SIGMA
INTERNATIONAL INSTRUMENTS
DIVISION SIGMA INSTRUMENTS, INC.
88 MARSH HILL ROAD · ORANGE, CONNECTICUT 06477 · PHONE: (203) 795-4711

September 30, 1980
Docket No. 99900284/80-01

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

Attention: Mr. Karl V. Seyfrit, Director

Reference: QA Program Inspection, conducted by Mr. W.E. Foster on August 5-7, 1980, at our facility at Orange, Connecticut

Gentlemen:

This letter is being written in response to your letter, dated September 4, 1980. In your letter you requested that we provide your office 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.

The following listed deviations were found and reported by your inspector. The corrective action and/or comment will be outlined below each reported deviation and unresolved items:

NOTICE OF DEVIATION

CRITERION V - DEVIATIONS

"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."

ITEM A

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. This has not been accomplished due to the vacancy in the position of Manufacturing Engineer.

United States Nuclear Regulatory Commission,
Attention: Mr. Karl V. Seyfrit, Director

CORRECTIVE ACTION

The position of Manufacturing Engineer has been filled, effective date August 1, 1980.

The Manufacturing Engineer was issued a copy Quality Assurance Procedure, QAP-108, on September 30, 1980 and was instructed to comply with this procedure.

ITEM B

Change Notices for Class 1 Instruments/Products had not been approved by the Quality Control Manager or his delegated representative.

CORRECTIVE ACTION

Change Notices for all Instruments/Products are approved by the Quality Control Manager or his delegated representative. Effective date, August 8, 1980.

ITEM C

An audit had not been performed to assure compliance with the corrective action commitments within sixty (60) working days of the cited letter, dated May 10, 1978.

CORRECTIVE ACTION

Attached is a copy of the re-audit cited in our letter, dated May 10, 1978. This re-audit was accomplished on September 30, 1980.

ITEM D

An approved Change Notice has not been used to change some drawings.

CORRECTIVE ACTION

A Temporary Authorization sheet, see attached, has been initiated to expedite changes. The formal Change Notice will be initiated from the Temporary Authorization, as required, and follow the normal procedure.

ITEM E

In-house fabricated parts and/or assemblies stored in stock, did not exhibit the Q.C. In-Process Inspection Form, QC-119.

CORRECTIVE ACTION

1. A memorandum, dated September 30, 1980, addressed to the Manufacturing Manager, has been issued stating the procedure to correct this deviation, see attached.

United States Nuclear Regulatory Commission,
Attention: Mr. Karl V. Seyfrit, Director

2. In paragraph 7.10 of the Quality Control Manual, the statement, "Quality Control Forms 118 and 119" will be changed to read, "Quality Control Form 118. This will be accomplished in Revision IV, target date for completion, October 31, 1980.

ITEM F

Quality Control had not documented the internal inspection status on Process Sheets for instruments on which internal inspection had been completed.

CORRECTIVE ACTION

The inspectors in this area were instructed on the procedure, which is stated on the Process Sheet, and to comply with same. Date of instruction was August 11, 1980.

ITEM G

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.

CORRECTIVE ACTION

1. All the inspectors in this area were instructed in the importance of the maintainence of the First Piece Log.

2. A First Piece Log is being used in the Control Assembly Area, date October 2, 1980.

ITEM H

A Model 1251 meter had not been stamped internally to indicate that internal inspection had been performed and accepted.

CORRECTIVE ACTION

A meeting on October 2, 1980, was held to restate the procedure for Class 1 material. The stamping procedure was the main topic of this meeting which was attended by the entire Quality Control Department.

September 30, 1980
Docket No. 99900284/80-01

United States Nuclear Regulatory Commission,
Attention: Mr. Karl V. Seyfrit, Director

RECURRENCE PREVENTION, CORRECTIVE ACTION AND DATE

(1) Description of steps that have been or will be taken to prevent recurrence.

a. All Corrective Actions will be instituted within one week of issuance of Standards, Quality Assurance Procedures or as indicated in this letter. An audit will be performed within sixty (60) days from the date of this letter to assure compliance so as to prevent recurrance.

