MARTIN MARIETTA ENERGY SYSTEMS LIBRARIES
3 4456 0425296 6

ornl

ORNL-6891

OAK RIDGE NATIONAL LABORATORY

LOCKHEED MARTIN

A Statistical Process Control–Based Metric for Management Systems

Thomas B. Powell

OAK RIDGE NATIONAL LABORATORY
CENTRAL RESEARCH LIBRARY
CIRCULATION SECTION
4500N ROOM 175
LIBRARY LOAN COPY
DO NOT TRANSFER TO ANOTHER PERSON
If you wish someone else to see this report, send in name with report and the library will arrange a loan.
UCN-7969 (3 9-77)

MANAGED BY
LOCKHEED MARTIN ENERGY SYSTEMS, INC.
FOR THE UNITED STATES
DEPARTMENT OF ENERGY

UCN-13873 (36 6-95)

This report has been reproduced directly from the best available copy.

Available to DOE and DOE contractors from the Office of Scientific and Technical Information, P.O. Box 62, Oak Ridge, TN 37831; prices available from (615) 576-8401.

Available to the public from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161.

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility 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 favoring 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.

ORNL-6891

90-S

A STATISTICAL PROCESS CONTROL–BASED METRIC FOR MANAGEMENT SYSTEMS

Thomas B. Powell

December 1995

Prepared by
OAK RIDGE NATIONAL LABORATORY
Oak Ridge, Tennessee 37831
managed by
LOCKHEED MARTIN ENERGY SYSTEMS, INC.
for the
U.S. DEPARTMENT OF ENERGY
under contract DE-AC05-84OR21400

MARTIN MARIETTA ENERGY SYSTEMS LIBRARIES

3 4456 0425296 6

DEDICATION

This document is dedicated to my father, L. Thorton (Tony) Powell, who after having received a Bachelor of Science in Agriculture from the University of California at Davis in 1933, owned and managed Powell Orchards for nearly 40 years and was founding president and manager of the California Freestone Peach Association, a cooperative marketing organization. In counseling me to obtain a Bachelor of Science in Mechanical Engineering, he noted that while agricultural science was an enterprising field for his generation, my generation would need to be more technologically oriented. He also reasoned that the best managers, as well as those who experienced the most rapid advancement in their careers, were those with a bachelor's degree in engineering and a master's degree in management. My father was right.

CONTENTS

	Page
LIST OF FIGURES	vii
LIST OF TABLES	ix
ACRONYMS AND INITIALISMS	xi
FOREWORD	xiii
ACKNOWLEDGMENTS	xv
ABSTRACT	xvii
1. INTRODUCTION	1
1.1 IDENTIFICATION OF NONCOMPLIANCES	1
1.2 MEASURING DEGREES OF COMPLIANCE	1
1.3 CULTURAL CONFLICT WITH CUSTOMER	2
2. ANALYSIS	4
2.1 MANAGEMENT SYSTEMS	4
2.1.1 Program Planning and Implementation	4
2.1.2 Evaluation	5
2.2 STATISTICAL PROCESS CONTROL	7
2.2.1 Product Quality	7
2.2.2 Management Effectiveness	8
3. RESULTS	10
4. CONCLUSIONS AND RECOMMENDATIONS	16
REFERENCES	17
BIBLIOGRAPHY	18
Appendix A: NEW PRODUCTION REACTOR ORGANIZATION AT OAK RIDGE NATIONAL LABORATORY	A-1
Appendix B: NEW PRODUCTION REACTOR STANDARD PRACTICE PROCEDURES	B-1
Appendix C: TYPICAL CHECKLIST	C-1
Appendix D: TYPICAL COMPLETED CHECKLIST	D-1
Appendix E: TYPICAL NEW PRODUCTION REACTOR SURVEILLANCE QUARTERLY SCHEDULE	E-1

LIST OF FIGURES

Figure		*Page*
1	Hierarchy of plans	4
2	Example P chart	9
3	Third quarter 1991 surveillance data and statistical process control chart	10
4	Fourth quarter 1991 surveillance data and statistical process control chart	13
5	First quarter 1992 surveillance data and statistical process control chart	14
6	Second quarter 1992 surveillance data and statistical process control chart	15
A.1	New Production Reactor organization at Oak Ridge National Laboratory	A-3

LIST OF TABLES

Table		*Page*
1	Oak Ridge National Laboratory cause codes	6

ACRONYMS AND INITIALISMS

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASQC	American Society of Quality Control
DOE	U.S. Department of Energy
NP	DOE Office of New Production Reactors
HWR	Heavy Water Reactor
ISO	International Standards Organization
LCL	lower control limit
MHTGR	Modular High-Temperature Gas-Cooled Reactor
NPR	New Production Reactor
ORNL	Oak Ridge National Laboratory
QA	quality assurance
QAM	quality assurance manager
QAR	quality assurance requirements
SAT	satisfactory
SPC	statistical process control
SPP	Standard Practice Procedure
SQR	square root
UNSAT	unsatisfactory
UCL	upper control limit

FOREWORD

Thomas B. Powell has taken the statistical process control concept, traditionally used to evaluate the quality of manufactured products, and successfully applied it as a metric for management systems at Oak Ridge National Laboratory (ORNL). The plotting of surveillance data from audit results of the ORNL New Production Reactor Project during 1991 and 1992, together with applied Total Quality Management attributes and team leadership, not only communicated to managers the degree of implementation that the documented management system had obtained but also identified specific opportunities for continuous improvement.

Powell has over 24 years of progressive experience in the U.S. Nuclear Navy, the commercial nuclear industry, the U.S. Nuclear Regulatory Commission, and the U.S. Department of Energy (DOE) Complex in technical management, regulatory compliance, conduct of operations/maintenance, quality engineering, and project management. He has led or participated in numerous assessments at Lockheed Martin Energy Systems, Inc., sites and has participated as a DOE assessment team member at various other DOE sites. He has participated in numerous operational readiness reviews. Powell's expertise is in the areas of regulatory compliance, quality engineering, conduct of operations/maintenance, and project management. He is a certified Lead Auditor (American Society of Mechanical Engineers, NQA-1), is certified by the American Society of Quality Control as a Quality Engineer and as a Quality Auditor, and is certified as an ISO-9000 Quality Systems Lead Auditor by the Registrar Accreditation Board.

Powell has a Bachelor of Science in Mechanical Engineering from the University of Idaho and a Master of Science in Engineering from the University of Alabama in Huntsville. This report was submitted as the Capstone Project document in partial fulfillment of the requirements for the master's degree.

—J. W. Turner, editor

ACKNOWLEDGMENTS

I express my sincere appreciation to Dr. Jerry Westbrook of the University of Alabama, Huntsville, for his counsel and instruction. I especially thank my wife, Mary, for her love and patience during the documentation of this project. And I appreciate the cooperation of Dr. David L. Moses, the Oak Ridge National Laboratory (ORNL) New Production Reactor (NPR) director when I was serving as the ORNL NPR Project quality assurance manager.

ABSTRACT

Traditionally, statistical process control (SPC) has been used to evaluate the quality of manufactured products. However, it can also be used to demonstrate the effectiveness of a management system. This concept was applied in measuring the degree of compliance within the New Production Reactor Project at Oak Ridge National Laboratory as well as in determining the effectiveness of its management systems. Results proved that this SPC-based metric is a valuable tool for determining the effectiveness of management systems, identifying opportunities for continuous improvement, and measuring the effectiveness of previous corrective actions.

1. INTRODUCTION

In the early 1940s, Oak Ridge National Laboratory (ORNL), together with the Oak Ridge Y-12 Plant and the K-25 Site, was established as part of the Manhattan Project, a secret undertaking that produced the first atomic bombs. Over the years the Oak Ridge Reservation, as it came to be known, continued to adapt to meet the changing defense and energy needs of the United States. The Y-12 Plant evolved into a key manufacturing technology center, the K-25 Site became a center for environmental restoration and waste management, and ORNL emerged as a large, multipurpose research laboratory. Today, these installations are managed by Lockheed Martin Energy Systems, Inc. (formerly Martin Marietta Energy Systems, Inc.) for the U.S. Department of Energy (DOE).

In the early 1990s, DOE started holding Energy Systems more accountable to verbatim compliance with rigorous federal rules, regulations, and DOE orders. While ORNL personnel were trained researchers, they had very little experience at managing within their rapidly changing regulatory environment. As DOE audit and appraisal teams evaluated ORNL more frequently, numerous noncompliances were indicated.

1.1 IDENTIFICATION OF NONCOMPLIANCES

Why had Energy Systems internal auditors not identified the noncompliances? This was a recurring question among many of the DOE audits and appraisals. A review of previous internal audit reports revealed that the issues that DOE audits were identifying had, in most cases, been previously identified by internal audits but had been misunderstood, given a low priority, and/or lost or forgotten because of the large number of issues being managed. It was also believed that everything was operating satisfactorily and that the noncompliances identified during audits and appraisals were isolated occurrences. However, *ORNL internal auditors had no metric to confirm that the noncompliances were not representative of the majority of work being performed.*

1.2 MEASURING DEGREES OF COMPLIANCE

This problem of measuring degrees of compliance was first addressed within the ORNL New Production Reactor (NPR) Project. As one of the participants in the NPR Project, which was under the direction of DOE's Office of New Production Reactors (NP), ORNL was assigned the responsibilities of developing experimental, analytical, and assessment and evaluation confirmatory data for use in the design, fabrication, and operation of NPR structures, systems, and components. The NPR Project was required to comply with contractual agreements, DOE Order 5700.6B, ANSI/ASME NQA-1, and DOE NP quality assurance requirements (QAR) (DOE 1990).

The ORNL NPR Project organization chart is shown in Appendix A. The ORNL NPR Project was a matrix-managed organization. Various functional divisions supplied technical experts to work for the project.

The ORNL NPR Project staff developed a procedural system to comply with and to implement a QA Program (i.e., management system) that met the applicable criteria of DOE Order 5700.6B, ANSI/ASME NQA-1, and the NP QAR. To ensure implementation of NQA-1 requirements, ORNL's Quality Department had developed a QA manual containing procedures that were to be implemented by each ORNL organization. Each ORNL organization could use the ORNL QA procedures or develop division-specific QA procedures provided such procedures met the

requirements of the Laboratory's QA manual. To comply with the NP QAR and the ORNL QA Program, the ORNL NPR Project staff developed NPR Standard Practice Procedures (SPPs) and applied these to supplement the existing Laboratory/division procedures. Appendix B lists the SPPs developed as well as the purpose and scope of each. These SPPs designate appropriate interfaces between the organizations providing services to the ORNL NPR Project and specify the responsibilities and accountabilities of each.

