TRICAT
Birch Pointe Commons
3840 Park Avenue
Edison, New Jersey 08820

NMSB1

U.S. Nuclear Regulatory Commission, Region I
Licensing Assistance Section
Nuclear Materials Safety Branch
475 Allendale Road
King of Prussia, Pa. 19406-1415

RECEIVED
REGION 1
2008 FEB -1 PM 12: 19

License # 29-30019-01 03033077

January 25, 2008

Re. Amendment Request

1. Add for Mira Chakravarty, M.D. "Oral administration of sodium iodide iodine-131 for Treatment of Thyroid Cancer" Attached is NRC Form 313A (Preceptor Attestation), signed by Dr. Patrick Conte. on 12/17/07.

Please note that Dr. Chakravarty is already authorized on our NRC license for 35.100, 35.200, and Oral administration of sodium iodide iodine-131 for imaging and localization studies and treatment of hyperthyroidism and cardiac dysfunction.

Dr. Conte has personally trained Dr. Chakravarty in at least 3 cases of I-131 Therapy of Thyroid Cancer.

2. Add Orestes Sanchez, M.D. for 35.100 and 35.200. Attached is NRC License 29-17895-01, Barnett Hospital authorizing Dr. Sanchez for these uses.

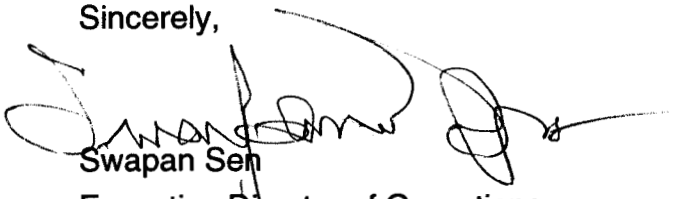
Please contact John Gochoco, Radiation Safety Officer @ 973-322-5590 if you need any additional information.

141782

NMSS/RGN1 MATERIALS-002

Thank you in advance for your assistance. We look forward to receiving our amendment.

Sincerely,



Swapan Sen
Executive Director of Operations

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

   Mira Chakravarty, M.D. (Proposed Authorization : I-131 Therapy for Thyroid Cancer)

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

   NJ

3. CERTIFICATION

a. Provide a copy of the board certification. *(Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)*

b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).

c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.

Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)

b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).

c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
OTHER			

NRC FORM 313A
(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
I-131	Thyroid Cancer	3	Patrick Conte, M.D.	TRICAT 29-30019-01	7/30/07, 9/15/07

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

☐ YES ☐ N/A Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervison. of _____ the RSO for License No. _____.

9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

☐ YES ☐ N/A Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

☐ YES ☐ N/A Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____ under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____.

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of *(if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each)* :

A. Name of Supervisor

Patrick Conte, M.D.

B. Supervisor is:

☑ Authorized User ☐ Authorized Medical Physicist

☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.300 .

for medical uses in Part 35, Section(s) 35.300 .

D. Address

Tricat - Edison Facility
3840 Park Avenue
Edison, NJ 08820

E. Materials License Number

29-30019-01

PART II -- PRECEPTOR ATTESTATION

Note: *This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).*

I attest the individual named in Item 1:

11a.

☐ has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) , as documented in section(s) of this form.

11b. Select one

☐ meets the requirements in ☐ 35.50(e) ☐ 35.51(c) ☐ 35.390(b)(1)(ii)(G) ☐ 35.690(c) for types of use, as documented in section(s) of this form.

☐ N/A

11c.

☐ has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **or**

☑ has achieved a level of competency sufficient to function independently as an authorized user of I-131 for Thyroid Cancer for 35.300 for I-131 Therapy uses (or units); **or**

☐ has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **or**

☐ N/A

11d.

