

U.S. NUCLEAR REGULATORY COMMISSION  
OFFICE OF INSPECTION AND ENFORCEMENT  
REGION IV

Report No. 99900284/80-01

Program No. 51400

Company: Sigma Instruments, Incorporated  
International Instruments Division  
88 Marsh Hill Road  
Orange, Connecticut 06477

Inspection Conducted: August 5-7, 1980

Inspector: W. E. Foster 8/21/80  
W. E. Foster, Contractor Inspector Date  
Components Section II  
Vendor Inspection Branch

Approved by: I. Barnes 8/21/80  
I. Barnes, Chief Date  
Components Section II  
Vendor Inspection Branch

Summary: Inspection on August 5-7, 1980 (99900284/80-01)

Areas Inspected: Implementation of 10 CFR 50, Appendix B criteria, and applicable codes and standards; including follow-up on inspector identified problems and unresolved items; follow-up on deviations; and manufacturing process control. The inspection involved twenty-five inspector-hours on site and three hours at the motel.

Results: In the three areas inspected, no unresolved items were identified, the following deficiency and eight deviations were identified:

Deficiency: Follow-up on Inspector Identified Problems and Unresolved Items - practice was not consistent with paragraph 21.6 of 10 CFR Part 21. (See Notice of Violation).

Deviations: Follow-up on Deviations - practices were not consistent with: (1) paragraph 2.1.1 of Quality Assurance Procedure No. 108, dated April 28, 1978 (See Notice of Deviation, Item A); (2) Sigma's corrective action response letter, dated May 10, 1978 (See Notice of Deviation, Items B and C).

Follow-up on Inspector Identified Problems and Unresolved Items - practice was not consistent with Sigma's corrective action response letter, dated

May 10, 1978, and paragraph 6.2.3.1 of the QC Manual, Revision 3, dated July 3, 1978 (See Notice of Deviation, Item D).

Manufacturing Process Control - practices were not consistent with Criterion V of Appendix B to 10 CFR 50; paragraphs 8.0.2 and 7.10 of the QC Manual, Revision 3, dated July 3, 1978 (See Notice of Deviation, Item E); paragraph 8.1.3.2 of the QC Manual, Revision 3, dated July 3, 1978 (See Notice of Deviation, Item F); paragraph 10.4.1 of the QC Manual, Revision 3, dated July 3, 1978 (See Notice of Deviation, Item G); and paragraph 1 of II Standard No. FIS-1000-1151/1251, dated September 14, 1975 (See Notice of Deviation, Item H).

Unresolved Items:

None.

DETAILS SECTIONA. Persons Contacted

- M. Antar, Group Leader - Stock Room
- J. Danbury, Supervisor - Final Assembly
- B. Dickinson, Foreman - Subassembly
- G. Hanson, Project Engineer - Nuclear
- \*M. R. Kalakay, Jr., Manager - Quality Control
- S. Kluck, Planner
- L. A. Laudano, Chief Inspector
- \*J. V. LeBlanc, Vice President and General Manager
- J. Meneely, Manager - Final Assembly
- \*R. M. Mershon, Chief Engineer
- S. Rainey, Chief Draftsman
- D. Rose, Manager - Traffic

\*Attended Exit Interview.

B. Follow-up on Deviations1. Objectives

The objectives of this area of the inspection were to verify that the vendor had taken the corrective actions and preventive measures stated in their correspondence to IE regarding items of noncompliances/ deviations.

2. Methods of Accomplishment

The preceding objectives were accomplished by:

- a. Reviewing Quality Control Manual, Revision 3, dated July 3, 1978, to verify that Attachment A identified the authorities and duties of managers and that it had been incorporated.
- b. Reviewing International Instruments Standard No. 820-190, dated May 5, 1978, to verify that it addressed calibration of the Model 9270 instruments and had been issued.
- c. Reviewing Quality Assurance Procedure No. 108, dated April 28, 1978, to verify that it established requirements to issue, review, and approve Operation Routing Orders.
- d. Reviewing the following Change Notices, for Class 1 Instruments/ Products, to verify that the Change Notices had been approved by a member (manager or designee) of the Quality Control Department:

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.

- e. Reviewing the following International Instruments Memorandum to determine what products were considered to have Class I applications: From: John O. Morin, V. P. - Engineering, To: Sam Rainey, Date: April 28, 1978, Subject: Document Control of Product Sold as Qualified to Nuclear Class I - Safety Related.
- f. Reviewing the following revised drawings to verify that the revision block contained the appropriate signatures or initials: KC-24200, Revision B, dated October 19, 1978; C-21-9062-002, Revision C, dated June 27, 1979; C-21-9062-001, Revision C, dated June 27, 1979; C-92-9062-001, Revision B, dated June 27, 1979; and C-92-9062-002, Revision B, dated June 27, 1979.
- g. Interviewing cognizant personnel to determine accomplishment of preventive measures identified in Sigma Instruments, International Instruments Division's corrective action response letter, dated May 10, 1978.

