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10 CFR 72, SUBPART G QUALITY ASSURANCE PROGRAM

FOR

DESIGN AND FABRICATION

OF

CONCRETE STORAGE CASKS

LETTER NUMBER QA-86-2

REVISION 1

FEBRUARY 18, 1987

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APPROVALS		
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INTRODUCTION

Nuclear Packaging, Inc. (NuPac) 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 radioactive shielding, casks, containers, and other structures, systems and components pertaining to Dry Spent Fuel Storage Casks (DSFSC).

The 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.

NuPac QA System and implementing Quality Procedures are designed and administered to meet the requirements of 10 CFR 72, Subpart G, 10 CFR 50, Appendix B and 10 CFR 71, Subpart H. Figure 1 is a matrix delineating the relationship between the 17 NuPac Quality Procedures and the 18 criteria of 10 CFR 50, Appendix B, 10 CFR 72, Subpart G and 10 CFR 71, Subpart H.

USNRC 10 CFR 71, Subpart H QA System Approval Number 0192 was awarded to the NuPac QA System in December, 1978. It was recently re-approved through December 31, 1990.

The following is a synopsis of the current NuPac 10 CFR 72, Subpart G QA System. This is the same basic system utilized on all 10 CFR 71, Subpart H and 10 CFR 50, Appendix B related design, license, fabrication and operation programs at NuPac.

DESCRIPTION OF THE NUPAC 10CFR72, SUBPART G QUALITY PROGRAM

Criterion 1, Organization

Full responsibility for the Quality Assurance (QA) Program adherence to 10 CFR 72, Subpart G criteria rests with NuPac. QA Program activities include calibration of measuring equipment, NDE and materials testing. NuPac surveys and qualifies all organizations performing these services to assure adherence to the 18 criteria prior to their use. All other QA activities are performed by NuPac QA personnel. However, the responsibility of the control of QA in the other organizations continues to rest with NuPac

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

The administrative function includes financial and legal activities.

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

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

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

The NuPac Quality Assurance Department has complete authority and organizational freedom to identify QA problems, establish QA programs, implement corrective action and verify corrective action effectiveness.

Additionally, the Quality Assurance Department is independent from other organizations within NuPac and reports directly to the President of NuPac.

The Quality Assurance Department is headed up by the Quality Assurance Director who is responsible for the development, implementation and administration of the entire NuPac Quality Assurance Program. The Quality Assurance Program, manual and procedures developed by the Quality Assurance Director are approved by the NuPac President. The Quality Assurance Director must have sufficient expertise in the entire field of Quality to enable him to direct the entire QA function in close adherence to the 18 criteria and the NuPac Quality Assurance Manual.

The Quality Assurance Program and supporting manual and procedures developed by the Quality Assurance Director are approved by the President of NuPac.

Responsibility for development of QA acceptance requirements, inspections, and NDE activities rest with the Quality Assurance Director. It is also his responsibility to delegate and evaluate the performance of all Quality Assurance related tasks for NuPac through the authority of the president.

It is delineated in writing through the Quality Assurance Director 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 monitoring of special processes utilizing NuPac equipment, personnel and procedures such as waste processing, field erection, in-service inspections, etc.

Production responsibilities include scheduling of in-service inspection and administration of all fabrication activities, both within NuPac and at qualified suppliers. The shipping and receiving function is also the responsibility of the Production Department but is performed through the Procurement activity.

On-site activities such as waste processing, in-service inspections, field erection, etc. are administered as a joint effort of the operations and engineering personnel of NuPac and other Corporate subsidiaries. The Quality Assurance Department 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 Quality Assurance Director and all other Q ersonnel and/or organizations within, or utilized by NuPac, ar ully qualified for their Quality Assurance responsibilitie . Qualification records are maintained in the NuPac Quality Assurance Record File.

Criterion 2. Quality Assurance Program

NuPac has established and implemented a QA Program for the control of quality in the design, fabrication, operation and maintenance of storage containers for nuclear products.

