

## QUALITY ASSURANCE IN A LARGE RESEARCH AND DEVELOPMENT LABORATORY

Frank H. Neill  
QA Program Director  
Oak Ridge National Laboratory  
Post Office Box X  
Oak Ridge, Tennessee 37830

# MASTER

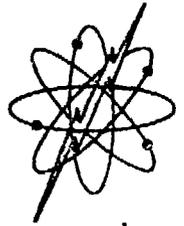
By acceptance of this article, the publisher or recipient acknowledges the U.S. Government's right to retain a nonexclusive, royalty-free license in and to any copyright covering the article.

### DISCLAIMER

This document was prepared as part of work sponsored by an agency of the United States Government. For the United States Government and any agency thereof, not any of their employees, sponsors, agents, or contractors, no warranty, no legal liability, or responsibility is assumed for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or approval by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.



## SEVENTH ANNUAL NATIONAL ENERGY DIVISION CONFERENCE



### QUALITY ASSURANCE PROGRAMS IN RESEARCH AND DEVELOPMENT QUALITY ASSURANCE IN A LARGE RESEARCH AND DEVELOPMENT LABORATORY

Frank H. Neill  
QA Program Director \*  
Oak Ridge National Laboratory  
Post Office Box X  
Oak Ridge, Tennessee 37830

#### ABSTRACT

Developing a quality assurance program for a large research and development laboratory provided a unique opportunity for innovative planning. The quality assurance program that emerged has been tailored to meet the requirements of several sponsoring organizations and contains the flexibility for experimental programs ranging from large engineering-scale development projects to bench-scale basic research programs.

#### WHO WE ARE - - -

I believe a brief description of the Oak Ridge National Laboratory (ORNL) and the diversity of its research programs will be helpful in orienting the reader in the environment in which the QA program was developed.

ORNL is one of the nation's largest federal, multipurpose, research and development installations, with major missions in non-nuclear as well as nuclear energy development. Perhaps ORNL could best be described as a national energy laboratory. Its principal mission is the development of safe, economic and environmentally acceptable technologies for efficient production and use of energy from various sources. Union Carbide's Nuclear Division, of which ORNL is a part, is a prime contractor to the Department of Energy (DOE).

The Laboratory is comprised of 22 research, development, administrative and service divisions, with over 5000 employees and an annual operating budget in excess of \$300,000,000. Approximately 80% of our funding comes from DOE and about 20% from the Nuclear Regulatory Commission (NRC), National Institutes of Health, National Science Foundation and the Environmental Protection Agency.

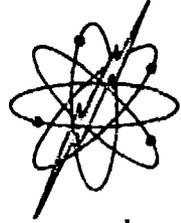
Examples of our experimental programs include very large fusion energy experiments, a nuclear fuel reprocessing pilot plant, heavy ion research facilities, cyclotrons, four research reactors as well as the individual scientists working on bench-scale experiments.

At ORNL a matrix organizational structure is traditional. It is composed of a line-organization consisting of divisions, such as Physics, Chemistry, and Environmental Science and a program-type organization that crosses divisional lines to coordinate the activities of multidisciplinary teams for large projects.

\* Operated for the U.S. Department of Energy by Union Carbide Corporation Nuclear Division under Contract W-7405-eng-26.



## SEVENTH ANNUAL NATIONAL ENERGY DIVISION CONFERENCE



Engineering, Computer Sciences and Purchasing services are furnished to ORNL by the Nuclear Division. The mix of line and program organization with an independent engineering organization requires a unique type of QA program.

