October 16, 2009

Mr. Richard E. Campbell
Corporate Director, Quality Assurance
Energy*Solutions*
140 Stoneridge Drive
Columbia, South Carolina 29210

SUBJECT: U. S. NUCLEAR REGULATORY COMMISSION (NRC) INSPECTION REPORT NO. 71-0935/2009-201 AND NOTICE OF VIOLATION

Dear Mr. Campbell:

This letter refers to two team inspections conducted by the U.S. Nuclear Regulatory Commission (NRC). The first inspection occurred during May 4-8, 2009, at Energy*Solutions* (ES) located in Columbia, South Carolina (Enclosure 1, Part A). The second inspection of ES occurred during August 24-27, 2009, at Columbiana Hi Tech (CHT), LLC located in Greensboro, North Carolina (Enclosure 1, Part B). The purpose of the inspections was to determine if activities associated with the transportation of radioactive material being performed by ES were in accordance with the requirements of 10 CFR Parts 21, "Reporting of Defects and Noncompliance," and 71, "Packaging and Transportation of Radioactive Material," applicable Certificates of Compliance, and Safety Analysis Reports, and ES's NRC-approved Quality Assurance (QA) Program. The enclosed (Enclosure 1) two part report presents the results of both inspections.

As a result of the inspections, the team assessed that ES's implementation of its NRC-approved QA program was adequate. However, the team noted that ES initiated a licensing agreement in February of 2004 to CHT that authorized CHT to use, manufacture, lease, upgrade, sell to third parties and/or refurbish Model UX-30 overpacks in accordance with the NRC Certificate of Compliance (CoC) without the required oversight typically provided by a CoC holder. The NRC determined that an inspection of the contractor's facility and the associated activities regarding the UX-30 overpacks was required and is addressed in the second half of this report.

Based on the results of the inspections, the NRC has determined that two (2) Severity Level IV violations of NRC requirements occurred, one with multiple examples. The violations are cited in the enclosed Notice of Violation (Enclosure 2) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because they were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

David W. Pstrak, Chief
Rules, Inspections, and Operations Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0935

Enclosures:
1. Executive Summary
2. NRC Inspection Report No. 71-0935/2009-201
   Part A: Energy*Solutions*, Columbia, SC
   Part B: Columbiana HI Tech LLC, Greensboro, NC
3. Notice of Violation (Notice)

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Docket 71-0935
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OFC:	SFST	E	SFST	E	SFST	E
NAME:	JPearson		MDeBose		DPstrak	
DATE:	10/08/09		10/14/09		10/ 16 /09	

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EXECUTIVE SUMMARY

NRC Inspection Report 71-0935/2009-201

On May 4-8 and August 24-27, 2009, the U. S. Nuclear Regulatory Commission (NRC) conducted two announced team inspections. The first inspection of Energy*Solutions* (ES) was performed at their facility in Columbia, South Carolina, and the second inspection also of ES was performed at the Columbiana HI TECH, (CHT) facility at Greensboro, North Carolina. The purpose of the inspections was to determine if activities associated with the transportation of radioactive material being performed by ES were in accordance with the requirements of 10 CFR Parts 21, "Reporting of Defects and Noncompliance," and 71, "Packaging and Transportation of Radioactive Material," applicable Certificates of Compliance (CoC), Safety Analysis Reports (SARs), and ES's NRC-approved Quality Assurance (QA) Program. The team inspected ES's management, design, fabrication, and maintenance activities. The enclosed two part report presents the results of this inspection.

During the first inspection, the team determined that ES initiated a licensing agreement in February of 2004 to CHT that authorized CHT to use, manufacture, lease, upgrade, sell to third parties and/or refurbish Model UX-30 overpacks in accordance with the NRC Certificate of Compliance (CoC). The team noted that ES failed to: a) issue a purchase order; b) maintain CHT on their ASL; c) perform periodic audits, work surveillances, or in-plant oversight of fabrication activities; d) amend the licensing agreement which reflects Duratek Services, Inc., in lieu of ES; e) verify that CHT is a registered user for shipment of radioactive material; and f) to demonstrate transmittal to CHT, Revision 24 of NRC CoC No. 9196 (Packaging ID No. USA/9196/B(U)F-96) dated April 14, 2009. The team determined that a second inspection was warranted at the CHT facility to provide the NRC with some assurance of the adequacy of the overpack fabrication.

The team also identified two procedural violations. The first was where Nuclear Industry Assessment Committee (NIAC), was not listed on ES's Approved Suppliers List (ASL) as required and the process for review and approval of NIAC audits was not defined within a procedure. The second violation was that certain ES procedures require review of procurement documents, as well as, the development of a comprehensive procurement document that includes appropriate technical and quality requirements and the use of a qualified vendor and that a commercial grade item survey be performed for dedication purposes. The team identified that ES failed to commercially dedicate and initiate the appropriate commercial procurement document for this vendor and to adequately evaluate NIAC's audit that was used as a basis for listing the vendor on the ASL.

While the second inspection confirmed that a pre-fabrication audit had been performed of Columbiana Hi Tech LLC by Duratek (now Energy*Solutions*) on October 26 and 27, 2004, no actual oversight was provided by ES during the fabrication of UX-30 overpacks by Columbiana Hi Tech LLC. The team noted the results of the overall inspection found both ES and CHT activities to be adequate in regard to the UX-30 overpack fabrication activities, with the exception of oversight by ES.

