

MEMORANDUM TO: FILE

FROM: MICHAEL M. LAFRANZO *ml 4/6/09*
MATERIALS INSPECTOR, DNMS, RIII

SUBJECT: SAINT JOSEPH REGIONAL MEDICAL CENTER;
SOUTH BEND, INDIANA TELEPHONIC CONTACT

On April 3, 2009, the licensee contacted the NRC, via telephone, to discuss regulatory issued concerning its High-Dose Rate (HDR) Afterloader program. The list of attendees are below. Specifically, the Radiation Safety Officer (RSO) was concerned that an Authorized User (AU), Dr. Binh NguyenTran, had inadequate in-house training concerning the HDR program and had discussed with the RSO using a rectal applicator when performing HDR treatments instead of the manufacturer's recommendation of using a vaginal applicator. The RSO felt that, without modifications to procedures and dose assessment calculations, an incorrect dose could be delivered to patients by this AU.

During the conversation, the NRC explained to the licensee that they are to ensure compliance with NRC requirements concerning dose delivery to patients. Specifically, the licensee shall prescribe and document the intended dose to the patient in a written directive prior to treatment and that the dose actually delivered to the patient shall be within acceptable limits as compared with the prescribed dose. In addition, the licensee's procedures used to ensure compliance with NRC requirements will be developed, maintained and implemented and that deviations from those procedures could result in: 1) a medical event; and 2) issuance of one or more violations.

Licensee Telephone Participants:
Laurie Price – Chief Operating Officer
Joni Pintada – Radiation Safety Officer

NRC Telephone Participants
Kenneth Lambert, Acting Chief, Materials Inspection Branch
Michael LaFranzo, Materials Inspector

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