



## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER:

EnergySolutions  
2105 S. Bascom Avenue, Suite 230  
Campbell, CA. 95008

## 2. NRC/REGIONAL OFFICE

Headquarters  
U. S. Nuclear Regulatory Commission  
Mail Stop 3WFN 14C-28  
Washington, DC 20555-0001

## REPORT NUMBER(S)

71-0935/2016-201

## 3. CERTIFICATE/QAP DOCKET NUMBER(S)

71-0935

## 4. INSPECTION LOCATION

Campbell, CA

## 5. DATE(S) OF INSPECTION

February 1 - 3, 2016

## CERTIFICATE/QUALITY ASSURANCE PROGRAM HOLDER:

The inspection was an examination of the activities conducted under your QAP as they relate to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your QAP Approval and/or Certificate(s) of Compliance. 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 were identified.
- ☐ 2. Previous violation(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, to exercise discretion, were satisfied.

One

Non-cited violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

The NRC determined that a Severity Level IV violation of NRC requirements occurred with two examples. Specifically, 10 CFR 71.111, "Instructions, Procedures, and Drawings," requires, in part, that the certificate holder shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and require that these instructions, procedures, and drawings be followed. Contrary to, as of February 3, 2016, ES personnel did not follow ES-AD-PR-018, Attachment 5.1, Step 2 and ES-QA-PR-010, Step 4.9 for receipt inspection activities and inspection of critical characteristics for important to safety category A components, respectively. ES entered this violation into their corrective action program.

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

(Violations 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.

TITLE	PRINTED NAME	SIGNATURE	DATE
CERTIFICATE/QAP REPRESENTATIVE	Mike Nicol		3/16/16
NRC INSPECTOR	Marlone Davis		3/16/16
BRANCH CHIEF	Patricia Silva		3/17/16



### INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder	EnergySolutions 2105 S. Bascom Avenue, Suite 230 Campbell, CA. 95008
Licensee/Certificate Holder contact and phone number	Mr. Mike Nicol, Corporate Quality Assurance Director Regulatory Affairs 865-481-6303
Docket No.	71-0935
Inspection Report No.	71-0935/2016-201
Inspection Date(s)	February 1 - 3, 2016
Inspection Location(s)	2105 S. Bascom Avenue, Suite 230 Campbell, CA. 95008
Inspectors	Marlone Davis, Team Leader, Senior Safety Inspector Earl Love, Senior Safety Inspector Jeremy Tapp, Safety Inspector
Summary of Findings and Actions	<p>The purpose of the inspection was to verify the adequacy of activities related to design, modification, fabrication, and procurement of transportation packaging(s) activity at the Energy Solutions (ES) Campbell, Ca. facility. The focus of the inspection was to assess and determine whether ES 10 CFR Part 71 activities are in accordance with commitments and requirements specified in the CoC, Safety Analysis Report for Packaging (SARP), NRC-approved Quality Assurance Program (QAP) for Transportation of Radioactive Materials, and 10 CFR Parts 21 and 71 requirements.</p> <p>The team of inspectors determined that the transportation packaging was safe to use based on a review of selected quality records and other supporting documentation. The team assessed that ES implementation of its NRC-approved QAP was adequate.</p> <p>The team did identify one non-cited violation with two examples related to instructions, procedures, and drawings for the ES QAP. ES acknowledged this finding during an exit on February 3, 2016 and documented this non-cited violation in their corrective action program.</p>
Lead Inspector	Marlone Davis
Signature/Date	 3/16/16
Inspector Notes Approval	Patricia Silva
Branch Chief Signature/Date	 3/17/16

## Inspector Notes

On April 2, 2015, the U.S. Nuclear Regulatory Commission (NRC) approved the latest submitted Quality Assurance Program (QAP) from EnergySolutions (ES) for radioactive material packages designated under docket number 71-0935. The approval satisfied Title 10 of the *Code of Federal Regulations* (10 CFR) for Part 71, "Packing and Transportation of Radioactive Material" requirements.

