13.0 QUALITY ASSURANCE

13.1 INTRODUCTION

Pacific Sierra Nuclear Associates (PSN) has developed a Quality Assurance System to assure traceability and control the quality of all materials and processes utilized in the design, licensing and production of equipment and components important to safety for Concrete Dry Fuel Storage Casks.

The PSN Quality Assurance 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.

PSN's Quality Assurance System adopts the Pacific Nuclear Systems, Inc. (PNSI) Quality Assurance Program and Manual. PNSI is one of the major owners of PSN and, hence, PSN implements the PNSI Quality Assurance Manual as do the other PNSI affiliates (NuPac, PN Services, etc.). The PNSI* QA program first received NRC approval in December 1978 for the design and fabrication of transportation cask. It was again approved by the NRC in 1987 for the design and fabrication of concrete dry fuel storage cask. This action was taken as part of the NRC review of the CP-9 storage cask topical. The implementation of the PNSI program and the program description and procedures (i.e., the PNSI Quality Assurance Manual) are completely covered and made part of the PSN Quality Assurance Manual.

The PSN Quality Assurance Program as described in the Quality Assurance Manual is designed and administered to meet the 18 criteria of 10 CFR 72, Subpart G, 10 CFR 50, Appendix B and 10 CFR 71, Subpart H. Table 13.1-1 is a matrix delineating the relationship between the 18 Quality Procedures and the 18 criteria of 10 CFR 50, Appendix B, 10 CFR 71, Subpart H and 10 CFR 72, Subpart G.

The PSN QA Program has been reviewed, audited and approved by major utilities and the Department of Energy. These approvals have been via physical audit and/or evaluation.

A synopsis of the current PSN QA Program has been developed and is included in Section 13.2 of this Topical. This is the same system utilized on all 10 CFR 71, Subpart H, 10 CFR 72, Subpart G and 10 CFR 50, Appendix B related design, license, fabrication and operation programs at PSN, its parent company PNSI and their other affiliates.

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* This manual was previously titled the NuPac QA Manual. NuPac is another subsidiary of PNSI

TABLE 13.1-1
10 CFR 50 QA CRITERIA COMPARED TO PSN QA

CRITERIA OF 10 CFR 50 APPENDIX B 10 CFR 71, SUBPART H 10 CFR 72, SUBPART G	RESPONDING PSN QA PROCEDURE
I. ORGANIZATION	QA PROGRAM & ORGANIZATION CHART QP 1: QA MANUAL QP 14: QA TRAINING
II. QUALITY ASSURANCE PROGRAM	SAME AS ABOVE
III. DESIGN CONTROL	QP 2: DESIGN REVIEW QP 15: ENGINEERING HOLDS QP 17: DESIGN CONTROL
IV. PROCUREMENT DOCUMENT CONTROL	QP 4: PROCUREMENT CONTROL QP 15: ENGINEERING HOLDS
V. INSTRUCTIONS, PROCEDURES & DRAWINGS	QP 3: DOCUMENT CONTROL QP 5: QUALITY PLANNING QP 15: ENGINEERING HOLDS
VI. DOCUMENT CONTROL	QP 3: DOCUMENT CONTROL QP 15: ENGINEERING HOLDS
VII. CONTROL OF PURCHASED MATERIAL, EQUIPMENT & SERVICES	QP 4: PROCUREMENT CONTROL QP 12: MATERIAL CONTROL

TABLE 13.1-1 (CONTINUED)

VIII. IDENTIFICATION & CONTROL OF MATERIALS, PARTS & COMPONENTS	QP 3: DOCUMENT CONTROL QP 12: MATERIAL CONTROL
IX. CONTROL OF SPECIAL PROCESSES	QP 4: PROCUREMENT CONTROL QP 5: QUALITY PLANNING QP 6: INSPECTION & VERIFICATION QP 16: SPECIAL PROCESS QUALIFICATION & CONTROL
X. INSPECTION	QP 6: INSPECTION & VERIFICATION
I. TEST CONTROL	QP 5: QUALITY PLANNING QP 6: INSPECTION & VERIFICATION QP 15: ENGINEERING HOLDS
XII. CONTROL OF MEASURING & TEST EQUIPMENT	QP 11: CALIBRATION CONTROL
XIII. HANDLING, STORAGE & SHIPPING	QP 12: MATERIAL CONTROL
XIV. INSPECTION, TEST & OPERATING STATUS	QP 6: INSPECTION & VERIFICATION
XV. NONCONFORMING MATERIALS, PARTS OR COMPONENTS	QP 7: DISCREPANCY REPORTING & CONTROL

TABLE 13.1-1 (CONTINUED)

XVI. CORRECTIVE ACTION	QP 8: CORRECTIVE ACTION
XVII. QA RECORDS	QP 1: QA MANUAL QP 9: QA RECORDS QP 10: QA FORMS CONTROL
XVIII. AUDITS	QP 13: AUDITS

13.2 SYNOPSIS OF PSN QUALITY ASSURANCE PROGRAM

The following discussions identify the manner in which PSN implements the PNSI Quality Assurance Program.

PSN is an affiliate of PNSI, and as such implements the PNSI QA program as do the other PNSI affiliates. The PNSI organization is shown in Figure 13.2-1. PSN's organization is shown in Figures 13.2-2 and 13.2-3. PSN QA program implements the PNSI QA program.

13.2.1 SYNOPSIS OF PSN IMPLEMENTING PROCEDURES

The QA Program Matrix for 10 CFR identified in Table 13.1-1 is applicable to the PSN QA Program.

Managers, when appropriately qualified, may assume the duties and responsibilities of their subordinates, i.e., the Manager Quality Assurance may have the responsibility and perform the duties of the Project QA Manager or the Quality Engineer and the Quality Control Inspector without being in conflict with the intent of the Quality Assurance Program.

Managers, when appropriately qualified, may assume the duties and responsibilities of managers and personnel in other departments or groups but only with the written consent of the senior manager responsible for both areas.

