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25 March 2016

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

Subject: Reply to Notice of Violation, Docket No. 71-0121, Report Number 2015-201

Reference: U.S. Nuclear Regulatory Commission Letter from Patricia Silva, Dated February 25, 2016, regarding Inspection Report No. 71-0121/2015-201 and Notice of Violation (including inspection report and notice of violation)

Dear Document Control Desk:

I am writing in response to the above referenced Notice of Violation that was received on 2 March 2016. I have attached the details of our response in Enclosure 1.

If you require additional information, please feel free to contact me at (301) 349-5001 or Mr. Keith Burns at (304) 725-7041.

Sincerely,

William L. Ransohoff
President
Neutron Products, Inc.

Enclosures:
1. Reply to Notice of Violation

Copy to:
U.S. Nuclear Regulatory Commission
Attn: Patricia Silva, Chief
Inspections, and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards
Washington, DC 20555-0001

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Enclosure 1
Reply to Notice of Violation

Subject: Reply to Notice of Violation, Docket No. 71-0121, Report Number 2015-201

Reference: U.S. Nuclear Regulatory Commission Letter from Patricia Silva, Dated February 25, 2016, regarding Inspection Report No. 71-0121/2015-201 and Notice of Violation (including inspection report and notice of violation)

As a result of the NRC inspection conducted on 16-17 December 2015, at Neutron Products' Ranson, West Virginia facility, two Severity Level IV violations were cited by the above referenced Notice of Violation. The violations are stated below with our responses.

Violation A

10 CFR 71.133, "Corrective action," requires, in part, that 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.

Contrary to the above, from October 2009 to October 2015, NPI did not take prompt corrective action to develop and issue a design control procedure for licensing drawing deficiencies. Specifically, NPI did not correct the drawing deficiencies with an approved design procedure at the first available opportunity and did not provide appropriate subsequent justification to delay the corrective action for another two years.

Violation A Response

1. Discussion

   As a preliminary matter, following the referenced NRC inspection, we conducted a big picture analysis of our CAPA program in an effort to determine the extent of the problem identified in the inspection. Analysis of all CAPAs opened during calendar years 2012 through 2015 identified a total of 35 CAPAs of which 28 had been closed (at the time of the analysis). Please note that this analysis includes 4 CAPAs that were opened in 2015 as a result of the NRC audit of 16/17 December 2015, of which 2 have since been closed. The analysis indicated that 3 CAPAs (all related to the drawing deficiencies) were the only CAPAs opened in excess of 12 months, with 24 of the 28 closed CAPAs being closed within 6 months.

   Based upon that review, we conclude that the problem identified is not systemic. That said, Neutron acknowledges that corrective action to develop and issue a design control procedure and the subsequent drawing revision has been long overdue. As previously determined, license drawing 240116 Rev G would benefit from additional detail. Since the material specifications currently missing from the drawing can generally be found in the Safety Analysis Report and since no additional packages are permitted to be manufactured to these specifications, the sense of urgency to update the drawing was less than appropriate, accounting for a significant delay at the beginning of and throughout the process.

   In addition, for quite some time there was a lack of conviction on the part of senior management as to how to best proceed. The ultimate irony is that, in the process of implementing Procedure R-5518, Rev. 0, Design Control in October 2015 (which enabled us to

close CA-2013-RT-001 regarding development of a design control procedure), it became apparent that the intended revision to drawing 240116, Rev. G would likely not constitute design changes as opposed to addition of detail and missing information. Thus, it is likely that the completion of CA-2013-RT-002 (regarding update of the drawing) need not have been delayed by the implementation of the new design control procedure.

The process was also made unnecessarily cumbersome by the decision to leave open CA-2012-RT-002 (the original CAPA from which CA-2013-RT-001 and CA-2013-RT-002 were generated) while also opening other corrective actions which addressed the same issues.

All of the factors described above resulted in this action being open for an inexcusable period of time.

