



ROBATEL
technologies

April 30, 2013

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

and

Mr. Eric Benner, Chief
Rules, Inspections and Operations Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: Reply to a Notice of Violation;

- o Mr. Eric Benner letter dated 27 March 2013 transmitting U.S. NRC Inspection Report No. 71-0952/2013-201; and
- o Robatel Technologies, LLC QA Program Docket 71-0952 Rev 0.

Dear Mr. Benner:

I am writing in response to the referenced Notice of Violation (NOV) dated 27 March 2013 which was received by U.S. Postal Service on 2 April 2013. The NOV followed an audit by your staff of Robatel Technologies, LLC NRC approved QA program #0952.

On detail review following notification of the audit findings, we concur with the audit team's assessment including the two (2) violations. In the attachment to this letter we provide detailed information on our corrective actions as well as their status as of the date of this letter.

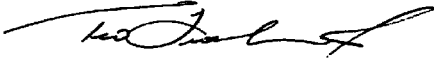
I would also like to clarify two items referenced in your communication. The first, in the body of your letter, refers to Robatel Technologies, LLC functioning as a "...pass through entity with regard to design activities." This is not accurate. Robatel Technologies is chartered to be a design engineering firm and functions as such. I will return to this reference as part of our response to one of the NOV's. The second item relates to a reference to our corporate lineage made in Section 1.0 "Background" in the report details. Robatel Technologies, LLC is in fact wholly owned by Robatel Investors, Inc. The latter's parent is Robatel SA. Therefore Robatel Technologies, LLC is not owned by Robatel Industries, contrary to what was stated in the communication. Robatel Technologies and Robatel Industries are independently operated corporate affiliates with a common parent. Neither Robatel Technologies, LLC or Robatel Industries has managerial or operational control of the other.

Those documents referenced in this response as the corrective actions required for full compliance are, or will be, available for your review in our Roanoke, VA office

IE07

Please do not hesitate to contact me should you require any additional information or have any questions regarding this response.

Respectfully,



Teo Grochowski, Jr.
CEO

Enclosure:
Robatel Technologies, LLC Response to NRC NOV (5 pages)

cc:

Mr. Eric Benner, Chief
Rules, Inspections and Operations Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Mayhew, E.
Jobson, G.
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Dane, C.
Martin, D.

INSPECTION REPORT 71-0952/2013-201
REPLY TO NOTICE OF VIOLATION

I. Restatement of Notice of Violation 71-0952/2013-201

During an NRC inspection conducted on February 12-14, 2013, at Robatel Technologies, LLC, (RT), violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the Violations 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 Procedure (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.

This is a Severity Level IV Violation (Enforcement Policy Section 6.2).

- 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 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.

This is a Severity Level IV Violation (Enforcement Policy Section 6.2).

II. Robatel Technologies Reply to the Notice of Violation

1. Reason for the Violation

- A.1 The reason for this violation was a misunderstanding within RT that the design subcontractors had been audited and approved for their specific scope of work and that monitoring was being performed by RT in the form of surveillances and meetings while the subcontractors were allowed to perform their work in accordance with their audited and approved programs.

Based on this, the design subcontractors were allowed to submit design documents which were reviewed and documented informally by RT rather than through a formal controlled system. Robatel failed to recognize its responsibility that as the potential holder of the NRC license all design and quality documents must come to RT for review and acceptance and be maintained in a Master Controlled Log.

RT recognizes the error of not being an active participant in the design control meetings with its subcontractors.

The basis of this violation was the reliance on fully approved subcontractors and the failure to recognize the extent of involvement required by Robatel Technologies as the potential NRC license holder.

RT incorrectly believed that the documents being maintained in approved supplier's document control systems was sufficient.

- A.2 The reason for the violation was RT's misunderstanding that since the design subcontractors had been audited and approved for their specific scope of work and with monitoring being performed by RT in the form of surveillances and meetings that the subcontractors were then allowed to perform their work in accordance with their audited and approved program.

Based on this, the design subcontractors were allowed to submit design documents which were reviewed and documented informally by RT rather than with a formal, controlled system. Robatel failed to recognize its responsibility that as the potential holder of the NRC license all design

and quality documents must come to RT for review and acceptance and must be maintained in a Master Controlled Log.

It was an unintentional oversight on the part of RT for not having issued a Project Plan that described the interfaces and coordination among the participants working on the RT-100 design.

