAGE 1 OF 4

SUPERSEDES ISSUE DATED

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 Plans for Design and Construction, ORNL QA Procedure QA L-1-104.
- C. Quality Assurance Plans for Operation, ORNL QA Procedure QA L-1-106.
- D. Quality Assurance Planning for Capital Projects, ORNL QA Procedure QA L-1-108.
- E. Quality Assurance Requirements, DOE Standard RDT F 2-2.

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 Fig. 1 of this procedure and implement the QA assessment and planning 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 and 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.

OAK RIDGE NATIONAL LABORATORY
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QUALITY ASSURANCE PROGRAM

PROCEDURE NO.

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TITLE: QA PLANNING

ADDITIONAL CONSIDERATIONS FOR REF. E. COMPLIANCE

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

OAK RIDGE NATIONAL LABORATORY
QUALITY ASSURANCE PROGRAM

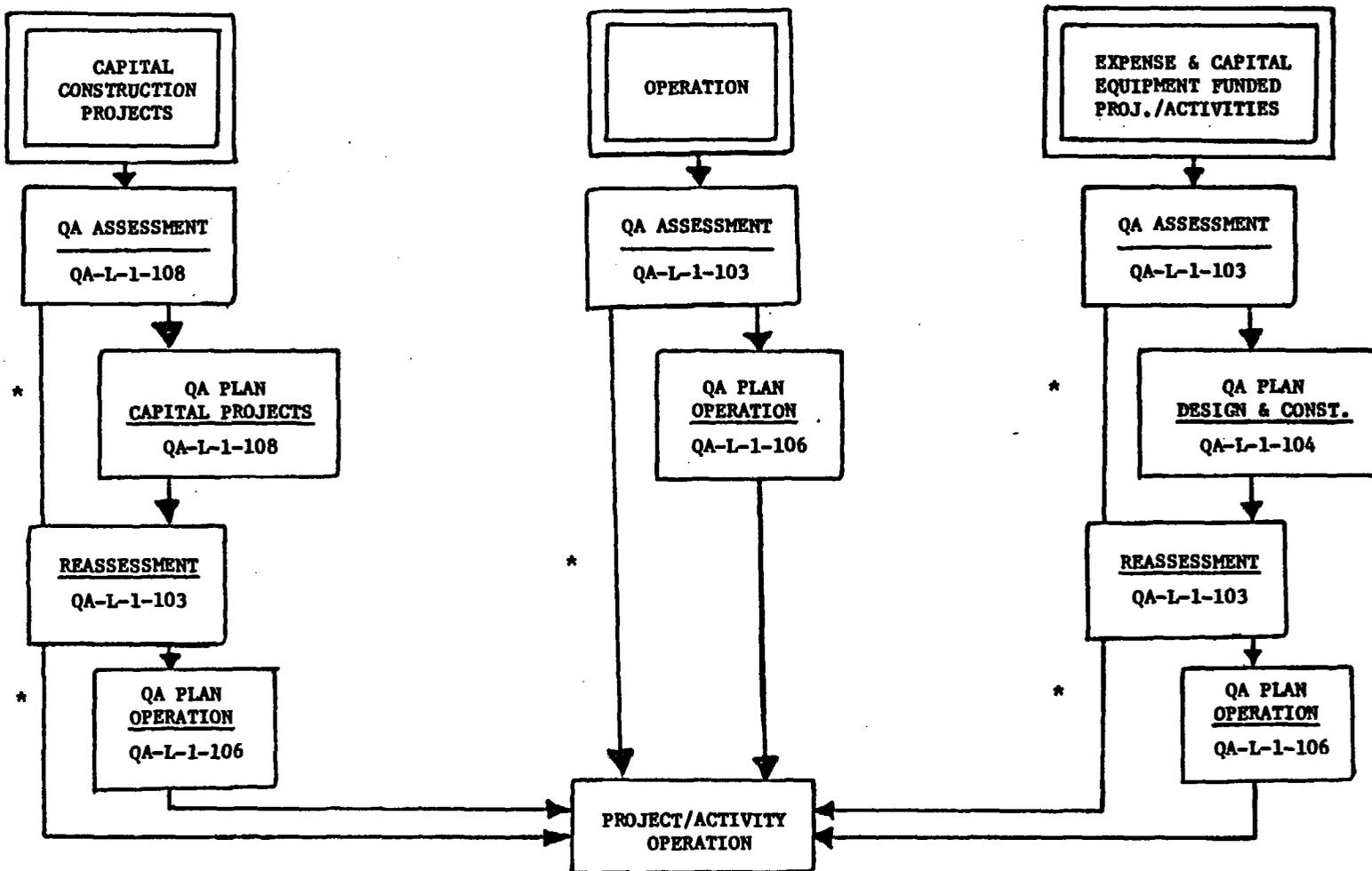
QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-L-1-101

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TITLE: QA PLANNING

FIGURE 1
 QA ASSESSMENT AND PLANNING GUIDE



*Use Standard QA Practices

UCN-9938A
 (3-5-71)

OAK RIDGE NATIONAL LABORATORY
QUALITY ASSURANCE PROGRAM

QUALITY ASSURANCE PROCEDURE

PROCEDURE NO. QA-L-1-101

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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-1-103

DATE March 1, 1979

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SUPERSEDES ISSUE DATED

TITLE: QUALITY ASSURANCE ASSESSMENTS

Purpose:

To define the requirements for conducting Quality Assurance Assessments (QAA) to determine the extent of QA effort to be applied on projects and activities. QAAs identify critical items for which QA plans must be prepared; and identify noncritical items for which standard QA practices will be adequate to assure quality of such items.