2. Corrective steps taken and results achieved

CA-2012-RT-002 and CA-2013-RT-001 have now been closed. An action plan including schedule and planned completion date for CA-2013-RT-002 has been developed and is being implemented. A purchase order was issued to an approved vendor for engineering services to update the drawing[1]. This effort encompasses the creation of an accurate 3-dimensional (3-D) model from which the 2-dimensional (2D) images will be generated to create the views for the drawing. The 3-D modelling has been completed and the initial 2-D drawing has been received for review. The drawing is currently under initial internal review. We expect this to be an iterative process with the approved vendor, and anticipate that the final drawing will be completed by 25 May 2016.

Corrective action CA-2015-RT-007 was issued on 17 December 2015 prior to completion of the NRC inspection to address corrective actions that were not promptly closed in a timely manner. A root cause analysis was performed which indicated that executive management was the bottle neck in the CAPA process. Due to other responsibilities/priorities regarding operation/management of the company, failure to delegate CAPA tasks to other capable personnel and lack of an action plan there had been lengthy periods of inactivity associated with completion of corrective actions CA-2012-RT-002, CA-2013-RT-001 and CA-2013-RT-002.

Under corrective action CA-2015-RT-007, the Quality Assurance Program Manual (QAP) and Procedure R-5514, Corrective and Preventive Action – Radioactive Materials Transportation (RMT) were reviewed to determine if the existing process was adequate. The QAP and procedure were found to conflict each other with regard to corrective action closeout and verification of effectiveness. Some responsibilities were also not clearly defined. Based on these findings, the procedure has been updated to align with the QAP and additional clarification has been added to define closeout and verification of effectiveness. Furthermore, some executive management responsibilities have been delegated to others, as appropriate and in accordance with the root cause analysis. In addition, some other responsibilities have been better clarified. The Corrective/Preventive Action form was also revised to support the procedural updates. The

[1] The approved vendor performing the engineering services to update the drawing had been audited in 2014. The vendor was also audited in March 2016 to survey in-house material testing capabilities at which time the engineering design control process was reviewed and found to be in accordance with 10 CFR part 71, Subpart H requirements.

modified procedure and form have been approved and made effective. Accordingly, corrective action CA-2015-RT-007 has been completed and closed out.

As a point of clarification, the NRC inspection report indicated that CA-2015-RT-009 was opened to address a violation of minor safety significance regarding failure to document a planned completion date or schedule for CA-2013-RT-002. However, this action was actually taken under CA-2015-RT-007 due to the similar nature. CA-2015-RT-009 was opened to address the finding of typographical errors and minor inaccuracies to several procedures not cited in this violation.

3. Corrective steps that will be taken to avoid further violations

   Procedure R-5514, Corrective and Preventive Action - RMT has been revised as previously discussed to clarify CAPA closeout and verification of effectiveness and to clarify responsibilities. This revision includes a change in responsibility for periodic review of corrective actions files to be initiated by the Quality Assurance Manager rather than Executive Management which will ensure more timely review of CAPA files in an effort to comply with planned schedules. An active corrective action log has also been developed to track progress, including adherence to schedules, and to support periodic reviews. Executive Management still retains overall responsibility for effective implementation of the corrective action program and the performance of periodic reviews.

4. Date when full compliance will be achieved.

   Once the drawing revision has been completed, it will be determined whether or not the revisions are of a nature which require regulatory approval. If not, full compliance is expected to be achieved by 8 June 2016. This includes closing of CA-2013-RT-002, completion of drawing revisions and a determination that submittal is not necessary. However, if the drawing modifications warrant a submittal for request for modification of the certificate, compliance will not be achieved until such request is approved. In that case, the schedule is to submit the revised drawing for regulatory approval by 8 June 2016.

Violation B

10 CFR 71.115, "Control of Purchased Material, Equipment, and Services," requires, in part, that the licensee, certificate holder, and applicant for a CoC shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor, and examination of products on delivery.

