UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CONTAINER SUPPLIER INSPECTION PROGRAM

Inspection Report

ORGANIZATION: Pacific Nuclear Systems, Inc.
ADDRESS: 1010 South 336th Street
Federal Way, WA 98003

CONTACT: Dr. C. J. Temus TELEPHONE: 206-874-2235
TITLE: Technical Director

ACTIVITY: Design, fabricate and supply radioactive material packages

QUALITY ASSURANCE PROGRAM APPROVAL NO.: 0192

Report Number:	Inspection Dates:	Inspection On-Site
710192/89-01	4/25-27/89	Person-Hrs: 96

INSPECTION BASES AND SCOPE:

A. BASES: Title 10 CFR Parts 21 and 71, and Certificate of Compliance Nos. 5806, 6244, 6601, 9070, 9079, 9080, 9081, 9108, 9111, 9151 9159, 9168, 9216.

B. SCOPE: To determine whether the organization has established, documented and executed procedures which fulfill the commitments made in the organization's NRC-approved quality assurance program.

To determine whether fabricated packages were manufactured in accordance with the design approved by the Commission.

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FINDINGS: Noncoformances with the requirements of 10 CFR Sections 71.37(b); 71.103; 71.115(b) 71.135 were identified.

INSPECTION TEAM LEADER: John P Jankovich — DATE: 11/3/89
John P. Jankovich, NMSS

OTHER NRC INSPECTORS: L Len Gordon — DATE: 11/3/89
L. Len Gordon, NMSS

John R. Cook — DATE: 11/3/89
John R. Cook, NMSS

NRC CONTRACTOR: H. M. Stromberg
INEL/EG&G Idaho, Inc.

REPORT APPROVED BY: Charles E MacDonald — DATE: 11/3/89
Charles E. MacDonald, Chief
Transportation Branch, NMSS

1. SUMMARY

An announced team inspection of Pacific Nuclear Systems, Inc. (NUPAC) was conducted on April 25-27, 1989. The U.S. Nuclear Regulatory Commission (NRC) conducted the inspection using the Temporary Instruction, "Transportation Package Suppliers Inspection", the Draft Technical Report, "Container Supplier Inspection Guide", and the attached Container Supplier Inspection Tree (Fig. 1). Inspection findings are based on data collected through observation of selected activities, review of implementation procedures and controls, review of selected documents and records, and interviews with personnel. The inspection included an assessment of the Quality Assurance (QA) activities of two principal vendors at their facilities. The inspection team concluded that the implementation of the QA program was satisfactory. However, it identified specific items of nonconformance on some aspects of QA management (10 CFR Section 71.103), the fabrication process (10 CFR Subsection 71.37(b)), materials control (10 CFR Subsection 71.115(b)) and design modification (10 CFR Section 71.135). The team discussed tentative findings with the organization's representatives, at the exit meeting.

2. CONTAINER SUPPLIER INSPECTION

The inspection was an announced team inspection of container design, fabrication, maintenance and facility management activities. The objectives of the inspection were to determine how well NUPAC's QA program complied with commitments made to NRC, to review the implementation of the QA program, and to verify whether the products were fabricated and maintained in compliance with NRC requirements. The team evaluated NUPAC's QA activities, during the inspection, in the framework of seven functional elements: (1) QA management; (2) Fabrication Process; (3) Materials; (4) Testing/Inspection; (5) Design Modification/Verification; (6) Maintenance Control; and (7) Handling and Storage Control. The inspection team visited the facilities of two principal vendors, Lee Fabricators and Ideal Machine and Manufacturing Cos., to evaluate the QA activities related to the certificates of compliance for the NUPAC containers. The vendor inspections were also conducted in the framework of the seven aforementioned functional elements.

2.1. Persons Contacted

The NRC inspection team interviewed the following persons.

Pacific Nuclear Systems, Inc.