### ORNL QUALITY ASSURANCE PROGRAM

QA Program Objectives: In dealing with a professional staff, we have found that it is better to gain understanding and acceptance of the QA program and to work with the professional staff to tailor a QA program to meet their individual needs rather than to enforce a strict disciplined formal program without adequate explanation. This is reflected in the strong reliance we have placed on division QA Coordinators and on the QA programs they have developed for their respective divisions. We believe that the ultimate mark of a successful QA program is one that will result in a project being built on schedule, functioning as intended and producing data that is accurate and reliable throughout its entire life, from design to operation and maintenance. We believe that the QA program must be cost effective and sufficiently sophisticated to provide adequate assurance for our very large experimental programs and still it must not be unduly burdensome for the individual scientist in his/her laboratory, where program cost are frequently relatively lower than the larger Engineering-scale development projects and deadlines less stringent.

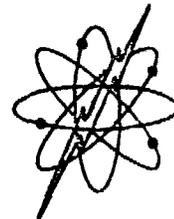
QA Program Organization: To provide the necessary flexibility to meet the individual needs of the wide range of experimental R&D programs, the QA organization is strongly oriented toward the individual divisions with the ORNL QA Program Office responsible for coordinating and administering the overall program. To carry out division responsibilities, each division has one or more QA Coordinators, appointed by division management, to administer the QA program for their division. The prime responsibility for QA rests with the line-organization and the QA Coordinators are responsible to division management for the QA in their respective divisions.

The QA Program Director has responsibility for developing a cost-effective QA program that is consistent with the Nuclear Division QA requirements and one that is responsive to the QA requirements of our sponsoring organizations. This program is documented in a manual of QA procedures which is maintained current by the QA staff. Additionally, the QA Program Office provides assurance to management that the QA program is being implemented in an effective manner and it serves as the primary focal point for contacts with outside organizations on QA-related matters.

Training and motivation are another facet of the QA program that is coordinated through the QA Office. As part of this program all new employees are given a brief introduction to QA during their orientation program. The necessity for QA is emphasized and the important part each employee contributes in the overall QA program is explained. The employee is then referred to his/her division QA Coordinator for more detailed instructions. Periodic discussion sessions are held with division staff members to introduce changes in the program and to serve as refresher sessions. QA Posters are periodically displayed through the installation as a QA reminder.



## SEVENTH ANNUAL NATIONAL ENERGY DIVISION CONFERENCE



To emphasize management's concern and support for QA, video tapes have been prepared in which the President of the Nuclear Division and the ORNL Director express the need for a strong QA program. These techniques are similar to those used by the safety department for many years with a high degree of success.

Previously it was indicated that ORNL functions under a matrix organization. With this arrangement, much of the funding is funneled into the various projects through the program organization. The program organization therefore serves as a focal point between sponsoring organizations and the participants in the experimental programs for the flow of information, including QA requirements.

Constraints on the QA program: Before discussing the details of the program we need to consider the different QA standards and QA requirements that are imposed on ORNL by the various organizations sponsoring research and development (R&D) programs. First, there is an overall umbrella QA standard required by the Oak Ridge Operations Office (ORO), DOE. This standard, known as IMD 02XX(1), is applied to all experimental R&D programs that have not otherwise been given specific QA requirements from the sponsoring organizations and to all support activities. Specific requirements contained in this standard will be discussed in more detail in a later section. Another blanket type of QA requirements are those imposed on the manufacture and in-service inspection by the ASME Code.

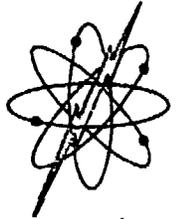
Sponsors QA standards for specific program at ORNL include:

<u>Sponsoring Organization or Program</u>	<u>QA Standard Number</u>
Office of Nuclear Energy, DOE	RDT F2-2(2), ANSI NQA-1(3) & ANSI N45.2(4)
Research Reactors	AECM Chapter 0540(5)
Packaging of Radioactive Material	AECM Chapter 0529(6)
Radioactive Waste Program	ANSI N46.2(7)
NRC Sponsored Programs	NRC Guidelines(8)

