

Dates of Audit

Date of Report

June 22-23, 1999

July 12, 1999

Audit Team

James J. Evans, Lead Auditor

Purpose/Scope of Audit

This was a management audit requested by AEA Technology QSA, Inc. management as required by the NRC. The scope of this audit was to evaluate the compliance with the 10 CFR 71 Quality Assurance Program for fabrication and testing and specifically audit Models OP-660 and OPL-660.

QUALITY ASSURANCE PROGRAM ELEMENTS INCLUDED IN AUDIT:

QA criteria contained with Subpart H to 10 CFR 71 included within this audit is: 7.0 Control of Purchased Material, 8.0 Identification and Control of Material, Parts, and Components, 9.0 Special Processes, 10.0 Internal Inspection, 13.0 Handling, Storage and Shipping, 14.0 Inspection, Test and Operating Status, 15.0 Nonconforming Material, Parts, and Components, and 16.0 Corrective Action.

The assembly area for Models OP-660 and OPL-660 and the applicable criteria was also audited. The status of the nonconformances issued during the September 15-16, 1998, December 2-3, 1998 and March 10-11, 1999 were reviewed and corrective action verified.

Audit requirements and Applicable Documents

10 CFR 71, Subpart H
AEA Technology QSA, Inc. Quality Assurance Manual
AEA Technology QSA, Inc. Standard Operating Procedures
AEA Technology QSA, Inc. Work Instructions

Audit Contacts

<u>Name</u>	<u>Kickoff Meeting</u>	<u>Audit</u>	<u>Closing Meeting</u>
W. McDaniel	x		x
D. Kurtz	x	x	x
C. Ferrera	x	x	
M. Starble	x	x	x
E. Okvist	x		
M. St. Ours	x	x	x
R. Evans	x	x	x
K. Roughan	x		

<u>Name</u>	<u>Kickoff Meeting</u>	<u>Audit</u>	<u>Closing Meeting</u>
R. Monroe	x		x
M. Tremblay	x	x	x
E. Shaffer	x		x
C. Larzalere		x	
D. Annis		x	
T. Shea		x	
R. Bourque		x	
D. Ward		x	

The audit kickoff meeting was held June 22 at 10:00.

The audit close out meeting was held June 23 at 12:30.

Summary/Evaluation

The audit resulted in the issuance of no audit findings.

The audit results reflect that the AEA Technology/QSA, Inc. quality assurance program elements audited were being satisfactorily implemented.

Status of Audit Findings resulting from the March 10 and 11, 1999 audit

The AEA Technology QSA, Inc. response to the findings is contained in letter dated May 25, 1999 to the NRC.

AFR #99-01: SOP E001-02 “New Product Design and Design Modification Procedure” Paragraph 4.1 states “A New Radiographic Product Specification Form must be completed in accordance with WI E06...prior to engaging in any design work.” The New Radiographic Product Specification Form dated April 1, 1998 for the Model 660 Overpack Development Plan did not contain the required ANSI/ISO classification information.

Status as of June 23, 1999: The corrective action plan is acceptable to PacTec. SOPs and WIs are being revised. This finding remains open until the SOPs and WIs are approved and released.

AFR #99-02: 10 CFR 71.107 Package Design Control requires in part that design inputs to be defined. SOP E001-02 “New Product Design and Design Modification Procedure” does require design inputs but is not clear on the design input requirements. Model 660 Overpack Development Plan dated April 1, 1998 list only 10 CFR 71 as the design input. The design package contains other design inputs, which were utilized for the design output but were not identified on the plan.

Status as of June 23, 1999: The corrective action plan is acceptable to PacTec. SOPs and WIs are being revised. This finding remains open until the SOPs and WIs are approved and released.

AFR #99-03: SOP E001-02 "New Product Design and Design Modification Procedure" Paragraph 4.4 states: "The Project Manager shall develop an Operations Quality Plan identifying the steps, and associated procedures and work instructions required to manufacture the new product...The Project Manager shall audit compliance with this plan through the first manufacturing cycle." The Model 969 Source Assembly design record did not contain objective evidence of a quality plan or the project manager audits.

Status as of June 23, 1999: The corrective action plan is acceptable to PacTec. SOPs and WIs are being revised. This finding remains open until the SOPs and WIs are approved and released.