When signatures are used to affirm an agreement, this affirmation shall mean the following:

The signator affirming that to the best of his/her ability the item

1. Meets the requirements established by the QA Manual and Procedures
2. Meets the specified acceptance criteria
3. Has been correctly documented
4. Has been reviewed and accepted within the expertise, experience and capability of the signator.

The PSN General Manager has final and ultimate responsibility for assuring that PSN technical and quality assurance contractual requirements have been met before PSN certification of acceptability is provided on any product of PSN work.

Forms used for PSN work where different from the forms specified in the PNSI QA Manual are specified in the PSN QA Manual.

The Project Manager is responsible for the review of contractual requirements and for final acceptance of all new or revised plans or Quality Procedures which are to be applied to the Project.

The Project QA Manager is responsible for review of acceptance of all Quality Procedures which become applied to the Project.

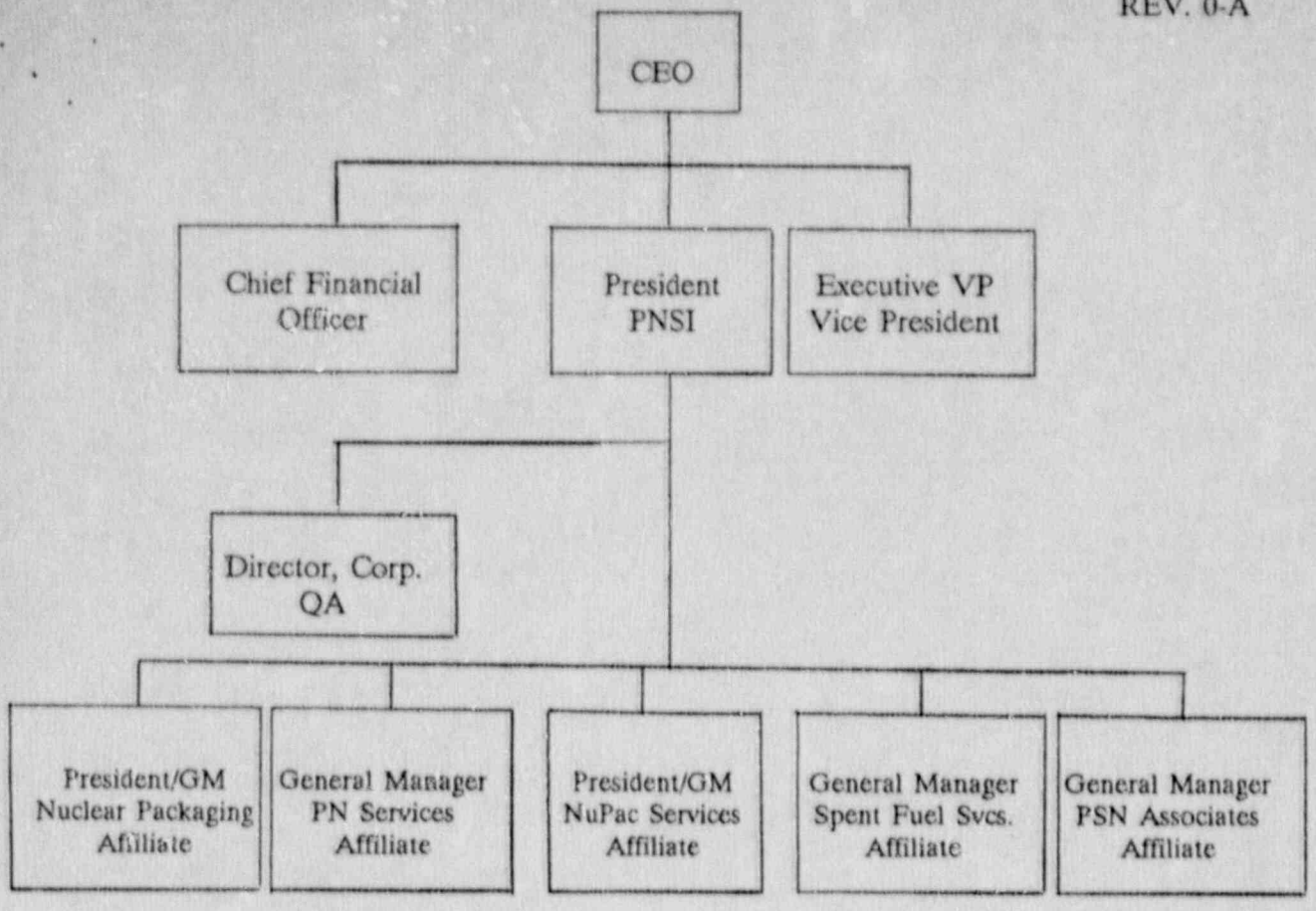
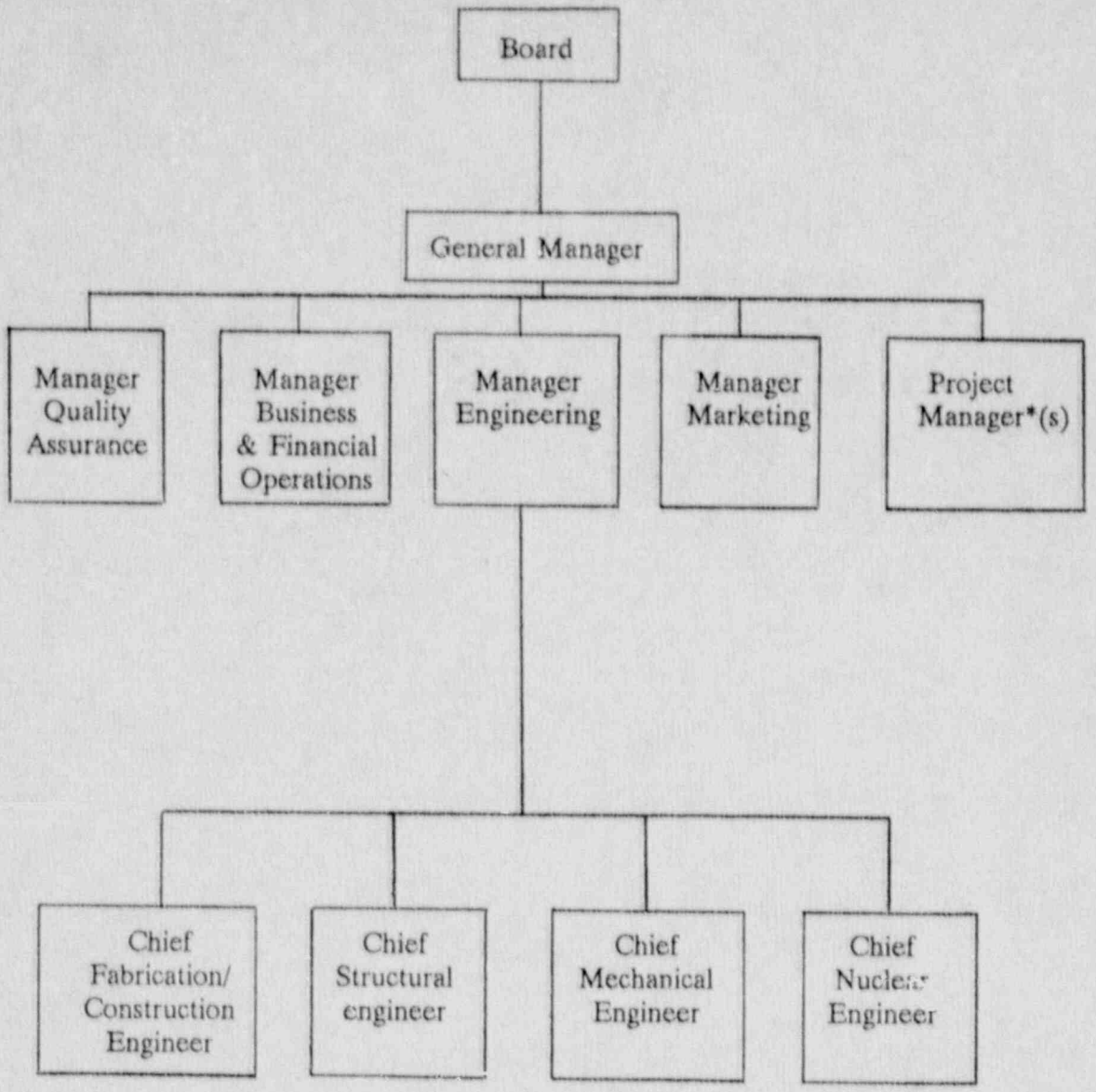


