NRC FORM 591S PART 1
(10-2013)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER	2 NRC/REGIONAL OFFICE
Robatel Technologies, LLC (RT) 5115 Bernard Drive, Suite 304 Roanoke, VA 24018	Headquarters U. S. Nuclear Regulatory Commission Mail Stop 3WFN 14C-28 Washington, DC 20555-0001
REPORT NUMBER(S) 71-00952/2018-201	

3. CERTIFICATE/QAP DOCKET NUMBER(S)	4 INSPECTION LOCATION	5. DATE(S) OF INSPECTION
071-00952	Roanoke, VA	February 21-22, 2018

CERTIFICATE/QUALITY ASSURANCE PROGRAM HOLDER:

The inspection was an examination of the activities conducted under your QAP as they relate to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your QAP Approval and/or Certificate(s) of Compliance. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☑ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

2 Non-cited violation(s) was/were discussed involving the following requirement(s) and Corrective Actions(s):

See NRC Form 591S Part 2 for a complete description of the non-cited violations.

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
CERTIFICATE/QAP REPRESENTATIVE	Donna Martin, Operations Manager	Donna Martin	4/4/18
NRC INSPECTOR	Earl C. Love	Earl C. Love	4/4/18
BRANCH CHIEF	Meraj Rahimi	Meraj Rahimi	4/6/18

NRC FORM 591S PART 2
(10-2013)
10 CFR 2 201

U.S. NUCLEAR REGULATORY COMMISSION

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1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER:	2. NRC/REGIONAL OFFICE
Robatel Technologies, LLC (RT) 5115 Bernard Drive, Suite 304 Roanoke, VA 24018	Headquarters U. S. Nuclear Regulatory Commission Mail Stop 3WFN 14C-28 Washington, DC 20555-0001
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071-00952	Roanoke, VA	February 21-22, 2018

(Continued)

A. 10 CFR 71.111 Instructions, procedures, and drawings," states, in part, "The licensee, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed."

Contrary to this requirement, RT implementation of certain procurement procedural requirements were not followed. Specifically, scheduling of a supplier audit, assessment of supplier controls with respect to important to safety procurement of spare parts, and annual supplier evaluations.

B. 10 CFR 71.133, "Corrective action," states, in part, "The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition."

Contrary to this requirement, RT corrective action system quality procedure QP-16-01 did not provide sufficient guidance as to how to identify SCAQ, measures to determine the cause of the condition, and the corrective action necessary to preclude repetition.

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	Robatel Technologies, LLC (RT) 5115 Bernard Drive, Suite 304 Roanoke, VA 24018
Licensee/Certificate Holder contact and phone number	Donna Martin, Operations Manager 540-989-2878
Docket No.	071-00952
Inspection Report No.	07100952/2018-201
Inspection Dates(s)	February 21-22, 2018
Inspection Location(s)	Roanoke, VA
Inspectors	Earl Love, Team Leader, Senior Transportation and Storage Safety Inspector Marlone Davis, Senior Transportation and Storage Safety Inspector MRD William Allen, Project Manager, Division of Spent Fuel Management, Spent Fuel Licensing Branch
Summary of Findings and Actions	During the week of February 21-22, 2018, a team of U.S. Nuclear Regulatory Commission (NRC) inspectors conducted inspection activities applicable to the transportation of radioactive material packaging at RT's Roanoke, VA facility. The purpose of the inspection was to assess RT's compliance with the provisions of their approved NRC Quality Assurance Program (QAP) for radioactive material packages, in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 21 and 71 and it's applicable Certificate of Compliance (CoC) No. 71-9365. The inspection team assessed activities related to the design, inspection and testing, procurement, and maintenance of transportation of radioactive material packaging RT-100. Inspection activities were performed based on a review of RT's quality implementing procedures; inspection of selected quality and maintenance documents, records, and drawings; personnel training and qualifications; and interviews with personnel responsible for various engineering and maintenance activities. Based on the results of this inspection, the NRC identified two Severity Level IV non-cited violations (NCV's). Details of the NCV's are described in the attached inspector notes.
Lead Inspector Signature/Date	04/05/2018 Earl Love
Inspector Notes Approval Section Chief Signature/Date	4/6/2018 Meraj Rahimi

Inspection History

On February 12-14, 2013, the NRC performed a team inspection of the implementation of the NRC approved QAP at RT in Roanoke, VA (Agencywide Documents Access and Management System (ADAMS) Accession Number ML13086A197). The inspection activities focused on management and design controls and resulted in violations with regard to RT's control of design information and documents. Based on the results of the inspection, the NRC determined that two Severity Level IV Violations of NRC requirements occurred.

