10 CFR 71 QUA ITY ASSURANCE PROGRAM

FOR

RADIOACTIVE MATERIAL

SHIPPING PACKAGES

LETTER NUMBER QA-78-1

REVISION 6

DATE: SEPTEMBER 13, 1990

PACIFIC NUCLEAR SYSTEMS, INC.
1010 SOUTH 336TH STREET
FEDERAL WAY, WA 98003

APPROVALS

(Previous Revision Approvals on File at PNSI)

Revision 6

David F. Jones 9-13-90

David F. Jones Date
Chairman and Chief Executive

R. Howard Smith 9.13.90

R. Howard Smith Date
Director, Corporate Quality Assurance

INTRODUCTION

Pacific Nuclear Systems, Inc. (PNSI) has developed a quality system to assure traceability and control the quality of all materials and processes utilized in the production of radioactive shielding, cask, containers and other equipment pertaining to shipping packaging for radioactive material.

The 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 System and implemerting Quality Procedures are designed and administered to meet the 18 criteria of 10 CFR 71, Subpart H. Attachment 1 is a matrix delineating the relationship between the PNSI Quality Procedures and the 18 10CFR71, Subpart H criteria.

The quality manual contains a statement of policy and authority, signed by the Chairman and Chief Executive which defines the quality manual as the Corporation's policy related to quality. The quality manual states the policies, assigns the responsibilities, and describes and summarizes the procedures governing the design, procurement, construction, testing and operations of safety related components, systems and structures as defined by contract or licensing/ certification regulations.

The policies described in the quality manual implement the requirements of Title 10, Code of Federal Regulations, Part 50, Appendix B; Part 71, Subpart H, and Part 72, Subpart G as well as additional requirements of ANSI, ASME, Regulatory Guides, and Military Standards as applied to organizations performing design, procurement, construction, testing and operational activities for nuclear applications to the extent specified by contract or licensing/certification regulations.

The statement of policy and authority includes provision to specify that attainment of quality objectives is the responsibility of all personnel at PNSI. It also states that compliance with the PNSI Quality Assurance Program as described in the Quality Manual is mandatory for all PNSI divisions and personnel whose activities affect quality.

The Director, Corporate Quality Assurance, reporting to the Chairman and Chief Executive, is given full responsibility for maintaining the Quality Manual and for assuring uniform implementation of the quality assurance program throughout PNSI and its divisions. He has the authority to initiate management action to limit further processing on items of indeterminate quality, to initiate corporate management action to resolve any deficiencies and to assure that satisfactory resolutions have been achieved prior to authorizing further processing.

The Quality System is implemented throughout the Company and its operating divisions. The divisions include: Pacific Nuclear Systems, Inc., Nuclear Packaging, Inc., NuPac Services, Inc., PN Services, Inc., ALARON, Inc., NUTECH Engineers, Inc., and Pacific Nuclear Fuel Services, Inc. As used in this document, PNSI includes all the listed divisions.

DESCRIPTION OF THE PNSI 10CFR71, SUBPART H QUALITY PROGRAM

Criterion 1, Organization

Full responsibility for the Quality Assurance (QA) Program adherence to 10CFR71, Subpart H criteria rests with PNSI. Quality Program activities include calibration of measuring equipment, 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 Chairman and Chief Executive 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 problems, implement corrective action and verify corrective action effectiveness.

Additionally, the Quality Department is independent from other organizations within PNSI and reports directly to the Chairman and Chief Executive of PNSI. The Quality Department is headed by the Director, Corporate Quality Assurance who is responsible for the development, implementation and administration of the entire PNSI Quality Program. He must have sufficient expertise in the field of Quality to enable him to direct the quality function in close adherence to the 18 criteria and the PNSI Quality Manual.

Responsibility for development of quality acceptance requirements, inspections and NDE activities rest with the Director, Corporate Quality Assurance. It is his responsibility to delegate and evaluate the performance of all quality related tasks for PNSI through the authority of the Chairman and Chief Executive.

A Quality Assurance Manager who reports directly to the Director, Corporate Quality Assurance is assigned to each operating division. The Quality Assurance Manager is responsible for implementing the Quality Assurance policies and practices as delineated in the approved PNSI Quality Assurance Manual within his division.