FIGURE 13.2-1

ORGANIZATION CHART

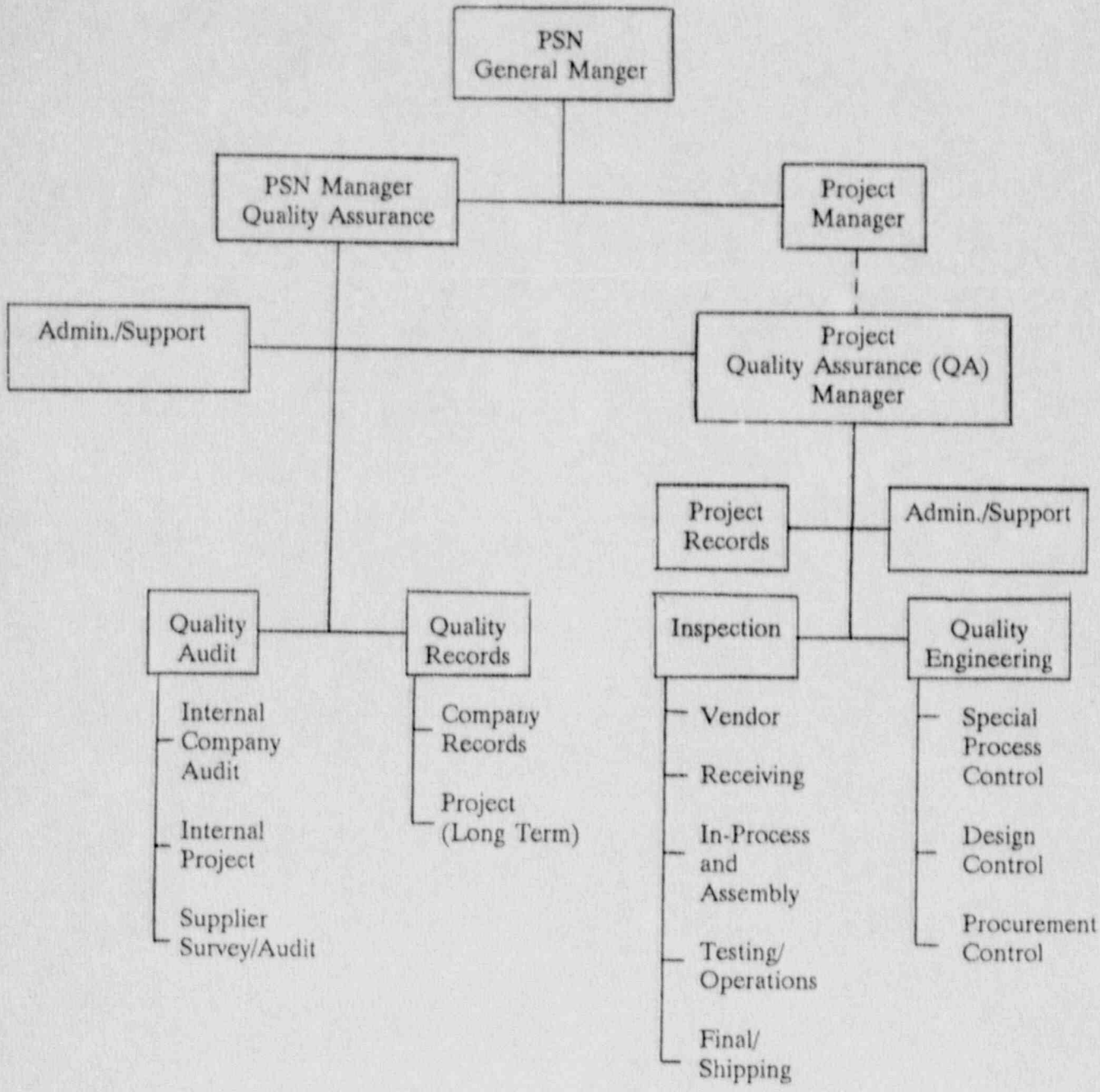
PACIFIC NUCLEAR SYSTEMS, INC.



