



November 13, 2009

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

Ref: USNRC Inspection Report 71-0935/2009-201

Subject: Reply to a Notice of Violation

Pursuant to the provisions of 10 CFR 2.201 EnergySolutions submits the enclosed reply to the Notice of Violation resulting from the U.S. Nuclear Regulatory Commission (NRC) inspection performed on May 4-8, 2009 at our Columbia, SC office and August 24-27, 2009 at Columbiana Hi Tech in Greensboro, NC. These inspections were related to certain EnergySolutions activities being performed under the requirements of 10 CFR Parts 21, "Reporting of Defects and Noncompliance", and 71, "Packaging and Transportation of Radioactive Material," and our NRC-approved Quality Assurance Program.

Should you or members of your staff have questions concerning the content of this reply, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Richard E. Campbell".

Richard E. Campbell
EnergySolutions
Corporate Director, Quality Assurance

cc: Mr. David W. Pstrak, Chief, Rules, Inspections, and Operations Branch



REPLY TO NOTICE OF VIOLATION

Notice of Violation

- A. "10 CFR 71.91(d), "Records," states in part, "The certificate holder shall maintain sufficient written records to furnish evidence of the quality of the packaging. The records to be maintained include results of the determinations required by 71.85; design, fabrication and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analysis; and results of maintenance, modification, and repair activities.

With respect to the UX-30 packaging, of which EnergySolutions (ES) is the certificate holder, the team noted that ES initiated an agreement in February, 2004 to Columbiana Hi-Tech Manufacturing (CHT), Greensboro, NC, to allow CHT to use, manufacture, lease, upgrade, sell to third parties and/or refurbish packages in accordance with the NRC Certificate of Compliance (CoC). The team noted that contrary to the above requirement, written records to furnish evidence of the quality of UX-30 packagings were not maintained.

Specifically, the inspection team noted that ES failed to: a) issue a purchase order; b) maintain CHT on their Approved Suppliers List (ASL); and c) perform periodic audits, work surveillances, or in-plant oversight of fabrication activities. Further, the inspection team noted that the licensing agreement was outdated and reflects Duratek Services, Inc., in lieu of ES and that CHT is not a registered user for the shipment of radioactive material. Lastly, the inspection team noted that objective evidence could not be furnished to demonstrate that ES had transmitted to CHT Revision 24 of the NRC CoC No. 9196 (package ID No. USA/9196//B(U)F-96) dated April 14, 2009."

EnergySolutions reply to Notice of Violation A

- 1) The reason for the violation

Because CHT had a 10CFR71, subpart H, Quality Assurance program approved by the NRC, and was a NRC Certificate holder for the ESP-30X Protective Shipping Package for 30-inch UF₆ Cylinders, it was EnergySolutions' belief that the license agreement between EnergySolutions and CHT was sufficient to maintain compliance with the regulations during fabrication of the packages. Additionally, EnergySolutions considered the review and approval of CHT's fabrication drawings and specifications by EnergySolutions Engineering and invoking CHT's NRC



approved Quality Assurance program in the licensing agreement sufficient to meet the requirements of the regulations.

2) The corrective steps that have been taken and the results achieved

EnergySolutions issued a Stop Work Order to CHT on May 7, 2009. This Order suspended all activities on the fabrication of the UX-30 overpacks until corrective measures were established to prevent further violations. A Quality Assurance audit was conducted by EnergySolutions with no findings identified and as a result the Stop Work Order was lifted on July 23, 2009.

Issuance of Purchase Order – EnergySolutions does not execute work with CHT via the use of purchase orders. Although no purchase order has been issued to CHT, the License Agreement, along with the Memo of Understanding (MOU) between EnergySolutions and CHT contain the necessary elements of a contract. EnergySolutions considers these mechanisms to provide appropriate documentation for this arrangement and to contain sufficient quality controls.

Approved Supplier List and Periodic Audits – EnergySolutions conducted a Quality Assurance audit of CHT on May 27-28, 2009 with no findings. As a result of this audit CHT has been added to the EnergySolutions Approved Suppliers List (ASL).

Transmission of CoC – EnergySolutions issued a controlled copy of the Certificate of Compliance, No. 9196 to CHT on July 17, 2009.

The MOU, signed July 20, 2009, clarified the company name by identifying “Duratek Services, dba EnergySolutions.”

