PDR-HQS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76012

04 SEP 1980

Docket No. 99900284/80-01

Sigma Instruments, Incorporated
International Instruments Division
Attn: Mr. J. V. LeBlanc
Corporate Vice President and
General Manager
88 Marsh Hill Road
Orange, Connecticut 06477

Gentlemen:

This refers to the QA Program inspection conducted by Mr. W. E. Foster of this office on August 5-7, 1980, of your facility at Orange, Connecticut associated with the manufacture of control/alarm instrumentation and systems, and to the discussions of our findings with you and members of your staff at the conclusion of the inspection.

This inspection was made to confirm that, in the areas inspected, your QA Program is being effectively implemented. The inspection effort is not designed to assure that unique quality requirements imposed by a customer are being implemented; nor to assure that a specific product, component or service provided by you to your customers, is of acceptable quality. As you know, the NRC requires each of its licensees to assume full responsibility for the quality of specific products, components or services procured from others. You should therefore not conclude that the NRC's inspection exempts you from inspections by an NRC licensee or his agents nor from taking effective corrective action in response to their findings.

Areas examined and our findings are discussed in the enclosed report. Within these areas, the inspection consisted of an examination of procedures and representative records, interviews with personnel, and observations by the inspector.

During the inspection it was found that the implementation of your QA Program failed to meet certain NRC requirements. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter.

Please provide us within thirty (30) days of your receipt of this report a written statement containing, (1) a description of steps that have been or will be taken to correct these items, (2) a description of steps that have been or will be taken to prevent recurrence, and (3) the date your corrective actions and preventive measures were or will be completed.

You will note that deviations B, C and D in the enclosure are related to management failure to assure compliance with committed corrective actions for inspection findings identified in Inspection Report No. 78-01.

Specifically, a corrective action response for deviation D in Inspection Report No. 78-01 was given in your letter of June 6, 1978, which informed us that Change Notices for Class 1 Instruments/Products would be approved by the Quality Control Manager or his designated representative. A commitment was also made in your letter of June 6, 1978, with respect to measures to prevent recurrence for the identified deviations, that an audit would be performed within sixty (60) working days from the corrective action letter date. Your letter also stated with respect to an unresolved item (Details Section, E.3.b), that Engineering change control within the Drafting Department would be in compliance with the Quality Control Manual by May 3, 1978. It was determined during this inspection that the above actions had not been implemented as committed.

Consequently, in your response, in addition to verifying correction of the specific deviations, as requested above, please inform us of what additional steps you have taken, or plan to take, to assure that management commitments will be both performed as stated and effectively implemented.

In accordance with Section 2.790 of the Commission's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter with enclosure and your reply, together with the enclosed inspection report will be placed in the Commission's Public Document Room. If this report contains any information that you believe to be proprietary, it is necessary that you make a written application within thirty (30) days to this office to withhold such information from public disclosure. Any such application must include a full statement of the reasons on the basis of which it is claimed that the information is proprietary, and should be prepared so that proprietary information identified in the application is contained in a separate part of the document. If we do not hear from you in this regard within the specified period, the report will be placed in the Public Document Room.

Should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

Karl V. Seyfrit
Director

Enclosures:
1. Notice of Violation
2. Notice of Deviation
3. Inspection Report No. 99900284/80-01