

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER: Robatel Technologies, LLC 5115 Bernard Drive; Suite 304 Roanoke, VA 24018		2. NRC/REGIONAL OFFICE Headquarters U. S. Nuclear Regulatory Commission Mail Stop 3WFN-14C28 Washington, DC 20555-0001	
REPORT NUMBER(S) 71-0952/2013-202			
3. CERTIFICATE/QAP DOCKET NUMBER(S) 71-0952	4. INSPECTION LOCATION Roanoke, VA	5. DATE(S) OF INSPECTION June 27-28, 2013	

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 violation(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.

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

- 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	Teo Grochowski, Jr.		7/22/13
NRC INSPECTOR	Robert R. Temps	By email for	7/22/2013
BRANCH CHIEF	Eric J. Benner		7/22/13

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	Robatel Technologies LLC 5115 Bernard Drive, Suite 304 Roanoke, VA 24018
Licensee/Certificate Holder contact and phone number	Mr. Teo Grochowski, Jr. 540-989-2878
Docket No.	71-0952
Inspection Report No.	71-0952/2013-202
Inspection Dates(s)	June 27-28, 2013
Inspection Location(s)	Roanoke, VA
Inspectors	Rob Temps, Team Leader, Senior Safety Inspector Pierre Saverot, Senior Project Manager Jon Woodfield, Safety Inspector
Summary of Findings and Actions	The team reviewed corrective actions taken by Robatel Technologies (RT) for a Notice of Violation (NOV) issued as a result of a program inspection conducted by the NRC in February 2013. The team assessed that, overall, RT has satisfactorily addressed the issues that led to the issuance of the NOV. Most corrective actions have been completed and the team assessed that for those actions still in process, achieved completion of the actions will fully address the underlying issues. During the review of new and revised procedures, the team identified some new observations to Robatel personnel and management and Robatel is taking satisfactory actions to address these observations through their corrective action program.
Lead Inspector Signature/Date	By email for Robert R. Temps <i>Jon W. Woodfield 7/22/2013</i>
Inspector Notes Approval Section Chief Signature/Date	<i>[Signature]</i> 7/22/13

Background and Inspection History

Robatel Technologies (RT) was granted an NRC 10 CFR Part 71 Quality Assurance Program (QAP) Approval in early 2012 as a prerequisite to its plans to submit an application for a new Type B radioactive material packaging called the RT-100. To date, RT has submitted an application for a Certificate of Compliance (CoC) for the RT-100 packaging design. RT plans to fabricate the new packagings at Robatel Industries (RI) located in Lyon, France. Packaging fabrication has commenced at risk pending NRC issuance of a CoC.

RT's QAP submittal was reviewed in March 2012 at their Roanoke facility and the Part 71 QAP Approval was granted soon thereafter. From February 12-14, 2013, the NRC performed an inspection at RT's Roanoke facility to assess RT's compliance with 10 CFR Parts 21 and 71. The focus of the inspection was to determine whether RT's activities were in accordance with their NRC-approved QAP. The inspection activities focused on management and design controls. The inspection report for the February 12-14, 2013 inspection was issued on March 27, 2013 (ML13086A197). Based on the results of the inspection, the NRC determined that two Severity Level IV Violations of NRC requirements had occurred. The violations were cited in a Notice of Violation (NOV) and the circumstances surrounding the violations were described in detail in the inspection report. RT was required to respond to the NOV and did so by letter to the NRC dated April 30, 2013. In the letter addressing the NOV, RT provided the reason for each violation, the corrective steps that had been taken, the results achieved, the corrective steps to be taken to avoid further violations, and the dates when full compliance was planned to be achieved.

Inspection Purpose

The purpose of this follow-up inspection was to verify that RT has taken and completed, or is completing, the actions to address the violations as discussed in their NOV response letter. Details of the NOV are listed below:

- A. 10 CFR 71.111, "Instructions, procedures, and drawings," states, in part, that "the applicant for a Certificate of Compliance (CoC) shall prescribe activities affecting quality by documented procedures of a type appropriate to the circumstances and shall require that these procedures be followed."

Contrary to the above:

1. The NRC determined that calculations, drawings, and other design documentation for the RT-100 packaging were not being controlled in accordance with RT's document control Quality Procedures (QPs) and that the QPs did not adequately prescribe how these activities should be controlled. Specifically, the NRC identified that various documents were stored informally on individual RT employee electronic storage devices and computers or by paper copies in individual employee offices. The NRC identified that design documents provided to various RT employees by contractors were not being formally reviewed, approved, and released within RT's document control system for proper distribution and revision control. Lastly, the NRC identified that an informal document receipt form was being used for some documents, but the form was not approved.

2. RT QP-03-03 states that the RT Engineering Manager shall ensure that formal documented reviews of the design results shall be planned and conducted at appropriate stages of design and that records of such reviews shall be maintained. The NRC determined that while such reviews were conducted by RT's design subcontractors, no representative from RT attended these reviews and therefore RT did not document the details of the reviews and their results.
- B. 10 CFR 71.107, "Packaging design," states, in part, that "the applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces."