<u>Overall</u>

The team assessed that, with the exceptions noted above, ES's implementation of its NRC-approved QA Program with regard to controlling activities subject to 10 CFR Part 21 and 10 CFR Part 71 was adequate. Based on the results of the inspections, the NRC determined that

two (2) Severity Level IV violations of NRC requirements occurred, one with multiple examples. The violations are summarized in Table 1.

U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Spent Fuel Storage and Transportation

Inspection Report

Docket:	71-0935
Report:	71-0935/2009-201
Certificate Holder:	Energy*Solutions* 140 Stoneridge Drive Columbia, South Carolina 29210
Date(s):	May 4-8, 2009 (Energy*Solutions*, Columbia, SC) August 24-27, 2009 (Columbiana HI Tech LLC, Greensboro, NC)
Inspection Team: (May 4-8, 2009)	Jim Pearson, Team Leader, SFST Earl Love, Inspector, SFST Clyde Morell, Inspector-In-Training, SFST Ata Istar, Technical Observer
Inspection Team: (August 24-27, 2009)	Jim Pearson, Team Leader, SFST Clyde Morell, Inspector-In-Training, SFST Ata Istar, Technical Observer
Approved by:	David W. Pstrak, Branch Chief Rules, Inspections, and Operations Branch Division of Spent Fuel Storage and Transportation Office of Nuclear Material Safety and Safeguards

Table 1

Summary of Inspection Findings (Both Inspections)

Regulatory Requirement 10 CFR Section	Subject of Violation or Noncompliance	Number of Findings *	Type of Finding	Report Section	Issue/Subject
71.91(d)	Records	(1)	Level IV Violation	Part A 4.1.2	Records
71.111	Instructions, Procedures & Drawings	(2)	Level IV Violation	Part A 4.1.2	Procedural noncompliances

* Numbers in parentheses indicate the number of instances supporting the violation.

REPORT DETAILS

ENERGY*SOLUTIONS*, COLUMBIA, SC

(PART A)

1.0 Inspection Scope and Background

The NRC inspected activities applicable to the transportation of radioactive material in order to verify implementation to the requirements of 10 CFR Parts 21 and 71, applicable CoCs, related SARs (as listed) and the NRC-approved QA Program. The team determined the acceptability of transportation activities through review of procedures and instructions; observations of activities; inspection of selected documents, records, and drawings; personnel training and qualifications; and interviews with personnel responsible for various engineering and fabrication activities.

Model #	Package ID#	Certificate	Revision	Expiration Date	Expired
CNS 3-55	USA/5805/B( )	5805	26	10/1/2008	x
IF-300	USA/9001/B( ) F	9001	40	10/1/2008	x
N-55	USA/9070/B(U)	9070	18	01/31/2010	
CNS 1-13C	USA/9081/B( )	9081	15	10/1/2008	x
UX-30	USA/9196/AF-96	9196	24	02/28/2011	
CNS 10-160B	USA/9204/B(U)-85	9204	12	01/31/2010	
10-142	USA/9208/B( )	9208	18	10/1/2008	x
CNS 1-13G	USA/9216/B( )F	9216	10	10/1/2008	x
MIDUS	USA/9320/B(U)-96	9320	1	05/31/2012	
CNS 8-120B	USA/9168/B(U)	9168	16	06/30/2010	
3-82B	USA/6575/B( )	6574	33	10/1/2008	x

1.1 Inspection Procedures Used

IP 86001, “Design, Fabrication, Testing, and Maintenance of Transportation Packagings”
NUREG/CR 6314, “Quality Assurance Inspections for Shipping and Storage Containers”

1.2 List of Acronyms Used

ASL	Approved Suppliers List
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
CR	Condition Report
DD	Descriptive Drawing
ERF	Engineering Request Form
IIR	Inspection Instruction and Record
M&TE	Measuring & Test Equipment
NCR	Nonconformance Report
NIAC	Nuclear Industry Assessment Committee
NRC	U.S. Nuclear Regulatory Commission
PO	Purchase Order
QA	Quality Assurance
QC	Quality Control
SAR	Safety Analysis Report

1.3 Persons Contacted

The team held an entrance meeting with ES on May 4, 2009, to present the scope and objectives of the NRC inspection. On May 7, 2009, the team held a de-briefing meeting with ES to present the preliminary results of the inspection and on August 27, 2009, after a second inspection at Columbiana Hi Tech LLC, the NRC held an exit meeting with ES to present the final inspection results. The individuals present at the entrance, de-briefing meetings, and exit meeting are listed in Table 2.

Table 2
Entrance, Debrief, and Exit Meetings Attendance

NAME	AFFILIATION	ENTRANCE	5/7/09 DEBRIEF	8/27/09 EXIT
Jim Pearson	NRC	X	X	X
Earl Love	NRC	X	X	
Clyde Morell	NRC	X	X	X
Ata Istar	NRC	X	X	X
Richard Byars	ES	X	X	
Bill House	ES	X	X	
David Kozlowsky	ES	X	X	X
Mirza Baig	ES	X		
Amy Gossett	ES	X		
D. M. Anderson	ES	X		
Phillip Thomas	ES		X	
Sam Pearson	ES		X	
Ahmad Ghandour	ES		X	
Patrick Paquin	ES		X	

2.0 Management Controls

2.1 Quality Assurance Policy

2.1.1 Scope

The team reviewed selected records and interviewed selected personnel to verify effective implementation of the quality assurance program, and that proper authority and independence existed.