On June 27-28, 2013, the NRC performed a follow-up team inspection at RT (ADAMS Accession Number ML13203A272). The purpose of the inspection was to verify that RT had taken and completed, or was completing, the actions to address the violations. The team determined that, overall, RT had satisfactorily addressed the issues that led to the issuance of the violations.

On November 4-7, 2013, the NRC performed a team inspection of the RT-100 fabrication facility at RI in Rue de Geneve, France (ADAMS Accession Number ML13358A059). The purpose of that inspection was to assess the status of the RT QAP in the areas of quality assurance (QA) program management, package design, and fabrication prior to issuance of the NRC RT-100 CoC. Overall, fabrication activities were in compliance with NRC requirements. However, a violation of NRC requirements was identified. The violation was for not following RT documented procedures with regard to activities affecting quality.

On August 20, 2014, the NRC performed a team inspection at RT (ADAMS Accession Number ML14274A001). The purpose of the inspection was to verify implementation of RT's corrective actions that addressed the violation from the November 2013 inspection. In addition, the team reviewed RT's design/engineering and document controls of the supporting basis for its pending request (at the time) to the NRC to ship activated metal from Rancho Seco in its RT-100 packaging. The inspection team determined that RT, as holder of the RT-100 CoC, had taken responsibility and ownership of the request to ship activated metal in the RT-100 packaging and was conducting the associated activities in compliance with their QAP and that RT had satisfactorily addressed the violation from the November 2013 inspection.

Inspection Purpose

During the week of February 21-22, 2018, a team of NRC inspectors conducted inspection activities applicable to the transportation of radioactive material packaging at RT's Roanoke, VA facility. The purpose of the inspection was to verify the adequacy of activities related to the design, modification, inspection and testing, procurement, repair, and maintenance of transportation of radioactive material packaging RT-100. The inspection team performed these activities based on a review of the quality implementing procedures; inspection of selected quality and maintenance documents, records, and drawings; personnel training and qualifications; and interviews with personnel responsible for various engineering and maintenance activities of the CoC holder, RT. The review focused on the following transportation package registered to RT:

Model	Package	Docket	Certificate / Revision
RT-100	USA/9365/B(U)-96	07109365	71-9365 / Revision 1

INSPECTOR NOTES: AS DESCRIBED BELOW, THE TEAM PERFORMED AND DOCUMENTED APPLICABLE PORTIONS OF 02.02 THROUGH 02.10 OF INSPECTION PROCEDURE (IP) 86001 AND USED NUREG/CR 6314 FOR THE INSPECTION RESULTS

4.1 Management Controls

4.1.1 Quality Assurance Policy

The team of NRC inspectors reviewed how RT performed work under its NRC-approved QAP, Quality Assurance Program Description (QAPD), Revision 0 dated 2012 and various quality implementing procedures. The team verified that the quality program authorities and responsibilities were clearly defined and documented, and the quality assurance organization functioned as an independent group. At the time of the inspection, the team noted that RT had not reported QAPD, Revision 1 and 2 changes that were being implemented. Specifically, QAPD revision 1 change occurred in November 2014. At that time and prior to implementation, all changes made to quality assurance programs required approval by the NRC.

In September of 2015, the NRC issued a letter (ADAMS Accession No. ML15247A541) describing changes made to Title 10 of the *Code of Federal Regulations* (10 CFR), Part 71 regulations. Among the changes described was a new regulation, 10 CFR 71.106, that requires changes to Part 71 quality assurance programs, that do not reduce commitments, be submitted to the NRC every 24-months. In December 2017, the NRC issued a letter (ADAMS Accession No. ML17360A007) informing RT that the NRC had not received a biennial change report as required by 10 CFR 71.106. Additionally, the letter requested that RT submit the required report by January 31, 2018 in accordance with the requirements in 10 CFR 71.1(a). Contrary to this and at the time of the inspection, RT had not submitted the required information. Upon discovery, RT entered this issue into their corrective action system for resolution as CAR 2018-22. The inspectors determined that the discrepancy constituted a violation of minor significance that is not subject to enforcement action in accordance with Section IV of the Enforcement Policy. This is in part because the QAPD changes were minor administrative changes that did not reduce the effectiveness of RT's QA program and that RT's organization chart and quality organizational structure, responsibilities and authorities for activities affecting quality were adequately defined.