Scope:

This procedure is applicable for the design and construction phases of programmatic capital equipment funded and expense funded projects;* and all operational and maintenance activities.* (See Ref. A.)

References:

A. QA Planning, ORNL QA-L-1-101

Requirements:

For projects or activities a documented QAA shall be made of the consequences and probability of the failure of items to perform satisfactorily in service. The QAA shall consider the impact of failure on human health and safety, environment, experimental data, meeting program objectives, schedule, and funding. The QAA shall be initiated in the early planning phase of projects and activities and be reviewed periodically to determine if updating is necessary. The organization conducting the QAA shall ensure that appropriate personnel participate in the QAA

Procedures:

- 100.1 A QAA shall be conducted for projects or activities covered by the Scope. (Refer to Figure 1.)
- 100.2 Division or program management, (or their designee such as the task leader) with the advice of the Quality Assurance Coordinator (QAC) shall conduct QAAs. For large and complex projects or activities a team shall be selected by the task leader to participate in the QAA. The team shall consist of knowledgeable personnel from major project/activity participating organizations.

* Unless required otherwise analytical programs (no hardware) are not included.

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- 100.3 The QAA shall be documented using the procedure outlined on QAA form UCN-12972. For minor activities other acceptable means of documentation may be used. (See Instructions for Conducting QA Assessments, Appendix A and attached example of QAA.)
- 100.4 The initial QAA shall be completed early in the design planning phase.
- 100.5 For a series of projects/activities with similar functional requirements, a single QAA may be used.
- 100.6 On projects that require the participation of several Laboratory divisions the QAA shall be conducted by the division with overall management responsibility or program management with input from participating divisions.
- 100.7 For multi-division projects/activities a single QAA shall be prepared.
- 100.8 When required, safety analysis reports will identify items that are critical because of safety considerations, and the environmental analysis report will identify items that are critical because of failure effects on the environment. The results of these documents should be considered during QAA if they are available.
- 100.9 Completed QAAs, as a minimum, shall be approved by division/program management, the task leader and the QAC. The ORNL QA Director (QAD) shall review QAAs for large projects/activities.
- 100.10 The task leader shall give approved QAAs adequate distribution which, as a minimum shall include all persons signing them, division/program management, the QAC the QAD, and QACs of participating organizations.
- 100.11 QAAs shall be reviewed at least every 12 months by the task leader and the QAC to determine if updating is necessary. (See Appendix A, Paragraph 7.)
- 100.12 Revised QAAs shall be reviewed, approved and distributed in the same manner as the initial QAA.
- 100.13 The QAC shall maintain a log of QAAs showing current status.

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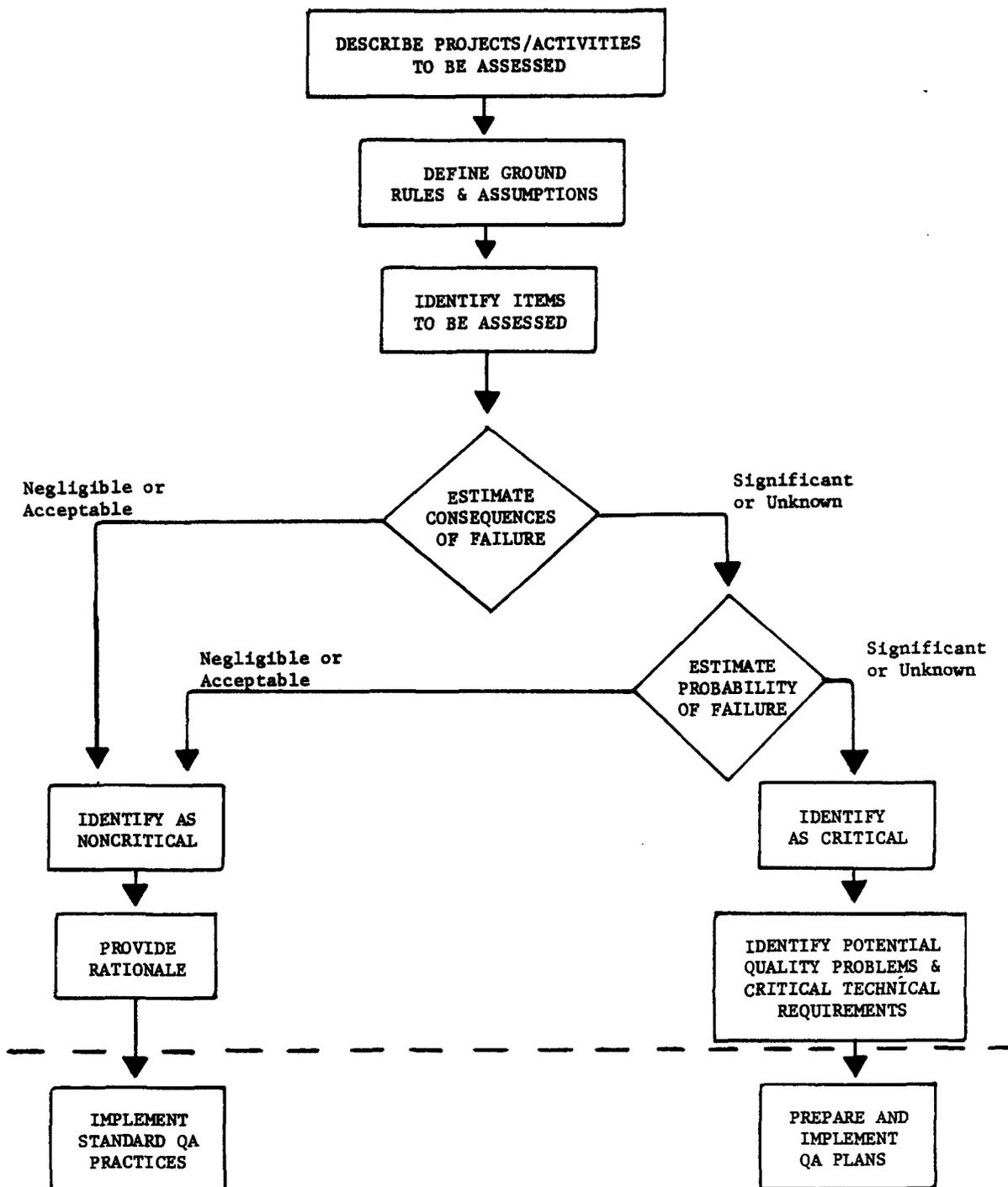


