

INSPECTOR NOTES: SECTIONS 02.02 THROUGH 02.10 OF IP 86001 WERE PERFORMED DURING THE INSPECTION WITH RESULTS DOCUMENTED BELOW:

02.02 Verify that the Certificate of Compliance (CoC) holder's activities related to transportation packagings are being conducted in accordance with the CoC, as well as the NRC-approved QA Program (reference Regulatory Guide 7.10), and that implementing procedures are in place and effective.

Inspector's Name: Pearson

The following documents were reviewed against activities, where possible:

SPEC's CoCs for the 2T, 150, & 300 radiography packages and the C1 source changer.  
Select portions of SPEC's QA Program and the associated Organizational Chart  
Procedures:

SPEC Quality System Procedure Manual:  
Section 1.0 Organization  
Section 2.0 Quality Assurance Organization

Authorities and responsibilities delineated in the SPEC's NRC approved QA Program were clear and appeared to be understood within the organization. Though the quality oversight group is small it was apparent that the QA personnel appeared to have the appropriate authority for witnessing and inspecting quality related work activities.

The results of documentation reviewed during the audit, as well as interview results with quality, production and manufacturing personnel provide evidence that SPEC is generally conducting their Part 71 activities in accordance with the NRC approved QA Program and the CoCs for their packagings.

Inspector's Name: Ross-Lee

Documents reviewed in regard to this and other portions of the inspection included all or select portions of the following:

QSPM12 - Control of Inspection Measuring and Test Equipment  
QA01 - Document Control System  
QA07 - Document Release and Distribution  
QA34 - C-1 DU Shield Receiving Survey  
QA47 - SPEC 300 DU Shield Survey

The inspector verified that the correct CoC drawings were in the system with the correct versions. The inspector looked at several working drawings to verify that there was a match between them and the CoC drawings for the critical information. The procedures reviewed have a sign off to verify the correct drawing revision.

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.

Inspector's Name: Pearson

SPEC's procedure from the Quality System Procedure Manual, Section 15.1, "Defect Notification," provided guidance in regard to the requirements of 10 CFR 21.21. The guidance included requirements for vendors as well as internal evaluation of defects. Posting requirements are also provided and postings were verified in both buildings. It was verified that purchase orders issued for components identified as "QA" require the Part 21 provisions to be passed down to suppliers.

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

Inspector's Name: Cook/Ross-Lee

DESIGN CONTROL - Development and Modifications

Drawings were all verified by the inspector for the revision control. Working documents also were verified and the drawings matched appropriately. SPEC CoC drawings were verified to be the same as those indicated on the CoCs. The inspector looked at the Engineering Change Request (ECR) process. The Change Review Board verifies whether the change affects the CoC drawings or not, and whether it requires NRC approval. The 2 ECRs the inspector looked at for drawings were completed correctly. The working procedures in the shop have a drawing revision check, which the QA Manager then later verifies. The ECRs reviewed by the inspector affected the working drawings and did not require NRC approval.

The following document was reviewed against activities, where possible:

WORK INSTRUCTION No.: EG03

Title: ENGINEERING CHANGE REQUEST

Form EG03F1 "Engineering Change Request"

No design modifications were in progress during the inspection. SPEC design modification procedures and practices were discussed with the Vice President and Quality Assurance Manager. Based on these discussions, SPEC does not often engage in design modifications, due to the stability of the small product line.

Most changes are minor revisions of the packaging fabrication drawings, usually to adjust tolerances. These changes are initiated through an ECR. Any individual may submit an ECR. Submitted ECRs are reviewed by the Change Review Board (CRB), comprised of Engineering, Production, and Quality Assurance Managers. This process assures that the ability to suggest changes (which could potentially affect safety) is not restricted to certain personnel, and that a record is provided for the disposition of all submitted ECRs. The CRB may approve or reject ECRs; at its option, the ECR may request approval by the President.

Review of a sample of completed ECRs indicates the EG03F1 Forms are completed in accordance with WORK INSTRUCTION No.: EG03. The ECR change review process and documentation controls were assessed to be good and the appropriate controls were in place.

02.05 Review selected drawings, procedures and records, and observe selected activities being performed to determine that the fabrication, test, and maintenance activities meet SARP design commitments and requirements documented In the CoC.

