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

January 24, 2007

Docket No. 030-36417 License No. 29-30840-01
EA-07-009

Ralph DeBellonia
Administrator
PET Scan of New Jersey
315 Elmora Avenue, Suite 200
Elizabeth, NJ 07208

SUBJECT: INSPECTION 030-36417/2006-001, PET SCAN OF NEW JERSEY, ELIZABETH, NEW JERSEY SITE AND NOTICE OF VIOLATION

Dear Mr. DeBellonia:

On November 14, 2006, Betsy Ullrich and Lizette Roldán of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in the telephone conversation on November 15, 2006, between Dr. Natalio Damien of your organization and Betsy Ullrich, was also examined as part of the inspection. The findings of the inspection were discussed with you on November 15, 2006, and at the conclusion of the inspection on January 19, 2007. The enclosed report presents the results of this inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes each violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Toolkit Index Page.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement,** then **Enforcement Policy.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Your cooperation with us is appreciated.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
1. Inspection Report No. 030-36417/2006-001
2. Notice of Violation

cc:
Natalio Damien, M.D., Radiation Safety Officer
State of New Jersey

Distribution:
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NOTICE OF VIOLATION

PET Scan of New Jersey
Elizabeth, NJ

Docket No. 030-36417
License No. 29-30840-01
EA 07-009

During an NRC inspection conducted on November 14-15, 2006, and January 19, 2007, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 30.34(c) requires, in part, that each licensee confine its use of byproduct materials to the purposes authorized by the license.

10 CFR 35.13 requires, in part, that a licensee apply for and receive a license amendment before it uses byproduct material for a type of use that is permitted under Part 35 but that is not authorized on the licensee's current license.

Condition No. 9 of Amendment No. 1 of License No. 29-30840-01 limits the use of licensed materials to diagnostic medical use of sealed sources permitted by 10 CFR 35.500, in compatible devices registered pursuant to 10 CFR 30.32(g).

Contrary to the above, during the period of July 28 through October 27, 2006, PET Scan of New Jersey: (1) did not confine its use of byproduct materials to the purposes authorized by the license; (2) did not apply for and receive a license amendment before it used byproduct material for a type of use that is permitted under Part 35 but that was not authorized on the licensee's current license; and (3) did not limit its use of licensed materials to diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g). Specifically, during that period, the licensee used technetium-99m for medical imaging and localization studies with 52 patients, pursuant to 10 CFR 35.200, a use not authorized by the license.

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 35.27(a)(1) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user, instruct the supervised individual in the regulations of this chapter and the license conditions with respect to the licensee's use of byproduct material.

Condition No. 15 of Amendment No. 1 of License No. 29-30840-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations and procedures contained in the application dated September 30, 2003. The application dated September 30, 2003, requires, in part, that the licensee implement a training program as described in Appendix A of Regulatory Guide 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs." Appendix A requires, in part, that personnel be instructed before assuming duties with radioactive material, during annual refresher training and whenever there is a significant change in the duties, regulations or the terms of the license. Appendix A also requires that the instruction include the applicable regulations and license conditions.

Contrary to the above, as of November 14, 2006, the licensee: (1) permitted the use of byproduct material by an individual under the supervision of an authorized user and the licensee did not instruct the supervised individual in the regulations of this chapter and the license conditions with respect to the licensee's use of byproduct material; and (2) did not instruct personnel during annual refresher training or when there was a significant change in the duties, regulations or terms of the license, including training on the applicable regulations and license conditions.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, PET Scan of New Jersey is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA 07-009" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This _24_ Day of _January_ 2007

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	030-36417/2006-001
Docket No.	030-36417
License No.	29-30840-01
Licensee:	PET Scan of New Jersey
Location:	315 Elmora Avenue, Elizabeth, New Jersey 07208
Inspection Dates:	November 14 and 15, 2006, and January 19, 2007

Inspectors:

Original Signed by: ***January 24, 2007***

Lizette Roldán
Health Physicist

Original signed by: ***January 24, 2007***

Betsy Ullrich
Senior Health Physicist

Approved By:

Original signed by James P. Dwyer ***January 24, 2007***

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

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EXECUTIVE SUMMARY

PET Scan of New Jersey
NRC Inspection Report No. 030-36417/2006-001

A special inspection of PET Scan of New Jersey was performed on November 14 and 15, 2006, to follow up on a radiopharmacy report that they had distributed Tc-99m labeled radiopharmaceuticals, normally used for medical procedures, to PET Scan of New Jersey when PET Scan of New Jersey was not licensed to perform medical procedures. A separate inspection of the radiopharmacy's operation was performed.