During the week of February 1, 2015, a team of NRC inspectors conducted inspection activities applicable to the transportation of radioactive material packaging at the ES's Campbell, California (CA) office. The purpose of the limited scope inspection was to verify the adequacy of activities related to the design, modification, fabrication, and procurement for transportation of radioactive material packaging. The team reviewed QAP implementing procedures and instructions, inspection of selected documents, records, and drawings. The inspectors also reviewed various engineering and fabrication activities of the following transportation packaging registered to ES:

Model #	Package ID#	Docket #	Certificate #
8-120B	USA/9168/B(U)-96	71-9168	9168
10-160B	USA/9204/B(U)F-96	71-9204	9204
MIDUS	USA/9320/B(U)-96	71-9320	9320
3-60B	USA/9321/B(U)-96	71-9321	9321

The team conducted the inspection activity requirements in accordance with NRC Inspection Procedure 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings". The team conducted the final exit meeting on February 3, 2015. The team identified one Severity Level IV violation with two examples of NRC requirements associated with 10 CFR 71.111, Instructions, Procedures, and Drawings. Specifically, ES personnel did not perform their activities in accordance with the requirements of ES's QAP implementing procedures ES-AD-PR-018 and ES-QA-PR-010. The NRC plans to treat the NRC identified finding as a non-cited violation consistent with section 2.3.2 of the NRC Enforcement Policy. ES acknowledged the information presented and documented the violation in their corrective action program.



**INSPECTOR NOTES: AS DESCRIBED BELOW, THE TEAM PERFORMED AND DOCUMENTED APPLICABLE PORTIONS OF 02.02 THROUGH 02.10 OF INSPECTION PROCEDURE (IP) 86001**

**02.02 Verify that the CoC holder's activities related to transportation packaging are being conducted in accordance with the CoC, as well as the NRC-approved QAP, and that implementing procedures are in place and effective.**

The team of inspectors reviewed ES's NRC-approved QAP (ES-QA-PG-001, Revision 3) and various implementing procedures to verify that ES conducted activities related to the transportation packages identified above were in accordance with their Certificate of Compliance (CoC). The team focused on the Projects, Products, and Technology Group of the ES organization. The team reviewed the organizational facility responsibilities and authority to determine and understand how the Projects, Products, and Technology Group implemented the NRC-approved QAP.

The team concluded that ES performed activities related to transportation packaging in accordance with their registered CoCs, NRC approved QAP and the QAP implementing procedures. The team determined that programs and procedures are in place and are effective for ES to conduct activities related to transportation packaging activities at their Campbell, CA. office.

**02.03 Verify that provisions are in place for reporting defects which could cause a substantial safety hazard, as required by 10 CFR Part 21**

The team reviewed ES Procedure ES-AD-PR-006, "Reporting of Defects and Noncompliance (10CFR21)" Revision 4, to determine if provisions were in place for reporting defects that could cause a substantial safety hazard. The inspectors requested a list of Part 21 evaluations and notifications associated with ES transportation packaging and interviewed personnel to determine if they were familiar with the implementing procedure ES-AD-PR-006. The inspectors noted that there were no defects or noncompliance reports identified over the last five years for Part 21 notifications. The inspectors also reviewed other nonconformance and condition reports initiated and dispositioned in the Campbell Office to determine if those met the criteria of reporting under Part 21. The team also verified that the ES Campbell Office complied with 10 CFR 21.6, "Posting requirements."

Based on the review, the team concluded that ES have provisions in place for reporting defects that could cause a substantial safety hazard, as required by 10 CFR Part 21.

**02.04 Interview selected personnel and review selected design documentation to determine that adequate design controls are implemented.**

The team reviewed selected design documentation to determine that ES implemented adequate design controls for the organization responsible for Engineering Change Notices (ECNs) and approve design modification changes. The team noted that the Projects, Products, and Technology Group at the ES Campbell facility evaluates the proposed changes to determine any significant impact to the design, modification, fabrication and procurement of all projects. The team also noted that ES recently developed new engineering procedures to implement the Design Control requirements of the ES QAP. ES plans to transition to the new procedures in the near future.