The goal of the ORNL NPR QA Project was to ensure that experimental, analytical, and assessment and evaluation confirmatory activities were carried out in a controlled manner. Some of the key elements of the ORNL NPR Project were:

- to ensure that all experimental or analytical simulations of proposed ORNL NPR facilities and all assessments and evaluations of ORNL NPR facility designs and design standards incorporate the appropriate facility design information including applicable codes and standards;
- to plan, to define, and to execute analytical studies, assessments, and evaluations with documentation of assumptions, bases, applicable codes, and standards with exceptions identified to support data sources, exploratory results, final results, and conclusions;
- to plan and to define experiments through the use of procedures; and
- to report results of experiments, analyses, assessments, and evaluations by issuing formal reports or papers that are independently reviewed within ORNL.

1.3 CULTURAL CONFLICT WITH CUSTOMER

The ORNL culture is typical of that found at most research institutions. McGregor's Theory Y (Bowen and Boone 1987, pp. 126–37) models the management structure used at ORNL and includes the following assumptions:

- Management is responsible for organizing the elements of productive enterprise—money, materials, equipment, and people—in the interest of economic ends.
- People are not by nature passive or resistant to organizational needs.
- The motivation, the potential for development, the capacity for assuming responsibility, the readiness to direct behavior toward organizational goals—all these are present in people. Management does not put them there. It is a responsibility of management to make it possible for people to recognize and to develop these human characteristics for themselves.
- The essential task of management is to arrange organization conditions and methods of operation so that people can achieve their own goals best by directing their own efforts toward organizational objectives.

Researchers at ORNL had traditionally thrived in this management culture. It allowed flexibility to be creative and innovative in meeting research and development objectives. ORNL management needed only to ensure appropriate allocation of people and material resources to the approved research or development project. This management culture allowed the researchers to meet their esteem and self-actualization needs described by Maslow (Bowen and Boone 1987, pp. 106–19). Researchers were motivated by the research work, recognition from the research, the responsibility of the research, and personal growth from the research, all of which are motivators described by Herzburg (Bowen and Boone 1987, pp. 168–83).

ORNL is organized into functional divisions depending on the research discipline and support offices (e.g., Metals and Ceramics Division, Engineering Technology Division, Instrumentation

and Controls Division, Office of Quality Programs and Inspection). Projects are managed out of the division with the majority of the work.

Once research projects had been authorized and funded and resources had been allocated, there was very little management control, such as approvals and formal written procedures. The exceptions to the lack of controls were laboratory notebooks, peer reviews of research work, and publication protocols for final research reports and professional journal articles.

Cultural conflicts arose from customer (i.e., DOE NP) expectations. NP expected bureaucratic controls discussed by Bowen and Boone (1987, pp. 5–16):

- centralization of authority;
- written rules, policies, procedures, and regulations;
- written records; and
- strict chain of command.

Additionally, NP treated ORNL, the contractor, with Theory X management assumptions (Bowen and Boone 1987, pp. 127–37):

- Management is responsible for organizing the elements of productive enterprise—money, materials, equipment, and people—in the interest of economic ends.
- With respect to people, this is a process of directing their efforts, motivating them, controlling their actions, and modifying their behavior to fit the needs of the organization.
- Without this active intervention by management, people would be passive—even resistant—to organizational needs. They must therefore be persuaded, rewarded, punished, controlled—their activities must be directed. This is management's task. We often sum it up by saying that management consists of getting things done through other people.
- The average employee is by nature indolent—working as little as possible; he or she lacks ambition, dislikes responsibility, prefers to be led, is self-centered, is indifferent to organization needs, is by nature resistant to change, is gullible, is not very bright, and is the ready dupe of the charlatan and the demagogue.

The frustration started after an NP QA audit of the ORNL NPR Project in the spring of 1991. This audit determined that there was inadequate centralization of authority, verbatim compliance to written procedures and policies, written records, and chain of command. As a result, NP nearly issued a "stop work" order because they felt that their management responsibility was to keep rigorous control of their contractors. Also these audit results caused a full-time quality assurance manager (QAM) (i.e., the author of this document) to be assigned to the project to lead the corrective action effort.

The new ORNL NPR QAM realized immediately the cultural conflict between the NP expectations of bureaucratic controls as opposed to the Laboratory tradition of trust and respect of its researchers. The QAM planned to use the Team-Building Approach consisting of respect and consideration, communication of responsibilities and standards, communication with employees, establishing individual and group goals, and loyalty to the team. Changes to resolve the cultural conflict needed to be implemented both within ORNL and NP. This would require the QAM to be persistent, patient, and diplomatic. The statistical process control–based (SPC) metric presented in this document would be used to measure the success of the change process.

2. ANALYSIS

2.1 MANAGEMENT SYSTEMS

2.1.1 Program Planning and Implementation

The bases for management systems are customer contract requirements (i.e., expectations), industrial consensus standards, and government regulations. Management usually develops plans that satisfy these bases and operates in accordance with the plans. "Planning involves selecting missions and objectives and the actions to achieve them" (Koontz and Weihrich 1988). Plans can be of various types and fall within a hierarchy. Figure 1 shows a typical hierarchy of plans (Koontz and Weihrich 1988), the definitions of which follow:

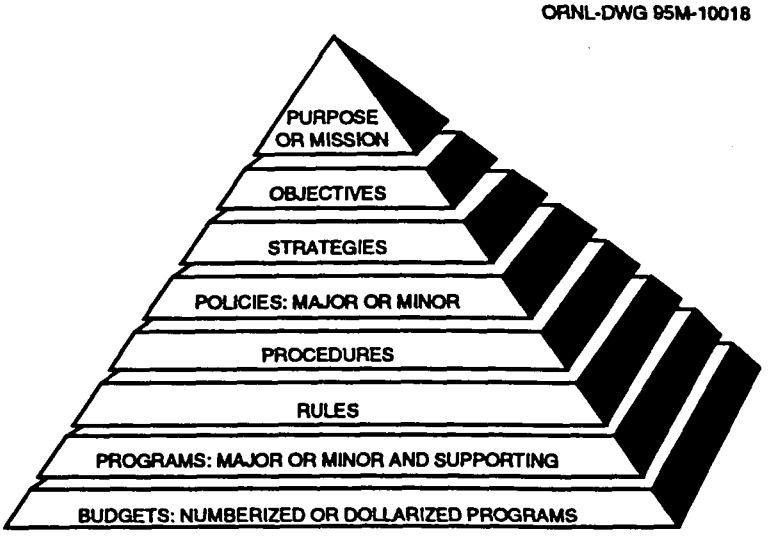

Fig. 1. Hierarchy of plans. *Source:* Redrawn with permission from Koontz, H. and H. Weihrich 1988. *Management*, 9th ed., McGraw-Hill, New York, Fig. 3-3, p. 62.

- mission, basic function or task;
- objectives, ends toward which activity is aimed;
- strategies, programs of action and deployment of resources;
- policies, general statements or understandings that guide or channel thinking in decision making;
- procedures, required method of handling activities;
- rules, required action or nonaction, allowing no discretion;
- programs, complex of objectives, policies, procedures, rules, and resources deployed to carry out a course of action; and
- budgets, expected results expressed in numeric terms.

As is stated in these definitions, the *management program* is the complex of objectives, policies, procedures, rules, and resource deployment. The *management system* is the documented management program and the implementation of that program. Implementation involves communication of the management program to the employees, training of the employees, and

employee actions to carry out the program. To be effective, implementation of the management system must:

- ensure that the requirements of contracts, specifications, industrial standards, government regulations, and customer expectations flow through the management program from the mission statement to the implementing procedures;
- ensure that appropriate actions are taken by personnel at all levels of the organization in implementation of the management program; and
- contain a policy of continuous improvement ensuring that appropriate corrective actions are taken when problems or inefficiencies are identified (additionally, numerous industrial standard-specific elements must be addressed).

Examples of typical elements that must be addressed in management programs are contained in the American Society of Quality Control (ASQC) Q90 series of standards, which are the U.S. standards for the implementation of International Standards Organization (ISO) 9000 series on quality management. These standards specify that a quality management program must describe:

- management responsibility;
- quality system;
- contract review;
- design control;
- document control;
- purchasing;
- control of supplied products;
- product identification and traceability;
- process control;
- inspection and testing;
- control of inspection, measuring, and test equipment;
- inspection and test status;
- control of nonconforming products;
- corrective action;
- handling, storage, packaging, and delivery;
- records;
- internal process audits;
- training;
- servicing; and
- statistical techniques.

The details that are expected to be described under the above 20 areas are covered in ANSI/ASQC Q90-1987 through Q94-1987. Note that other standards or customer expectations may require that other elements be addressed (e.g., environmental programs required by the U.S. Environmental Protection Agency). The Registrar Accreditation Board (i.e., the affiliate of ASQC that certifies companies' ISO-9000 QA systems and ISO-9000 auditors) has determined that ANSI/ASME NQA-1 is equivalent to the ASQC Q90 series of standards.

2.1.2 Evaluation

The success of implementation of a management system is generally measured using a checklist similar to that shown in Appendix C, which was developed to measure the effectiveness

of a program at ORNL. Note that the checklist gives in parentheses the reference where the requirement being checked is located.

An auditor or assessor reviews field operations to determine whether the requirements of the management system sample (defined in the checklist) were satisfactorily implemented. The auditor or assessor then documents his observations for each item on the checklist. A decision is made regarding whether the checklist item was found to be satisfactory, and this is documented on the checklist. For any item found unsatisfactory, the auditor or assessor records a cause code for the unsatisfactory observation. The cause codes used by ORNL are shown in Table 1. Appendix D is an example of a completed checklist.

Table 1. Oak Ridge National Laboratory cause codes

Cause code	Translation
	Equipment/material problems
1A	Defective or failed part
1B	Defective or failed material
1C	Defective weld, braze, or solder joint
1D	Mistake by manufacturer or shipping or marking
1E	Electrical or instrument noise
1F	Contamination
	Procuedure problems
2A	Defective or inadequate procedure
2B	Lack of procedure
	Personnel error
3A	Inadequate work environment
3B	Inattention to detail
3C	Disregard of requirement or procedure
3D	Verbal communication problem
3E	Other human mistake
	Design problem
4A	Inadequate man-machine interface
4B	Inadequate or defective design
4C	Mistake in equipment or material selection
4D	Mistake in drawing, specification, or data
	Training deficiencies
5A	No training provided
5B	Insufficient practice or hands-on experience
5C	Inadequate content
5D	Insufficient refresher training
5E	Inadequate presentation of materials
	Management problems
6A	Inadequate administrative control
6B	Work organization/planning deficiency
6C	Inadequate supervision
6D	Improper resource allocation
6E	Policy not adequately defined, disseminated, or explained
6F	Other management problem
	External phenomena
7A	Weather or ambient condition
7B	Power failure or transient
7C	External fire or explosion
7D	Theft, tampering, sabotage, or vandalism

Source: ORNL Root Cause Analysis Program, ORNL Standard Practice Procedure X-QA-5, Oct. 30, 1992.