Quality Assurance Managers must meet qualification requirements of ANSI N45.2.23 and NQA-1, Supplement 2S-3 as defined for lead auditor within 90 days of assuming the position.

It is delineated in writing through the Chairman and Chief Executive 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 using PNSI equipment, personnel and procedures such as waste processing, in-service inspections, etc.

Production responsibilities include scheduling of in-service inspection and administration of all fabrication activities, both within PNSI and at qualified suppliers. The shipping and receiving function is also included within the responsibility. Production activities may occur within either the Operations or the Engineering Departments.

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 Director, Corporate Quality Assurance 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.

Typical organizational charts are shown at the end of this document as Figures 1, 2 and 3.

Criterion 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. PNSI's training program requires that all employees who participate in the Quality Assurance Program will receive a level of classroom and on the job training commensurate with their involvement in the QA Program. When required by applicable codes and standards, qualified personnel shall be appropriately certified in accordance with approved quality procedures. PNSI personnel are encouraged to attend appropriate seminars and training courses although such attendance is not required by the training program.

PNSI personnel performing test and inspection shall be qualified and certified in accordance with ANSI/ASME N45.2.6. PNSI personnel performing nondestructive examination shall be qualified and certified in accordance with the American Society for Nondestructive Testing, recommended practice SNT-TC-1A.

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 Director, Corporate Quality Assurance of PNSI regularly evaluates the PNSI QA Program for adherence to the 18 point criteria in scope, implementation and effectiveness. Further, the PNSI Chairman and Chief Executive requires that the Quality System, including the QA Manual Policies and Procedures, be implemented and enforced on all applicable programs at PNSI.

PNSI commits to complying with the provisions of 10 CFR, Part 21 including internal posting and dissemination via procurement documents to appropriate PNSI vendors.

A Material Review Board, consisting of Engineering, Production (for PNSI fabricated items), and Quality Personnel has been established to disposition discrepancies or disagreements pertaining to the acceptability of material, hardware or safety related operations. The MRB is convened when determined necessary by the division QA Manager. Their dispositions are final and binding.

Criterion 3, Design Control

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

(a) Design activity is planned, controlled and documented.

(b) Regulatory and design requirements are correctly translated into specification, drawings and procedures.

(c) Design documents contain quality requirements.

(d) Deviations from quality requirements are controlled.

(e) Design verification is performed by competent engineering 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.

(f) Interface control is established and adequate.

(g) Design and specification changes are reviewed and approved by the same organization(s) as the original issue. In a case where a design change is to be implemented which potentially impacts licensed products, PNSI's QA Program provides for assuring that all licensing considerations have been reviewed and are complied with or otherwise reconciled by licensing amendment.

(h) Design errors and deficiencies are documented and corrective action to prevent recurrence is taken.

(i) Design organization(s) and their responsibilities and authorities are delineated and controlled via written procedures.

Criterion 4, Procurement Document Control

The PNSI QA Program assures that all purchased material, components, equipment and services adhere to the applicable requirements.

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

All procurement activity is performed in accordance with written procedures delineating requirements for preparation, review, approval and control of procurement documentation. 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 requests for quote and purchase orders. Quality Assurance personnel assign clauses from the sheets to the procurement document referencing 10CFR Part 71, Subpart H requirements appropriate to the contract.

Quality Assurance Clause Sheets require that PNSI suppliers maintain all QA records which evidence conformance to the procurement specification for five (5) years and that PNSI must be notified prior to disposal. Additionally, Quality Assurance Clause Sheets stipulate that in the event the suppliers business is discontinued, the subject records must be provided to PNSI.

Quality Assurance Clause Sheets include provisions for PNSI to designate the QA records which are to be submitted to PNSI. The following documents are required to be submitted, if appropriate to the scope of the procurement:

- Certified material test reports which provide chemical and physical test data
- Typical material test reports
- Certificate of Calibration
- Certificate of Conformance
- Red lined "As-Built" drawings containing variables (actual data taken) or attributes (basic acceptance indicated) data

- Completed inspection instructions, manufacturing/ inspection travelers or similar documents
- Certification, test data and related documentation
- Nonconformance reports dispositioned "Use-as-Is" or "Repair"
- Procedures for controlling special processes such as welding, NDE, heat treating, plating, painting, etc. including evidence of process qualifications

In addition, material information including grade, type, size and special physical and 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.

PNSI 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.

