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August 10, 1981

United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76011

Attn: William E. Foster

Docket No. 99900745/81-01

Gentlemen:

This is a response to the findings of the inspection conducted by Mr. W. E. Foster of your office on March 23-27, 1981 at our facility in Englewood, Colorado, associated with the fabrication of optical isolators.

We received the notice of your findings May 11, 1981. We have requested and received several extensions to the 25 day response requirement and do appreciate the additional time allowed.

If there are any questions in regard to this response, please don't hesitate to call upon me.

Sincerely,

John Tarnosky
Quality Assurance Manager

Enclosures

NOTICE OF VIOLATION

A. Posting of 10 CFR Part 21, Section 206 of the Energy Reorganization Act of 1974 or an appropriate notice had not been accomplished.

1. Corrective Action - 10 CFR Part 21, Section 206 of the Energy Reorganization Act of 1974 and an appropriate notice describing the regulations, procedures, including the name of the individual to whom reports may be made and where they may be examined was posted in a conspicuous place on March 25, 1981.

2. Preventive Measures - This posting requirement has been entered on the company's list of required postings and this requirement has also been included on the QP-27 quality assurance audit program check list as of June 14, 1981.

B. Notification Procedures had not been adopted to provide for: (1) evaluating deviations or informing the licensee or purchaser and (2) assuring that a director or responsible officer was informed if the supplied basic component (a) failed to comply or (b) contained a defect.

1. Corrective Action - Quality Procedure (006A005) will be included in E-MAX Instruments Quality Assurance Manual delineating the specific procedures to be adhered to for the reporting of deviations to the purchaser. This was accomplished June 14, 1981.

2. Preventive Measures - Closer attention to the requirements specified in 10 CFR Part 21 will be maintained by the Q.A. Manager and a section has been entered in the QP-27 Quality Assurance Audit Program check list "Q.A. Manager documentation review requirements" which was completed June 14, 1981.

NOTICE OF NONCONFORMANCE

A. The Optical Isolator shop traveler had two task accomplishment check blocks that did not have appropriate checks indicating that those tasks were accomplished. Item #3, on numerous optical isolators travelers, did not have an indication that a "comparison check" was made of parts pulled or that "number assigned" had been inspected. Item #6 of the traveler for a 300 series cabinet, number 258A did not have the pass/fail block checked off. Furthermore, the Optical Isolator Shop Traveler Instructions were undated.

1. Corrective Action: Inspection of all shop travelers in both instances reflected that an initial or stamp was entered in the appropriate "stuffed by" column of item #3 and the Quality Control Inspection hold point #2 item #6. On numerous occasions the "comparison check" and "number assigned" column was not checked off in item #3. Item #1 did have the appropriate S/N assigned. Material Inspection Reports were reviewed to determine if the isolators affected had failure reports from Quality Control Inspection hold point #1, which would reflect discrepancies up to that point. There were no failure reports of those isolators affected on June 15, 1981, the respective columns were checked off. The same was accomplished for the pass/fail columns in item #6. There were no failure reports of those isolators affected and on June 15, 1981, the pass column was checked.

The shop Optical Isolator Traveler Instruction was dated and a quality assurance approval block added. This was accomplished on June 15, 1981.

2. Preventive Measures - A meeting of all Quality Control Inspectors and the Q. A. Manager has been established for the end of each month in which quality guidelines are re-enforced and all deficiencies for that month attended to. This was instituted on March 31, 1981.

B. A 400 series, Cabinet No. 250A was observed on March 25, 1981, at 11:20 am as not having ambient burn-in temperature of 140° -F as required by Tennessee Valley Authority Spec., No 3611, Revision 0. The ambient termperature was measured as 101.5°F. System test procedures did not specify the required temperatures and time of burn-in test.

1. Corrective Action- As mentioned in the details section, paragraph E.3a. the 400 series cabinet temperatures were elevated by means of an internal lamp bulb with no means of control. At the time of measurement there was present only one 200 watt lamp providing an elevated temperature of 101°F. Insertion of a second 200 watt lamp and a fan to circulate the air, increased the temperature to between 140°F to 150°F depending on the position of the

electronic temperature probe. This was the normal equipment for elevating the temperature for this type cabinet. The burn-in time of the cabinet was extended so that the 168 hours at 140°F was satisfied. E-MAX has not tried to maintain the temperature at exactly 140°F because the purpose of the elevated temperature is to reveal infant mortality of components. We have only insured that the temperature was at least 140°F and suggest that the specifications are satisfied.

2. Preventive Measures - Added on the test procedures is a column specifying the temperature range of 140°-150°F/60°-65°C and the duration of test of 168 hour from time the temperature has been monitored to be within that range. Furthermore, a 24 hour temperature check is included on the test procedures so that daily temperature monitoring will be effected. Added to the test procedure will be the equipment required to obtain a temperature within the range specified for that type cabinet. These additions were implemented July 17, 1981.