Figure 1. QUALITY ASSURANCE ASSESSMENT

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APPENDIX A

INSTRUCTIONS FOR CONDUCTING QA ASSESSMENTS

(Reference paragraph 100.3 and Figure 1)

The QAA should include the following actions:

Documentation

Document the QAA on form UCN 12972. Entries on the form should be typed.

1. Project Description

- a. Describe the project/activity to be assessed.
- b. Define ground rules and assumptions that are used to limit the assessment process.

2. Project Breakdown

Identify items by groups within the project/activity, as appropriate. To ensure that effective QAAs are conducted, project/activities may be subdivided into systems subsystems, components, or parts and each subdivision may be assessed separately. Similar items may be combined to enable cost effective assessments.

3. Assessment of Consequences and Probability of Failure

- a. For each group of items estimate consequences of item failure as negligible (or acceptable), significant or unknown.¹ In estimating consequences of failure consider all significant potential failure modes of items and limit such failure modes to those failures caused by hardware failures. Consider the consequences of item failure on human health and safety and environment; loss of experimental data or meeting program objectives; and effect on funding and schedule.
- b. Identify those groups of items whose failure consequences are negligible or acceptable as noncritical items.
- c. Estimate the probability of failure as negligible (or acceptable), significant, or unknown¹ for each item whose consequences of failure is judged to be significant or unknown.¹ This estimate should include past experience plus knowledge of current practices.
- d. Identify each item with significant failure consequences and negligible (or acceptable) failure probability as a noncritical item.

¹Unknown consequences and probability of failure should normally be assigned to items which are approaching or exceeding the "state-of-the-art".

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- e. Identify each item with significant or unknown failure consequences and significant or unknown failure probability as a critical item.

4. Description of Potential Quality Problems

- a. For each critical item describe significant potential quality problems (failure modes and causes of such failures including uncertainties).
- b. For each identified significant potential quality problem describe the critical technical requirements that will prevent or reduce the probability of such potential quality problems from occurring.

5. Assessment Recommendations

Document the assessment or reassessment recommendation.

6. Rationale

Document the rationale for classifying items noncritical. The examples should be identified with existing or known projects. Reference to specific projects, drawings, description, etc. should be provided. Examples of rationale are listed below:

- a. Item is standard off-the-shelf hardware of proven application.
- b. An established reliable design will be used. Item has a history of low failure frequency in a similar application.
- c. Design, test, and operational experience of items provides design maturity.
- d. Proven and established standard practices will provide adequate confidence.
- e. Maintainability is very good.
- f. Training program and standard operating procedures will provide adequate confidence that the item will perform satisfactorily in service.

7. Reviewing and Updating the Assessment

State the date or milestone that the QAA will be reviewed and updated, if necessary. The initial QAA should be reviewed near the end of detail design to ensure that all significant potential quality problems and critical technical requirements have been determined. The QAA should be reviewed again prior to beginning routine operation to identify any significant potential quality problems and critical technical requirements that are unique to operations. In addition the QAA should be reviewed when there is a change in project scope.

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EXAMPLE

ASSESSMENT NO. CBP-1
REVISION NO. 0
DATE January 1, 1979
ISS. NO. 10003X

PROJECT TITLE Coal Burning Project (CBP)	
DIVISION Engineering Technology	PROGRAM Fossil Energy Development - Coal
PARTICIPATING DIVISIONS AND OUTSIDE ORGANIZATIONS Engineering, Plant and Equipment, Instrumentation and Controls	

APPLICABLE QA STANDARDS FOR THIS PROJECT
DOE-ORO-IMD 02XX

1. PROJECT DESCRIPTION

The CBP is a new facility to develop advanced and more efficient coal liquefaction processes and equipment. The process which combines high temperature, high pressure and fluidized bed operation uses hydrogen rich gas for fluidization. Ground Rules and Assumptions: The assessment will assess systems for only one failure occurrence at a time, and will not consider failures caused by flooding, earthquakes, and tornadoes.

