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

September 28, 2007

Docket No. 03035748 License No. 29-30646-01
EA-07-234

Rudy Rezzadeh, M.D.
539 Durie Avenue
Closter, NJ 07624

SUBJECT: INSPECTION 03035748/2007001, RUDY REZZADEH, M.D., CLOSTER, NEW JERSEY

Dear Dr. Rezzadeh:

This letter refers to your August 2, 2007, letter, in response to our July 8, 2007, letter and Notice of Violation. In your letter you alleged that the inspector who performed your inspection acted in an unprofessional manner and you questioned the validity of the two cited violations. Your allegation of unprofessional behavior is being separately reviewed. We will advise you of our conclusions in that area when our review is completed. This letter addresses the validity of the two cited violations.

Violation A

10 CFR 20.2104(a) requires in part, for each individual who is likely to receive in a year an occupational dose requiring monitoring pursuant to 10 CFR 20.1502, that the licensee shall determine the occupational radiation dose received during the current year. 10 CFR 20.1502 requires that each licensee monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20.

A violation of 10 CFR 20.2104(a) was cited because your nuclear medicine technologist stated, during a telephone discussion with the inspector on June 5, 2007, that he currently worked with licensed radioactive material at several other facilities and no records of these other exposures were maintained at your facility. The inspector reviewed the occupational radiation exposure report posted in your facility and noted it documented only the occupational doses received by the technologist at your facility. The inspector concluded from his discussion with the technologist that you, the licensee, only recorded and tracked the occupational dose received by the technologist at your facility and did not record or track the occupational dose received at all of the facilities where the technologist worked in a manner sufficient to determine the occupational dose the technologist received during the current year.

In your August 2, 2007, response to the Notice of Violation, you indicated that the technologist posted his occupational radiation exposure report from all of the facilities where he worked and he confirmed that at all times he was in compliance with the dose limits in 10 CFR Part 20. Your statement that the technologist posted his occupational

radiation exposure report from all of the facilities where he worked does not comport with what the inspector was told or observed at your facility. During a telephone discussion with your consultant on August 8, 2007, the NRC determined that your consultant recorded and tracked all of the exposures received by the technologist at the various facilities on your behalf. Based on this new information, we have concluded that the violation will be withdrawn.

Violation B

10 CFR 35.63(d) requires that, unless directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within a prescribed range or if the dosage differs from the prescribed dosage by more than 20 percent.

A violation of 10 CFR 35.63(d) was cited because the technologist administered dosages of technetium-99m (Tc-99m) that did not fall within the prescribed range and differed from the prescribed dosage by more than 20 percent. Specifically, during the inspection you informed the inspector that cardiac stress test patients were to receive dosages of between 15 and 25 millicuries of Tc-99m and that cardiac rest test patients were to be administered 8 millicurie dosages of Tc-99m. The inspector determined from his telephone discussion with the technologist on June 5, 2007, that when only the stress portion of the test was performed, the full dosage of about 30 millicuries was used and when both portions of the test were performed, the nuclear medicine technologist split a 30 millicurie dosage into two parts. The inspector noted during his review of records that the rest portion of the dosage usually exceeded 12 millicuries of Tc-99m.

In your August 2, 2007, response to the Notice of Violation, you indicated that the prescribed dosage range for the stress portion of the test is between 15 and 30 millicuries of Tc-99m, not between 15 and 25 millicuries as we understood from the discussion held during the inspection, and that the prescribed dosage for the rest portion of the test is actually a prescribed dosage range of between 8 and 10 millicuries of Tc-99m. You added that at no time did the technologist administer more than 12 millicuries of Tc-99m for the rest portion of the test (we note that administering a dosage greater than 10 millicuries, when a range of between 8 and 10 millicuries is prescribed, would still be a violation.)

During a telephone conversation with Mr. Jim Dwyer of my staff on September 17, 2007, you stated that the inspector must have been confused by your dosage administration records because your technologist never administered more than 10 millicuries of Tc-99m for the rest portion of the test. In order to resolve this discrepancy, you made your dosage administration records available for review by a second inspector on September 19, 2007. The second inspector noted that you maintained two records that included dosage administration information. The first record, titled “Unit dose Prescription Record,” included the label provided by the radiopharmacy and a single handwritten notation of the activity administered. The radiopharmacy label included the patient’s name, the date the dosage was prepared, the pharmaceutical name and the dosage activity at the time of calibration. The second record was an untitled table that included the patient’s name, the date of dosage administration, the dosage administered for the stress portion of the test, the dosage administered for the rest portion of the test,

if applicable, and the initials of the technologist. We noted from comparing the two records that the handwritten notation in the first record matched the activity administered for only the stress portion of the test, and there was no record of the dosage administered for the rest portion of the test in the first record. We determined that the first inspector only reviewed the first record during his inspection and, because this record only recorded the 15-30 millicurie dosages normally administered for the stress portion of the test, it appeared to him that any dosages administered for the rest portion of the test would have exceeded the prescribed amount by more than 20 percent or were outside of the prescribed range.

Separately, it is important to note that our review of the new information provided in the second record indicates that some dosages administered for the stress portion of the test were outside of the 15-30 millicurie range you, as the authorized user, specified for this procedure. This practice could result in a violation of 10 CFR 35.63(d) if these dosages were not directed by the authorized user. We noted during a follow up visit to your facility by Mr. Dwyer on September 24, 2007, that you are directly involved in the preparation and administration of these dosages and therefore you are in compliance with the requirements of 10 CFR 35.63(d).

Based on the new information received subsequent to our initial inspection, which included the untitled table with proper recording of the dosages administered for the rest portion of the test, we have concluded that the violation will be withdrawn.

Thank you for bringing your concerns about the validity of these violations to our attention. We intend to use the lessons learned in this case to improve our inspection program. Your cooperation with us is appreciated. Should you have any other questions, please contact Mr. Dwyer at (610) 337-5309.

Sincerely,

Original signed by Brian Holian

Brian E. Holian, Director
Division of Nuclear Materials Safety

cc:
State of New Jersey

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Brian E. Holian, Director
Division of Nuclear Materials Safety

cc:
State of New Jersey

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