The ES design control procedures reviewed during this inspection included the following:

- CG-EN-PR-101, revision 2, dated 02/02/2015, "Design Control"
- CG-EN-PR-201, revision 0, dated 11/27/2015, "Design Control" (New)
- CG-EN-PR-102, revision 1, dated 08/18/2014, "Preparation and Checking of Engineering Documents"
- CG-EN-PR-202, revision 0, dated 11/27/2015, "Preparation and Checking of Engineering Documents" (New)
- CG-EN-PR-301, Revision 0, dated 11/27/2015 "10 CFR 71 Change Evaluation" (New)
- ET-SF-EP-306, Revision 2, dated 11/01/2013, "Safety Analysis Reports"
- CG-EN-PR-303, Revision 1, effective 02/12/2016, "Safety Analysis Reports" (New)

Overall, the team verified that implementing procedures were in place and effective in controlling activities in accordance with their registered CoC. The team concluded from reviews and interviews with design personnel that ES has a mature quality program, which includes design and procurement procedural guidance.

#### **02.05 Review selected drawings, procedures and records, and observe selected activities being performed to determine that design & maintenance activities meet Safety Analysis Report for Packaging (SARP) design requirements documented in the CoC**

The team reviewed the latest design documentation applicable to 8-120B, 10-160B, 3-60B and MIDUS packages. First, the team noted that on January 14, 2016, ES submitted a request to amend the CoC for the 10-160B Type B Radwaste Shipping Cask. The team noted that the application requested the addition of an alternative material for the primary and secondary O-rings. The team also reviewed design documentation applicable to CoC No.: 9204 renewal (Docket No. 71-9204, Revision 21 dated 12/27/2013), which added a new variant to the existing 10-160B shield insert, designated as Shield Insert B, for shipping dry-loaded sources. It also changed the existing Safety Analysis Report (SAR) addendum for the 10-160B shield insert (re-designated as Shield Insert A). These included revisions to the insert and cribbing drawings, revisions to permit insert reuse, revision of the shielding analysis to correct the drain configuration, and other editorial corrections.

Secondly, the team noted that Diversified Metal Products (DMP) manufactured four (4) 8-120B casks. The team reviewed DMP's certificate of conformance for one of the cask Serial Number (S/N) 8-120B-6 dated 10/24/2014 and certified as-built fabrication drawing (No.: C-002-160000-015, revision 9, "8-120B Cask General Arrangement and Details). The team compared DMP's as-built drawing including a sample of ESs ECNs (Nos: 120CL1-001, -004, -008, and -010) to the SAR design drawing (No: C-110-E-0007, revision 22) and determined that the as-built configuration met the SARP design requirements. In addition, the team reviewed ECNs applicable to the SARP design drawing and noted that ES implemented adequate design controls. The team also noted that design activities met SARP design requirements documented in CoC 71-9168, Revision 22.

Next, the team reviewed ECN-12GCL1-017, dated 9/16/2015, which added a "drinking straw" to the 8-120B secondary lid O-ring test port in SAR drawing C-110-E-0007 (from: revision 21, to: revision 22), CoC Revision 22, and ES SAR Revision 9, dated 02/2015. The team noted that ES inadvertently omitted the drinking straw when ES modified the secondary lid for revision 19 of the CoC. ES manufactured the secondary lids on 8-120B-1, 2, 3 and 2S as replacement lids



without the drinking straws, in compliance with the current CoC at the time of fabrication. ES manufactured the remaining lids 8-120B-5 through 8 with the drinking straws. However, the ES manufactured lids with the drinking straws did not comply with CoC revision 21. Based on a previous 2015 NRC inspection (ML15317A461) at ES's Columbia, South Carolina (SC) facility, the NRC issued a Notice of Violation to address this issue. The team noted that the purpose of the ECN was to add the drinking straws into the CoC so that units with lids 5 through 8 would restore the primary function of the item and place the lids back into service.