Est. Design and Const. Cost \$1,500,000 Temp. Range 70-1500°F Press. Range 1 to 150 atm

2. PROJECT BREAKDOWN (Breakdown of the project into major structures, systems, subsystems, and components)

- GROUP 1 Pressurized Piping System Including Hydrogen System
- GROUP 2 Hydrocarbonizer Vessel
- GROUP 3 Safety and Data Collection System
- GROUP 4 Instrumentation and Controls and Electrical Systems
- GROUP 5 _____

3. ASSESSMENT OF CONSEQUENCE AND PROBABILITY OF FAILURE

(Indicate S if consequence is significant and S or U if the probability is significant or unknown. A blank space will indicate negligible or acceptable consequence or probability)

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

SIGNATURES

Originator John Jones Date 1-1-79 Approved by (QAC) C. A. Mills Date 1-4-79

Approved by R. E. MacPherson Date 1-2-79 _____ Date _____

Approved by H. E. Trammell Date 1-2-79 Reviewed by (QAD) F. H. Neill Date 1-5-79

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4. DESCRIPTION OF POTENTIAL QUALITY PROBLEM (For each group listed in part 2 in which the consequences of failure are significant and the probability of failure is significant or unknown, provide a brief description of the potential quality problem).

- Group 1 - Leaks in the piping system may occur due to corrosion of the pipe wall.
Critical Technical Requirement - Require the use of special alloy 123 with 3.2% Ni and 2.9% Mo.
- Group 3 - Overpressure and rupture of the vessel could result if the safety control valve receives a false signal.
Critical Technical Requirement - To be determined during preparation of the QA Plan.
- Group 4 - Failure of XYZ sensors will cause a prolonged shutdown of the project for repairs because of the relatively inaccessible location of many of the sensors.
Critical Technical Requirement - Require the use of sensors with a high degree of reliability.

5. ASSESSMENT RECOMMENDATIONS

- QA Plan Required (Required when the consequence of failure is significant and the probability is either significant or unknown).
- QA Plan not Required (Indicate rationale in Part 6).
- QA Program Index Required (Required for RDT F2-2 compliance, optional otherwise).
- Impact on current Project QA Plan necessitates its revision. Revise by _____

6. RATIONALE (Justify when no project QA Plan is required).

- Group 2 - Design of the vessel will be the same as shown on ORNL dwg. 10079. This design has a history of low failure frequency. Proven and standard QA practices in the Engineering Technology, and Plant and Equipment divisions will provide adequate confidence that design requirements will be implemented during fabrication and installation.

7. This Assessment will be reviewed and up-dated, if necessary, by _____ 6-1-79

DATE OR MILESTONE

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PROCEDURE NO. QA-L-3-100 (Rev. 1)

DATE January 18, 1979

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SUPERSEDES ISSUE DATED July 5, 1978

TITLE: CONTROL OF DOCUMENTS AND RECORDS

Purpose

To define the responsibilities and actions required to control documents affecting quality.

Scope

Documents to be considered under this procedure are those uniquely applicable to a specific project. Engineering drawings and specifications, special procedures, technical note books, and instructions for testing, fabrication, and inspection; data resulting from quality control or manufacturing activities; and quality assurance (QA) documents are typical of the types of documents that will be controlled under this procedure.

References

- | | |
|---|-----------------|
| A. Paper Work Reduction and Control Program | SPP D5-22 |
| B. Engineering Transmittal, UCC-ND Engineering, | EP-C-01 |
| C. Drawing Numbering, UCC-ND Engineering, | EP-C-03 |
| D. Design Change Control, UCC-ND Engineering | EP-C-18 |
| E. Guidelines for Document Review, Approval,
Distribution, and Filing, | EP-A-13 |
| F. I&C Drafting Procedures, ORNL, | QA-IC-6 |
| G. Design, ORNL, | QA-IC-13 |
| H. Operating Reactors and Critical Facilities
Control Modifications, ORNL, | QA-IC-11 |
| I. Preparation of Correspondence and Reports,
ND Office Guide, Chapter III, ORNL, | |
| J. Document Control System, ORNL | QA/ID/LRD-509-B |
| K. Document Control, Controlled Manufacturing
Manual, ORNL, | |
| L. Requirements for Collection, Storage, and
Maintenance of QA Records for Nuclear
Power Plants, | ANSI N 45.2.9 |
| M. Field Changes, UCC-ND Engineering, | EP-D-09 |
| N. Document Control, ORNL, | QA-PE-3/D.1.12 |
| O. Technical Notebooks as Research Records,
UCC-ND Patent Section, Law Department,
February 1974. | |

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Approved By: *F. H. Nail* Director
Quality Assurance Program

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E: CONTROL OF DOCUMENTS AND RECORDS

Requirements

When required by the complexity or the critical nature of a project, documents shall be controlled to the extent required to assure that the documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to prescribed organizations and locations.

Definitions

Quality Assurance Records: Those records which furnish documentary evidence of the quality of items and of activities affecting quality.

Lifetime QA Records: Lifetime records are those which meet one or more of the following criteria:

1. Those which would be of significant value in demonstrating capability for safe and reliable operation,
2. Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying the item,
3. Those which would be of significant value in determining the cause of an accident or malfunction of an item, and
4. Those which provide required baseline data for future inspection.

Lifetime records are required to be maintained for the life of the particular item.

Nonpermanent QA Records: Nonpermanent records are required to show objective evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item. Nonpermanent records meet none of the criteria stated for lifetime records.