QA Program Implementation: All major projects are provided direction and coordination through the design and construction phases by a Project Team. Typically, the Project Team includes representatives of the R&D Customer Division, Engineering, Quality Assurance representatives from the various participating organizations, and from support groups such as Safety, Security, Fire Protection and Maintenance. The leadership role of the Team changes as a project proceeds through the various design phases. In the earliest phase, the prime role most likely will be in the R&D and Operations organizations with assistance from Engineering. Later Engineering will play the lead role through the detail design phases of the project. On large projects, the A/E and the Contractor also participate with the Project Team. The principal role of the QA representatives is in the formulation of the QA Assessment and QA Plan for the project and in the establishment of inspection and inspection surveillance requirements. The Project Team meets regularly to formulate planning for all phases of the project. Typical QA representation on the Project Team during the planning phases of a project would be QA representatives from the ORNL QA Office, the customer division, Engineering, and on certain projects, from the project organization.



## SEVENTH ANNUAL NATIONAL ENERGY DIVISION CONFERENCE



At the other end of the spectrum, the small bench-scale experimental programs have a much less rigorous QA program; one better suited to programs where the consequence of failures are less critical. For the basic research experiments it is frequently acceptable to use the laboratory notebook for documented evidence of compliance and to incorporate peer review and publication in referred technical journals to satisfy certain QA requirements. Since the scientist's reputation rests on the accuracy of data reported to technical journals, his/her concern for accuracy and good QA practices rivals our own. In basic research, traceability of data from the raw experimental data, through the data analysis and computer manipulations, to the final report is an important QA consideration in basic research experiments. Instrument calibration is equally important in basic research as it is on the large engineering-scale project, particularly on safety instrumentation and on instruments used to produce experimental data.

Implementation of QA in the service organizations more nearly resembles the conventional QA practices found typically throughout industry in which many of the classical 18 QA elements are imposed. However one important difference is that in our fabrication shops most of our jobs are one-of-a-kind components.

The QA Manual: The ORNL QA Office is charged with the responsibility for preparing and maintaining current a QA manual. It is our intent that the QA manual serve at least three purposes: First, to provide specific instructions to the user on how QA requirements are to be implemented. Second, to provide management an overview of the QA program, and third, to provide the sponsoring organizations, in part, with objective evidence on how QA is being implemented on their programs. Experience has convinced us that it is important to strive to minimize the number and complexity of QA procedures because of the negative impact large QA manuals have on the staff. One action that we have taken to minimize the size of the ORNL QA manual is to limit the manual procedures to those that apply to ORNL personnel as a whole and to relegate procedures that affect only a segment of the Laboratory personnel to the appropriate division manuals. Typically, these would be procedures that set QA compliance requirements for service divisions. To coordinate this approach, the ORNL QA manual is divided into sections. One section provides a cross-reference, by titles and document numbers, to these division procedures. Other sections of the ORNL QA manual cross-reference the various sponsor QA standards to the ORNL QA procedures.

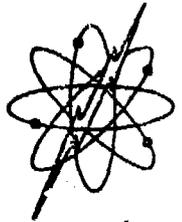
Using the above criteria, procedures contained in the ORNL QA manual include QA planning procedures such as QA assessments and QA Plans, which will be discussed later; deficiency reporting procedures, such as unusual occurrence reports, failure reports and nonconformance reports; QA interfacing procedures with engineering or outside organizations; and procedures related to the activities of the QA Program Office, such as auditing; Procedures are controlled by a computerized distribution list. All staff members with a need for the information and sponsoring organizations can receive copies.

Mr. Roberts(13) presents a discussion of the different approaches in his paper which was presented at the Sixth Annual National Energy Division Conference.

