E Max Instruments, Incorporated Docket No. 99900745/81-01

NOTICE OF VIOLATION

As a result of the inspection conducted on March 23-27, 1981, and in accordance with the Interim Enforcement Policy, 45 FR 66754 (October 7, 1980), the following violations were identified:

A. Paragraph 21.6 of Title 10, Part 21, of the Code of Federal Regulations, states in part, "Each individual partnership, corporation or other entity subject to the regulations in this part, shall post current copies of the following documents in a conspicuous position on any premises, within the United States where the activities subject to this part are conducted (1) the regulations in this part, (2) Section 206 of the Energy Reorganization Act of 1974, and (3) procedures adopted pursuant to the regulations in this part.

"If posting of the regulations in this part or the procedures adopted purs not to the regulations in this part is not practicable... in addit to posting section 206, post a notice which describes the regulations procedures, including the name of the individual to whom reports may be made, and states where they may be examined."

Contrary to the above, posting of 10 CFR Part 21, Section 206 of the Energy Reorganization Act of 1974 or an appropriate notice had not been accomplished.

This is a Severity Level VI Violation (Supplement II).

B. Paragraph 21.21(a) of Title 10, Part 21, of the Code of Federal Regulations, states in part, "Each individual, corporation, partnership or other entity subject to the regulations in this part shall adopt appropriate procedures to (1) provide for (i) evaluating deviations or (ii) informing the licensee or purchaser of the deviation in order that the licensee or purchaser may cause the deviation to be evaluated . . . and (2) assure that a director or responsible officer is informed if the . . . basic component supplied . . . (i) Fails to comply . . . relating to a substantial safety hazard, or (ii) Contains a defect."

Contrary to the above, 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.

This is a Severity Level VI Violation (Supplement II).

E-Max Instruments, Incorporated Docket No. 99900745/81-01

NOTICE OF NONCONFORMANCE

Based on the results of an NRC inspection conducted on March 23-27, 1981, it appears that certain of your activities were not conducted in accordance with NRC requirements as indicated below:

Criterion V of Appendix B to 10 CFR Part 50 states: "Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Nonconformances with these requirements are as follows:

- A. The Optical Isolator Shop Traveler Instructions, undated, contains the following requirements:
 - 1. Item No. 3 specifies that: (a) serial numbers be assigned to printed circuit boards (PCBs), and (b) a comparison check be made of the parts being installed on the PCBs and the appropriate bills of material.
 - 2. Item No. 6 specifies that "a qualified QC/QA inspector acknowledge passing or failing . . . "

In all instances, the corresponding item number on the traveler provides spaces for documenting accomplishment of the activities.

Contrary to the above, information to indicate task accomplishment had not been entered in the:

- a. Number Assigned and Comparison Check spaces for numerous optical isolators that had been shipped, and
- b. Pass or Fail spaces for the 300 Series, Cabin No. 258A which had been shipped.
- B. Paragraph 8.5.5 of the Tennessee Valley Authority Specification No. 3611, Revision 0, undated, states in part, "All completed units shall be subjected to a burn-in test of at least 168 hours at 140°F. Digital units shall have a 50 percent duty cycle and shall be switched a minimum of once per hour."

Contrary to the above, the 400 Series, Cabinet No. 250A was not being burned in at 140°F on March 25, 1981 at 11:20a, as evidenced by a portable electronic thermometer indicated temperature of 38.6°C (101.5°F). Attached records showed the burn-in test began on March 24, 1981 at 1530 (3:30p).

See Details Section, paragraph E.3.a.

C. Paragraph 2 and its subparagraph 2.1, of Quality Procedure No. 14, dated May 12, 1980, states in part: "Quality Assurance shall accept only those product items determined to be in conformance with the following acceptance criteria

"Requirements specified by Inspection Procedures, Test Instructions (T.I.'s) and/or Workmanship Standard and Classification of Defects."

Contrary to the above, Quality Assurance had not accepted only those product items that conformed with Test Instructions (Test Procedures) as evidenced by acceptance of preliminary electrical tests, on Part No. 175C307, Serial Nos. C500 through 0523, without using a test procedure.

See Details Section, paragraph E.3.a.

D. Item No. 5 of the In-Process Inspection section of Quality Control Plan No. 006A001, dated May 12, 1980 states, "All accepted assemblies shall have a mark to identify the inspector."

Contrary to the above, accepted printed circuit boards, Serial Numbers 0240 through 0248 for Part No. 175C311, did not have marks (stamps or initials) to identify the inspector.

E. Paragraph 4 and its subparagraph 4.5 of the Introduction to the Quality Assurance Manual, dated May 12, 1980 states, "Quality Assurance shall: "Study, interpret and approve engineering documents which form the basis for fabrication of product items to assure they are adequate to satisfy quality requirements."

Paragraph 1 of Quality Procedure No. 25, dated May 12, 1980, states in part, "Engineering Documents are defined as follows:

- Details of manufactured and/or purchased parts.
- b. Details of assemblies and subassemblies.
- c. Schematic diagrams, wiring diagrams, and wire identification sheets.
- d. Material Lists.
- e. Applicable customer documents."

Contrary to the above, Quality Assurance (QA) had not studied, interpreted and approved engineering documents, which formed the basis for fabrication of product items, as evidenced by the following engineering documents which bore no indication of QA approval: (1) Engineering Change Order Forms - Nos: 0283, dated June 10, 1980; 0299, dated July 16, 1980; 0300, dated July 17, 1980; 0325, dated February 2, 1981; and 0329, dated March 3, 1981; (2) Drawings - Nos: 175C115, Revision C. dated December 15, 1980; 175C146, dated December 5, 1980; and (3) Material Lists - Nos: 175C115, dated December 5, 1980; 175C131, dated December 5, 1980; and 175C146, dated December 5, 1980.

F. Quality Procedure No. 24, dated January 14, 1980 identifies the Engineering Change Order as a change control form and states in part, "Approvals required before changes: Engineering, Manufacturing, Customer (when applicable)."

Contrary to the above, the following Engineering Charge Orders (ECOs) had not been approved by Manufacturing before the changes had been implemented, Nos: 0283, dated June 10, 1980; 0300, dated July 17, 1980; 0303, dated July 21, 1980; and 0325, dated February 2, 1981. Additionally, the following ECOs had not been approved by Engineering or Manufacturing before the changes had been implemented, Nos: 0299, dated July 16, 1980; and 0329, dated March 3, 1981.

G. Item No. 6 of the Engineering section of Quality Control Procedure No. 006A002, dated January 14, 1980, states in part, "Three signatures are required for drawing approval. 1) Drawn by Checked by Approved by."

Contrary to the above, the following drawings had not been signed in three places, as indicated, for hardware that had been shipped, Nos: -175C146 dated December 5, 1980, no signature in the Checked by space; 175C147, dated December 5, 1980, no signature in the Checked by space; 175D2020-300, Revision D, dated July 29, 1980, no signature in the Approved by space on any of the eight sheets, and Revision E, undated, no signature in the Approved by space on the affected sheets.

- H. Quality Procedure No. 25, dated May 12, 1980, contains the following requirements:
 - Paragraph 5.1, states in part, "Approval and review of documentation such as drawings, specifications, work instructions and revisions, shall be implemented in the department in which they were originally generated."
 - Paragraph 5.3 states, "Distribution of current documentation shall be done by the Engineering Department with approval of the QA Department via section addit (QP-27)."

Contrary to the above, the following work instructions had not been reviewed, approved and distributed to the personnel performing the tasks: (1) Steps for Stuffing Board, and (2) Steps for Touch-up.

I. Paragraph 2 and its subparagraph d., of Quality Procedure No. 3, dated May 12, 1980 states, "Quality Assurance shall review Purchase Requisitions and/or Purchase orders for the following items: Compatibility and completeness of applicable Engineering data supplied and any other modifications or effective changes (e.g. latest revision)."

Contrary to the above, Quality Assurance had not reviewed the following Purchase Orders (PO) for compatibility and completeness of applicable Engineering data supplied, inasmuch as the POs did not indicate the applicability of Underwriters Laboratories Bulletin 44 as specified in the Tennessee Valley Authority Specification No. 3611: P.O. Nos.-5616, dated August 28, 1980; and 5608, dated August 27, 1980.

J. Paragraph 3.7 of the Introduction, dated January 14, 1980 of the Quality Assurance Manual states, "QA personnel shall be free and clear from and to only monitor procurement, manufacturing, fabrication, scheduling and construction of materials."

Contrary to the above, QA 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 QA management.

K. Paragraph 4.17 of Quality Procedure No. 29, dated January 14, 1980, states in part, "Quality Assurance and Control Personnel Qualification -- Employee must be fully familiar with QA manual, procedures, practices, rules and regulations governing such practices. Knowledge of the contents of 10 CFR 50, Appendix B, and ANSI 45.2 is a prerequisite for quality assurance and control qualification. Employee must also have a knowledge of contractual obligations as they apply to the QA function."

Contrary to the above, personnel performing in-process inspection, test, and final inspection are not Quality Assurance and Control qualified, fully familiar with the QA manual and knowledgeable of contractual QA obligations. This was evidenced by their lack of knowledge regarding the date and composition of the QA manual and the QA requirements of a purchase order. See Details Section, paragraph H.3.a.

- L. Quality Procedure No. 27, dated January 14, 1980, states in part:
 - "In order that the Quality Assurance programs continue to function at a high level of effectiveness, an independent review of the entire Quality Assurance system will be conducted semi-annually. This review will be done by qualified QA appointed personnel.
 - 2. "A quality assurance re-audit shall be made to guarantee that corrective measures needed as a result of the original audit have been implemented at a time no longer than three months after the original discrepancies were found."

Contrary to the above:

- 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 quality assurance reaudit had not been conducted to ensure correction of the discrepancies observed during the May 8, 1980 audit.