2.1.2 Observations and Findings

The team reviewed the following documents and interviewed the ES Corporate Manager, Quality Assurance – Commercial, and the ES Quality Control Manager to assess the independence and authority of the ES Quality Assurance organization and the depth of the implementation.

- ES-QA-PO-001 Revision 0, “Quality Assurance Policy”
- ES-QA-PG-001, Revision 0, “Quality Assurance Program”
- ES-QD-PR-003 “ESHQA Review Committees”

- DTK-AD-029, Revision 1, “Personnel Training Policy and Implementation Procedure”

2.1.3 Conclusions

The team determined that the ES organizational structure provided for independence of quality personnel. Also noted, was the authority granted to the quality organization to assist in the overall control of the quality program. ES provides for personnel training to ensure that qualified personnel are prepared to perform their individual job functions. No concerns were noted.

2.2 Nonconformance Controls

2.2.1 Scope

The team reviewed a sample of records and interviewed selected personnel to verify effective implementation of the nonconformance control program, and that corrective actions for identified deficiencies were technically sound and completed in a timely manner.

The team also reviewed training and implementing procedures, internal postings, supplier notifications, reporting processes, and program controls in accordance with the provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

2.2.2 Observations and Findings

The team reviewed the following documents and noted that the ES procedural controls for noncomforming conditions were satisfactory:

- ES-AD-PR-013, Revision 0, “Control of Non Conforming Items”
- ES-AD-PR-008, Revision 1, “Condition Reports”

The team reviewed the following samples of corrective action documents:

- NCR: 09-002, Depleted uranium radiography shields testing failures (QSA and SPEC).
- NCR: 09-005, Inappropriate weld procedure used on 8-120B-2S (Studsvik) primary lid lift lugs.
- NCR: 09-009, Replacement of 8-120B-2S cask upper impact limiter lift lug due to damage.
- NCR: 09-021, Incomplete nameplate on UX-30 package. (corrective action not yet completed).
- CR-07-055, Bolts supplied by contractor improperly manufactured (incorrect length). P.O. CN 40819 to be used for 3-55 casks.
- CR-07-115 Revision 1, During inspection of 3-55-2 a cask lead-in bolt was found to be damaged.
- CR-07-125, Soap bubble leak test not performed on 3-55-1 cask during “O” ring replacement.

- CR-07-167, Inspection of 101-160B-2 cask revealed the test ports and caps were not inspected as required per QA-QI-005, Revision 31, step 4.1.3.
- CR-07-172, Inspection of 10-160B-7 cask (DOE Cask) revealed multiple deficiencies.
- CR-07-178, Inspection of 8-120B-2S revealed multiple deficiencies (9).
- CR-VS-07-01-04, Use of obsolete electronic copies of weld maps provided inaccurate weld information by vendor (P.O. # 00039).
- CR-08-108, Supplier's process for lead auditor qualification not performed in accordance with Bull Run Metal Fabrication and Engineers Standard Operating Procedure – 215, rev. 0 "Qualification of QA Auditors, and Lead Auditors."
- CR-09-32-Pressure gauge for CO_2 test.
- CR-09-61, Revision 1, 8-120B lift lug weld preparation.

2.2.3 Conclusions

The team determined from a review of records and personnel interviews that the nonconformance control program was being effectively implemented technically and corrective actions were occurring in a timely manner and that training records, procedures, internal postings at multiple locations, supplier notifications, reporting processes, and program controls according to the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance," were satisfactory.

2.3 Documentation Controls

2.3.1 Scope

The team reviewed applicable instructions, procedures, and drawings to determine if controlled documents, including changes, were reviewed for adequacy, approved for release, and distributed and used at the location where the prescribed activity was performed.

2.3.2 Observations and Findings

The team interviewed specific ES personnel and reviewed applicable sections of ES's Quality Manual, as well as, Quality Procedures related to document controls and records management. The team reviewed Safety Analysis Reports for Model Nos. UX-30, 10-160B, and CNS 8-120B packages for comparison to the NRC issued Certificate of Compliance (CoC) and latest licensed drawings on file at ES. The team reviewed instructions, procedures, and drawings for adequacy, approval signatures, and release by authorized personnel, and availability to personnel. Further, the team reviewed documents such as inspection and test procedures, nonconformance reports, corrective action reports, procurement documents, maintenance logs, measuring and test equipment records/logs, and inspection reports to assure that they were properly identified, retrievable, controlled, and maintained. The inspectors verified from various interviews, observation of activities, as well as the review of multiple documents

associated with other aspects of this inspection, that adequate document control and records management exist.

2.3.3 Conclusions

The team assessed that at the time of the inspection, the ES documentation control program was adequately implemented. No concerns were noted.

