APPENDIX A

Isomedix (New Jersey) Inc.
Docket No. 99900913/85-01

NOTICE OF NONCONFORMANCE

Based on the results of an NRC inspection conducted on April 8-11, 1985, 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 Part 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."

Nonconformances with these requirements are as follows:

A. Paragraph 6.4 "Identification of Materials, Parts and Components" of the Isomedix Quality Assurance Manual (QAM) states, in part:..."Receiving and Product Accountability Record shall identify the test item with serial number, part number, or other suitable means...."

Contrary to the above, (1) Receiving and Product Accountability Record (RPAR) number 00766 identifies test items for customer No. 44330 only as "3 sensors" and (2) RPAR No. 00370 identifies test items for customer number 45500 only as "valve seats, 1 bx."

B. Paragraph 4.3 of Appendix C, "Reactor Component Irradiation Specification" of the Isomedix QAM states, in part: "A radiation report will be provided by the facility...As a minimum it shall include the following information:...
(c) Dose rate uniformity of the field...."

Contrary to the above, Isomedix irradiation reports dated 3/13/85 for customer 28325, 2/14/85 and 4/1/85 for customer 24200, 3/12/85 for customer 44330, and 3/4/85 for customer 45500 did not contain dose rate uniformity of the field information.

C. Paragraph 6.10.3 of the Isomedix QAM states, in part: "An appropriate entry will be made in the irradiation record to account for any non-conformity. Copies of other correspondence/documents generated by the non-conformity will be retained in the customer file."

Paragraph 6.11 of the QAM states, in part: "...The identification of the non-conformity, cause, and corrective action taken will be entered in the customer file."

Paragraph B.2 of Appendix B to the QAM states, in part: "...All revisions will originate from the customer in writing prior to irradiation."

Paragraph 17.3, a-f of Addendum I to the QAM states, in part: "Test records shall identify...action regarding deficiencies noted..."

Customer 44330 purchase order (PO) number 54-7-FLC-40416 states, in part: "Provide radiation (Gamma) testing for three magnetic sensors. Dose of 5×10^6 rads $-0_{6}+$ 10% using gamma radiation source of Cobalt-60 at a dose rate of -1×10^6 rads/hour."

Contrary to the above, the irradiation data$_5$sheet for this project indicates that the dose rate was approximately 5×10^5 rads/hour and there was no documented evidence that the customer was informed of this deviation from the technical requirement of the purchase order nor was there any documentation of the deviation, its cause or corrective action in the test file or written permission from the customer to deviate from the specification.