UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

December 11, 2002

EA No. 02-214
Docket No. 03002939 License No. 37-00118-07

Neal Nathanson, M.D.
Vice Provost
University of Pennsylvania
Radiation Safety Office
3160 Chestnut Street, Suite 400
Philadelphia, PA 19104-6021

SUBJECT: EXERCISE OF DISCRETION AND NOTICE OF VIOLATION
INSPECTION 03002939/2002001, UNIVERSITY OF PENNSYLVANIA,
CHILDREN'S HOSPITAL OF PHILADELPHIA, PENNSYLVANIA SITE

Dear Dr. Nathanson:

On September 26, 2002 and October 30, 2002, Penny Lanzisera of this office conducted an inspection at Children's Hospital of Pennsylvania facility located in Philadelphia, Pennsylvania of activities authorized by the above listed NRC license. The inspection consisted of a review of the circumstances surrounding an exposure in excess of regulatory limits to a member of the public that was reported to the NRC by your staff on September 11, 2002. Additional information provided in your written report, dated October 1, 2002, was also examined as part of the inspection. The findings of the inspection were discussed with you and members of your organization at the conclusion of the inspection on December 4, 2002. The enclosed report presents the results of this inspection.

Based on the results of this inspection, it appears that one of your activities was not conducted in full compliance with NRC requirements. The violation involved a parent of a child treated with iodine-131 receiving a total effective dose equivalent of 0.7 rem while providing care for the child during a treatment in September 2002. 10 CFR 20.1301 allows licensees to increase the dose to members of the public under certain similar circumstances. The version of 10 CFR 20.1301 in place at the time of this event limited such dose to 0.1 rem to members of the public, but allowed the dose to be as high as 0.5 rem in certain situations with prior NRC authorization. Although your staff had received prior authorization from the NRC on March 4, 2002, to exceed 0.1 rem, the individual was not authorized to receive greater than 0.5 rem. Therefore, by exceeding the 0.5 rem dose limit, this violation occurred as described in more detail in the enclosed inspection report.

After considering the circumstances associated with this case, I have decided, after consultation with the Office of Enforcement, and in accordance with Section VII.B.6 of the enforcement policy, to exercise enforcement discretion and not cite this violation because your staff took reasonable actions to keep the dose as low as reasonably achievable by giving training and direction to the parent and by monitoring the parent's dose with a personal dosimeter. Also, the NRC recently approved your request to authorize a 2.0 rem annual dose

limit for the parent involved with the treatment so that the parent could provide care to the child during a second treatment that was subsequently completed in November 2002.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/reading-rm.html.

Your cooperation with us is appreciated.

Sincerely,

/RA/ James T. Wiggins Acting For

Hubert J. Miller
Regional Administrator

Enclosure:
Inspection Report No. 03002939/2002001

cc:
Robert Forrest, C.H.P., Radiation Safety Officer
Commonwealth of Pennsylvania

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NAME	BFewell		FCongel *					
DATE	12/11/02		12/10/02					

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* No OE concurrence required as per telecon with S. Merchant on 12/10/02. OE & NMSS agreed with the proposed strategy at the panel held on 11/26/02.

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03002939/2002001
Docket No.	03002939
License No.	37-00118-07
Licensee:	University of Pennsylvania
Address:	Radiation Safety Office 3160 Chestnut Street, Suite 400 Philadelphia, PA 19104-6287
Locations Inspected:	Children's Hospital of Philadelphia
Inspection Dates:	September 26 and October 30, 2002
Date Followup Information Received:	October 3, 2002 and November 19, 2002

Inspector: ***/RA/*** ***12/10/02***
Penny Lanzisera date
Senior Health Physicist

Approved By: ***/RA/*** ***12/10/02***
Pamela J. Henderson, Chief date
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

University of Pennsylvania
NRC Inspection Report No. 03002939/2002001

An announced special inspection was performed on September 26, 2002, to review the circumstances surrounding an exposure in excess of the regulatory limits to a member of the public that was reported to the NRC by the licensee on September 11, 2002. The exposure involved a patient visitor providing primary care-giver duties for their child, as allowed by the license. The licensee's review of the root causes concluded that the most likely causes of the incident, were that the visitor moved the bedside shield out of position during the treatment and that the therapy dose was unusually large.