Procedures

- 100.1 The R&D division or program task leader in consultation with the project team shall establish distribution lists consistent with the requirements of Ref. A upon the initiation of a new project these lists will be unique to the project and to various types of documents to be issued during the project. These lists shall be updated periodically and shall indicate the Record Control (RC) copy.

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TITLE: CONTROL OF DOCUMENTS AND RECORDS

- 100.2 The UCC-ND Engineering project engineer shall assure that design drawings and specifications are controlled in accordance with the requirements of Refs. B, C, D, and E.
- 100.3 Deviations to drawings and specifications shall be recorded on form UCN-5458A in accordance with QA-L-6-106 and shall be made part of the lifetime file.
- 100.4 The instrumentation task leader shall assure that design drawings and specifications are controlled in accordance with the requirements of Refs. F, G, and H.
- 100.5 The R&D division or program task leader or manager shall designate the extent of document control to be applied to project documents other than those designated in 100.2 and 100.3. Ref. I describes the minimum control system for documents to assure a record copy and identification of the recipients. Ref. J provides a comprehensive document control system and the actions to be implemented by the task leader.
- 100.6 For ASME Boiler and Pressure Vessel Code fabrications, document control in compliance with Ref. K is mandatory. Ref. K shall also be invoked by the task leader or program manager on other types of fabrication when justified by the complexity or the critical nature of the design.
- 100.7 The task leader and the program manager shall identify those documents that are to be placed in lifetime storage and those documents that are to be placed in nonpermanent storage (see Definition Section). Appendix A of Ref. L shall be used as a guide in determining the records to be placed in lifetime storage and in nonpermanent storage.
- 100.8 The UCC-ND Engineering construction engineers shall ensure that the provisions of Ref. M are invoked during construction on field changes.
- 100.9 The QAC-P&E division shall assure that documents are controlled in accordance with paragraph 100.6 or by Ref. N, as appropriate, during ORNL shop fabrications.
- 100.10 When technical notebooks are used, they shall be maintained in a format consistent with division or program QA procedures and shall, as a minimum, meet the requirements of Appendix A.
- 100.11 The task leader shall assure that all pertinent design, fabrication, and installation records are collected, cataloged, and filed during preoperational testing. All files to be placed in storage shall be checked against the lists developed in paragraph 100.7 to assure that all necessary documents have been placed in storage.

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TITLE: CONTROL OF DOCUMENTS AND RECORDS

APPENDIX A

Technical Notebooks

The task leader or his designee shall maintain a technical logbook during the conduct of an experiment for recording the chronological history of significant events which relate to the experiment or testing program. Entries in the logbook shall be complete and self-explanatory, such as:

- a. Date and time of entry on each page.
- b. Instrumentation changes (e.g., recalibration, range, change, etc.) and changes to the apparatus.
- c. Identification of supporting information or documentation including test data records, inspection records, audits, drawings, or specifications.
- d. Signature or initials of individual(s) making entry or entries. Technical logbooks shall be bound, accountable, and identified with the experiment or test. The technical logbooks shall be prepared and processed in accordance with ORNL Standard Practice Procedures Part D5-5, Part I, relative to potential discoveries or inventions.

Also see Reference 0 for additional UCCND requirements.

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PROCEDURE NO. QA-L-6-101 (Rev. 1)

DATE April 18, 1980

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SUPERSEDES ISSUE DATED
May 5, 1978

TITLE: REPORTING OF QUALITY DEFICIENCIES

Purpose:

To define the requirements for reporting quality deficiencies.

References:

- A. Unusual Occurrences Notification, Investigation, and Reporting, ORNL SPP D-5-16.
- B. Identification and Control of Nonconforming Items at ORNL, QA-L-6-100.
- C. Unusual Occurrence Reporting under RDT Standard F1-3T, QA-L-6-102.
- D. Failure Analysis and Investigation, QA-L-6-103.
- E. Deficiency Reporting by Supplier, QA-L-9-102.
- F. Corrective Action, QA-L-6-104.

Requirements:

All significant quality deficiencies shall be investigated, documented for management review and, when appropriate, corrective actions taken.

Procedures:

- 100.1 The task leader upon determining that an unexpected, significant, quality deficiency occurred during design, manufacture, procurement, assembly, testing, maintenance, or operation of an activity, project, or experiment shall notify the division quality assurance coordinator (QAC). The division director shall determine if other members of Laboratory management are to be notified.
- 100.2 Using Fig. 1 for guidance, the task leader shall select the correct QA procedure (Ref. A through F) to be used to investigate, document, and to initiate necessary corrective actions on the quality deficiency.
- 100.3 The task leader, with assistance from the division QAC, shall review the QA assessment, QA plan, and the division or program QA procedures, with respect to the quality deficiency, to determine if changes are needed to strengthen the QA program to minimize the possibility of a recurrence of the quality deficiency.

