

INSPECTOR NOTES COVER SHEET

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Licensee/Certificate Holder contact/address	Mr. Jerome M. Ebner Director, Environmental Safety, Health, and Quality 7207 IBM Drive, CLT-1D Charlotte, NC 28262
Docket No.	071-0938
Inspection Report No.	2011201
Inspection Dates	February 1 through 3, 2011
Inspection Location	Tacoma, WA
Inspectors	Rob Temps, Team Leader, Senior Safety Inspector Jim Pearson, Senior Safety Inspector Jon Woodfield – Safety Inspector
Summary of Findings and Actions	<p>The purpose of this routine inspection was to assess the compliance of AREVA Federal Services (AFS), LLC, at the Tacoma, WA, location, to the requirements of 10 CFR Parts 71 and 21. The inspection activities focused on management and design.</p> <p>The team identified one violation of NRC requirements as cited in the attached Form 591 and as described in the following inspector notes. Overall, AFS's implementation of their NRC-approved Part 71 Quality Assurance Program at the Tacoma location was assessed to be adequate.</p>
Lead Inspector Signature/Date	Robert Temps  02/18/11
Inspector Notes Approval Branch Chief Signature/Date	Eric Benner  2/18/11

1. MANAGEMENT CONTROLS

Quality Assurance Policy

The team reviewed the AREVA Federal Services, LLC (AFS) document AFS-QA-POL-001, Revision 99, "Quality Policy." The team noted that the policy commits to AFS-QA-PMD-001, the AFS Quality Assurance Program Description (QAPD) and associated implementing procedures. The team verified independence of the AFS Environmental, Safety, Health, and Quality (ESH &Q) Organization through review of Section 201 of the AFS Organization portion of the QAPD and Figure 1-1 of the QAPD. The team determined that the QAPD adequately addressed the eighteen Subpart H quality assurance (QA) criteria. No concerns were identified.

Audits

The team reviewed section 18 of the AFS QAPD, "Audit and Surveillance," and procedure AFS-QA-PRC-18.1, "Internal Audits." The team reviewed the internal audit notifications, audit reports and audit checklists for several internal audits, as well as various revisions of the 2008, 2009, 2010 and 2011 audit and surveillance and annual evaluation schedules; the team noted they were all performed in accordance with AFS-QA-PRC-18.1 requirements.

The team reviewed procedure AFS-PRC-2.2, "Qualification of Audit Personnel," and a sampling of records attesting to the qualification, and ongoing proficiency of audit personnel. No concerns were identified.

Nonconformance Controls

The team reviewed and assessed the status of the corrective action program used by AFS through review of corrective action program administrative procedures and by review of Corrective Actions Records (CARs) and Nonconformance Reports (NCRs). The team reviewed procedures AFS-QA-PRC-15.1, "Control of Nonconforming Items," and AFS-QA-PRC-16.1, "Corrective Actions Records," together with a sampling of relevant CARs and NCRs. The team also reviewed required quarterly trend and annual assessment reports related to the corrective actions program. Overall, the resolution of issues in CARs and NCRs was assessed to be adequate. However, several discrepancies were identified and discussed with AFS for resolution. These included: 1) several instances in which the "N/A" box on completed NCR forms were not completed in accordance with AFS-QA-PRC-15.1, 2) one instance in which a required concurrence signature related to the significance evaluation was not made (NCR 2009-50), and 3) one instance in which a corrective action for a closed CAR (2009-5243) was not properly implemented. AFS initiated CARs 2011-745 and 748 to document and address the team's findings and observations.

The failure to properly fill out the NCR forms in accordance with the requirements of procedure AFS-QA-PRC-15.1 is a violation of 10 CFR 71.111, "Instructions, procedures, and drawings," which states, in part, that a certificate holder shall prescribe activities affecting quality by documented procedures and shall require that these procedures be followed. The violation is cited in the attached Form 591.

The team also reviewed and verified the completion of AFS's corrective actions to a Notice of Violation issued with regard to NRC inspection report 71-0938/2009-201. The inspection was conducted in 2009 and involved fabrication activities for the BRR packaging. No concerns were identified in AFS's corrective actions and the NOV is considered closed.

