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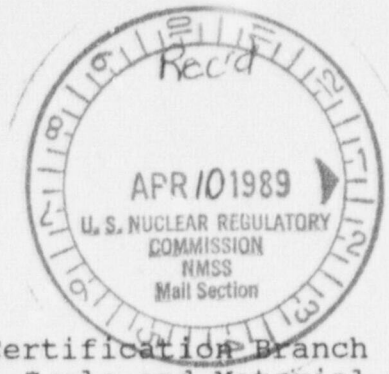
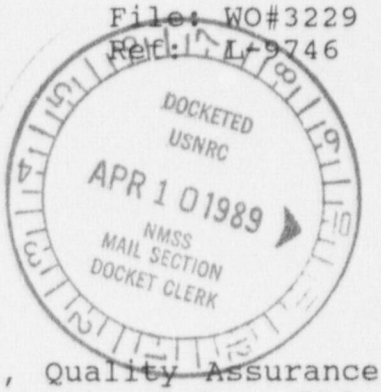


PACIFIC NUCLEAR SYSTEMS

April 7, 1989

File: WO#3229
Ref: L-9746



Mr. Henry Lee
Transportation Certification Branch
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission
1 White Flint North
11555 Rockville Pike
Rockville, MD 20852

SUBJECT: Replacement Pages for Section 9.0, Quality Assurance, Certificate of Compliance No. 9184, NuPac PAS-1 Packaging

Dear Mr. Lee:

Please find enclosed Section 9.0 of the NuPac PAS-1 Packaging Safety Analysis Report (SAR) as replacement for the previously submitted copy.

If you have any questions, please contact us at (206) 874-2235.

Sincerely,

NUCLEAR PACKAGING, INC.

Steven A. Porter
Engineering Specialist

SAP/man

Enclosures: As stated

FEE NOT REQUIRED

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9.0 QUALITY ASSURANCE

The NuPac PAS-1 Packaging has been designed and will be fabricated by Nuclear Packaging, Inc., (NuPac) Federal Way, Washington. The Quality Assurance Program used for the design, fabrication, assembly, testing, use and maintenance of the NuPac PAS-1 satisfies the eighteen (18) criteria of 10 CFR 71, Subpart H in its entirity. NuPac's Quality Assurance Program meeting these criteria has been submitted to the United States Nuclear Regulatory Commission and has been awarded Approval Number 0192, Revision 1.

A synopsis of the Pacific Nuclear Systems, Inc./Nuclear Packaging, Inc. Quality Assurance Program follows:

9.1 Introduction

Pacific Nuclear Systems, Inc. (PNSI) has developed a quality program to (1) assure traceability, and (2) control the quality of all materials and processes utilized in the production of radioactive shielding, casks, containers, and other equipment pertaining to shipping packages for irradiated fuel, high level waste, and plutonium.

A Quality Manual delineates requirements and procedures necessary to exercise control over design, documentation, procurement, material, fabrication, inspection, operational testing, equipment operation and use, maintenance, repair, modification, inventory, shipment and quality data retention.

The PNSI Quality Program is implemented by Quality Procedures which are designed and administered to meet the 18 criteria of 10 CFR 71, Subpart H. The Quality Program is implemented throughout the company and its subsidiaries. The Subsidiaries include: Pacific Nuclear Systems, Inc., Nuclear Packaging, Inc., NuPac Leasing, Inc., and Pacific Nuclear Systems and Services, Inc.

9.2 Description of the PNSI, 10 CFR 71, Subpart H Quality Program

9.2.1 Organization

Full responsibility for the Quality Assurance (QA) Program adherence to 10 CFR 71, Subpart H criteria rests with PNSI. Quality Program activities include calibration of measuring equipment, non-destructive examination (NDE), and materials testing. PNSI surveys and qualifies all organizations performing these services to assure adherence to the 18 criteria prior to their use. All other quality activities are performed by PNSI quality personnel. However, the responsibility of the control of quality in the other organizations continues to rest with PNSI.

PNSI's President has full authority over all functions of the company, and delegates authority and responsibility for selected functions to other personnel within the company.

The administrative function includes financial, legal, and marketing activities.

Procurement department personnel perform purchasing activities and maintain supplier performance records. The Engineering Department is responsible for research and development of shipping container technology, design of casks for licensing and fabrication, and design documentation.

The PNSI Quality Department has sufficient authority and organizational freedom to identify quality programs, implement corrective action, and verify corrective action effectiveness.