2.2 STATISTICAL PROCESS CONTROL

2.2.1 Product Quality

In a manufacturing process, a large number of products produced over time can be evaluated by taking a relatively small sample, inspecting the samples, and determining the percent nonconformance to production specifications. If the percent nonconforming is above the acceptance level, then the manufacturing process is out of control and must be adjusted to return the manufacturing process to be in control (Montgomery 1991). Sampling occurs at uniform periods. The percent nonconforming (p_i) for each sample is calculated using

$$p_i = d_i/n_i \ ,$$

where d_i is the number of defects found in sample i, and n_i is the number of items in sample i.

The desired maximum proportion nonconforming (p_d) (i.e., acceptance level) is determined by the manufacturer. Because p_i is subject to variability, a band around p_d is determined by taking three times the estimated standard deviation of the sample. The limits of this band are called the upper and lower control limits (UCL and LCL) respectively. The UCL_i and LCL_i are calculated by

$$UCL_i = p_d + 3 \times SQR[p_d(1 - p_d)/n_i]$$

and

$$LCL_i = p_d - 3 \times SQR[p_d(1 - p_d)/n_i] \ ,$$

where SQR is the square root (Montgomery 1991). If the manufacturer desires that the process produce no more than 1% (i.e., $p_d = 0.01$), the UCL would be

$$UCL_i = 0.01 + 3 \times SQR[0.01(0.99)/n_i] = 0.01 + 0.298/SQR(n_i)$$

and

$$LCL_i = 0.01 - 3 \times SQR[0.01(0.99)/n_i] = 0.01 - 0.298/SQR(n_i) \ .$$

Solving for various n_i yields

n_i	LCL_i	UCL_i	n_i	LCL_i	UCL_i
10	none	0.104	200	none	0.031
50	none	0.052	300	none	0.027
100	none	0.040	500	none	0.023
150	none	0.034	1000	0.0006	0.019

Note that when the calculation of LCL < 0, then there is no LCL. The larger n_i becomes, the more UCL approaches p_d. For smaller n_i, more variability is possible in the estimation of p_i. On the other hand, the larger n_i, the more costly the sampling process becomes. The goal is to select n_i

large enough to be a good estimation of the proportion of defective products being produced by the manufacturing process while keeping n_i small enough to make the sampling process cost-effective.

Note that the equations for UCL_i, LCL_i, and min. n_i take on the general form of

$$UCL_i = p_d + k \times SQR[p_d(1 - p_d)/n_i] ,$$

$$LCL_i = p_d - k \times SQR[p_d(1 - p_d)/n_i] ,$$

and

$$\text{min. } n_i = k/p_d ,$$

where k is the number of standard deviation units of one-half the width of the control band (i.e., $UCL_i - LCL_i$).

The purpose of these calculations is that if $p_i \leq UCL$, then it can be assumed with a high level of confidence (i.e., 99.73% at k = 3) that the manufacturing process is producing defective products at a rate less than p_d. Figure 2 shows an example P chart (Wortman 1993).

2.2.2 Management Effectiveness

As is pointed out in Subsect. 2.1.1, a management system is described by documents defining missions, objectives, strategies, policies, procedures, rules, programs, and budgets. Each document can contain numerous actions to be taken under specific circumstances. Each action should in part contribute to fulfilling some aspect of the management system. Each could be required to be performed numerous times over a period of time (e.g., over a month). Taking the sum of all the actions occurring during the specified period to satisfy the requirements of the management system yields a large number in complex management systems. This is analogous to the total number of products manufactured when discussing a manufacturing process.

Each required action within the management system presents an opportunity to succeed or to fail in satisfying the requirements of the management system. A measure of the degree of success of the management system can be obtained by analyzing the data from management systems evaluations (e.g., audits, appraisals, surveillances). The success of the management system, over a specified period (e.g., a month) can be estimated as

$$p_i = SUM(\#\ UNSAT_j)/SUM(\#\ SAT_j + \#\ UNSAT_j) \quad \text{for j from j = 1 to j = m} ,$$

where j represents a particular management evaluation of the management evaluations conducted within the specified period, # SAT_j is the number of satisfactorily implemented management requirements found in the jth management evaluation, and # $UNSAT_j$ is the number of unsatisfactorily implemented management requirements found in the jth management evaluation. The total number of management system requirements sampled over the specified time, n_i, can be calculated as

$$n_i = SUM(\#\ SAT_j + UNSAT_j) \quad \text{for j from j = 1 to j = m} .$$

If management has set an implementation goal of the management system to be at least Z% effectively implemented, then the maximum desired proportion nonconforming $p_d = 1 - (Z/100)$. The UCL_i and LCL_i can then be calculated as is shown in Subsect. 2.2.1 of this document. *Note:*

ORNL-DWG 95-10175

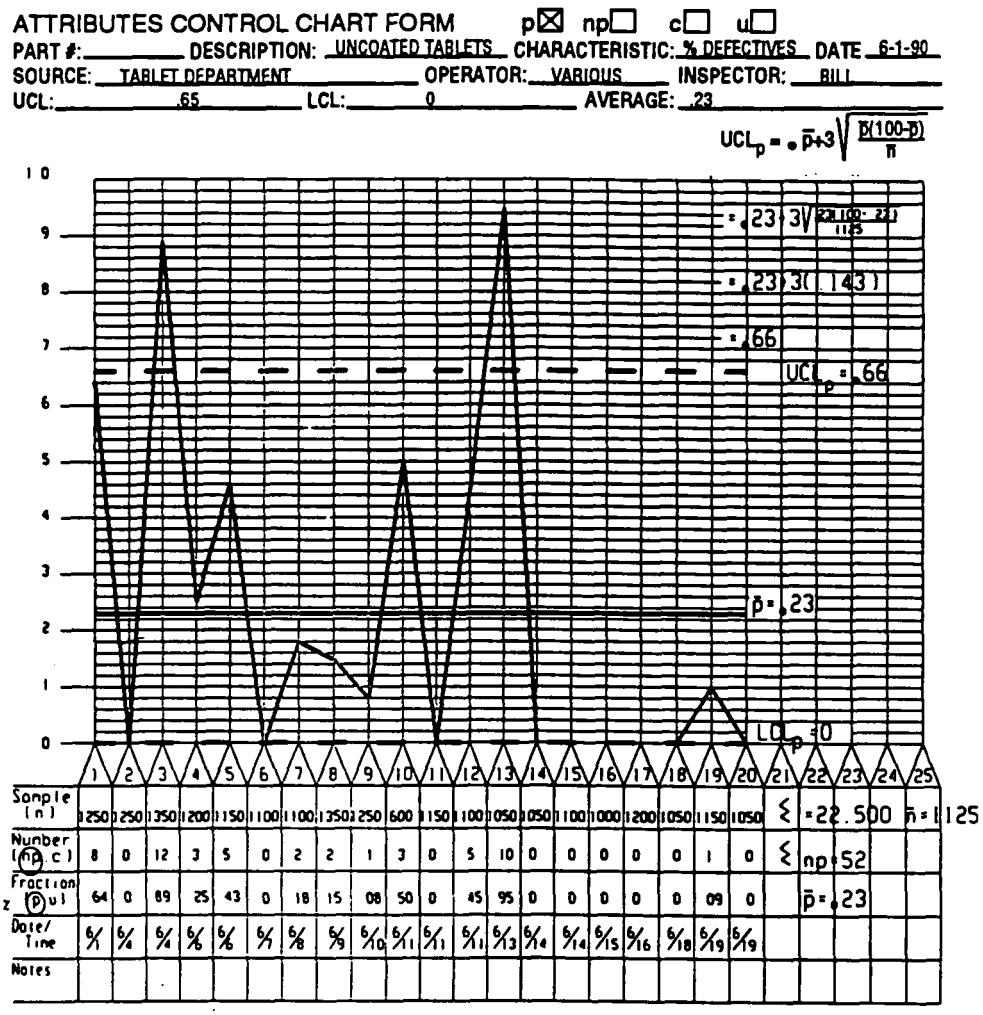

Fig. 2. Example P chart. *Source:* Reprinted with permission from Wortman, B. 1993. *Certified Quality Technician Primer*, 3d ed., Quality Council of Indiana, Milwaukee, Wis., P chart, p. VIII-76.

The process explained in Subsect. 2.2.2 of this document is an expansion of the concept discussed in Subsect. 12.4.1 of Mills (1989). None of the other books in the literature review for this project included anything on the topic discussed in this section.

3. RESULTS

The management systems of the ORNL NPR Project were evaluated periodically using surveillances of various activities each quarter. These surveillances form a process audit that evaluates a process operation against established instruction and standards. The process audit measures conformance of the processed item or activity to established standards. It also measures the effectiveness of process instructions (Wortman 1993). An example ORNL NPR surveillance schedule is shown in Appendix E. Surveillances were performed using checklists similar to the one shown in Appendix C and completed similar to the checklist shown in Appendix D. At the end of each quarter, the data from the surveillances were entered in a spreadsheet computer database (Excel software) similar to the one shown in Fig. 3*a*.