2.4 Audit Program

2.4.1 Scope

The team reviewed ES's audit program to determine whether plans, procedures, and records were available and adequate. The team reviewed whether ES scheduled and performed internal QA audits and vendor audits in accordance with approved procedures or checklists; whether qualified, independent personnel performed the audits; whether ES management reviewed the audit results; and whether ES took appropriate follow-up actions in those areas found deficient in the audits.

2.4.2 Observations and Findings

The team reviewed the following ES procedures: ES-QA-PR-001, Revision 1, "Audits," ES-QA-PR-008, Revision 1, "Auditor and Lead Auditor Qualifications and Certification," and ES-QA-PR-002, Revision 0, "Quality Assurance Surveillances." In addition, the team reviewed three (3) lead auditor qualifications, as well as, internal and external audit reports of Commercial Services, Columbia, S.C.; Barnwell Disposal Facility; Hittman Transportation; Columbia Maintenance Facility; Vacuum Technology Inc. (VTI); and Aircraft Seal and Gasket Corporation. The team noted that the audit of VTI was performed by the Nuclear Industry Assessment Committee (NIAC), and that ES failed to qualify VTI consistent with a Commercial Grade Dedication process. In addition the team noted that ES failed to audit CHT to allow use, manufacture, lease, upgrade, sell to third parties and/or refurbish packages in accordance with the NRC CoC (refer to Section 4.1.2 of this report for details).

2.4.3 Conclusions

With the exceptions noted above, the team assessed that ES audits and personnel qualifications were adequate to meet 10 CFR Part 71 requirements.

3.0 Design Controls

3.1 Design and Modifications

3.1.1 Scope

The scope of the inspection of design development included the review of design control and design modification control, design organization interfaces, use of appropriate regulatory requirements and quality standards in design activities, and design deviation control.

3.1.2 Observations and Findings

The team reviewed procedures, selected drawings and records to ensure that design modifications received the same level of review as the original design, and that the modifications were correctly reflected in the design documentation. The team reviewed a sampling of design change documents (drawings and procedures) and determined that the changes were made in accordance with the design change procedures and that none of the changes required submittal to the NRC for changes to licensing basis documents.

The team reviewed design drawings from the Safety Analysis Report (SAR) for Model No. CNS 8-120B, "Type B Shipping Package," Revision 6 and noted that certain items (i.e., polyurethane foam and plate material) were adequately procured according to design requirements.

3.1.3 Conclusions

Overall, the team assessed that ES procedures related to design development and modification were adequate in addressing related requirements of 10 CFR Part 71, Subpart H.

4.0 Fabrication Controls

4.1 Material Procurement

4.1.1 Scope

The team reviewed procedures, selected drawings and records, and interviewed selected personnel, to verify that the procurement specifications for materials, equipment, and services met the design requirements.

4.1.2 Observations and Findings

ES-QA-PR-004, Revision 0, "Procurement Document Review," implements the requirements for review of procurement documents by Quality Assurance. The team noted that the review encompasses work scope, technical and quality requirements, documentation and records, right of access, nonconformance controls, and other specifics needed. The team noted that Quality Assurance, Engineering, and the Procurement department are responsible, collectively, for developing a comprehensive procurement document that includes appropriate technical and quality requirements and the use of a qualified vendor.

The team noted that procedure No. ES-QA-PR-004, Section 4.2, "Procurement through Contracts," requires the Contract Administrators to have overall responsibility for contract documentation and that an ES contract may be issued to obtain items and services. Further, procedure Section 4.2, states that, contracts require transmittal to the appropriate and affected organizations for acknowledgements, as well as, technical and quality planning, reviews, and approvals. Specific to the UX-30 package, of which ES is the certificate holder, the team noted that ES initiated a licensing agreement to CHT in February 2004, to allow CHT to use, manufacture, lease, upgrade, sell to third parties and/or refurbish packages in accordance with the NRC CoC. The inspection team noted

that ES failed to: a) issue a purchase order; b) maintain CHT on their 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 reflected Duratek Services, Inc., in lieu of ES and that CHT was and continues not to be a registered user for 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 NRC CoC No. 9196 (Packaging ID No. USA/9196/B(U)F-96) dated April 14, 2009. This is a violation of 10 CFR 71.91(d) which states, in part, that "The certificate holder shall maintain sufficient written records to furnish evidence of the quality of 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."

The team noted that procedure ES-QA-PR-009, Revision 0, "Quality Levels," defines the criteria and responsibilities for a graded approach to quality and establishes controls over items, services, and activities affecting quality to an extent consistent with their importance through the assignment of defined Quality Levels (QL) I, II, and III with QL I being critical to safe operation and QL III as having a minor impact on safety. The team noted that Engineering personnel were responsible for evaluating items or services for quality level and documenting the results of their evaluation and that Quality Assurance was responsible for reviewing the quality level evaluations and concurring with the results. Further, the team noted that Quality Assurance was also responsible for maintaining and approving a "Q-List" that includes items or services that are classified according to importance to quality/safety. For procurement of items or services that are quality related, the quality level shall be included on the purchase order along with the applicable quality requirements.