Overall, RT continues to perform activities related to RT-100 package in accordance with its CoC and Safety Analysis Report (SAR), Revision 6, as well as its QAPD, Revision 2 and quality implementing procedures. The inspection team noted that as part of RT's corrective actions, RT submitted a 24 month period QAPD change report. The report concluded that there were no QAPD reductions in commitments to the previously approved program.

4.1.2 Nonconformance and Corrective Action Controls

The team reviewed a sample of nonconformance records and interviewed selected personnel to evaluate how RT implemented their nonconformance control program. The team reviewed completed nonconformance reports (NCRs) to evaluate if RT identified nonconforming items concerning materials, parts or components in accordance with applicable requirements. The inspectors reviewed nonconformance and corrective action reports (CARs) from the previous five years. The team focused the review on use-as-is and repair type dispositions to evaluate

how RT technically justified the NCR. The team also discussed the NCRs and CARs with the RT staff. The team used the following quality procedures to review the NCRs and CARs:

QP-15-01, "Nonconforming Items," Revision 6
QP-16-01, "Corrective Action System," Revision 4

The team determined that RT effectively implemented its nonconformance control program and have an adequate procedure in place to ensure compliance with the applicable regulations and approved QA Program requirements. The team also assessed the implementing quality procedure QP-16-01, "Corrective Action System," Revision 4. The team noted that QP-16-01 provides guidance for identifying conditions adverse to quality and significant conditions adverse to quality (SCAQ). However, the implementing procedures did not provide guidance on a root-cause analysis program to determine the root causes of failures or rework events associated with SCAQ. Specifically, the team identified that RT corrective action implementing procedure QP-16-01 did not provide guidance to determine the cause of SCAQ, and the corrective action necessary to preclude repetition of an SCAQ as described in the RT QAPD, Revision 2. The procedure lacked specific guidance that described systematic methodology that RT personnel could use to identify the causes of SCAQ, how to address extent of condition and extent of cause, and corrective action taken to address and preclude repetition such that there is a corrective action for each root and contributing causes.

The team determined that this was a violation of NRC requirements. Specifically, 10 CFR 71.133, "Corrective Action," states, in part, that the licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality are promptly identified and corrected. In the case of a SCAQ, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of SCAQ, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management. Contrary to this requirement, RT's corrective action system quality procedure QP-16-01 did not provide sufficient guidance as to how to evaluate the cause of SCAQ conditions, and the corrective actions necessary to preclude repetition. The inspectors determined that this violation was more than minor because if left uncorrected it could prevent RT from being able to take appropriate action on safety-significant activities. The team dispositioned the violation in accordance with Section 2.3 of the NRC Enforcement Policy. The team characterized the finding as a Severity Level IV non-cited violation. The NRC plans to treat the NRC identified finding as a non-cited violation consistent with section 2.3.2 of the NRC Enforcement Policy. RT entered this issue into their corrective action system for resolution as CAR 2018-23.

Part 21 Requirements

The inspection team reviewed Part 21 Procedure QP-15-02, "10 CFR 21 Requirements," Revision 3, to evaluate if provisions were in place for evaluating deviations that could cause a substantial safety hazard and complete the required notification in a timely manner. The inspectors requested a list of Part 21 evaluations and notifications associated with the RT-100 transportation packaging cask and interviewed personnel to verify if they were familiar with the implementing procedure QP-15-02. The team also reviewed RT posting of Part 21requirements in accordance with the 10 CFR 21.6, "Posting requirements".

The inspection team determined that RT has provisions in place for evaluating deviations and reporting defects, as required by 10 CFR Part 21. The team noted that RT did not have any

Part 21 reports within the last five years. The team did notice that RT did not have the most recent version of the 10 CFR Part 21 posted in the spare parts storage room.

4.1.3 Documentation Controls

The team reviewed RT's documentation control program to assess the effectiveness of controls established for the approval, issuance, revision and use of quality documents. The team reviewed QP-06-01, "Control of Robatel Technologies, LLC Documents," Revision 6.

Detailed instructions on controlled documents including planning, preparing, reviewing, approving, filing and distributing were documented in Administrative Procedure RT-AD-01-03 "Control of Robatel Technologies, LLC Documents."

The team verified that RT approved the quality documents per procedure by appropriate personnel and the most current version was available for use. The team observed RT's use of an electronic records management system. The team noted personnel were knowledgeable of the program requirements and were implementing it as required. The team also verified a sample of controlled documents in the system to ensure that the latest revision was available. Additionally, the team reviewed QP 17-01, "Quality Records," Revision 5.