The surveillance program did not effectively start until the third quarter of 1991. An initial goal set by management was fewer than 5% noncompliances. Therefore, the equations for the UCL_i and LCL_i are

$$UCL_i = 0.05 + 3 \times SQR[0.05(0.95)/n_i] = 0.05 + 0.654/SQR(n_i)$$

ORNL-DWG 95M-10019

SURVEILLANCE #	TOPIC	ITEMS CHECKED	# UNSAT	CAUSE 1	2	3	4	5	6	7
NPR-91-006	PROCEDURE CONTROL PROCESS	5	4		1	3				
NPR-91-007	WORK PLANNING	8	7		3	4				
NPR-91-008	READINESS REVIEW OF PIE	7	6		1	5				
	SUMS	20	17	0	5	12	0	0	0	0
PERCENT FAILURE	P1 = # UNSAT ITEMS CHECKED		86%	0%	29%	71%	0%	0%	0%	0%
	5% GOAL UCL		20%							

(a)

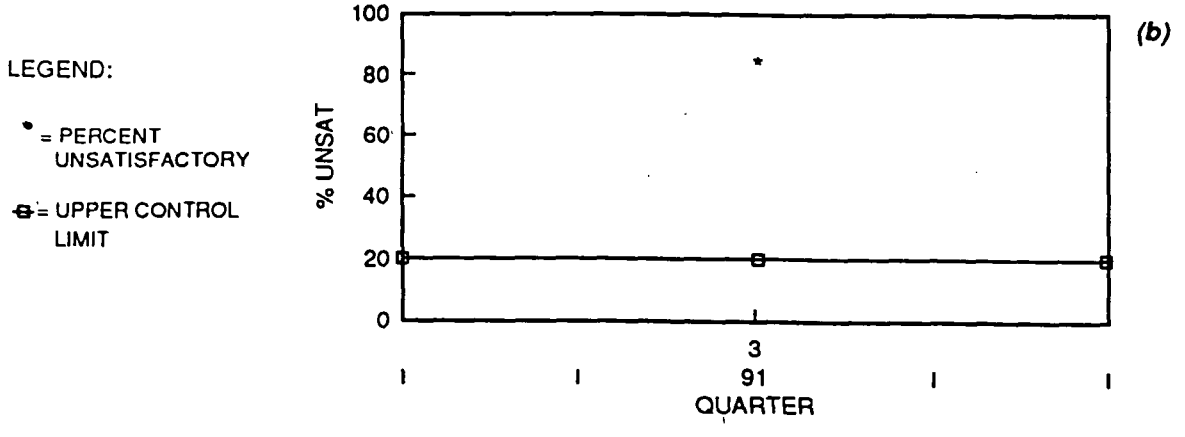

Fig. 3. Third quarter 1991 (*a*) surveillance data and (*b*) statistical process control chart.

and

$$LCL_i = 0.05 - 3 \times SQR[0.05(0.95)/n_i] = 0.05 - 0.654/SQR(n_i) .$$

Solving for various n_i yields

n_i	LCL_i	UCL_i	n_i	LCL_i	UCL_i
7	none	0.297	90	none	0.119
10	none	0.257	100	none	0.115
14	none	0.225	150	none	0.103
21	none	0.193	200	0.004	0.096

The surveillance results for the third quarter of 1991 (Fig. 3*a*) showed 85% noncompliance with the established management system. Also shown in Fig. 3*a* is that 71% of the noncompliances were due to disregard of requirement or procedure (see Table 1) and that 29% were due to inadequate procedures. The SPC chart for the third quarter of 1991 (Fig. 3*b*) shows a UCL of 20% and the 85% UNSAT, which is above the UCL. This indicates that the management goal of having less than 5% UNSAT was not obtained (i.e., the management system is out of control). The ORNL NPR QAM (i.e., the author of this document) was immediately concerned. To communicate this concern, the ORNL QAM began sending quarterly trend reports to the ORNL NPR Project director.

The ORNL NPR Project director and QAM discussed this adverse trend (i.e., 85% noncompliance), and a Quality Improvement Committee was established consisting of the ORNL NPR Project director, the QAM, assistant project directors, and task managers. While the number of requirements sampled each quarter needed to be greater than 60 for statistical significance, only 20 had been sampled this quarter. The small sample size for this quarter was not a concern because the percent UNSAT was so large. Any error with the small sample size was insignificant compared with the largeness of the percent UNSAT statistic. However, to maintain the statistical significance of the management system metric, the ORNL NPR Project director and the QAM agreed to an objective of sampling at least 60 requirements each quarter.

The QAM wanted the Quality Improvement Committee to be the agent for change. Its charter and composition was developed to utilize group forces, leadership from the committee, participation, shared rewards, and open communication in order to resolve the total technical problems, not just quality.

The Quality Improvement Committee first addressed the procedural noncompliance (i.e., cause codes 3B and 3C from Table 1). Agreement was reached that a training session would be held for all personnel involved in the ORNL NPR Project (regardless of the functional division in which the personnel resided) that would include:

- a statement by the ORNL NPR Project director indicating his support for the management systems defined by the procedures in Appendix B and his expectation that all personnel involved with the ORNL NPR Project would comply with these procedures,
- a presentation by the ORNL NPR Project QAM noting the elements of a QA (i.e., management) program (see ANSI/ASQC Q90-1987 through Q94-1987),
- a presentation by the ORNL NPR Project QAM emphasizing the requirements of the procedures listed in Appendix B, and

- distribution by the ORNL NPR Project QAM of a required reading assignment of the procedures listed in Appendix B with review questions (each ORNL NPR participant was expected to complete the review questions and to return them as a record for the ORNL NPR files).

The Quality Improvement Committee agreed to meet weekly to provide leadership in brainstorming for solutions to problems. Additionally, the ORNL NPR QA staff spent many hours coaching line management and researchers on the management system defined by the procedures in Appendix B. During the Quality Improvement Committee's brainstorming sessions, root cause techniques such as barrier analysis and cause and effect diagrams were used to identify actions to prevent recurrence.

One cause of many of the noncompliances was the resistance of research scientists to conform to a formal procedural system (i.e., a change in culture). The ORNL NPR QAM was frustrated because he knew that a bureaucratic procedural system was not the best management structure for high-technology research. The assumptions of bureaucracy are mass production, low levels of technology, simple products and services, low competition, stable environment, and excess capacity of labor (Bowen and Boone 1987, pp. 5–16). ORNL's business, that is research, involves no mass production, new high levels of technology, complex products and services, some competition, and an unstable environment with constantly changing rules and objectives. ORNL does have division of labor with craftsmen, technicians, clerical, and professional job classifications. Because ORNL did not fit the bureaucracy model, it seemed mission degrading to implement a bureaucracy.

However, the client (i.e., DOE) expected a verbatim compliant procedure bureaucratic system. This impasse was resolved by:

- Convincing NP that a strict verbatim compliant procedural system hampered flexibility and innovation that was critical for research. A compromise was reached of having guideline documents (i.e., research protocols) that would establish the constraints and boundaries in which the innovative research could take place.
- Pointing out to the research scientist that the intent of the formal documentation required by the management system could be met if scientists kept their research notebooks as formal as they had kept them in their collegiate laboratory classes. The research scientists could relate to the idea that some may have become lax in the entry of data in laboratory notebooks. The problem boiled down to lack of understanding by research scientists regarding the "quality-eze" jargon presented initially by the new QA Program (i.e., management system).

The surveillance results for the fourth quarter of 1991 (Fig. 4*a*) showed 75% noncompliance with the established management system. Also shown in Fig. 4*a* is that 100% of the noncompliances were due to disregard of requirement or procedure (Table 1). The SPC chart for the fourth quarter of 1991 (Fig. 4*b*) shows a UCL of 28% and the 75% UNSAT, which was still above the UCL. This indicates that the management goal of having less than 5% UNSAT still had not been obtained (i.e., the management system is out of control). The Quality Improvement Committee continued to meet and to provide leadership and solutions to problems.

At the end of the first quarter of 1992, the data in Fig. 5*a* and the SPC chart in Fig. 5*b* showed that the degree of noncompliance had decreased to 58% but that the majority of causes of the noncompliances had shifted to inadequate procedures (57%). This showed that the actions taken had caused improvement in procedural compliance, but revisions to the ORNL NPR SPPs were necessary.

ORNL-DWG 95M-10020

SURVEILLANCE #	TOPIC	ITEMS CHECKED	# UNSAT	CAUSE 1	2	3	4	5	6	7
NPR-91-009	DOCUMENT CONTROL CENTER	4	3			3				
NPR-91-010	PIPE BREAK TEST	4	3			3				
	SUMS	8	6	0	0	6	0	0	0	0
PERCENT FAILURE	P1 = # UNSAT ITEMS CHECKED		75%	0%	0%	100%	0%	0%	0%	0%
	5% GOAL UCL		28%							

(a)

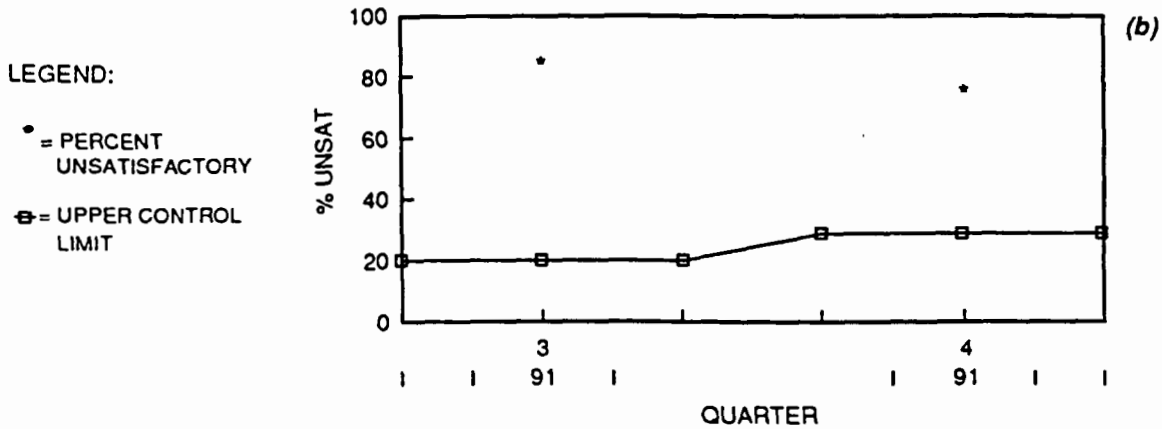

Fig. 4. Fourth quarter 1991 (*a*) surveillance data and (*b*) statistical process control chart.

The ORNL NPR Quality Improvement Committee began identifying the scope of changes necessary for the procedures listed in Appendix B and assigned responsible persons to revise the procedures. Additionally, the Quality Improvement Committee established a schedule to issue the revised procedures.

The procedures were quickly revised and issued, and training sessions were held for all involved ORNL NPR personnel to discuss the changes. The results of the procedure revisions were quickly seen. Improvement is shown in Fig. 6*a* as a decrease to 20% noncompliances for the second quarter of 1992. Additionally, Fig. 6*a* shows that the majority of noncompliances had shifted back to the failure of personnel to follow procedures (89%). This can be attributed to personnel unfamiliarity with the changes in the revised procedures. Figure 6b shows that the 20% noncompliance is still above the UCL of 12%; however, the percent UNSAT trend indicates that within one or two more quarters of improvement, the percent UNSAT statistic should be below the UCL. This would indicate that the management system was operating within the goals set by management.

