

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 030-37113/2008002
Docket No. 030-37113
License No. 29-31119-01
Licensee: New Jersey Institute of Radiology
Location: 630 Broad Street
Carlstadt, New Jersey 07072
Inspection Dates: October 31, 2008 thru February 8, 2010
Exit Meeting Performed: February 9, 2010

Inspector: _____/RA by JPD For/ _____ February 12, 2010 _____
Dennis R. Lawyer date
Health Physicist

Approved By: _____/RA/ _____ February 12, 2010 _____
James P. Dwyer, Chief date
Commercial and R&D Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

New Jersey Institute of Radiology
NRC Inspection Report No. 030-37113/2008002

A special inspection was performed on October 31, 2008, at the New Jersey Institute of Radiology (NJIR) facility located at 630 Broad Street, Carlstadt, New Jersey. The inspection was performed because the licensee/owner of record submitted a letter to NRC dated October 23, 2008, stating: (1) that the license had been transferred to new ownership; (2) that he, as an authorized user, was no longer associated with the license; and (3) that the only other authorized user listed on the license had resigned effective October 20, 2008.

The inspector concluded that management oversight of the licensed program was continuous and oversight of radiation safety activities was adequate; however, the licensee did not notify the NRC and receive the NRC's consent prior to transferring control of the license to new ownership. This is an apparent violation of 10 CFR 30.34(b). Corrective action for the apparent violation was completed on January 9, 2009, with the issuance of Amendment No. 4 of the license.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

The inspector toured facilities, observed licensed activities, interviewed current and former employees, and reviewed records.

b. Observations and Findings

The onsite inspection of the New Jersey Institute of Radiology (NJIR or the licensee) licensed program was performed on October 31, 2008. The NJIR license in effect at that time (Amendment No. 3, issued October 30, 2008) authorized the medical use of byproduct material for diagnostic procedures described in 10 CFR 35.100 and 35.200, as well as for diagnostic and therapeutic procedures described in 10 CFR 35.300 where the patient could be released in accordance with 10 CFR 35.75.1 Amendment No. 3 of the license identified three authorized users responsible for supervising the medical use of NRC-licensed radioactive materials: Hussein M. Abdel-Dayem, M.D.; Mahmoud Dakhel, M.D.; and Shelley Ann Quarless, D.O. The licensee employed two Nuclear Medicine Technologists. One of the technologists also served as the Office Manager. Licensed activities were performed at only the Carlstadt Office. The inspector observed that NRC-licensed materials were used to perform less than 20 diagnostic procedures each month and that medical procedures described in 10 CFR 35.300 and requiring a written directive in accordance with 10 CFR 35.40(a) were performed on only three occasions since the license was amended to add 10 CFR 35.300 procedures in November 2007. Other diagnostic imaging procedures, using accelerator-produced radioactive materials, were also performed at the licensee's facility.

c. Conclusions

No violations or safety concerns were identified.

II. Management Oversight of the Program

a. Inspection Scope

The inspector interviewed the former owner, interviewed current and former employees, and reviewed records.

b. Observations and Findings

The NJIR license was issued to Dr. Abdel-Dayem on February 14, 2006. In a letter to NRC Region I dated October 23, 2008, Dr. Abdel-Dayem stated that he was no longer the owner of NJIR, he was no longer performing the duties of an authorized user under the license and he requested that his name be removed from the license. The inspector

1 The license was amended on February 4, 2009, removing authorization to perform 10 CFR 35.300 procedures.

determined that Dr. Abdel-Dayem began negotiations with another physician, on January 23, 2008, to sell NJIR and that these negotiations ended with the sale of NJIR to the physician and his practice, Urology Specialty Care, P.A., on September 8, 2008. The inspector determined that Dr. Abdel-Dayem had no association with NJIR after September 8, 2008.

10 CFR 30.34(b) requires, in part, that no license issued pursuant to the regulations in 10 CFR Parts 30 and 35 shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Atomic Energy Act and shall give its consent in writing. Contrary to the above, on September 8, 2008, the licensee transferred control of License No. 29-31119-01 to new ownership without first receiving the Commission's consent in writing.

The failure to obtain written consent from the Commission prior to transferring control of License No. 29-31119-01 to new ownership is an apparent violation of 10 CFR 30.34(b). Corrective action for this apparent violation was completed on January 9, 2009, when Amendment No. 4 of the license was issued.

The inspector determined that, beginning with the negotiations to sell NJIR on January 23, 2008, the potential new owner placed Adel Mustafa, Ph.D. in charge of operations and named him President of NJIR. This was documented by an electronic mail from the potential new owner. As President of NJIR, Dr. Mustafa has carried out management oversight of the program as he has signed correspondence with the NRC since January 23, 2008, and made management decisions associated with physician positions at the practice.

c. Conclusions

Management oversight of the program was continuous and oversight of radiation safety activities was adequate; however, the licensee did not notify the NRC and receive the NRC's consent prior to transferring control of the license to new ownership. This is an apparent violation of 10 CFR 30.34(b) for which corrective action has been completed.

