

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<p>1. LICENSEE/CERTIFICATE HOLDER Energy Solutions, Spent Fuel Division 2105 South Bascom Ave, Suite 160 Campbell, CA 95008</p> <p>REPORT 71-00804/2007-202</p>	<p>2. NRC/REGIONAL OFFICE Division of Spent Fuel Storage and Transportation (SFST) M/S O-13-D-13 Washington, DC 20555-0001</p>
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<p>3. LICENSEE/CERTIFICATE 71-00804</p>	<p>4. INSPECTION LOCATION Campbell, CA</p>	<p>5. DATE(S) OF INSPECTION March 5 - 9, 2007</p>
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The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license or Certificate of Compliance (CoC). The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations or nonconformances were identified.
- 2. Previous violation(s) or nonconformance(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

\_\_\_\_\_ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation or nonconformance of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION OR NONCONFORMANCE, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations, Nonconformances, and Corrective Actions)

**STATEMENT OF CORRECTIVE ACTIONS**

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested; **OR**

Written Response requested in 30 days     YES     NO

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE	DOUGLAS A. BROWN	<i>Douglas A Brown</i>	MAR. 7, 2007
NRC INSPECTOR	Mike Karmis	<i>Mike Karmis</i>	March 7, 07

**INSPECTOR NOTES COVER SHEET**

Licensee/Certificate Holder (name and address)	EnergySolutions, Spent Fuel Division (SFD) 2105 South Bascom Ave., Suite 160 Campbell, CA 95008
Licensee/Certificate Holder contact and phone number	Bob Quinn (408) 558-3508
Docket No.	71-00804
Inspection Report No.	71-00804/2007202
Inspection Date(s)	March 5 - 8, 2007
Inspection Location(s)	Campbell, CA
Inspectors	G. Michael Karmis, Frank Jacobs, Robert Temps
Summary of Findings and Actions	<p>This inspection involved a review of EnergySolutions, SFD, henceforth referred to as SFD, QA Program implementation at their office in Campbell, CA. Inspection activities focused on management controls, design activities, and fabrication controls, and how these activities are being controlled under SFD's NRC-approved QA program.</p> <p>Overall, SFD's activities were found to be in compliance with NRC Part 71 regulations and with Energy Solutions SFD's NRC approved QA Program. No violations of NRC Part 71 requirements were identified. The inspection notes are provided in the Form 591 which was issued at the exit meeting and as documented in the attached.</p>
Lead Inspector Signature/Date	G. Michael Karmis <i>G. Michael Karmis</i> / Apr. 4, 2007
Inspector Notes Approval Section Chief Signature/Date	Kevin Williams, Acting <i>K. Williams</i> 4/4/07

**INSPECTOR NOTES:** IP 86001 WAS USED IN CONJUNCTION WITH APPLICABLE PARTS OF NUREG/CR 6314. INSPECTION RESULTS USING THE NUREG/CR 6314 FORMAT ARE DOCUMENTED BELOW:

#### **4.1.1 Quality Assurance Policy**

The team reviewed SFD's quality assurance (QA) program to determine if QA policies had been documented, approved, and implemented; if the QA program authorities and responsibilities had been clearly defined and documented; if the materials, structures, systems, and components important to safety had been identified and a graded approach was applied consistent with importance to safety; and if the QA organization functioned independently with sufficient freedom and authority to identify and resolve quality problems and was not subject to cost and schedule influences.

The team found that the relatively small number of SFD's personnel necessitated that some personnel perform multiple functions however, the assignment of authorities and responsibilities for activities affecting quality were clearly defined and documented, and appeared to maintain an adequate independence of QA activities. In the review of various documents and records, the team found that items and activities important to safety were appropriately identified and controlled. From the interviews conducted and processes reviewed, the team assessed the QA organization had sufficient freedom and authority to identify and resolve quality problems and was not subject to cost and schedule influences.