10 CFR Part 21 Postings and Procedures

The team verified the presence of required Part 21 postings and reviewed procedure AFS-QA-PRC-15.2, "Reporting Defects and Noncompliances per 10CFR21 and PAAA." The team verified that for Part 71 related purchase order, Part 21 requirements were imposed. The team determined that these documents provided acceptable controls for identification and handling of Part 21 issues.

Training

The team examined a sample of five (5) training records and learning histories of AFS personnel, and reviewed procedure AFS-TR-PRC-001, "Training." The team noted from the review that required reading had been completed by AFS personnel for training to support compliance to 10 CFR Part 21. No concerns were identified with regard to training records.

Supplier Evaluations and Audits

The team reviewed procedure AFS-QA-PRC-7.2, "Supplier Evaluations," and also examined supplier evaluation documents for a metal supplier listed on AFS' approved supplier listing (ASL). The company was listed on the ASL as a supplier of ferrous and nonferrous materials, and the team noted, based on AFS's evaluation of the company, that restrictions and conditions had been placed upon it. No concerns were identified with regard to supplier evaluations.

The team reviewed procedure AFS-QA-PRC-7.3, "Supplier Audits," and also reviewed a sample audit, audit notification letter, and audit checklist for an audit of ABW Technologies, listed on the AFS ASL as a supplier of fabricated parts and components. No concerns were identified with regard to supplier audits.

The team reviewed procedure AFS-QA-PRC-7.1, "Control of Purchased Materials, Parts, and Components," and procedure AFS-PR-PRC-001, "Purchase Requests," with regard to material purchases for fabrication of the TRUPACT III packaging design. The team reviewed a purchase order to Rainer Rubber Company and verified that the company was listed on the AFS ASL. The team requested the delegation of authority required for signatures provided on the approval blocks for two purchase requests where individuals had indicated signature via delegation. AFS was unable to provide documentation for the approval/authorization of the delegation; the team noted that procedure AFS-QA-PRC-1.1, "Organization and Delegation of Authority," Section 6.2, "Delegation of Authority," requires documentation in writing or by electronic mail (e-mail). The team identified this as a violation of 10 CFR 71.111, "Instructions, procedures, and drawings," which states, in part, that a certificate holder shall prescribe activities affecting quality by documented procedures and shall require that these procedures be followed. The violation is cited in the attached Form 591.

2. DESIGN CONTROLS

The team reviewed the AFS QAPD and various implementing procedures that address design development and modification activities. The team reviewed AFS's engineering procedures that address design development and modification activities and reviewed AFS design activities related to the certificated TRUPACT-III and BEA Research Reactor Cask packagings, and pre-licensing design activities for the LANL B packaging design. The team interviewed various AFS personnel and reviewed the design control portions of the applicable AFS implementing procedures. The following AFS engineering procedures were reviewed:

AFS Engineering Procedure Number	Title
AFS-EN-PRC-001	Design Control
AFS-EN-PRC-002	Calculations
AFS-EN-PRC-003	Engineering Drawings
AFS-EN-PRC-004	Specifications
AFS-EN-PRC-005	Design Changes
AFS-EN-PRC-006	Software Development Quality Assurance
AFS-EN-PRC-007	Commercial Grade Items
AFS-EN-PRC-010	Test Control
AFS-EN-PRC-013	Control of Software Used for Calculations and Analysis
AFS-EN-PRC-015	Class of Components for 10CFR71 and 10CFR72 Applications
AFS-EN-PRC-018	Licensing

The team reviewed the project plan for the LANL B Cask Project and determined that the plan was thorough, that technical and quality roles and responsibilities related to design were properly defined, and that it contained the proper reviews and signatures in accordance AFS-EN-PRC-001, "Design Control." The team also reviewed the associated Design Basis Requirement Document PKG-DBR-SPC-006 and determined that it documented the design criteria and design basis qualification for the package design. The team determined the document was thorough, and contained the proper procedurally required reviews and signatures.

The team reviewed design report TAD-0113 for the Transportation, Aging and Disposal Waste Package Spacer Project. The team determined that the document was thorough and the final design well documented with the drawings, calculations, and associated reports identified for the package. The document had the proper procedurally required reviews and signatures.