The NPR QAM realized that change was being successfully managed within the ORNL NPR Project. The indicator for this was that 18 months earlier it had been necessary for the ORNL QAM to be the driving force for quality improvement, but now this responsibility had shifted to the project director and assistant project directors. At the Quality Improvement Committee meetings the ORNL NPR QAM no longer had to coach on the right things to do; instead, the

SURVEILLANCE #	TOPIC	ITEMS CHECKED	# UNSAT	CAUSE 1	2	3	4	5	6	7
NPR-92-001	CORRECTIVE ACTION SYSTEM	4	3		1	1			1	
NPR-92-002	MANAGEMENT ASSESSMENTS	3	1		1					
NPR-92-003	GRAPHITE TESTING	5	3		2	1				
	SUMS	12	7	0	4	2	0	0	1	0
PERCENT FAILURE	P1 = # UNSAT ITEMS CHECKED		58%	0%	57%	29%	0%	0%	14%	0%
	5% GOAL UCL		24%							

(a)

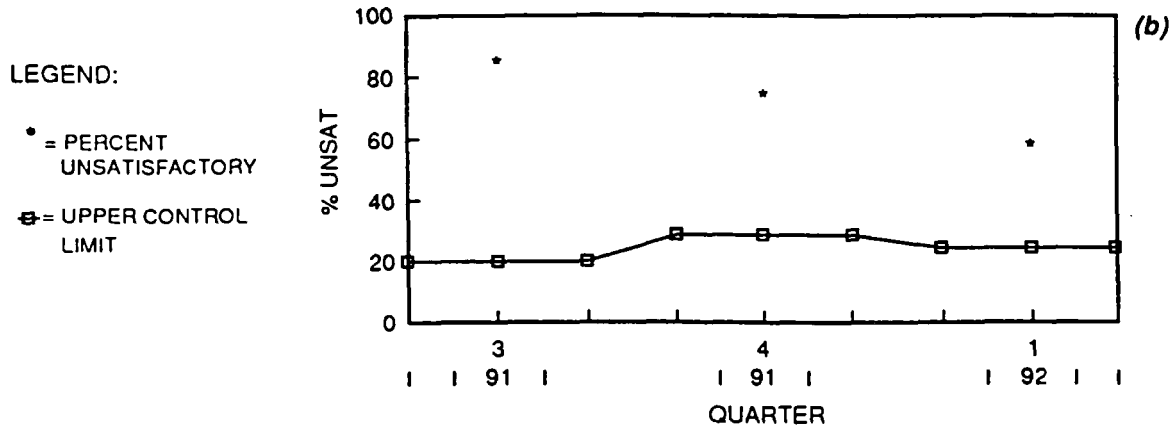

Fig. 5. First quarter 1992 (*a*) surveillance data and (*b*) statistical process control chart.

project director and assistant directors took charge and provided leadership in meeting customer expectations.

The attributes of Total Quality Management were working within the Quality Improvement Committee as follows:

- participatory culture (responsibility had shifted from QAM to team leadership),
- customer orientation (both internal and external customer expectations were being addressed),
- teamwork (organizational improvement was being accomplished as a team),
- problem resolution (problems were being pinpointed),
- continuous improvement (solutions were being implemented), and
- application of the SPC-based metric for management systems (the effectiveness of the management system was being determined, opportunities for continuous improvement were being identified, and degrees of compliance were being measured).

DOE canceled the NPR Project in the summer of 1992. If the project had continued and if the degree of noncompliance to the management system had dropped below the upper control limit (UCL = 12% for the second quarter of 1992) for three or four quarters, the ORNL NPR QAM would have recommended that the goal for compliance to the management system be changed from 5 to 2% or 3% (i.e., p_d). This would have driven the ORNL NPR Project on the path of continuous improvement.

SURVEILLANCE #	TOPIC	ITEMS CHECKED	# UNSAT	CAUSE 1	2	3	4	5	6	7
NPR-92-004	LABORATORY NOTEBOOKS	10	3		1	2			1	
NPR-92-005	CONTROLLED MANUALS	15	1		1					
NPR-92-006	TRAINING	13	3			3				
NPR-92-007	POST IRRADIATION EXAMINATION (PIE)	20	6			6				
NPR-92-008	NONCONFORMANCES	17	4			4				0
NPR-92-009	RECORDS MANAGEMENT	16	2			2				
	SUMS	91	19	0	2	17	0	0	1	0
PERCENT FAILURE	P1 = # UNSAT ITEMS CHECKED		21%	0%	11%	88%	0%	0%	5%	0%
	5% GOAL UCL		12%							

(a)

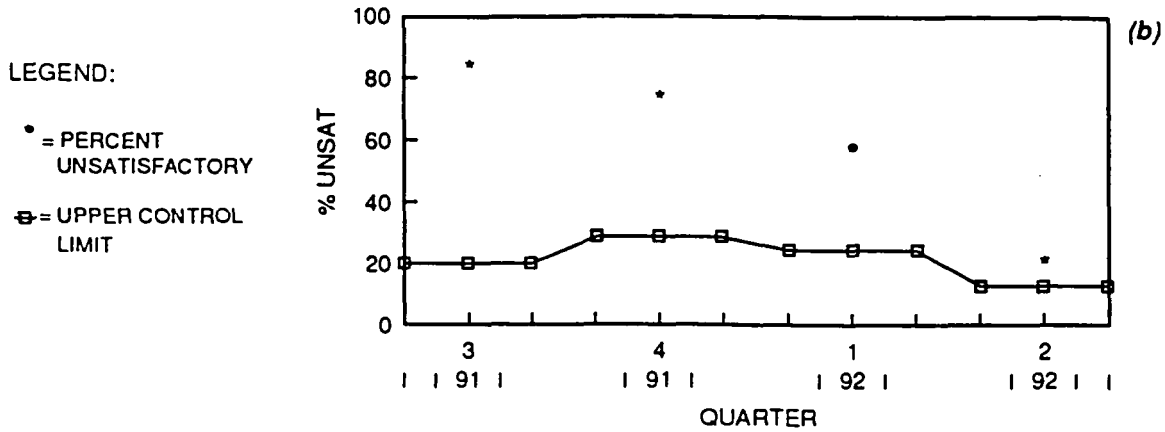

Fig. 6. Second quarter 1992 (*a*) surveillance data and (*b*) statistical process control chart.

4. CONCLUSIONS AND RECOMMENDATIONS

The plotting of the percent UNSAT statistics from audit results proved to be a valuable metric that communicated to managers the degree of implementation that the documented management system had obtained. Management could no longer assume that audit findings from its customer (i.e., DOE) were insignificant, isolated events. The percent UNSAT from audit results plotted on an SPC P chart provided an excellent means to monitor continuous improvement, and the Quality Improvement Committee proved to be effective in involving management in quality improvement as well as in identifying improvements that would be practical when implemented. The SPC metric for management systems is therefore recommended as a management indicator to drive continuous improvement.

REFERENCES

ANSI/ASME 1989. *Quality Assurance Program Requirements for Nuclear Facilities*, ANSI/ASME NQA-1, American National Standards Institute–American Society of Mechanical Engineers.

ANSI/ASQC Q90-1987. *Quality Management and Quality Assurance Standards—Guidelines for Selection and Use*, American National Standards Institute–American Society of Quality Control.

ANSI/ASQC Q91-1987. *Model for Quality Assurance in Design/Development, Production, Installation, and Servicing*, American National Standards Institute–American Society of Quality Control.

ANSI/ASQC Q92-1987. *Model for Quality Assurance in Production and Installation*, American National Standards Institute–American Society of Quality Control.

ANSI/ASQC Q93-1987. *Model for Quality Assurance in Final Inspection and Test*, American National Standards Institute–American Society of Quality Control.

ANSI/ASQC Q94-1987. *Quality Management and Quality System Elements—Guidelines*, American National Standards Institute–American Society of Quality Control.

Bowen, D. D., and Boone, L. E. 1987. *The Great Writings in Management and Organizational Behavior*, Random, New York.

DOE 1990. *Quality Assurance Requirements for the New Production Reactor*, DOE/NP-0001.

DOE Aug. 21, 1991. *Quality Assurance*, DOE Order 5700.6C.

Koontz, H., and Weihrick, H. 1988. *Management*, 9th ed., McGraw-Hill, New York.

Mills, C. A. 1989. *The Quality Audit—A Management Evaluation Tool*, ASQC Qual. Press, Milwaukee.

Montgomery, D. C. 1991. *Statistical Quality Control*, 2d ed., Wiley, New York.

Wortman, B. 1993. *Certified Quality Technician Primer*, 3d ed., Qual. Counc. of Ind., Milwaukee.

BIBLIOGRAPHY

Arter, D. R. 1989. *Quality Audits for Improved Performance*, ASQC Qual. Press, Milwaukee.

Asaka, T., and Ozeki, K., eds. 1990. *Handbook of Quality Tools,* Productivity Press, Norwalk, Conn.

Mowery, N., et al. 1994. *Customer Focused Quality*, SPC Press, Knoxville, Tenn.

Sayle, A. J. 1985. *Management Audits, The Assessment of Quality Management Systems,* ASQC Qual. Press, Milwaukee.

Talley, D. J. 1988. *Management Audits for Excellence*, ASQC Qual. Press, Milwaukee.

Walsh, L., et al., 1986. *Quality Management Handbook*, ASQC Qual. Press, Milwaukee.

Wickman, R. F., and Doyle, R. S. 1993. *Breakthrough Quality Improvement for Leaders Who Want Results*, ASQC Qual. Press, Milwaukee.

