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FACSIMILE TRANSMISSION
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August 28, 1997

Mr. Tom Matula
Mail Stop 06F18
Transportation, Safety & Inspection Branch
Spent Fuel Project Office, NMSS
U. S. Nuclear Regulatory Commission
Washington D.C. 20555

FAX No: 301-415-8555

Reference: Confirmatory Action Letter No. 97-7-006, dated June 24, 1997.

Dear Tom:

Attached please find the independent QA Audit Report submitted by Mr. Cassius L. Tillman of Quality Management Support, Inc. The hard copy will be mailed on Tuesday, September 2, 1997. Part B of the report identifies the root causes and includes recommendations for improvements. This will be used to supplement SPEC's audit report and the NRC's inspection report to develop the Phase III Corrective Action Plan.

Please note that the completion of the independent audit satisfies item 5 of NRC Corrective Action Letter No. 97-7-006. We have completed all of the items in the CAL but we are not yet requesting for the NRC to close the CAL since we are still implementing Phase II corrective actions. The Phase III Plan will be submitted to the NRC by September 15, 1997.

Sincerely,

R. D. (Donny) Dicharry
President

Enclosed: QA Audit Report dated August 25, 1997, Quality Management Support, Inc.

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NTO2

08-28-97.GC1

Quality System Review/Evaluation

Review Dates: August 19 and 25, 1997

Lead Auditor: Cassius L. Tillman, IV, Quality Management Support, Inc.

Source Production and Equipment Company, Inc.
St. Rose Facility

Part A

A review of each corrective action to SPEC findings and NRC Inspection Observation was made, associated new procedures, changed procedures, training records, and other types of documentation were reviewed. Corrective Action 15 A through 36 A were reviewed as follows:

15A Reviewed Procedure 1.1 and the Engineering change orders system

16A Reviewed revised shop order travelers for Asm Lock Assembly
Spec 150 Main Traveler both contained print ID and revision level from quality with a comparisor and documentation of the print used.

17A See 15A

18A All non in-process travelers have been removed from the shop floor. Ken Joslyn issues work orders for production, the Quality Department ensures latest edition of shop traveler issuance and print control. Work Orders released to Production after Quality Department sign off.

19A See above, a variety of re-issued travelers were reviewed. All had General Manager sign off as well as Quality Department sign off.

20A A review of documentation on the shop floor contained no "Sketches". Sketches have been removed from operational existence.

Sketch Spec 150 S tube cut off dated 10-4-95 stored in non-production file drawer are red lined "/" through text marked obsolete.

21A Reviewed revised form QA 7.8 for shield

22A Reviewed training retraining record of July 18, 1997 and revised traveler 150008

23A Preliminary status has been made obsolete. All drawings require the same review and approval process for control. Changes are controlled through the use of the Engineering Change Request System.

24A Calipers reviewed in use in production areas were found to have the appropriate current calibration sticker, i.e. s/n 0034930 Mitatoyo. Training records of 7-14-97 of QA personnel to Calibration and Control of Calipers reviewed

25A Reviewed revised Standard Operating Procedure 6.10, "Survey Meter Calibration".

26A Reviewed document control procedure 1.10, "Engineering Document Control" paragraph 7.4 dealing with red line changes to engineering documents. Red Line ability has not been eliminated from the system, but controls are more definitive.

27A Reviewed Ship Traveler 150008, "Casting Depleted Uranium Shield", Revision 2 July 18, 1997. Reviewed file for Spec 150 Camera s/n 0496. Certificate of Compliance from Manufacturing Science Corporation
804 Kerr Hollow Road
Oak Ridge, TN 37830
was readily available.

28A Drawing books located at three different locations were reviewed against the most current revision of the Master list. The latest revisions were available.

29A Reviewed newly generated procedures for SPEC 150 procedure #1.30, "Document Distribution", Revision 0, 7-18-97.

30A Revised Training records:
The majority of personnel were trained on July 16, 1997. A make up training session was provided for three people on July 24, 1997. Traveler Training was provided on 7-17-97.

31A Reviewed new shop order procedure #3.05, "Shop Orders", Revision 0, 7-18-97.
Reviewed shop orders and shop order log.

32.A Reviewed documentation of reinspection of parts in questions.

33.A Reviewed newly generated form titled Inspection/Fabrication Documentation Audit Checklist. Checklist will be utilized to verify completion of all required process steps, and inspections and test requires QA Sign off.

34.A A nonconformance room, locked, complete with file cabinets for records and storage for nonconforming material has been established. A review of items in nonconformance area was performed. All items had appropriate marking red tags and copies of pertinent Nonconformance Reports attached.

35.A Reviewed newly generated form and procedure QA 18.1 "Spot Audits" and records of those "Spot Audits" performed. Limited number to date due to the implementation time cycle.

36.A Reviewed procedures for Engineering Change Orders 3.0 QAM Section 3 Scope - Prototype and production drawing will require the same nature and extent of review and approval.

Completion corrective actions associated with Phase I have been verified. Evaluation of the effectiveness of these actions will require the passing of time and utilization of the system.