Criterion 5, Instructions, Procedures and Drawings

Quality planning is developed for activities requiring quality participation in accordance with PNSI QA procedures by qualified Quality Engineers and are approved by the Quality Assurance Manager.

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.

Changes to instructions, procedures and drawings, shall be developed, reviewed, approved, utilized and controlled using the same requirements as applied to the original documents.

Criterion 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 specification 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 concurrent with the release of the basic approved change.

Documentation listings are maintained delineating the title, number and current revision for all drawings, procedures and specifications under the scope of our 10CFR71 QA Program.

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

Criterion 7, Control of Purchased Materials, Parts and Components

Procurement documents are reviewed for acceptability of suggested suppliers based on the quality requirements of the item and the PNSI approved suppliers 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:

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

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

(3) 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.

Requirements are imposed on the supplier by procurement documents to identify any material, item or service supplied which does not adhere to specified procurement requirements including the requirements not adhered to, as well as a requirement to provide technical justification for nonconforming items or services dispositioned by the supplier as "accept-as-is" or "repair".

The PNSI QA Program provides for surveillance of supplier in-process activities to the extent determined necessary by the QA Manager to verify the suppliers compliance with the procurement documents. When determined to be necessary, the need for surveillance shall be noted in approved quality planning documents and shall be conducted and documented in accordance with approved PNSI QA Procedures.

Quality planning is prepared and approved by the Quality Department for performance of all source, test, shipping and/or receiving inspections and surveillance activities in accordance with approved design requirements, applicable 10CFR71 criteria procurement document requirements and contract specifications.

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

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

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

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

(4) 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.

Criterion 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:

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

(2) When appropriate, due to contractual or safety related requirements, Quality Assurance personnel assure that identification is traceable to materials, components, specifications, procurement documents, manufacturing and inspection records, discrepancy reports and material test data.

(3) Quality Assurance personnel assure, via drawings and inspection planning requirements, that identification locations do not affect the fit, interfacing capability, function, 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.

Items having limited shelf or operating life shall be controlled to prevent their inappropriate use. Prior to their inclusion in PNSI fabricated structures, packages, or systems, limited shelf life shall be noted by stamps, tags or labels and controlled by PNSI QA personnel. After inclusion in PNSI designed structures, packages or systems, shelf or operating life limitations shall be controlled in accordance with the approved Safety Analysis Report by PNSI operating or Quality Assurance personnel and documented in accordance with approved Quality Procedures.

Criterion 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, 10CFR71 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 PNSI quality files, and are maintained in a current status by Quality Assurance personnel.

These documents are controlled as delineated in Criterion 6 of this Quality System description.

Criterion 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 Assurance Manager prior to performance of the inspection activity. The inspection activity is performed in strict accordance with approved quality planning prepared by qualified QA personnel (See also Criterion 5 discussion).

Quality Inspection personnel are independent from all other organizations within PNSI and report directly to the Division Quality Assurance 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 American Society for Quality Control 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 criteria.

When PNSI has the responsibility for shipping radioactive material, approved quality planning shall be employed by QA personnel to ensure that package operation requirements defined by Chapter 7 (Operations) of the Safety Analysis Report (or applicable operation requirements for nonlicensed packages) are verified prior to release to the package carrier.

Radioactive material packages maintained by PNSI are visually inspected by PNSI personnel prior to each use to assure compliance with the applicable Certificate of Compliance. Additionally, approved quality planning is used to provide the inspection and maintenance activities (such as gasket replacements) defined by Chapter 8 (Maintenance) of the Safety Analysis Report.

Criterion 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 that original or new test inspection planning is prepared and adhered to as appropriate.

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.

Criterion 12, Control of Measuring and Test 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 measuring and test equipment (M&TE) 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 when such standards exist. When such standards do not exist, the basis of calibration is documented. All calibrated equipment is identified and is traceable to the calibration test data.

Calibrated M&TE shall be identified with a calibration label and the following information:

- M&TE serial number
- Date of calibration
- Date calibration is due

M&TE determined to be out of calibration shall be identified with appropriate markings or immediately removed from service to prevent its inadvertent use.

Whenever M&TE is found to be out of calibration, all items inspected during that period are submitted for review action for possible re-inspection or other appropriate corrective action.

