ISOMEDIX

June 26, 1985

Mr. Gary G. Zech, Chief
Vendor Program Branch
Office of Inspection and Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Zech:

On May 28, 1985 we received Mr. Alexander's report concerning the E.Q. inspection held at Isomedix, NJ from April 8-11, 1985. This letter documents our response to the observations listed in section B (Nonconformances) of that report.

I.) Report reference B.1

To correct this item, the serial numbers for the test specimens in question have been added to the appropriate Receiving and Product Accountability Records. This was completed on June 26, 1985. To prevent recurrance, we have stressed to the individuals responsible for recording this information the necessity to correctly identify (via serial number, part number, etc.) the test specimens in all of our documentation. We have also recently added the position of Quality Assurance Inspector at each of our facilities. Document review is a major responsibility of this position.

II.) Report references B.2, E.2

We acknowledge the accuracy of this finding. However, in reviewing this situation, we questioned among ourselves the usefulness of the "dose rate uniformity of the field" information to the customer. Equipment qualification tests typically specify total integrated dose, air equivalent. In this situation the dose rate to which the component is exposed is defined as the free field measurement at the geometric centerline of the component. Limits on the magnitude of the dose rate are typical test requirements, but limits on its uniformity are almost never specified. Also, the uniformity of the exposure is often greatly improved by sequential rotation of components during irradiation . Therefore, the current requirement for including "dose rate uniformity of the field" information in our reports will be deleted. This will be completed by September 1, 1985 as part of the current QA Manual revision. However, this information will be provided whenever specifically required by customer specifications.

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III.) Report references B.3, E.3

Several factors contributed to the incident in question. Foremost among them was the fact that the purchase order was still in the mail when the components were delivered for processing. The delivery was made by a member of the customer's staff, and was accompanied by a copy of the customer's test plan. Processing was done in accordance with this test plan, which specified a dose rate of $\leq 1 \times 10^6$ rads/hour. Several days after the completion of the job the P.O. arrived. Its wording was identical to that of the test plan, except for one typographical error: the dose rate was specified as -1×10^6 rads/hour. This was not noticed during the paperwork review, and the documentation package was filed without any customer notification. To correct this item the customer has been contacted and will provide written assurance that the dose rate used in the test was acceptable. As a preventative measure, all personnel involved have been cautioned to be extremely thorough in reviewing purchase order and test plan requirements. Further aid in preventing a recurrance of this type of situation will come from the utilization of a new irradiation instructions form and from the additional review provided by the QA Inspector. The new irradiation instructions form will be implemented as part of the aforementioned QA Manual revision, due by September 1, 1985.

Sincerely yours,

Steven R. Thompson
Quality Assurance Manager

cc: G. Dietz
C. Herring
J. Young
S. Yap