STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
Rhode Island Atomic Energy Commission
16 Reactor Road
Narragansett, RI 02882-1165
Telephone # 401-874-2600

January 7, 2019

Docket No. 50-193
License No. R-95

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555-0001

Subject: Response to Request for Additional Information Dated December 26, 2019, Re: Part 71 Quality Assurance Program

Ms. Silva,

This letter and attachments contain the Rhode Island Nuclear Science Center's (RINSC's) responses to the Nuclear Regulatory Commission's request for additional information (RAI) dated December 26, 2018 and a clean copy of the RINSC's Quality Assurance Plan because it was reformatted to match our existing plans.

If there are any questions regarding this matter, please feel free to contact me at (401) 874-2600.

Sincerely,

Cameron Goodwin, PhD, Director
Rhode Island Nuclear Science Center

I certify under penalty of perjury that the representations made above are true and correct.

Executed on: 1/7/2019 By: _____

cc: P Boyle
C Roque-Cruz

Enclosure 1: Responses to Request for Additional Information

Section 2.1 Facility Organization

1. Provide a description of how the current organization provides assurance that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

   All Reactor Operations and Health Physics personnel may perform functions under this QA program as designated by the Facility Director or Assistant Directors. Individuals performing QA functions have the responsibility and authority to stop unsatisfactory work or use of nonconforming materials and have direct access to the Assistant Directors or Director to ensure the accomplishment of quality-related activities. Personnel performing functions under the QA program must also report unsatisfactory work or use of nonconforming materials to the Nuclear and Radiation Safety Committee (NRSC), which acts as an oversight body, independent from the Reactor Operations group.

Section 2.2 Quality Assurance Oversight

1. Please describe the indoctrination program and training requirements for the single individual who will be delegated responsibility of Quality Assurance Manager.
2. Please describe the training requirements, if any, for the individual designated to perform the QA review in the case that the QA manager is unable to perform the review.

   Indoctrination and training shall be included as part of an existing requalification program so that personnel performing quality related activities are trained and qualified to perform these activities. Changes to the QA plan or procedures shall necessitate the retraining and requalification of all individuals involved. The QA Manager will be familiar with the operational procedures, Quality Assurance procedures, and appropriate methods for performing qualitative and quantitative inspections (as required) at operational hold points. An individual designated to perform a QA review in place of the QA Manager will be trained to the same requirements.

Section 16 Nonconforming Materials, Parts, or Components

1. Please describe the program to address nonconforming material.
2. Please explain if nonconformance reports will be developed to document the nonconformance in addition to identifying the nonconformance in the inspection report and who will disposition the nonconforming item.

   RINSC will prepare a nonconformance report documenting the nature of the nonconformance and the quantitative metrics used to identify the issue. The reports will need to be submitted to the package owner for correction. If the nonconformance prohibits the use of the cask, then work must be stopped until the package owner is able to conduct repairs under their QA program. Copies of the procurement and quality assurance documents obtained by the package owner to resolve the nonconformance will be maintained by RINSC as Quality Assurance documents.

Section 17 Corrective Actions

1. Please describe the process to correct any conditions adverse to quality identified by your QAP.

   Conditions that are adverse to quality, such as deficiencies, deviations, defective material and equipment nonconformances shall be promptly identified and not used by RINSC. Non-compliance items shall be returned to the vendor and shall not be used until the vendor provides compliance with applicable regulations. Items of non-compliance shall be reported to the Director or Assistant Directors and to the NRSC.

Section 19 Audits

1. Please describe the training requirements for the individual chosen to perform the audits.

   All Operations and Health Physics personnel will be trained as part of the requalification program and shall also be retrained whenever changes are made to the QA Plan or Procedures.

Rhode Island Nuclear Science Center

Quality Assurance Plan

Revision 7 DRAFT

QUALITY ASSURANCE PLAN

1 INTRODUCTION

The Quality Assurance Plan submitted here is to assist in the handling of shipments of Materials Test Reactor (MTR) low-enriched uranium (LEU) type reactor fuel, and other packages containing Type B quantities of special nuclear material.