The inspector reviewed the training records for two SFD personnel and for two technical consultants, one active and one inactive. Contract personnel were required to complete and maintain training applicable to the work assignment the same as in-house personnel. All training records were maintained in a database which tracked training requirements for each individual and facilitated determination of current training status and qualification to perform work. Individual training requirements appeared to be appropriate for the work responsibilities. No discrepancies were noted.

In the area of QA policy, the team had no findings.

#### **4.1.2 Nonconformance Controls**

The team reviewed the procedures controlling the problem identification and corrective action program used by SFD. Discussions were held with QA personnel, and the team also reviewed selected nonconformance reports and condition reports. Pertinent governing Quality Assurance Procedures (QAPs) reviewed by the team included:

- QAP 15.0, "Nonconforming Material, Parts, Components, or Services"
- QAP 15.2, "Reporting of Defects and Noncompliances"
- QAP 16.0, "Corrective Action Process"
- QAP 16.1, "Cause Analysis"
- QAP 16.3, "Effectiveness Reviews"

The team determined that QAP 15.0 is used for identifying, reporting and dispositioning nonconforming conditions in quality-affecting products or services. Nonconforming conditions involving work by SFD are documented in nonconformance reports (NCRs) and those identified by suppliers are documented in supplier deficiency reports (SDRs). The team assessed that QAP 15.0 provides detailed instructions on the processing of NCRs and SDRs and that provisions are in place for the periodic review of NCRs and SDRs by the QA Manager for the identification of any trends. A sample of SDRs related to the MIDUS package were reviewed by the team. The resolution of issues documented in the SDRs were appropriate to the nature of the problem and were resolved in a timely manner. No NCRs (SFD related work) have been issued for the past several years. No concerns were identified by the team with regard to the implementation of QAP 15.0 requirements.

The team determined that QAP 15.2 is used for the review of nonconforming conditions against the reporting requirements of 10 CFR Part 21. The team assessed that QAP 15.2 provides appropriate guidance with regard to Part 21. The team also verified that required postings of Part 21 requirements were in place at SFD's office and that Part 21 reporting requirements were invoked in purchasing documents where required. No concerns were identified by the team with regard to the implementation of QAP 15.2 requirements.

The team determined that QAP 16.0, and its supporting procedures QAP 16.1 and 16.3, are used for documenting and evaluating conditions adverse to quality. SFD uses condition reports (CRs) to document such issues. The team assessed that QAPs 16.0, 16.1, and 16.3 are quite detailed and provide extensive and robust guidance on the processing of CRs. All CRs are reviewed by a corrective action review board (CARB) and CRs are assigned one of four levels, I (highest) to IV (lowest). Each CR level requires different actions; for example, level I CRs require the performance of full root cause analysis whereas level III CRs require the identification of proximate cause. Provisions are in place for the tracking and trending of CRs and for the performance of effectiveness reviews. SFD's resolution of the issues documented in various CRs reviewed by the team was assessed to be appropriate and the reports were closed in a time frame commensurate to their importance. The team identified proper tracking and trending of CR cause codes and reporting of such in various management documents. No concerns were identified by the team with regard to the implementation of QAP 16.0, 16.1, and 16.3 requirements.

#### **4.1.3 Documentation Controls**

The team reviewed SFD's documentation control program to determine if documentation controlling the fabrication, maintenance, and procurement processes was approved in accordance with procedures; if a procedure development program was established; if supplied material and services were covered by adequate QA procedures; if quality records were identified, controlled, and retrievable; if a completed document close-out review was implemented; if appropriate procedures were available at job locations; if changes to controlled documents were reviewed and approved in accordance with procedures; and if measures were established for the issuance of controlled documentation.

The team reviewed QAP 6.0, "Document Control," Rev. 13, dated 1/19/07, and interviewed the person responsible for the issuance of controlled procedures and documentation. The team also reviewed QAP 17.0, "Quality Records," Rev. 19, dated 1/19/07.

The team observed current controlled copies of the QA manual and procedures at various work locations. All quality procedures, documents, and records requested by the inspection team were properly filed and readily retrievable. The design, procurement, and fabrication documents reviewed by the team were covered by adequate QA procedures and appeared to contain appropriate QA requirements and approvals.