Part B

No one single element of the quality system, nor one single event is responsible for the lapses in the current quality system at SPEC. Our root cause analysis uncovered a number of contributing factors, which exclusively may have minor effect on the quality system, but collectively have had a major negative impact.

Five major root causes have been identified for improvement:

1) Quality System Documentation and Document Control

2) Qualification and Training

3) Control and Calibration of Inspection, Measuring and Test Equipment

4) Nonconformance Reporting

5) Corrective Action System.

Quality System Documentation and Document Control

The current quality system documentation is disjointed with little flow from the Quality Program Manual to Quality Assurance Manual to the bulk of the Quality System which is presented in the Standard Operating Procedure Manual. In some cases there is no continuity between requirements of one manual and those of another. Multiple authors over time have been a contributing factor to this problem

In some areas, i.e. corrective action, the requirements of when to use and how to use have not been well defined.

Recommendation:

A total review of and rewrite of the quality system documentation with emphasis on:

Definition of requirements

Consistency of requirements

A methodology to connect the multi-tiered quality system to provide a logical flow from least specific document (Quality System Manual) to the most specific document (Work Instructions).

Review/rewrite of area specific portions of the manual and procedures should be done in concert with the personnel who perform this work. Their involvement in the process will help with acceptance of and ownership of the quality system.

Qualification and Training

The current system for defining and documenting qualification requirements and training needs is inadequate. Qualification requirements are not well defined. Required training for

personnel has not been established. Training is not "Evergreen" you can't do it once and expect it to last forever.

Recommendation:

Rewrite the appropriate Quality Manual Section to define:

Method of qualification of personnel for each defined job classification.

Training required:
- Quality System Training
- Job Specific Training

Establish methods, i.e. checklist, to document training required and training completed.

Training attendance records need to be revised to include at a minimum:
- Detailed description of training provided
- Date of training
- Duration of training
- Name of person providing the training
- List of attendees

If training to "all Personnel" is identified, the system has to have proper checks and balances to assure that all personnel receive the required training.

A training schedule needs to be established and published.

As needed training needs to be identified and provided.

Control and Calibration of Inspection, Measuring and Test Equipment

The calibration system needs to be reviewed and revised to more thoroughly detail the requirements for calibration, documentation and traceability back to NIST for standards used.

Recommendation:

Equipment calibration records should be expanded to include an identification of which standard was used in the calibration.

The procedure need to be reviewed revised for calibration of standard used.

The procedure 7.22 for the calibration of calipers/micrometers be reviewed and revised to ensure full scale calibration.

Purchasing documents of inspection, measuring, and test equipment (including standards) sent out for calibration should include a paragraph similar to attachment 1.

Nonconformance Reporting

Nonconformances are currently being well documented at the time of occurrence. The systems weakness seems to be in the timely review and disposition of the nonconforming material. The system also lacks controls to ensure evaluation of repetitive nonconformances.

Recommendations:

That the nonconformance requirements in the quality manual be expanded to include a requirement for timely review and disposition of nonconforming material.

At a minimum, twice yearly reviews of nonconformances be performed and documented by the Quality Manager, Production Manager, and the General Manager to evaluate and identify repetitive trends. The corrective action system should be utilized as the vehicle for documentation.

Procedures should be reviewed/revised to ensure defined requirements can be met, i.e. sign off by the President on all scrap dispositions.

Corrective Action

The corrective action system as currently defined and implemented is inadequate and provides little value added.

Recommendation:

Manual section and appropriate procedures associated with Corrective Action Requests should be revised rewritten and greatly strengthened. The requirements of ISO 9000 element 4.14, "Corrective and Preventive Action" would provide a good basic guideline for this section.

Corrective Action should be generated to address audit findings.

That the SPEC Failure Reporting program be tied to, become part of the Corrective Action System.

A method for the evaluation of the effectiveness of corrective action taken be established and utilized.

The corrective action reporting form be expanded to address action steps taken. Items which cause the generation of a corrective action report usually do not have a simple one line answer. Normally multiple action need to be taken and traced. Performance and completion is often by different people with different close out dates.

The problems with SPEC Quality System are not limited to the five items listed above. The philosophy of quality , including the discipline and consistency required by a quality system. needs to be reintroduced throughout all areas of the facility including all personnel involved.

On a positive note, during my two day visit to the SPEC facility, SPEC personnel's positive attitudes stood out.

Positives

The Shop Order/Traveler System (already in the works) with checks and balances to ensure only the latest revision of the correct print is utilized.

All personnel interviewed during my two day visit were interested and expressed a desire to do it the right best way.

Management personnel expressed a desire to not only correct the problems but to have this experience be value added and the end results be a better quality system to work with and a better final product.

The SPEC Equipment Fail Reporting System is very good. Formally connecting it to the Corrective Action would make it even better.

The Spot Audit Process provides an effective means to involve all levels of management and all departments in the QA system.

Challenges to meet

Implementation of rewritten update, stronger quality system throughout the facility.

Ensuring ownership of the Quality System by all SPEC personnel.

Maintaining long term focus on and attention to the Quality System.