The Quality Assurance Program will be the responsibility of the Facility Director at the Rhode Island Nuclear Science Center (RINSC). The transport of all Type B quantities of special nuclear material will be conducted by a licensed carrier. The shipping package will be a Type B package with an approved Certificate of Compliance (CoC). The packages will be on loan from entities such as the Department of Energy or leased from a prime contractor.

The RINSC does not design, fabricate, assemble, or test packages, and does not intend to procure any package for ownership. The RINSC does not intend to rework, repair, maintain or modify the package. The RINSC is ultimately responsible for ensuring that the package conforms to the Certificate of Compliance when acting as the consignor of a shipment of licensed material. Repair and maintenance of the package will remain the responsibility of the package owner.

This QA Program is submitted pursuant to 10 CFR Part 71 Subpart H. Each section of this program is intended to address the requirements of Subpart H that are applicable to the activities planned at RINSC.

Pending approval of this QA program, a record shall be maintained of all changes to this program pursuant to 10 CFR 71.106(c). If no changes have occurred, the Facility Director shall indicate in writing to the Nuclear Regulatory Commission that no changes have been made at least once every 24 months. Additionally, pending approval of this QA Program the RINSC shall notify the NRC in writing prior to the first use of any approved package.

2 QUALITY ORGANIZATION

2.1 Facility Organization

Figure 1 shows the organization chart for the operation of the reactor facility. The Quality Assurance Program will be performed within the Operating Organization required by the RINSC's reactor license. The Nuclear and Radiation Safety Committee (NRSC) will review and approve all written procedures including Quality Assurance Procedures associated with this Quality Program. The Reactor Operations personnel and the Health Physics personnel will have primary responsibility for monitoring all packaging, shipping and receiving activities. All Reactor Operations and Health Physics personnel may perform functions under this QA program as designated by the Facility Director or Assistant Directors. Individuals performing QA functions have the responsibility and authority to stop unsatisfactory work or use of nonconforming materials and have direct access to the Assistant Directors or Director to ensure the accomplishment of quality-related activities. Personnel performing functions under the QA program must also report

unsatisfactory work or use of nonconforming materials to the Nuclear and Radiation Safety Committee (NRSC), which acts as an oversight body, independent from the Reactor Operations group.