Contrary to the above, as of December 2015, NPI did not establish adequate source evaluations, objective evidence of quality furnished, and perform a complete examination of the products on delivery. Specifically, NPI did not identify and verify all the appropriate critical characteristics for some Category 'A' components and did not conduct commercial–grade surveys of commercial grade vendors, as applicable. This included NPI not adequately dedicating commercial components and services or establishing adequate controls for the acceptance of these parts through NPI's CGD program in accordance with procedures.

Violation B Response

1. Discussion

Neutron Products' commercial grade dedication (CGD) process is derived from provisions in the Quality Assurance Program for the Transportation of Radioactive Materials, and is implemented by Procedure R-5517, Commercial Grade Dedication and a series of process documents.

During the course of the inspection, commercial grade dedication records from procurement of maintenance parts were reviewed. Inspectors identified substantive flaws with the records supporting the procurement of grade 8 cap screws.

In addition, inspectors identified programmatic flaws with Neutron's CGD process. At the time of the referenced inspection, Neutron's program did not require process plans related to the procurement of specific items and services to be controlled documents, nor were those process plans subject to independent review. Critical characteristics and acceptance criteria were not adequately defined in these documents and the methods for accepting commercial grade items was not adequately identified. In some cases (such as for the procurement of the grade 8 cap screws mentioned above), the program relied upon certificates of conformance and test certificates provided by approved vendors who had not been adequately surveyed by Neutron.

During the course of the extent of condition evaluation which was conducted following the inspection, Neutron reviewed and studied the following specifications, standards, regulations and other guidance documents associated with the dedication process: 10 CFR part 21, ASME NQA-1, NUREG/CR-6407, NRC Information Notices IN 2011-01 and IN 96-40 and NRC Generic Letters 89-02 and 91-05, Final Safety Evaluation for Technical Report NEI 14-05 Revision 1, and EPRI TR-017218-R1.

Based upon this evaluation, Neutron has concluded that the underlying cause of this violation was at the programmatic level. In general, the CGD guidance provided in the QAP and the procedures resulting therefrom were followed. The problem was not with the faithful execution of the procedures, but was rather with flawed and inadequate procedures. Those procedures were adopted due to a corporate-wide fundamental misinterpretation of some of the required elements of commercial grade dedication.

2. Corrective steps taken and results achieved

Prior to the completion of the NRC Inspection on 17 December 2015, Neutron opened two corrective actions to address the NRC findings as described below.

CA-2015-RT-006 was opened to address the issue that existing dedication process documents were not subject to independent review. A total of five (5) commercial grade dedication process documents were not subjected to independent review. These process documents were developed to support Procedure R-5517, Commercial Grade Dedication – RMT and were not developed as or considered to be controlled documents. Therefore, these process documents were not subjected to the requirements of Procedure R-5512, Preparation of Quality System Programs and Procedures – RMT and Procedure R-5513, Document Control – RMT that would have specified independent review. These procedures include specific instructions for

development of procedures, controlled forms, drawings and master lists but do not provide guidance for development of other types of documents mentioned in the QAP that may include, but not be limited to, special process procedures, inspection plans, calibration procedures, test procedures and manufacturing plans.

Procedures R-5512 and R-5513 have been updated to include information describing how "other documents", including dedication plans, are processed and controlled. Both procedures have been approved and made effective and training of appropriate personnel has been conducted.

Corrective action CA-2015-RT-006 has been completed and closed out.

CA-2015-RT-008 was opened to address the issue that the commercial grade dedication process was not being adequately implemented. Neutron Products has reviewed all internal documentation associated with our commercial grade dedication process and determined that a substantial re-write is required to bring our process into compliance.

A total of nine (9) maintenance parts (including the Grade 8 cap screws) are identified in Procedure R-2019G, Maintenance and Storage Procedure for USA/9215/B(U) Package. Our investigation indicates that dedication deficiencies are applicable to all maintenance parts.

Neutron Procedure R-5517, Commercial Grade Dedication was revised to incorporate content and to better follow the logic of ASME NQA-1 requirements for commercial grade dedication. Personnel responsibilities were also updated. The revised procedure has been approved and made effective.

