



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

October 28, 2021

Mr. Andrew Langston
Director, Engineering and Packaging
Services
Orano-Transport Logistics International, Inc.
8161 Maple Lawn Blvd, Suite 480
Fulton, MD 20759

SUBJECT: ORANO-TRANSPORT LOGISTICS INTERNATIONAL, INC. - NRC INSPECTION
REPORT NO. 71-0947/2021-201

Dear Mr. Langston:

This letter refers to the inspection conducted on September 13 to 16, 2021, at the Orano-Transport Logistics International, Inc. (TLI) facility in Fulton, Maryland. The purpose of the inspection was to verify and assess the adequacy of TLI's activities associated with the transportation of radioactive material to determine if they were performed in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," and TLI's U.S. Nuclear Regulatory Commission (NRC) approved Certificate of Compliance (CoC) and Quality Assurance Program (QAP). The inspection scope included management, design, and fabrication controls. The enclosed report presents the results of this inspection.

The inspection examined activities conducted under your NRC approved QAP as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of the applicable CoC. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

No violations of more than minor significance were identified during this inspection.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in cursive script that reads "Francis Peduzzi".

Francis Paul Peduzzi, Chief
Inspection and Oversight Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0947

Enclosure: Inspection Report No. 71-0947/2021-201

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***via email**

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NAME:	JTapp		SFIGueroa*		FPeduzzi*	
DATE:	10/21/2021		10/24/2021		10/26/2021	

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**U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Fuel Management**

Inspection Report

Docket No.: 71-0947

Report No.: 71-0947/2021-201

Certificate Holder: Orano-Transport Logistics International, Inc.
8161 Maple Lawn Blvd, Suite 480
Fulton, MD 20759

Inspection Dates: September 13 - 16, 2021

Inspectors: Jeremy Tapp, Transportation and Storage Safety Inspector, Team Leader
Marlone Davis, Senior Transportation and Storage Safety Inspector
Jon Woodfield, Transportation and Storage Safety Inspector

Approved by: Francis Paul Peduzzi, Chief
Inspection and Oversight Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Enclosure

EXECUTIVE SUMMARY

Orano-Transport Logistics International, Inc. NRC Inspection Report 71-0947/2021-201

This routine inspection evaluated the on-going activities at Orano-Transport Logistics International, Inc.'s (TLI's) facility in Fulton, Maryland related to transportation of radioactive material from September 13 to 16. The purpose of the inspection was to verify and assess the adequacy of TLI's activities associated with the transportation of radioactive material to determine if they were performed in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," and TLI's NRC approved Certificate of Compliance (CoC) and Quality Assurance Program (QAP). The inspection scope included management, design, and fabrication controls.

Based on the results of this inspection, the NRC inspection team assessed that the overall implementation of TLI's QAP was adequate. No violations of more than minor safety significance were identified.

Management Controls

The team concluded that TLI had adequate quality assurance controls and independence related to other activities. The team also determined that TLI conducts its training of personnel and graded approach for important-to-safety (ITS) components in accordance with their NRC approved QAP.

The team concluded that TLI effectively implemented its nonconformance control program and has adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements. The team also concluded that TLI has provisions in place for reporting defects that could cause a substantial safety hazard that could affect the transportation package and its intended safety functions, as required by 10 CFR Part 21. The Part 21 postings in the TLI corporate office met the applicable requirements of 10 CFR Part 21. In addition, the team determined that overall, TLI had an adequate corrective action program (CAP) in place to resolve identified issues. The team determined that TLI, in general, completed corrective actions for identified deficiencies in a technically sound and timely manner.

The team concluded that TLI was effectively implementing its document and records control program and has adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements. The team also determined that TLI's record procedures were adequate for the classification and assignment of retention times for quality records generated by TLI.

The team concluded that TLI had an adequate audit program in place to schedule, develop an audit plan and evaluate applicable elements of their QAP. The team determined that TLI appropriately identified issues and implemented corrective actions, as applicable, in a time frame commensurate with their safety significance when auditors identify findings or observations during audits or surveillances.