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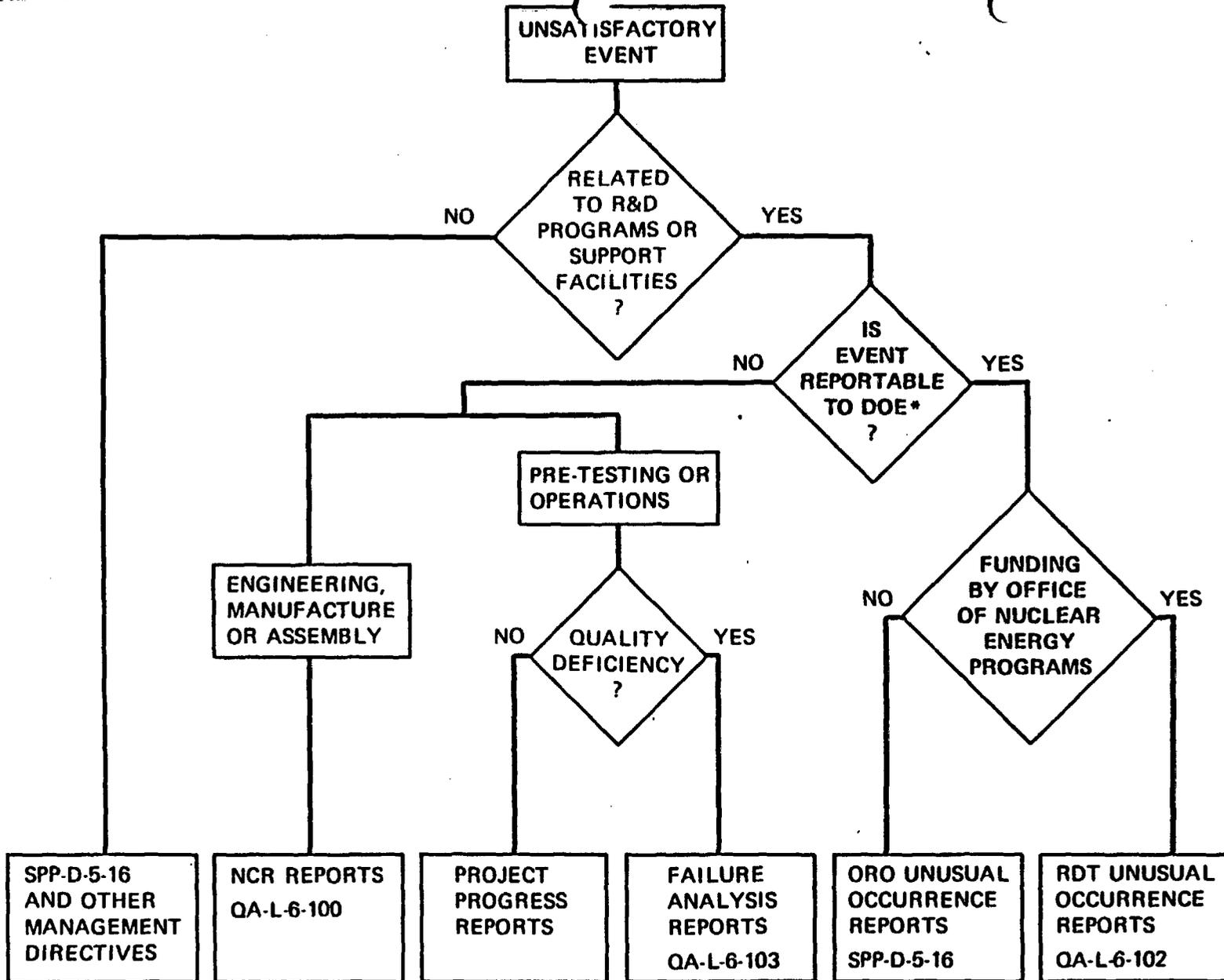
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TITLE: REPORTING OF QUALITY DEFICIENCIES



*Guidance on types of unusual occurrences reportable to DOE

For ORO-DOE Compliance: See SPP-D-5-16, Unusual Occurrences Notification, Investigation, and Reporting.

For DOE Office of Nuclear Energy Program Compliance: See RDT F1-3T, Preparation of Unusual Occurrence Reports.

FIGURE 1. REPORTING OF QUALITY DEFICIENCIES

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PROCEDURE NO.	QA- L-8-100 (Rev. 5)
DATE	November 19, 1979
PAGE	1 OF 2
SUPERSEDES ISSUE DATED	December 15, 1977

TITLE: QA AUDITS

Purpose:

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

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.

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.

Procedures - ORNL QA Audits

100.1 The QALA will schedule audits of ORNL organizations, ORNL support forces, and ORNL suppliers as required. He is responsible for the composition of the audit team, which will normally have from two to four members selected for their expertise in management, in the technical field audited, and in quality engineering.

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Approved By: F. H. Neill
F. H. Neill, Director
Quality Assurance Program

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TITLE: QA AUDITS

- 100.2 The audit team will prepare a written audit plan and checklist for each audit. The checklist details the scope, criteria, and procedures to be followed. Date, time and location of the audit as shown in the audit plan will be determined in cooperation with the auditee management.
- 100.3 An audit notification will be transmitted to the auditee organization director by the QAD, with copies to the ORNL Associate Director responsible for the auditee organization, the Head of the Department of Quality Assurance and Inspection, and to the audit team. The notification to be sent no less than one week in advance of the audit date, will include the audit plan and checklist.
- 100.4 The audit team will perform the audit and record its observations and findings, and any required corrective actions.
- 100.5 At a post-audit meeting between the audit team, the QAC, and auditee management the QALA will present the report of the audit team. The auditee organization director, or others authorized to make commitments for him, will be asked to review the draft report and to indicate by signature agreement and commitments for corrective action.
- When agreement can not be reached, the unresolved issues shall be referred to the next higher level of auditee management.
- 100.6 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.
- 100.7 All provisions of the above procedures apply to any required re-audits.