Contrary to the above, the NRC identified that QP-03-01 does not provide any guidance for the turnover or acceptance by RT of design documents developed by an approved subcontractor. Specifically: 1) there are no controlled forms in the QP for RT personnel to document the review and acceptance of design documents developed by an approved subcontractor, 2) there is no direction in the QP for identifying and tracking open items from in-house or subcontractor design activities, and 3) there is no direction for transmitting design activity results to other organizations, or the transmittal of design activity documents to document control.

Inspection Details

The team inspected the following areas that were addressed by RT's corrective actions to the NOV.

Nonconformance Controls

One of RT's corrective actions to the NOV was to develop a new procedure, QP-15-03, "Review of Supplier Nonconformance Reports," to address the NRC concern that RT had no formal process in place to process supplier non-conformance reports sent to them under contract requirements. The team reviewed the new QP-15-03 and noted that it provided adequate instruction to RT personnel on the process for entering and processing vendor supplied nonconformance reports (NCRs). However, several observations were made with regard to the QP as well as RI generated NCRs.

Terms and definitions in QP-15-03 were not consistent with some terms and definitions used in QP-15-01, "Nonconforming Items," Revision 2 as well as the RT QAP Manual. Form QP-15-01-01, "Nonconformance Report," contained an "other" disposition block without this term being defined in the QP. QP-15-03 did not address the criteria to be imposed on vendors/suppliers for when NCRs must be sent to RT for review/approval. The team discussed with RT personnel that the general industry practice is that all NCRs are sent for information purposes, but those with a disposition of repair or use-as-is may require certificate holder approval depending on what threshold has been set in the contract and project specification documents. RT referred the team to the purchase order (PO) issued to RI for packaging fabrication (PO Number 0024). Section 15 of the PO contained clauses that addressed reporting of RI identified NCRs to RT. In reviewing the clauses, it was not clear to the team when RI would be required to submit

NCRs to RT for approval and on further review; RT personnel agreed that the PO requirements were not clear. The team was able to review several NCRs that the RT project manager had in his possession for current fabrication (at risk) of the RT-100 packagings at RI. The NCRs had not been formally entered into RT's documentation system as they had been sent informally to the project manager. The team identified some NCRs that they considered should probably have been sent to RT formally for review and approval. The team noted as well that the RI NCR form used terms not compatible with RT's NCR categories such as a combined repair/rework category. Repair is a separate process from rework and generally requires development of a repair plan and approval by the certificate holder of the proposed repair activity.

These observations were discussed with RT QA personnel and management and two corrective actions reports (CARs) were issued. One CAR was written to address actions by RT to review their internal procedures for consistency and to place guidance in QP-04-01, "Procurement Documents," for a standard procurement clause to clarify reporting of NCRs by suppliers/vendors to RT. The other CAR was written to have RI address concerns with the format of their NCR form when used for RT fabrication and to require that all NCRs be submitted to RT; further, all use-as-is and repair disposition NCRs will be submitted to RT for their review and acceptance. RT also planned to review all NCRs generated to date for RT-100 fabrication for consistency in how the NCRs were being dispositioned. The team considered these actions by RT to be appropriate for the stated observations and of low safety significance since fabrication efforts are still early in the process, are being done at risk, and RT's corrective actions will address future NCRs as well as those already generated but not sent formally to RT.

Documentation Controls

The team reviewed the following RT document control QPs that had been revised since the February 2013 inspection, and a new document control administrative procedure. These included:

QP-06-01, "Document Control – Control of Robatel Technologies, LLC Documents," Rev. 1

QP-17-01, "Quality Assurance Records – Quality Records," Rev. 2

RT-AD-01-03, "Control of Robatel Technologies, LLC Documents," Rev.0

The team interviewed the same RT individual as from the February 2013 inspection assigned responsibilities for maintaining documents in RT's Document Control (DC) system.

The team determined that the revised QPs in combination with the new administrative procedure should provide adequate direction to DC personnel, and other RT employees, in the control of all RT-100 project documents. The team determined that form QP 06-01-02, used for receipt acknowledgement of controlled QPs, had been corrected and that the receipt form was now being properly returned to DC. The team did identify a concern with QP-06-01 in that it was stated that DC was to determine if a change to a document was major or minor and if minor, the document did not require the same review and approval as the original document. The team considered that the determination was not an appropriate responsibility of DC and RT wrote CAR-2013-08 to address and correct the issue. Going forward, the project manager will work with DC to determine the appropriate classification of major versus minor change.

The team verified through discussions with the DC individual that all calculations, drawings, and other design quality documentation for the RT-100 project were now stored in a locked fire proof file cabinet with controlled access and that a backup system for these documents was in place. The team verified that all the RT-100 quality documents were now contained on a Master List

with adequate processes in place for RT employees to check documents in and out from DC and to get copies from DC as needed.

The team determined that since the February 2013 inspection, RT established an email address specifically dedicated to DC for the receipt of all quality documents from all design/engineering sources. The team also determined that all the revised and new design control QPs that are used to develop design documents or review/change forms, now had specific direction to forward all quality documents directly to RT DC for logging in the Master List.