Design Controls

The team assessed that overall, TLI had an adequate design control program to develop quality project plans, specifications, calculations, design change notices (DCNs), safety analysis report (SAR) revisions, and drawings by performing the proper quality reviews and approvals with

qualified engineering staff. The team also assessed that adequate implementing procedures were in place and effective in controlling activities in accordance with the applicable regulations and the approved CoC.

Fabrication Controls

The team determined that the material procurement controls were adequate and TLI was effectively implementing their procurement program. In addition, TLI's review and acceptance of the final document package records related to fabrication and assembly, inspection and test, and tools and equipment, including welder and quality control (QC) inspector qualifications, as a part of their implementation of fabrication controls was assessed, overall, to be adequate.

REPORT DETAILS

1. Management Controls

1.1 Quality Assurance Policy

a. Inspection Scope

The team reviewed Orano-Transport Logistics International, Inc.'s (TLI's) Quality Assurance Program Description (QAPD), Revision 3 and various implementing procedures designated as Quality Procedures (QPs) to assess the effectiveness of their Quality Assurance Program (QAP) implementation. The team conducted reviews of TLI's QAP procedures and work instructions to determine whether TLI adequately controlled and implemented activities under their NRC approved QAP and activities subject to 10 CFR Part 71 regulations. The team reviewed procedures to verify if TLI clearly defined and documented the quality program authorities and responsibilities and that the quality assurance organization functioned as an independent group. The team also reviewed procedures for the use of a graded approach for identifying important-to-safety (ITS) components and whether TLI applied this graded quality level to procurement documents. The team reviewed procedures and documents regarding training, qualification, and certification of personnel involved in quality activities. Additionally, the team reviewed training records of a random selection of employees in quality related positions to determine if they received the required QA indoctrination and QA program revision training. The team reviewed the following specific QPs:

- QP-1.0.01, "Organization and Responsibilities," Revision 4
- QP-2.0.01, "Control of the Quality Assurance Program," Revision 5
- QP-2.0.02, "Quality-Related Training," Revision 12
- QP-3.0.07, "Identification of Quality Categories," Revision 5

b. Observations and Findings

The team assessed that TLI had a QAP and implementing procedures in place that were generally effective in conducting activities in accordance with their transportation package Certificate of Compliance (CoC) for the Versa-Pac as well as their NRC approved QAP. The team verified that the QAP authorities and responsibilities were clearly defined and documented, and the quality assurance organization functioned as an independent group. Additionally, the team verified TLI's quality assurance procedures discussed a graded approach for identifying ITS components quality categories. The team also determined that for the sample of TLI staff member training records reviewed that each staff member completed the required training.

No issues of significance were identified.

c. Conclusions

The team concluded that TLI had adequate quality assurance controls and independence related to other activities. The team also determined that TLI conducts its training of personnel and graded approach for ITS components in accordance with their NRC approved QAP.

1.2 Nonconformance Controls

a. Scope

The team reviewed selected records and interviewed personnel to verify that TLI effectively implemented a nonconformance control program in accordance with their NRC approved QAP and the requirements of 10 CFR Parts 21 and 71. Specifically, the team reviewed TLI's approved procedure, QP-15.0.01, "Nonconforming Material, Parts, and Components," Revision 2. The team selected applicable nonconformance reports (NCRs) from the fabrication of the Versa-Pac to verify that the NCRs were identifiable, traceable, and dispositioned in accordance with approved QPs. The team reviewed NCRs since the previous 2016 inspection and concentrated on issues involving ITS components. The team reviewed these NCRs to evaluate if the disposition was appropriate, adequately performed as necessary, and TLI properly closed out the NCR in accordance with QP-15.0.01. The team focused the review on accept-as-is and repair dispositions because generally these NCRs require a technical justification or engineering evaluation.