2. Corrective Steps that Have Been Taken and the Results Achieved

NRC NOV Item A.1

Robatel issued a Corrective Action Report (CAR) to address the issues identified in the NRC Notice of Nonconformance.

Status:

The actions required by this CAR included a review of the RT QA Program manual and all implementing QPs along with the generation of 3 new QPs:

- A. QP-03-04, "Design Change Control"
- B. QP-07-03, "Supplier Document Review"
- C. QP-15-03, "Review of Supplier Nonconformance Reports"

These have been completed on March 29, 2013 and the CAR was closed on 4/3/2013.

A Meeting was held immediately following the NRC Inspection with RT Employees and subcontractors where the responsibility of RT as the potential licensee holder was stressed. It was stressed to employees the importance and necessity for maintaining ALL design and quality records associated with the RT-100.

Status:

A post audit debrief and planning meeting was held the afternoon of February 14, 2013 to address issues resulting from NRC inspection.

NRC NOV Item A.2

Robatel recognizes the need to obtain documented evidence from the Design Reviews that have been held on the RT-100 design and the resolution to any action items resulting from these reviews. 2 CARS were generated during the audit: CAR-2013-01 and CAR-2013-02. Both are now closed. CAR-2013-04 has been opened to capture prior Design Review meeting summaries. RT subcontractors Enercon and Robatel Industries both involved in RT-100 design review meetings have been contacted for the records of their Design Review minutes action items and resolutions to them.

Status:

This CAR remains open at this time.

NRC NOV Item B

Robatel issued a Corrective Action Request (CAR) to address the issues identified in the NRC Notice of Nonconformance

Status:

The actions required in this CAR, including a review of the RT QA Program manual and all implementing QPs, and generation of 3 new QPs have been completed on March 29, 2013 and the CAR was closed on 4/3/2013. QP-03-01 was revised in addition to the generation of new procedure, QP-07-03 –*Supplier Document Review* to address the concerns identified.

The three (3) newly generated QPs are:

- A. QP-03-04, "Design Change Control"
- B. QP-07-03, "Supplier Document Review"
- C. QP-15-03, "Review of Supplier Nonconformance Reports"

Robatel has also generated an administrative procedure providing guidelines for preparing a Project Plan Document.

Status:

This procedure is in final review including a decision to assign the document as a QP or an administrative procedure.

A Project Plan is under development for the RT-100 project that will define the interfaces and coordination required between the design subcontractors and RT.

Status:

The Project Plan is being developed and expected to issue momentarily. Some recent internal adjustments to the RT-100 project are being incorporated.

3. Corrective Action that Will Be Taken to Avoid Further Non-Compliances

NRC NOV Item A.1

Robatel has put in place additional requirements and additional procedures to assure that all design and quality documents are processed in a controlled manner using formal procedures.

Robatel has enhanced its document control function through the creation of a single point of contact for all documents to pass through for entrance into the RT Document Control system, dissemination for review and approval and maintenance in the RT Master Document Control system and retention. Robatel's Operations Manager has assumed the additional responsibility of Document Control / Records Management and a dedicated email for records management / archive has been created. Robatel's management has instructed employees and subcontractors to the importance of document control compliance.

The annual internal audit on the Robatel QA Program will place additional emphasis in this area to assure these new and revised procedures are in compliance.

NRC NOV Item A.2

Robatel will not rely on its subcontractors for design acceptance and any changes required in the design of its product. Robatel will participate in all future design reviews that need to be performed.

Future internal audits will review in depth the design process, the involvement of RT and the records maintained of these reviews.

NRC NOV Item B

Robatel has put in place additional requirements and procedures to assure that all design and quality documents are processed in a controlled manner using formal procedures. Reviews of these documents are on controlled forms.

Robatel has enhanced its document control function through the creation of a single point of contact for all documents to pass through for entrance into the RT Document Control system, dissemination for review and approval and maintenance in the RT Master Document Control system and retention. Robatel's Operations Manager has assumed the additional responsibility of Document Control / Records Management and a dedicated email for records management / archive has been created. Robatel's management has instructed employees and subcontractors to the importance of document control compliance.

Future internal audits will review in depth the document control process and the implementation of these new procedures.

II. Date When Corrective Actions Will be Completed.

All corrective actions will be completed on or before Friday, May 31, 2013.