Additionally, the Quality Department is independent from other organizations within PNSI and reports directly to the President of PNSI. The Quality Department is headed by the Corporate Quality Director who is responsible for the development, implementation, and administration of the entire PNSI Quality

Program. He must have sufficient expertise in the entire field of Quality to enable him to direct the entire quality function in close adherence to the 18 criteria of 10 CFR 71 and the PNSI Quality Manual. Responsibility for

development of quality acceptance requirements, inspections, and NDE activities rests with the Corporate Quality Director. It is his responsibility to delegate and evaluate the performance of all quality related tasks for PNSI through the authority of the president.

It is delineated in writing through the Corporate Quality Director that designated QA personnel have the authority to prevent the continued processing, fabrication, installation, or delivery of unsatisfactory work.

This authority also extends to the quality monitoring of special processes utilizing PNSI equipment, personnel and procedures such as waste processing, in-service inspections, etc.

Production responsibilities include scheduling or in-service inspection and administration of all fabrication activities, both within PNSI and at qualified suppliers. The shipping and receiving function is also the responsibility of the Production Department.

On-site activities such as waste processing, in-service inspections, etc. are administered as a joint effort of the operations and engineering personnel. Quality supports these activities with written procedures that provide methods, process controls and check points. Inspection personnel perform monitoring activities and verifications of regulatory, contractual, and technical requirements during these operations.

The Corporate Quality Director and all other quality personnel and/or organizations within, or utilized by PNSI, are fully qualified for their quality responsibilities. Qualification records are maintained in the PNSI Quality Record File.

9.2.2 Quality Assurance Program

PNSI has established and implemented a QA Program for the control of quality in the design, fabrication, operation, and maintenance of shipping containers for nuclear products. Training and/or evaluation of personnel qualifications are required for all QA functions in accordance with written procedures and

are approved by the Quality Manager. The QA Program assures that all quality requirements, engineering specifications, and specific provisions of any package design approval are met. Those characteristics critical to safety are emphasized.

The President of PNSI regularly evaluates the PNSI QA program for adherence to the 18 criteria in scope, implementation, and effectiveness. Further, the President requires that the Quality System, including the QA Manual Policies and Procedures, be implemented and enforced on all applicable programs at PNSI.

A Material Review Board, consisting of Engineering, Procurement Production, and Quality Personnel has been established to resolve all discrepancies or disagreements pertaining to the acceptability of material, hardware, or safety related operations. Their dispositions are final and binding.

9.2.3 Design Control

PNSI Quality Procedures (QP's) have been developed, approved, and implemented to control design review in such a manner to assure that the following occur:

9.2.3.1 Design activity is planned, controlled, and documented.

9.2.3.2 Regulatory and design requirements are correctly translated into specification, drawings, and procedures.

9.2.3.3 Design documents contain quality requirements.

9.2.3.4 Deviations from quality requirements are controlled.

9.2.3.5 Design verification is performed by Quality Assurance personnel independent of the design activity. These verifications may include tolerance studies, alternate calculations or tests. Qualification tests are conducted in accordance with approved test programs and procedures

9.2.3.6 Interface control is established and adequate.

9.2.3.7 Design and specification changes are reviewed and approved by the same organization(s) as the original issue.

9.2.3.8 Design errors and deficiencies are documented and corrective action is taken to prevent recurrence.

9.2.3.9 Design organization(s) and their responsibilities and authorities are delineated and controlled via written procedure.

9.2.4 Procurement Document Control

The PNSI QA Program assures that all purchased material, components, equipment, and services adhere to design specifications.

Supplier evaluation and selection, objective evidence of supplier quality, assignment of quality requirements to procurement documents and related design documents, and source, in-process, and receiving inspections are all administered and controlled in accordance with approved PNSI QA procedures.

All procurement activity is performed in accordance with written procedures delineating requirements for preparation, review, approval, and control of procurement documentation. Particular emphasis is placed on assuring that revisions to procurement documentation are reviewed and approved by the same cognizant groups as the original.

Quality Assurance clause sheets are included with all request for quotes and purchase orders. Quality Assurance personnel assign clauses from the sheets to the procurement document referencing 10 CFR 71, Subpart H requirements appropriate to the contract. In addition, material information including grade, type, size, and special physical or chemical data requirements is included on the procurement documents. Other documentation and information such as drawings, procedures, inspection and test requirements, hold points, welding and other process qualification requirements are delineated on the

procurement documents by the Quality Assurance personnel as appropriate to the contract.