Quality of design, documentation, procurement, product, services and the reputation of Nuclear Packaging, Inc. (NuPac) is the responsibility of every employee. Orientation of each employee emphasizes this fact. All personnel in the company are provided with controlled copies of the QA Manual or have access to it and are required to adhere to it's requirements in all applicable activities. The main precept of NuPac QA is that quality must start with the design idea and proceed with it all the way to the final product or service to assure complete adherence to the 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 Quality Assurance Director.

These procedures provide NuPac QA Personnel and NuPac supplier and contract QA personnel qualification and training status record forms which are retained in the QA Personnel record file under the control of the Quality Assurance Director.

The data retained in the qualification record includes: diplomas, resumes, certifications, test scores, work performance evaluations and other related data attesting to the individual's QA related expertise and capabilities.

The data is evaluated and updated biannually. Additional training, orientation and or schooling is specified by the Quality Assurance Director when impending personnel assignment changes or contractual or regulatory applications justify it.

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

The President of NuPac regularly evaluates the NuPac QA program for adherence to the 18 criteria of 10 CFR 72, Subpart G in scope, implementation, and effectiveness via internal audits as delineated in Criterion 18 of this synopsis. Further, the President requires that the Quality Assurance System, including the QA Manual Policies and Procedures, be implemented and enforced on all applicable programs at NuPac. (See also Criterion 16, "Corrective Action")

During design development, disagreements pertaining to the acceptability of material, hardware or operation selection and/or criteria are resolved by the president of NuPac. After final design approvals, a Material Review Board, consisting of Engineering, Procurement Production, Document Control and Quality Assurance Personnel has been established to disposition all discrepancies or disagreements pertaining to the acceptability of material, hardware, processes or operations, both within Nupac and at it's suppliers. Their dispositions are final and binding.

Criterion 3. Design Control

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

(a) QA personnel participate in the design development and review process. This is done to assure adherence to all applicable design criteria. The activity includes engineering, program management, QA and other support organization personnel 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 inspections and tests which will 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) Design verification method selection is based on regulatory and contractual requirements, level of complexity of the design and "state-of-the-art" considerations, i.e.: materials, fabrication processes, etc. and operating conditions.

(h) When qualification testing or computer simulation is selected as the design verification method, the worst case or design, regulatory or contract specified test conditions are selected.

(i) Interface control is established and adequate to assure the review, approval, release, distribution and revision of design documents involving interfaces are performed with all 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 NuPac QA approved personnel 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 to prevent recurrence is taken.

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

Criterion 4. Procurement Document Control

The NuPac 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 NuPac QA procedures.

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

The QA department checks procurement documents for complete review and approval by the cognizant organizations in accordance with written QA procedures pertaining to the procurement function prior to QA approval.

Quality Assurance clause sheets are included with all request for quotes and purchase orders. QA personnel assign clauses from the sheets to the procurement document referencing 10 CFR Part 72, Subpart G requirements appropriate to the contract.

Material information including grade, type, size and physical and chemical data requirements is included on the 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 requirements and information such as drawings, procedures, material test data and certifications, inspection and test requirements, hold points, welding and other process qualification requirements and personnel qualifications are delineated, or verified to be present, on the procurement documents by QA personnel as appropriate to the contract.

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

NuPac 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. Instructions, Procedures and Drawings

QA Inspection Instructions are developed for all activities requiring design configuration and/or performance verification, witnessing, measurements, testing, audits or other Quality Assurance related activities in accordance with approved NuPac QA

procedures by qualified Quality Engineers (QE's). These instructions are approved by the Quality Assurance Director.

All design documents, i.e., drawings, specifications, special processes, test and calibration procedures, etc. affecting quality are reviewed by the QA Department and referenced in QA Inspection Instructions as necessary to assure adherence to package design approvals and the applicable criteria of 10 CFR 72, Subpart G.

The QA Inspection Instructions also include acceptance criteria appropriate to the subject matter of the instruction such as dimensions, tolerances, operating limits, workmanship standards, and other related qualitative and quantitative data.

All instructions, procedures, and drawings are developed, reviewed, approved, utilized and controlled in accordance with the requirements of written quality assurance procedures. (Please also see Criterion 6, "Document Control".)