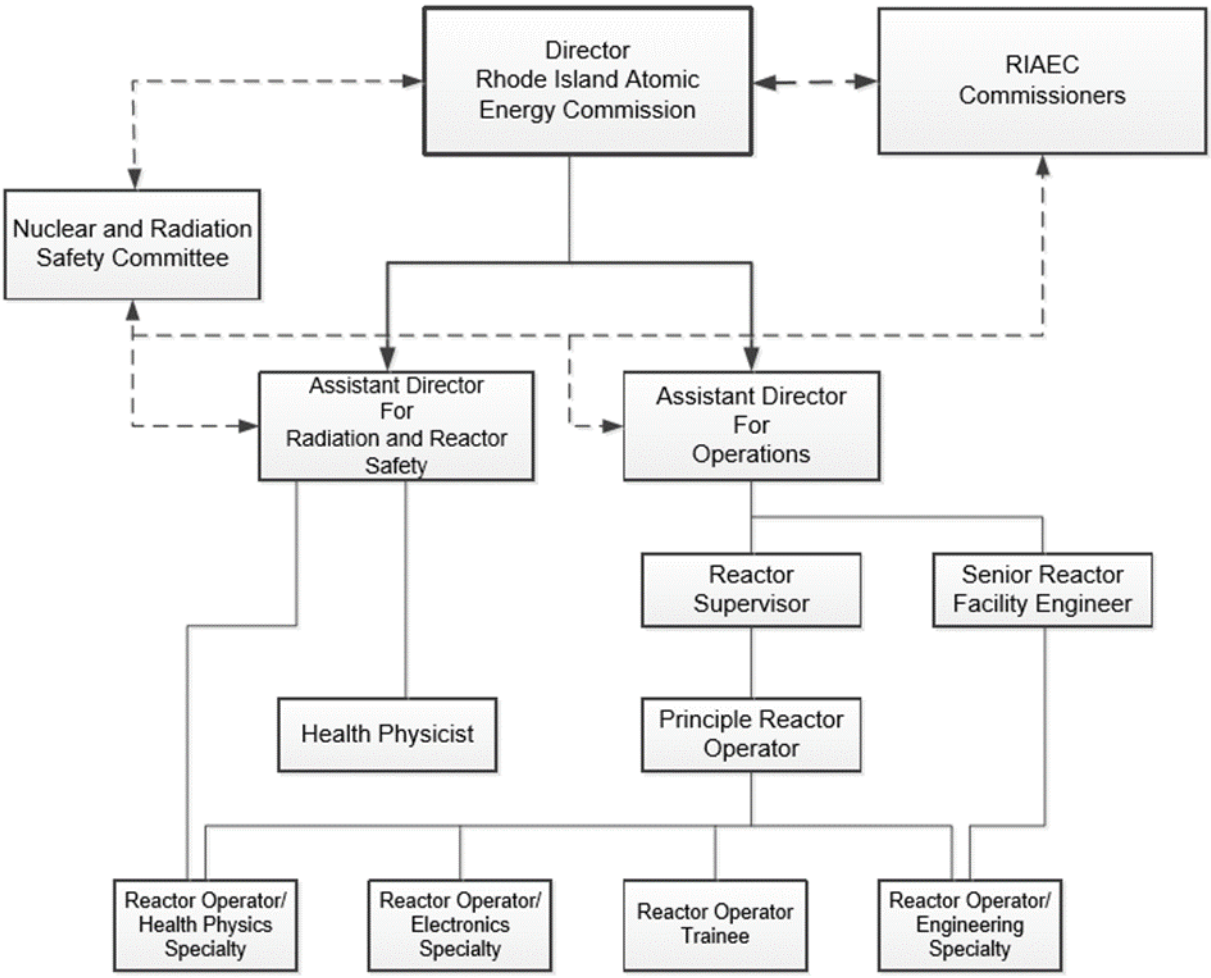

Figure 1: RINSC Organization Chart

2.2 Quality Assurance Oversight

Throughout the activity planned at RINSC a single individual will be delegated the responsibility of Quality Assurance Manager. This individual will have primary responsibility for ensuring that this Quality Assurance Program is implemented, and that the implementation is recorded and documented pursuant to 10 CFR 71.135. The Quality Assurance Manager may not have oversite over the project budget, or ultimate responsibility for the success of the project as this may present a conflict of interest.

The name, title, specific duties, and qualifications of the QA Manager will be documented prior to the start of the planned activities.

The QA Manager has the responsibility and authority to stop unsatisfactory work or use of nonconforming parts. The QA Manager shall have direct access to facility management in order to initiate corrective action.

The QA Manager shall not review the conformance of activities that he or she directly performs. Due to the limited staffing size of RINSC, this may not always be possible. Therefore, in such circumstanced where a QA review is required and the QA Manager is unable to perform the review, he or she may designate another individual who was not involved in the performance of the work to perform the QA review.

The designee of the QA Manager must receive written endorsement from facility management prior to performing a QA function.

Indoctrination and training shall be included as part of an existing requalification program so that personnel performing quality related activities are trained and qualified to perform these activities. Changes to the QA plan or procedures shall necessitate the retraining and requalification of all individuals involved. The QA Manager will be familiar with the operational procedures, QA procedures, and appropriate methods for performing qualitative and quantitative inspections (as required) at operational hold points. An individual designated to perform a QA review in place of the QA Manager will be trained to the same requirements.