The team reviewed ECN-12GCL1-014, dated 2/12/2015, that changed the tolerance requirement on the cask cavity height. The reason for the change was to accommodate as-built cavity length of the 8-120B-5 Cask. ES incorporated this change in SAR drawing C-110-E-0007 (from: revision 19, to: revision 21), CoC, Revision 21, and ES SAR, Revision 9 dated 02/2015.

The team reviewed ECN-12GCL1-0008, dated 5/8/2013, to add a shielding plate to the lower impact limiter and to make other changes in order to resolve errors or provide clarifications as documented in various condition reports. ES incorporated this ECN in SAR drawing C-110-E-0007 (from: revision 18, to: revision 19), CoC Revision 20, and ES SAR Revision 7 dated 11/13/2013.

The team noted that Petersen Technologies, Inc. (PTI) manufactured one (1) 3-60B cask. The team reviewed PTI's certificate of conformance dated 06/09/2015 along with the certified as-built fabrication drawings of the Inner Containment (drawing No.: CSK-12-CV01-ME-009, revision 3), and Lid (drawing No.: CSK-12CV01-ME-012, revision 2). The team compared PTI's as-built drawings together with applicable ES ECNs (Nos: 12CV01-19, -22, -43, and -68) to the SARP design drawing (No: C-002-165024-001, revision 5) and determined that the as-built configuration met the SARP design requirements. In addition, the team reviewed ECNs (Nos.: 165024-001 through -006) applicable to the SARP design drawing and noted that ES implemented adequate design controls. The team also noted that design activities met SARP design requirements documented in CoC 71-9204, Revision 22.

The team noted that on 08/14/2015, the NRC granted ES a renewal to the 10-160B package (CoC 9204, revision 22) and that as part of the application there were no changes in the package design, operating procedures, acceptance tests and maintenance program or contents of the package. Subsequently, the team noted that ES submitted an amendment request, dated 01/14/2016, which requests the addition of ethylene propylene rubber as a material alternative for the primary and secondary lid O-rings. The team noted that the application is currently under NRC review.

Finally, with respect to the MIDUS package (CoC 71-9320, Revision 2), the team noted that there were no changes in the package design, operating procedures, acceptance tests and maintenance program or contents of the package since 2012. However, the team noted that ES plans to submit an application to amend the CoC to add a solid type and form of material for the transport of medical isotopes in order to accommodate a future package user (North Star Medical) request. In addition, the application will request a change to the nameplate to incorporate the users' name. In addition, the team noted that fabrication of (2 of 6) MIDUS packages is in the planning stages and will be at-risk, in part, due to pending submittal of a ES request to amend CoC No. 71-9320, Revision 2. Further, the team noted that ES recently completed an "at-risk" fabrication of the 3-60B package. The team noted this as an observation. ES stated that the new engineering design procedures would capture "at-risk" design controls.



The team assessed that ES was effectively implementing its design control procedures. The team concluded that ES processed and developed design, licensing, and fabrication drawings, ECNs in accordance with the applicable procedures. This included receiving the proper independent verification reviews and approvals. Overall, the team identified no concerns in the design control area. Additionally, the team did not note concerns with the construction, fabrication, and testing of the packages.

#### **02.07 Review selected drawings and records, and interview selected personnel, to verify that the procurement specifications for materials, equipment, and services received by the QA Program holder meet the design requirements**

The team reviewed selected drawings and records, and interviewed selected personnel to verify that the procurement specifications for materials, equipment, and services performed at the Campbell, CA office met design requirements of ES's registered transportation packaging. The team reviewed the procurement documents specific to Model No. 3-60B associated with the cask O-rings, and foam for the impact limiters. For both procurement specifications, ES procured the O-rings and the foam as Important to Safety (ITS) Category A components. The team determined that ES developed the procurement documents consistent with design requirements. The team noted that ES properly transferred the description of the Category A from the design drawing to the Purchase Order (PO). The team noted that the requirements of the supplier in the PO for the Category A items were appropriate. The team also verified that the vendors for the O-rings and foam, Pawling Engineered Products, Inc., and General Plastics Manufacturing Company, were on the ES Approved Suppliers List, dated November 25, 2015.