*L. E. Kapinos, Vice President/General Manager
*C. J. Temus, Technical Director
*R. H. Smith, Director, Corporate Quality Assurance
*F. L. Bamford, Quality Assurance Manager
*D. E. Rodgers, Senior QA Inspector
*N. K. Hanna, Inspection Supervisor
*J. D. Kent, Engineer III
*D. L. Swannack, Section Manager
*W. L. Henkel, Director of Engineering
*S. A. Porter, Analysis Manager
N. Swannack, Document Control Manager
J. Frith, Engineer

Pacific Nuclear Systems, Inc. Subcontractors

Lee Fabricators P.O. Box 4307
Bremerton, WA 98312

D. D. Lee, Owner
R. Segerman, Certified Welding Inspector

Ideal Machine & Manufacturing 3611 South Warner Avenue
Tacoma, WA 98409

J. Anderson, QA/Quality Control (QC) Manager

2.2 QA Management

The QA management element was reviewed to determine the effectiveness of the QA program and the proficiency and independence of the assigned QA personnel responsible for fulfilling the QA commitment. The inspectors interviewed the Vice/President General Manager Quality Assurance Manager; Corporate Quality Assurance Director; Technical Director; Director of Engineering; a Section Manager; the Analysis Manager; and staff personnel performing safety-related activities. In addition, the team inspected contractor facilities and interviewed contractor personnel. The inspectors also examined QA documents, administrative procedures, organization charts, completed container manufacturing documents, modification controls, contractor inspection reports, and contractor QA programs.

The inspection of this element included a review in two primary areas: Program and Personnel. It was found that the facility management had implemented an effective and detailed QA program. The program addressed

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*Attended exit meeting.

personnel and control for most aspects of the design, certification, manufacturing, testing/inspection, and handling and storage processes. The emphasis NUPAC places on ensuring a quality product is a major strength of its operation. It was evident, in most areas of the process, that management had been a driving force. Its involvement was clear and documented.

A nonconformance was identified with regard to 10 CFR Section 71.103, which requires that the authority and duties of persons performing activities affecting safety-related functions be clearly established and delineated in writing. In nonconformance with this Section, the Technical Director's job description did not completely describe his responsibilities. It did not list his responsibility to review any deficiencies or nonconformances and manufacturing changes to determine if there are any implications for the Safety Analyses Report (SAR) evaluation analysis. The inspection team was concerned that if Technical Director was replaced, this critical portion of their process would not be performed adequately.

2.3 Fabrication Process

The team inspected this element to verify that all phases of the fabrication process are properly controlled. The fabrication processes are to be controlled, verifiable, and traceable, from the onset of design through completion of the assembly process. The team reviewed documents to verify the completeness of processes, hold points, acceptance criteria, and the controls provided for the fabrication process. The team performed contractor facility walk-through inspections to determine the adequacy of contractor controls and programs.

The inspection of this element considered three major areas: Program, Process, and QA. The inspection determined that the fabrication process program was exemplary. Hold points were identified during the fabrication process. When they were reached, fabrication stopped until the inspection or testing was witnessed by NUPAC inspectors. The hold points were established at strategic points in the process, helping to ensure a quality product.

The team reviewed implementing procedures concerning defect and noncompliance reporting requirements which are applicable to purchases of goods/services. The procedures were adequate and met the requirements of 10 CFR Part 21.

A nonconformance with regard to 10 CFR Subsection 71.37(b) which requires that established codes and standards proposed for use in package design, fabrication, assembly, testing, maintenance and use be identified. NUPAC's contractor was not aware of any restrictions on the cleaning of stainless steel. NUPAC, as required by 10 CFR 71.37(b), had not identified the requirement to clean stainless steel with a fluid that is low in chloride concentration.

2.4 Materials

The materials inspection element was reviewed to determine the effectiveness of the controls used to ensure compliance with requirements placed on materials. Materials should be controlled, verifiable, and traceable from the time of purchase through the life of the container. The inspection of this element considered three major areas: Program, Process, and QA. Documents were reviewed to ensure completeness of material identification and certification, to verify that the specified material was used, and to evaluate material controls and QA program controls. The contractor facility controls were inspected to verify that they also met material control requirements.