3 QUALITY ASSURANCE PROGRAM

3.1 Scope

The scope of this program includes handling, loading, and delivering to a carrier for transport an approved package for the transport of MTR fuel. Specifically, the shipment(s) at RINSC will include:

(a) receipt of empty package
(b) package inspections
(c) package handling
(d) package loading
(e) closing
(f) drying
(g) leak testing
(h) post-loading inspections, and
(i) loading onto vehicle for transport

Quality assurance will be exercised primarily through the use of written procedures, checklists, and internal audits. Applicable portions of the RINSC's Radiation Safety Procedures, specific procedures developed by the owner of the package (e.g. package operating procedures specified in the package Safety Analysis Report), and other procedures developed for the purpose of packaging and transportation planning will be utilized as Quality Assurance Documents. Quality Assurance will be implemented by formatting these procedures as check-lists where possible, or by including QA hold points

within the procedures to be used by the individual assigned the responsibility of QA Manager.

The RINSC Management shall implement an indoctrination program to ensure that the QA Manager is qualified to perform the duties necessary to document the conformance of the planned activities.

3.2 Applicability

This Quality Assurance Program applies to the handling, loading, packaging, and shipping of an approved Type B package to ship irradiated reactor fuel from the Rhode Island Nuclear Science Center. General areas important to safety that must specifically be controlled are:

(a) Ensuring that the package provided is in good working order, and in full compliance with an approved Certificate of Compliance when it arrives from the package owner.
(b) Ensuring the package owner's Quality Assurance Program is sufficient to ensure that the package as-supplied conforms in all respects to the provisions of the QA plan under which it has been manufactured and maintained.
    a. This may be accomplished by the RINSC requesting a copy of a third-party audit (i.e. a NUPIC audit) of the package owner's Quality Assurance Program.
    b. Or by requesting an NRC approval of the package owner's Quality Assurance Program.
(c) Ensuring that the package arrives at the RINSC in a ready-to-use condition by verifying the acceptability of the annual maintenance certificate as provided by the package supplier.
(d) Ensuring that the package handling will be accomplished in a method which will not compromise the integrity or safety of the package.
(e) Ensuring that the package loading is accomplished safely and in accordance with proper loading for transport as described in the package Certificate of Compliance and Safety Analysis Report
(f) Ensuring that the package is assembled, tested, and prepared for transport in accordance with the package Certificate of Compliance, NRC, and DOT regulations for the transportation of irradiated reactor fuel.
(g) Ensuring that the package is delivered to a qualified carrier and is properly secured to the vehicle for transport.
(h) Ensuring that proper en-route safety and security protocols are observed pursuant to NRC and DOT regulations.

3.3 Documentation

The general areas listed above have been identified as important to safety and pertinent to the planned activities at RINSC. Therefore, each of the above listed activities will be subject to a procedure or checklist that verifies the conformance of the activity. These documents will be developed according to 10 CFR 71.11 and maintained as quality

records per 10 CFR 71.135. A master index of all QA procedures and checklists will be developed.

3.4 Controlled Conditions and Assignment of Responsibilities

Activities important to safety will be monitored and controlled by the QA Manager. Additionally, work important to safety will be documented by creating procedures containing QA hold-points to ensure quality is maintained.

The Quality Assurance Manager shall ensure that package testing equipment is properly maintained and/or calibrated prior to use by verifying that the certificates and maintenance records are valid and current. The QA Manager will additionally verify the current training qualifications of any individual performing quality controlled package testing.

Copies of the work procedures with verified QA hold points, as well as calibration certificates will be maintained as Quality Assurance Records.

4 PACKAGE DESIGN CONTROL *(10 CFR 71.107)*

The RINSC must validate that the package was designed in accordance with a NRC approved Quality Assurance Program by requesting a copy of the QA Program approval under which the package was fabricated, and a current copy of the Certificate of Compliance.

5 PROCUREMENT DOCUMENT CONTROL *(10 CFR 71.109)*

No procurement documents are expected to be generated during this use of the package other than the procurement documents for the package itself. Procurement of the package is conducted via contract between the package user and the package owner. For details see section 5.1 below.