The team reviewed ES's evaluations for classification of component quality levels, Q-List, Revision 24, dated March 16, 2009, and noted evaluation of items such as fasteners, gaskets, O-rings, containers, lids, licensed casks, and services were satisfactorily performed according to procedure No. ES-QA-PR-009, Rev. 0, "Quality Levels". The team noted QA concurrence with the results of quality level evaluations. Further, the team noted that commercial grade items may be procured for a Quality Level I application provided it meets the definition of a commercial grade item and are dedicated per the requirements of an approved procedure.

The team reviewed a sample of Quality Level I procurement documents specific to items and services (i.e., gaskets, O-rings, hex-screws, and calibration) of maintenance related activities. With the exception of calibration of a halogen leak standard, the team determined that procurements were made consistent with their importance according to approved procedures and Quality Level I requirements. Concerning the halogen leak standard, the team reviewed ES's purchase order, PO-006363, issued to Vacuum Technology, Inc. (VTI) for compliance to ES's procurement process (i.e., completion of procurement documentation, appropriate technical and quality requirements, and the use of a qualified vendor). The team noted that according to Q-List, Revision, 24, as well as, the results of a May 2008 audit of VTI, performed by Nuclear Industry Assessment Committee (NIAC), that ES failed to qualify VTI and to invoke the correct Quality Level consistent with Commercial Grade Dedication. The team noted that the NIAC audit classified VTI as a commercial grade supplier for calibration services. ES's failure to: a) commercially dedicate and initiate the appropriate commercial procurement

document for Q-Level I application; b) adequately evaluate the third-party audit (NIAC) that was used as a basis for VTI's QL-I listing on the ASL; and c) maintain NIAC as a third party approved auditing organization on the ASL is a violation of 10 CFR 71.111, which states, in part, that "The certificate holder shall prescribe activities affecting quality by documented procedures and shall require that these procedures be followed."

4.1.3 Conclusions

The inspection team concluded that ES failed to define the appropriate method to substantiate procurement of services and activities affecting quality to an extent consistent with their importance. In this case, the procurement process was determined to be commercial grade and lacked appropriate process (i.e., selection of critical characteristics) expected of commercial grade item or services acceptance for activities affecting quality.

4.2 Tools & Equipment

4.2.1 Measuring & Test Equipment (M&TE)

4.2.2 Scope

The team reviewed selected measuring and test equipment including records to assure that equipment used in activities affecting quality were properly controlled and calibrated.

4.2.3 Observations and Findings

The team reviewed ES's controls on M&TE. Procedure NS-AD-002, Rev. 7, "Measuring and Test Equipment," describes the methods and responsibilities for selecting, calibrating and controlling M&TE. The team reviewed a halogen leak standard, torque wrenches, survey meters, and weld rod oven gauges to assure that equipment was calibrated, and maintained at scheduled intervals against appropriate standards. The team also noted that current certificates of calibration and equipment inspections had been completed as noted on applicable equipment history.

4.2.4 Conclusions

ES's implementation of M&TE controls was assessed to be adequate. No concerns were noted.

5.0 Maintenance Controls

5.1 Material, Maintenance and Training

5.1.2 Scope

The team interviewed selected personnel and reviewed selected maintenance records to determine if: a) adequate maintenance controls were implemented; b) maintenance activities met design specifications identified in the Safety Analysis Report (SAR) and CoC; c) individuals performing activities affecting quality were properly trained and qualified; and d) management and quality assurance (QA) staff were cognizant and provide appropriate oversight.

5.1.3 Observations and Findings

The team reviewed ES's controls for inspecting and maintaining transport packages in order to verify that ES procedures and processes were established to ensure that maintenance requirements were adequately identified and performed in regard to 10 CFR Part 71. The team noted from observations of a maintenance activity, review of documents, and interviews with ES personnel, that inspection and evaluation of transportation packagings were adequately addressed routinely at a dedicated cask maintenance facility. The team reviewed logs depicting past and scheduled maintenance activities according to a matrix dated May 05, 2009. The team reviewed a sample of cask release inspection reports for verification of satisfactory completion of maintenance tasks applicable to cask Model Nos. 8-120B (s/n: 1) and 10-160B (s/n: 2). The team noted that inspections included but were not limited to cask body, lid, bolts and/or replacement of gaskets and O-rings.

The team reviewed welder qualification and Quality Control inspection personnel NDT/NDE certification records in various disciplines and levels and noted that personnel were appropriately trained and qualified as defined by ES Procedure Nos.: NS-OP-009, "Welder/Welding Procedure Certification Program," and ES-QA-PG-006, "Certification of Nondestructive Examination Personnel." No concerns were identified.

The team determined adequate oversight through the review of ES's status reports for nonconforming material and corrective action, as well as, appropriate Quality Control (QC) sign-offs on cask inspection reports.

5.1.4 Conclusions on Maintenance Controls

ES's implementation of maintenance controls, including training, qualification and oversight activities was assessed to be satisfactory. No concerns were identified.

6.0 Exit Meeting

On May 7, 2009, at the conclusion of the inspection, the team conducted a debrief with ES management. The preliminary inspection findings were presented during the debrief. In addition, the debrief allowed for an explanation of how the NRC inspection staff will discuss the inspection findings with NRC management and assist as necessary with any additional evaluation before an exit meeting can be held at a later date. At the end of the debrief ES management verbally acknowledged the inspection findings presented by the team. On August 27, 2009, after a separate inspection of Columbiana Hi Tech LLC, an exit meeting was held where the inspection findings were presented to ES Management.