It was determined that material control was adequate and met the regulatory requirements and QA application commitments.

A nonconformance was identified with regard to 10 CFR Subsection 71.115(b) which requires that documentation showing conformation to the procurement specifications be available for the life of the packages. Suppliers provide to NUPAC a certificate of conformance which states that materials conform to the procurement specifications. The certificate is based on the information provided to them by their suppliers. Typically, NUPAC

is not provided with the name of the original supplier. When asked if the original supplier could be identified, NUPAC's response was that it was possible but may be difficult. Because this information may not be available, material may not be traceable to its original supplier and documentation, as required by 10 CFR Subsection 71.115(b), may not be available.

2.5 Testing/Inspection

The various areas involving tests and inspections were reviewed to determine the effectiveness of the controls used to ensure compliance with requirements placed on the testing and inspection program. Tests and inspections should be controlled, verifiable, and traceable, from the design-basis events through the entire testing and inspection program, up to and including the review of closed-out procedures and inspection reports. Documents were reviewed for: completeness of testing and inspection requirements; verification that the testing and inspection controls and QA program controls were met. The contractor facility controls were inspected to verify that they also met measurement, testing, inspection, and calibration control requirements.

The inspection of this element considered three major areas: Program, Implementation, and QA. It was determined that testing and inspection controls were adequate and met the regulatory requirements and QA application commitments. There was one area of major strength identified during the inspection of this element. The inspectors found the testing and inspection personnel training and qualification to be exemplary. It was sufficiently detailed and exceeded the regulatory requirements.

2.6 Design Modification Verification Process

A review of the design modification process was made to verify that adequate controls had been developed and implemented ensuring compliance with the SAR and QA requirements. The design modification process should be controlled and traceable from the onset of design through completion of testing and delivery to owners or users. Documents were reviewed for completeness, adequacy and verification that design modification requirements

were met. The review also evaluated design-modification controls and QA program controls.

The inspection of this element considered three major areas: Program, Process, and QA. It was determined that design modification controls appeared adequate however, one nonconformance was identified.

A nonconformance was identified with regard to 10 CFR Section 71.135 which requires that written records describing the activities affecting quality be maintained for three years beyond the date when the licensee last engages in the activity for which the QA progam was developed. The team found occasions where changes had been made to containers. The Technical Director reviewed the changes to determine if the SAR requirements were satisfied or if further review by NUPAC personnel was required. The results of the review, as required by 10 CFR Section 71.135, were not documented or referenced in any documentation.

2.7 Maintenance Control

The performance of maintenance ensures that the container will remain in a safe and usable condition. The goals of maintenance inspection are to identify the maintenance that should be performed on the container to ensure it will meet its design objectives, and then inform the owner/user of the required maintenance. Documents were reviewed for: completeness of maintenance controls; follow-up of maintenance after container sale; and QA program controls. The inspection of this element considered three major areas: Program, Process, and QA. It was determined that maintenance controls appeared to be adequate and that controls provide sufficient control to satisfy the SAR and QA application commitments.

2.8 Handling and Storage Control

The inspection of handling and storage control verifies that adequate measures are established to prevent damage or deterioration of materials and equipment during handling, storage, shipping, cleaning and preservation. Documents were reviewed for handling and storage requirements and

QA program controls. The adequacy of handling and storage operations were reviewed. The need for handling and storage control is limited since containers are usually manufactured only after a purchase order is received, not as shelf items. It was found that procedures for storage gave consideration to required maintenance. Handling controls were adequate and the procedures for storage were exemplary.