Appendix A

NEW PRODUCTION REACTOR ORGANIZATION AT OAK RIDGE NATIONAL LABORATORY

ORNL-DWG 95M-10023

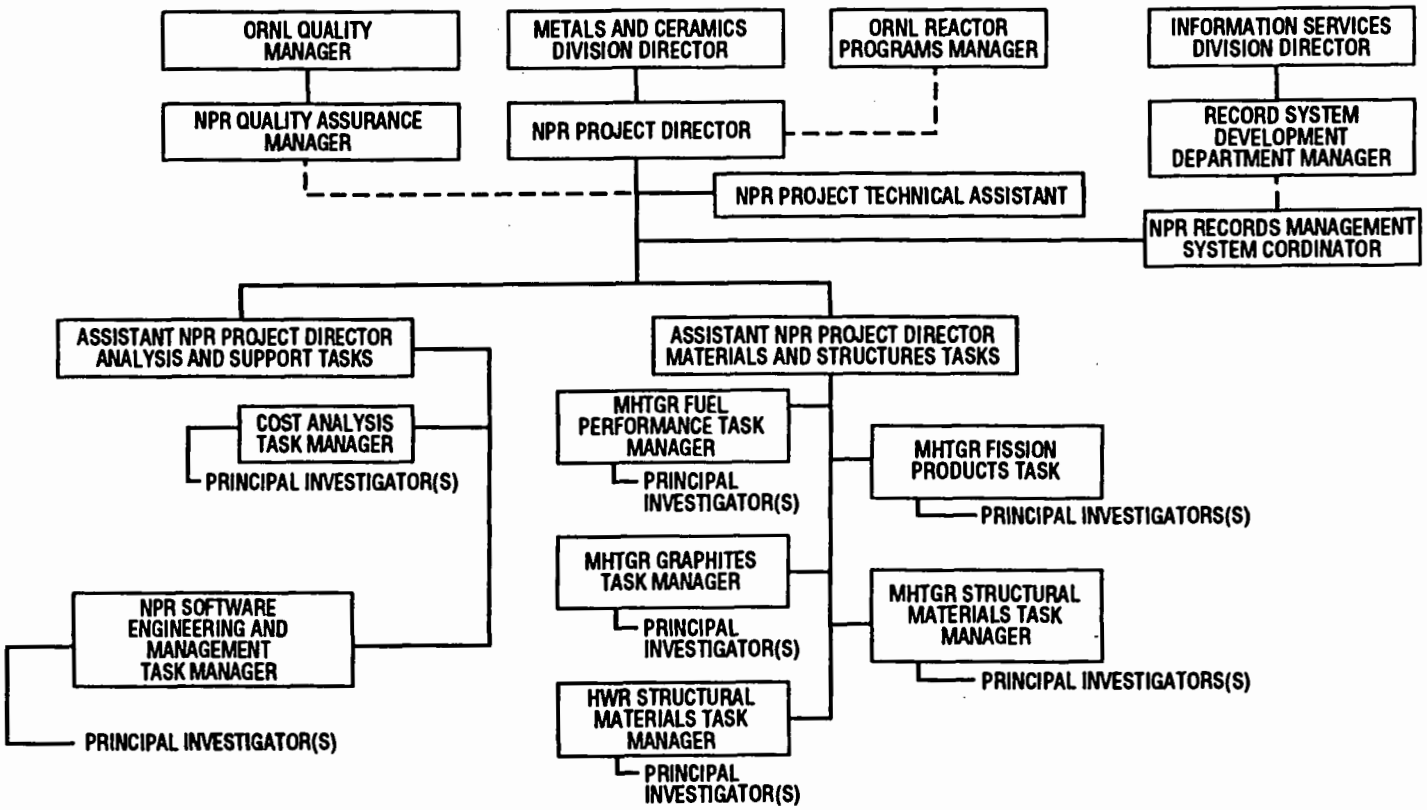

Fig. A.1. New Production Reactor organization at Oak Ridge National Laboratory.

Appendix B

NEW PRODUCTION REACTOR STANDARD PRACTICE PROCEDURES

NPR SPP#	TITLE	PURPOSE	SCOPE
1.1	Organization	This administrative procedure describes the functional organization of the Oak Ridge National Laboratory (ORNL) New Production Reactor (NPR) Project and defines the responsibilities of its project office, Quality Assurance, and revisions performing NPR work. The primary NPR mission at ORNL is to conduct developmental activities. ORNL has been assigned responsibilities for developing confirmatory data (specifically experimental data, analytical data, and assessment and evaluation data) for future use by the DOE-NP Program.	This procedure contains information concerning: (1) the organization of the ORNL NPR Project; (2) the responsibility, accountability, and authority of the project office; (3) the responsibility, accountability, and authority of the NPR QAS; (4) the responsibility, accountability, and authority of Division QASs; and (5) the responsibility, accountability, and authority or the ORNL Divisions performing the NPR tasks.
1.2	NPR Project Work Scope and Activities	This Standard Practice Procedure provides the information, description, and instructions to ensure control of NPR Project work/activities through organizational delegation of authority and responsibility to achieve overall mission success while complying with the stipulations of the DOE-NPR quality assurance requirements.	This Standard Practice Procedure is applicable to activities funded by or for the ORNL NPR Project office.
1.3	Stop Work/Restart Authority	To define and establish a mechanism for NPR Project management and Quality Department personnel to stop unsatisfactory work based on severity or repetition of significant conditions adverse to quality that jeopardize the ORNL NPR Project mission, imperil human health or safety, or insult the environment. Requirements identified herein are in addition to those established in Environmental, Safety, and Health Compliance and in ORNL quality assurance documents. *Note:* The Environmental Safety and Health Compliance (ESHC) Department personnel also have stop work authority under their charter.	This procedure applies to all work activities that affect the quality of products or services resulting from ORNL NPR Project activities.
2.1	Quality Program Policy	This administrative procedure defined the Quality Assurance Policy delineated by ORNL Quality Assurance Department and the NPR Project management.	This policy applies to all ORNL organizations performing NPR-funded or -directed work.

NPR SPP#	TITLE	PURPOSE	SCOPE
2.2	Work Planning	The purpose of this Standard Practice Procedure is to prescribe the minimum contents of development plans and the controls required for activities that implement the development plans.	This Standard Practice Procedure applies to all ORNL NPR Project activities and all personnel engaged in the development activities.
2.4	Control of Computer Software	To establish the procedure for controlling computer software used for confirmatory development activities for the ORNL NPR Project.	This procedure is applicable to computer software used in the ORNL NPR Project.
2.5	Management Assessments	To provide the policy and procedure for conducting management assessments of the ORNL NPR Project.	This procedure applies to all ORNL NPR Project work.
2.6	Readiness Review	This Standard Practice Procedure provides instructions for performing ORNL NPR Project readiness reviews. It provides the methodology for verifying and ensuring that all necessary activities and actions have been completed prior to scheduled or planned activities that could affect: — quality of operations, data, and other results; — environment, safety, or health of workers or the public; or — ORNL NPR Project mission success.	This Standard Practice Procedure is applicable to activities funded by, or under the cognizance of, the NPR Project office.
2.7	ORNL NPR Project Surveillance	To establish the procedure for performing surveillances within the ORNL NPR Project.	This procedure is applicable to all ORNL NPR Project participants.
2.8	NPR Project Commitment Tracking System	To establish the procedure for the ORNL Project NPR Commitment Tracking System.	This procedure is applicable for the tracking of ORNL NPR Project management commitments, action items, and corrective actions (i.e., QA, safety, and environmental).
2.9	Indoctrination and Training	To establish the policy, requirements, and responsibilities for ORNL NPR training for activities that may affect NPR Project quality.	This procedure applies to all personnel performing work for the ORNL NPR Project office.
3.1	Design Control	To establish the procedure for controlling the design of new and modified test apparatus and equipment used to support ORNL NPR Project work.	This procedure applies to all ORNL organizations performing ORNL NPR Project work.

NPR SPP#	TITLE	PURPOSE	SCOPE
4.1	Procurement Document Control	To establish the procedure for controlling documents for purchased items or services through the Energy Systems Procurement Division.	This procedure applies to all ORNL organizations performing ORNL NPR Project work.
5.1	Instructions, Procedures, and Drawings	It is the policy of the ORNL NPR Project that confirmatory development activities shall be prescribed by, and performed in accordance with, documented instructions, procedures, or drawings of a type appropriate to the circumstances.	This procedure is applicable to all confirmatory development activities in the ORNL NPR Project.
6.1	Preparation, Review, Approval, and Revisions of Procedures and Documents	To establish the procedure for preparation, review, approval, and revisions to procedures and documents used to control/specify NPR Project work.	It is the policy of the ORNL NPR Project office that all activities including administration, confirmatory analysis, and testing shall be performed in accordance with approved written procedures. This procedure outlines the approach to the development of ORNL NPR Project procedures and documents.
6.2	Internally Controlled Documents	To establish a methodology for the identification and control of internal documents used to perform work activities within the NPR Project to ensure they are complete, updated, and are distributed to the work location.	This procedure applies to those types of documents identified by the NPR Project as requiring controlled status for operation of the project. Documents and revisions to documents generated internally are subject to this procedure. Externally generated, controlled documents are addressed in NPR SPP 6.5 (to be written).
7.1	Control of Purchased Items and Services	To establish the procedure for procuring items and services through the Energy Systems Procurement Division.	This procedure applies to all ORNL organizations performing ORNL NPR Project work.
7.2	Receipt Inspection	To establish the procedure for performing receipt inspection of items used in the ORNL NPR Project.	This procedure applies to all ORNL organizations performing ORNL NPR Project work.
11.1	Test Package Control	To establish the program for controlling technical documents and procedures (test packages) used in the ORNL NPR Project to collect developmental and confirmatory data for contributing to design development. These technical documents and the results of testing will be compiled as "test packages" at the conclusion of test activities.	This procedure applies to all organizations performing ORNL NPR Project tests.

NPR SPP#	TITLE	PURPOSE	SCOPE
11.3	Maintenance of Technical Notebooks and other Test Records	To establish the procedure for maintenance of technical notebooks and other test records used for recording test data for the ORNL NPR Project.	This procedure applies to all activities performed for the ORNL NPR Project.
12.1	Control of Measuring and Test Equipment	To establish the procedure for controlling measuring and test equipment within the ORNL NPR Project.	This procedure is applicable to all ORNL NPR Project participants.
13.1	Handling, Storage, and Shipping	To establish the procedure for handling, storage, cleaning, packaging, shipping, and preservation of items for the ORNL NPR Project.	This procedure applies to all ORNL organizations performing ORNL NPR Project work.
15.1	Control of Nonconforming Items	To establish the procedure for controlling nonconforming items within the ORNL NPR Project.	This procedure is applicable to all ORNL NPR Project participants.
16.1	Occurrence Report System	To establish the procedure for reporting occurrences that affect quality of planned or actual NPR work.	This procedure applies to all ORNL organizations performing NPR work.
16.2	Corrective Action	To establish the procedure or identifying, tracking, and verification of corrective actions identified for the ORNL NPR Project.	This procedure applies to all ORNL organizations performing ORNL NPR Project work.
16.3	Trending of Quality Information	To establish the procedure for trending quality information from audit reports, surveillance reports, nonconformance reports, corrective action, status reports, and other related documents for the ORNL NPR Project.	This procedure applies to all the activities performed for the ORNL NPR Project.
17.1	NPR Records Management System	To establish the procedure for storage, indexing, and retrieval of identified NPR Project records.	This procedure is applicable for all documents or records developed for, or used by, the ORNL NPR Project. Additionally, this procedure addresses receipt, indexing, filing, and storage of records submitted to the ORNL NPR Records Management System Document Control Center.
18.1	Audits	To establish procedures for audits within the ORNL NPR Project.	This procedure is applicable to all confirmatory development activities in the ORNL NPR Project.