As a result of the inspection, the inspectors concluded that, between July 28 and October 27, 2006, the licensee, PET Scan of New Jersey, did perform medical studies pursuant to 10 CFR 35.200 but were not authorized to do so. The inspectors determined that the licensee did not fully understand the regulations and the conditions of the license, but incorrectly believed that the medical use of Tc-99m was authorized pursuant to 10 CFR 35.65. The inspectors determined that licensed activities were performed under the supervision of an individual who was qualified to be an authorized user pursuant to 10 CFR 35.200, and that the nuclear medicine technician followed standard NRC guidance for radiological safety with radiopharmaceuticals.

Two violations were identified: A) PET Scan of New Jersey used Tc-99m to perform medical studies that were not authorized by Amendment 1 of License No. 29-30840-01 between July 28 and October 27, 2006, a violation of 10 CFR 30.34(c) and 35.13. [Section I]; and B) the Radiation Safety Officer and the supervised individuals did not receive training in, and/or understand the applicable regulations and conditions of the license, a violation of 10 CFR 35.27(a)(1) and the conditions of the license [Section IV].

REPORT DETAILS

I. Scope of Authorized and Unauthorized Activities

a. Inspection Scope

Inspectors interviewed licensee personnel and reviewed licensee records to determine the scope of NRC activities. Particular attention was paid to the length of time and type of activities that were performed.

b. Observations and Findings

PET Scan of New Jersey, located in Elizabeth, New Jersey, is a small, privately-owned company that offers a variety of medical imaging services such as computed tomography (CT), magnetic resonance imaging (MRI), diagnostic X-ray, and positron emission tomography (PET). They were first issued an NRC license in October, 2003, for the use of sealed sources for diagnosis pursuant to 10 CFR 35.500, in support of their activities with PET scanning. Because PET Scan of New Jersey is a Part 35 medical licensee, they are also authorized under 10 CFR 35.65 to use both sealed and unsealed sources of radioactive material for calibration, transmission, and reference use. Although they had not obtained sources for use under their 10 CFR 35.500 authorization, the licensee had obtained licensed materials for calibration in accordance with 10 CFR 35.65. At the time of this inspection, the licensee possessed three small sealed calibration sources containing cesium-137, and had used unsealed technetium-99m (Tc-99m) for calibration on multiple occasions pursuant to 10 CFR 35.65.

Early in 2006, PET Scan of New Jersey decided to add nuclear medicine studies to their business. When adjacent space became available in the spring of 2006, they requested amendment of their NRC license to add a new imaging area and the equipment needed for nuclear medicine studies. However, in their letter received May 26, 2006, they did not state that they were planning to add nuclear medicine studies and did not request authorization to perform any new NRC-licensed activities, but confirmed that they could possess Tc-99m as authorized by 10 CFR 35.65. License reviewers believed that the licensee only wished to perform current activities in the new location, and Amendment No. 1 was issued on June 21, 2006, authorizing licensed activities in the new location.

Between July 28 and October 27, 2006, the licensee performed 52 patient studies pursuant to 10 CFR 35.200 using Tc-99m labeled radiopharmaceuticals to perform thyroid, gallbladder, liver/spleen, whole body and bone scans; cardiac stress tests; and renal flow and function tests. Nuclear medicine studies were typically performed 1 or 2 days each week, with 1 to 5 patients per day. No other materials under NRC jurisdiction were used for patient studies during this period, or prior to that time.

The inspectors determined that the administrator, the consultant, the nuclear medicine technician (NMT) and the radiation safety officer (RSO) did not realize that they had not requested authorization to perform patient studies pursuant to 10 CFR 35.200 when they requested to have the new clinical imaging room be added to their NRC license.

They did not understand that Amendment No. 1 of the license did not authorize medical use of Tc-99m. The administrator and RSO did not understand that 10 CFR 35.65 authorizes Tc-99m only as needed for calibration, transmission, and reference use, but thought that they could perform medical use of Tc-99m under this regulation. The inspectors verified that the staff waited to receive Amendment No. 1 prior to beginning patient studies with Tc-99m in the new location.

