



Terrance G. Alexander, Executive Director

November 12, 2009

Geoffrey Warren, Health Physicist
Materials Inspection Branch
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532 - 4352

**RE: Medical Event (October 14, 2009)
Corrective Actions & Implementation Date
(I-131 mIBG Infusion Protocol MIP-IB13)**

Dear Mr. Warren:

In accordance with the inspection you conducted October 29, 2009 and our recent telephone discussions, please find enclosed a correspondence from the University of Michigan – Department of Radiology / Division of Nuclear Medicine committing to implement corrective actions for the apparent medical event that occurred on October 14, 2009.

The implementation date for these corrective actions will be December 1, 2009 or prior to conducting the next patient infusion procedure under the Molecular Insight Pharmaceutical protocol MIP-IB13, whichever occurs first.

Please do not hesitate to contact Senior Health Physicist Dennis Palmieri [(734) 764-9182] or me [(734) 647-2251] at Radiation Safety Service / OSEH should you have any questions or comments regarding the Nuclear Medicine corrective actions or implementation date for these corrective actions.

Sincerely,

Mark L. Driscoll
Director / Radiation Safety Officer
Radiation Safety Service / OSEH

cc: Kirk Frey, M.D., Ph.D., Chief – Nuclear Medicine, Radiology
David Hubers, R.Ph., BCNP, Authorized Nuclear Pharmacist, Radiology / Nuclear Medicine
Files

RECEIVED NOV 17 2009



University of Michigan
Health System

Department of Radiology
Division of Nuclear Medicine
B1-G505 University Hospital
1500 E. Medical Center Drive
Ann Arbor, Michigan 48109-5028
Phone: (734) 936-5387
Fax: (734) 936-8182

MEMORANDUM

TO: Mark Driscoll
Director / Radiation Safety Officer
Radiation Safety Service / OSEH
1239 Kipke Drive / SPC 1010
Ann Arbor, Michigan 48109

FROM: Kirk Frey, M.D.
Chief, Division of Nuclear Medicine

David Hubers, R.Ph., BCNP
Authorized Nuclear Pharmacist

(Signature) 11/12/2009

(Signature) 11/12/2009

DATE: 12, November 2009

RE: Commitment Letter re: Molecular Insight I-131 MIBG Infusions

The Division of Nuclear Medicine commits to authoring an addendum to the 'Procedures for Administrations Requiring a Written Directive' document. The addendum specifically addresses I-131 MIBG infusions performed under the Molecular Insight Pharmaceutical protocol MIP-IB13. Corrective actions to be included in the addendum will address the following three topics:

- 1) Development of a written method for confirmation of volume calculations and / or final patient vial volume.
- 2) A commitment to programming the IV pump to alarm when 40 ml volume has been infused into the patient. This act will alert the Nuclear Medicine Technologist (NMT) performing the 50 ml infusion that only 20% of the infusion volume remains in the patient dose vial and that the NMT should carefully observe the secondary infusion line for the presence of air bubbles.
- 3) The research NMT will author a document describing a means of dosage recovery from IV infusion lines in the event of an interrupted administration that will permit a safe, timely recovery & completion of the IV administration to the patient.

This written addendum will be completed and implemented by December 1, 2009 or before the next patient infusion under the Molecular Insight Pharmaceutical protocol MIP-IB13, which ever occurs first.