ES procured the O-rings with PO # 653934, Revision 2. The team noted that the receiving reports contained the applicable Certificate of Conformance that assured adequacy and traceability of the procured O-rings. The team reviewed the receipt inspection documentation for the O-rings to verify ES performed all required inspections as discussed in quality procedure ES-AD-PR-018, "Receipt Inspection," Revision 1. The team noted that the receipt inspection for the ITS Category A, O-rings, ES-AD-PR-018, Attachment 5.1, Step 2, states, in part, that if the PO specify a durometer value then Quality Control (QC) shall verify that the durometer value is within the stated tolerance using a calibrated instrument. The team noted the PO referenced specification SP-12CV01-001, "Seal Specification for the 3-60B Cask," Revision 1. Specification SP-12CV01-001 described a required durometer value for the O-rings. The team identified that the receipt inspection documentation did not discuss a durometer test or provide any test results. When asked about the test, ES could not provide any objective evidence to the team that QC performed the durometer test for the O-rings procured with PO # 653934. The team determine that ES could not provide collaborating information such that the team could determine whether ES failed to perform the task or merely failed to record it.

The team concluded that ES did not perform the required receipt inspection durometer test for the O-rings procured under PO 653934 (i.e., to verify that the O-rings met the required hardness criteria specified in the PO). The inspectors determined this was a violation of 10 CFR 71.111, Instructions, Procedures, and Drawings because ES personnel did not follow ES-AD-PR-018, Attachment 5.1, Step 2 and did not provide the record. 10 CFR 71.111 requires, 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. These instructions, procedures, or drawings must include appropriate acceptance criteria for determining that the certificate holder satisfactorily accomplished these important activities. Contrary to, as of February 3, ES did not



follow procedure ES-AD-PR-018 and did not document the record to verify ES personnel satisfactorily accomplished the durometer test.

The team determined that the violation was more than minor because the absent of the record calls into question whether or not ES followed the procedure and accomplish the task to test an ITS Category A component. The team dispositioned the violation in accordance with Section 2.3 of the NRC Enforcement Policy. The team characterized the finding as a Severity Level IV violation. The NRC plans to treat the NRC identified finding as a non-cited violation consistent with section 2.3.2 of the NRC Enforcement Policy. ES captured this issue in their corrective action program as ES-COM-CR-2016-37, dated February 3, 2016.

In addition, the team also reviewed selected drawings and records to verify that selected commercial grade dedication plans and associated activities performed out of the Campbell office received by ES met design requirements. The team reviewed the commercial grade dedication documents specific to the Model No. 8-120B cask for the bottom impact limiter shield plate (BILSP) and threaded inserts. ES commercially purchased and dedicated four BILSP under Commercial Grade Item (CGI) Dedication No.: CGI-13-001, Revision 1. The BILSP are ITS Category A component. The team reviewed the critical characteristics form for CGI-13-001 and noted it identified material type, plate thickness, and plate diameter as critical characteristics. ES design engineering determined that these critical characteristics were appropriate for a carbon steel plate in this application.

The team reviewed CGI Dedication File GLD-003-014, dated March 11, 2014, to determine if ES adequately verified all the critical characteristics. For the material type critical characteristic, the team assessed the chemical test reports for the four shield plates performed by Applied Technical Services, Inc., who is on the ES Approved Suppliers List, dated November 25, 2015. The team discovered that the four shield plates met the acceptance criteria for A36 carbon steel and that the vendor performed tests per the approved dedication method in CGI-13-001. For the plate thickness critical characteristic, the approved dedication method was to measure at one location using a calibrated instrument, but the team did not identify any thickness measurements documented in the dedication file. The team discussed this with ES and ES could not provide any objective evidence that ES personnel performed the plate thickness measurement for the four BILSPs as required by the approved dedication method.

