**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
**WASHINGTON, D.C. 20555-0001**

December 26, 2018

Dr. Cameron Goodwin, PhD, Director
Rhode Island Nuclear Science Center
16 Reactor Road
Narragansett, RI, 02882-1165

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR REVIEW AND APPROVAL OF THE RHODE ISLAND NUCLEAR SCIENCE CENTER PART 71 QUALITY ASSURANCE PROGRAM FOR PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Dear Dr. Goodwin:

By letter dated August 31, 2018, the Rhode Island Atomic Energy Commission submitted an application for approval of a new quality assurance (QA) program under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71. The request is for approval of the Rhode Island Nuclear Science Center's QA program to support shipping of Materials Test Reactor low-enriched uranium type reactor fuel and other packages containing Type B quantities of special nuclear material under the 10 CFR Part 71 general license provisions.

The information identified in the enclosure to this letter is needed to complete the staff's review. We request that you provide this information by January 25, 2018. Inform us at your earliest convenience, but no later than January 11, 2018, if you are not able to provide the information by that date. To assist us in re-scheduling your review, you should include a new proposed submittal date and the reasons for the delay.

Please reference Docket No. 50-193 in future correspondence related to this request. If you have any questions regarding this matter, you may contact Carla Roque-Cruz of my staff at 301-415-1455 or email: Carla.Roque-Cruz@nrc.gov.

Sincerely,

**/RA/**

Patricia A. Silva, Chief
Inspections and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No.: 50-193

Enclosure:
Request for Additional Information

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR REVIEW AND APPROVAL OF THE RHODE ISLAND NUCLEAR SCIENCE CENTER PART 71 QUALITY ASSURANCE PROGRAM FOR PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL, DOCUMENT DATED: December 26, 2018

Docket No.: 50-193

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| **Name:** | CRoque-Cruz | SFigueroa | PSilva |
| **Date:** | 12/12/2018 | 12/12/2018 | 12/ 26/2018 |

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Request for Additional Information
Rhode Island Nuclear Science Center Quality Assurance Program
Facility License R-95, Docket 50-193

By letter dated August 31, 2018, the Rhode Island Atomic Energy Commission submitted an application for approval of a new quality assurance (QA) program under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71. The request is for approval of the Rhode Island Nuclear Science Center's (RINSC) QA program to support shipping of Materials Test Reactor low-enriched uranium type reactor fuel and other packages containing Type B quantities of special nuclear material under the 10 CFR Part 71 general license provisions.

This request of additional information identifies information needed by the U.S. Nuclear Regulatory Commission staff in connection with its review of the draft RINSC, quality assurance program (QAP), Revision 7, dated August 31, 2018.

**Section 2 Quality Organization**

**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.

Under the current organization chart and organization description, it appears that the QAP and RINSC daily operations will be performed within the Operating organization.

This information is needed to determine compliance with 10 CFR 71.103(d).

**Section 2.2 Quality Assurance Oversight**

1. Please describe the indoctrination program and training requirements for the single individual who will be delegated the 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.

Section 2.2, "Quality Assurance Oversight" states, in part, that throughout the activity planned at RINSC a single individual will be delegated the responsibility of Quality Assurance Manager. Further, this section states, in part, that due to the limited staffing size in RINSC it may not always be possible for the QA manager to not be directly involved in a QA activity that he/she will need to review. In this case, the QA manager will delegate another individual to perform the QA review.

This information is needed to determine compliance with 10 CFR 71.105(d)

**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.

Section 16, “Nonconforming Materials, Parts, or Components” states, in part, that any part that is damaged or unable to perform its intended function shall be identified in the inspection report. Section 18, “Quality Assurance Records” states, in part, that at a minimum certain types of information will be maintained as a QA record including nonconformance reports. However, Section 16 only mentions the inspection report and makes no mention of initiating nonconformance reports, dispositioning the nonconformances and documenting the closeout of nonconformances.

This information is needed to determine compliance with 10 CFR 71.131.

**Section 17 Corrective Actions**

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

Section 17.1, “Reporting” states, in part, that conditions that are detrimental to quality will be promptly identified and reported to the RINSC Management. Section 17.1 also states, in part, that measures will be established to identify and obtain any corrective action required from suppliers and that corrective actions were implemented and effective. Section 17.1 does not address how any conditions adverse to quality related to QA activities performed by RINSC will be corrected.

This information is needed to determine compliance with 10 CFR 71.133.

**Section 19 Audits**

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

Section 19.3, “Team Selection”, states, in part, that an independent individual will be chosen that has an understanding of the program and the requirements for compliance. This QAP does not address if only one individual will be trained and selected to perform audits, or individuals will be selected to perform audits and trained at the time of the audit. In addition, this QAP does not address training requirements or regulatory guidance to be used to assure that the audit leader and members (if necessary) are adequately trained.

This information is needed to determine compliance with 10 CFR 71.137.