C. Quality Assurance had not accepted only those product items that conform with Test Instructions (Test Procedures) as evidenced by acceptance of preliminary electrical test on Part No. 175C307, S/N 0500 through 0523 without using a test procedure. In addition, test personnel were not aware of Test Procedure 175C307, Rev. A.

1. Corrective Action - New test procedures were revised for testing Part No. 175C307 Digital Optical Isolator. These procedures reflect in them the change in test fixture and additional metering equipment. 175C307, Rev. B, dated July 7, 1981 is properly included in the master files and will be submitted upon request, to Tennessee Valley Authority for inspection and confirmation that they are in fact equivalent to the 175C307, Rev. A Test Procedures approved on July 9, 1981.

2. Preventive Measures - An addition has been made July 10, 1981, to QP15 specifying that written procedures be provided before test are carried out at any level of production test. The addition is Paragraph 2.5 (Insure that all personnel have appropriate test instructions as per their proficiency qualifications and that those instructions be visibly present during the performance of these tests.

All technicians will have test procedures as appropriate per their proficiency qualifications. Q. A. will routinely conduct spot checks to insure that test procedures are visibly present during any type production testing. Personnel will reflect any deviation noted during these routine checks.

D. Serial Number 0240 thru 0248 for part number 175C311 did not have marks (stamps or initials) to identify the In-Process Inspector.

1. Corrective Action - In Process Inspectors had noted their inspections on the in-house traveler that accompanies each board through manufacturing and test. All persons involved in the manufacturing, test, and inspection aspects of assembled products have been re-

advised of their responsibilities to affix their stamps at appropriate stages of in-process.

2. Preventive Measures - Re-emphasis has been placed on Quality Control Plan Number 006A001 with the Q.A. Inspectors adhering to these guidelines. This deficiency was presented at the end-of-the month Q.A. meeting on June 30, 1981, and entered in the minutes of that meeting.

E. The following items did not have Quality Assurance approval indication.

(1.) Engineering Change Order Forms - Numbers 0283, Dated June 10, 1980; 0299, Dated July 16, 1980; 0300, Dated July 17, 1980; 0325 Dated February 2, 1981; 0329, dated March 3, 1981.

(2.) Drawings - Numbers 175C115, Rev. C, Dated December 15, 1980; 175C146, Dated December 5, 1980; 175C147, Dated December 5, 1980;

(3.) Material Lists - Numbers 175C115, Dated December 5, 1980; 175C131, Dated December 5, 1980; and 175C146, Dated December 5, 1980.

1. Corrective Action - The above were reviewed on August 3, 1981, and appropriate Quality Assurance approval indicated or change orders initiated with subsequent Quality Assurance approval. There were no discrepancies found during the review of these documents.

2. Preventive Measures - All of the following type documents are being reviewed for Quality Assurance approval.

   a. Details of manufactured and/or purchased parts.

   b. Details of assemblies and subassemblies.

   c. Schematic diagrams, wiring diagrams, and wire identification sheets.

   d. Material list.

   e. Applicable customer documents.

The time table for completion of review of these documents for all products is September 15, 1981. All documents listed above have been currently reviewed for a particular product prior to the products in-process for manufacturing, as manufacturing schedules dictate.

F. The following Engineering Change Orders (ECO's) had not been approved by Manufacturing before the changes had been implemented. Numbers 0283, dated June 10, 1980; 0300, dated July 17, 1980; 0303, dated July 21, 1980; and 0325, dated February 2, 1981. Additionally, the following ECO's had not been approved by Engineering or Manufacturing before the changes had been implemented. Numbers 0299, dated July 16, 1980; and 0329, dated March 3, 1981.

1. Corrective Action - The above items were reviewed on August 3, 1981, and the appropriate Engineering or Manufacturing initials anoted on those documents. There were no discrepancies found.

2. Preventive Measures -All Engineering Change Orders (ECO's) are currently being reviewed and completion of this review is scheduled for September 15, 1981. To insure that all currently manufactured products have had ECO manufacture and engineering approvals, the documents are being examined prior to their manufacturing schedule for in-process.

G. In accordance with Quality Procedure Number 006A002, dated January 14, 1980, the following drawings did not have signatures with the Drawn by, Checked by, Approved by blocks. Numbers 175C146, dated December 5, 1980, no signature in the checked space; 175C147, dated December 5, 1989, no signature in the checked by space. 175D2020-300, Revision D, dated July 29, 1980, had no signature in the Approved by space of the eight sheets, and Revision E, Undated, no signature in the Approved by space on the affected sheets.

1. Corrective Action - The above drawings were reviewed on August 3, 1981, and the appropriate spaces signatured or revisions dated. There were no discrepancies found in the review of these drawings.

2. Preventive Measures - All drawings are currently being reviewed for accuracy prior to manufacturing in-process and as dictated by manufacturing scheduled requirements. A complete review is scheduled for completion by September 15, 1981.

H. Contrary to QP25, Paragraph 5.1 in part and Paragraph 5.3, the following work instructions had not been reviewed, approved, and distributed to the personnel performing the task: (1) Steps for stuffing board, and (2) Steps for touch-up.

1. Corrective Action - The above work instructions were reviewed by the Engineering Manager on July 22, 1981, and the Quality Assurance Manager performed approval on July 23, 1981. Work instructions were then given the Production Superintendent for distribution on July 24, 1981.

2. Preventive Measures - QP 27 (Audit Check List) was revised on August 1, 1981 with the inclusion of Paragraph 3H requiring inspection of "proper work instructions" under the production section.

I. Contraty to QP3, Section 2d, dated May 12, 1989, Quality Assurance had not reviewed Purchase Requisitions and/or Purchase Orders for; Compatibility and completeness of applicable Engineering data supplied. Purchase Order Number 5616 dated August 28, 1980, and 5608 dated August 27, 1980, did not indicate the applicability of Underwriters Laboratory Bulletin 44 as specified in Tennessee Valley Authority specification number 3611, Rev 0.

1. Corrective Action - The above purchase orders for Teflon were reviewed on March 25, 1980, and appropriate certificates found that reflected that this wire exceeds Underwriters Laboratory Bulletin 44 and 94. Teflon wire adheres to Underwriters Laboratory Bulletin 224 and MIL-1-23-53/5, which are more stringent requirements than Underwriters Laboratory Bulletin 44 and 94. Certification was reviewed August 27, 1980 indicating this fact.

2. Preventive Measures - During Quality Assurance review of all Purchase Orders and/or Purchase Requisitions, cross references are being conducted to invoke required certification on those orders where customer specifications require it.

J. Contrary to Paragraph 3.7 of the Introduction dated January 14, 1980, Quality Assurance personnel were not free and clear from manufacturing, fabrication, and scheduling, inasmuch as the personnel performing acceptance inspection and test activities report directly to Manufacturing and Engineering management, and not to Quality Assurance management.

1. Corrective Action - Personnel assigned task as Quality Inspectors cannot necessarily be in comformance with Paragraph 3.7 of the Quality Assurance Manual as a direct consequence of the company's size. From an effective manpower utilization standpoint, it is necessary that personnel provide service for more than one department. In conjuction with the guidelines of ANSI 45.2, Paragraph 3.7 has been revised to read:

"Quality Assurance personnel shall be free and clear from and to only monitor procurement, manufacturing, fabrication, scheduling, and construction of materials when feasible as company manpower strength provides. When not feasible, those persons designated Quality Assurance personnel shall, primarily be directly responsible to the Quality Assurance Manager, Departments other than Quality Assurance that enjoin their performance of duty outside of Quality Assurance shall coordinate these activities with the Quality Assurance Manager.

2. Preventive Measures - On August 3, 1981 an inter-company memorandum was issued to Manager of Manufacturing and to Manager of Engineering reflecting this change and designating those personnel affected by this change.

K. Contrary to QP29, personnel performing in process inspection, test, and final inspection were deemed not Quality Assurance and Control qualified, fully familiar with the Quality Assurance Manual, nor knowledgeable of contractual Q.A. obligations. This was evidenced by their lack of knowledge regarding the date and composition of the Q.A. Manual and the Q.A. requirements of a purchase order.

1. Corrective Action - On March 31, 1981, Q.A Manuals were distributed to designated Quality Assurance Inspectors. This was accomplished during the end-of-month Quality Assurance meeting. At this time all contracts currently scheduled for the following month by manufacturing for production were reviewed and notes made by the inspectors as to particular compliance requirements for in-process and test of those contracts.

2. Preventive Measures - During the Quality Assurance end-of-month meeting, changes in the Quality Assurance Manual and any descrepancies noted that month in the manual are topics for discussion and have been included in the meeting syllabus outline. In addition, as mentioned above, inspection of contractual requirements for in-process manufacturing and test have been included as part of the meetings topics for discussion. Added to the Quality Assurance Manual is; Addendum 006A006 (Q.A Monthly Meeting Outline).

L. Contrary to QP27 dated, January 14, 1980, the following items were observed:

a. An independent review of the entire quality assurance system had not been conducted semi-annually, as evidenced by the latest audit report,dated May 8, 1980.

b. A quiality assurance re-audit had not been conducted to ensure correction of the discrepancies observed during the May 8, 1980 audit.

1. Corrective Action - An independent review of the entire quality assurance system is scheduled to be completed August 12, 1981. A quality assurance re-audit of discrepancies observed on the May 8, 1980 audit was completed April 22, 1981. A re-audit of the discrepancies found on August 12, 1981 is scheduled to be conducted September 22, 1981.

2. Preventive Measures - Semi-annual audits as per QP27 (Quality Assurance Audit Program for In-House Audits) will be conducted in September and March of every year.