In the area of documentation controls, the team had no findings.

#### **4.1.4 Audit Program**

The team reviewed SFD's audit program to determine if the audit program covered all applicable aspects of the QA program; if audits were scheduled and conducted periodically in accordance with approved procedures or checklists; if audit personnel were appropriately trained and did not have direct responsibility in the areas audited; if audit results were documented, reviewed, and approved by management; if an audit discrepancy resolution program and corrective action follow-up program were implemented; if contractors were approved and maintained on an approved vendor list; and if supplied materials and services were verified through appropriate inspections and audits.

The team reviewed Section 18 of "Manual of Quality Assurance for EnergySolutions Spent Fuel Division," Rev. 12, dated 9/13/06, and QAP 18.0, "Audits and Surveys," Rev. 10, dated 2/8/07. An internal audit of the entire QA system is required annually, and an external audit of active suppliers is required once every three years. The inspector reviewed QAP 18.1, "Qualification and Certification of QA Audit Personnel," Rev. 5, dated 2/8/07, and QAP 18.3, "Internal Surveillance," Rev. 1, dated 2/8/07. The purpose of QAP 18.3 is to provide confidence to management of the effectiveness of the company's quality assurance program.

The team reviewed the audit schedule dated 3/2/07 and the annual internal audits for the past three years. The audits were conducted in accordance with written and approved checklists by trained and qualified audit personnel not having direct responsibility in the areas being audited. The audit reports were approved by management and corrective action had been initiated for the audit findings. The team reviewed selected bimonthly surveillances performed in accordance with a written checklist, and semiannual and annual reports addressing the status of the QA program.

The team reviewed the training and qualifications of two lead auditors and found the records to adequately document the required training.

The team reviewed QAP 7.1, "Supplier Evaluation," Rev. 13, dated 1/19/07, and QAP 18.2, "Quality Assurance Surveillance of Suppliers," Rev. 7, dated 2/8/07. The purpose of QAP 18.2 is to assure the supplier's QA program is operating adequately and effectively throughout the project.

The team reviewed SFD's Approved Suppliers List (ASL) dated 1/26/07, which contained for each supplier, the date of the last evaluation, the next evaluation due date, any restrictions, and the quality level approved for. The ASL included Manufacturing Sciences Corporation (MSC),

the fabricator of the MIDUS package, as a current supplier. The team reviewed the audit and evaluation for MSC conducted 6/1-3/05 and an annual evaluation conducted 10/25-27/06 which also assessed readiness to begin fabrication. Data on the ASL was consistent with the results of the evaluations.

The team reviewed a corporate QA audit of SFD conducted 8/9/05 by the corporate QA Manager, and reviewed two audits by Office of Civilian Radioactive Waste Management (OCRWM) and Entergy to retain SFD on their respective qualified supplier lists.

In the audit program area, the team had no findings.

## **4.2 Design Controls**

### **4.2.1 Design Development**

The team interviewed SFD engineering personnel responsible for the preparation and approval of design documents. The team found the design control process in support of the above reviewed documents to be adequately accomplished. Pertinent documents reviewed related to this activity included:

- QAP 3.0, Revision 13, effective 1/19/07, "Design Control"
- QAP 3.1, Revision 6, effective 2/08/07, "Design Input"
- QAP 3.2, Revision 10, effective date 1/19/07, "Calculations"
- QAP 3.6, Revision 8, effective date 2/08/07, "Safety Analysis Reports"
- License Amendment Request 9276-0003, VSC-24 Multi-Assembly Sealed Basket Transportation SAR
- Fuel Solutions Storage System, FSAR Document Number WSNF-120, WSNF-221, and WSNF-123
- TYCO MIDUS Medical Isotope Transport Package SARP and RAIs (in process).

All personnel interviewed were able to provide detailed descriptions of the control and review processes for design control activities being performed. Through discussion and review of documents, the team assessed that the SFD design control process is adequate.