Criterion 6. Document Control

Policy and procedure for review, approval, release and change control of all controlled, quality related documents are delineated in approved NuPac QA Procedures. These procedures establish review and approval cycles and sequences and require that all such approved documents are subjected to the same approval cycle and sequence when revised. 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. Transmittal sheets with receipt acknowledgment provisions are utilized to assure proper controlled document transmittal and receipt records maintenance for original issues and subsequent revisions.

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) QA Inspection Instructions for receiving, source, in-process, in-service, test and/or shipping inspections

(g) Source surveillance and evaluation reports

(h) Test procedures

(i) Audit reports

(j) Operational test procedures and data.

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

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

Quality Assurance Personnel assure that all required support documentation of the correct revision is available at the work area prior to the initiation of the work effort. A system of drawing status indicators such as "controlled", "uncontrolled", Certified for Construction", "Inspection Record Copy", etc., along with status verification steps have been established by the Document Control and Quality Assurance departments to assure correct documentation use.

Criterion 7. Control of Purchased Materials, Parts and Components

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

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

(a) The capability of the supplier to comply with the requirements of 10 CFR Part 72, Subpart G, that are applicable 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 his capability to supply a product which meets the design, manufacturing, and quality requirements. (Quality Assurance, Procurement and Engineering)

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

Annual audits are conducted at active supplier's facilities during, but independent of, source inspection activities to assure continued adherence to NuPac imposed QA, design and contract performance criteria.

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.

Requirements 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 are imposed on supplier as a minimum.

QA Inspection Instructions are prepared and approved by the Quality Assurance Department for performance of all receiving, source, in-process, in-service, test and/or shipping inspections in accordance with approved designs, applicable 10 CFR 72, Subpart G criteria, procurement document requirements and contract specifications. (Please also see Criterion 5, "Instructions, Procedures and Drawings".)

Receiving inspection is performed by NuPac Quality Assurance personnel to determine that the following, as appropriate to the contract, are assured:

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

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

(c) Inspection records and/or certificates of conformance attesting to acceptance of material and components are available prior to use. Audits and/or inspection overchecks are performed by NuPac QA personnel to assure the validity of supplier documentation.

(d) All documentation pertaining to deviations from procurement requirements including Quality Discrepancy Reports (QDR) and Supplier Disposition Requests (SDR) have been completed in accordance their disposition. (Please also see Criterion 15, "Non-Conforming Material, Parts or Components".)

(e) Items accepted and released are identified by inspection status prior to forwarding controlled storage areas or 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 NuPac 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 Assurance Department in accordance with approved NuPac QA Procedures. These procedures address quality status tags, maintenance of material identification and traceability, part identification, and related documentation. Some of the details of these procedures follow:

(a) Material identification procedures included in 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 engraving, stamping, stencil, 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 implementation into design/fabrication documentation 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 NuPac procedures and are utilized during NuPac QA reviews to assure adherence.

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

Criterion 9. Control of Special Processes

NuPac approved QA Procedures delineate the policies and procedures established to control such special processes as: welding, heat treating, lead pouring, non-destructive examination, waste processing, etc. in accordance with applicable codes, standards, specifications, 10 CFR 72, Subpart G criteria and other requirements. Special processes developed by NuPac suppliers and by NuPac are documented, reviewed and approved by QA and cognizant NuPac, regulatory and/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 the Quality Assurance Department 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, "Design Control" and Criterion 6, "Document Control " by personnel qualified and approved by the Quality Assurance Director for the subject matter of the special process.

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

These documents are controlled as delineated in Criterion 6, "Document Control", of this Quality Assurance System description.

QA Inspection Instructions prepared as described in Criterion 5, "Instructions, Procedures and Drawings" and utilized in accordance with Criterion 10, "Inspection " include requirements for witnessing of special processes when applicable and practical or verification via data review after the fact when appropriate. This assures that special processes are performed by qualified personnel using qualified equipment in accordance with written process sheets (or equivalent) with recorded evidence of witness or verification.

Criterion 10. Inspection

All receiving, source, in-process, in-service, test and/or shipping inspection activities are performed in accordance with approved NuPac QA procedures. All inspection personnel and/or organization qualifications are reviewed and accepted by the Quality Assurance Director prior to inspection activity. The inspection activity is performed in strict accordance with approved QA inspection instructions prepared by qualified QA personnel. (Please also see Criterion 5, "Instructions, Procedures and Drawings" discussion.)