Quality Assurance Program Manual for the Transportation of Radioactive Materials (QAP), was also reviewed for adequacy at the program level. Section 4.7.2 Vendor Qualification and Section 4.7.5 Verification Activities were both found to contain inadequate/insufficient language pertaining to vendor qualification and verification activities of materials associated with commercial grade dedication. The QAP will be revised to correct this language. A regulatory submission for changes to the QAP is not anticipated at this time since this will not be a reduction in commitment.

Neutron Procedure R-5516, Receiving Inspection – RMT and associated controlled forms are in the process of being updated to update personnel responsibilities and process steps impacted by the changes to the commercial grade dedication process. This document is in the review process and is expected to be finalized, with associated forms, within the next two weeks.

The uncontrolled process documents previously used will be discarded. New commercial grade dedication plans are being developed to address maintenance parts subject to commercial grade dedication. Each plan, as appropriate, will identify the item, safety function performed, critical characteristics and acceptance criteria, and dedication methods. Dedication plans for the Quality Category A, Grade 8 cap screws and two Quality Category B items (grade 5 cap screws and nuts) have been approved and made effective. Dedication plans for the remaining maintenance parts will also be generated.

Dedication plans are being developed in accordance with Procedures R-5512 and R-5513 (revised under CA-2015-RT-006) to ensure the appropriate level of review is conducted prior to release.

New controlled forms are being developed to support the dedication plans and to record dedication activities conducted upon verification of acceptance criteria. A global dedication form is currently being reviewed to ensure format and content is sufficient for all commercial grade items.

A vendor that provides material testing services (including chemical composition, mechanical properties and calibration) has been audited/surveyed and added to the Master List of Approved Vendors. Commercial grade items will be submitted to this vendor and subjected to the appropriate material testing.

3. Corrective steps that will be taken to avoid further violations

   As mentioned above, procedure R-5512 and R-5513 have been revised to address the processing of "other documents" which will include creation of dedication plans to ensure such plans are subjected to independent review. Procedure R-5517 has been revised to align with NQA-1 requirements to define Neutron's dedication process including the development of dedication plans. Controlled commercial grade dedication plans are being developed to support dedication of each maintenance part and service identified in procedure R-2019G that meets the commercial grade definition. These dedication plans will ensure that critical characteristics and verification criteria are identified for each commercial grade item and that each item will be subjected to the appropriate test, inspection and analysis. Dedication results will be documented on a controlled form.

   Prior to the purchase of any additional commercial grade items, suppliers will be audited or subjected to commercial grade survey as appropriate. A suitable checklist will be used to support and document the audit/survey.

4. Date when full compliance will be achieved.

   Full compliance is expected to be obtained by 17 June 2016. This will include closeout of corrective action CA-2015-RT-008.

As a final note made only in the interest of trying to ensure that the record is complete, our investigation following the inspection also revealed that the laboratory which had provided the test results upon which we had mistakenly relied when accepting the grade 8 bolts had a current ISO/IEC 17025:2005 accreditation. For several years, such accreditation was accepted by the NRC for calibration labs, but not for testing labs. However, in NRC letter dated 9 February 2015, Final Safety Evaluation for Technical Report NEI 14-05, "Guidelines for the Use of Accreditation in lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, the NRC staff concluded that NEI 14-05 Revision 1 provides an acceptable approach for using laboratory accreditations that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial grade dedication process for calibration and testing services. This letter also provided the conditions of use that must be met.

While we took a tiny bit of solace from this realization, it has in no way affected our response to the findings of the inspection team as we have been addressing the flaws in our program. As described above, we have identified an acceptable testing lab (which also holds a current ISO 17025 accreditation), and we have conducted an appropriate survey on site at that laboratory in order to support the addition of that lab to our Master List of Approved Vendors.

We firmly believe that the improvements we are making to both our CAPA and CGD processes as a result of the inspection findings will strengthen our overall quality program in a material way, and we appreciate the constructive nature of the inspection and the resulting NOV.

Response provided by:
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