* Project Managers as needed for jobs over $100,000. Managers for smaller jobs report to the Lead Chief Engineer.

FIGURE 13.2-2

ORGANZATION OF PSN



——————— Line of technical authority, information and counsel

– – – – – – Line of project administrative control

FIGURE 13.2-3

TYPICAL PSN QA/QC ORGANIZATION FOR A PROJECT

The PSN Project Plan shall be used to document project schedules, project QA requirements, project organization, design interfaces and detailed project work scope.

PSN retains Lifetime Quality Records (which are required to be retained for the item by regulations, codes and standards) by submitting them to the PSN customers (i.e., owner of the equipment) for retention and retaining duplicates of these Quality Records in PSNs offices.

Calculation packages are checked and check-copies or memo's to file are used to document the checking.

Design review, checking and design verification are performed by qualified personnel selected by the project engineer or project manager. Only personnel having no involvement in the design element being reviewed, checked or verified shall be selected.

Control of the design interface is the responsibility of the Project Manager. Normally the daily working level control is achieved by routine and continual contact between the project engineers, by project meetings and by in-process design reviews. Through these activities it is assured that engineering design is based on the latest applicable project documents. Because of this continual internal interaction design documents used on a project are transmitted informally between the engineering, QA and fabrication groups. It is the responsibility of each design engineer to assure that the latest revision of all design documents (design input, calculations, drawings, reports, etc) are used for the applicable design activity. Access to the latest revision of all controlled documents in the project files is provided by the Project Manager. When outside design organizations are used to accomplish design, the Project Manager shall be responsible to assure that authorized design documents for the design activity are submitted to that design organization in a controlled manner as specified in Quality Procedure QP-3.

Final verification that the correct design documents were used in design is accomplished during the performance of internal design reviews of all drawings and calculations by the project manager and the project engineers.

Signature of the project engineers and/or project manager on the applicable drawings and/or calculations shall indicate that this review has been performed.

The requirements pertaining to orientation and training programs, addressed in QP 14, paragraph 3.1, apply to PSN personnel required to perform an activity controlled by the PSN QA Program. All PSN personnel shall be provided training and orientation in the requirements of PSN's QA Program as documented in the PSN Implementation Program Manual (IPM)."

To assure the effectiveness of the PSN QA program the PSN QA Manager shall be responsible to continuously evaluate the PSN QA procedures and practices to assure that the PSN QA Program is assuring compliance with appropriate regulations and standards. This evaluation shall be accomplished by separate audit or by compilation of the results of the previous years internal (self) audits, or a combination of both. Emphasis shall be placed on problem areas identified in the results from past audits. The PSN QA Manager shall be responsible to prepare and submit a report of the results of this evaluation annually to the PSN General Manager.

Annually, an audit and evaluation of the PSN QA system will be performed by corporate management.

Submittals of PSN supplier QA Records and other documents shall contain the appropriate authorities signature and date as accepted by PSN in the supplier's quality program description (QA Manual/Procedure). This is acceptable in lieu of requiring a Quality Assurance persons signature on all Quality Records.

PSN may use any of the following three (3) types of computer programs for engineering calculations:

(1) Supported
(2) PSN or PSN Affiliate Originated
(3) Client Supplied

Supported programs are those maintained by engineering institutions, service bureaus and government agencies. The user pays a fee for access to the codes, program data, maintenance and updates for a specified period. It shall be required that error notices be issued to PSN to meet 10 CFR 21 requirements. PSN policy is for the user to identify means of demonstrating that the program is suitable for the particular application. These means could include reference to similar applications or independent verifications of some aspect of the particular analysis. Any other verification is the responsibility of the maintenance bureau and listed users of the program.

Supported programs may be obtained through any reputable engineering institution or service bureau, or government agency. Prior to the authorization for application of a supported program to a PSN project, the applicable PSN Project Manager shall assure that the program to be used for the Project is suitable for use by checking solutions of simple problems against known correct solutions. This verification shall be conducted in the mathematical realm of the intended use of the program.

PSN or PSN affiliate originated programs are those which have been initiated and developed by PSN or PSN affiliate personnel to assist in a particular project analysis. All such programs shall be verified by alternate methods and reviewed by personnel having no involvement in originating the program. The project manager or his delegate shall assign the verifying personnel.

Client supplied programs are those maintained and checked by the client. Should a Client's contract or purchase order with PSN include such a provision, the client shall be required to supply any verification and future error notices.

Computer program files shall be established to collect all documentation on computer program identity, updates, error notices and program verifications. The General Manager shall assure these files are established and maintained current.

Records of all computer program input codes, keys, abbreviations and outputs pertaining to a calculation package governed by this manual shall be part of the calculation package.

PSN shall maintain a listing of all computer programs authorized for use. The listing shall identify the program and version authorized, the program type and the provider of the program. Error notices affecting programs shall be noted on this listing.

13.2.2 SYNOPOSIS OF PACIFIC NUCLEAR SYSTEMS, INC., QUALITY ASSURANCE PROGRAM

The PNSI QA Program is applicable to all quality related work done by any PNSI affiliate. Currently, the major affiliates are: NuPac, NuPac Services, PN Services, Pacific Sierra Nuclear Associates and Pacific Nuclear Spent Fuel Services.