The licensee submitted a written report dated October 1, 2002, as required by 10 CFR 20.2203, and described corrective and preventive actions taken to prevent similar incidents in the future.

Within the scope of this inspection, one violation, that is not being cited, was identified involving failure to limit the radiation dose received by a member of the public to 500 millirem, in accordance with NRC License No. 37-00118-07. Specifically, one parent of a minor patient who received inpatient radiopharmaceutical therapy at the Children's Hospital of Philadelphia received 700 millirem while providing direct care for their child during treatment.

REPORT DETAILS

I. Event Description

a. Inspection Scope

The inspection focused on a review of the iodine-131 meta-iodobenzylguanidine (I-131 MIBG) program at Children's Hospital of Philadelphia (CHOP) and the circumstances surrounding the reported exposure to a member of the public in excess of the regulatory limits. In order to assess compliance with regulatory requirements and license conditions during I-131 MIBG treatments at CHOP, the inspector interviewed a physician involved in the treatments; toured the facilities used by the licensee for an I-131 MIBG treatment occurring on the day of the inspection; reviewed the training, exposure monitoring, and safety precautions implemented for one parent; interviewed the parent and nurses involved with the patient's care; and interviewed the Radiation Safety Staff about their involvement in the program.

b. Observations and Findings

I-131 MIBG Program

The University of Pennsylvania's broad scope medical license authorizes clinical and research activities at several facilities, including CHOP. As described in the license, parents of patients undergoing treatment with I-131 MIBG at CHOP are permitted to act as the primary care-giver for their child and receive exposures up to 500 millirem.

The physician/authorized user responsible for the I-131 MIBG program at CHOP stated that I-131 MIBG is administered to children diagnosed with end stage neuroblastoma, a rare form of childhood cancer. The median age of the patient at the time of diagnosis is 17 months and the current average age of children treated with I-131 MIBG is 6 years. The treatments are done under an FDA approved Phase II study and originally allowed up to 80 patients, which has been increased to 200 patients. The licensee currently administers 18 millicuries of I-131 per kilogram of body weight to the patient if the patient has a stem cell source and 12 millicuries of I-131 per kilogram of body weight, otherwise. I-131 MIBG is supplied by the University of Michigan's Phoenix Laboratories. The tagging of the radionuclide is verified by chromatography. Normal dosages are in the range of 400 to 600 millicuries; however, up to 1 curie has been administered. Some patients receive more than 1 treatment, with up to 3 treatments possible. Approximately 36 I-131 MIBG treatments have been conducted under the current protocol, with an average of 3 treatments per month conducted at the licensee's facilities.

The inspector observed that the patients are treated in a special suite located off the main corridor. The treatment room is posted and control is maintained by nursing and radiation safety staff for the purpose of radiation protection. The room is equipped with a single bed surrounded by 2 inch thick lead shields that measure 2 foot by 4 foot. The shields completely enclose the bed on three sides but leave a gap at the top of the bed

so that the patient can view the parent, and vice versa, from a distance. The parent is instructed to stay behind the shields whenever possible. Patients are catheterized and urine is collected in a fully shielded container located next to the bed. An area outside of the treatment room, equipped with windows, is used by hospital staff to service and visually monitor the patient. Access to this area is restricted. A radiation monitor is located at the outside doorway of the treatment room for personnel monitoring prior to leaving the restricted area. The average patient stay is 5 days.