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license. 10 CFR 35.13 requires, in part, that a licensee apply for and receive a license amendment before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part but that is not authorized on the licensee's current license.

On October 31, 2006, when ordering patient doses, the licensee was informed by their radiopharmaceutical supplier that the radiopharmacy would not provide them patient doses of NRC-licensed materials because the radiopharmacy's review of the PET Scan of New Jersey NRC license indicated that PET Scan of New Jersey was not authorized to perform patient studies. The licensee submitted a letter to the NRC Region I office that was received on November 1, 2006, requesting to amend the license to authorize 10 CFR 35.200 activities, and requesting that the review be expedited. The letter did not explain the need for expediting the review, and, based on the staff workload, it was expected that the action would be reviewed during the week of November 6.

On November 3, a representative of the radiopharmacy contacted the Region I office to report that they had provided patient doses to PET Scan of New Jersey on multiple occasions in 2006, and that it did not appear to the radiopharmacy representatives that PET Scan of New Jersey was authorized to perform patient studies. The radiopharmacy added that they did not identify this until following up on an October 31 order for a patient dose from PET Scan of New Jersey. On November 3, the Region I staff contacted PET Scan of New Jersey to verify the information provided by the radiopharmacy and to obtain written confirmation that patient studies using Tc-99m were discontinued until the license was amended.

Amendment No. 2 of License No. 29-30840-01, authorizing medical studies pursuant to 10 CFR 35.200, was issued on November 6, 2006, because the authorized user listed on the license was also qualified to perform these studies. Patient studies using Tc-99m resumed on November 8, 2006

c. Conclusions

The finding that PET Scan of New Jersey used Tc-99m to perform medical studies that were not authorized by Amendment 1 of License No. 29-30840-01, between July 28 and October 27, 2006, is an apparent violation of 10 CFR 30.34(c) and 35.13.

II. Management Oversight of the Program

a. Inspection Scope

The inspectors interviewed licensee personnel and reviewed records to determine the involvement of management in oversight of the activities under NRC jurisdiction.

b. Observations and Findings

PET Scan of New Jersey is owned by a small group of private individuals. Ralph DeBellonia is employed by Pet Scan of New Jersey and serves as the Administrator for the licensee. Mr. DeBellonia also performs certain medical activities not under NRC jurisdiction. His administrative duties include oversight of patient scheduling for all activities performed at the Elizabeth facility. He also signs all correspondence letters to the NRC as the management representative for the licensee. He provides some administrative oversight for the NMT and other medical staff.

Natalio Damien, MD, is a physician employed by PET Scan of New Jersey. He is named as the Radiation Safety Officer and the only authorized user on the NRC license. He is qualified by training and experience to be a Radiation Safety Officer and an authorized user for 10 CFR 35.200 and 35.500 activities, in accordance with current NRC regulations. Dr. Damien is usually present on site part of each day. He stated that he reviews the schedules for all modalities with the NMT and approves the orders for radiopharmaceuticals needed for nuclear medicine studies. Most of his involvement with the nuclear medicine is the reading of bone scans. He does not participate in performance of, or review of, cardiac stress tests using Tc-99m. Dr. Damien was not aware of the license commitment to implement the duties of the Radiation Safety Officer as listed in Regulatory Guide 10.8, Revision 2, Appendix G. These duties include performing: an annual review of the radiation safety program; a quarterly review of occupational exposures; a quarterly review of survey records; and briefings and education in, development of, and review of ALARA practices. Dr. Damien stated that he has not performed any audits of the NRC-licensed activities himself but does receive and review the reports of audits performed quarterly by the consultant, and has reviewed dosimetry records periodically. However, only some of the quarterly audits and dosimetry records were signed or initialed as reviewed by Dr. Damien. On various occasions, the report from the consultant included a note that read “Staff is reminded to have RSO sign the required elements of these Radiation Safety Audit reports”. During the telephone interview with Dr. Damien on November 15, the inspector reminded Dr. Damien that he is the Radiation Safety Officer and the only authorized user named on the license and is responsible for all use of byproduct materials under this license.

PET Scan of New Jersey employs a health physics consultant who assisted the licensee in obtaining the initial NRC license and subsequent amendments, and in setting up the facility for nuclear medicine use. He prepared draft correspondence to the NRC for the licensee. The consultant visited the facility quarterly to perform calibration of the dose calibrator, other services as needed, and to audit the facility. He provided written reports of the audits to the Radiation Safety Officer. He also provided basic radiation

safety training to employees as needed, but stated that he had not reviewed with them the applicable regulations or conditions of the license.