Inspector's Name: Cook

A review of design and fabrication drawings for shields components indicated that Purchase Orders were properly specifying component materials and dimensions. Discussions with production personnel also indicated that they were aware of possible component fabrication issues (e.g., shield porosity), and had instituted procedures to individually evaluate each component with respect to porosity acceptability. SPEC has an established process to make minor shielding modifications, along with associated radiation level and weight measurements (using calibrated instruments) to assure the acceptability of shield components before they are installed in a packaging. These materials and fabricated components thus meet the package design requirements as established by the Certificate of Compliance.

Inspector's Name: Ross-Lee

The inspector verified that adequate maintenance activities procedures were in place, and the appropriate QA checks were identified. The workers appeared knowledgeable about the procedures and processes. There were QA hold points in procedures. Traceability could be verified as heat and lot numbers were on the travelers and the equipment. The inspector reviewed 3 Corrective/Preventative Action Request/Reports that complete and appropriately processed. The inspector determined that the requirements found in the CoC , as applicable, were being met.

02.06 Observe activities affecting safety aspects of the packaging (such as fabrication, assembly, and testing) to verify that they are performed in accordance with approved methods, procedures, and specifications.

Inspector's Name: Cook

#### FABRICATION CONTROLS - Material Procurement

The following documents were reviewed against activities, where possible:

##### Purchase Orders

The procurement of shields was reviewed. The design specifications for the shields were specified on fabrication drawings that provided considerably more detail than the design drawings. The Purchase Orders specified a minimum depleted uranium assay that was consistent with the design and fabrication drawings.

#### FABRICATION CONTROLS - Fabrication and Assembly

The following documents were reviewed against activities, where possible:

QA18F4 SPEC 150 w/ Lock Module Rev. Date 2/23/04 for SPEC 150 Serial: 0857

SPEC 150 Main Traveler  
QA55F4 SPEC 150 Shell Inspection Checklist  
SPEC 150 Shell Traveler  
Drawing 15B002A, Rev. 5  
QA24F11 Final Inspection Report SPEC C-1 Serial: 0293  
SPEC 300 Traveler

From review of these documents and discussion with various SPEC QA and production personnel, it was concluded that overall, the fabrication and assembly process conducted by SPEC is adequate.

However, one SPEC fabrication process nonconformance was identified that was determined to be a violation of NRC regulations. Specifically, 10 CFR Part 71.85 (c) states in part that "Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Commission."

Contrary to this requirement, SPEC travelers for the Type B SPEC-150 and SPEC-150 shells specify the application of the model number before the Lock Module has been installed in the packaging. The Lock Module is identified as a component of SPEC Model No. SPEC-150, as shown on Drawing No. 15B002A, Rev. 5 for NRC Certificate of Compliance USA/9263/B(U)-85.

Discussions with SPEC personnel confirmed that the lock module is integral to the safety performance of the package. These discussions also confirmed, however, that the SPEC-150 is not transported without the lock module assembly; i.e., the lock module assembly is installed in the package before it is transported. Thus there does not appear to be any safety significance for this nonconformance; rather, it is a matter of regulatory compliance.

In regard to the discovery of the violation of nameplate placement, SPEC immediately initiated a Corrective/Preventative Action Request/Report QA50F1 (C/PAR) No. 04006 to address the regulatory compliance issue. SPEC also issued an associated Engineering Change Request (ECR) No. 040512-2, approved by the Change Review Board on 5/12/2004, to make revisions as needed to document that the SPEC-150 complies with the Certificate of Compliance design requirements before the model number is attached.

Fabrication processes are controlled through SPEC Shop Order Instructions. These in turn refer to fabrication drawings that specify materials, dimensions and tolerances. The fabrication drawings are consistent with the design drawings identified in the NRC Certificate of Compliance.

A review of fluids used indicated that SPEC staff had not established shelf life requirements for foams and dye penetrants, nor were they monitoring shelf lives for these fluids. In regard to this issue SPEC initiated a Corrective/Preventative Action Request/Report QA50F1 (C/PAR) No. 04008 to address the regulatory compliance issue.

Welding rods were being kept in an improvised oven that included a thermometer (uncalibrated). In regard to this issue SPEC initiated a Corrective/Preventative Action Request/Report QA50F1 (C/PAR) No. 04009 to address the regulatory compliance issue.