### 3. Findings

- a. (Closed) Deviation (Inspection Report No. 78-01): The inspector verified that Attachment A identified authorities and duties of managers and its incorporation into the Quality Control Manual, Revision 3, dated July 3, 1978.
- b. (Closed) Deviation (Inspection Report No. 78-01): The inspector verified that International Instruments Standard No. 820-190, dated May 5, 1978, addressed calibration of the Model 9270 instrument and that it had been issued.
- c. (Closed) Deviation (Inspection Report No. 78-01): The inspector verified that Quality Assurance Procedure No. 108, dated April 28, 1978, had been issued. During evaluation of implementation, it was determined that one document had not been processed as required. See Notice of Deviation, Item A.
- d. (Open) Deviation (Inspection Report No. 78-01): The inspector determined that Change Notices, related to Class I products, had not been approved by "The Quality Control Manager or his delegated representative." See Notice of Deviation, Item B.

This item was previously reported as non-adherence to paragraph 6.2.3.1 of the QC Manual, Revision 2, dated July 5, 1977 (Item D of the Notice of Deviation of Inspection Report No. 78-01). Therefore, this is a repeat deviation.

- e. (Closed) Deviation (Inspection Report No. 78-01): The inspector verified that the revision blocks of revised drawings contained the appropriate signatures or initials.
- f. (Open - Preventive Measures) Deviations (Inspection Report No. 78-01): The inspector determined that an audit had not been "performed . . . to assure compliance so as to prevent recurrences." See Notice of Deviation, Item C.

C. Follow-up on Inspector Identified Problems and Unresolved Items

1. Objectives

The objectives of this area of the inspection were to verify that inspector identified problems and unresolved items, during previous inspections, had been corrected and resolved satisfactorily.

2. Methods of Accomplishment

The preceding objectives were accomplished by:

- a. Interviewing cognizant personnel to determine the types of materials being purchased to determine applicability of safety-related identification of purchase orders.
- b. Reviewing the Procedure For Reporting of Defects and Noncompliance per 10 CFR 21, dated May 5, 1978, and posting to verify adherence to 10 CFR Part 21.
- c. Reviewing the following customer purchase orders (P.O.) and attendant documents to verify that 10 CFR Part 21 had been invoked: Bechtel Power Corporation P.O. No. 11406-M-2336-AC and United Engineers and Constructors, Incorporated P.O. No. 9763.006-170-5.
- d. Reviewing the following Engineering Releases to determine that the changes had been in accordance with approved change notices: Nos. -45-310006-BB, dated May 11, 1978; 54-302002-DQ, dated August 4, 1978; 45-310007-X, dated October 31, 1978; 54-503000-CV, dated December 18, 1978; and 45-510006-A, dated June 6, 1979.

3. Findings

- a. (Closed) Unresolved Item (Inspection Report No. 78-01): The inspector was informed that purchases did not include items that were identifiable as basic components. Therefore, invoking 10 CFR 21 or Appendix B of 10 CFR 50 was deemed unnecessary.

- b. (Closed) Unresolved Item (Inspection Report No. 78-01): The inspector verified that 10 CFR 21 was a contractual requirement and Sigma Instruments, International Instruments Division had initiated a procedure for compliance with 10 CFR 21. Posting had not been accomplished as required by 10 CFR 21. See Notice of Violation.
- c. (Closed) Unresolved Item (Inspection Report No. 78-01): The inspector verified that drawings had been released without an approved change notice. See Notice of Deviation, Item D.

D. Manufacturing Process Control

1. Objectives

The objectives of this area of the inspection were to verify that measures had been established and documented to control manufacturing, inspection and test activities. Also, to verify these activities had been accomplished in accordance with the established and documented measures. Additionally, verification of indication of mandatory hold points in appropriate documents.

2. Methods of Accomplishment

The preceding objectives were accomplished by:

- a. Reviewing the following documents to verify measures had been established and documented to control manufacturing, inspection and test activities:
  - (1) Quality Control Manual, Revision 3, dated July 3, 1978, Section V, VI, VIII, IX, X, XI, and XIV.
  - (2) International Instruments Standard No. FIS-1000 for Model Nos. 1135, 1136, and 1145 dated November 18, 1975; Model Nos. 1151, and 1251 dated September 14, 1975.
- b. Observing activities in the following areas to verify that accomplishment had been in accordance with established and documented measures: stock room; sub-assembly, assembly, and final assembly areas; inprocess, and final inspection.

3. Findings

a. Deviations From Commitment

- (1) See Notice of Deviation, Item E.

- (2) See Notice of Deviation, Item F.
- (3) See Notice of Deviation, Item G.
- (4) See Notice of Deviation, Item H.

Process Sheets identified in Item F. of the Notice of Deviation contain the requirement that the instruments be submitted to Quality Control for internal inspection. The instruments, associated with the Process Sheets did exhibit an external stamp to indicate that internal inspection had been performed.

The meter identified in Item H of the Notice of Deviation was one of two on which the cover was removed, at the inspector's request, for verification of internal stamps. Both meters exhibited external inspection stamps.

b. Unresolved Items

None.

E. Exit Interview

1. The inspector met with management representatives denoted in paragraph A. at the conclusion of the inspection on August 7, 1980.
2. The following subjects were discussed:
  - a. Areas inspected.
  - b. Violation identified.
  - c. Deviations identified.
  - d. Contractor response to the report.

The contractor was requested to structure his response under headings of corrective action, preventive measures, and dates for each deviation.

Additionally, management representatives were requested to notify the Commission in writing if dates require adjustment, commitments require modification, etc.

3. Management representatives acknowledged the comments made by the inspector.