3. DOCUMENTS REVIEWED

Document ID	Rev. No.	Title
WO No. Z41 container		Fabrication documents for a 10-142
WO No. 2019 container		Fabrication documents for a 10-142
WO No. GN container		Fabrication documents for a 14-210
WO No. Z70		Fabrication documents for a 14-210 container
WO No. 3522 container		Fabrication documents for a 14-210
WO No. XX2		Fabrication documents for a N-55 container
NPI.F-0018-NP		N-55 Polyurthane Foam Specification
OM-08,	Rev. 0	Operation and Maintenance Manual for the NUPAC PAS-2 Sampling Cask and Transportation Packaging
OM-12,	Rev. 3	Operation and Maintenance Manual for NUPAC OH-142 Shipping Cask Typical Trailers and Standard Liners

FS-01,	Rev. 7	Specification for Machining and Fabricating Equipment
Q1-5,	Rev. 0	QA Planning
QP-5,	Rev. 07	QA Planning
OM-10,	Rev. 4	Installation and Torquing of NUPAC Binders
LT-04,	Rev. 3	General Procedure for Soap Bubble (Low Pressure) Leak Test
L-01,	Rev. 7	Specification for Pouring Molten Lead for Radiation Shielding
GS-001,	Rev. 4	General Procedure for Gamma Scan of Shielded Container
QANPI.0305.LF8901		Lee Fabricators Audit File from 1/19/1989
QANPI.0305.LF8605		Lee Fabricators Audit File from 5/29/1986
QANPI.0305.IM&M8610		Ideal Machine and Mfg. Audit File from 10/22/1986
QANPI.0305.IM&M8609		Ideal Machine and Mfg. Audit File from 9/29/1986

QP-6	Rev. 5	Inspection and Verification
QP-7	Rev. 0	Discrepancy Reporting
IM-6, 15, 16, 23		Welding Procedures, NDE
QP-4		10 CFR 21 Reporting Requirements Package
QANPI.0305.MPL8610		Metalex Products, LTD Audit File from 10/09/1986
QANPI.0305.MPL8504		Metalex Products, LTD Audit File from 04/29/1985

Purchase Order No. 7363-3566 to Lee Fabricators, file from 11/21/88 to present.

4. NONCONFORMANCES

The following nonconformances were identified:

Nonconformance 1

10 CFR Section 71.103, requires, in part, that the authority and duties of persons and organizations performing activities affecting safety-related functions must be clearly established and delineated in writing.

In nonconformance with 10 CFR Section 71.103, the Technical Director's job description did not list the responsibility for reviewing deficiencies and nonconformances and manufacturing changes to determine implications for the SAR evaluations or analyses. (Reference Section 2.2, Page 6)

Nonconformance 2

10 CFR Subsection 71.37(b), requires that established codes and standards proposed for use in package design, fabrication, assembly, testing, maintenance and use be identified.

In nonconformance with 10 CFR Subsection 71.37(b), procedures do not specify applicable codes, standards and regulations concerning cleaning fluids used in the fabrication process. (Reference Section 2.3, Page 7)

Nonconformance 3

10 CFR Section 71.115(b) requires documentation which shows that material and equipment conforms to procurement specifications to be retained or to be available for the life of the package.

In nonconformance with 10 CFR Section 71.115(b), documentation of material and equipment suppliers was not available. (Reference Section 2.4, Page 7)

Nonconformance 4

10 CFR Section 71.135, specifies that written records describing the activities affecting quality be maintained for three years beyond the date when the licensee last engages in the activity for which the QA Program was developed.

In nonconformance with 10 CFR Section 71.135, the results of the review of design modification changed against the SAR were not documented. (Reference Section 2.4, Page 9)

5. EXIT MEETING

On April 27, 1989, an exit meeting was conducted with facility management, supervisors, and engineers. The following personnel attendeo the exit meeting:

L. E. Kapinos, Vice President/General Manager
C. J. Temus, Technical Director
R. H. Smith, Director, Corporate Quality Assurance
F. L Bamford, Quality Assurance Manager
D. E. Rodgers, Senior Quality Assurance Inspector
N. K. Hanna, Inspection Supervisor

J. D. Kent, Engineer III
D. L. Swannack, Section Manager
W. L. Henkel, Director of Engineering
S. A. Porter, Analysis Manager

In the meeting, the team members summarized the preliminary results of the inspection and discussed a draft of the inspection tree with the meeting participants.