III. Supervision of Licensed Activities

a. Inspection Scope

The inspector observed license activities, interviewed current and former licensee employees and reviewed records.

b. Observations and Findings

The previous inspection (Inspection No. 2008001) conducted on April 24, 2008, identified that radioactive materials described in 10 CFR 35.300 were administered to two patients and that the written directives required by 10 CFR 35.40(a) for the two patient administrations were signed by Dr. Dakhel, not the authorized user identified on the

license, Dr. Abdel-Dayem. A Notice of Violation was issued. In response to the finding, the licensee stated that Dr. Dakhel consulted with the authorized user, Dr. Abdel-Dayem, and that Dr. Abdel-Dayem authorized the two patient administrations. In addition, the licensee submitted a request for an amendment of the license to add Dr. Dakhel to the license. This amendment was approved on July 7, 2008. The inspector who conducted the current inspection (Inspection No. 2008002) determined that the licensee's corrective and preventive actions were adequate and that this violation has not recurred.

On August 27, 2008, NRC received a request to amend the NJIR license adding Dr. Quarless as an authorized user. The letter transmitting the amendment request was dated August 20, 2008; however, the application was dated August 25, 2008.

On October 27, 2008, NRC received a letter dated October 23, 2008 from Dr. Abdel-Dayem, stating that he was no longer the owner of NJIR, he was no longer performing the duties of an authorized user under the license and he requested that his name be removed from the license. Furthermore, Dr. Abdel-Dayem advised NRC that Dr. Dakhel had resigned from NJIR effective October 20, 2008. The NRC was concerned because Dr. Quarless had not yet been approved as an authorized user and the two authorized users listed on the NJIR license had apparently resigned from the licensed program. The amendment naming Dr. Quarless as an authorized user was completed on October 30, 2008.

An onsite inspection was performed on October 31, 2008. The inspector determined that between October 20 and October 29, 2008, NRC-regulated materials were administered to 10 patients. Of the 10 administrations, none required a written directive.

The inspector determined that Dr. Mustafa and Kristien A. Bonagura, the Nuclear Medicine Technician and Office Manager, both thought that Dr. Dakhel was authorizing and supervising the use of NRC-regulated materials through the end of October 2008. Dr. Mustafa said that he knew that Dr. Dakhel had resigned; however, he expected Dr. Dakhel to return and review imaging results for the patient procedures he had previously authorized. The inspector learned that Dr. Dakhel had called in sick to the licensee after October 20, that he had performed a review of imaging procedures performed after October 20, and that he appeared to have been paid for his services through the end of October. Based on this information, the inspector concluded that Dr. Dakhel continued to act as an authorized user through the end of October when Dr. Quarless became an authorized user.

The inspector noted that Dr. Quarless had been employed by NJIR since August 2008, that she met the requirements of 10 CFR 35.13(b)(1) and 35.13(b)(4), and she therefore could have been permitted to work as an authorized user by the licensee prior to receiving NRC approval in a license amendment. Dr. Mustafa stated that NJIR did not allow her to authorize the use, or supervise the use of NRC licensed material until her name was specifically listed on the license. Dr. Quarless also confirmed that she did not authorize the use nor supervise the use of NRC-regulated materials until she was listed on the license.

On January 13, 2009, the licensee notified NRC that Dr. Quarless would no longer function as authorized user under the NJIR license as of that date. Recognizing that they

had no authorized user to oversee licensed activities, the licensee stated that they suspended patient treatments. The licensee requested an expedited review of their request to add a new authorized user. NRC was unable to approve of the proposed authorized user with the existing license authorization so the licensee requested that authorization for materials described in 10 CFR 35.300 be removed from the license. This was done and the amendment naming the new authorized user was issued on February 4, 2009.

c. Conclusions

The inspector concluded that Dr. Dakhel continued to act as an authorized user through the end of October when Dr. Quarless became an authorized user. The inspector also concluded that the licensee took effective corrective and preventive actions for the violation identified during the previous inspection.

IV. Exit Meeting

The inspector met with the individuals identified in the attached list and described the findings of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Hussein M. Abdel-Dayem, M.D., Former Owner and Authorized User

Mahmoud Dakhel, M.D., Authorized User

*Adel Mustafa, Ph.D., President and Radiation Safety Officer

Shelly Ann Quarless, D.O., Ph.D., Authorized User

*#Kristien A Bonagura, MHA, CNMT, RT(N)

* Present at the entrance meeting

Present at the exit meeting