Prior to the treatment, parents who elect to be the primary care-givers for their children during the I-131 MIBG therapy are instructed by several staff on the treatment their child is to receive and precautions the parent should take while performing care-giver tasks. This training includes: the use of time, distance and shielding to minimize their exposure; methods to minimize the spread of contamination; the use of electronic dosimeters; the biological effects of radiation; protective clothing use; and limitations following release of the patient from the hospital. Staff providing training include the nurse practitioner responsible for obtaining informed consents from the parents, the oncology staff, and the radiation safety staff. The inspector interviewed the parent present during the inspection about the training provided. The parent offered that they are responsible for routine care of their child during treatment, including changing bedding and giving medication. The parent also described the use of the bedside shields to reduce their radiation exposure and demonstrated correct placement of the shields. Adequate protective clothing was worn by the parent. The physician responsible for the I-131 MIBG therapy stated that the parent's involvement contributed greatly to the success of the therapy and without their involvement, the facility would be forced to sedate many patients or that many parents would choose not to treat their child.

The licensee requested authorization to operate up to a 500 millirem annual dose limit for an individual member of the public on February 28, 2002, and a license amendment authorizing this dose limit was issued on March 4, 2002. Additionally, on April 24, 2002, 10 CFR 20.1301(c) was revised to allow a licensee to permit visitors to a patient to receive up to 500 millirem if the authorized user determined that it is appropriate. Since the licensee was concerned that I-131 MIBG dose escalation and multiple treatments would result in annual exposures to parents exceeding 500 millirem, the licensee requested an exemption from the regulations to allow parents who care for their minor children during therapy procedures to receive radiation exposures of up to 2 rem in a year in letters dated March 15 and April 11, 2002. This exemption request is still under review. In addition, the licensee requested an exemption from the regulations to allow, on a one-time-basis, the parent that had already received 700 millirem to receive up to 2 rem total for an additional treatment of their child in November 2002. The license amendment authorizing this one time dose limit was issued on November 20, 2002.

Notification of the Incident

On September 11, 2002, the licensee notified the NRC Operations Center of the exposure of a member of the public in excess of the regulatory limits that had occurred between September 4 and 9, 2002. A written report of the incident was submitted to the NRC on October 1, 2002, as required by 10 CFR 20.2203. The inspector reviewed the

report and followed up with a telephone call to the Radiation Safety Officer on October 30, 2002, to confirm statements about visitor training and compliance with training.

As discussed in the report and during the inspection, the factors leading to the exposure to the parent in excess of the 500 millirem limit included: 1) an unusually large dose of I-131 (1 curie) was administered to the patient; 2) the patient had a low excretion rate of I-131 causing a prolonged hospital stay; 3) only one family member assisted in the care of the patient, where usually two participate; 4) the parent moved the bedside shield out of position; and 5) the elevated dose was initially not noticed due to multiple entries by the parent in the dosimetry log in different locations.

Licensee's Corrective and Preventive Actions

During the inspection conducted on September 26, 2002, and in a letter dated October 1, 2002, the licensee provided the following corrective and preventive actions:

1. Parental training before each therapy procedure will strongly emphasize the importance of maintaining doses 'as low as reasonably achievable' and below the applicable limits, and maintaining protective equipment in place.

2. The health physics technical staff were retrained to perform daily checks of the position and use of protective equipment by parents and to review the dosimeter log frequently.

3. The dosimeter log was revised to record dosimeter results for parents in one designated section.

c. Conclusions

The inspector concluded that the licensee properly reported the exposure in excess of the regulatory limits; that clinical staff involved with the I-131 MIBG program were well trained; and that visitor training was adequate to limit exposure. The inspector also concluded that the dose to a member of the public exceeded the regulatory limit of 500 millirem in a year allowed by the license and by 10 CFR 20.1301(c). Specifically, the parent received 700 millirem. However, this violation was not cited because: 1) appropriate controls and training were implemented to ensure that doses to members of the public were within regulatory limits; and 2) a request to authorize an increase in the dose limit to 2 rem on a one time basis for this parent was approved on November 20, 2002.

II. Exit Meeting

An exit meeting was conducted on December 4, 2002, with those individuals noted below.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Lisa Balistreri, Nurse
John Maris, M.D., Oncology
*Robert Forrest, Radiation Safety Officer, Environmental Health & Radiation Safety (EHRS)
William Davidson, Senior Health Physicist, EHRS
*Neal Nathanson, M.D., Vice Provost

*indicates individual present at telephonic exit meeting