LEGEND

FABRICATORS/SUPPLIERS PRESENTATION INSPECTION TREE
CONTAINER SYSTEMATIC INSPECTION TREE

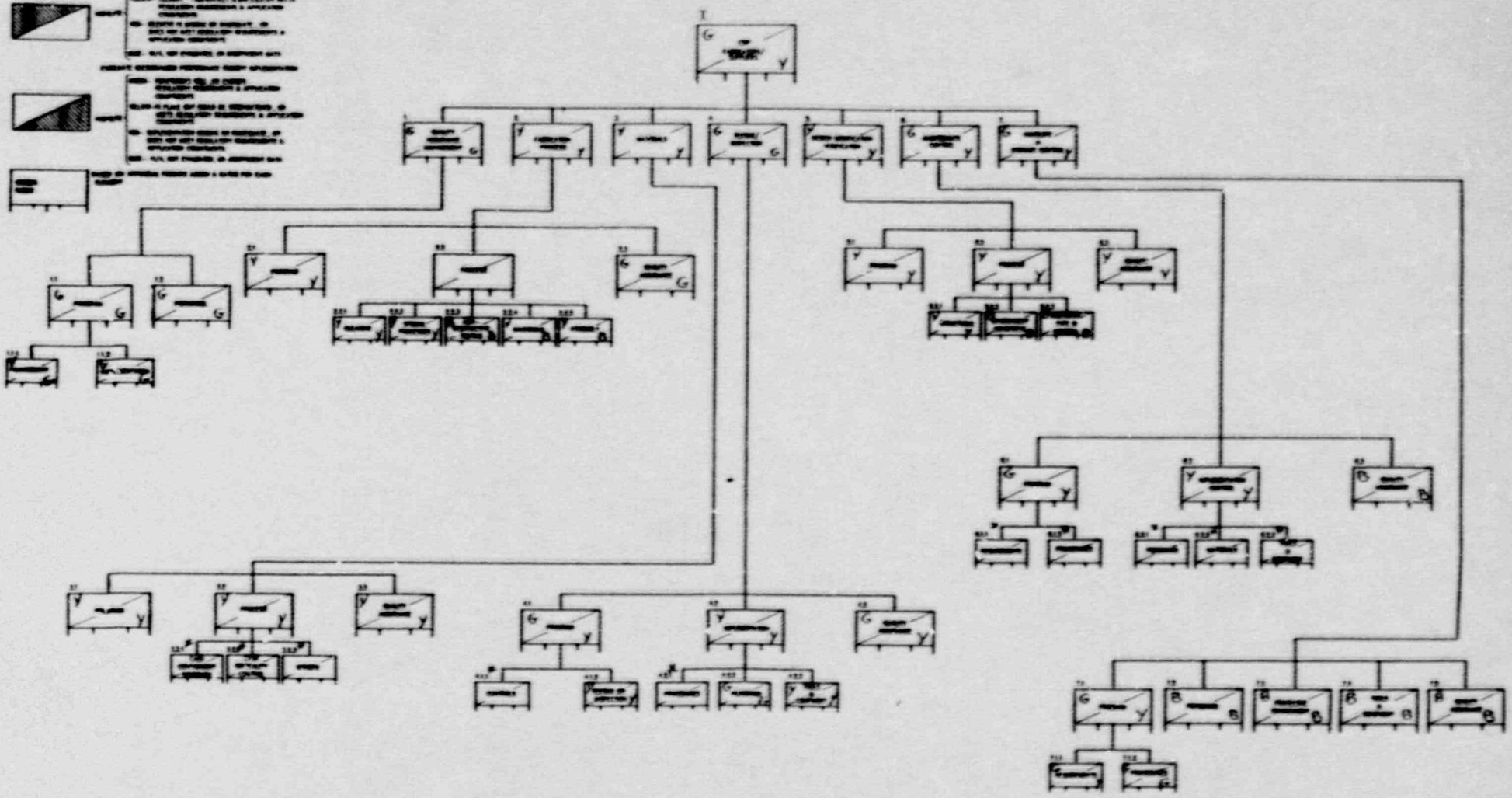

FIGURE 1