The team discussed how RT personnel implemented the applicable regulatory and procedural requirements for quality record control. Specifically, the team discussed how RT personnel stored the quality documents and how long they retained these documents. Overall, the team evaluated that RT implemented its document control program, including quality record control, as required by the applicable regulatory and procedural requirements. The inspection team determined that the procedures provided adequate guidance for the processing of quality document approvals, revisions, and distribution of newly issued documents. The team noted that RT controlled the use in accordance with the applicable requirements.

4.1.4 Audit Program

The team reviewed the RT audit program to determine if RT scheduled, planned, and performed internal audits in accordance with approved implementing procedures. Specifically, the team reviewed QP-18-02, "Internal Audits" and QP-18-01, "Lead Auditor Qualifications". The team selected internal audits from the last four years, particularly related to transportation activities. The team reviewed the audit results to determine if RT identified deficiencies and addressed the deficiencies with their corrective action program.

Overall, the inspection team determined that for the internal audits sampled; RT generally conducted audits with qualified and certified personnel, and schedules and evaluates applicable elements of their QA program. The team noted that some of the observations identified as a result of the internal audits met the definition of a finding as described in QP-18-02. As stated in this quality procedure, a finding is a discrepancy that violates quality assurance, technical or administrative requirements. The team noted that if RT captures these observations as findings, then according to QP-18-02, RT shall document those findings on a corrective action report.

4.2 Design Controls

The RT-100 package is a mature design. Since 2013, there has not been any new orders placed for this system which would require new fabrication. In January 30, 2015, as supplemented on March 5 and May 21, 2015, RT submitted an amendment request to revise

the CoC for the Model No. RT-100 package. The basis of the amendment was to revise the shielding analyses, gas generation analyses as well as analyses associated with the lead shielding to address stresses associated with fabrication of the lead shielding and the performance of the lead shielding during hypothetical accident conditions, to allow the transport of material which has undergone "gross" dewatering, to allow additional leak testing methods, and to update operational procedures as appropriate. The staff determined that the CoC changes did not affect the ability of the package to meet the requirements of 10 CFR Part 71. Subsequently, CoC, Revision 1 was issued that incorporated the changes. Since that time there have been no new design changes or design modifications to the package.

The inspection team reviewed the design control section of the RT QAP and the RT implementing procedures that address design controls to verify they were being properly implemented at RT for the RT-100 package design. The team specifically reviewed the following procedures associated with design control:

CG-EN-PR-201, "Design Control," Revision 1
CG-EN-PR-202, "Preparation and Checking of Engineering Documents," Revision 1
CG-EN-PR-203, "Calculations," Revision 1

The inspection team determined that all the current design control related procedures contained adequate steps, detail, and the required independent reviews to ensure proper quality and to adequately implement the design control portion of the RT QAP.

4.4 Maintenance Controls

4.4.1 Maintenance Activities

Currently, there (4) RT-100 cask systems in service, of which, RT is responsible for performing maintenance on an annual basis. Further, maintenance activities are performed by a RT audited and approved vendor, Engineered Products Division (EPD) a division of NFT, Carlsbad, NM and records are maintained at RT's corporate facility in Roanoke, VA.

The team reviewed selected records and interviewed personnel to verify that RT effectively implements a maintenance control program in accordance with their NRC approved QAP, CoC conditions, and the requirements of 10 CFR Part 71 for the transportation of radioactive material. The team performed a review on maintenance activities related to the RT-100 packaging for a period of five years for model numbers 2 and 4. The team evaluated annual maintenance activities conducted at various maintenance facilities. The evaluation included a review of maintenance requirements identified in the Safety Analysis Report (SAR) and CoC, inspection and maintenance procedures, completed maintenance records, and personnel and qualification training records.

The team reviewed the following quality and maintenance implementing procedures:

QP-14-01, "Inspection, Test and Operating Status Control" Revision 3

2014-017-PR-MT-007, "Annual Maintenance Procedure for Transport Cask Model RT-100," Revision 1

2013-015-PR-CB-003, "Periodic and Maintenance Leak Test Procedure for Transport Cask Model RT-100," Revision 2

Based on a review of the maintenance records and procedures, the team assessed that RT used appropriate maintenance materials, tools and equipment to conduct the annual maintenance activities for the RT-100 packaging cask. The team verified that the inspections were comprehensive and met acceptance criteria for tests identified in the maintenance records and procedures. The team assessed and verified the results of the visual weld inspection and helium leakage rate testing of the RT-100. The team verified that RT appropriately inspected attributes of the cask body, impact limiters, and lids. The team also verified that maintenance personnel and technicians recorded the proper information on the applicable forms and data sheets as defined and required in the RT quality and maintenance procedures. The team determined that the maintenance tests satisfied the requirements identified in the RT-100 SAR and CoC.