Procedures - Division/Program Internal Audits

- 200.1 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.
- 200.2 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.
- 200.3 The QAC shall distribute the audit report to Division or Program Management, and maintain a copy in his files.

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PROCEDURE NO.	QA-L-14-100 Rev. 1
DATE	April 18, 1979
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SUPERSEDES ISSUE DATED	January 21, 1972

TITLE: INSTRUMENTATION CONTROL AND CALIBRATION

Purpose:

To define requirements for the control and calibration of instruments affecting quality.

Scope:

This procedure sets forth the requirements for a calibration, control, and verification program for instruments used for measurement and control of processes; this measuring and controlling equipment (MTE) includes working (installed) instruments and transfer (field and secondary) standards used for calibration of working instruments.

To be considered under this procedure are all instruments used in fabrication, shipment, construction, installation, testing, operation, and maintenance of projects, experiments, and facilities.

References:

- A. Calibration of End-Use Instruments, ORNL-IC-5.
- B. Procedures for Calibration of Measuring Instruments, ORNL 14-F-2 thru 6.
- C. Instrument Control Program, Books 1, 2, & 3, UCC-ND Y-12 plant.
- D. Measurement Standards Management, ORNL-IC-3 (I&C Division only).
- E. Inspection and Gaging Tools Serial Number Code, ORNL-14-F-1.
- F. Pressure Gage Calibration, ORNL NDE 81.

Requirements:

Instruments used during fabrication, installation, construction, preoperational testing, operation, and maintenance activities shall be controlled and calibrated as necessary to meet program objectives and assure safe, reliable, economical, and timely operation.

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TITLE: INSTRUMENTATION CONTROL AND CALIBRATION

Procedures:

- 100.1 Before their use the task leader shall designate and list those instruments that will require calibration on experimental projects during preoperational testing or during the operation/maintenance of the project/activity, and shall ensure that such calibration is accomplished in a timely manner. As a minimum, all instruments relied upon for safe operation and for the production of reportable experimental data shall be calibrated.
- 100.2 Where appropriate, the task leader shall, in consultation with Instrumentation and Controls (I&C) Division or Plant and Equipment (P&E) Division personnel (or the respective Y-12 organizations for ORNL Divisions at Y-12), select a suitable recalibration schedule and place the above designated instruments in the appropriate programmed recalibration and maintenance system of the I&C, P&E, or Y-12 Divisions. The task leader shall assure that the agreed upon schedule is implemented. (Ref. A and B for ORNL divisions at X-10, Ref. C for ORNL divisions at Y-12.)
- 100.3 Department heads in service division doing fabrication, maintenance, and inspection activities shall list and document those instrument under their control that require calibration and shall assure that these instruments are placed on the programmed recalibration and maintenance schedules of the I&C, P&E, or Y-12 Divisions.
- 100.4 Management of the Instrumentation and Controls Divisions, the Plant & Equipment Division, and the Quality Assurance and Inspection Department shall be responsible for calibration standards management activities performed by their respective divisions consistent with the requirement of Ref. D, E, and F. This includes instrument numbering, preparation of calibration procedures, instrument calibration and certification, status labelling, inventory and recall control, and record keeping associated with instrument and accessory management.

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PROCEDURE NO. QA-L-16-100

DATE December 22, 1982

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SUPERSEDES ISSUE DATED

TITLE: QUALITY ASSURANCE RECORDS

Purpose:

To define actions and responsibilities required for retention and disposition of documents (records) that provide documentary evidence of quality.

Scope:

This procedure applies to all projects including Research and Development projects. This procedure applies to completed and "as built" quality-related documents. QA records shall include, but not be limited to: QA documents, such as, QA assessments and plans, quality investigation reports, QA audit reports, unusual occurrence reports, nonconformance reports, inspection and test reports, measuring and test equipment calibration reports; Design documents, such as, drawings, specifications, drawing change requests, deviation requests, procedures and special instructions, and inspection and test plans; Purchase documents, such as, requisitions and orders; Technical inputs and outputs, such as, computer programs, computer tapes, printouts and data analyses, Test documents, such as, plans, specifications, procedures, and results; and Technical notebooks and operating logs. This procedure is responsive to Reference A.

References:

- A. Records Disposition, DOE-ORO Order 1324.2.
- B. Retention and Disposition of Records, UCC-ND SPP D-2-10.
- C. Record Retention and Disposition, UCC-ND Accounting Manual, Section 18.0.
- D. QA Program Requirements for Nuclear Power Plants, ANSI/ASME NQA-1.
- E. ASME Boiler and Pressure Vessel Code, ASME Section III, Division 1 and ASME Section VIII, Division 1.
- F. Quality Assurance Program Requirements, RDT F2-2.
- G. Record Storage Center Procedure, QA/ID/LRD-509A, Information Division QA Manual.

Requirements:

Records that furnish documentary evidence of quality (fitness for intended use) shall be specified, prepared, and maintained. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

OAK RIDGE NATIONAL LABORATORY
OPERATED BY
UNION CARBIDE CORPORATION
NUCLEAR DIVISION

Submitted by: F. H. Nail
QA Program Director

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

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TITLE: QUALITY ASSURANCE RECORDS

Definitions:

Nonrecord Material (NoRC) - Those classes of documentary material that have little or no retentive value from an overall operational standpoint and are used for short-term reference purposes by small segments within each Company Division. Such material may include notes containing data to be duplicated in technical reports or other project records or of such a routine or fragmentary nature that their retention would not benefit the project (Reference B).