3) The corrective steps that will be taken to avoid further violations

An MOU between EnergySolutions and CHT was signed into effect on July 20, 2009 that invoked the requirement for maintaining sufficient written records to show evidence of quality of packagings fabricated at CHT. The records to be maintained include results of the determinations required by 10 CFR 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities.

The MOU was revised on November 10, 2009 requiring CHT to:



- require CHT to register as an Authorized User of the UX-30 overpacks and to maintain Authorization User Status as long as CHT fabricates, maintains or owns UX-30 overpacks, and
- to establish *EnergySolutions* Inspection Hold Points in the UX-30 fabrication travelers prior to release of the overpacks for foaming and prior to final acceptance of the overpacks for use. These inspections by *EnergySolutions* will include a review of the CHT fabrication record packages.

CHT will be audited on a triennial basis for maintenance on the *EnergySolutions* ASL and will be subject to the annual QA evaluation in accordance with our procedures.

4) The date when full compliance will be achieved:

All corrective actions and actions to avoid further violations will be completed by November 30, 2009.



- B. "10 CFR 71.111, "Instructions, procedures, and drawings," states, in part, "The certificate holder 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 the above, the following instances were identified by the NRC where activities affecting quality were not prescribed in documented instructions, procedures, or drawings or where instructions, procedures, or drawings for activities affecting quality were not followed:

1. ES procedure, ES-QA-PR-003, Revision 0, "Supplier Evaluation," step 4.1, states "Supplier audits performed by Nuclear Industry Assessment Committee (NIAC) may be used in lieu of ES's audits, if the audit report is reviewed and accepted by QA. The team identified that NIAC, a third party auditing organization, was not listed on ES's ASL as an approved auditing organization and the process for review and approval of NIAC audits is not defined within ES procedures.
2. ES procedure ES-QA-PR-004, Revision 0, "Procurement Document Review," states the requirements for review of procurement documents and requires development of a comprehensive procurements document that includes appropriate technical and quality requirements and the use of a qualified vendor. Further, ES procedure, ES-QA-PR-001, Revision 0, states, that commercial grade item surveys shall be performed as required for dedication purposes. The team identified that a NIAC audit classified a vendor (VTI) as commercial grade for calibration services and that ES failed to implement their quality program specific to commercial grade dedication and initiate the correct procurement document (i.e., purchase order) for a Q-Level I application."

EnergySolutions reply to the Notice of Violation B

1) The reason for the violation

Because EnergySolutions is a member of NIAC and evaluates the Lead Auditor certifications and the supplier audits conducted by NIAC prior to placing a supplier on the EnergySolutions ASL, we incorrectly assumed that it was not necessary to place NIAC on the ASL. The necessary actions for review and approval of NIAC audit reports were being performed by a single Certified Lead



Auditor prior to placing the suppliers on the ASL. As a result, *EnergySolutions* did not believe that all of these detailed steps were required to be included in the procedure.

The *EnergySolutions* ASL incorrectly listed Vacuum Technologies Inc. (VTI) as having an NQA-1 QA Program although the NIAC audit being used to place them on the ASL clearly stated that VTI had a commercial QA Program. In 2008, a review of the Quality Level I suppliers on listed on the ASL was conducted to ensure that these suppliers had the appropriate QA Programs and if not they were removed. As a result of a personnel error and oversight, VTI was not removed from the ASL. VTI should not have been on the ASL and the commercial grade dedication process should have been implemented.

2) The corrective steps that have been taken and the results achieved

Procedure ES-QA-PR-003 "Supplier Evaluation" was revised to provide additional instructions on reviewing and approving NIAC audit reports prior to use. This revision also addressed including on the ASL the QA program basis for qualification to ensure that Quality Level I suppliers have the appropriate QA programs for their scope of supply.

NIAC has been placed on the *EnergySolutions* ASL.

VTI was removed from the *EnergySolutions* ASL.

A commercial grade dedication plan was developed and implemented for the VTI leak standards which resulted in the dedication of the leak standards.

3) The corrective steps that will be taken to avoid further violations

Procedure ES-QA-PR-003 "Supplier Evaluation" was revised to provide additional instructions on reviewing and approving NIAC audit reports prior to use.

A review of the *EnergySolutions* ASL was conducted to ensure that no other suppliers were included that did not have the appropriate nuclear QA programs. The QA Certified Lead Auditor responsible for maintaining the ASL was re-trained to ensure understanding of the QA requirements necessary for placing suppliers on the ASL.



4) The date when full compliance will be achieved:

All corrective actions and actions to avoid further violations have been completed as of November 10, 2009.