Procurement Controls

The inspection team reviewed selected RT-100 maintenance and procurement records to verify that the procurement specifications for materials, equipment, and services was performed in support of maintenance in accordance with SAR requirements. The team specifically reviewed the following procedures associated with procurement control:

QP-04-01	"Procurement Documents," Revision 6
QP-04-03	"Commercial Grade dedication," Revision 3
QP-07-01	"Supplier Control," Revision 3
QP-07-02	"Approved Supplier List," Revision 3
QP-07-03	"Supplier Document Review," Revision 2

The team reviewed the procurement documents specific to RT-100 spare parts available for use during cask maintenance. The team reviewed RT purchase order No. 75 dated February 2015, issued to RI, Genas, France. Five (5) of nine (9) spare parts itemized in PO 75 were designated as important-to-safety, category A (ITS-A) components and were traceable to procurement specifications, standards, and acceptance criteria including inspection and test records for acceptability. The team reviewed records to verify that various ITS-A commercial grade dedication plans (O-ring seals, lid bolts and threaded inserts) and associated activities performed by RI and received by RT met design requirements. The team noted RT's receipt inspection was based on a review of RI's documentation, as well as, visual conformance to specified requirements. All components were adequately stored in a locked cabinet and contained traceable identification markings.

The team noted that RT subcontracts maintenance services on the RT-100 Class B waste shipping cask to EPD a division of NFT. NFT, Golden, CO, specializes in processing, handling and storage of radioactive nuclear waste. EPD, Carlsbad, NM, a subsidiary, is a metals fabrication company primarily engaged in the manufacturing of specialty and commercial vessels and structural items.

The team reviewed RT's audit program to determine if RT scheduled and performed internal and external supplier audits in accordance with approved quality procedures. Specifically, the team reviewed RT's procedures associated with audits:

QP-18-03	"Supplier Audits," Revision 5
QP-18-04	"Internal Audits," Revision 2

The inspection team reviewed RT's triennial audits of RI, Genas, France (SA-2016-03 performed Sep 6-9, 2016) and EPD (SA-2014-04 performed Oct 28-30, 2014). The team verified that the audits were comprehensive, contained a detailed checklist, evaluated elements of 10CFR Part 71 Subpart H, QA programs, and were conducted by qualified and certified auditors and that adequate CAs were taken.

The team assessed that RT effectively implemented its procurement control program and have an adequate procedure in place to ensure compliance with the applicable regulations and approved QAP requirements. The team noted that QP-18-03 defines RT's responsibilities for scheduling, preparing, conducting and reporting results of audits performed at a supplier's facility, as well as, the conduct of annual supplier evaluations. However, the team noted that 90 day grace period for re-audit of a vendor (EPD) was past due, RT's audit of a supplier (RI) excluded an assessment of procurement control activities associated with RT-100 cask system procurement of ITS-A spare parts, and annual supplier evaluations were not performed.

The inspection team determined that this was a violation of NRC requirements. Specifically, 10 CFR 71.111 "Instructions, procedures, and drawings," states, in part, that the licensee, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. Contrary to, RT's implementation of certain procurement activities was inadequate such that certain conditions within RT's procedure were not followed. The team characterized the finding as a Severity Level IV non-cited violation. The NRC plans to treat the NRC identified finding as a non-cited violation consistent with section 2.3.2 of the NRC Enforcement Policy. RT entered this issue into their corrective action system for resolution as CAR 2018-24.

Control of Measuring and Test Equipment

The team reviewed the control of measuring and test equipment (M&TE) procedure to evaluate how RT identified, specified, and controlled tools and equipment in accordance with applicable standards and regulatory requirements. Specifically, the team reviewed QP 12-01, "Control of Measuring and Test Equipment," Revision 2. The team selected a sample of the M&TE used during the annual maintenance of the RT-100 cask. The sample included a review of travelers that identified pressure gages, torque wrenches, a light meter, and thermometer. The team also reviewed the calibration reports to verify calibration dates, testing standards, and traceability of the associated M&TE.

Overall, the inspection team determined that RT established controls of M&TE in accordance with standards and regulatory requirements. The team assessed that RT maintenance and operation personnel provided the appropriate information on work travelers in accordance with approved procedures. The team verified that personnel used M&TE within their rated capacities and sensitivities as documented in the annual maintenance work package. The team noted that outside vendor performed the actual calibration of torque wrenches, and helium leak-rate equipment. The team found the M&TE program to be adequate with no concerns.