Records - Books, papers, maps, microfilm, magnetic tapes, photographs or other documenting material regardless of physical form or characteristics, made or received by the Company (Reference B).

Record Material (RC) - Those classes of documentary material that have legal, fiscal, historical, or operational value, the preservation of which is required for extended reference use, or by contract or law, and for which disposal must have DOE approval (Reference B).

Retention Period - Time period established for a filing unit or filing item that must elapse before the records may be disposed. Period is usually stated in terms of years or months, but is often expressed as contingent upon the occurrence of an event. A retention period is to be distinguished from a retirement period. A retention period includes the active period in the originating office plus the retirement period in the Records Storage Area (Reference C).

Retirement Period - The time period established for a filing unit or filing item after the expiration of which the records are removed from a current file area to a Records Storage Area (Reference C).

Technical Notebook - A permanently bound notebook used to record all original data, calculations, notes, sketches, ideas, experimental endeavors and the results thereof. The pages are serially numbered and the notebook has been assigned a Laboratory Records Department identification number (Reference B).

Procedure:ESTABLISHING THE RECORD SYSTEM

- 100.1 At the beginning of each project the task leader shall establish an effective and economical system for assuring collection, identification, retention, retrieval, and disposition of QA records. Consideration should be given to duplicating important records and storing them in dual facilities. Requirements for traceability of raw experimental data through published reports should be considered. The record system that is established shall be consistent with division procedures, this procedure, ORNL policy, and sponsor requirements.
- 100.2 Advance planning by the task leader shall include review of sponsor and programmatic requirements for collection, retention, and disposition of QA records, such as those imposed by References D, E, and F.
- 100.3 Records shall be classified and identified as Record Material (RC) or Nonrecord Material (NoRC) consistent with requirements in Reference B and C.

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STORAGE

- 100.4 Records shall be stored in a manner to preclude deterioration of records, and to preclude larceny and vandalism of records.
- 100.5 Computer magnetic tapes shall be stored in clean facilities free of excessive electrical and magnetic fields. Consideration should be given to duplicating vital data that have been collected on magnetic tapes and storing these records in dual facilities.*
- 100.6 Records needed for reference on a routine basis may be stored in office files. Official records of the projects that are not needed on a routine basis shall be retired and stored in the ORNL Records Center (Reference G) or equivalent.

RETENTION TIME, RETRIEVABILITY, AND DISPOSITION OF RECORDS

- 100.7 Record and nonrecord copy material shall be retained for periods of time consistent with References B and C. As a general rule, records not listed in Reference C should be retained for the life of the project or until determined by qualified personnel that records have no probable value. The retention period for selected records is listed in Appendix A.
- 100.8 Records shall be indexed (cataloged) and stored in such a manner to permit retrieval by the task leader and other authorized personnel for reference use and/or disposition. The record system shall provide for retrieval of needed records within a reasonable length of time.
- 100.9 The record custodian shall dispose of QA records at the termination of the retention period. Records, stored for an indefinite time period, shall be reviewed on a periodic basis to determine their need for future storage or disposition (it is suggested that records be reviewed every 2 years). The custodian of the records shall obtain concurrence with the current task leader or owner of the records before destroying the records.

Records retired in the ORNL Records Center will be reviewed periodically and disposed of in accordance with References C and G.
- 100.10 Records, as mutually agreed upon with the sponsor, shall be collected, identified, packaged, and transferred to the sponsoring organization. Transfer of these records shall be completed within three months after completion of the work unless otherwise mutually agreed upon with the sponsor. Records may be destroyed, at the option of the sponsor, if they have no further use to ORNL. In general, ORNL will not store records for the sponsor after completion of the work.

*When the ORNL Computer Science Division is involved in computer processing of data, these data are collected every day on high speed storage discs. These data are transferred later to magnetic tapes on a daily or weekly basis, depending on the computer system used. When requested, magnetic tapes can be stored in the Computer Science Archive for up to 3 years.

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APPENDIX A
 RECORD RETENTION PERIODS⁽¹⁾

SELECTED RECORDS	RETENTION PERIOD
Technical Notebooks	25 Years ⁽²⁾
Technical Documents produced as a result of work for or on the behalf of sponsoring organizations outside ORNL (does not include DOE)	Until completion of work (see paragraph 100.10)
QA Assessments, QA Plan, Quality Investigation Reports, Nonconformance Reports, QA Audit Reports, Unusual Occurrence (detailed) reports	Until item is removed from service ⁽³⁾
Deviation and drawing change requests	Until project completion or until incorporated in drawings
Experimental research data files	Until determined by qualified scientific personnel that records have no probable value ⁽²⁾
Copies of drawings	Until revised or superseded or upon completion of project (nonrecord) ⁽²⁾
Bills of material and job specification	Until of no further reference value (nonrecord) ⁽²⁾
Reactor operations QA Records	Retain for operational life of facility, or until determined by qualified scientific personnel that records have no probable value ⁽²⁾

⁽¹⁾ Refer to Reference C for a more complete listing of records and retention periods.

⁽²⁾ Reference C.

⁽³⁾ Reference A (Contractor Records Schedule 22).