In addition, the team reviewed TLI's approved procedure QP-15.0.02, "Reporting of Defects and Noncompliance in Accordance with 10CFR21," Revision 5, to determine if provisions were in place for reporting defects that could cause a substantial safety hazard from the NCRs and corrective action reports (CARs) identified. This review also included an assessment of NCRs and CAR logs for deficiencies identified for 10 CFR 71.95 Reports. The team also reviewed the Part 21 posting in the TLI corporate office.

b. Observations and Findings

The team assessed that TLI adequately dispositioned and closed each selected NCR in accordance with the requirements of QP-15.0.01, as applicable. In addition, the team noted that there were no Part 21 reports issued since the previous 2016 inspection.

No issues of significance were identified.

c. Conclusions

The team concluded that TLI effectively implemented its nonconformance control program and has adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements. The team also concluded that TLI has provisions in place for reporting defects that could cause a substantial safety hazard that could affect the transportation package and its intended safety functions, as required by 10 CFR Part 21. The Part 21 postings in the TLI corporate office met the applicable requirements of 10 CFR Part 21.

1.3 Corrective Actions Controls

a. Scope

The team reviewed selected records and interviewed personnel to verify that TLI effectively implemented a corrective action program (CAP) in accordance with their NRC approved QAPD and the requirements of 10 CFR Part 71. The team reviewed TLI's approved procedure QP-16.0.01, "Corrective Action," Revision 2 and the NRC approved QAPD. The team reviewed CARs documented on form 16.01-FM-1 or equivalent since the previous 2016 inspection and concentrated on issues involving ITS components. The team reviewed select records and interviewed personnel to verify that TLI completed corrective actions for identified deficiencies in a technically sound and timely manner. Additionally, the team included a review of TLI CARs associated with the previous two inspections to evaluate how TLI closed the violations.

b. Observations and Findings

The team assessed that TLI had an adequate CAP in place to resolve conditions and, if necessary, significant conditions adverse to quality based on the review of their approved procedure QP-16.0.01. Based on the review of previous violations, TLI entered the conditions adverse to quality into the CAP and resolved the identified deficiencies in a technically sound and timely manner.

No issues of significance were identified.

c. Conclusions

Overall, the team determined that TLI had an adequate CAP in place to resolve identified issues. The team determined that TLI, in general, completed corrective actions for identified deficiencies in a technically sound and timely manner.

1.4 Documentation Controls

a. Scope

The team reviewed TLI's documentation and quality records control program and associated QPs to assess the effectiveness of controls established for the development, review, approval, issuance, use, and revisions of quality documents. The team also reviewed the tracking, verification, and storage of quality records. The team reviewed a sampling of TLI documents and records including instructions, procedures, calculations, design change notices (DCNs), fabrication records as part of a final document package, drawings, and specifications to verify that TLI had developed and was controlling document and record quality related activities. The team reviewed the following QAP, quality procedure, and work instruction documents:

- QAPD, Section 6.1, "Document Control Requirements," Revision 3
- QAPD, Section 17.1, "QA Record Requirements," Revision 3
- QP-0.0.01, "Quality Assurance Program and Quality Procedures," Revision 5
- QP-2.0.02, "Quality Related Training," Revision 12

- QP-4.0.01, "Procurement Document Control," Revision 6
- QP-6.0.01, "Document Control," Revision 6
- QP-17.0.01, "Quality Assurance Records," Revision 5
- WI 03-02, "Design Change Procedure," Revision 6
- WI 03-04, "Drawings," Revision 0
- WI 03-06, "Specifications," Revision 1

In addition, the team interviewed quality assurance personnel regarding documentation and record controls and had TLI demonstrate its electronic document control and quality record management system, designated the Electronic Data Management System (EDMS). The team reviewed samples of the records TLI maintains to document that staff have been trained on new or revised procedures added to the EDMS.

b. Observations and Findings

The team observed that through the EDMS, TLI Business Unit Directors and their document control record management delegate, with support from TLI information technology staff, are responsible for controlling documents and records. Through the EDMS, the current revisions of procedures, work instructions, DCNs, drawings, calculations, specifications, and quality records are controlled electronically. Except for drawings, in general, signatures of preparers, reviewers, and approvers are all added electronically. Working copies of calculations and drawings are kept in an area of the EDMS with access limited to engineering and drafting staff. All obsolete copies of electronic documents are kept in the EDMS with limited access controls.