5.1 Package Procurement

Specific terms of use of the package will be stipulated in the contract or by memorandum between RINSC and the package owner for use of the package. These contract terms will include, at a minimum:

(a) A copy of the package Safety Analysis Report including all drawings and diagrams
(b) Specify the scope of work intended for the package
(c) Require the package owner to demonstrate that the package conforms to the specifications contained within the Certificate of Compliance (i.e. by providing a valid and signed Certificate of Compliance, and a copy of the most recent package certification inspection and maintenance records).
(d) Demonstrate that the package owner's QA program complies with <u>all sections</u> of 10 CFR 71 Subpart H by allowing the RINSC management to perform a concurrence review on the package owner's QA program insofar as it pertains to this use of the package.

(e) Request that the package owner provide procurement and quality records for any parts or materials procured for the package in relation to its use at the RINSC, as well as the procurement documents for any assembly, testing, maintenance, or repair services performed in relation to this use of the package. A list of the documents to be transmitted should be included in the contract
(f) The package owner will specify the manner and reporting lines for the RINSC QA Manager to report nonconformance issues that must be addressed by the package owner.
(g) All quality documentation generated during this use of the package will be maintained by both the package owner and the RINSC
(h) Testing services required as part of the use of the package (i.e. leak testing) will be specified in the contract. Personnel and equipment necessary to perform this testing must meet the requirements of the package owner's QA program.

The contract or memorandum containing the terms of package use must be reviewed and signed by an authorized representative of the RINSC. This contract will be retained by the RINSC as a quality assurance document.

5.2 Replacement Part Procurement

This section applies only to replacement parts that are necessary during the RINSC's use of the package. This usage period begins when the package arrives at the RINSC in a "ready to use" configuration from the owner, and terminates when the loaded package arrives at the destination facility (i.e. when responsibility for the shipment transfers to the consignee).

Any replacement parts shall be procured by the package owner under the owner's quality assurance program. The package owner shall furnish the RINSC with complete copies of the reviewed and approved procurement records for replacement parts intended for use during RINSC's use of the package. The RINSC Quality Assurance Manager shall review the procurement records supplied by the package owner and verify that they meet the following criteria:

(a) They are signed and certified as being in compliance with the package owner's quality assurance plan
(b) They are identical to the original parts as described in the Safety Analysis Report
(c) The parts were ordered from the original manufacturer previously qualified during package fabrication, or an equivalently qualified manufacturer

Additionally, the package owner shall furnish the RINSC with copies of quality assurance records relating to the installation of any replacement parts on the package. These installation quality records shall be reviewed by the RINSC Quality Assurance Manager.

Procurement quality records supplied by the package owner will be retained by the RINSC as a quality document.

6 INSTRUCTIONS, PROCEDURES, AND DRAWINGS *(10 CFR 71.111)*

6.1 Quality Assurance Procedures

Activities important to safety will be conducted in accordance with their applicable procedures as specified in Section 3.3 of this document. All procedures utilized during this activity must be approved as prescribed in the RINSC Technical Specifications by appropriate levels of facility management and by the NRSC.

The RINSC QA Manager is responsible for coordinating the use of procedures developed according to Section 3.3 above are properly implemented and contain the appropriate inspection and hold points necessary to ensure that the work has been performed satisfactorily.

All procedures governing activities important to safety will include both a quantitative acceptance criteria and a qualitative acceptance criteria.

6.2 Quality Assurance Review

The RINSC QA manager must review and approval all inspection plans, tests, and calibrations as they relate to this use of the package. Approval will be documented by a signature page included with each inspection plan, test, or calibration.

7 DOCUMENT CONTROL *(10 CFR 71.113)*

Control shall be exercised over the documents that are used in this shipping activity. The documents include:

(a) Master document index with revision version and issue date
(b) Receipt inspection procedures,
(c) Cask handling procedures,
(d) Loading and assembly procedures,
(e) Inspection and testing procedures,
(f) Package certification documents,
(g) Radiation survey records
(h) Shipping papers.
(i) Audit records
(j) Nonconformance reports

Document control will be executed via a review and approval process. Changes will be approved via the same process as the original documents.

