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Corporate Environmental Health & Safety
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May 15, 1997

Dr. Bruce S. Mallett
Acting Deputy Regional Administrator
U.S. Nuclear Regulatory Commission
Region II
Atlanta Federal Center
61 Forsyth Street SW, Suite 23T85
Atlanta, Georgia 30303

Re: Supplemental Information for the Isomedix Operations, Inc. Predecisional Enforcement Conference, Docket No. 030-30578, conducted May 8, 1997.

Ref: (a) Letter dated March 19, 1997 from Frank F. Miller, Abbott Laboratories to the Nuclear Regulatory Commission (NRC) Operations Center.

Dear Dr. Mallett,

Thank you again for the opportunity to attend the subject conference. We wish to emphasize and supplement the information that Abbott provided at the conference, and trust that you will find it helpful in your assessment process.

On March 17, 1997, two days prior to the sale of our Vega Alta, Puerto Rico panoramic irradiator facility, the site Radiation Safety Officer (RSO), Mr. Arnaldo Rosado, notified me that he had investigated and identified an operating condition that he believed may have represented a violation of the regulations. The apparent violation involved operation of the irradiator for a period of about three hours without the attendance of a certified irradiator operator.

Despite the short time remaining prior to the sale of the facility, Abbott took immediate steps within those two days to develop and implement actions to prevent recurrence. These actions were completed prior to the sale of the facility and included:

1. Completion of an internal review of the training program and operator staffing levels.

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2. Completion of retraining of all irradiator operators on the 10 CFR 36.65 attending operator qualification requirements.
3. Implementation of a new procedure for turnover of irradiator control at shift change. The new process requires irradiator operators to sign and certify that they have been present during the entire shift when the irradiator is operating. The names of all irradiator operators are listed on the associated form to avoid any confusion regarding the training status of any particular operator who may be requested to take over operation of the irradiator.

Recognizing the uniqueness of the circumstances, Abbott elected to notify the NRC and Isomedix's Senior Management (see Reference (a)) as a courtesy even though the information was not required to be reported. The notification, which was made prior to the sale of the irradiator, provided Abbott's findings and the status of actions initiated by Abbott to prevent recurrence. By making the notification, Abbott communicated its concern and its desire to ensure that lasting and comprehensive corrective actions were taken, even though it was clear that Abbott would not have authority to follow-up after the transfer of ownership.

Lastly, the Vega Alta irradiator has had an exemplary performance and safety record, as evidenced by the results of five independent reviews conducted by qualified individuals. There were no substantive findings during any of these reviews. They included two thorough annual radiation protection program reviews that I conducted in May, 1995 and 1996, and three consecutive NRC inspections (8/9/95, 5/15/96, and 10/30/96) where no violations were cited. The issue of concern regarding the attendance of an irradiator operator had never been previously identified and it is not an issue that could reasonably have been prevented by corrective actions taken as a response to any previous findings.

During your assessment of NRC enforcement policies and procedures as they apply to this particular circumstance, it is requested that consideration be given to the following: (a) through diligent internal investigation, Abbott identified the apparent violation; (b) Abbott notified the NRC of the apparent violation soon after its discovery and confirmation; (c) without this internal investigation, self-identification, and notification it is very unlikely that Abbott or the NRC would have become aware of the event; and (d) Abbott took immediate action, which went beyond its own future control of the facility operations, to strengthen its procedures to prevent a recurrence of the event. In view of the uniqueness of the situation and the foregoing mitigating circumstances, it is requested that NRC exercise its discretion and waive further enforcement action.



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Please call me if I can provide any additional clarification or information. We look forward to hearing from you in this matter.

Sincerely,

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cc: Frank F. Miller
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