Criterion 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 is also addressed in the planning, when applicable. The requirements in quality planning pertaining to shipping must be met prior to release for shipment.

Criterion 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 setups. (See also Criterion 15 discussion).

Criterion 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-conforming items by authorized individuals and re-inspection activities are performed and controlled in strict accordance with these procedures.

Nonconformance Reports (NCRs) are utilized by the PNSI Quality Department to identify discrepant items, describe the discrepancy, provide disposition and re-inspection requirements. The signature of authorized cognizant personnel are placed on the NCR to signify approval of the disposition. These personnel must be approved by the Division Quality Assurance Manager 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 NCR disposition. This assures that the item is re-tested and/or re-inspected to a degree at least equal to the original acceptance activity.

The PNSI QA Program requires that a documented review by authorized personnel be performed of all significant deficiencies adverse to quality to determine potential reportability to the Nuclear Regulatory Commission in accordance with the 10 CFR 21 requirements.

Criterion 16, Corrective Action

Significant and/or repetitive failures, malfunctions and deficiencies in material, components, equipment and services are identified and reported to the Director, Corporate Quality Assurance using a Corrective Action Report (CAR). The cause of the condition and corrective action necessary to prevent recurrence is identified, implemented and then followed up to verify corrective action effectiveness. Detail requirements for this activity are delineated in approved PNSI QA Procedures.

The Quality Assurance Manager of the PNSI operating division is responsible for assuring implementation of the corrective action program, including follow up and close out actions.

Criterion 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. 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 identifies 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 a minimum of two years, but no more than five years unless otherwise specified by contract.

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

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

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

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

(4) Information related to noted discrepancies.

(5) Inspector or data recorder information.

(6) Evidence of acceptance.

Quality Records are maintained in facilities designed to prevent their loss or deterioration and shall comply with one of the following:

(a) Two sets of identical records are maintained at separate storage locations, or

(b) The official copy of QA records is maintained in approved fire-proof files or vaults, at a single location.

Criteria 18, Audits

Quality program audits are performed on a periodic, scheduled basis by personnel without direct responsibilities in the areas being audited. Audit team leaders are certified quality assurance lead auditors who have met all requirements of ANSI N 45.2.23. Written audit plans and check lists are utilized. Audit results including noted findings 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 to be deficient during audits are reaudited to verify corrective action implementation and effectiveness. Management audits of all division Quality Assurance Managers are conducted on an annual basis by the Director, Corporate Quality Assurance. Details of the PNSI Audit System are delineated in approved PNSI QA Procedures.

After initial qualification, PNSI suppliers are subjected to periodic (yearly) evaluation of their compliance with PNSI Purchase Order requirements. Those suppliers whose initial qualification was based partially on an audit by PNSI QA personnel are reaudited on a triennial basis (or more frequently if determined necessary by the QA Manager).

An audit plan is prepared by the audit team leader for each audit which is to be conducted. The audit plan identifies the audit team, the audit scope, the requirements, the activities to be audited, the organizations to be notified, the applicable documents, the schedule and audit checklists.

Audit checklists provided by the audit team leader are used by PNSI audit personnel to assure audit consistency and objectivity. Audit checklists delineate procedural requirements, follow up items and requirements unique to the organization being audited which are within the scope of the audit. Documentation examined during the audit shall be identified in the checklist by the auditor.

Audit results shall be documented in an Audit Report within thirty (30) days of the post audit conference. Any audit findings (AFRs) noted during the audit must be responded to within thirty (30) days of the date of AFR issuance. AFR responses either state that the subject deficiency is resolved and provide or reference objective evidence for verification or, provide a date when specified corrective actions will be complete.

References

(1) 10 CFR 71, Subpart H, Criteria 1-18 as contained in 10 CFR, Revised as of January 1, 199^, "Quality Assurance Criteria for Shipping Packages for Radioactive Material."

(2) PNSI Corporate Quality Manual, dated March 23, 1990.

Figures

(1) "Organization Chart of Pacific Nuclear Systems, Inc."

(2) "Typical Division Organization Chart."