Documentation revision control will be managed by RINSC's Management, and this responsibility includes ensuring that the current issues are provided to the workers during the planned activities.

8 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES *(10 CFR 71.115)*

Procurement and use of the package itself is described in Section 5 of this document including procurement of leak testing services and equipment required as part of the package license.

Control over services applicable to the use of the packages (e.g. loading, unloading, opening, and closing the package) will be exercised via a contract scope of work, and will, in all respects, be performed in accordance with the operating procedures developed for this use of the cask. The on-site work of service providers is subject to oversight by the QA Manager. Additionally, loading and shipping services must conform to the limits and specifications of the package Certificate of Compliance, as well as the NRC and DOT regulations. Equipment provided by vendors that performs a quality function must be accompanied by a current calibration certificate. Copies of the calibration certificates will be maintained by the QA Manager as a quality record.

Proper loading of the cask will be demonstrated via inspections in accordance with Section 11 of this plan, and adherence to the operating procedures specified in the package SAR. Checklists and QA hold points will be added to the procedures as necessary to provide the QA Manager with confidence that the activities are in conformance with quality requirements.

9 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS *(10 CFR 71.117)*

No materials, part or components are intended to be identified or controlled for this activity. The package should arrive at the RINSC in a “ready to use” configuration, fully assembled.

The package will be inspected for conformance upon receipt and the results of this inspection will be maintained as a quality record.

In the event that a package component is damaged during transit to the RINSC, spare or replacement parts must be obtained from the package owner under the owner’s quality assurance program.

The quality control documents required by the package owner’s Quality Assurance Program for any spare or replacement parts should be furnished to the RINSC and reviewed by the Facility Director or designee prior to those parts being used in a shipment from the RINSC. Copies of the Quality Assurance Documents will be retained by the RINSC along with a complete summary of all parts that were replaced during the contracted package use.

10 CONTROL OF SPECIAL PROCESSES *(10 CFR 71.119)*

No special processes are to be undertaken for this activity.

11 INTERNAL INSPECTION *(10 CFR 71.121)*

Inspections will be conducted by the QA Manager or his or her designee who has been approved in writing by the RINSC quality organization.

Inspections must be conducted according to checklists that contain methods for identifying what characteristics are being inspected as well as methods for identifying a nonconformance. Inspection checklists should incorporate QA hold points with signatory verification to ensure quality is maintained throughout activities requiring a quality review.

Inspection results should be recorded and objectively verifiable.

The following inspection activities will be implemented:

11.1 Receiving Inspections

Checklists with QA hold points will be established to ensure receipt inspections are performed to verify:

(a) Proper package assembly according to the package SAR
(b) External dose rates are congruent with those listed on the radioactive shipping paperwork
(c) Shipping papers are properly completed
(d) Packages are conspicuously and durably marked in compliance with USDOT regulations
(e) Measures are established to ensure that the consignee is present to accept receipt of the package

11.2 Shipping Inspections

Checklists with QA hold points will be established to ensure inspections are performed to verify:

(a) Proper package assembly
(b) Moderators and neutron absorbers are present (if applicable)
(c) Valves are set to specification and to prevent tampering
(d) Shipping papers are properly completed and signed by an authorized individual
(e) Packages are conspicuously and durably marked in compliance with USDOT regulations

11.3 Maintenance Inspections

The RINSC will not perform maintenance inspections, however the most recent maintenance records provided by the package owner as part of the procurement process will be verified during a concurrence review.

11.4 Inspection Documentation

Inspection records will be maintained in accordance with Section 7 of this document.

12 TEST CONTROL *(10 CFR 71.123)*

12.1 Procedures

Measures will be established to ensure that the package owner's design requirements are captured in procedures developed for this activity. Specifically:

(a) Procedures will specify instruments necessary for testing and required calibration interval
(b) Procedures will specify training requirements for technicians performing tests

12.2 Acceptance Tests

Procedures and QA hold points will be established to ensure that acceptance tests are performed prior to offering a package for transport. Tests may include structural integrity, leak tightness, component performance, and shielding and thermal integrity.

