10CFR71 QUALITY ASSURANCE PROGRAM

FOR

SHIPPING PACKAGES FOR IRRADIATED FUEL,
HIGH LEVEL WASTE AND PLUTONIUM

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Revision 1

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APPROVALS

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Initial Issue Revisions	Larry L. Stamen Joe R. Olivadoti	8/8/78 8-8-78
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INTRODUCTION

Nuclear Packaging, Inc. (NuPac) has developed a quality system to assure traceability and control the quality of all materials and processes utilized in the production of radioactive shielding, casks, containers, and other equipment pertaining to shipping packaging for irradiated fuel, high level waste, and plutonium.

The Quality Manual delineates requirements and procedures necessary to exercise control over design, documentation, procurement, material, fabrication, inspection, inventory, shipment and quality data retention.

NuPac Quality System and implementing Quality Procedures are designed and administered to meet the 18 criteria of 10CFR71, Appendix E. Figure 1 is a matrix delineating the relationship between the 17 NuPac Quality Procedures and the 18 10CFR71, Appendix E criteria.

DESCRIPTION OF THE NUPAC 10CFR71, APPENDIX E QUALITY PROGRAM

Criterion 1, Organization

Full responsibility for the Quality Assurance (QA) Program adherence to 10CFR71, Appendix E criteria rests with NuPac. Quality 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 quality activities are performed by NuPac quality personnel. However, the responsibility of the control of quality 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, legal, and marketing activities.

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

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

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

of NuPac. The Quality Department is headed up by the Quality Manager who is responsible for the development, implementation and administration of the entire NuPac Quality Program. He must have sufficient expertise in the entire field of Quality to enable him to direct the entire quality function in close adherence to the 18 criteria and the NuPac Quality Manual. Responsibility for development of quality acceptance requirements, inspections, and NDE activities rest with the Quality Manager. It is his responsibility to delegate and evaluate the performance of all quality related tasks for NuPac through the authority of the president.

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

Production responsibilities include scheduling 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.

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

See Figure 2, "Organization Chart, Nuclear Packaging, Inc."

Criterion 2, Quality Assurance Program

NuPac has established and implemented a QA Program for the control of quality in the design and fabrication of shipping containers for nuclear products. Training and/or evaluation of personnel qualifications are required for all QA functions in accordance with written procedures and are approved by the Quality Manager. The QA Program assures that all quality requirements, engineering specifications, and specific provisions of any package design approval are met. Those characteristics critical to safety are emphasized.

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

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

Criterion 3, Design Control

NuPac 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) Design activity is planned, controlled, and documented.

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

(c) Design documents contain quality requirements.

(d) Deviations from quality requirements are controlled.

(e) Designs are reviewed to assure adequate design verification activities, i.e., stress, thermal, accident analysis, etc., are performed and that design characteristics can be controlled, inspected and tested, and that acceptance criteria are identified.

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

(g) Interface control is established and adequate.

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

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

(j) 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.

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.

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 10CFR Part 71, Appendix E requirements appropriate to the contract. In addition, material information including grade, type, size, special physical and chemical data requirements is included on the procurement documents. Other documentation and information such as drawings, procedures, inspection and test requirements, hold points, welding and other process qualification requirements are delineated on the procurement documents by the Quality Assurance personnel as appropriate to the contract.

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

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

Criterion 5, Instruction, Procedures and Drawings

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

All design documents, i.e., drawings, specifications, special processes, etc. affecting quality are reviewed by the Quality Department and referenced in quality planning as necessary to assure adherence to package design approvals and the applicable criteria of 10CFR71, Appendix E.

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

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. Provisions are provided in the QA Procedures for identification of individuals/organizations responsible for review, approval and issuance of documents. Document control responsibilities, facilities and distribution requirements are also addressed.

Controlled documents include, but are not limited to:

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

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

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

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

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:

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

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

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

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

Quality requirements and standard clauses are added to procurement documents to require suppliers to identify material, provide test reports, control special processes, certify equipment and personnel, etc. Requirements to identify material and specific codes, specifications and/or design requiremetns 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.

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

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

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

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

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

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

All described activities are delineated in approved 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 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:

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

(2) When appropriate, due to contractural or safety related requirements, Quality Assurance personnel assure that identification of materials, components, and/or hardware is traceable to applicable drawings, specifications, procurement documentations, manufacturing, and inspection records, discrepancy reports, and material test data.

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

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, etc. in accordance with applicable codes, standards, specifications, 10CFR71 criteria and other requirements. Special processes developed by NuPac suppliers and by NuPac are documented.