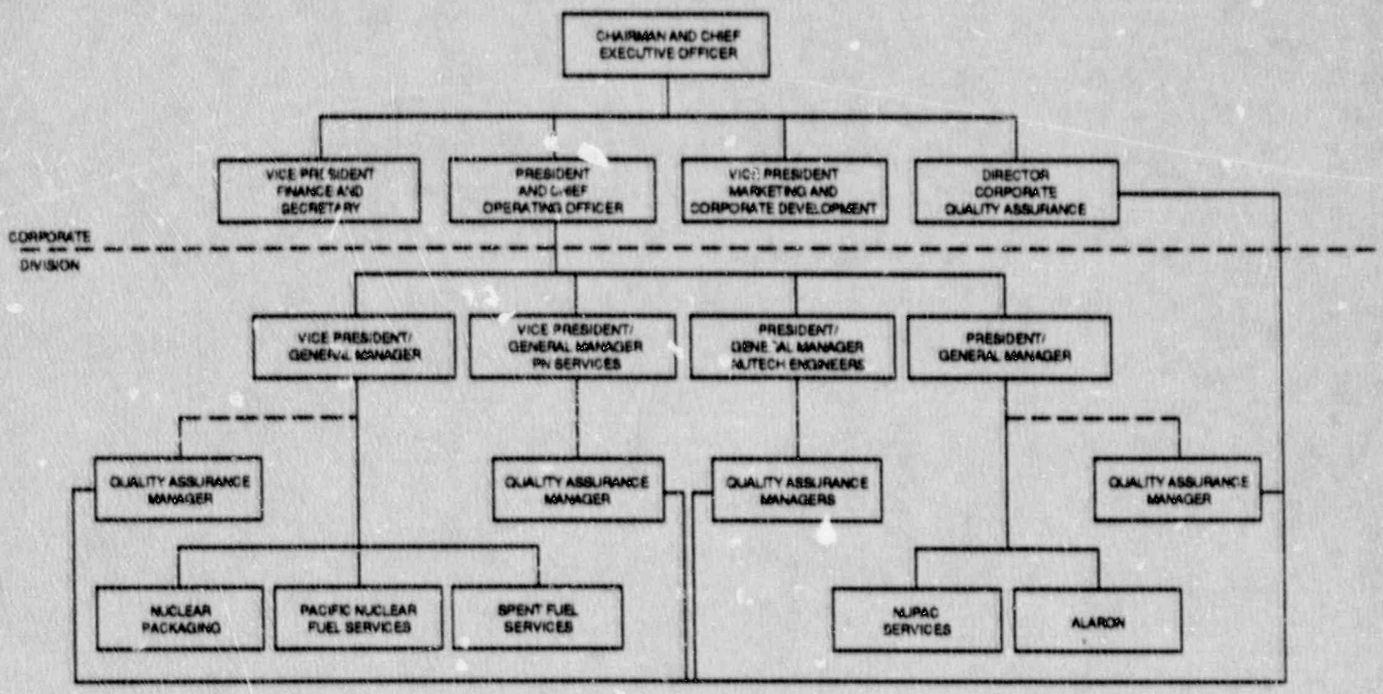
(3) "Typical Organization Chart, Quality Assurance Department."

Attachment

"Quality Requirements Matrix - 10 CFR 71, Subpart H, Criteria 1-18 vs. PNSI Quality Procedures".

Figure 1

ORGANIZATION CHART
PACIFIC NUCLEAR SYSTEMS, INC.



NOTES

- SEE FIGURE 1-2 FOR TYPICAL DIVISION ORGANIZATION (INCLUDING REGIONAL OR BRANCH OFFICES)
- DOTTED LINE DENOTES LINE OF COMMUNICATION