Overall, the team assessed that the DC function was much improved from the February 2013 inspection with more detailed procedures and controls in place. RT has made substantial improvements in addressing the deficiencies noted in the NOV against 10 CFR 71.111 requirements.

Design Development

The team reviewed the following RT quality procedures that had been revised since the February 2013 inspection, two new RT QPs and a new administrative procedure. The procedures were all associated with design controls or project organization.

- QP-03-01, "Design Control – Design/Calculation Documentation," Rev. 2
- QP-03-02, "Design Control – Software Validation," Rev. 1
- QP-03-03, "Design Control – Technical Review," Rev. 2
- QP-03-04, "Design Control - Design Change Control," Rev. 0
- QP-05-02, "Instructions, Procedures and Drawings – Drawings," Rev. 2
- QP-07-03, "Control of Purchased Materials, Equipment and Services - Supplier Document Review," Rev. 0
- QP-08-01, "Identification and Control of Material, Equipment and Services - Robatel Technologies LLC - Identification and Control of Material, Equipment and Services," Rev. 2
- RT-AD-01-02, "Preparing a Project Plan Document," Rev. 0

The team also interviewed RT's project manager for the RT-100 project as well as the project manager for design engineering subcontractor Enercon Federal Services, Inc (EFS).

The team reviewed the Project Plan Document for the RT-100 Type B Cask that had been prepared since the February 2013 inspection in accordance with new administrative procedure RT-AD-01-02. The team determined that the Project Plan was written in accordance with the procedure and contained important information on the project scope, involved organizations, individual responsibilities, schedule, and quality procedures. The team assessed the Project Plan to be adequate when combined with the two new QPs for describing the interfaces and required coordination between the design organizations.

During the February 2013 inspection, RT was cited for violations against 10 CFR 71.107 for not having any guidance or procedures for the turnover or acceptance by RT of design documents developed by an approved subcontractor. The team reviewed new QP-07-03 that has been developed by RT to address this issue. The new procedure provides direction for having subcontractors submit documents to RT DC only and not to individuals. By procedure, DC is required to log all incoming documents for acceptance review. With the RT-100 Project Manager's direction, DC will then disseminate the document with an official review form 07-03-01, "Supplier Document Review," to the proper RT employee for technical acceptance review.

After the technical review, the document will go through a Quality Assurance and Project Manager review. At all three review levels, the reviewer has three options: to accept the document as is, accept the document with comments, or reject the document. If the document is accepted with or without comments, a copy of the completed review form is sent back to the originating organization and the original is kept in document control with the accepted document. If the document is rejected, the originating organization must make corrections and re-submit it. DC is required to track all documents requiring review through to review completion after initially logging them in. The team assessed that the new procedure adequately addresses the design control issues cited in the February 2013 inspection NOV against 10 CFR 71.107.

Another issue noted from the February 2013 inspection and NOV against 10 CFR 71.107 was the lack, by RT, of identifying and tracking open items identified on subcontractor submitted calculations. The team verified that a data base has been created in DC for logging and tracking all previous open items. RT DC personnel stated that a written procedure did not currently exist for tracking open items but an official written open item procedure was planned to be developed in the short term. The team considered this acceptable as currently there were no new calculations being developed at the time of the inspection. RT stated that the new open item procedure will be in place prior to design calculations being revised to address NRC requests for additional information generated during the NRC technical review of the RT-100 design submittal.

The team reviewed new QP-03-04 and found that it provided a very structured approach for the review of any design changes to the RT-100 packaging. The procedure contains a design change request (DCR) form QP-03-01-02 that provides for a formal review with individual signoffs by project principals justifying the desired change and noting the impact on supporting design documents. The form has a section for documenting the impact the design change may have on licensing documents and the need for NRC approval of the design change. DC assigns an initial number to the DCR for logging and tracking, and upon completion, files the DCR and all associated documents in DC. The team assessed the procedure to be adequate for controlling design changes, identifying design documents affected by a design change, and performing a licensing review of the design change to determine if NRC approval is required. At the time of the inspection, no DCRs had been written for the team to review so actual implementation of the requirements could not be assessed.

An issue cited in the NOV against 10 CFR 71.111 was that the RT Project Manager (PM) was not conducting formal design reviews for the RT-100 project as required by QP-03-03. RT subcontractors RI and EFS were conducting design reviews but RT personnel were not attending and documenting the review meetings as required by the procedure. DC personnel stated that for the design reviews that had previously taken place for the RT-100, RT obtained copies of the minutes/report of the meetings from RI and EFS and placed the records in DC. The current RT PM for the RT-100 project stated that going forward he would attend all required formal design review meetings and document discussions, results, and action items from the design review meetings. The team assessed that documenting past design review meetings and the commitment by the current RT-100 PM to attend and document future design review meetings was an acceptable means to address the violation against 10 CFR 71.111.

Just as for Document Controls, the team found RT Design Controls to be improved from the February 2013 inspection with more detailed procedures and controls in place. For Design Controls, RT has also made substantial improvements in addressing the issues noted in the NOV against 10 CFR 71.111 and 10 CFR 71.107 requirements.