Quality Assurance personnel assure that requirements for acceptance of hardware and documentation appropriate to the contract are included in procurement documentation.

PNSI Quality Assurance personnel maintain the right of access to all supplier facilities and documentation for source inspection and/or audit activities. A statement to this effect is included on procurement documentation when it is appropriate to the contract.

9.2.5 Instruction, Procedures and Drawings

Quality planning is developed by qualified Quality Engineers (QE's) for all activities requiring quality participation in accordance with approved PNSI QA procedures and is approved by the Corporate Quality Director.

All design documents (i.e., drawings, specifications, special processes, etc.) affecting quality are reviewed by the Quality Department and referenced in quality planning as necessary to assure adherence to package design approvals and the applicable criteria of 10 CFR 71, Subpart H.

All instructions, procedures, and drawings are developed, reviewed, approved, utilized, and controlled in accordance with the requirements of written quality assurance procedures.

9.2.6 Document Control

Policy and procedure for review, approval, release and change control of all controlled, quality related documents are delineated in approved PNSI QA Procedures. Provisions are provided in the QA Procedures for identification of individuals/organizations responsible for review, approval, and issuance of documents. Document control responsibilities, facilities, and distribution requirements are also addressed.

Controlled documents include, but are not limited to:

(a) Design specifications
(b) Design manufacturing drawings
(c) Special process specifications and procedures
(d) Procurement documents
(e) QA Procedures and manuals
(f) Quality Planning for receiving, in-process, source and in-service inspections
(g) Source surveillance and evaluation reports
(h) Test procedures
(i) Audit reports
(j) Operational test procedures and data.

When revised documents appear in other documents as references, supplements, or exhibits, appropriate revisions are made to those documents prior to the release of the basic approved change.

Documentation listings are maintained delineating the title, number and current revision for all drawings, procedures, specifications, and purchase orders.

The Quality Personnel assure that all required support documentation is available at the work area prior to the initiation of the work effort.

9.2.7 Control of Purchased Materials, Parts and Components

Procurement documents are reviewed for acceptability of suggested suppliers based on the PNSI approved supplier lists.

In addition, and as required, supplier surveys are conducted by qualified PNSI personnel to further assure supplier acceptability. These evaluations are based on one or all of the following criteria:

(a) The supplier's capability to comply with the requirements of 10 CFR 71, Subpart H, that are applicable to the contract.

(b) A review of previous records and performance of the supplier.

(c) A survey of the supplier's facilities and QA program to determine his capability to supply a product which meets the design, manufacturing, and quality requirements.

Results of all supplier evaluations are recorded on Supplier Evaluation forms and are retained in the Quality Data File.

Quality requirements and standard clauses are added to procurement documents to require suppliers to identify material, provide test reports, control special processes, certify equipment and personnel, etc. As a minimum, requirements are imposed on suppliers to identify materials, specific codes, specifications and/or design not adhered to during fabrication. Justifications for 'accept-as is' or 'repair' dispositions are also required to be sumitted to the Material Review Board for review and acceptance.

Quality planning is prepared and approved by the Quality Department for performance of all source, test, shipping and/or receiving inspections in accordance with approved design requirements, applicable 10 CFR 71 criteria, procurement document requirements, and contract specifications.

Receiving inspection is performed to determine that the following, as appropriate to the contract, are assured:

(a) The material, component, or equipment is properly identified and corresponds with the identification on receiving documentation.

(b) Material, components, equipment, and acceptance records are inspected and are acceptable in accordance with inspection instructions, prior to installation or use.

(c) Inspection records and/or certificates of conformance attesting to the acceptance of material and components are available prior to installation or use.

(d) Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for further work.

All described activities are delineated in approved PNSI QA procedures.

9.2.8 Identification and Control of Materials, Parts, and Components

The identification and control of materials, parts, components, and completed and in-process assemblies is administered by the Quality Department in accordance with approved PNSI QA Procedures. These procedures address quality status tags, maintenance of material identification and traceability, part identification, and related documentation. Some of the details of these procedures follow:

(a) Material identification procedures included in inspection planning and fabrication drawings require that identification of material, components, and/or hardware be maintained on the item or in traceable records to prevent use of incorrect or defective items.

(b) When appropriate, due to contractual or safety related concerns requiring specific identification and Material Review Board action, Quality Assurance personnel assure that identification of materials, components, specifications, procurement documentations, manufacturing, and inspection records, discrepancy reports, and material test data is provided and is complete.