Criterion 1, Organization

Typical organizational charts are presented in Figures 13-1, 13-2 and 13-3.

Responsibility for the quality assurance (QA) program adherence to the criteria imposed by the different regulations and industry standards (i.e. 10CFR72 Subpart G, for spent fuel storage systems; 10CFR71 Subpart H, for licensed transport casks; 10CFR50 Appendix B, ANSI N45.2, ASME/ANSI NQA-1 and others, for other goods and services) rests with the Pacific Nuclear affiliate providing the goods or services. QA program activities include; calibration of measuring equipment, NDE and materials testing. The affiliate's QA 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 affiliate quality personnel. However, the responsibility of the control of quality in the other organizations continues to rest with the affiliate QA.

The senior manager (president/vice president/general manager) for each affiliate has full authority over all functions within the affiliate, and delegates authority and responsibility for selected functions to other personnel.

The administrative function includes financial and legal activities.

Marketing activities are performed by personnel reporting directly to the senior manager. They are charged with the duty to identify and develop new business for the affiliate.

Procurement department personnel perform purchasing activities and maintain supplier performance records.

The Engineering Department, as appropriate, is responsible for research and development of shipping and storage container technology, design of casks for licensing and fabrication and design documentation.

The affiliate quality assurance organization has complete authority and organizational freedom to identify QA problems, establish QA programs, implement corrective action and verify corrective action effectiveness.

Additionally, the QA personnel are independent from other organizations within the affiliate and reports directly to the affiliate's senior manager.

The quality assurance department is headed by the affiliate's Quality Assurance Director/Manager who is responsible for the development, implementation and administration of the affiliate's Quality Assurance Program. The implementing quality assurance procedures and quality assurance manual (when needed), are developed by the QA Director/Manager and approved by the affiliate's senior manager. The QA Director/Manager must have sufficient expertise in the field of quality to enable him/her to direct the entire QA function in close adherence to the 18 criteria as well as the Pacific Nuclear and affiliate QA manual (when one is established).

The affiliate quality assurance program and any supporting manual and implementing procedures are approved by the affiliate's senior manager.

Responsibility for development of quality acceptance requirements, inspections, and NDE activities rest with the affiliate QA Director/Manager. It is also his/her responsibility to delegate and evaluate the performance of all quality assurance related tasks for the affiliate, through the authority of the affiliate's senior manager.

It is delineated in writing through the affiliate's quality assurance director/manager that designated QA personnel have the authority to prevent the continued processing, fabrication, installation or delivery of unsatisfactory work.

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

Affiliate production/operations responsibilities include scheduling of in-service inspection and administration of fabrication activities, within each affiliate and at each affiliate's qualified suppliers. Shipping and receiving activities are also the responsibility of production/operations, but may be performed along with the procurement activities.

On-site activities such as waste processing, in-service inspection, field erection, and etc. are administered as a joint effort between affiliate production/operations and engineering personnel and other involved affiliates of the company. The affiliate QA department supports these activities with written procedures that provide methods, process controls and check points. Inspection personnel perform monitoring activities and verification of regulatory, contractual and technical requirements during these operations.

The affiliate QA director/manager, other QA personnel and/or other organizations utilized by the QA organization, are fully qualified for their quality assurance responsibilities. Qualification records are maintained in the affiliate's quality assurance records file.

Criterion 2, Quality Assurance Program

Pacific Nuclear has established a QA program that has been implemented within its operating affiliates, for the control of quality in the design, fabrication, operation and maintenance of storage containers for nuclear products and services to nuclear utilities.

Quality of design, documentation, procured products, finished products, delivered services, plus the affiliate and company's reputation are the responsibility of every employee. Orientation of each employee emphasizes this concept. All personnel in each affiliate are provided with controlled copies of the QA program manual or have direct access to a controlled copy and are required to adhere to it's requirements in applicable activities. The main

precept of the QA program implemented in each affiliate, is that quality muststart with the design idea and proceed all the way to the final product or service, to assure complete adherence to regulatory and contractual criteria of the nuclear industry.

To this end, training and/or evaluation of personnel qualifications are required for all QA and quality related functions in accordance with written procedures and are approved by the affiliate QA Director/Manager.

These procedures provide for developing and retaining qualification and training status records for affiliate QA personnel and supplier/contract QA personnel, as appropriate. These records are maintained in the affiliate's QA personnel records file, under the control of the affiliate QA director/manager.

Qualification and training records include, where appropriate; diploma(s), a resume', certifications, test scores, work performance evaluations, and other related information attesting to the an individual's QA related expertise and capabilities.

The qualification and training data are updated and evaluated biannually. Additional individual training, orientation and/or schooling may be specified by the affiliate QA director/manager when justified by impending changes in personnel assignments, regulatory requirements or contractual applications.

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

The identification of characteristics important to safety is based upon the details of "Topical and Safety Analysis Reports" produced in accordance with regulatory and contractual requirements. Items important to safety are identified in the topical and safety analysis reports. The appropriate "Topical and Safety Analysis Report" and drawings are referenced on applicable design and fabrication drawings.

The affiliate's senior manager regularly evaluates the QA program for adherence to the 18 criteria of the appropriate standards and regulations (i.e. 10CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ASME/ANSI NQA-1 and others) in scope, implementation, and effectiveness via internal audits as delineated in Criterion 18 below. Further, the affiliate's senior manager requires that the QA Program, including the QA Manual policies and procedures, are implemented and enforced incident with applicable affiliate programs (see Criterion 16 below).

During design development, disagreements pertaining to acceptability of material, hardware or operation selection and/or criteria, are resolved by the affiliate's senior manager. After final design approval, a Material Review Board (MRB), with representatives from Engineering (where appropriate), Procurement, Production/Operations, Document Control and Quality Assurance is established to disposition discrepancies or disagreements pertaining to the acceptability of material, hardware, processes or operations within the affiliate and at it's suppliers. Their dispositions are final and binding.