The team also observed that notification is sent to all affected managers when documents are revised. It is their responsibility to ensure direct reports affected by the change are aware of new revisions using crew briefs or assigning required reading. All documents and records added to the electronic database system are user controlled in that the user of a document is required to verify that they have the latest version before using that document.

The team noted that fabrication quality records are also electronic and put in the EDMS when completed. Quality records for each Versa-Pac being fabricated are associated with a specific Versa-Pac identification number. In EDMS, all the fabrication quality records associated with each Versa-Pac identification number are used to create the final document package.

No issues of significance were identified.

c. Conclusions

The team concluded that TLI was effectively implementing its document and records control program and has adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements. The team also determined that TLI's record procedures were adequate for the classification and assignment of retention times for quality records generated by TLI.

1.5 Audit Program

a. Scope

The team reviewed TLI's audit program to determine if TLI scheduled, planned, and performed internal and external audits and surveillances in accordance with their approved implementing QPs and described in the TLI QAPD. The team selected a sample of audits and surveillances from the last five years, particularly related to transportation activities. The team reviewed the audit results to determine if TLI identified deficiencies and whether TLI addressed these deficiencies within their CAP. The team also evaluated whether TLI provided adequate supervision with quality assurance personnel for appropriate oversight of ITS activities. The team reviewed the following TLI QPs:

- QP-18.0.01, "Audits," Revision 9
- QP-2.0.03, "Qualification of Audit Personnel," Revision 5
- QP-7.0.01, "Control of Purchased Materials, Equipment," Revision 9
- QP-7.0.03, "Surveillance of Activities Affecting Quality," Revision 3

Additionally, the team reviewed applicable procedures and records to determine if individuals performing quality related activities established and maintained training qualifications and certifications. The team selected a random sample of audit personnel records, including lead auditors, to determine if they met the requirements stated in QP-2.0.03.

b. Observations and Findings

Overall, the team assessed that for the audits sampled TLI generally conducted audits with qualified and certified personnel and scheduled and evaluated applicable elements of their QAP. The team noted that TLI identified observations and findings as applicable within the audits and documented as necessary in accordance with the approved QPs.

c. Conclusions

The team concluded that TLI had an adequate audit program in place to schedule, develop an audit plan and evaluate applicable elements of their QAP. The team determined that TLI appropriately identified issues and implemented corrective actions, as applicable, in a time frame commensurate with their safety significance when auditors identify findings or observations during audits or surveillances.

2. Design Controls

2.1 Design Development

a. Scope

The team reviewed the design control section of the TLI QAPD and applicable implementing quality instructions and procedures associated with design control to verify that TLI properly implemented their design control program. The team reviewed design

documents and interviewed selected personnel to verify that TLI had control of all phases of the design process from the onset of the design through the fabrication activities.

The team focused its review on TLI design activities associated with Revision 16 of CoC No. 9342 and Safety Analysis Report (SAR) Revision 12 for the Versa-Pac packaging. The team reviewed the following TLI QAP, quality procedure, and work instruction documents associated with design control:

- QAPD, Section 3.1, "Design Control," Revision 3
- QP-2.0.06, "Qualification of Engineering Personnel," Revision 4
- QP-3.0.01, "Design Control," Revision 5
- QP-3.0.03, "Computer Software Control," Revision 5
- QP-3.0.06, "Project Planning," Revision 6
- QP-3.0.07, "Identification of Quality Categories," Revision 5
- QP-7.0.05, "Dedication of Commercial Grade Items and Services," Revision 7
- WI 03-01, "Preparation and Control of Calculations," Revision 8
- WI 03-02, "Design Change Procedure," Revision 6
- WI 03-03, "Reporting and Evaluating Commercial Computer Code Errors," Revision 4
- WI 03-04, "Drawings," Revision 0
- WI 03-05, "Engineering Instructions," Revision 0
- WI 03-06, "Specifications," Revision 1

The team reviewed the project plan for the design engineering associated with Versa-Pac CoC 9342, Revision 16, to verify it was developed in accordance with QP-3.0.06. The team also reviewed the latest revision of the Versa-Pac component safety classification technical report to determine if the component classifications were compliant with NRC component classification guidance documents for packagings.

The team reviewed a sample of calculations from the CoC Revision 16 project to verify that the calculations were performed in compliance with WI 03-01 and included all the proper initiator, reviewer, and approver signatures and the required reviewer checklists completed. The team also reviewed a sample of the TLI verification and validation calculations used to qualify the commercial grade analysis software programs to verify that the verification and validation calculations were performed in compliance with QP-3.0.03. The team performed personnel interviews regarding the process for finding and evaluating computer code errors identified by the software vendors on their websites and reviewed a sample of the records of this process to verify conformance with WI 03-03 requirements.

The team also reviewed a sample of the Vera-Pac SAR, Revision 12, chapter changes and associated licensing drawing revisions. The team then reviewed a sample of the DCNs initiated to make the licensing drawing changes to verify they were performed in accordance with WI 03-02, including the required review and approval signatures.

In addition, the team reviewed selected drawings, design specifications, and purchasing specifications to TLI's Versa-Pac fabricator to verify the design controls in place between TLI and its fabricator were adequate.

b. Observations and Findings

The team assessed that overall, TLI had an adequate design control program to develop quality project plans, specifications, calculations, DCNs, SAR revisions, and drawings by performing the proper quality reviews and approvals with qualified engineering staff. The team also assessed that adequate implementing procedures were in place and effective in controlling activities in accordance with the applicable regulations and the approved CoC.

No issues of significance were identified.

c. Conclusions

The team concluded that TLI was effectively implementing their design control program.

3. Fabrication Controls

3.1 Procurement Controls

a. Scope

The team reviewed TLI's procurement of ITS materials and services, which included the review of procurement documents, drawings and procedures, and receipt inspection records. The team reviewed the following TLI procedures associated with procurement:

- QP-4.0.01, "Procurement Document Control," Revision 6
- QP-7.0.01, "Control of Purchased Materials, Equipment, and Services," Revision 9
- QP-7.0.02, "Facility Survey Performance for CAT B or C Q Items or Services," Revision 1
- QP-7.0.04, "Receiving Inspection," Revision 5

The procedures were reviewed to verify if they were being properly implemented. The team also reviewed TLI's Approved Suppliers List, Revision 61, to determine if materials and services were being procured from qualified suppliers and the suppliers were being acceptably qualified.

The team selected a sample of qualified suppliers and ITS materials for review. The sample included the Container Products Corporation (CPC) supplier to TLI and Versa-Pac outer drum material.

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

The team determined that the material procurement controls were adequate and TLI was effectively implementing their procurement program.

3.2 Fabrication and Assembly

a. Scope

The team reviewed records associated with fabrication and welding of the Versa-Pac packaging, specifically Versa-Pac serial number 18-004 to verify that the fabrication and assembly processes were properly controlled and implemented. Since TLI contracted the fabrication of the Versa-Pac to the CPC fabrication facility, TLI's responsibility for fabrication and assembly controls resided in part, in the review and acceptance of the final document package for the completed Versa-Pac packaging. Therefore, the team reviewed records that were part of the final document package accepted by TLI from CPC. The records reviewed included Welding Procedure Specification 1100, Revision 8 and Procedure Qualification Records 1101, Revision 5, 1102, Revision 5, and 1103, Revision 2 used in production welding; and the CPC Fabrication Control TLI record (shop traveler) for Versa-Pac 18-004 to verify that fabrication and assembly activities were accomplished and appropriately documented according to the controlled drawings and QPs, including TR-20000-NQA-003, "55 Gallon Versa-Pac (VP-55) Product Specification," Revision 4. The team also reviewed applicable welder qualification and certification records.

