

December 23, 2008

US NRC
Materials Licensing Branch
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352

RE: Inspection at St. John Oakland USNRC # 21-11494-01

This is our formal response to your NRC inspection report 030-02101/2008-001; EA-08-329.

To start we have stopped our Therapy Implant program until we have resolved this issue in completion.

The reason for our apparent violation is multi-layered, and we would like to take just time to explain. Our facility has in the past, employed two Radiation Safety Officers, one for the diagnostic side, and one for the therapy seed implant joint venture side, with MIRO. As you are already aware, Mrs, F. Bagne has left the employment of MIRO. It was never mentioned to our facility that Mrs. Bagne had resigned and/or sold her portion of the business to Twenty-First Century Therapy well over one year ago.

To present some insight into our past history with MIRO, we were directly affiliated with the facility, and MIRO was previously located on St. John Oakland property. MIRO has over two years ago moved off-sight to an upgraded facility. Our relationship continued throughout this transition, and the seed implants have as always remained at our facility. While we did have several phone conversations with physics support, Mike Klein, for MIRO thru the sale of MIRO to Twenty-First Century, never during these conversation was it mentioned to anyone at our facility that Mrs. Bagne had left or resigned from her duties, or her sale of the business to Twenty first Century. We had continued paying MIRO for her Radiation Safety Officer duties during the entire period Mrs. F. Bagne had resigned until your identification of her leaving. We also agree we had not seen any

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representative from their side, MIRO/Twenty-First Century, during our RSC meeting, except a quick visit from Mike Klein at our February 2008 meeting, in which his name was not documented on the RSC minutes, due to his quick and late arrival and then departure, although all members present, recall his attendance. Again during this RSC meeting, it was not mentioned that RSO therapy support had resigned. After each and every RSC meeting Mike Klein was contacted by Ray Carlson, the diagnostic RSO, and both discussed if there were outstanding issues, which none were reported at any time. A signed document from Mike Klein and Ray Carlson can be forwarded if you prefer to confirm those conversations.

The corrective steps that have been taken and the results achieved are: We have already assigned a new and single Radiation Safety Officer to replace the previous double Radiation Safety Officers for different areas of our facility. Laura T. Smith, MS, DABR – the current Radiation Safety Officer at our sister hospital – St. John Hospital and Medical Center, 22101 Moross, Detroit, MI – USRNC #21-03210-01. As you might be aware, Laura Smith, has an excellent reputation as a Radiation Safety Officer, and we are confident that she is repairing our program with the attention that it deserves.

Laura Smith, has performed a comprehensive audit of our Radiation Therapy program, Nuclear Medicine department and our Radiology department. We are glad to report she has identified no patient related safety issues.

The corrective steps that will be taken to avoid further violations are: Mrs. Smith, has also started a complete review of our Radiation Safety Policy and Procedure Manual. She has already updated our Radiation Safety Committee Charter, to include – Radiation Safety Committee Members who have missed two consecutive Radiation Safety Committee (RSC) meetings (without sending representation), will be contacted in-person directly by the Radiation Safety Officer, and/or other board member.

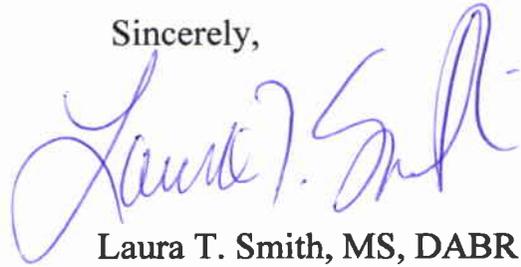
Laura Smith, will also provide annual audits of the Therapy department, and report these to the RSC. Laura Smith will also follow her procedure as she does at the St. John Moross location of also conducting mini audits of the therapy program throughout the year. We believe the combination of the new single St. John employee (non-contract, non-joint venture employee) along with the RSC policy charter update, and the audits performed by a St. John direct employee will prevent this unfortunate lapse in oversight in Radiation Safety Officer duties from ever happening again in the future.

We will gladly assist with any further questions or concerns you might have, and look forward to resolving this issue as quickly as possible, so as we can provide excellent care for our patients. We believe all of our outstanding issues within our Therapy Implant program and Radiation Safety Officer position have been resolved and we are currently within full compliance.

Sincerely,

Connie Franko *CF*
St. John VP Operations

Sincerely,


Laura T. Smith, MS, DABR
Radiation Safety Officer

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