These tests will require an independent verification or witness before acceptance.

12.3 Results

Measures will be established to ensure that test results are documented, evaluated, and maintained as QA records. The RINSC Management will determine acceptability of the records.

13 CONTROL OF MEASURING AND TEST EQUIPMENT *(10 CFR 71.125)*

13.1 Calibration Control

Leak testing equipment will be calibrated and maintained as discussed in NRC Regulatory Guide 7.4 "Leakage Tests on Packages for Shipment of Radioactive Material" unless a different acceptable standard is required by the package SAR. Copies of the calibration records should be maintained with the test results as a QA record.

Radiation measuring equipment will be used for this operation. This equipment will be the property of the Rhode Island Nuclear Science Center's Radiation Safety Office. Calibration records for this equipment will be maintained by the Radiation Safety Office as per their existing standard operating procedures.

Additionally, calibrated torque wrenches will be used for cask closure. The torque wrenches will be calibrated with traceable standards, and the calibration records will be maintained by the RINSC QA Manager.

13.2 Out of Calibration Equipment

The calibration of equipment will be verified prior to its use in a safety related activity. If equipment is found to be out of calibration after work is performed, all work performed since the date of the last calibration must be verified.

14 HANDLING, STORAGE, AND SHIPPING CONTROL *(10 CFR 71.127)*

14.1 Preservation

Measures will be established to ensure that cleaning, handling, storage, and shipping are accomplished in accordance with the package design requirements to prevent damage or deterioration by environmental conditions. Provisions for use of special equipment such as cranes or lifting devices will adequately identify and protect package components. Conditions identified in the CoC, as well as NRC and DOT regulations will be adhered to when loading or unloading packaging.

14.2 Preparation, Release and Delivery to Purchaser

Measures will be established to ensure that the following requirements are completed prior to shipping:

(a) Cavities have been adequately dried
(b) All conditions and tests have been completed prior to offering for transport
(c) All USNRC and USDOT requirements have been satisfied prior to offering for transport
(d) All shipping papers have been completed and reviewed for accuracy and completeness

15 INSPECTION, TEST, AND OPERATING STATUS *(10 CFR 71.129)*

A master check-list will be established to track the status of inspections, test, and operating conditions.

16 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS *(10 CFR 71.131)*

Shipping and receiving inspections will be conducted according to Section 11 of this plan.

These inspections will include identification of parts that are unable to meet the specifications listed in the package Certificate of Compliance, and package Safety Analysis Report. Any part that is damaged or unable to perform its intended function as specified in the package CoC or SAR shall be identified in the inspection report and removed from service. The package owner must be immediately notified of any non-conforming parts via the method specified in Section 5.1 of this document.

RINSC will prepare a nonconformance report documenting the nature of the nonconformance and the quantitative metrics used to identify the issue. The reports will need to be submitted to the package owner for correction. If the nonconformance prohibits the use of the cask, then work must be stopped until the package owner is able to conduct repairs under their QA program. Copies of the procurement and quality assurance documents obtained by the package owner to resolve the nonconformance will be maintained by RINSC as Quality Assurance documents.

Nonconforming parts must be clearly labeled and removed from the work area to prevent their inadvertent use. Replacement parts must be obtained from the package

owner. Control over the replacement parts must be exercised in accordance with section 5.2 of this plan.

Additionally, an assessment must be made on whether or not the replacement part has impacted the validity of the CoC, or if the package must be recertified by the package owner. A copy of this assessment, and the new package certification (if necessary) must be retained by the RINSC.

17 CORRECTIVE ACTION *(10 CFR 71.133)*

17.1 Reporting

Causes of conditions that are detrimental to quality will be promptly identified and reported to the RINSC Management. Measures will be established to identify and obtain any corrective action required from suppliers and that corrective actions were implemented and effective.