REPORT DETAILS

COLUMBIANA HI-TECH (CHT), GREENSBORO, NC

(PART B)

1.0 Inspection Scope and Background

The NRC inspected activities applicable to the transportation of radioactive material in order to verify implementation to the requirements of 10 CFR Parts 21 and 71, and specifically the control of activities for the CoC, related SAR for the UX-30 model overpack, and the NRC-approved QA Program. The team determined, specifically for the Model UX-30 overpack, the acceptability of transportation activities through review of procedures and instructions; observations of activities; inspection of selected documents, records, and drawings; personnel training and qualifications; and interviews with personnel responsible for various engineering and fabrication activities.

Model #	Package ID#	Certificate	Revision	Expiration Date
UX-30	USA/9196/AF-96	9196	24	02/28/2011

1.1 Inspection Procedures Used

IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"
NUREG/CR 6314, "Quality Assurance Inspections for Shipping and Storage Containers"

1.2 List of Acronyms Used

ASL Approved Suppliers List
CFR Code of Federal Regulations
CoC Certificate of Compliance
CR Condition Report
DD Descriptive Drawing
ERF Engineering Request Form
GENE General Electric Nuclear Energy
IIR Inspection Instruction and Record
NCR Nonconformance Report
NDE Non-Destructive Examination
NRC U.S. Nuclear Regulatory Commission
PO Purchase Order
QA Quality Assurance
QC Quality Control
SAR Safety Analysis Report
USEC United States Enrichment Corporation

1.3 Persons Contacted

The team held an entrance meeting with ES on May 4, 2009, to present the scope and objectives of the NRC inspection. On May 8, 2009, the team held a de-briefing meeting with ES to present the preliminary results of the inspection, and on August 27, 2009, after a separate inspection at Columbiana Hi Tech LLC, the NRC held an exit meeting

with ES to present the final inspection results. The individuals present at the entrance, de-briefing meetings and exit meeting are listed in Table 2.

Table 2
Entrance, Debrief, and Exit Meetings Attendance

NAME	AFFILIATION	ENTRANCE	8/27/09 EXIT
Jim Pearson	NRC	X	X
Clyde Morell	NRC	X	X
Ata Istar	NRC	X	X
David Koslowsky	ES	X	X
Don Olson	CHT	X	X
John Burchfield	CHT	X	X
Curt Crissman	CHT	X	X
Susan Lambert	CHT	X	X

2.0 Management Controls

2.1 Nonconformance Controls

2.1.1 Scope

The team reviewed selected records and interviewed selected personnel to verify effective implementation of the nonconformance control program, and that corrective actions for identified deficiencies were technically sound and completed in a timely manner. The team reviewed applicable documents and postings for 10 CFR Part 21.

2.1.2 Observations and Findings

The team reviewed the CHT procedures; Q-5, Revision 0, “Control of Nonconformance Items and Services” and Q-11, Revision 0, “Corrective Action Procedure.” The team also reviewed the only two CHT NCRs (Nos.: 1719 & 1775) associated with the fabrication activities for the Model No. UX-30 overpacks. The team noted that the two CHT NCRs were processed according to procedural guidance. The team reviewed multiple postings for 10 CFR Part 21 and the associated procedure and samples of training records.

2.1.3 Conclusions

The team’s review of records, procedures, and postings, supplier notifications, reporting processes, and program controls indicated that the provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance" were adequately controlled. No concerns were noted.

2.2 Quality Assurance

2.2.1 Scope

The team reviewed selected records and interviewed selected personnel to verify effective implementation of the nonconformance control program, and that corrective

actions for identified deficiencies were technically sound and completed in a timely manner.

2.2.2 Observations and Findings

As a result of interviews with the CHT Senior Project Manager, and the CHT Vice President – Quality, and review of CHT quality policies and procedures, the team determined that the CHT management had a good understanding of the fabrication controls required to fabricate the ES UX-30 overpack and had adequate procedures to support implementation of their QA program.

2.2.3 Conclusions

The team determined that the CHT organizational structure provided for independence of quality personnel. The team also noted that sufficient authority had been granted to the quality assurance organization to provide for the overall control of the quality program implementation. CHT has provided for an adequately qualified staff and adequate procedures to support their fabrication activities. While ES did not provide oversight of CHT for fabrication of the UX-30 overpacks, ES has since determined through an audit that CHT is an acceptable supplier. No concerns were noted.

2.3 Documentation Controls

2.3.1 Scope

The team reviewed CHT's documentation control program to determine the effectiveness of the QA program in controlling quality-related documentation and records. The team reviewed instructions, procedures and drawings for adequacy. The team also verified approval signatures, the release by authority, and availability of the documents to personnel. The team reviewed documents such as inspection and test procedures, nonconformance reports, QA procedures, and UX-30 overpack drawings. The team reviewed quality records to assure that they were properly identified, retrievable, controlled, and maintained.