Figure 2

FUNCTIONAL ORGANIZATION CHARTS

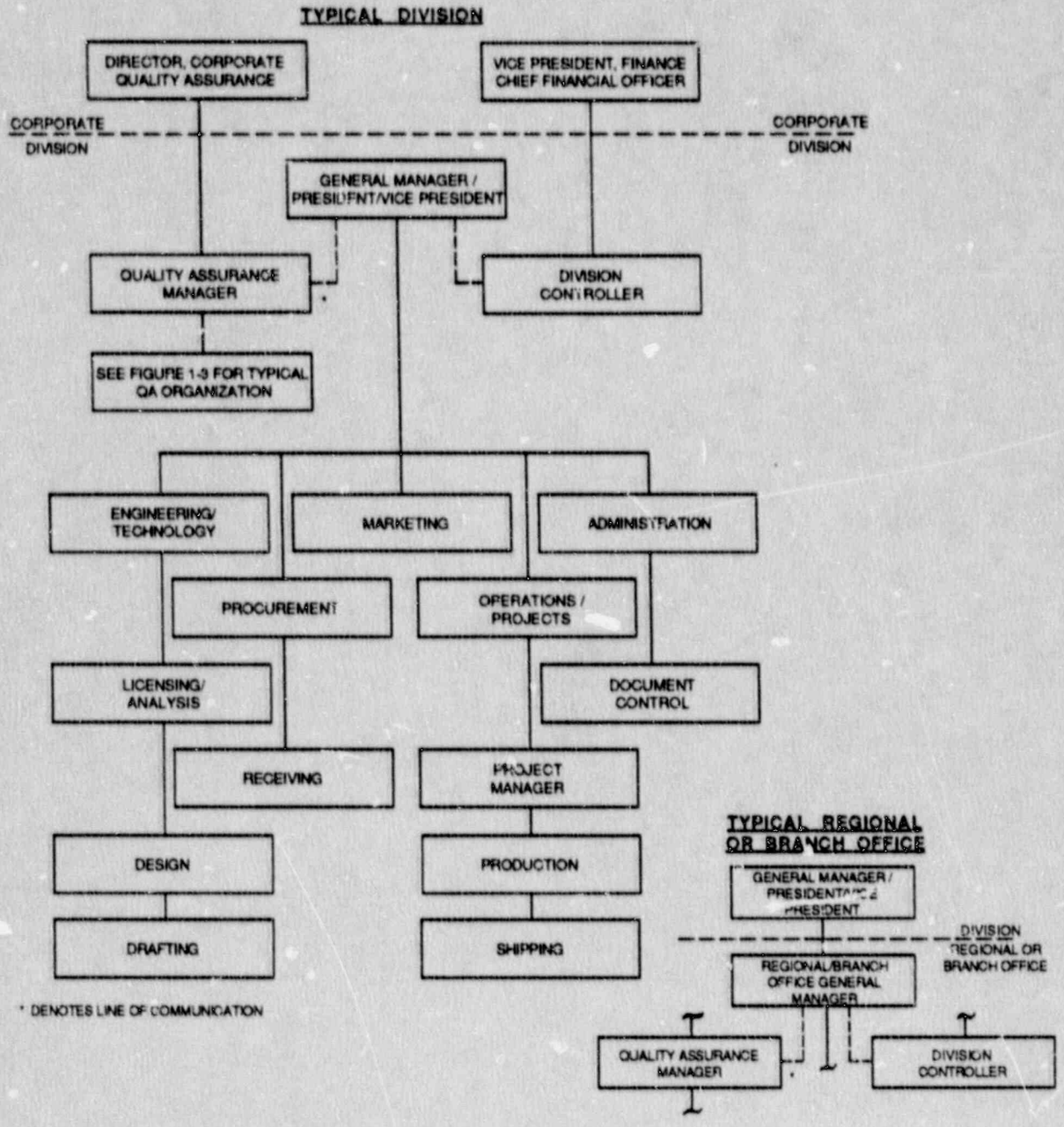
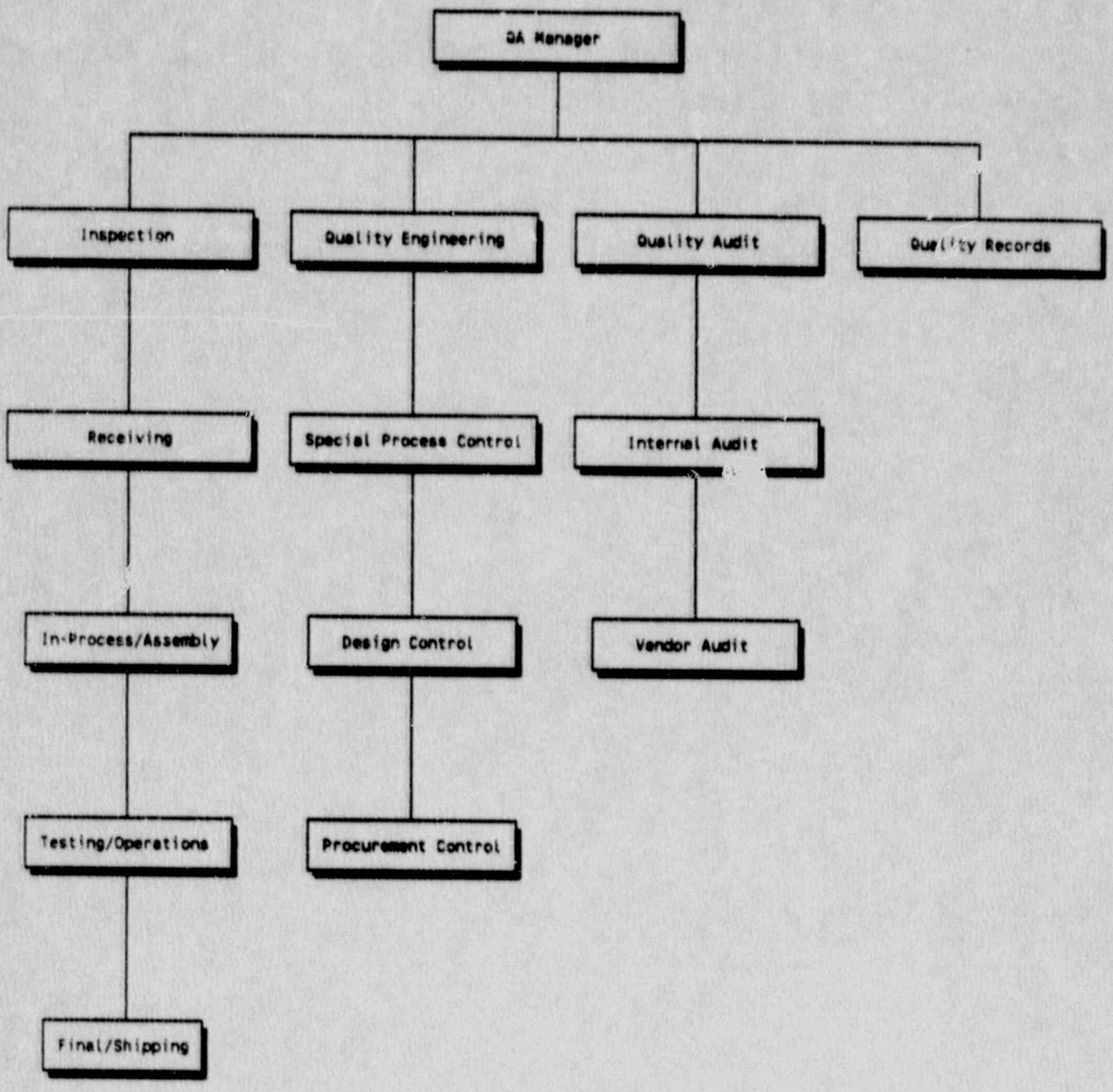