Conditions that are adverse to quality, such as deficiencies, deviations, defective material and equipment nonconformances shall be promptly identified and not used by RINSC. Non-compliance items shall be returned to the vendor and shall not be used until the vendor provides compliance with applicable regulations. Items of non-compliance shall be reported to the Director or Assistant Directors and to the NRSC.

17.2 Closeout, Retrieval, and Disposition of Records

Measures will be established upon completion of a corrective action to preclude a recurrence. Upon closeout, the QA Manager will identify by function or position the individual or organization responsible for closing out the corrective action and documenting its resolution.

18 QUALITY ASSURANCE RECORDS *(10 CFR 71.135)*

18.1 General

QA records will be generated through all phases of the activity planned for RINSC. These records will be listed in the Master Document Index. At a minimum the following information will be maintained as a QA record:

(a) Procurement records
(b) Supplier evaluations
(c) Nonconformance reports
(d) Results of inspection and tests
(e) Qualification of personnel, procedures, and equipment
(f) Calibration procedures
(g) Training records
(h) Corrective action reports
(i) Records verifying repair, rework, or replacement as supplied by the package owner
(j) Audit plans, reports, and corrective actions

(k) Records documenting changes to the QA Program

The records will provide objective evidence of the activities that affect quality and will contain sufficient detail to readily identify the activities to which they apply. Additionally, the records will contain evidence of package delivery to a carrier and these records must prove that all NRC and DOT requirements have been satisfied.

Inspection and test records will identify:

(a) The observation performed
(b) Show that the tests or inspections were completed
(c) Results test with associated data
(d) Identify any conditions that are detrimental to quality
(e) Names of individuals performing the tests or inspections
(f) Acceptability of results

18.2 Generating Records

Measures will be established to generate and store records such that they are retrievable, intelligible, and reliable. Paper copies of records generated will be stored in secure files. Additionally, documents will be scanned in a pdf format for electronic storage.

18.3 Indexing and Classification Records

Records generated for these activities will be designated as non-permanent and will be retained in accordance with the RINSC Technical Specifications.

In the event that procedures or checklists are superseded, the RINSC will maintain a copy of the superseded material in accordance with the RINSC Technical Specifications.

18.4 Receipt, Retrieval, and Disposition of Records

The records generated by these activities will be maintained by the RINSC in accordance with the RINSC Technical Specifications.

18.5 Storage, Preservation, and Safekeeping

Measures will be established to maintain records for the required period.

19 AUDITS *(10 CFR 71.137)*

19.1 Elements of an Audit Program

Due to the small number of uses of any package an audit will be conducted after each use of a package. An auditor will be appointed by the NRSC or the RINSC Management.

The Audit Program will include the following elements:

(a) Authority to report directly to facility management
(b) Organizational independence
(c) Commitment to adequate manpower, funding, and facilities to conduct the audit

(d) Identification of auditors and their qualifications
(e) Provisions to allow for timely access to facilities, documents, and personnel necessary to perform the audit
(f) Use of procedures and checklists
(g) Methods for reporting audit results to management of both the audited and auditing organizations
    a. Auditors must have access to the level of management that can prescribe corrective action
(h) Method for verifying the effectiveness of corrective action

19.2 Scheduling of Audits

An audit will be performed after each shipment to ensure that elements of the program are in place and that appropriate documentation was generated and maintained.

19.3 Team Selection

Due to the small scope of this activity an independent individual will be chosen that has an understanding of the program and the requirements for compliance. All Operations and Health Physics personnel will be trained as part of the requalification program and shall also be trained whenever changes are made to the QA Plan or Procedures.

19.4 Various Audit Actions

The auditor will meet prior to the audit to discuss scope and objectives and after the audit to discuss findings, clarify facts, and to ensure all appropriate information has been gathered. A report will be generated to identify deficiencies and a response is required to address deficiencies. The auditor will ensure that a schedule for resolving the items identified is presented and that corrective action is implemented.