

Report of a Medical Event

Licensee's name:
Hackley Hospital
NRC Material License No. 21-04125-01

Date of incident:
December 13, 2007

Name of prescribing physician:
Dr. Richard Wilcox

Brief description of event:

The event occurred during a thyroid ablation procedure in Nuclear Medicine department on 12/13/07. The patient was scheduled for a thyroid ablation with 100 mCi of NaI-131. The dose arrived with 3 capsules of NaI-131. The nuclear medicine technologist administered only 1 of the 3 capsules and sent the patient home. Thus, the patient only received approximately 21.39 mCi of NaI-131 instead of the prescribed 100 mCi.

Why the event occurred:

The event occurred because the nuclear medicine technologist did not verify the radiopharmacy label. In order to administer the prescribed 100 mCi of NaI-131, a total of 3 capsules were needed. The nuclear medicine technologist administered only 1 of the 3 capsules and sent the patient home.

The following day (12/14/07), the radiopharmacy notified Hackley Hospital's Nuclear Medicine department of 2 unused capsules they received. The nuclear medicine technologist informed the authorized user of the situation at hand. It was decided to have the patient return and receive the remaining 2 capsules.

Short-Term Corrective Action:

- The nuclear medicine technologist involved with the event was disciplined.
- We reiterated to nuclear medicine technologists administering therapy to verify the written directive, patient information, and the number of capsules to be given.
- There will be 2 technologists verifying the original dose in the dose calibrator with the written directive.
- Once the dose is administered, 2 technologists will verify the vial in the dose calibrator prior to releasing the patient.
- The checklist prior to NaI-131 administration was also modified to reflect the second technologist verifications.

Long-Term Corrective Action:

- Modified the procedure to insure the intent of the written directive is followed as required by 10 CFR 35.41.
- Require that the Authorized User will be contacted prior to the administration of the prescribed dose in accordance with the written directive.
- Added a procedure to address issues regarding NaI-131 therapy. Should there be incidents which may deviate from the written directive, a joint decision will be made after the Authorized User, Radiation Safety Officer, and Physics Consultant collectively discuss the course of action.

Effect on the individual:

The authorized users discussed the incident and determined that there would be no adverse effect on the patient. Medical Physics Consultants submitted a report to calculate the organ dose and whole body dose. Please see copy of the calculations.

Written report submitted by:



Carlo Santa Ana, MS, DABR
Chief Clinical Physicist
Radiation Safety Officer
1/10/08



January 8, 2008

Sara Crain, CNMT
Nuclear Medicine Department
HACKLEY HOSPITAL
1700 Clinton Street
Muskegon, MI 49443

Dear Ms Crain:

This report is to calculate the organ and whole body dose for the following adult patient:

Patient Name: [REDACTED]
Medical Records Number: [REDACTED]
Date: December 13, 2007
Dose Intended: 100 mCi NaI-131
Dose Received: 21.9 mCi NaI-131

As you will see below, the accidental administration which occurred at your facility does **does** meet the definition of a medical event under these rules.

10 CFR Part 35.3045 Definitions

Medical event means the administration of:

a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in--

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2309 Shelby Avenue
Ann Arbor, MI 48103
(734) 662-9224 Fax
(734) 662-3197

70 E. 91st Street, Suite 106
Indianapolis, IN 46240
(317) 581-1931 Fax
(317) 581-1911

1780 E. Logan Avenue
Salt Lake City, UT 84108
(801) 467-8774 Office & Fax

N7375 Crystal Ridge Drive
Beaver Dam, WI 53916
(920) 885-9872 Fax
(920) 885-9870

www.mpcphysics.com

Dose Calculations:

1. *Dosage received on 12-13-07:*

Radionuclide: I-131
Pharmaceutical: Nal-131
Activity: 21.9 mCi
(0% uptake used for the most conservative estimate)

Bladder Wall Dose Equivalent from ICRP 53: 2.257 rem/mCi
Highest Dose Equivalent from 21.9 mCi: 49.43 rem
Effective Dose Equivalent from ICRP 80: 0.2257 rem/mCi
Effective Dose Equivalent from 21.9 mCi: 4.943 rem

2. *Dosage prescribed for 12-13-07:*

Radionuclide: I-131
Pharmaceutical: Nal-131
Activity: 100 mCi
(0% uptake used for the most conservative estimate)

Bladder Wall Dose Equivalent from ICRP 53: 2.257 rem/mCi
Highest Dose Equivalent from 100 mCi: 225.7 rem
Effective Dose Equivalent from ICRP 80: 0.2257 rem/mCi
Effective Dose Equivalent from 100 mCi: 22.57 rem

This qualifies for a medical event for the following reasons:

- The initial dosage was not within 20% of the prescribed dosage.
- The difference in organ dose (225.7 rem - 49.43 rem = 176.3 rem) is greater than 50 rem.
- The difference in effective dose equivalent (22.57 rem - 4.9 rem = 17.67 rem) is greater than 5 rem.

3. Combined dosage including a second dosage given on 12-14-08:

Radionuclide: I-131
Pharmaceutical: Nal-131
Activity: 21.9 mCi on 12-13-07 and 69.7 mCi on 12-14-07.
(0% uptake used for the most conservative estimate)

Bladder Wall Dose Equivalent from ICRP 53: 2.257 rem/mCi

Highest Dose Equivalent from 91.6 mCi: 206.74 rem

Effective Dose Equivalent from ICRP 80: 0.2257 rem/mCi

Effective Dose Equivalent from 91.6 mCi: 20.67 rem

If you have any questions or require any further information please contact me at (734) 662-3197 or by email at dedwards@mpcphysics.com.

Sincerely,



Dawn M. Edwards, M.S.
Radiological Physicist
ABR Certified, Medical Nuclear Physics