(c) Quality Assurance personnel assure, via drawings and inspection planning requirements, that identification locations do not affect the fit-up, interfacing capability, performance or overall quality of the finished product. Identification, in accordance with drawings and inspection planning requirements, is verified prior to releasing the item for further processing or delivery.

9.2.9 Control of Special Processes

PNSI approved QA Procedures delineate the policies and procedures established to control such special processes as: welding, heat treating, lead pouring, non-destructive examination, waste processing, etc. in accordance with applicable codes, standards, specifications, 10 CFR 71 criteria, and other requirements. Special processes developed by PNSI suppliers and by PNSI are documented.

All procedures for special processes and the personnel required to perform them are qualified under the cognizance of the Quality Department in accordance with applicable codes, standards, specifications, and contract requirements.

All qualification records and support data are retained in the Quality Data file, and are maintained in a current status by Quality Assurance personnel.

These documents are controlled as delineated in Section 9.2.6 of this Quality System description.

9.2.10 Inspection

All receiving, source, in-process, and in-service inspection activities are performed in accordance with approved PNSI QA procedures. All inspection personnel and/or organization qualifications are reviewed and accepted by the Quality Manager prior to inspection activity. The inspection activity is

performed in strict accordance with approved quality planning prepared by qualified QA personnel (See also Section 9.2.5 discussion).

Quality Inspection personnel are independent from all other organizations within PNSI and report directly to the Corporate Quality Director or the Subsidiary Quality Manager.

Inspection personnel qualifications are based on their capability to perform the required inspection functions in accordance with applicable codes, standards, professional society programs such as the ASQC quality technician certification, and PNSI training programs. Qualification reviews are performed periodically to maintain personnel proficiency and assure current qualification.

Mandatory hold points, inspection equipment requirements, accept reject criteria, personnel requirements, characteristics to inspect, variable/attributes recording instructions, reference documentation, and other requirements are included in the inspection planning.

The Quality Assurance department assures that any replacements, modifications, or repairs performed after final acceptance of material, components or hardware are inspected in accordance with the original inspection planning or new planning prepared as appropriate.

9.2.11 Test Control

A test control program, as it applies to quality, is addressed in approved PNSI QA Procedures and assures, via required planning, that all required testing, such as proof and acceptance tests, are identified and performed in accordance with test procedures, design requirements, and limitations. Prerequisites, accept/reject criteria, data recording criteria, instrumentation calibration, environmental conditions, documentation and evaluation requirements, etc. are delineated in the test procedures. Changes to the test procedures are required to be reviewed/approved by the same organization(s) as the original issue.

Whenever equipment, components, and/or assemblies require modification, repairs, or replacement which could result in requirements for re-test or additional testing, Quality Assurance personnel assure, as appropriate, that original or new test inspection planning is prepared and adhered to.

In any case, test results are documented, evaluated, and accepted by qualified personnel as required by the test inspection plan prepared for the test under the cognizance of Quality Assurance personnel.

9.2.12 Control of Measuring and Testing Equipment

Administration of the calibration of measuring equipment and instrumentation is performed by the Quality Department in accordance with approved PNSI QA Procedures. The calibration system assures that all standard measuring instruments (SMI) used in the acceptance of material, equipment, and assemblies are calibrated and properly adjusted at specified intervals to maintain accuracy within pre-determined limits. Calibration is performed using equipment traceable to national standards. All calibrated equipment is identified and is traceable to the calibration test data.

Whenever SMI are found to be out of calibration during or immediately after use, all items inspected during that period are rejected by inspection and are submitted to review action for possible re-inspection or other appropriate corrective action.

9.2.13 Handling, Storage, and Shipping

PNSI approved QA Procedures require that handling, storage, and shipping requirements adherence verification criteria be included in quality planning. These requirements are designed to prevent damage or deterioration of material and equipment. Information pertaining to shelf life, environment, packaging, temperature, cleaning, handling, preservation, etc., is included as required to meet design, NRC package approval and/or U.S. Department of Transportation shipping requirements.

Shipping documentation preparation, departure and arrival time, and destination data recording are also addressed in the planning, when applicable. Shipping requirements in quality planning must be met prior to release for shipment.

9.2.14 Inspection, Test and Operating Status

The use of inspection status tags, quality inspection stamps, and other means to indicate inspection and test status at, or for, PNSI are delineated in approved PNSI QA Procedures.