The team reviewed the approved software list in AFS's Record Management/Document Control (RM/DC). Calculation 01910.01.C004-06, revision 2, "BEA Research Reactor Package Basket Structural Calculation", was reviewed. Its check print was also provided from RM/DC. The team determined that the calculation format, the check print, the documented calculation revisions, and required approvals/signatures, were all conducted in compliance with AFS-EN-PRC-002, "Calculations."

The team reviewed five engineering drawings that had associated Engineering Change Notices (ECNs). Several check prints were provided from the drawing checker, QA reviewer, and

responsible engineer reviews. The drawings all had the proper reviews and signatures and were compliant with the requirements of AFS-EN-PRC-003, "Engineering Drawings." The team reviewed the ECNs associated with the five drawings and determined they were properly processed, reviewed, and approved in accordance with AFS-EN-PRC-005, "Design Changes." The team interviewed the manager of RM/DC to verify ECN/FCN numbers were assigned by RM/DC per the procedure and that the ECN/FCNs were being attached to the parent drawings also as required per the procedure. The team determined that AFS's control of design changes was in compliance with AFS-EN-PRC-005.

The team reviewed Specification PKG-FP-SPC-014, revision 0, "Polyurethane Foam Specification for the Los Alamos National Laboratory Type B (LANL B) Container, Certification Test Unit Impact Limiters." A check print was also provided with reviewer comments. The specification had the desired procedure format with proper reviews and signatures. The team found the design control of the Specification to be compliant with AFS-EN-PRC-004, "Specifications."

The team reviewed procedure AFS-EN-PRC-010, Section 6.2, "Conduct of Test and Documentation of Results." Section 6.2, states in part, that a Test Conductor leads the test in accordance with the approved test plan and/or test procedure and documents the test results. Test records are controlled and identify, as a minimum, the following: item tested, date of test, person performing the test and/or recording test results, observations and conditions, results and evaluation of acceptability, corrective action or retest, if any, to correct non-acceptance result, and person evaluating and/or checking test results.

The team reviewed the Test Plan, Test Procedure and Final Test Report for the BEA Research Reactor Package Certification Test. The team focused on the Final Test Report and the minimum test records required by section 6.2 of AFS-EN-PRC-010. The team noted that the Final Test Report did not contain an evaluation of acceptability of the test results. AFS stated that the evaluation of acceptability was instead provided in the Safety Analysis Report (SAR) for the packaging design. The team noted that the coversheets for the Test Plan, Test Procedure, and Final Test Report were the standard coversheet used for Specifications. Since the coversheets were for Specifications, there was no signature block provided for engineering manager approval as required by AFS-EN-PRC-010. The EM stated that although there was no specific title block for the EM's signature, he would have signed in the block for Project Manager Approval on all three documents. The EM stated that he had delegated signature authority as allowed. These observations were discussed with AFS personnel who issued CAR 2011-766 for tracking and resolution.

As part of design control, procedure AFS-EN-PRC-018, "Licensing," states that fabrication of licensed hardware must conform to the requirements and conditions specified in the Certificate of Compliance issued by the regulatory authority. The SAR drawings establish the design requirements and must be adhered to. Section 6.7.1, "Reconciliation of the SAR to Fabrication Documents," states that prior to application of the nameplate to licensed hardware, and using released drawings, the Project Engineer shall perform a reconciliation between the SAR and the fabrication documents. The reconciliation shall be documented on form AFS-EN-FRM-010, "SAR/Fabrication Document Reconciliation." The form shall not be signed until all discrepancies are resolved. Evidence of the reconciliation, such as marked up drawings, shall be attached to the form.

The team requested a completed form AFS-EN-FRM-010 for a BEA Research Reactor Cask Amendment that was subject to the requirements of procedure AFS-EN-PRC-018. The team determined that while the required reconciliation was performed, it was not documented on form AFS-EN-FRM-010 as required by AFS-EN-PRC-018. The failure to document the reconciliation in accordance with the requirements of procedure AFS-EN-PRC-018 is a violation of 10 CFR 71.111, "Instructions, procedures, and drawings," which states, in part, that a certificate holder shall prescribe activities affecting quality by documented procedures and shall require that these procedures be followed. The violation is cited in the attached Form 591. AFS personnel acknowledged that the procedure had not been followed and initiated CAR 2011-752 to document the finding.

Overall, with regard to design control activities, the team assessed that AFS was effectively implementing procedures governing project planning, design development, design input, design verification, and design drawing configuration control.