REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

February 6, 2009

Docket No. 03035600 License No. 29-30606-01
EA-08-341

Jill Baer
Administrator
Central Jersey Radiologists
2128 Kings Hwy. & Route 35 South
Oakhurst, NJ 07755

SUBJECT: YOUR LETTERS DATED NOVEMBER 3, 2008, AND NOVEMBER 25, 2008, IN RESPONSE TO NRC NOTICE OF VIOLATION ISSUED ON OCTOBER 14, 2008

Dear Ms. Baer:

We have completed our review of the November 3, 2008, and November 25, 2008, letters from Dr. Irving Stein, your Radiation Safety Officer and Manager, in response to our letter dated October 14, 2008.

Our October 14, 2008, letter and Notice of Violation (NOV) described a Severity Level IV violation, identified during an NRC inspection, involving the failure to perform surveys on a patient after being administered sodium iodide iodine-131 in quantities exceeding 33 millicuries. Such surveys are required in order to determine if the total effective dose equivalent to any other individual from exposure to the released individual is likely to exceed 5 mSv (0.5 rem). In your November 3, 2008, response you stated that you believe that the violation was in error, because: (1) 10 CFR 35.75(a) does not require that the facility perform a survey prior to release of a patient receiving in excess of 33 millicuries of sodium iodide iodine-131; and (2) Appendix U of NUREG-1556, Vol. 9, Rev. 2, states that using the NRC estimates for occupancy factors in combination with the physical half-life will produce a conservative estimate of the dose to family members, and therefore, thyroid cancer patients that were administered 150 millicuries of sodium iodide iodine-131 or less would not have to remain under the licensee's control and could be released under 10 CFR 35.75.

On November 25, 2008, you submitted additional information stating that, although you are still disputing the violation, you made several improvements to your program. Among these are updates to your written directive to include surveying the patient and recording the patient's dose rate measurements at one meter after the patient has been administered sodium iodide iodine-131 in quantities exceeding 33 millicuries. In addition, you agreed to collect patient-specific information to support the use of the occupancy factors identified in Appendix U of NUREG-1556, Volume 9.

Based on further review of the information submitted, the NRC has determined that a violation of 10 CFR 20.1501(a)(2) and 35.75(a) occurred. Specifically, 10 CFR 35.75(a) allows, in part, the release from licensee control any individual who has been administered unsealed byproduct material (e.g., sodium iodide iodine-131) if the total effective dose equivalent to any other

individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). However, 10 CFR 20.1501(a)(2) requires that each licensee make or cause to be made surveys that are reasonable to evaluate, in part, the magnitude and extent of radiation levels and the potential radiological hazards. 10 CFR 20.1003 defines a survey as "an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation" and states that an evaluation includes a physical survey and measurements, or calculations of levels of radiation present. Appendix U of NUREG-1556, Vol. 9, Rev. 2, provides a model procedure for release of patients or human research subjects administered radioactive materials that licensees may use when developing their program. The model procedure in Appendix U states that "licensees should use one of the following options to release a patient to whom unsealed byproduct material or implants containing byproduct material have been administered in accordance with regulatory requirements" in 10 CFR 35.75(a):

1. "Release of Patients Based on Administered Activity - In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table U.1. In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child." "The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.40 and 35.63." The value for sodium iodide iodine-131 found in Column 1 of Table U.1 is 33 millicuries.

2. "Release of Patients Based on Measured Dose Rate - Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table U.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table U.1 for that radionuclide. In this case, however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue." The value for sodium iodide iodine-131 found in Column 2 of Table U.1 is 7 millirem/hour at 1 meter.

3. "Release of Patients Based on Patient-Specific Dose Calculations - Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. The patient may be released, if the calculated maximum likely dose to an individual is no greater than 5 millisievert (0.5 rem). Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table U.1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by 10 CFR 35.75(c). If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c)."

During the NRC inspection, the inspector identified that the appropriate record required by 10 CFR 35.40 was maintained for all patients administered less than 33 millicuries of sodium iodide iodine-131 and released, as described in Item 1 above. Also during the inspection, the inspector identified through interviews with your staff that neither a dose rate measurement of the patient, as described in Item 2 above, nor a calculation using patient-specific criteria, as described in Item 3 above, were performed to support the release of patients administered greater than 33 millicuries of sodium iodide iodine-131, under 10 CFR 35.75. In addition, the

inspector identified that no records existed to support release of the patients administered greater than 33 millicuries of sodium iodide iodine-131, as described in Items 2 and 3 above. Hence, we find your statements from your November 3, 2008, letter, indicating that a survey was not required and that you were following the guidelines of NUREG-1556, Vol. 9, Rev. 2, for the release of patients, to be inadequate. Specifically, your implementation of the procedures described in NUREG-1556, Vol. 9, Rev. 2, relied solely on providing patients with written safety instructions required by 10 CFR 35.75(b) and did not include the required provisions for either a radiation level survey of the patient or a patient-specific calculation as described in Items 2 and 3 above. Therefore, based on the above, the violation remains as noted in the NRC NOV enclosed with the letter dated October 14, 2008. As such, absent any additional information, the NRC plans no further action regarding your request to retract the violation.

Thank you for the corrective actions described in your November, 25, 2008, letter. However, after reviewing the information described therein, it is our understanding that you plan to release future patients pursuant to 10 CFR 35.75(a) based solely on radiation level survey results and a commitment to provide written instructions to each patient. Please note that the maximum patient radiation level measurement referenced in NUREG-1556, Vol. 9, App. U, Table U.1, is 7 mR/hour at 1 meter to support release of a patient. In general, this is equivalent to approximately 33 millicuries administered to a patient. Therefore, for administrations exceeding 33 millicuries, patient-specific calculations to support the release of each patient administered sodium iodide iodine-131 may also be necessary, as described in Item 3 above. Please re-submit your corrective actions and confirm that when releasing patients as described in Item 2 above, that you will perform and document the required survey of the patient. Additionally, when releasing patients as described in Item 3 above, confirm that you will perform and document patient-specific calculations.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

Sincerely,

/RA Daniel S. Collins Acting for/

John D. Kinneman, Director
Division of Nuclear Materials Safety

cc:
Irving Stein, D.O., RSO
State of New Jersey

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cc:
Irving Stein, D.O., RSO
State of New Jersey

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