Limited machining processes were observed, and were found to be conducted in accordance with Shop Order Instructions. Calibrations instruments were checked and found to be within calibration periods.

Assembly instructions were available in both electronic and hard copy format. No assembly operations were in progress during the inspection.

Inspector's name: Ross-Lee

SPEC has a monthly check of all tools and equipment needing calibration as determined by a review of computerized records. The procedures have a sign-off verifying that calibration was checked. The inspector verified calibration stickers on tools and receipt tags in the shop at the work sites. The inspector also reviewed several working packages in the shop and found all the necessary paperwork in the package. Equipment controls were found to be in place.

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.

Inspector's Name: Cook/Ross-Lee

A review of design and fabrication drawings for shields components indicated that Purchase Orders were properly specifying component materials and dimensions. Discussions with production personnel also indicated that they were aware of possible component fabrication issues (e.g., shield porosity), and had instituted procedures to individually evaluate each component with respect to porosity acceptability. SPEC has an established process to make minor shielding modifications, along with associated radiation level and weight measurements (using calibrated instruments) to assure the acceptability of shield components before they are installed in a packaging. These materials and fabricated components thus meet the package design requirements as established by the Certificate of Compliance.

The inspector reviewed a sample of travelers and they all appeared to be complete with all the necessary sign-offs and check points in place.

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.

Inspector's Name: Pearson/Cook

A sample of Corrective/Preventative Action Request/Reports (Form No.:QA50F1) were examined:

- C/PAR # 04004, Subject: Acceptable pigtail roundness for source capsules.
- C/PAR # 00005, Subject: Leak Test Work Instruction not being followed (Stop Work)
- C/PAR # 02001, Subject: Document Distribution Form Not Returned in 25 Days
- C/PAR # 02002, Subject: Internal Work Instruction Appears to Contain Values that Conflict with Regulatory Requirements
- C/PAR # 02008, Subject: Piston on T-5 Connector Hard to Depress

C/PAR # 03002, Subject: Missing Material Certification  
C/PAR # 03004, Subject: C-1 Not Shipped in Accordance with Required Operating Procedures

From review of these SPEC's Condition/Nonconformance Report documents and from discussions with various OA/QC and production personnel, it was concluded that overall, SPEC's problem identification and corrective action program is adequate and meets regulatory requirements. Issues, including those identified during audits, are entered into the corrective action system for proper resolution. Provisions are in place to ensure that significant conditions adverse to quality receive a higher level of attention and are required to have both a root cause analysis and a corrective/preventative action report documented according to the requirements of the SPEC Quality System Procedure Manual, Section 16, "Corrective and Preventative Actions."

02.09 Review selected records and procedures, Interview selected personnel, and observe selected activities affecting the safety aspects of the packaging to verify that individuals performing activities affecting quality are properly trained and qualified, and to verify that management and QA staff are cognizant and provide appropriate oversight..

Inspector's Name: Ross-Lee

The inspector verified that SPEC maintains records in two different places. There is a hard copy in a fire rated safe, and they also have two back up tapes made daily of the computer files. These are stored in two locations. The document control procedure (QA07) and document control system (QA01) had the appropriate level of control. The procedures are easy to retrieve and legible. QA07 has a system in place for control of issuance of new procedures as well as return of old ones. The inspector reviewed a corrective action showing this system working. Old procedures are filed in a separate sub-directory on the computer. Computer access is available to all, but only the QA Manager can add/delete or change documents in the system.

Inspector's Name: Pearson

Select portions of the following documents were reviewed:

- Work Instruction AD 25, Indoctrination, Training, Qualification, and Certification
- Work Instruction PR 20, Personnel Qualification Requirements for Welders
- Work Instruction PR 22, SMAW Welding for stainless steel (300 Series)
- Work Instruction PR 23, GTAW Welding for Stainless Steel (300 Series)
- Work Instruction PR 29, Personnel Training for Welders
- Work Instruction QA 27, Visual Weld Inspection
- Work Instruction QA 28, Liquid Penetrant Inspection

The qualification/certification packages for SPEC's welders were reviewed and found acceptable with one exception.