The QA Program Requirements: The ORNL QA program is strongly oriented toward the Pareto Principal of stressing the critical few. With this philosophy we have a set of QA procedures which generally cover the typical 18 elements of



## SEVENTH ANNUAL NATIONAL ENERGY DIVISION CONFERENCE



QA. The procedures are applied to R&D programs with varying degrees of intensity depending on the particular needs of the project or experiment. On large projects these needs are determined by the Project Team during the QA Assessment evaluation. QA Assessments are conducted on each new project. The purpose of the QA Assessment is to focus on those postulated failures that could have the most significant effect on the R&D effort. Early in the design phase of a project, the Project Team, with QA representation from the customer division, the ORNL QA Office and Engineering meet to review project requirements and to evaluate potential quality problems that may occur. The consequence of the failure of each component or subsystem is considered in terms of human health and safety, effect on the environment, loss of experimental data and meeting program objectives, and finally, the effect on funding and project schedules. When it is determined that a failure could have a significant effect, the probability of such a potential failure is then assessed. When the consequence and probability of a failure are determined to be either significant or unknown, the assessment designates the component or subsystem for special QA treatment to prevent or minimize the identified potential failures. On those components or subsystems which have been identified as having a low risk of failure, the base QA procedures are applied as applicable.

On large complex projects where there is relatively little previous experience on the performance of a component or subsystem, determining the probability of failure can be difficult. In these cases, it is frequently necessary to resort to such techniques as fault tree analysis, failure modes and effects analysis, etc. On these types of projects, close quality control by ORNL over outside contractors becomes of paramount importance to the success of the project.

QA Assessments are reviewed periodically and updated, as required, as additional information becomes available during the later design phases of the project. All assessments are approved by the Project Team and reviewed by the QA Program Director.

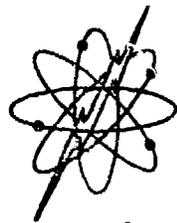
QA Planning: Those components or subsystems that were identified in the QA Assessment as having a significant risk of failure are given detailed consideration in a QA Plan. Critical technical requirements are developed to minimize or prevent the potential quality failures indicated in the Assessment. QA actions are also specified in the QA plan to assure that the critical technical requirements are implemented. The QA Plan designates responsibilities for these actions and a date for completion. Like the Assessment, the QA Plan is updated periodically as the project proceeds.

At the conclusion of the design, construction and installation phases of a project, the facility operating group will review the Assessment and Plan with respect to the operation of the facility. At this point it is frequently desirable to prepare a new Assessment and Plan which specifically addresses potential problems associated with the operation of the facility.

Both government and industry have a number of publications that can assist in identifying potential quality problems by providing examples of failures that have occurred on similar equipment throughout industry. The Nuclear Standards Management Center(9), which is funded by DOE, provides periodic summaries of unusual occurrences reported by installations funded by the Office of Nuclear



## SEVENTH ANNUAL NATIONAL ENERGY DIVISION CONFERENCE



Energy. The Nuclear Safety Information Center(10) can provide summaries of public documents resulting from the findings of NRC inspectors at the nuclear power installations. The Nuclear Plant Reliability Data System(11) and the Government-Industry Data Exchange Program(12) are examples of other programs that provide component failure information.

Finding Quality Related Problems: In spite of our best efforts in analysis for potential quality problems, we cannot assume that when QA Assessments and QA Plans are completed we will have a guarantee of success. We cannot foresee all the problems that may occur in spite of our best efforts. This is particularly true in the case of projects utilizing state-of-the-art equipment, which is frequently the case at ORNL. The key to successfully seeking out of potential quality problems is early and continuing QA participation in projects. It is most important not to delay QA surveillance until the usual quality control activities during fabrication and installation. Instead, QA Surveillance should be active and continuing from the inception of a project to its termination.

QA audits are a good method for seeking out quality-related problem areas and involving management in QA activities. Unfortunately, QA audits are both expensive and time consuming for the participants, and certainly should not be relied upon to detect all problem areas. At ORNL the QA Program Director's staff conduct monthly QA audits among the divisions and programs. These are supplemented by an independent auditing program by the Division QA Coordinators. QA auditing is only as good as the personnel conducting the audits. We believe auditor training is an essential part of the complete QA program. The ORNL training course is based on the material contained in ANSI/ASME NQA-1(3).

