Garden State Imaging
formerly Open MRI of Union County
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315 Elmora Ave., Suite 200 & 208 • Elizabeth, NJ 07208
Main Tel: 908-282-1100 • Fax: 908-282-9090

Br. 2

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

12/08/2008

RECEIVED
REGION 1
2008 DEC 15 AM 11:57

RE: NRC License Amendment Request
License # 29-30840-01
Docket # ~~030-36447~~ 03036417 RLJ

To Whom It May Concern:

Please accept this letter as a request to amend our existing NRC license to reflect the addition of the oral administration of sodium iodide, iodice-131 by Allen C. Pomerantz, MD as an authorized user of materials covered under 10CFR35.100 and 10CFR35.200. 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 the license is attached for your reference.

Please find a attached a copy of our proposed QM Program for our facility.

Additionally, we are requesting that Allen C Pomerantz, MD, also be named as the Radiation Safety Officer to replace Natalio Damien, MD, our current Radiation Safety Officer.

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

Sincerely,

Ralph DeBellonia
Administrator

(Ref. 142783)

143093
NMSS/RGN1 MATERIALS-002

The authorized user must date and sign a written directive for a specific patient prior to the administration of any dose of I-131 in excess of 30 uCi. The written directive must include the date, radioisotope, route of administration, amount to be given, patient's name, and clearly written signature of the authorized user.

A written revision to an existing written directive is permitted provided that the revision is signed and dated by an authorized user prior to the administration of the therapy dose.

If a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. Information contained in the oral directive must be documented immediately in the patient's record. A written directive must be prepared within 24 hours of the oral directive.

If a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented immediately in the patient's record. A revised written directive signed and dated by the authorized user must be provided within 48 hours of the oral revision.

Each written directive shall be retained for three years.

If a worker does not understand how to carry out the written directive, then the authorized user or supervisor should be contacted for guidance.

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 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 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 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.

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

12/8/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (29-30840-01)

☒ 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

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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** 143093.
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