Figure 3
TYPICAL ORGANIZATION CHART
QA DEPARTMENT



ATTACHMENT 1
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QUALITY REQUIREMENTS MATRIX

10 CFR vs. PNSI

10 CFR 50, Appendix B 10 CFR 71, Subpart H		PNSI Corporate Quality Manual
I.	Organization Chart	Quality Program & Organization Chart
		Quality Procedure Description Quality Control Manual Quality Assurance Training
II.	Quality Assurance Program	Same as above
III.	Design Control	Design Review Design Control
IV.	Procurement Document Control	Procurement Control
V.	Instructions, Procedures and Drawings	Document Control Quality Planning
VI.	Document Control	Document Control
VII.	Control of Purchased Material, Equipment and Services	Procurement Control Material Control
VIII.	Identification and Control of Materials, Parts and Components	Document Control Material Control
IX.	Control of Special Processes	Procurement Control Quality Planning Inspection and Verification Special Process Qualifications and Control
X.	Inspection	Inspection and Verification
XI.	Test Control	Quality Planning Inspection and Verification

ATTACHMENT 1
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XII.	Control of Measuring and Test Equipment	Calibration Control
XIII.	Handling, Storage and Shipping	Material Control
XIV.	Inspection, Test and Operating Status	Inspection and Verification
XV.	Nonconforming Materials, Parts or Components	Discrepancy Reporting and Control
VXI.	Corrective Action	Corrective Action
XVII.	Quality Assurance Records	Quality Control Manual Quality Records Quality Forms Control
XVIII.	Audits	Audits