British Nuclear Group (BNG) Commitment Compliance Matrix, TYCO1.1008.01, Form QAP 3.0-4 Revision 13 was reviewed. The compliance matrix identified required information and deliverables to be received from MSC. MIDUS Transportation Package Fabrication Specification, TYCO 1.1042, Rev. 0, December 7, 2006, was reviewed and found to be adequately developed and controlled in accordance with procedures.

In summary, SFD was found to have well developed QAPs for controlling initial designs, as well as ongoing modification and fabrication processes for transportation and storage packagings and containers. Forms were well developed and the screening, calculations, engineering change and design change/modification processes were adequately accomplished. No findings were identified and implementation of the controlling processes was assessed to be adequate.

#### 4.2.2 Design Changes/Modifications

The team reviewed selected drawings, procedures and records, and observed selected activities being-performed to determine that design change and modification activities met design commitments and requirements documented in the CoC. The inspector reviewed the VSC-24 and Fuel Solutions CoC and associated amendment requests. The team reviewed the control of design changes to MSC for the MIDUS package through a review of the design, fabrication, and test procedures in the SFD QAP. Pertinent documents reviewed related to this activity included:

- QAP 3.9, Revision 4, effective date 2/08/07, "72.48 Screening Review"
- QAP 3.15, Revision 2, effective date 2/08/07, "10 CFR 72.48 Evaluation"
- QAP 3.16, Revision 1, effective date 2/08/07, "10 CFR 71 Change Evaluation"

The team reviewed a sample of SFD Certificates of Compliance in order to determine the adequacy of the engineering change, design control, modification and 10 CFR 72.48 screening processes. The inspector reviewed the VSC-24 and Fuel Solutions CoC and associated amendment requests. The inspector also reviewed a number of completed design control forms, processes and associated documents including the 10 CFR 72.48 log. 10 CFR 72.48 Screening Review Forms were reviewed and found to be adequately completed. A sample of 10 CFR 72.48 evaluations from 2001 forward, were reviewed and found to be adequately completed in accordance with procedures. The team also reviewed SFD's 10 CFR 71 design change process and found the process to be accomplished in accordance with procedures and the forms to be adequately completed. No findings were identified and implementation of the controlling processes was assessed to be adequate.

#### 4.3. Fabrication Controls

The team evaluated the fabrication process to ensure that it was controlled and verifiable from the onset of design through the completion of the manufacturing process. The team reviewed SFD's QAPs with regard to fabrication controls to verify that fabrication activities are properly controlled and implemented at the facilities of its contractors and subcontractors. In particular, the team focused its review on the controls SFD imposed for the ongoing fabrication of the TYCO MIDUS Medical IsotopeTransport Package design, for which SFD is the Certificate of Compliance holder, at the Manufacturing Sciences Corporation fabrication facility in Oak Ridge, Tennessee. Pertinent documents reviewed related to this activity included:

- TYC01.005, "TYC-01 Project Plan"
- TYC01.1042, "MIDUS Transportation Package Fabrication Specification"
- IMITP302006.03.02, "Integrated Manufacturing, Inspection and Test Plan for MIDUS Transportation Units"

From a review of the above documents as well as conversations with SFD personnel, the team assessed that SFD has imposed appropriate and detailed controls governing all aspects of the fabrication of the TYCO MIDUS Medical IsotopeTransport Package at its fabricator. No concerns were identified in this area.

#### **4.4 Maintenance Controls**

The team reviewed SFD activities regarding maintenance and found this area to be inactive at this time. It was noted that procedures were in place to control these activities in the future.

**ENTRANCE MEETING**

G. Michael Karmis  
Frank Jacobs  
Bill Ruland  
Rob Temps  
Steve Sisley  
Douglas A Brown  
Bob Quinn

NRC/SFST  
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Licensing/Regulatory Compliance Manager  
QA Manager SFD/ES  
President Spent Fuel Division, ES

**EXIT MEETING**

G. Michael Karmis  
Frank Jacobs  
Bill Ruland  
Rob Temps  
Patrick Quinn  
Robert A. Leaner  
Steve Sisley  
Douglas A Brown  
Ram Srinivasan  
Bob Quinn

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