GARDEN STATE IMAGING

315 Elmora Ave., Suite 200 & 208, Elizabeth, NJ 07208
Tel: 908.282.1100 Fax: 908.282.9090

N.J. Licensed Ambulatory Care Center

A.C.R. & MQSA Accredited

USNRC Region I
Licensing Material Section
475 Allendale Road
King of Prussia, PA 19406-1415

Br 2

September 02, 2008

29-30040-01
03036417

To Whom It May Concern:

Please accept this letter as a request to amend our existing NRC license to reflect the addition of oral administration of sodium iodide, iodice-131 by Allen C. Pomerantz, MD as an authorized user of materials covered under 10CFR35.100 and 10FR35.200. Dr. Pomerantz is currently listed as an authorized user on NRC License for Tri-County Imaging Center, license # 29-30019-01, docket # 030-33077 which provides for the use of I-131 by oral administration. A copy of this license is attached for your reference.

Additionally, please find attached copies of our proposed QM Program for our facility.

Should you have any questions regarding this amendment application, please feel free to contact me at (908) 282-1100.

Sincerely,

Ralph DeBellonia
Administrator

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State of New Jersey

Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415, Trenton, NJ 08625-0415
Phone (609) 984-5462

New Jersey Radioactive Materials License

Pursuant to the New Jersey Radiation Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive or use the naturally occurring and/or accelerator produced material(s) (NARM) designated below; and to such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the State Department of Environmental Protection, now or hereafter in effect, and to any conditions specified below.

1. License No.: NJSL-20799/01/004

2. Expiration Date: 12/31/2008

3. Licensee: PET SCAN OF NEW JERSEY

4. Address: 315 Elmora Avenue, Suite 200
Elizabeth NJ 07208

Radiation Safety Officer: Natalio Damien, M.D.

Administrator: Ralph DeBellonia

County: Union
Telephone: (908) 282-1100

5. Reference No.: 650

RADIOACTIVE MATERIALS DATA (A)

	6. Material	7. Limit (mCi)	8. Form
A.	Any naturally occurring and/or accelerator produced material included under Group II, Section 4.7 of NJAC	30.0000	Any radiopharmaceutical included under Group II Section 4.7 of NJAC 7:28-4.
B.	CO-57	20.0000	Sealed Source
C.	F-18	1020.0000	FDG
D.	Ge-68	15.0000	Sealed Source

RADIOACTIVE MATERIALS DATA (B)

	9. Authorized Use
A.	Any diagnostic procedure under Group II of NJAC 7:28-4, Section 4.7
B.	For calibrating and checking of instruments.
C.	Human use imaging and instrument calibration.
D.	PET Scanner Quality Assurance.

Conditions begin on the following page.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-30019-01

Docket or Reference Number
030-33077

Amendment No. 10

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

B. The following individuals are authorized users for medical use as indicated:

Authorized Users	Material and Use
Steven R. Parmett, M.D.	35.100; 35.200; 35.300
E. Gordon DePuey, M.D.	35.100; 35.200
Munir Ghesani, M.D.	35.100; 35.200; 35.300
Rajendra H. Patel, M.D.	35.100; 35.200
Allen C. Pomerantz, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131
Fukiat Ongseng, M.D.	35.100; 35.200; 35.300
Mira Chakravarty, M.D.	35.100; 35.200
Peeyush Bhargava, M.D.	35.100; 35.200; 35.300
Rustico Pulitan, M.D.	35.100; 35.200

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

Before administering a therapeutic dose, the identity of the patient as the individual named in the written directive shall be established by asking the patient's name and confirming the name. In addition, the birth date, address, social security number, the name on the patient's ID bracelet or hospital ID card, name on the patient's medical insurance card, or name on the driver's license is to be compared with the corresponding information in the patient's record.

In the case of an unresponsive patient or a child, a family member or guardian or health care worker to whom the patient is known can establish the identity of the patient.

The authorized user or qualified person under the supervision of an authorized user shall verify that the radioisotope and amount to be administered are in agreement with the written directive and plan of treatment.

The qualified person may be a physician, physicist or technologist, but the authorized user must designate these individuals in writing.

An authorized user or a qualified person under the supervision of an authorized user must check the dose calculations before the total prescribed dose has been administered.

If an unintended deviation from the written directive is identified during review of the QMP or at any other time, then this information shall be communicated to the radiation safety officer for evaluation and appropriate corrective action.

A recordable event is defined as one of the following:

a) Administration of the therapy dose without a written directive except in those cases where an oral directive is deemed appropriate.

b) Failure to record the therapy dose in the patient's record.

c) The calculated administered therapy dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Within 30 days after discovery of a recordable event the relevant facts including the cause are to be assembled and corrective action, if any, to prevent recurrence identified. A record of relevant facts and corrective action taken shall be retained for three years.

A misadministration is defined as one of the following:

a) Therapy radiation dose administered to the wrong patient.

b) Administering the wrong radioisotope.

c) The calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Training

All supervised individuals in the QMP will receive instruction before assuming duties or whenever there is a significant change in conditions of the QMP. Instruction will be provided by RSO, consulting physicist, authorized user, or technologist approved by RSO. A copy of the current QMP is available for review by supervised individuals.

This is to acknowledge the receipt of your letter/application dated

9/2/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (29-30810-01)

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 142783.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader