

Sigma Instruments, Incorporated
International Instruments Division
Docket No. 99900284/80-01

NOTICE OF DEVIATION

Based on the results of an NRC inspection conducted on August 5-7, 1980, 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 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." Deviations from these requirements are as follows:

- A. Paragraph 2.1.1 of Quality Assurance Procedure No. 108, dated April 28, 1978, states in part, "It will be the responsibility of the Manufacturing Engineer to initiate, prepare and approve O.R.O.s to be issued by Material Control to Manufacturing. The Manufacturing Engineer will approve all O.R.O.s with his signature or initial and date."

Contrary to the above, Operations Routing Order (O.R.O.), issued July 17, 1980, for Part No. 92-9487-000, Work Order No. 19807, had not been approved and dated by the Manufacturing Engineer, prior to its issuance to the Manufacturing Department.

- B. The Sigma Instruments, Incorporated-International Instruments Division's corrective action response letter, dated May 10, 1978, states in part, "Change Notices for Class 1 Instruments/Products will be approved by the Quality Control Manager or his delegated representative. Effective date, May 3, 1978."

Contrary to the above, Change Notices for Class 1 Instruments/Products had not been approved by the Quality Control Manager or his delegated representative, as evidenced by the following: Nos. 78-027, dated July 31, 1978; 78-033, dated July 18, 1979 (second release); 79-010, dated April 12, 1979; 79-019, dated October 3, 1979; and 80-001, dated January 21, 1980.

See Details Section, paragraph B.3.d.

- C. The Sigma Instruments, Incorporated-International Instruments Division's corrective action response letter, dated May 10, 1978, states in part, "An audit will be performed within sixty (60) working days from the date of this letter to assure compliance so as to prevent recurrence."

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Contrary to the above, an audit had not been performed to assure compliance with the corrective action commitments of the cited letter and prevent recurrence of the deviations identified in Inspection Report No. 78-01.

- D. The Sigma Instruments, Incorporated-International Instruments Division's corrective action response letter, dated May 10, 1978, states in part, "Engineering change control within the Drafting Department will be in compliance with Quality Control Manual. Effective date May 3, 1978."

Paragraph 6.2.3.1 of the Quality Control Manual, Revision 3, dated July 3, 1978, states in part, "All released drawings shall be changed only when authorized by an approved Change Notice, Form 335-2"

Contrary to the above, an approved Change Notice had not been used to change the following drawings, which had been released: Nos. - KC-24200, Revision B, dated October 19, 1978; C21-9062-002 through 010, Revision C, dated June 27, 1979; C21-9062-001 through 009, Revision C, dated June 27, 1979; C92-9062-002, Revision B, dated June 27, 1979; and C92-9062-001, Revision B, dated June 27, 1979.

- E. Paragraphs 8.0.2, and 7.10 of the Quality Control Manual, Revision 3, dated July 3, 1978, state, respectively:

1. "All in-house fabricated parts and/or assemblies received by the Stock Room must be identified by an Operations Route Order (or ORO issue number) and Q.C. In-Process Inspection Form No. QC-119 to show proof of inspection."
2. "Quality Control Forms 118 and 119 (Appendix, figure 16) is used by the Quality Control Receiving Inspector to show acceptance of material entering and stored in stock."

Contrary to the above, the following in-house fabricated parts and/or assemblies stored in stock, did not exhibit the Q.C. In-Process Inspection Form: Semifinished Chassis, Part No. 29-9270-601; Printed Circuit Boards, Part Nos. 29064-1, and 29065-006.

- F. Paragraph 8.1.3.2 of the Quality Control Manual, Revision 3, dated July 3, 1978 states, "Quality Control will document their inspection status and data on the Process Sheet and file this in the Quality Control files for Quality record purposes."

Contrary to the above, Quality Control had not documented the internal inspection status on Process Sheets for the following instruments on which internal inspection had been completed: Nos. -9-1136-688; 9-1136-689; 9-1136-694; 1251-203; 1251-204; and 1251-205.

See Details Section, paragraph D.3.a.

- G. Paragraph 10.4.1 of the Quality Control Manual, Revision 3, dated July 3, 1978, states in part, "A First Piece Inspection shall be performed to completely check customer requirements. When conformance has been established, Quality Control First Piece Log Book shall be filled out, signed and dated by the First Piece Inspector."

Contrary to the above:

1. The First Piece Inspector had not signed and dated the First Piece Log for conforming items in the Meter Assembly Area.
 2. A First Piece Log had not been maintained in the Control Assembly Area. First piece inspection is performed in this area.
- H. Paragraph 1. of II Standard No. FIS-1000-1151/1251, dated September 14, 1975, states in part, "Also, Class 1 instruments shall be visually inspected internally . . . and stamped by Inspection with an in-process stamp internally and on the outside of the instrument case to indicate internal inspection has been performed and accepted."

Contrary to the above, a Model 1251 meter, Serial No. 3082, had not been stamped internally to indicate that internal inspection had been performed and accepted.

See Details Section, paragraph D.3.a.