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

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

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

Criterion 10, Inspection

All receiving, source and in-process 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 Manager prior to inspection activity. The inspection activity is performed in strict accordance with approved quality planning prepared by qualified QA personnel (See also Criterion 5 discussion).

Quality Inspection personnel are independent from all other organizations within NuPac and report directly to the Quality Manager.

Inspection personnel qualifications are based on their capability to perform the required inspection functions in accordance with applicable codes, standards, professional society programs such as the ASQC quality technician certification and NuPac 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, variables/attributes recording instructions, reference documentation and other requirements are included in the inspection planning.

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

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. Prerequisities, accept/reject criteria, data recording criteria, instrumentation calibration, environmental conditions, documentation and evaluation requirements, etc. are delineated in the test procedures. Changes to the test procedures are required to be reviewed/approved by the same organization(s) as the original issue.

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

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

Criterion 12, Control of Measuring and Test Equipment

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

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

Criterion 13, Handling, Storage, and Shipping

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

Shipping documentation preparation, departure, and arrival time and destination data recording 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, 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 Department approval/Material Review disposition is assured via these procedures. The Quality Assurance Department assures via Quality Procedure, interoffice memoranda, training sessions, and audit that all NuPac personnel are aware of and understand the meaning and use 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, and equipment that do not conform to requirements are controlled to prevent their inadvertent use. Identification, segregation, discrepancy reporting, disposition of non-conformances by authorized individuals and re-inspection activities are performed and controlled in strict accordance with these procedures.

Quality Discrepancy Reports (QDR) are utilized by the NuPac quality department to identify discrepant items, describe the discrepancy, 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 Quality Manager and President and must be from the same groups approving the original design. In conjunction with repair or rework dispositions, quality assurance personnel provide supplimental inspection planning to verify proper implimentation of the QDR disposition. This assures that the item is retested and/or reinspected 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 Quality Manager and the President. The cause of the condition and corrective action necessary to prevent recurrence is identified, implemented and then followed up to verify corrective action effectiveness. Detail requirements for this activity are delineated in approved NuPac QA Procedures.

Criterion 17, Quality Assurance Records

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

Design related records such as calculations, drawings, research and development test reports, etc., are retained in the Quality Assurance records system for the life of the shipping package. All other quality related records are retained for a minimum of two years, but no more than five years unless otherwise specified by contract.

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

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

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

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

(4) Information related to noted discrepancies.

(5) Inspector or data recorder identification.

(6) Evidence of acceptance.

Criterion 18, Audits

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

REFERENCES

(1) 10CFR71, Appendix E, Criteria 1-18, "Quality Assurance Criteria for Shipping Packages for Radioactive Material".

(2) NuPac Quality Manual, dated May 1, 1978.

ATTACHMENTS

Figure 1: "Quality Requirements Matrix - 10CFR71, Appendix E, Criteria 1-18 vs. NuPac Quality Procedure Numbers 1-17".

Figure 2: "Organization Chart, Nuclear Packaging, Inc."

QUALITY REQUIREMENTS MATRIX

10 CFR VS NuPac

10CFR50, Appendix B 10CFR71, Appendix E	NuPac Quality Manual
I. Organization	Quality Program & Organization Chart QP 1 - Quality Control Manual QP 14 - Quality Assurance 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 and 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 and Services	QP 4 - Procurement Control QP 12 - Material Control
VIII. Identification and Control of Materials, Parts and Components	QP 3 - Document Control QP 12 - Material Control

IX. Control of Special Process	QP 4 - Procurement Control QP 5 - Quality Planning QP 6 - Inspection and Verification QP 16 - Special Process Qualifications and Control
X. Inspection	QP 6 - Inspection and Verification
XI. Test Control	QP 5 - Quality Planning QP 6 - Inspection and Verification QP 15 - Engineering Holds
XII. Control of Measuring and Test Equipment	QP 11 - Calibration Control
XIII. Handling, Storage and Shipping	QP 12 - Material Control
XIV. Inspection, Test and Operating Status	QP 6 - Inspection and Verification
XV. Nonconforming Materials, Parts, or Components	QP 7 - Discrepancy Reporting and Control
XVI. Correction Action	QP 8 - Corrective Action
XVII. Quality Assurance Records	QP 1 - Quality Control Manual QP 9 - Quality Records QP 10 - Quality Forms Control
XVIII. Audits	QP 13 - Audits

EXHIBIT A

ORGANIZATION CHART

NUCLEAR PACKAGING INCORPORATED