The qualification/certification packages were reviewed and found acceptable for the single employee that performs the essentially all of the visual weld examinations and NDE inspections. The inspection team noted that SPEC has attempted to train and certify additional personnel for

the visual weld and NDE inspection areas. All of the qualification/certification documents were in place and acceptable, with the exception of the appropriate color perception testing for one newer qualified person. NRC Regulation 71.119, Control of special processes states in part that... special processes, including welding, heat treating, and non-destructive testing are controlled and accomplished by qualified personnel. The color perception testing is required by SPEC Quality Procedure Manual, Section 9.0, Control of Special Processes and various lower tier SPEC documents. However, prior to the end of the inspection SPEC had acceptably tested the employee by appropriate testing and SPEC had determined that the employee had not performed any actual inspections yet. In regard to this issue SPEC initiated a Corrective/Preventative Action Request/Report QA50F1 (C/PAR) No. 04005 to address the regulatory compliance issue.

Appropriate oversight was determined through the review of SPEC's status reports for nonconforming material and Corrective action as well as the QA sign-offs found on various process travelers.

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.

Inspector's Name: Pearson

The SPEC audit schedules were reviewed along with Work Instruction QA 36, "QA Audit for Vendors" as well as the SPEC Quality System Procedure Manual, Section 18.0, "Internal Quality Audits." These guidance documents were found to provide adequate guidance

The qualification packages for all of SPEC's Lead Auditors were reviewed and found acceptable.

From review of these documents and from discussions with various QA/QC personnel, it was concluded that overall, the audit and vendor surveillance program conducted by SPEC is adequate and meets regulatory requirements. Both internal and external audits are planned and conducted according to a prepared schedule. Internal audits of SPEC's QA program are conducted on an annual basis; audits of vendors on the Approved Vendors List are conducted on a triennial basis. The QA group is itself audited by independent auditors not responsible for the quality assurance area, thus maintaining the regulatory required independence.

The following Internal audits were reviewed and determined to be acceptable:

Audit Date 1/17/2000	Audit subject: Criterion 8, Product identification, Traceability, and Serialization Criterion 14, Inspection/Test/Operating Status
Audit Date: 2/16/2000	Audit Subject: Criterion 10 Inspection Criterion 11 Testing

Audit Date: 12/24/2000

Audit Subject:  
Criterion 1, Organization  
Criterion 2, Quality Assurance Program

All of the audit checklists reviewed, were well prepared and found to be adequate.

Work Instruction QA 36, "QA Audit for Vendors," requires that vendor audits be documented on Form QA 36F1, Evaluation of Supplier Record. The following vendor audits were reviewed and determined to be adequate:

<u>Company</u>	<u>Audit Date</u>
Cameco Corp.	5/12/03
Cameco Corp.	5/18/01
NDS Products Limited	2/19/04
NDS Products Limited	2/10/03
NDS Products Limited	2/25/02
Cal Tech Inc.	11/03/03
Cal Tech Inc.	11/20/02
Starmet Corporation	11/20/01
Starmet Corporation	10/30/00
Starmet Corporation	10/28/99

The inspection team also verified that all five corrective actions from the previous NRC inspection were complete and implemented. The subject areas and a characterization of the corrective actions follow:

SPEC organizational chart was not current. The SPEC Org. Chart found in the SPEC Quality System Procedure Manual, revision 23 accurately reflects the SPEC organization and was updated as of 2/27/2004.

Nonconforming material was not reported by fabrication personnel. Training on "Control of Nonconforming Product" and "Defect Notification" Quality System Procedure Manual, Sections 15.0 and 15.1, respectively. The training was completed on 11/9/99 and 12/7/99 for SPEC fabrication personnel.

The method for the dating of work instructions was unclear. Guidance for dating work Instruction now exists in revision 6, step 7.6 of QA 07, Document Release and Distribution."

Audits were not performed by personnel independent from the work activity. Quality System Procedure Manual section 18, "Internal Quality Audits" requires that independence of auditors from the area being audited.

One instance of the lack of procedural use during fabrication had been identified. All of SPEC shop personnel were trained on 9/13/99 on the following subject areas: SPEC 150 Traveler, Rev. 11, The use of the SPEC NCR process, and The use of private fabrication notes versus controlled SPEC drawings.