Criterion 3, Design Control

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

(a) QA personnel participate in the design development and review processes. This is done to assure adherence to applicable design criteria. The activity includes personnel from engineering, program management, QA and other supporting organizations, as appropriate to the specific design, regulatory and contractual requirements.

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

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

(d) Design documents contain quality assurance requirements for the inspections and tests which assure control, inspection and testing of design characteristics.

(e) Deviations from quality requirements are controlled.

(f) Design verification is performed by quality assurance approved personnel independent of the design activity, but with a skill level at least equal to that of the original design personnel. These verifications may include tolerance studies, alternate calculations or tests. Qualification tests are conducted in accordance with approved test programs and procedures

(g) Selection of the design verification method is based on the regulatory and contractual requirements, the level of design complexity, and "state-of -the-art" considerations (i.e. materials, fabrication processes, etc.) and operating conditions.

(h) When either qualification testing or computer simulation is selected as the design verification method, the "worse-case" design, regulatory, or contract specified conditions are utilized.

(i) Interface control is established and adequate to assure the review, approval, release, distribution and revision of design documents involving interfaces, are performed with cognizant design personnel.

(j) Design checks to confirm numerical accuracy of calculations, validity of computer programs or formulae, basic assumptions, tolerances, material selection and availability, welding criteria, inspectability, etc. are performed by personnel approved by the affiliate QA that are independent of the design activity.

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

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

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

Criterion 4, Procurement Document Control

The QA program assures that all purchased material, components, equipment, and services adhere to design specifications, regulatory and contractual requirements.

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 inspection are all administered and controlled in accordance with approved QA procedures.

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.

PSN QA personnel check procurement documents for complete review and approval by the cognizant organizations in accordance with written QA procedures prior to QA approval.

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 CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ASME/ANSI NQA-1, or other requirements appropriate to the contract.

Material information including grade, type, size, and physical and chemical data requirements is included on procurement documents. Review of the data includes verification of the suitability of standard items for the use delineated on the applicable drawings and design specifications and inclusion of valid industry standards, references, and related data when applicable.

Other documentation, appropriate to the contract such as, requirements and information such as drawings, procedures, material test data and certifications, inspection and test requirements, hold points, welding and other process and personnel qualification requirements are either delineated or verified to be present on procurement documents by the quality assurance personnel.

QA personnel assure that requirements for acceptance of hardware and documentation, such as the affiliate's or a supplier's submittal and retention instructions appropriate to the contract, are included in procurement documentation.

QA 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, Instruction, Procedures and Drawings

QA inspection instructions are developed by qualified Quality Engineers and in accordance with approved quality assurance procedures, for activities requiring design configuration and/or performance verification, witnessing, measurements, testing, audits or other quality assurance related activities. These instructions are approved by the affiliate QA Director/Manager.

All design documents (i.e., drawings, specifications, special processes, test and calibration procedures, etc.) affecting quality are reviewed by affiliate QA personnel and referenced in QA inspection instructions as necessary to assure adherence to package, system or other design approvals and the applicable criteria of 10 CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ASME/ANSI NQA-1, or other requirements appropriate to the contract.

The QA inspection instructions also include appropriate acceptance criteria such as dimensions, tolerances, operating limits, workmanship standards, and other qualitative and quantitative measures.

All instructions, procedures, and drawings are developed, reviewed, approved, utilized and controlled in accordance with the requirements of written quality assurance procedures. (See Criterion 6 below.)

Criterion 6, Document Control

Policy and procedure for review, approval, release and control of revision/change control of quality related documents are delineated in approved QA procedures. These procedures establish review and approval cycles and sequences as well as require that revisions/changes to all such approved documents be subjected to the same approval cycle and sequence. Provisions are provided in the QA procedures for identifying individuals/organizations responsible for review, approval and issuance of documents. Document control responsibilities, facilities and distribution requirements are also addressed. Transmittal sheets with provision for acknowledging receipt are utilized to provide proper records of the transmittal and receipt of controlled document and subsequent revisions/changes.

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 assurance inspection instructions for receiving, in-process, source and in-service inspection
(g) Source surveillance and evaluation reports
(h) Test procedures
(i) Audit reports
(j) Operational test procedures and data.

When a document is to be revised and it has been included in other documents by reference, supplement or exhibit, those documents are revised/changed prior to release of a change to the basic approved change.

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

QA personnel assure that all required support documentation is available at the work area prior to the 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 affiliate's approved supplier lists.

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

(a) The capability of the supplier to comply with the requirements of 10 CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ASME/ANSI NQA-1, or other requirements appropriate to the contract (Quality Assurance).

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

(c) A survey of the supplier's facilities and QA program to determine their capability for supplying a product which meets the design, manufacturing, and quality requirements. (Quality Assurance, Procurement and Engineering)

Results of the supplier evaluations are recorded on Supplier Evaluation Forms which are retained in the QA data files.

Audits are conducted at active supplier's facilities during, but independent of, source inspection activities, to assure continued adherence to the imposed QA, design and contract performance criteria. These audits are conducted at least every three years.

QA 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 the supplier to identify material and specific codes, specifications and/or design requirements pertaining to the fabricated items and procurement specifications not adhered to with justification for "accept-as is" or "repair" dispositions.

QA inspection instructions are prepared and approved by the Quality Assurance for performance of all source, in-process, in-service, test, shipping and/or receiving inspections in accordance with approved design requirements, applicable 10 CFR 72, Subpart G; 10 CFR 71, Subpart H; 10 CFR 50, Appendix B; ANSI N45.2; ASME/ANSI NQA-1 or other criteria, procurement document requirements and contract specifications. (Also see Criterion 5, above)

Receiving inspection, appropriate to the contract's requirements, is performed by affiliate QA personnel, to assure the following:

(a) The material, component, or equipment is properly identified, refers to applicable codes, standards and specifications and corresponds with the identification on receiving documentation.

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

(c) Inspection records and/or certificates of conformance are available that attest to the acceptance of materials and components prior to their installation or use.