The NMT employed by PET Scan of New Jersey performs PET scans and nuclear medicine scans. The NMT performed most of the activities involving Tc-99m, such as ordering patient doses from the radiopharmacy, receiving incoming packages of radioactive materials, assaying patient doses, injecting patients, scanning patients, and surveying the work area at the end of each day of use.

c. Conclusions

The inspectors did not identify any violations related to management oversight, but are concerned that the individual named as Radiation Safety Officer and authorized user was not fully aware of his responsibilities under the license and the regulations.

III. Implementation of the Radiation Safety Program

a. Inspection Scope

Inspectors observed a variety of activities and interviewed licensee employees to determine how the licensee implemented the radiation safety program.

b. Observations and Findings

The inspectors determined that the facilities were as described in the license application and determined that equipment was available, operable and calibrated as required. Inspectors determined that the NMT followed required procedures for material receipt, use, control, and return of materials to the radiopharmacy. The inspectors observed the NMT using required radiation protection procedures such as wearing of laboratory coats, gloves, and dosimetry. Inspectors reviewed dosimetry records and determined that all doses were within NRC limits and met the licensee's ALARA criteria. The inspectors discussed with the NMT the procedures for return of radiopharmacy material and decay-in-storage of waste, and determined that the procedures were in accordance with NRC requirements. The inspectors observed postings and labeling to be in accordance with NRC requirements. Inspectors surveyed the nuclear medicine imaging room, stress laboratory, and injection area and all radiation levels were indistinguishable from background. Inspectors also reviewed license procedure documents and records of routine radiation safety activities.

c. Conclusions

The NMT implemented the radiation protection activities as required by the NRC license and regulations.

IV. Training of Workers

a. Inspection Scope

Inspectors interviewed licensee staff to determine their training in, and knowledge of, radiation safety practices and procedures, and the regulations and conditions of the license.

b. Observations and Findings

The NMT stated that he had formal training in nuclear medicine and radiation safety approximately 20 years ago, and has been working in the field since that time. The NMT was able to describe appropriate practices for use and storage of the licensed materials at PET Scan of New Jersey. The NMT did not recall having formal initial training when first employed by the licensee three years ago, although he recalled meeting with the Radiation Safety Officer then. The NMT stated that he interacted with the consultant during his quarterly visits but neither the NMT nor the consultant could recall any review or training in the conditions of the license or the regulations.

The Radiation Safety Officer was not aware of the license commitment to implement the duties of the Model Training Program as listed in Regulatory Guide 10.8, Revision 2, Appendix A. This training program requires, in part, that training be provided whenever there is a significant change in the duties, regulations, or terms of the license, and that topics include, in part, the applicable regulations and license conditions. The licensee is also required to provide instruction in the regulations of Part 35 and the license conditions by 10 CFR 35.27(a)(1).

As discussed in Section I of this report, the inspectors determined that the administrator, the consultant, the NMT and the RSO did not realize that the license did not authorize patient studies pursuant to 10 CFR 35.200 when the new location of use was approved under Amendment No. 1. The administrator and the RSO also did not understand that 10 CFR 35.65 authorizes Tc-99m only as needed for calibration, transmission, and reference use, but thought that they could perform medical use of Tc-99m under this regulation. The inspectors determined that the administrator, the consultant, the RSO and the NMT understood the regulations and license conditions that were discussed with them during the inspection.

c. Conclusions

The finding that the Radiation Safety Officer and the supervised individual did not receive training in, and/or understand the applicable regulations and conditions of the license, is an apparent violation of 10 CFR 35.27(a)(1) and the conditions of the license.

V. Exit Meeting

The inspectors met with Ralph DeBellonia prior to leaving the site on November 14 to review the findings of the on-site inspection. The inspectors contacted him by telephone on November 15, 2006, after the telephone interview with the Radiation Safety Officer was completed, to update the findings of the inspection. An exit meeting was held by the inspectors with Mr. DeBellonia by telephone on January 19, 2007, to discuss the results of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Natalio Damien, MD, Radiation Safety Officer
Ralph DeBellonia, Administrator
Gopal Doshi, Nuclear Medicine Technician
Richard W. Brown, Health Physicist, Applied Medical Physics in Radiology (consultant)