

Fax Transmittal



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Westmoreland Regional Hospital
532 West Pittsburgh Street
Greensburg, PA 15601
724/832-4000

MS 16

L-2

37-02894-02

03009731

To: RANDOLPH RAGLAND Company: NRC Region I

From: Daniel A. BENKLEY, MSO Department: RAD Safety

Sender's Phone Number: 724 832 4267 Sender's Fax Number: 724 832 1834

Receiver's Fax: 610 337 5269 Pages Including Cover: 9

Date: 4/20/06 Re: Amendment On BASHYAN

Urgent For Review Please Comment Please Reply Please Recycle

Dear Mr. Ragland,

Enclosed you will find the document request. I reviewed it with Dr. Kowalyk and had him re-initial the Proceptor form. While this was going on I received word on ~~the~~ ^{BASHYAN} license was named on a NRC license. The license is enclosed for your review. I hope this helps the situation

Daniel Benkley, MSO
4/20/06



138596

NUMS/RGN MATERIALS-002



American Association of Clinical Endocrinologists

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Yank D. Cobin, Jr., MD, MACP, MACE
Jacksonville, FL

October 5, 2005

Mani Bashyam, MD
3007 Lexington Ct.
Export, PA 15632

Dear Dr. Bashyam:

The American Association of Clinical Endocrinologists (AACE) certifies that you successfully completed the following educational activity:

Program Title: AACE Nuclear Medicine Course

Date: September 24-October 1, 2005

Location: Kansas City, MO

Awarded: 80.25 category 1 credit(s) toward the AMA Physician's Recognition Award

The American Association of Clinical Endocrinologists (AACE) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The American Association of Clinical Endocrinologists designates this educational activity for a maximum of **80.25** category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Please feel free to contact the AACE office if you have any questions.

Sincerely,

AACE CME Department

NRC FORM 313A (10-2002)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3180-0128 EXPIRES: 10/31/2008
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT		

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 regulations.

AACE TRAINING

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

MANI BASHYAM

35:190
35:392
35:394

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

P.A

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified
INTERNAL MEDICINE BOARD	CERTIFIED	1995
ENDOCRINOLOGY BOARD	CERTIFIED	1997

Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.

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

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Kansas city, MO.	25	Sept 24 to OCT 1 st 2005
Radiation Protection))))	25))
Mathematics Pertaining to the Use and Measurement of Radioactivity))))	10))
Radiation Biology))))	10))
Chemistry of Byproduct Material for Medical Use))))	10))
OTHER			

NRC FORM 315A
(10-2002)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

5a. WORK EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
ORDERING, RECEIVING, UNPACKING SURVIVAL RADIOACTIVE PACKAGES	Dr. S. Kowalyk	WESTMORELAND Regional HOSP. 37-02894-02	JAN-DEC 2005 10 hours
Performing Q.C. procedures on survey meters and dose CALIBRATORS	"	WESTMORGLAND Reg. HOSP. 37-02894-02	"
Calculating, measuring, preparing Patient Doseages	"	"	"
Using Administrative Controls to prevent a medical event	"	"	"
Using Procedures to contain Patient Radioactive Spills and DECONTAMINATION	"	"	"

5b. SUPERVISED CLINICAL CASE EXPERIENCE

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
Na I ¹³¹	< 33 mCi	3	Dr. S. Kowalyk MD	WMH	3hr
Na I ¹³¹	> 33 mCi	3	Dr. S. Kowalyk MD	WMH	3hrs

NRC FORM 313A
(10-2002)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicians)

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)
-NA-			

7. RADIATION SAFETY OFFICER - ONE-YEAR FULL-TIME WORK EXPERIENCE

YES Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision of _____ the RSO for License No. _____

N/A

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

YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of _____ who meets requirements for Authorized Medical Physicists; and

N/A

YES Completed 1-year of full-time work experience (for areas identified in item 5a) for _____ who meets

N/A modality(ies) under the supervision of _____ requirements of Authorized Medical Physicists for _____ modality(ies).

9. 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 35, provide the following information for each):

A. Name of Supervisor

Dr. S. Kowalyk, MD

B. Supervisor is:

- Authorized User
- Radiation Safety Officer
- Authorized Medical Physicist
- Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 190 392 394

for medical uses in Part 35, Section(s) 35:100 35:392 35:394

D. Address

E. Materials License Number

37 02894-02

NRC FORM 313A
(10-2002)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II - PRECEPTOR STATEMENT

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 the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

YES 10. The individual named in item 1 has satisfactorily completed the training requirements in 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.
 N/A

YES 11a. The individual named in item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 100 392 394
 N/A

YES 11b. The individual named in item 1 is competent to independently function as an authorized USER for ORAL ADMINISTRATION of NaI-131 uses (or units). 131
 N/A
ORAL ADMINISTRATION of NaI