2.3.2 Observations and Findings

The team determined that CHT had developed a hierarchy of "Nuclear Quality/Assurance (Q/A) Manuals" that describe the methods for nuclear applications as required in Subpart H "Quality Assurance" of 10 CFR Part 71. The Nuclear Q/A Manuals identified with the designations of "N-XX." CHT developed two-volume policy/procedure manuals that included relevant procedures to manufacture structures, systems and components for the nuclear industry. Volume 1 includes the following sub-sections with numerous procedures: quality, material control, purchasing, engineering, and manufacturing. CHT has also developed specific manufacturing and maintenance procedures that apply to the UX-30 overpack only. Those procedures are as follows: UX-30-CP "Cleaning," Rev. 0, QIP-VT "Visual Inspection," Rev. 2, UX-30-VT, "Acceptance Supplement for Visual Inspection," Rev. 1 and Welding Procedure Specifications: 08082-104 Revision 0, 08082-106, Revision 0, 08081-101 Revision 6, 08082-101, Revision 2, 01082-101, Revision 2, and 08081-103, Revision 1.

Based on the review of the selected documents (i.e. manuals, procedures, and maintenance records) the staff did not identify any issues. The application of such documents for UX-30 overpack manufacturing and maintenance activities were applied properly. The team noted issuance of travelers and effective implementation through production and testing. The team reviewed maintenance records (Traveler Serial Nos. 15254, 15256, 15259, etc.) and noted compliance to the requirement of conditions prescribed within CoC, Docket No. 71-9196.

The team reviewed ES general description drawing of C-110-B-57922-0001 "UX-30 Overpack," and did not identify any issue. In addition, the team reviewed CHT fabrication drawing, Nos. X-20-238E, "Fabrication and Assembly UX-30 Overpack," and X-20-325 "Fabrication and Assembly Cradle," and noted that CHT provided proper written correspondences between ES and CHT for approval for the most recent revisions. No concerns were noted.

The team interviewed CHT management and QA staff in lieu of observing fabrication activities due to lack of scheduled shop activities of the UX-30 overpack during the performance of this inspection. The team discussed an ongoing issue concerning galvanic corrosion of "ball lock pins." Accordingly, there are ten (10) ball lock pins per UX-30 overpack, used to fasten the lid to its base. The team noted that United States Enrichment Corporation (USEC) and General Electric Nuclear Energy (GENE) issued 10 CFR Part 71.95 reports related to identification of abnormal conditions dated July 1, 2009 and September 3, 1998, respectively. According to CHT management, as well as, a review of documentation specific to this issues, the team noted that the cause was due to galvanic corrosion of dissimilar materials under saltwater environment conditions, which in turn, caused the aluminum cap to crack and become detached from the stainless steel shank, and/or the plunger mechanism to seize, stopping the balls from functioning properly. The team noted that during the recertification of UX-30 overpacks process only few malfunctioning ball-lock pins were identified by the CHT staff. CHT has committed to ES to replace all aluminum capped ball-lock pins with all stainless steel pins during the upcoming recertification process. The team noted CHT management acknowledgement of the galvanic corrosion conditions on ball-lock pins, and responded to this issue with supporting documentation in a timely manner.

The team reviewed CHT procedure No. EO-2 "Traveler Preparation, Verification & Control," Revision 0 and verified implementation by reviewing traveler (S/N: 13982) specific to the fabrication of a new UX-30 overpack. The team noted that the traveler included an overpack material list, fabrication processes (including welding), visual inspection records, and final dimensional inspections. No concerns were noted.

2.3.3 Conclusions

The team determined that document and records management controls at CHT were adequate.

3.0 Design Controls

3.1 Design Development and Modifications

3.1.2 Scope

The scope of the inspection of design development included the review of design control and design modification control, design organization interfaces, use of appropriate regulatory requirements and quality standards in design activities, and design deviation control.

3.1.3 Observations and Findings

The team compared CoC requirements (including design drawings) and noted that CHT fabrication process of the UX-30 overpack was satisfactory. The team reviewed the following CHT procedures to verify compliance to the CoC:

1. Q-01, "Calibration of Measuring and Test Equipment," Rev. 0, dated 8/10/07
2. UX-30-CP, "Cleaning Procedure," Rev. 0, dated 5/27/05
3. Q-03, "Welding Performance Testing and Records," Rev. 1, dated 6/12/05
4. QIP-VT, "Visual Examination Procedure," Rev. 2 dated 4/26/04
5. Q-14, "Criteria for Preparation of Certificate of Conformance and Customer Specified Data Package," Rev. 0 dated 4/26/02

3.1.4 Conclusions

The team noted appropriate fabrication drawing details (i.e., material, weld joints, and weld procedures) specifically, drawing No. X-20-238E, "Fabrication and Assembly UX-30 Overpack." Overall, based on the discussions with CHT management and documentation reviews no concerns were noted. The team assessed that ES procedures related to design development and modifications were adequate in addressing requirements of 10 CFR Part 71, Subpart H.

4.0 Fabrication Controls

4.1 Material procurement

4.1.1 Scope

The team reviewed procedures, drawings and records, and interviewed selected personnel, to verify that the materials and the associated procurement specifications for materials, equipment, and services met UX-30 overpack design requirements.