The team noted that ES-QA-PR-010, "Dedication of Commercial Grade Items/Services," Revision 4, Step 4.9 requires, in part, that QC shall perform any inspections or testing as specified on the critical characteristics form that has not yet been completed. The team concluded that ES failed to perform the required dimensional inspection for the four BILSPs to complete all dedication activities required by CGI-13-001. This was a violation of 10 CFR 71.111, Instructions, Procedures, and Drawings because ES personnel did not follow and did not provide collaborating information in accordance with ES-QA-PR-010, Step 4.9. 10 CFR 71.111 requires, 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. The team determined that this violation was another example similar to the O-ring finding but in the commercial grade dedication area. The team decided to document one non-cited violation with two examples. ES also captured this issue in their corrective action program as ES-COM-CR-2016-41, dated 2/3/2016. The team did note that ES have not used the shield plates for transportation of radioactive material before the NRC identified this issue.



Next, the team reviewed ES's commercial dedicated threaded inserts for the 8-120B cask. ES purchased one hundred (100) threaded inserts from Consolidated Power Supply with PO # 603216, Revision 0 and then dedicated them under CGI Dedication No.: CGI-10-001, Revision 0, as ITS Category A. The team verified that Consolidated Power Supply was on the ES Approved Suppliers List, dated November 25, 2015. The team reviewed the critical characteristics form for CGI-10-001 and noted it identified part number, material, and tensile strength as critical characteristics. The team determined that these were appropriate for threaded inserts used in ITS Category A applications such as the containment boundary.

The team then reviewed CGI Dedication File E&L 10-087, dated August 25, 2010, to determine if ES adequately verified all the critical characteristics. The team determined that ES performed all three critical characteristics dedication methods as required by CGI-10-001. The team found that the results of the dedication activities showed the critical characteristics met the applicable acceptance criteria.

Although the team identified two issues involving procurement receipt and inspection activities, overall, the team concluded that the procurement documents issued by the Campbell office were of high quality.

**02.08 Review selected records and interview selected personnel to verify that a nonconformance control program is effectively implemented, and that corrective actions for identified deficiencies are technically sound and completed in a timely manner**

The inspectors reviewed selected records and interviewed selected personnel to verify that ES effectively implemented a nonconformance control program, and that ES completed corrective actions for identified deficiencies in a technically sound and timely manner. Specifically, the inspectors reviewed ES approved procedures ES-AD-PR-008 and ES-AD-PR-013, Condition Reports and Control of Nonconforming Items, respectively. The inspectors also reviewed nonconformance and condition reports from the previous five years associated with work performed at the Campbell office.

Overall, the team concluded that ES had an adequate corrective action system in place to resolve deficiencies.

**02.10 Verify that audits of the QA Program and activities affecting the safety aspects of the packaging are scheduled, have been performed as scheduled, and that identified deficiencies have been satisfactorily resolved in a timely manner**

The team reviewed ES' audit program to determine whether plans, procedures, and records were available and adequate. The team reviewed whether ES scheduled and performed internal QA audits in accordance with approved procedures or checklists. The team reviewed ES' procedure ES-QA-PR-018, "Quality Assurance Audits" as well as the 2014 and 2015 internal audit reports of the Campbell, CA office (Projects, Products, and Technology Group). The team also reviewed corrective actions associated with audit findings. The team noted during the review of the 2015 internal audit of the Campbell office that there was no associated audit checklist in the documentation package. The required audit report was available for the team to assess, even though it did not contain as much detail as the checklist. The team discussed with ES the benefit of keeping the checklist so that a future third party reviewer could assess the details of the audit. ES acknowledged the observation provided by the team.



Overall, the team concluded that ES adequately implemented the audit elements contained in ES-QA-PR-018 and conducted their audit program in accordance with Part 71 requirements for internal audit reports of the Campbell, CA office.