NuPac QA personnel are independent from all other organizations and report directly to the Quality Assurance Director.

Quality Assurance Inspection personnel qualifications are based on their capability to perform the required inspection functions in accordance with applicable codes, standards, professional society programs such as the ASQC quality technician certification, AWS QC1, SNT-TC-1A and NuPac training programs. Qualification reviews are performed periodically to maintain personnel proficiency and assure current qualification.

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

The QA inspection instructions, when completed, also include inspection results and supporting information such as variables and attributes data, test results, NDE records, welding information, certified material test reports and/or certifications, 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 buyoff by QA personnel before further processing.

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

Criterion 11. Test Control

A test control program, as it applies to quality, is addressed in approved NuPac 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.

NuPac QA personnel assure, during test procedure reviews prior to release, that, whenever practical, the normal and anticipated off-normal operational performance described in applicable design, regulatory and contractual documents are re-created during the testing activity.

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 QA inspection instructions are prepared and adhered to as appropriate.

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

Criterion 12. Control of Measuring and Testing Equipment

Administration of of measuring equipment and instrumentation calibration is performed by the QA Department in accordance with approved NuPac QA Procedures. The calibration system assures that all standard measuring instruments (SMI) requiring calibration for use 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.

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 Bureau of Standards that have an accuracy that is at least four (4) times greater than the equipment being calibrated unless limited by the 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 submitted to review action for possible re-inspection or other appropriate corrective action.

Criterion 13. Handling, Storage, and Shipping

NuPac approved QA Procedures require that handling, storage, and shipping requirements adherence verification criteria be included in QA inspection instructions. 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 as appropriate.

Shipping documentation preparation, departure, and arrival time and destination data recording is also addressed in the planning, when applicable. The requirements in Quality Assurance 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, NuPac are delineated in approved NuPac 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 Assurance Department approval and Material Review disposition is assured via these procedures. The Quality Assurance Department assures via Quality Procedure, interoffice memoranda, training sessions, and audit that all NuPac 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

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

Quality Discrepancy Reports (QDR) and Supplier Disposition Requests (SDR) are utilized by the NuPac Quality Assurance Department and NuPac suppliers to identify discrepant items, describe the discrepancy, provide disposition and re-inspection requirements. The signatures of authorized cognizant personnel are placed on the QDR/SDR to signify approval of the disposition. These personnel must be approved by the QA Director and President and must be from the same groups approving the original design.

Quality Assurance assures that all "accept-as-is" or "repair" dispositions include technical justification that indicates and assures continued compliance with all design, regulatory and contractual requirements. Copies of all such dispositions are forwarded by NuPac QA to the equipment owner or user.

In conjunction with repair or re-work dispositions, QA personnel provide supplemental inspection planning to verify proper implementation of the QDR/SDR 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 QA Director and the President. The cause of the condition and corrective action necessary to prevent recurrence is identified, implemented and followed up to verify corrective action effectiveness.

An analysis of discrepancies is conducted on a continuous basis. This analysis establishes quality trends and pinpoints problem areas for corrective action. Trends within NuPac and at suppliers are identified and evaluated. The analysis, quality trends and related reports are prepared by the NuPac QA Director and presented to the NuPac President for review, information and action as the President deems appropriate. An annual Quality Trend analysis and summary is also issued to the President.

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

Criterion 17. Quality Assurance Records

A QA Records system is in effect at NuPac and is administered in accordance with approved NuPac QA procedures. The purpose of the QA Record system is to assure that documented evidence pertaining to quality related activities is maintained and available for use by NuPac and its customers, and/or regulatory agencies as applicable. 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. All records are identified by work order number, part number, contract number, or drawing number as appropriate to the record type. A complete list of all quality records is maintained and provides cross reference between the different identity methods described above and pinpoints the record location.

Design related records such as calculations, drawings, research and development test reports, etc., are retained in the QA Records system for the life of the 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 requirements.

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.

All QA records are retained in duplicated, separate and equal storage with access control, fire, flood, deterioration and theft protection.