4.1.2 Observations and Findings

The team reviewed Purchase Order Nos.: 20070125, 20070172, and 20080054. The team noted that 20080054 was appropriately issued for purchase of welding wire and that the material was acceptably received from the review of procurement documents. The team also reviewed vendor audits for J. A. King, Arcos Industries, and Consolidated Power Supply, which were all on the CHT ASL. These acceptable reviews support the fabrication of Model UX-30 overpacks. The team noted that adequate measures were

established and implemented for release and distribution to fabrication shop work stations.

4.1.3 Conclusions

The inspection team concluded from the review performed of procurement documents that there were no concerns.

4.2 Fabrication & Assembly

4.2.1 Scope

The team interviewed personnel and reviewed documentation of fabrication activities affecting safety aspects of the packaging to verify if they were performed in accordance with approved methods, procedures, and specifications.

4.2.2 Observation and Findings

Because there was no fabrication on-going at the time of the inspection, the team reviewed 149 documentation packages of completed items. Of the 149 packages 59 contained process control travelers. The team reviewed the 59 process control travelers and noted adequate controls specific to fabrication, procurement, welding, welder and Inspector qualifications, and material traceability.

The team reviewed selected drawings and records and verified that procurement specifications for materials, equipment, and services delivered to customers (Licensee's) met design requirements. In addition, the team reviewed CHT fabrication work orders and verified compliance with Licensee QA Program requirements as noted:

	Work Order No.	**Customer Name**	**CHT Serial No.**	**Customer S/N**
1	05-008	Columbiana Financial	1098-1142	5-001 thru 5-045
2	06-009	Global Nuclear Fuel	1193-1217	GNFA-124 thru 148
3	06-035	Korea Nuclear Fuel Co.	1558-1279	KNFC-7316 thru 7337
4	06-035	Global Nuclear Fuel	1258-1319	GNFA-149 thru GNFA-189
5	07-013	Korea Nuclear Fuel Co.	1142 and 1663 thru1419	KNFC-7338 thru KNFC-7395

4.2.3 Conclusions

The team noted adequate fabrication controls. No concerns were noted.

4.3 Special Processes

4.3.1 Scope

The team reviewed Non-Destructive Examination (NDE) and welder qualification records to determine if components were being fabricated and examined in accordance with procedures, specifications, drawings, and NRC requirements.

4.3.2 Observation and Findings

The team reviewed CHT inspector qualification and eye examination records of three (3) NDE Inspectors. The team concluded that all qualifications complied with CHT procedure requirements, and that NDE certifications and eye examinations were current.

In addition, the team reviewed CHT procedural requirements (CHT-Q-03) for welder qualifications for the following CHT personnel (Welder stamp number correlates to a specific CHT employee):

Welder Stamp No.	Process
W-27	GMAW Manual ¾" to 1"
W-27	GMAW Semi Auto ½" to ½"
W-1	GMAW Semi Auto 1" to 1"
W-1	GTAW
W-8	GMAW Manual 1" to 1"
W-8	GMAW Semi Manual 1" to 1"

4.3.3. Conclusions

The team concluded that inspector and welder qualifications complied with CHT procedure requirements, and that NDE certifications and eye examinations were current.

4.4 Tools & Equipment

4.4.1 Measuring & Test Equipment

4.4.2 Scope

The team reviewed selected measuring and test equipment including records to assure that equipment used in activities affecting quality were properly controlled and calibrated.

4.4.3 Observations and Findings

The team toured the CHT fabrication shop and verified that various measuring and test equipment as listed on CHT traveler No. 13964 were calibrated in accordance with CHT calibration procedure No. CHT Q-01, Rev. 8, Dated 8/10/07.

4.4.4 Conclusions

The team determined that implementation of M&TE controls was adequate. No concerns were noted.

5.0 Maintenance Controls

5.1 Material, Maintenance and Training

5.1.2 Scope

The team interviewed selected personnel and reviewed selected maintenance records to determine if: a) adequate maintenance controls were implemented; b) maintenance activities met design specifications identified in the Safety Analysis Report (SAR) c) Certificate of Compliance (CoC) individuals performing activities affecting quality were properly trained and qualified; and d) management and quality assurance (QA) staff were cognizant and provided appropriate oversight.

5.1.3 Observations and Findings

The team interviewed the CHT Project Manager for the UX-30 overpacks and the CHT Quality Assurance Manager. The team reviewed maintenance activities and discussed maintenance cycles and parts availability and installation.

5.1.4 Conclusions

CHT implementation of maintenance controls, including training/qualification as well as oversight activities by CHT QA was assessed to be satisfactory. No concerns were identified.

6.0 Exit Meeting

On August 27, 2009, at the conclusion of the inspection, the team conducted an exit meeting with ES management and associated Columbiana Hi Tech personnel. During the meeting the preliminary inspection findings were presented.

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 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 Energy*Solutions* (ES) is the certificate holder, the team noted that ES initiated an agreement in February of 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 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 NRC CoC No. 9196 (package ID No. USA/9196/B(U)F-96) dated April 14, 2009.

This is a Severity Level IV violation (Supplement V).

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 procurement 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 service 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.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, Energy*Solutions* is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to David W. Pstrak, Chief, Rules, Inspections, and Operations Branch, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), http://www.nrc.gov/NRC/ADAMS/index.html to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, (the Public Electronic Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 16th day of October, 2009.