Quality Deficiency Reporting: When deficiencies do occur in a project, it is important to not only take immediate actions to correct the deficiency, but equally important to seek out the technical reason for the deficiency and to correct the system to prevent a recurrence of the same type of deficiency. We also place strong emphasis on the importance for reviewing the QA program to determine if it could be improved in some way to anticipate the deficiency.

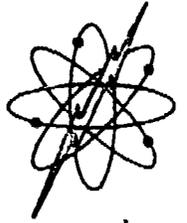
A nonconformance reporting system is used to identify deficiencies occurring prior to the preoperational phases of a project. Failure and unusual occurrence reporting is used to identify component failures during the preoperational testing and operation of the facility. All deficiency reports are initiated by the line-organization, approved by the appropriate division QA coordinator, and become part of the permanent project file. These reports can be used to update design drawings and to produce as-built drawings. Nonconformance reports are summarized and placed in a computer data base for periodic trend analysis studies by the ORNL QA Office.

Copies of failure reports are submitted to the Nuclear Division QA Office where they are summarized and issued quarterly along with similar reports from other Nuclear Division installations. These computerized summaries are cross-referenced by subject matter in a KWIC format and provide a good data base of equipment failures for future reference.

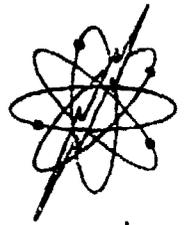
Monthly reports are prepared for ORNL management review which highlights the more significant failures and provides a cost summary of all failures by monthly totals and cumulative totals.



## SEVENTH ANNUAL NATIONAL ENERGY DIVISION CONFERENCE



In Summary: We feel that we have developed a QA program that serves a large multidisciplined laboratory adequately. The Oak Ridge Operations Office, DOE, conducts an annual week-long appraisal and over the past several years, ORNL has received an "Excellent" rating each year for its QA program. This is not intended to mean that we are satisfied or complacent with the results of the program, rather we still feel that innovative ideas should be sought and the best incorporated into the QA program.



REFERENCES

1. Quality Assurance, OR IMD 02XX, January 30, 1978, U.S. Department of Energy, DOE-ORO Manual.
2. Quality Assurance Program Requirements, RDT F2-2, Office of Nuclear Energy, USDOE, August 1973.
3. Quality Assurance Program Requirements for Nuclear Power Plants, ANSI/ASME NQA-1-1977, American Society of Mechanical Engineers, August 31, 1979.
4. Quality Assurance Program Requirements for Nuclear Facilities, ANSI/ASME N45.2-1977, American Society of Mechanical Engineers, April 7, 1977.
5. Safety of AEC-Owned Reactors, AECM Chapter 0540, May 13, 1974.
6. Safety Standards for the Packaging of Fissile and other Radioactive Materials, Chapter OR 0529, Oak Ridge Operations Office, USDOE, September 6, 1973.
7. Quality Assurance Program Requirements for Post Reactor Nuclear Fuel Cycle Facilities, ANSI N46.2, American National Standards Institute, October 19, 1978.
8. For a discussion of the NRC QA philosophy for research see: QA in NRC Research Programs, G. L. Benett, F. J. Liederbach, ANS 36th Annual Meeting, June 1980.
9. Nuclear Standards Office, Oak Ridge National Laboratory, Post Office Box Y, Oak Ridge Tennessee 37830.
10. Nuclear Safety Information Center, Oak Ridge National Laboratory, Post Office Box Y, Oak Ridge, Tennessee 37830.
11. Nuclear Plant Reliability Data System, Southwest Research Institute, Post Office Drawer 28510, San Antonio Texas 78284.
12. Government-Industry Data Exchange Program, Director, GIDEP Operations Center, Corona, California 91720.
13. How to Tailor Your QA Program To Fit your Needs for an R&D Project, G. W. Roberts, ASQC Sixth Annual National Energy Division Conference.