AFR #99-04: Some Deviation Requests for SOPs were in the SOP Manuals past the expiration date. Manual 4 SOP P11-02 "660 Posilock End Plate Assembly" had Deviation Request DR 98-03 attached. The DR applied to SOP P11 and SOP P12. DR 98-03 was issued January 5, 1998 with an original expiration date of March 31, 1998. On August 28, 1998 it was extended to September 14, 1998. On December 1, 1998 it was extended to January 31, 1999. No further extensions were in the manual. Also DR 98-23 for SOP Q001 with expiration date of December 31, 1998, DR 98-24 for SOP P14 with expiration date of December 31, 1998 and DR 98-28 for SOP Q006 with expiration date of January 30, 1999 were in Manual 4.

Status as of June 23, 1999: The corrective action plan is acceptable to PacTec. AEA is implementing an aggressive program to implement corrective action. This finding remains open.

AFR #99-05: 10 CFR 71.117 "Identification and Control of Materials, Parts and Components" requires in part "The licensee shall establish measures for the identification and control of material, parts and components." Not all parts for the 660 assembly were properly identified. Examples included: Front nut, shipping plugs and handles.

Corrective action was taken by AEA Technology personnel and verified by the auditor. This finding was closed during the March audit.

Status of Audit Findings resulting from the September 15-16, 1998 Audit #E9816

The AEA Technology QSA, Inc. response to the findings is contained in letter dated November 17, 1998 to the NRC.

AFR #98-10: There was a lack of objective evidence that SOP-W006-01, "Qualification of Tack Welder", dated 9/13/92 had been reviewed by the department manager within the four year time period required by SOP-Q024-08.

Status as of Dec. 2-3, 1998 audit: The corrective action plan is acceptable to PacTec. SOP-W006 revision 2 was issued November 30, 1998. Appropriate personnel were trained. The auditor reviewed the SOP "log for review" and an action plan was in place to review all applicable SOPs and progress was being achieved. This finding will remain open pending the review of all applicable SOPs. Schedule for completion is Dec. 31, 1998.

Status as of March 10-11, 1999: Six SOPs have been reviewed and revisions issued. There are fifteen (15) SOPs to have revisions issued as a result of the review. Six of the SOPs are waiting for final approval, 8 are in final review and 1 was marked up for revision.

Status as of June 23, 1999: All SOPs have been reviewed in accordance with SOP-Q024-07. This finding is closed.

All audit findings pertaining to this audit are closed and this audit is considered complete.

Status of Audit Findings resulting from the December 2-3, 1998 Audit #E9817

The AEA Technology QSA, Inc. response to the findings is contained in letter dated January 28, 1999 to the NRC.

AFR 98-15: There were differences between the May, 1997 organization charts in the Quality Assurance Manual and the Current Organization.

Status as of March 10-11, 1999: The corrective action plan is acceptable to PacTec. SOP Q051 was revised and issued on March 8, 1999 with the current organization chart used by AEA Technology QSA. The Quality Manual is scheduled for revision by April 30, 1999.

Status as of June 23, 1999: The AEA Technology QSA, Inc. Quality Assurance Manual was revised and approved on June 23, 1999. NRC approval is pending. This finding is closed.

AFR 98-17: The corrective action plan is acceptable to PacTec. Several CPARs had late causes and corrective action plans responses from the responsible personnel. Some had inadequate causes and corrective action plans. Numerous CPARs remain open. The requirements of SOP Q-16-03 were not being completely implemented.

Status as of March 10-11, 1999: The Management Review meeting of March 2, 1999 established an aggressive action plan to implement corrective action.

Status as of June 23, 1999: AEA Technology has implemented effective corrective action. This finding is closed.

All audit findings pertaining to this audit are closed and this audit is considered complete.

Program Element Discussion**CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES**

The current approved supplier list was issued June 21, 1999. Suppliers of Safety Class "A" material are audited and suppliers of Safety Class "B" are evaluated.

Observation: The address of the supplier on the approved supplier list and the address on the purchase order are not always the same because of billing requirements. It is recommended that the address on the purchase order be the same as the address on the approved suppliers list for which the audit and/or evaluation was conducted.

Observation: The approved supplier list of June 21, 1999 does not contain any comments or restrictions for suppliers. However, Advanced Heat Treat who was audited October 22, 1998 was "conditional approved as an "A" supplier for heat treating." Six findings were issued with a requested reply due date of February 12, 1999. As of June 23 AEA Technology has received no response. CPAR 99-C27 had been issued against the approved suppliers list prior to this audit.