12. PRECEPTOR APPROVAL AND CERTIFICATION

I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

OR

I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;

OR

I certify the approval of items 11a and 11b, and I certify that I meet the requirements of 100 392 394 or equivalent Agreement State requirements to be a preceptor authorized _____ for the following uses (or units) of byproduct material: _____

A. Address
Stephan Kowalyk
Medical Commons 1 #G40
530 South St.
GREENSBURG, PA
15601

B. Materials License Number
37 02894 02

C. NAME OF PRECEPTOR (print clearly)
Dr. S. Kowalyk, MD

D. SIGNATURE - PRECEPTOR
[Signature]

E. DATE
10/15/5

SLL 4-2006

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U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 3 PAGES
 Amendment No. 32

MATERIALS LICENSE

724542 1834

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.

<p>Licensee</p> <p>1. Mercy Jeannette Hospital</p> <p>2. 600 Jefferson Avenue Jeannette, Pennsylvania 15644</p>	<p>In accordance with the letter dated December 16, 2005,</p> <p>3. License number 37-15471-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date February 28, 2014</p> <p>5. Docket No. 030-09165 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 35.400</p> <p>E. Any byproduct material permitted by 10 CFR 35.500</p> <p>F. Any byproduct material permitted by 10 CFR 31.11</p>	<p>7. Chemical and/or physical form of</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed Sources (Iodine-125- (C.R. Bard Co. Model Proseed)</p> <p>E. Sealed Sources (Isotope Products Laboratories Model NES8426)</p> <p>F. Prepackaged Kits</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 300 millicuries</p> <p>D. 2 curies</p> <p>E. 500 millicuries</p> <p>F. 200 microcuries</p>
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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.
 - D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.

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U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE
 SUPPLEMENTARY SHEET**

License Number 37-15471-01	
Docket or Reference Number 030-09165	
Amendment No. 32	

- E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- F. In vitro studies.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 600 Jefferson Avenue, Jeannette, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Edwin Miller.
- 12. Licensed material is only authorized for use by, or under the supervision of:

Authorized Users

Material and Use

Benedict P. Mariano, M.D.	35.100; 35.200; <u>in vitro</u> studies
Karunakar S. Shetty, M.D.	35.100; 35.200; <u>in vitro</u> studies
Srinivas Annamraju, M.D.	35.100; 35.200; 35.300; <u>in vitro</u> studies
Chandra R. Polam, M.D.	35.200
Yaser Kalash, M.D.	35.200
Ragoor K. Reddy, M.D.	35.200
Bassam Khanna, M.D.	35.200
Shyam Vijay Gohel, M.D.	35.100; 35.200; 35.300; 35.500; <u>in vitro</u> studies
Stephan Kowalyk, M.D.	Oral administration of sodium iodide Iodine-131
Jotinder K. Patheja, M.D.	35.400
Mani Bashyam, M.D.	Oral administration of sodium iodide Iodine-131

- 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 financial assurance for decommissioning.
- 14. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.
- 15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

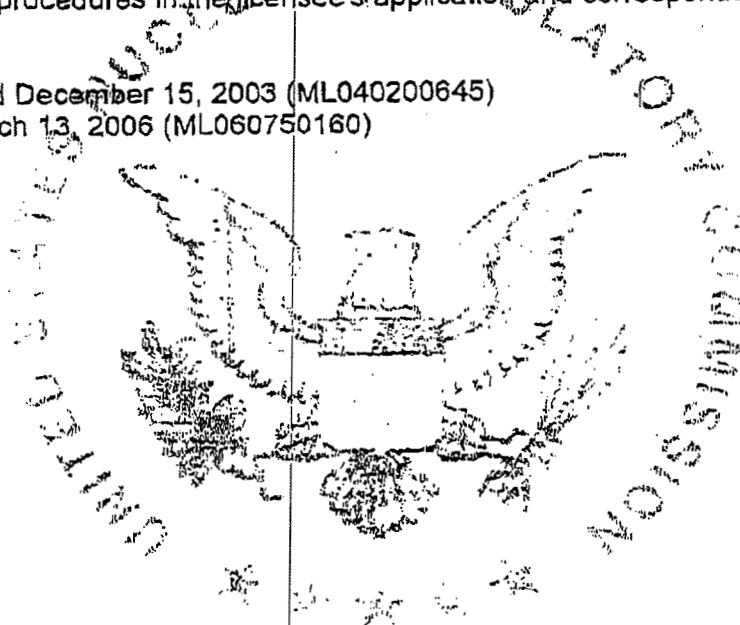
License Number
37-15471-01

Docket or Reference Number
030-09165

Amendment No. 32

16. 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 to 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 dated December 15, 2003 (ML040200645)
- B. Letter dated March 13, 2006 (ML060750160)



For the U.S. Nuclear Regulatory Commission

Date March 30, 2006

By Original signed by Tara L. Weidner

Tara L. Weidner
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406