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

TLI's review and acceptance of the final document package records related to fabrication and assembly, including welder qualifications, as a part of their implementation of fabrication controls was assessed to be adequate and effective.

3.3 Test and Inspection

a. Scope

The team reviewed records associated with the test and inspection of the Versa-Pac packaging, specifically Versa-Pac serial number 18-004 to verify that the test and inspection processes were properly controlled and implemented. Like Section 3.2 above, the team reviewed records that were part of the final document package accepted by TLI from CPC. The records reviewed included the Visual Weld Report, Magnetic Particle Inspection Reports dated 5/30/2019 and 6/25/2019, Critical Dimension Inspection Report dated 6/19/2019, and CPC Box Weight Record dated 10/10/2019 to verify that test and inspection activities were accomplished and appropriately documented according to the controlled drawings and QPs, including the shop traveler and package specification, TR-20000-NQA-003, Revision 4. The team also reviewed applicable quality control (QC) inspector qualification and certification records.

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

TLI's review and acceptance of the final document package records related to inspection and test, including QC inspector qualifications, as a part of their implementation of fabrication controls was assessed, overall, to be adequate.

3.4 Tools and Equipment

a. Scope

The team reviewed records associated with the measuring and test equipment (M&TE) used during the fabrication of the Versa-Pac packaging, specifically Versa-Pac serial number 18-004 to verify that the use of calibrated M&TE was properly controlled and implemented. Like Sections 3.2 and 3.3 above, the team reviewed records that were part of the final document package accepted by TLI from CPC. The records reviewed included M&TE calibration records for a torque wrench, scale, and magnetic particle testing yoke to verify the equipment was properly calibrated.

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

TLI's review and acceptance of the final document package records related to M&TE as a part of their implementation of fabrication controls was assessed, overall, to be adequate.

4. Entrance and Exit Meeting

On September 13, 2021, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Mr. Andy Langston and other members of the TLI staff. On September 16, 2021, the NRC inspection team presented the inspection results and observations during an onsite exit meeting. Section 1 of the attachment to this report shows the attendance for the entrance and exit meetings.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND INDIVIDUALS INTERVIEWED

<u>Name</u>	<u>Title</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Exit</u>
Jeremy Tapp	Inspection Team Leader	NRC	X	X
Marlone Davis	Inspector	NRC	X	X
Jon Woodfield	Inspector	NRC	X	X
Andy Langston	Director, Engineering and Packaging Services	TLI	X	X
Tom Barron	Designate, Quality Assurance	TLI	X	X
Phil Sewell	Principal Engineer	TLI	X	X

2. INSPECTION PROCEDURES USED

IP 86001	Design, Fabrication, Testing, and Maintenance of Transportation Packagings
NUREG/CR-6407	Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety
NUREG/CR 6314	Quality Assurance Inspections for Shipping and Storage Containers

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

None

4. LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
CAP	Corrective Action Program
CAR	Corrective Action Report
CFR	Code of Federal Regulations
CPC	Container Products Corporation
CoC	Certificate of Compliance
DCN	Design Change Notice
EDMS	Electronic Data Management System
IP	Inspection Procedure
ITS	Important-to-Safety
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report
NRC	Nuclear Regulatory Commission
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
QC	Quality Control
QP	Quality Procedure
SAR	Safety Analysis Report

5. DOCUMENTS REVIEWED

Certificate holder documents reviewed during the inspection were specifically identified in the Report Details above.