Appendix C

TYPICAL CHECKLIST

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
1. Does the plan/program reference DOE Order 5820.2A, DOE Order 5700.6C, ASME NQA-1, and other appropriate standards such as ASQC E-4? (NVO-325, Appendix C, Policy)			
2. Does the plan/program indicate the elements of DOE Order 5700.6C and ASME NQA-1 that are applicable and give justification for those elements that are not considered applicable? (NVO-325, Appendix C, Policy)			
3. Does the plan/program provide provisions for quality control hold points to be monitored by waste management staff to ensure that program quality has been satisfactorily accomplished? (NVO-325, Appendix C, Introduction)			
4. Does the plan.program identify other standards for inspection, sampling, and testing? (NVO-325, Appendix C, Introduction)			
5. Does the plan/program contain an organizational chart that shows the organizations that generate, characterize, package, ship, inspect, conduct surveillances and audits, perform support functions such as procurement, calibration, document control, laboratory services including data validation, RCRA oversight, training, and any other applicable function? (NVO-325, Appendix C, paragraph 1)			
6. Does the plan/program organization chart show the independence of the Waste Certification Officer (WCO) and Package Certifier and identify by dotted line direct access to the facility manager? (NVO-325, Appendix C, paragraph 1)			
7. Does the plan/program provide descriptive paragraphs for each organizational unit shown on the organizational chart? (NVO-325, Appendix C, paragraph 1)			

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
8. Does the plan/program describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work? (DOE Order 5700.6C, paragraph 9.b.(1).(a) and ASME NQA-1, Basic Requirement #1)			
9. Does the plan/program describe the management system, including planning, scheduling, and cost control consideration? (DOE Order 5700.6C, paragraph 9.b.(1).(a))			
10. Does the plan/program describe the process for control of nonconforming items? (ASME NQA-1, Supplement 1S-1, paragraph 2.3)			
11. Where more than one organization is involved in the execution of activities, does the plan/program describe the responsibilities and authority of each organization? (ASME NQA-1, Supplement 1S-1, paragraph 3.1)			
12. Does the plan/program defined internal and external interfaces? (ASME NQA-1, Supplement 1S-1, paragraph 3.2)			
13. Does the plan/program give persons or organizations responsible for verifying that activities affecting quality have been correctly performed sufficient authority, access to work, and organizational freedom? (ASME NQA-1, Basic Requirement #1)			
14. Does the plan/program reference the Energy Systems Policies, Standards, and Procedures where appropriate and deal specifically with activities unique to the waste management program? (NVO-325, Appendix C, paragraph 2)			

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
15. Does the plan/program describe how personnel will be trained and qualified to ensure they are capable of performing their assigned work and how personnel will be continuously trained to ensure that job proficiency is maintained? (NVO-325, Appendix C, paragraph 19; DOE Order 5700.6C, paragraph 9.b.(1).(b); and ASME NQA-1, Basic Requirement #2 & Supplements 2S-4)			
16. Does the plan/program describe how inspection and test personnel will be qualified? (ASME NQA-1, Supplement 2S-1)			
17. Does the plan/program describe how quality assurance audit personnel will be qualified? (ASME NQA-1, Supplement 2S-3)			
18. Does the plan/program describe how quality problems will be detected and prevented to ensure quality improvement? (DOE Order 5700.6C, paragraph 9.b.(1).(c))			
19. Does the plan/program describe design controls for facilities designed and constructed to satisfy waste certification criteria? (NVO-325 Appendix C, paragraph 3; ASME NQA-1, Basic Requirement #3 & Supplement 3S-1)			
20. Does the plan/program describe the procurement process for items and services critical to the waste certification program? (NVO-325, Appendix C, paragraph 4; DOE Order 5700.6C, paragraph 9.b.(2).(c); and ASME NQA-1, Basic Requirement #4 & Supplement 4S-1)			

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE*
21. Does the plan/program describe the instructions, procedures, or other appropriate means that control work processes critical to the waste certification program? (NVO-325, Appendix C, paragraph 5; DOE Order 5700.6C, paragraph 9.b.(2).(a); and ASME NQA-1, Basic Requirement #5)			
22. Does the plan/program describe the system which controls authorization, preparation, review and approval, distribution, recall, and update of documents important to waste certification? (NVO-325, Appendix C, paragraph 6; DOE Order 5700.6C, paragraph 9.b.(1).(d); and ASME NQA-1, Basic Requirement #6 & Supplement 6S-1)			
23. Does the plan/program describe the process for control of purchased items and services? (NVO-325, Appendix C, paragraph 7; DOE Order 5700.6C, paragraph 9.b.(2).(c); and ASME NQA-1, Basic Requirement #7 & Supplement 7S-1)			
24. Does the plan/program describe the process for control of material, parts, and components important to the waste certification processes? (NVO-325, Appendix C, paragraph 8; DOE Order 5700.6C, paragraph 9.b.(2).(a); and ASME NQA-1, Basic Requirement #8 & Supplement 8S-1)			
25. Does the plan/program provide controls or verification steps for processes or series of activities important to waste certification? (NVO-325, Appendix C, paragraph 9; DOE Order 5700.6C, paragraph 9.b.(2).(a); and ASME NQA-1, Basic Requirement #9 & Supplement 9S-1)			
26. Does the plan/program describe the inspection process? (NVO-325, Appendix C, paragraph 10; DOE Order 5700.6C, paragraph 9.b.(2).(d); and ASME NQA-1, Basic Requirement #10 & Supplement 10S-1)			

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
27. Does the plan/program describe how tests that verify conformance to specified requirements will be planned and executed? (NVO-325, Appendix C, paragraph 11; DOE Order 5700.6C, paragraph 9.b.(2).(d); and ASME NQA-1, Basic Requirement #11 & Supplements 11S-1 & 11S-2)			
28. Does the plan/program describe the process for control of measuring and test equipment? (NVO-325, Appendix C, paragraph 12; DOE Order 5700.6C, paragraph 9.b.(2).(d); and ASME NQA-1, Basic Requirement #12 & Supplement 12S-1)			
29. Does the plan/program describe the process for handling, storage, and shipping of wastes? (NVO-325, Appendix C, paragraph 13; DOE Order 5700.6C, paragraph 9.b.(2).(a); and ASME NQA-1, Basic Requirement #13 & Supplement 13S-1)			
30. Does the plan/program describe the process for controlling inspection, test, and operational status? (NVO-325, Appendix C, paragraph 14; and ASME NQA-1, Basic Requirement #14)			
31. Does the plan/program describe the process for controlling nonconforming items? (NVO-325, Appendix C, paragraph 15; DOE Order 5700.6C, paragraph 9.b.(1).(c); and ASME NQA-1, Basic Requirement #15 & Supplement 15S-1)			
32. Does the plan/program describe the corrective action process? (NVO-325, Appendix C, paragraph 16; DOE Order 5700.6C, paragraph 9.b.(1).(c); and ASME NQA-1, Basic Requirement #16)			

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
33. Does the plan/program describe the process for maintaining records that demonstrate compliance with waste certification criteria? (NVO-325, Appendix C, paragraph 17; DOE Order 5700.6C, paragraph 9.b.(1).(d); and ASME NQA-1, Basic Requirement #17 & Supplement 17S-1)			
34. Does the plan/program describe the audit and surveillance process that verifies compliance with all aspects of the waste management program? (NVO-325, Appendix C, paragraph 18; DOE Order 5700.6C, paragraph 9.b.(3).(b); and ASME NQA-1, Basic Requirement #18 & Supplement 18S-1)			
35. Does the plan/program describe the management assessment process? (DOE Order 5700.6C, paragraph 9.b.(3).(a))			

[a]If UNSAT, cause code is from *Energy Systems Action Management System (ESAMS) Cause Code Entries*, ORNL SPP X-QA-3, Oct. 30, 1992, Appendix 4, Table 1.3.

Appendix D

TYPICAL COMPLETED CHECKLIST

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
1. Does the plan/program reference DOE Order 5820.2A, DOE Order 5700.6C, ASME NQA-1, and other appropriate standards such as ASQC E-4? (NVO-325, Appendix C, Policy)	Plan/program does not reference DOE Order 5820.2A, DOE Order 5700.6C, ASME NQA-1, and other appropriate standards.	UNSAT	2A
2. Does the plan/program indicate the elements of DOE Order 5700.6C and ASME NQA-1 that are applicable and give justification for those elements that are not considered applicable? (NVO-325, Appendix C, Policy)	*b*	UNSAT	2A
3. Does the plan/program provide provisions for quality control hold points to be monitored by waste management staff to ensure that program quality has been satisfactorily accomplished? (NVO-325, Appendix C, Introduction)	Not addressed.	UNSAT	2A
4. Does the plan/program identify other standards for inspection, sampling, and testing? (NVO-325, Appendix C, Introduction)	The plan/program identifies other standards for sampling and testing in the QA Plan, paragraph 4.1, "Methodologies."	SAT	
5. Does the plan/program contain an organizational chart that shows the organizations that generate, characterize, package, ship, inspect, conduct surveillances and audits, perform support functions such as procurement, calibration, document control, laboratory services including data validation, RCRA oversight, training, and any other applicable function? (NVO-325, Appendix C, paragraph 1)		SAT	
6. Does the plan/program organization chart show the independence of the Waste Certification Officer (WCO) and Package Certifier and identify by dotted line direct access to the facility manager? (NVO-325, Appendix C, paragraph 1)	Not applicable for an analytic laboratory.	N/A	
7. Does the plan/program provide descriptive paragraphs for each organizational unit show on the organizational chart? (NVO-325, Appendix C, paragraph 1)	The plan/program provides job descriptions for the senior managers but not for each organization unit shown.	UNSAT	2A

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE*
8. Does the plan/program describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work? (DOE Order 5700.6C, paragraph 9.b.(1).(a) and ASME NQA-1, Basic Requirement #1)	Not addressed	UNSAT	2A
9. Does the plan/program describe the management system, including planning, scheduling, and cost control consideration? (DOE Order 5700.6C, paragraph 9.b.(1).(a))	Not addressed.	UNSAT	2A
10. Does the plan/program describe the process for control of nonconforming items? (ASME NQA-1, Supplement 1S-1, paragraph 2.3)	Not addressed.	UNSAT	2A
11. Where more than one organization is involved in the execution of activities, does the plan/program describe the responsibilities and authority of each organization? (ASME NQA-1, Supplement 1S-1, paragraph 3.1)	Not addressed.	UNSAT	2A
12. Does the plan/program defined internal and external interfaces? (ASME NQA-1, Supplement 1S-1, paragraph 3.2)	Not addressed.	UNSAT	2A
13. Does the plan/program give persons or organizations responsible for verifying that activities affecting quality have been correctly performed sufficient authority, access to work, and organizational freedom? (ASME NQA-1, Basic Requirement #1)	Not addressed.	UNSAT	2A
14. Does the plan/program reference the Energy Systems Policies, Standards, and Procedures where appropriate and deal specifically with activities unique to the waste management program? (NVO-325, Appendix C, paragraph 2)	Not applicable for a support contractor as long as the flowdown of requirements is accomplished as discussed in #2 above.	N/A	