☐ I am an Authorized Nuclear Pharmacist; **or** ☐ I am a Radiation Safety Officer; **or**

☑ I meet the requirements of 35.300 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor ☑ AU or ☐ AMP

for the following byproduct material uses (or units): I-131 for Thyroid Cancer

A. Address

Patrick Conte, M.D.
TRICAT
3840 Park Avenue
Edison, NJ 08820

B. Materials License Number

29-30019-01

C. NAME OF PRECEPTOR *(print clearly)*	D. SIGNATURE – PRECEPTOR	E. DATE
Patrick Conte, M.D.		

NRC FORM 313A U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL – IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of [if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each]:

A. Name of Supervisor: Patrick Conte, M.D.

B. Supervisor is:
- [x] Authorized User
- [ ] Authorized Medical Physicist
- [ ] Radiation Safety Officer
- [ ] Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.390
for medical uses in Part 35, Section(s) 35.390

D. Address:
Tricat - Edison Facility
3640 Park Avenue
Edison, NJ 08820

E. Materials License Number: 29-30018-01

PART II – PRECEPTOR ATTESTATION

Note: *This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.490 or Part 35, Subpart J (except 35.980).*

I attest the individual named in Item 1:

11a.
- [ ] has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) _____ as documented in section(s) _____ of this form.

11b. Select one
- [ ] meets the requirements in [ ] 35.50(a) [ ] 35.51(c) [ ] 35.390(b)(1)(ii)(G) [ ] 35.690(c) for _____ types of use, as documented in section(s) _____ of this form.
- [ ] N/A

11c
- [ ] has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **or**
- [x] has achieved a level of competency sufficient to function independently as an authorized user of I-131 for Thyroid Cancer for 35.390 for I-131 Therapy uses (or units); **or**
- [ ] has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; **or**
- [ ] N/A

11d.
- [ ] I am an Authorized Nuclear Pharmacist, **or** [ ] I am a Radiation Safety Officer **or**
- [x] I meet the requirements of 35.500 section(s) of 10 CFR Part 35 or equivalent Agreement State requirements to be a preceptor [x] AU or [ ] AMP for the following byproduct material uses (or units): I-131 for Thyroid Cancer

A. Address:
Patrick Conte, M.D.
TRICAT
3640 Park Avenue
Edison, NJ 08820

B. Materials License Number: 29-30018-01

C. NAME OF PRECEPTOR (type or print)	D. SIGNATURE – PRECEPTOR	E. DATE
Patrick Conte, M.D.	Patrick Conte MD	12/17/07

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 3 PAGES
Amendment No. 21

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated February 23, 2007,
1. Barnert Hospital	3. License number 29-17895-01 is amended in its entirety to read as follows:
2. 680 Broadway Paterson, New Jersey 07514	4. Expiration date February 28, 2015
	5. Docket No. 030-19606 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Iodine 131 permitted by 10 CFR 35.300	C. Any	C. 100 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed Sources (Medi-Physics Inc. and Amersham Health Model 6711, Bard Brachytherapy, Inc. Model STM125, North American Scientific Model MED3631)	D. 600 millicuries

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
B. Any imaging and localization study permitted by 10 CFR 35.200.
C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300, for which the patient can be released under the provisions of 10 CFR 35.75.
D. Any manual brachytherapy procedure permitted by 10 CFR 35.400, for which the patient can be released under the provisions of 10 CFR 35.75.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION

PAGE 2 of 3 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-17895-01

Docket or Reference Number
030-13606

Amendment No. 21

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 680 Broadway, Paterson, New Jersey.

11. The Radiation Safety Officer for this license is Valery Kalika, M.D.

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
Joel S. Cooperman, M.D.	35.[illegible].200, Oral administration of sodium iodide-131 for imaging and localization studies and treatment of hyperthyroidism and thyroid dysfunction;
Michael A. Kessler, M.D.	35.100; 35.200
Orestes Sanchez, M.D.	35.200
Valery Kalika, M.D.	35.100; 35.200
Corey Weiner, M.D.	35.100; 35.200
Sam I. Brown, M.D.	35.400
George A. Dawson, M.D.	35.400

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."

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-17895-01

Docket or Reference Number
030-13606

Amendment No. 21

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes in the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application received October 08, 2004
B. Letter dated January 28, 2005 (page 10 &11)

For the U.S. Nuclear Regulatory Commission

Date April 18, 2007

By *Original signed by Shirley Xu*

Shirley Xu
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406
Wednesday, April 18, 2007 11:30:42 AM

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

1/25/2008, and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMCND. 29-30019-01 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** 141782.
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