Observation: SOP Q22-05 "Supplier Selection and Audit" and SOP Q21-01 "Internal Audits" requires auditors to submit reports to management. However, the procedures do not require a report due date. Consequently some audits reports are not issued in a timely fashion. It is recommended that a 30-day time limit be established.

Observation: Class "B" and "A" items should be purchased from only suppliers on the approved suppliers list and not rely on QC to hold the items until the supplier is placed on the ASL.

Cobalt Overpack Type B Box was ordered from Capsacorp and received February 5, 1999. QC placed a hold on the boxes until the supplier was evaluated and placed on the approved suppliers' list, which occurred on April 29, 1999. The boxes were inspected and released on May 7, 1999.

Observation: AEA Technology is continuing to dedicate commercial grade items to Safety Class "A". However the procedures and/or work instructions need to be revised as identified in CPAR 98-12. The current schedule of completion is July 1999.

Observation: Safety Class "B" screws SCR-200 identified in lot 99074-1 in March 1999 were not analyzed as required by the Inspection Instruction and Record. The 20 screws were in the nonconforming material cage on the "out of service" shelf without any tag or identification. NCR 4869 was issued on June 23 to scrap the screws. This was an isolated occurrence.

Receiving assigns lots number when required by procedure for incoming parts. Safety Class "A" items are sent directly to quality control for inspection. QC utilizes inspection Instruction and Records for the inspections. Receiving inspects all other items.

IDENTIFICATION AND CONTROL OF MATERIAL, PARTS AND COMPONENTS

Work Order 103830 for the manufacture of Guide Tube assembly (3-½ ft.) was audited. WI-AS19-03 and the work order were utilized in the manufacture of the 2 Guide Tubes. All die and instruments were inspected and calibrated as required. The required pull test was completed satisfactorily.

Work Order 102210 Cobalt Overpack Type B Box was audited. No discrepancies were noted.

Work Order 101500 Rear Plate Assembly for 660 Posilok was audited. All items were identified. Rear Plate serial numbers B4099 through B4148 were on the appropriate plate. Torque wrench S/N 171 had been calibrated.

No discrepancies were noted for the identification and control of material, parts and components.

CONTROL OF SPECIAL PROCESSES

Vultafoam was audited to verify effective corrective action of a finding issued during the PacTec audit of September 15-16, 1998. The work instruction that had been revised December 9, 1998 was being effectively implemented and no discrepancies were noted.

INTERNAL INSPECTION

Personnel performing inspection actions are independent of those responsible for the work being inspected. The quality control inspectors report to the Quality Assurance Manager. The Quality Assurance Manager certifies inspectors. In-process and final inspections are recorded as required on the route cards and Inspection Instruction and Record. Quality Assurance reviews and signs the route cards before shipping.

No discrepancies were noted for the internal inspection.

HANDLING, STORAGE AND SHIPPING

The storeroom was audited. Items including Safety Class "A" were segregated and identified. Material in the Certified Raw Material Area had the required QC tags attached. WI-M25-03 requires a visual inspection to be conducted during cycle counting.

Several work instructions are applicable to the shipping area. Several items were being prepared for shipping and those items conformed to the requirements of the applicable work instructions.

No discrepancies were noted.

INSPECTION, TEST AND OPERATING STATUS

Inspection status was recorded on the route cards. Quality Control conducted the inspections and indicated the status on the route cards. QC used inspection instruction and records for the status of items inspected.

The requirements were being effectively implemented and no discrepancies were note.

NONCONFORMING MATERIALS, PARTS AND COMPONENTS

Several non-conformance reports were audited (4863, 4845, 4864, 4849, 4850, 4858, 4864, 4851, and 4869). For those NCR's open the required NCR tag was attached to the part and the parts were segregated in the Nonconforming Area in Quality Control. The status is monitored and logged in the Non-Conformance Report Log. SOP-Q005-05 Control of Non-Conforming Material was available and was being implemented effectively.

The requirements were being effectively implemented and no discrepancies were noted.

CORRECTIVE ACTION

As a result of PacTec audit finding report 98-17 this area was audited for effective implementation of the requirements and of SOP Q16-04. Audit finding report 98-17 was closed as a result of this audit. Management commitment and effective implementation was documented (reference memorandum from C. Ferrera dated June 12, 1999, subject: CPAR Update). As expected, CPARs remain open but were being actively pursued.



Bernard C. R. Counterman
Quality Assurance Manager

cc: W. McDaniel - Director of Operations, AEA Technology/QSA, Inc.
G. L. Clark - PacTec Vice President