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
15. Does the plan/program describe how personnel will be trained and qualified to ensure they are capable of performing their assigned work and how personnel will be continuously trained to ensure that job proficiency is maintained? (NVO-325, Appendix C, paragraph 19; DOE Order 5700.6C, paragraph 9.b.(1).(b); and ASME NQA-1, Basic Requirement #2 & Supplements 2S-4)	Not addressed.	UNSAT	2A
16. Does the plan/program describe how inspection and test personnel will be qualified? (ASME NQA-1, Supplement 2S-1)	Not addressed.	UNSAT	2A
17. Does the plan/program describe how quality assurance audit personnel will be qualified? (ASME NQA-1, Supplement 2S-3)	Addressed in procedure GL-1520.	SAT	
18. Does the plan/program describe how quality problems will be detected and prevented to ensure quality improvement? (DOE Order 5700.6C, paragraph 9.b.(1).(c))	Addressed in procedures GL-1601, 1602, and 1605.[c]	SAT	
19. Does the plan/program describe design controls for facilities designed and constructed to satisfy waste certification criteria? (NVO-325 Appendix C, paragraph 3; ASME NQA-1, Basic Requirement #3 & Supplement 3S-1)	Not applicable for an analytic laboratory.	N/A	
20. Does the plan/program describe the procurement process for items and services critical to the waste certification program? (NVO-325, Appendix C, paragraph 4; DOE Order 5700.6C, paragraph 9.b.(2).(c); and ASME NQA-1, Basic Requirement #4 & Supplement 4S-1)	Not addressed.	UNSAT	2A

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
21. Does the plan/program describe the instructions, procedures, or other appropriate means that control work processes critical to the waste certification program? (NVO-325, Appendix C, paragraph 5; DOE Order 5700.6C, paragraph 9.b.(2).(a); and ASME NQA-1, Basic Requirement #5)	*d*	UNSAT	2A
22. Does the plan/program describe the system which controls authorization, preparation, review and approval, distribution, recall, and update of documents important to waste certification? (NVO-325, Appendix C, paragraph 6; DOE Order 5700.6C, paragraph 9.b.(1).(d); and ASME NQA-1, Basic Requirement #6 & Supplement 6S-1)	Addressed in procedure GL-1500-A.	SAT	
23. Does the plan/program describe the process for control of purchased items and services? (NVO-325, Appendix C, paragraph 7; DOE Order 5700.6C, paragraph 9.b.(2).(c); and ASME NQA-1, Basic Requirement #7 & Supplement 7S-1)	Not addressed.	UNSAT	2A
24. Does the plan/program describe the process for control of material, parts, and components important to the waste certification processes? (NVO-325, Appendix C, paragraph 8; DOE Order 5700.6C, paragraph 9.b.(2).(a); and ASME NQA-1, Basic Requirement #8 & Supplement 8S-1)	*e*	SAT	
25. Does the plan/program provide controls or verification steps for processes or series of activities important to waste certification? (NVO-325, Appendix C, paragraph 9; DOE Order 5700.6C, paragraph 9.b.(2).(a); and ASME NQA-1, Basic Requirement #9 & Supplement 9S-1)	Not addressed.	UNSAT	2A
26. Does the plan/program describe the inspection process? (NVO-325, Appendix C, paragraph 10; DOE Order 5700.6C, paragraph 9.b.(2).(d); and ASME NQA-1, Basic Requirement #10 & Supplement 10S-1	Not applicable for an analytic laboratory.	N/A	

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
27. Does the plan/program describe how tests that verify conformance to specified requirements will be planned and executed? (NVO-325, Appendix C, paragraph 11; DOE Order 5700.6C, paragraph 9.b.(2).(d); and ASME NQA-1, Basic Requirement #11 & Supplements 11S-1 & 11S-2)	Not addressed.	UNSAT	2A
28. Does the plan/program describe the process for control of measuring and test equipment? (NVO-325, Appendix C, paragraph 12; DOE Order 5700.6C, paragraph 9.b.(2).(d); and ASME NQA-1, Basic Requirement #12 & Supplement 12S-1)	*f*	UNSAT	2A
29. Does the plan/program describe the process for handling, storage, and shipping of wastes? (NVO-325, Appendix C, paragraph 13; DOE Order 5700.6C, paragraph 9.b.(2).(a); and ASME NQA-1, Basic Requirement #13 & Supplement 13S-1)	Address in the QA Plan, Sect. 7.0 on Sample Custody.	SAT	
30. Does the plan/program describe the process for controlling inspection, test, and operational status? (NVO-325, Appendix C, paragraph 14; and ASME NQA-1, Basic Requirement #14)	Not applicable for an analytical laboratory.	N/A	
31. Does the plan/program describe the process for controlling nonconforming items? (NVO-325, Appendix C, paragraph 15; DOE Order 5700.6C, paragraph 9.b.(1).(c); and ASME NQA-1, Basic Requirement #15 & Supplement 15S-1)	Not addressed.	UNSAT	2A
32. Does the plan/program describe the corrective action process? (NVO-325, Appendix C, paragraph 16; DOE Order 5700.6C, paragraph 9.b.(1).(c); and ASME NQA-1, Basic Requirement #16)	Addressed in the QA Plan, Sect. 13.0.	SAT	

REQUIREMENTS	FINDING(S)/OBSERVATIONS	SAT/ UNSAT	CAUSE CODE[a]
33. Does the plan/program describe the process for maintaining records that demonstrate compliance with waste certification criteria? (NVO-325, Appendix C, paragraph 17; DOE Order 5700.6C, paragraph 9.b.(1).(d); and ASME NQA-1, Basic Requirement #17 & Supplement 17S-1)	Addressed in procedure GL-1500-A.	SAT	
34. Does the plan/program describe the audit and surveillance process that verifies compliance with all aspects of the waste management program? (NVO-325, Appendix C, paragraph 18; DOE Order 5700.6C, paragraph 9.b.(3).(b); and ASME NQA-1, Basic Requirement #18 & Supplement 18S-1)	Addressed in procedure GL-1600.	SAT	
35. Does the plan/program describe the management assessment process? (DOE Order 5700.6C, paragraph 9.b.(3).(a))	Not addressed.	UNSAT	2A

[a]If UNSAT, cause code is from *Energy Systems Action Management System (ESAMS) Cause Code Entries*, ORNL SPP X-QA-3, Oct. 30, 1992, Appendix 4, Table 1.3.

[b]The Quality Assurance Plan/Program does not clearly identify those elements of DOE Order 5700.6C and NQA-1 that will be implemented, nor does it give justification for those elements of DOE Order 5700.6C and NQA-1 that will not be implemented. The Quality Assurance Plan/Program does not clearly describe the requirements flowdown from NVO-325, DOE Order 5700.6C, and NQA-1 through Energy Systems Procedures and Energy Systems Waste Management Organization procedures to the subcontractor QA Plan and procedures. This is usually done with a requirements flowdown matrix that is attached to the Quality Assurance Plan.

[c]This item is only marginally satisfactory. The plan/program needs improvement in the area of QA information analysis and trending to be in full compliance with DOE Order 5700.6C, paragraph 9.b.(10.(c).

[d]Volume II of the *QA Manual* provides procedures. The QA plan needs to provide a policy that activities shall be performed in accordance with instructions, procedures, or other appropriate means and explain how this policy will be implemented.

[e]Sample Custody is covered in the QA Plan in Sect. 7.0. Reagent shelf life is covered in the QA Plan, Table 8-2.

[f]Calibration of instruments is covered in the QA Plan, Sect. 9.0. The following requirements of ASME NQA-1, Supplement 12S-1, paragraphs 3.2 and 5, are not addressed:

1. When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested.
2. Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated.
3. If any measuring or test equipment is found consistently to be out of calibration, it shall be repaired or replaced.
4. A calibration shall be performed when the accuracy of the equipment is suspect.
5. Records shall be maintained and equipment shall be suitably marked to indicate calibration status.

Appendix E

TYPICAL NEW PRODUCTION REACTOR SURVEILLANCE QUARTERLY SCHEDULE

Quarter beginning: July 1, 1992

Prepared by: T. B. Powell

Concur: T. B. Powell
Project QAS

Approved: D. L. Moses
Project Director

Surveillance Identification No.	Activity Description	Surveillant	Anticipated Surv. Date (Week of...)
ORNL-NPR-SURV-I-92-0018	Readiness Review of Graphite Multiaxial Testing	J. Thompson T. B. Powell	July 20, 1992
ORNL-NPR-SURV-I-92-0019	Maintenance of NPR Controlled Manuals	C. F. Walden T. B. Powell	July 27, 1992
ORNL-NPR-SURV-I-92-0020	Maintenance of Technical Notebooks and Test Records	D. L. Moses W. I. Dothard	August 10, 1992
ORNL-NPR-SURV-I-92-0021	NPR Procedure Review, Approval, Revision, and Distribution Process	M. J. Kania T. B. Powell	August 17, 1992
ORNL-NPR-SURV-I-92-0017	Work Planning	P. L. Rittenhouse W. I. Dothard	August 24, 1992
ORNL-NPR-SURV-I-92-0022	Conduct of NRP-1 and NPR-2 Post Irradiation Examination (PIE)	F. J. Homan W. I. Dothard	September 7, 1992
ORNL-NPR-SURV-I-92-0023	Conduct of Graphite Mechanical and Thermal Properties Tests	W. A. Gabbard T. B. Powell	September 14, 1992

Internal Distribution

1. W. D. Altman
2. J. C. Glowienka
3. R. E. Fenstermaker
4. P. B. Hoke
5. D. C. Jones
6. D. L. Moses

7–16. T. B. Powell
17. J. W. Turner
18. Central Research Library, ORNL
19–20. ORNL Laboratory Records
21. ORNL Laboratory Records RC
22. ORNL Patent Office

External Distribution

23–27. Jerry Westbrook, University of Alabama in Huntsville, Engineering Management Office, Bldg. EB, Loop and Lakeside Drive, Huntsville, Ala. 35899.

28–29. Office of Scientific and Technical Information.