The clarity of the status indication, prevention of inspection, and/or test step by-passing, and prohibition of removal or modification of status indications, except with Quality Department approval/Material Review disposition, is assured via these procedures. The Quality Assurance Department assures via Quality Procedure, interoffice memoranda, training sessions, and audit that all PNSI personnel are aware of and understand the meaning and uses of status tags on all hardware, material, and test set-ups (see also Section 9.2.15 discussion).

9.2.15 Non-conforming Material, Parts, or Components

PNSI approved QA Procedures require that material, components, and equipment that do not conform to requirements are controlled to prevent their inadvertent use. Identification, segregation, discrepancy reporting, disposition of non-conformances by authorized individuals, and re-inspection activities are performed and controlled in strict accordance with these procedures.

Quality Discrepancy Reports (QDR) are utilized by the PNSI quality department to identify discrepant items, describe the discrepancy, and provide disposition and re-inspection requirements. The signatures of authorized cognizant personnel are placed on the QDR to signify approval of the disposition. These personnel must be approved by the Corporate Quality Director and President and must be from the same groups approving the original design. In conjunction

with repair or re-work dispositions, quality assurance personnel provide supplemental inspection planning to verify proper implementation of the QDR disposition. This assures that the item is re-tested and/or re-inspected to a degree at least equal to the original acceptance activity.

9.2.16 Corrective Action

Failures, malfunctions, and deficiencies in material, components, equipment, and services are identified and reported to the Corporate Quality Director and the President. The cause of the condition and corrective action necessary to prevent recurrence is identified, implemented and then followed up to verify corrective action effectiveness. All reporting requirements of applicable contractual and regulatory specifications and regulations are adhered to as part of any corrective action activity. Detail requirements for this activity are delineated in approved PNSI QA Procedures.

9.2.17 Quality Assurance Records

A quality records system is in effect at PNSI and is administered in accordance with approved PNSI QA procedures. The purpose of the quality record system is to assure that documented evidence pertaining to quality related activities is maintained and available for use by PNSI, its customers, and/or regulatory agencies as applicable. Quality Records include, but are not limited to, inspection and test records, audit reports, quality personnel qualifications, design reviews, quality related procurement data, supplier evaluation reports, etc. All records are identified by work order number, part number, contract number, or drawing number as appropriate to the record type. A complete list of all quality records is maintained and provides cross reference between the different identity methods described above and pinpoints the record location.

Design related records such as calculations, drawings, research and development test reports, etc., are retained in the Quality Assurance records system for the life of the shipping package. All other quality related records are retained for the life of the shipping package in accordance with 10 CFR

71.91(c) unless otherwise specified in related contractual or regulatory requirements.

Inspection records retained in the Quality Assurance records system provide the following data when applicable:

(a) Inspection type, i.e., in-process, in-service, testing, receiving, and shipping.

(b) Evidence of completion and verification of manufacturing, inspection, or test operation.

(c) The date and results of the inspection or test.

(d) Information related to noted discrepancies.

(e) Inspector or data recorder identification.

(f) Evidence of acceptance.

9.2.18 Audits

Quality program audits are performed on a periodic, scheduled basis by personnel without direct responsibilities in the areas being audited. Audit personnel are certified quality assurance lead auditors who have met all requirements of ANSI N 45.2.23. Written planning sheets and check lists are utilized. Audit results and corrective action activity are reported to management, in writing, and are retained in the quality assurance record file. Responsible management personnel are required to respond to audit findings with the necessary action to correct the noted deficiencies. Current PNSI practice is to audit all quality functions on an annual basis. Areas found deficient during audits are reaudited on a first priority basis to verify corrective action implementation and effectiveness. Details of the PNSI Audit System are delineated in approved PNSI QA Procedures.

9.3 References

9.3.1 Title 10, Code of Federal Regulations, Part 71 (10 CFR 71), Packaging and Transportation of Radioactive Materials, August, 24, 1983.

9.3.2 PNSI Corporate Quality Manual, Revision 15, dated February 1, 1988.

9.3.3 NRC Approval No. 0192 pertaining to the Pacific Nuclear Systems/ Nuclear Packaging, 10 CFR 71, Subpart H, QA System.

DOCKET NO. 71-9184
CONTROL NO. 25406
DATE OF DOC. April 7, 1989
DATE RCVD. April 10, 1989
FCUF _____ PDR ✓
FCAF _____ LPDR _____
I&E REF. ✓
SAFEGUARDS _____
FCTC ✓ OTHER _____
DATE 4/10/89 INITIAL _____