(d) Documentation pertaining to deviations from procurement requirements including Quality Discrepancy Reports (QDR) and Supplier Disposition Requests (SDR) have been completed in accordance with their prescribed disposition. (Also see Criterion 15, below)

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

Source inspection is performed on those items where verification of procurement requirements cannot be determined upon receipt.

All described activities are delineated in approved QA procedures.

Criterion 8, Identification and Control of Materials, Parts, and Components

A process for identifying and controlling materials, parts, components and completed and in-process assemblies is administered by the QA personnel in accordance with approved 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 are as follows:

(a) Material identification procedures included in QA inspection instructions 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 "important to safety" related requirements specified in applicable topical and/or safety analysis reports, QA personnel assure that identification of materials, components and equipment is verified via alloy overchecks, supplier audits and independent inspections.

(c) Specifications, procurement documentation, fabrication and inspection records, discrepancy reports and material test data are also periodically audited to assure continued adherence to design, regulatory and contractual requirements.

(d) Identification requirements such as method, (i.e. engraving, stamping, stenciling) size, etc. are specified on design and fabrication drawings and reviewed by QA personnel. The review assures adherence to design, regulatory and contractual requirements for legibility, durability and information content. Identification requirements and their inclusion within design/fabrication documents also address traceability to contract and work order numbers and related project specifications via a series of prefix/suffix identifiers. The requirements are delineated in written procedures and are utilized during QA reviews to assure adherence.

(e) QA personnel assure, via drawings and quality inspection requirements, that identification locations do not affect the fit, interface 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.

Criterion 9, Control of Special Processes

Approved QA procedures delineate the policies and practices established to control such special processes as: welding, heat treating, lead pouring, non-destructive examination, waste processing, etc., in accordance with 10 CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ASME/ANSI NQA-1, or other applicable codes, standards, specifications or requirements. Special processes developed by suppliers and/or PNSI are documented, reviewed and approved by QA and other cognizant technical personnel within the company, regulatory or customer organizations. In addition, special process equipment is identified, inspected and performance tested, prior to use.

All procedures for special processes and the personnel required to perform them are qualified under the cognizance of QA personnel, in accordance with applicable codes, standards, specifications and contract requirements. They are subjected to full review and approval cycles and sequences as delineated in "Criterion 3" and "Criterion 6" above, by personnel qualified and approved by the affiliate's QA Director/Manager for the subject matter relating to the special process.

Qualification records and support data are retained in QA data files, and are maintained in a current status by QA personnel.

These documents are controlled in the manner delineated in "Criterion 6" above.

Criterion 10, Inspection

Receiving, source, test, shipping, in-process and in-service inspection activities are performed in accordance with approved QA procedures. Inspection personnel and/or organization qualifications are reviewed and accepted by the affiliate's QA Director/Manager, prior to inspection activity. The inspection activity is performed in strict adherence with approved QA inspection instructions prepared by qualified QA personnel. (also see Criterion 5 above)

QA personnel are independent from all other organizations and report directly to the affiliate's QA Director/Manager.

The qualifications of QA inspection personnel 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, AWS QC1, SNT-TC-1A and affiliate 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 QA inspection instructions.

The inspection instructions, when completed, also include inspection results and supporting information such as variables and attributes data, test results, NDE records, welding information, certified materials test report and/or certification, special process data, discrepancy reports and related MRB dispositions and resultant re-inspection data, etc.

Enforcement of mandatory inspection hold points assures that in-process work does not proceed beyond the point where it can be properly inspected or verified. They also prevent unsatisfactory in-process work quality by specifying hold point buy-off by QA personnel, before further processing.

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

Criterion 11, Test Control

A test control program, as it applies to quality, is addressed by approved QA procedures and assures, via required QA inspection instructions, that 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.

QA personnel assure, whenever possible during review and prior to the release of test procedures, that both "normal" and anticipated "off-normal" operational performance described in applicable design, regulatory and contractual documents are re-created by testing activities.
Changes to test procedures are required to be reviewed/approved by the same organization(s) in the same cycle and sequence 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, QA personnel assure that original or new test inspection instructions are prepared and adhered to as appropriate.

Test results are documented, evaluated and accepted by qualified personnel as required by the test's QA inspection instructions prepared for the test under the cognizance of QA personnel.

Criterion 12, Control of Measuring and Testing Equipment

The program for calibration of measuring equipment and instrumentation is administered by the QA organization, in accordance with approved QA procedures. The calibration process 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. Calibration is performed using equipment traceable to national standards.

Calibrated equipment is identified and is traceable to the calibration test data. Identification includes the equipment property number, next calibration due date and inspector's or calibrator's stamp, attesting to the accuracy and validity of the calibration.

Calibration accuracy is maintained by utilizing standards traceable to the National Institute of Standards Technology (NIST) and have an accuracy that is at least four (4) times greater than the equipment being calibrated, unless limited by current state-of-the-art.

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 subjected to review for possible re-inspection or other appropriate corrective action.

Criterion 13, Handling, Storage, and Shipping

Approved QA procedures require that QA inspection instructions contain verification criteria for handling, storage, and shipping requirements. 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 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 the company, is delineated in approved QA procedures.

These procedures assure that the status indications are clear, inspection and/or test steps are not by-passed, and removal or modification of status indication are prohibited, except with quality assurance department approval/Material Review Board (MRB) disposition. The Quality Assurance Department assures via QA procedure, interoffice memoranda, training sessions, and audit that affiliate personnel are aware of and understand the meaning and

uses of status tags on hardware, material, and test setups. (See also Criterion 15 discussion.)

Criterion 15, Non-conforming Material, Parts or Components

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 (QDRs) and Supplier Disposition Requests (SDRs) are utilized by the company's quality assurance personnel and its suppliers, 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 affiliate's quality assurance director/manager and president/general manager and must be from the same groups approving the original design.

These documents are reviewed by quality assurance personnel to assure that "accept-as-is" or "repair" dispositions include technical justification to indicate and assure continued compliance with design, regulatory and contractual requirements. When appropriate, copies of dispositions are forwarded to the owners and users of the affected equipment.