Criterion 18. Audits

MANAGEMENT AUDITS

Internal QA Program audits are performed annually by personnel not under the full time employ of NuPac and without direct responsibilities in the areas being audited.

These audits provide comprehensive, independent verification and evaluation of the implementation of the entire 10 CFR 72, Subpart G NuPac QA System.

Written planning sheets and check lists prepared by the auditor are utilized. At audit completion, the NuPac QA Director evaluates the planning and check lists to verify that the audit addressed all facets of the NuPac QA system.

Audit results and corrective action activity are reported to the NuPac QA Director and President, in writing, and are retained in the QA record file. 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.

INTERNAL AUDITS

The NuPac QA Director conducts audits of all quality related functions within NuPac on an continuous basis. These audits are performed to assure continued adherence to the 18 criteria of 10 CFR 72, Subpart G and the NuPac QA program. These programmatic audits quickly identify and assure correction of any deviations from the NuPac QA system during its actual utilization.

Written audit check lists are utilized to record the results of the audits. The NuPac QA Director reviews the written audit results with management personnel responsible for the activity being audited.

Any required corrective actions are agreed to between responsible management personnel and the QA Director and implemented as appropriate. The agreed to corrective actions are reviewed during future internal audits to verify corrective action implementation and effectiveness.

The complete NuPac QA program and the 18 Criteria are audited annually in this manner.

EXTERNAL AUDITS

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

Written audit checklists are utilized during all supplier audits conducted by the NuPac QA auditors.

Written audit results are reviewed with the affected supplier. Mutually acceptable Corrective Actions are established as applicable. Corrective action implementation and effectiveness is evaluated by NuPac QA personnel as part of the supplier's continued approval status review via subsequent audits and inspections.

GENERAL

NuPac and contract audit personnel are certified Quality Assurance Lead Auditors, with applicable experience and expertise, who have met all requirements of ANSI N45.2.23.

During Internal and External audits, other NuPac or contract personnel are utilized to supplement the auditors, when required, to provide direct expertise in specific areas of the audit. This assures that the technical adequacies of the areas being audited are properly addressed. The selection of supplemental audit personnel is the responsibility of the NuPac Quality Assurance Director and the cognizant Department Manager.

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

Problem areas established by Quality Trend Analysis 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 analyzed by the NuPac Quality Assurance Director. After this preliminary review, cognizant NuPac management personnel from the activity affected by the audit are consulted for input and response to the audit findings and agreed to corrective actions.

Corrective action may include, but not be limited to: personnel evaluation and training, procedural re-evaluation, changes or enforcement, facility re-design, etc. (Please also see Criterion 16, "Corrective Action".)

After completion of these steps, all audit results and agreed to corrective actions, Audit Trend Analysis reports delineating Quality Trends and QA Program Effectiveness and any additional input resulting from the post audit review are forwarded to the NuPac President. The President reviews the complete audit and supporting data for information and any additional action as appropriate.

References

(1) 10 CFR 72, Subpart G, "Quality Assurance"

(2) 10 CFR 50, Appendix B, Criteria 1-18: "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants".

(3) 10 CFR 71, Subpart H, Criteria 1-18: "Quality Assurance Criteria for Shipping Packages for Radioactive Material".

(4) NuPac/PNSI Corporate Quality Manual

Attachments

Figure 1: "Quality Requirements Matrix - 10 CFR 50, Appendix B and 10 CFR 71, Subpart H, Criteria 1-18 vs. NuPac Quality Procedure Numbers 1-17".

Figure 2: Nuclear Packaging, Inc.: General Organization Chart, Dated 10/6/86.