(2) The date Corrective Actions and Preventive Measures will be completed.

a. Corrective Actions and Preventive Measures will be completed as described above is the first sentence.

Your findings and comments have been thoroughly reviewed and the appropriate Corrective Action has been initiated. Your comments are appreciated and we want to assure you of our continued cooperation.

Very truly yours,

INTERNATIONAL INSTRUMENTS
DIVISION SIGMA INSTRUMENTS

Joseph V. LeBlanc

Joseph V. LeBlanc,
Vice President

JVL:mp

Attachments:
1. Temporary Authorization
2. Memorandum dated September 30, 1980
3. Memorandum dated October 6, 1980

TEMPORARY AUTHORIZATION

DATE _____

PRODUCTION NO.	ISSUE

THE FOLLOWING DESCRIBED OPERATION, DIMENSIONAL OR TOLERANCE VARIATIONS ARE HEREBY AUTHORIZED FOR PRODUCTION ACCEPTANCE. THIS NOTICE EFFECTIVE UNTIL FOLLOWING CONDITIONS HAVE BEEN MET ONLY.

PART _____

DESCRIPTION:

REASON:

NUMBER OF PIECES INVOLVED _____

DISPOSITION OF EXISTING STOCK _____

FUTURE PRODUCTION _____ _____

DISTRIBUTION

☐ MAT'L. CONTROL ☐ PURCHASING ☐ PLANT MGR. ☐ PRODUCTION ☐

APPROVED

Q.C. MANAGER _____

PRODUCT DEV. ENGINEER _____

PRODUCTION ENGINEER _____

SIGMA | INTERNATIONAL INSTRUMENTS

MEMORANDUM

FROM:	SUBJECT:	DATE:
M.R. Kalakay	QC-118 and QC-119 Forms	Sept. 30, 1980

TO: E.J. O'Hara

Mr. W.E. Foster of the Nuclear Regulatory Commission performed an audit at our facility on August 5-7, 1980.

The following deviation, as stated in his report, was noted:

E. Paragraphs 8.0.2 and 7.10 of the Quality Control Manual, Revision 3, dated July 3, 1978, states 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 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 No. 29064-1, and 29-65-006.

INFORMATION COPIES TO:

J.V. LeBlanc
H. Kendall
Rec. Inspec.

In view of this deviation, I recommend we conform to our existing procedure which is, Forms QC-118 and QC-119 accompany and be retained with the material in stock.

Your cooperation to insure this corrective action will keep us in conformance with our Q.A. Manual.

Michael R. Kalakay

MRK:mp

SIGMA | INTERNATIONAL INSTRUMENTS

MEMORANDUM

FROM:
M. R. Kalakay

SUBJECT:
RE-AUDIT OF 1978 CORRECTIVE ACTION FOR NRC AUDIT.

DATE:
October 6, 1980

TO:
J. V. LeBlanc

The re-audit was conducted on October 2, 1980, reference DOCKET NUMBER 99900284/78-1, Dated May 10, 1978.

ITEM A
Corrective action has been accomplished by Revision 3 of our Quality Control Manual, dated July 3, 1978.

ITEM B
Corrective action has been accomplished as per our response letter, dated May 10, 1978.

ITEM C
This deviation was cited again on the audit conducted August 4-8, 1980, reference DOCKET NUMBER 99900284/80-01, dated September 4, 1980. Corrective action has been accomplished, effective date August 8, 1980.

ITEM D
This deviation was also cited again and corrective action taken, effective date September 30, 1980.

INFORMATION COPIES TO:

ITEM E
Corrective action for this deviation has been accomplished effective date August 8, 1980.

Mike Kalakay

MK:ma