

OAKWOOD ANNAPOLIS HOSPITAL
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WAYNE, MICHIGAN 48184
FAX DISTRIBUTION COVER SHEET

DATE: 12/20/10

RECIPIENT: Tammy Bloomer, Chief

DEPARTMENT: Materials Inspection Branch

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SUBJECT: NRC Event Notification

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SENDER: Nawn Baker License# 21-11457-02

PHONE NUMBER: 734-467-4192

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Notes: 4 pages, including cover letter

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December 20, 2010

Ms. Tammy Bloomer, Chief
Materials Inspection Branch
Region III – Division of Nuclear Materials Safety
2443 Warrenville Rd., Ste. 210
Lisle, IL 60532-4352

RE: Medical Event Report to NRC as per 10 CFR 35.3045 (d)

- (i) **Licensee Name:** Oakwood Annapolis Hospital
Materials License Number: 21-11457-02
- (ii) **Prescribing Physician:** Ashok B. Jain, M.D.
- (iii) **Brief Description of Event:**

12/4/2010: Patient was scheduled for a Tc-99m Myoview diagnostic cardiac resting perfusion study. Prescribed dosage was 10 mCi as noted on the departmental "Prescribed Dosage List". These dosages are delivered as unit dose quantities along with Tc-99m in bulk quantity.

12/4/2010 @ approximately 0600: Technetium-99m was delivered in bulk quantity in a 3cc syringe as 150 mCi calibrated for 1200.

12/4/2010 @ approximately 0900: A MAA kit was made by withdrawing 64 mCi from the bulk allotment.

12/4/2010 @ approximately 1030: The nuclear medicine technologist inadvertently picked up the syringe containing Tc-99m as pertechnetate in bulk quantity (124.5 mCi) and without confirmatory assay in the dose calibrator, injected the patient.

12/4/2010 @ approximately 1100 - 1200: Upon discovery of the event, the technologist informed the patient that the wrong product had been used and that her exam would not be completed. The technologist informed the patient's physician, via phone, of the event. The technologist immediately called his supervisor to also report. The supervisor reported to the Imaging Manager and the RSO. A complete hospital internal investigation began.

12/4/2010 @ approximately 1250: The Physicist was contacted via phone by Lead Nuclear Medicine Technologist and known event details were reported that near 100 mCi of Tc-99m had been administered. Advice was obtained regarding appropriate medical treatment to the patient as to not delay any medical care, including any

necessary remedial care as a result of the medical event. The physicist advised that the patient did not require medical treatment and stated that based on the information provided, that the event was not reportable.

12/6/2010 @ approximately 1030: Physicist requested additional details in writing from Hospital Lead Nuclear Medicine Technologist.

12/6/2010 @ 1235: Received notification via email letter, from Physicist with a narrative of the details and information that it was deemed a medical event as defined by the NRC and must be reported per requirements. As per 10 CFR 35.3045 (a)(1), the dose delivered differs from the prescribed dose by greater than 5 rem effective dose equivalent (EDE). However the upper large intestine (ULI) dose does not differ by more than 50 rads from the dose to be delivered from the prescribed dosage as follows:

Prescribed Dosage (10 mCi) EDE:	0.481 rem
Administered Dosage (31.4 mCi) EDE:	5.988 rem (Difference = 5.507 rem)
ULI Dose from Prescribed Dosage (10 mCi)	2.109 rads
ULI Dose From Administered Dosage (124.5 mCi)	26.257 rads (Difference = 24.148 rads)

As per 10 CFR 35.3045 (a)(1)(ii), the administered dosage (124.5 mCi) differs from the prescribed dosage (10 mCi) by greater than the limit of 20%.

12/6/2010 @ 1530: NRC notified of medical event.

- (iv) **Why the Event Occurred:** Unit dose of Tc-99m Myoview was in a 3 cc syringe and the bulk Technetium-99m was also in a 3 cc syringe. Technologist picked up the incorrect 3 cc syringe of Technetium-99m. Departmental Radiation Safety Policy was not followed because administered dose was not assayed in the dose calibrator prior to administration.
- (v) **The effect, if any, on the individual who received the administration:** None (per Hospital Physicist)
- (vi) **Planned Actions to Prevent Recurrence:**
 - a. 12/4/2010: Technologist involved in event immediately placed under direct supervision. Disciplinary action is presently being evaluated by Hospital Human Resources.
 - b. 12/8/2010: GE Healthcare Nuclear Pharmacy contacted. All bulk Technetium-99m to be delivered in vials only.
 - c. 12/10/2010: Quality Department met and discussed improved process for isotope administration. Oakwood Annapolis Hospital will no longer accept bulk Technetium-99m in syringes. All vials will be stored and segregated according to like isotopes. All isotopes will be calibrated prior to administration.
 - d. 12/13/2010 – 12/17/2010: All staff was re-educated on policies and procedures for appropriate handling of isotopes. Nuclear Medicine Technologist Worker Instruction Program and Competency Training sheets developed by Medical

Physics Consultants Inc. were reviewed with nuclear medicine staff. Staff attested they received and understood the training. Further educational training and competencies are currently being developed with an expectation that staff will complete annually.

e. Random visual audits of process will be performed by management/designee to verify accurate staff performance, including assay of dose in the dose calibrator prior to administration, according to policies and procedures.

(vii) **Certification individual notified:** Hospital Risk Management confirmed during the internal hospital investigation that the physician informed the patient about the incident and explained the situation to the patient's son.

12/20/2010: An annotated copy of report provided to the NRC was also provided to the referring physician with name of the individual subject to the event and identification number (medical record number).

Respectfully Submitted,



Ashok B. Jain MD – Chief of Radiology
Annapolis Hospital Radiation Safety Officer