FIGURE 1

NUPAC QUALITY ASSURANCE MATRIX: 10 CFR VS NUPAC QA PROCEDURE

10 CFR 50, APPENDIX B 10 CFR 71, SUBPART H	. NUPAC QA PROCEDURE
I. ORGANIZATION CHART	QA PROGRAM & ORGANIZATION 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
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 AND VERIFICATION QP16: SPECIAL PROCESS QUALIFICATIONS AND CONTROL
X. INSPECTION	. QP 6: INSPECTION AND VERIFICATION

FIGURE 1 (CONTINUED)

10 CFR 50, APPENDIX B 10 CFR 71, SUBPART H	. NUPAC QA PROCEDURE
XI. TEST CONTROL	. QP 5: QUALITY PLANNING QP 6: INSPECTION AND 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
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

FIGURE 2A:

NUCLEAR PACKAGING, INC.: GENERAL ORGANIZATION CHART, DATED 10/6/86

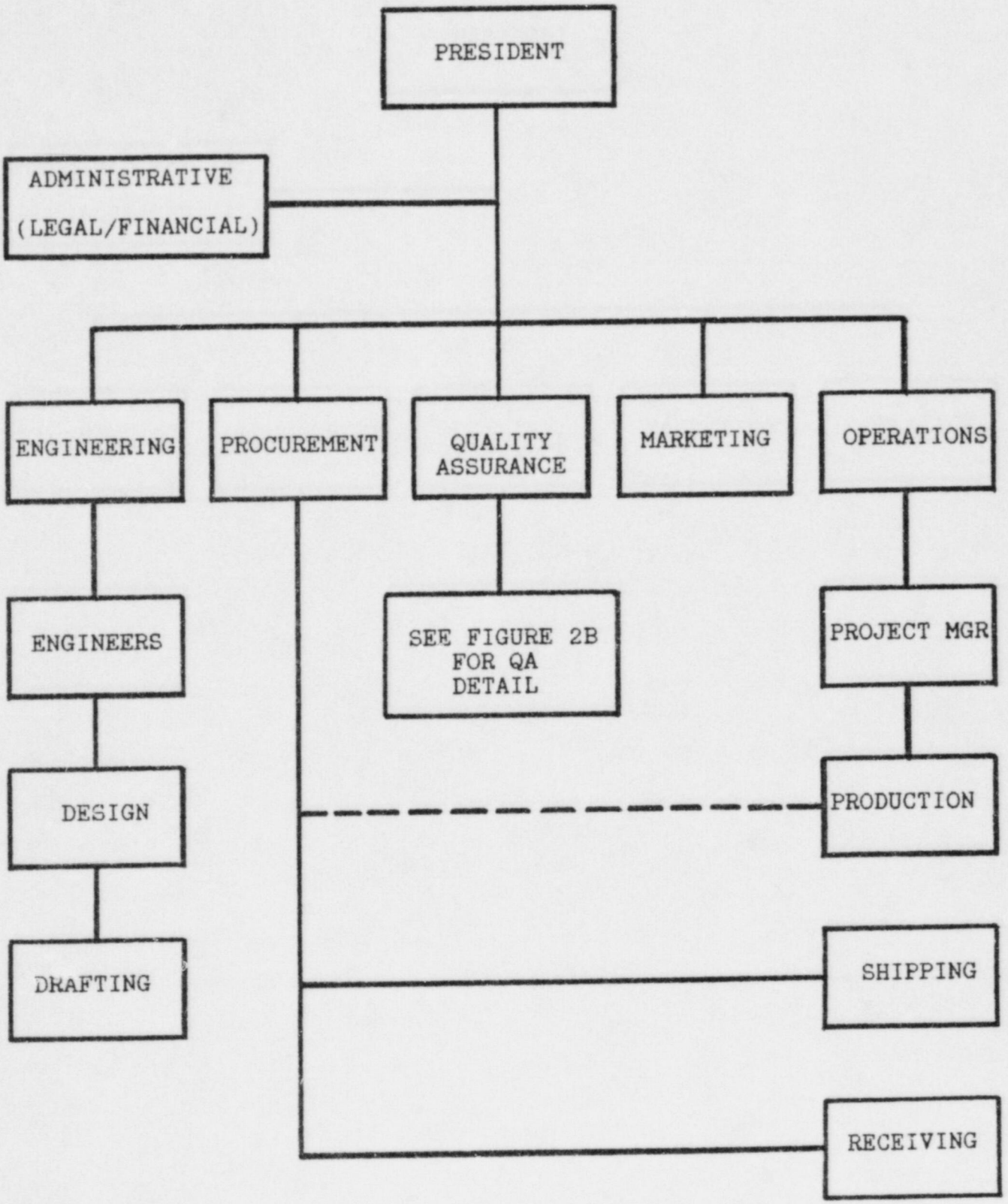
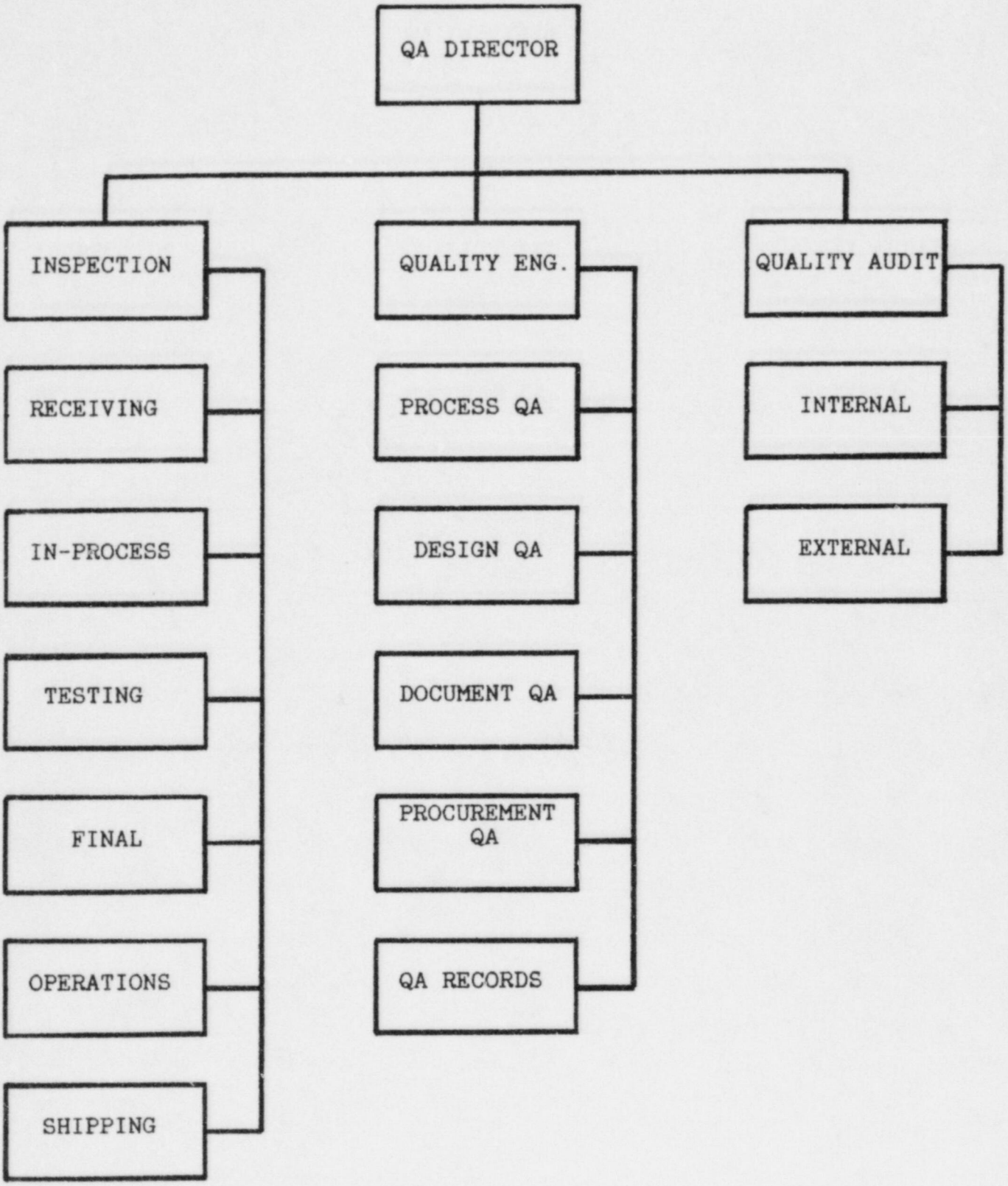


FIGURE 2B,

NUCLEAR PACKAGING, INC.: GENERAL ORGANIZATION CHART: QA, DATED 10/6/86



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