In conjunction with repair or re-work dispositions, quality assurance personnel provide supplemental inspection planning to verify compliance with 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.

Criterion 16, Corrective Action

Failures, malfunctions, and deficiencies in material, components, equipment and services are identified and reported to the respective affiliate QA director/manager and the president/general manager. A copy of each report is also forwarded to the director, corporate QA for review and analysis. The cause of the condition and corrective action necessary to prevent recurrence is identified, implemented and then followed up to verify corrective action effectiveness.

Analyses of discrepancies are conducted on a continuing basis. These analyses establish quality trends and help to pin-point problem areas in need of corrective action. The analyses, quality trends and related reports are prepared by affiliate QA personnel and presented to the affiliate's president/general manager for review and action at that level. An annual analysis of quality trends is also prepared and forwarded to the affiliate president/general manager. Copies of these reports and analyses are also provided to the director, corporate QA for review and analysis.

Detail requirements for this activity are delineated in approved QA Procedures.

Criterion 17, Quality Assurance Records

A QA records system is established within each affiliate and is administered in accordance with approved QA procedures. The purpose of the QA records system is to assure that documented evidence pertaining to quality related activities is maintained and available for use by company, customer, and/or regulatory agency personnel, as appropriate. QA 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. Each affiliate maintains a complete list of QA records to provide identity and location information.

Design related records such as calculations, drawings, research and development test reports, etc., are retained in the QA records system for the life of the equipment or shipping/storage container. All other quality related records are retained for a minimum of two years, but no more than five years unless otherwise specified by applicable regulatory, code, standard or contractual requirement.

Inspection records retained in the QA 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.

Protection for QA records is provided by using one of the following storage methods:

(a) Two sets of identical records are maintained at separate and equivalent storage locations, with access control, security and protection from fire, flooding and abnormal deterioration; or

(b) The official copies of all QA records are maintained in approved fire-proof files or vault, at a single location.

Criterion 18, Audits

MANAGEMENT AUDITS

Internal QA program audits are performed annually by personnel not under the full time employ of the specific affiliate and without direct responsibilities

in the areas being audited. These audits provide comprehensive, independent verification and evaluation of the implementation of the entire QA system established in response to the appropriate requirements of 10 CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ASME/ANSI NQA-1, and other applicable codes, standards, specifications and requirements.

Written planning sheets and check lists are prepared and utilized by the auditor. At the completion of each audit, the affiliate QA director/manager evaluates the planning sheets and check lists to confirm that the audit effectively addressed all the appropriate QA program elements.

Audit results and corrective action activity are reported to the affiliate QA director/manager and president/general manager in writing, and are retained in the QA records files. Responsible management personnel are required to respond to audit findings with the necessary action to correct the noted deficiencies.

Areas found deficient during these audits are re-audited on a first priority basis to verify corrective action implementation and effectiveness.

SELF AUDITS

The affiliate QA director/manager conducts audits of all quality related functions within the affiliate, on a continuing basis. These audits are performed to assure continued adherence to the 18 criteria of 10 CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ASME/ANSI NQA-1, as well as other applicable codes and standards. These program audits quickly identify and assure correction of any deviations from the prescribed QA program during actual performance.

Written audit check lists are utilized to record the results of these self audits. The affiliate QA director/manager reviews the written audit results with management personnel responsible for the activity being audited.

Required corrective actions are agreed upon by the responsible management personnel and the affiliate QA director/manager, and appropriately carried out. The agreed upon corrective actions are reviewed during future internal audits to verify corrective action implementation and effectiveness.

All the segments of the QA program are audited by this process, during the course of each calendar year.

EXTERNAL AUDITS

Affiliate QA auditors perform annual audits of active suppliers to assure continued adherence to imposed design, procurement and QA requirements.

Written audit check lists are utilized during all supplier audits conducted by affiliate QA personnel.

Written audit results are reviewed with the affected supplier, and appropriate and mutually accepted corrective actions are prescribed. Corrective action implementation and effectiveness is evaluated by affiliate QA personnel as part of subsequent audits to review the supplier for continued approval.

GENERAL

Affiliate and contract audit personnel are certified as QA Lead Auditor in accordance with the experience and expertise requirements of ANSI N45.2.23.

Other affiliate or contract personnel are utilized as members of an audit team, for the conduct of both internal and external audits, when appropriate and beneficial to provide specific expertise or knowledge in an audit area. This assures that the technical areas of an audit are adequately addressed. The selection of supplemental audit personnel is the responsibility of the affiliate QA director/manager and cognizant management personnel.

Audits are scheduled to assure timely performance prior to the need for the related internal or external function. Need is established via projection of upcoming contracts and design, procurement, fabrication, inspection and/or testing phases of existing contracts.

Problem areas established by QA trend analyses reports and previous audits are also utilized to establish future audit priorities.

To assure objectivity, final audit reports and corrective action agreements from both internal and external audits are initially evaluated by the affiliate QA director/manager. After this preliminary evaluation, the cognizant management personnel associated with the audited activities, are consulted for input and response to the audit findings and agreed to corrective actions.

Corrective action may include, but are not limited to; (a) personnel evaluation and training, (b) procedure re-evaluation, (c) changes of enforcement, (d) facility re-design, etc. (See also Criterion 16)

The audit results, agreed to corrective actions, audit trend analysis reports, and any additional information acquired during the post audit evaluation, are forwarded to the affiliate president/general manager for his/her review and action.

References

(a) 10CFR72 Subpart G; "Quality Assurance"

(b) 10CFR71 Subpart H, Criteria 1-18; "Quality Assurance Criteria for Shipping Packages for Radioactive Material".

(c) 10CFR50 Appendix B, Criteria 1-18; "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants".

(d) ANSI N45.2, Criteria 1-18.

(e) ASME/ANSI NQA-1.

(f) Pacific Nuclear Systems, Inc.; "Quality Assurance Program Manual"

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