Excela Health

NMSB1

March 10, 2006

U. S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

03012161

Re: License No. 37-17080-01 – **FRICK HOSPITAL**

To Whom It May Concern:

We wish to make the following changes to our license:

1. Delete Daniel O'Roark, M.D. from the list of authorized users.

2. Add Mani Bashyam, M.D. for Oral administration of sodium iodide-131. Attached is supporting documentation for Dr. Bashyam.

3. Add the following physicians as authorized users to our license. They are currently authorized users on another NRC license #37-02894-02 or #37-09463-01. The physicians and use are as follows:

User	Use
Juan Chahin, M.D.	35.200 for cardiovascular clinical procedures
James E. Adisey, M.D.	35.200 for cardiovascular clinical procedures
Chester David Graves, M.D.	35.100; 35.200; I-131 NaI for imaging and localization studies.
William J. Hoffman, M.D.	35.100; 35.200; 35.300; except thyroid carcinoma
Edward Szabo, M.D.	35.200
Kevin Kelly, M.D.	35.100; 35.200; Iodine-131 NaI for imaging and localization studies; in vitro studies

138594

Copies of licenses on which these physicians are authorized are attached.

If you have any questions, please contact our Radiation Safety Officer, Daniel A. Berkley, at 724-832-4267.

Sincerely,

Sam Raneri
Senior Vice President
Clinical Operations
Excela Health

SR/DB/pp

NRC FORM 313A (10-2002) U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2005

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 1st 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 313A (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

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
NaI^{131}	< 33 mCi	3	Dr. S. Kowaly KMD	WMH	3hr
NaI^{131}	> 33 mCi	3	Dr. S. Kowaly KMD	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

NA

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

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

NA

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

☐ YES ☐ N/A Completed 1-year of full-time work experience (for areas identified in item 5a) for _____ modality(ies) under the supervision of _____ who meets 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. Kowaly K MD

B. Supervisor is:

☒ Authorized User ☐ Authorized Medical Physicist
☐ Radiation Safety Officer ☐ 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

_____

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

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

☒ YES ☐ N/A 11b. The individual named in item 1. is competent to independently function as an authorized _____ for _____ uses (or units).

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	B. Materials License Number
	_____

C. NAME OF PRECEPTOR *(print clearly)*	D. SIGNATURE -- PRECEPTOR	E. DATE
Dr. S. Kowalyk, MD		10/15/5

American Association of Clinical Endocrinologists

1000 Riverside Avenue • Suite 205 • Jacksonville, FL 32204 • Ph: (904) 353-7878 • Fax: (904) 353-8185 • www.aace.com

Donald C. Jones
Jacksonville, FL
Chief Executive Officer

October 5, 2005

Mani Bashyam, MD
[redacted]

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 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 3 PAGES

Amendment No. 38

Duplicate ■ MATERIALS LICENSE ■ Duplicate

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 14, 2005,
1. Westmoreland Regional Hospital	3. License number 37-02894-02 is amended in its entirety to read as follows:
2. 532 West Pittsburgh Street Greensburg, Pennsylvania 15601	4. Expiration date July 31, 2011
	5. Docket No. 030-09731 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 in 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 1000 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources (AEA Technology QSA, Inc. Series 6500 [formerly 6D6C]; 3M Model 6711; 3M Model 6D1A)	D. 3000 millicuries
E. Any byproduct material permitted by in 10 CFR 35.500	E. Sealed sources (North American Scientific Model MED 3601)	E. 1.5 curies per source and 4.5 curies total
F. Depleted Uranium	F. Metal	F. 160 kilograms

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

Duplicate Duplicate ■ Duplicate

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-02894-02
Docket or Reference Number
030-09731

Amendment No. 38

F. Shielding in a linear accelerator.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 532 West Pittsburgh Street, Greensburg, Pennsylvania.

11. The Radiation Safety Officer for this license is Daniel A. Berkley.

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
Donald D. Haas, M.D.	35.100; 35.200; 35.300
Murray B. Gordon, M.D.	Oral administration of sodium iodide iodine-131
Stephan Kowalyk, M.D.	Oral administration of sodium iodide iodine-131
Joseph A. Kearney, M.D.	35.100; 35.200; 35.500
David G. Meyers, M.D.	35.100; 35.200; 35.500
Alan J. Thornburg, M.D.	35.100; 35.200; 35.500
John J. Duda, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 for imaging and localization studies and treatment of hyperthyroidism and cardiac dysfunction; 35.500
Juan Chahin, M.D.	35.200
Joseph M. Kettering, M.D.	35.100; 35.200
James E. Adisey, M.D.	35.200
Harry Katz, M.D.	35.400; Depleted Uranium
James E. Oskin, D.O.	35.100; 35.200; 35.300
David Buck, M.D.	35.100; 35.200

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-02894-02
Docket or Reference Number
030-09731
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Authorized Users	Material and Use
Matthew Banks, M.D.	35.100; 35.200
Margaret Clark, M.D.	35.100; 35.200
Paul DePippo, M.D.	35.100; 35.200
Sanjeev Bahri, M.D.	35.400
Robert S. Malyapa, M.D.	35.300; 35.400
Daniel O' Roark, 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), 40.36(b), and 70.25(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."

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 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 May 23, 2001 (ML011560463)

For the U.S. Nuclear Regulatory Commission

Date May 13, 2005

By ***Original signed by Tara L. Weidner***

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

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 56

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 application dated January 28, 2005,
1. Latrobe Area Hospital	3. License number 37-09463-01 is amended in its entirety to read as follows:
2. 121 W. 2nd Avenue Latrobe, Pennsylvania 15650-1096	4. Expiration date July 31, 2015
	5. Docket No. 03003115 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. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 425 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed Sources (North American Scientific Model MED 3631, Mills Biopharmaceuticals Inc. Models 125SL and 125SH, Medi-Physics Inc. Model 6711, International Brachytherapy, SA Model 1251L, Draximage Inc. Model LS-1, Best Medical International Model 2301)	D. 1 curie
E. Any byproduct material permitted by 10 CFR 31.11	E. Prepackaged Kits	E. 10 millicuries
F. Iridium-192 permitted by 10 CFR 35.600	F. Sealed Sources (Nucletron Model 105.002 [manufactured by Mallinckrodt Medical B.V. or AEA Technology])	F. 2 sources, 1 source not to exceed 12 curies and 1 source not to exceed 10 curies

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-09463-01

Docket or Reference Number
03003115

Amendment No. 56

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.
E. In vitro studies.
F. One source for medical use permitted by 10 CFR 35.600, in a Nucletron Corporation microSelectron HDR Model 105.999 remote afterloader unit. The source activity may not exceed 10 curies at the time of use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

CONDITIONS

10. A. Licensed material may be used or stored at the licensee's facilities located at 121 W. 2nd Avenue, Latrobe, Pennsylvania.

B. Licensed material authorized by 10 CFR 35.65 may be used or stored at the licensee's facilities located at Mt. View Diagnostic Testing & Imaging Center, 2000 Village Drive, Greensburg, Pennsylvania.

11. The Radiation Safety Officer for this license is Andrew G. Bukovitz.

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

A. Individuals permitted to work as an authorized user and/or authorized medical physicist 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
Yoshio Arai, M.D.	Iridium-192 for uses in a high dose rate remote afterloader unit
Sanjeev Bahri, M.D.	35.400; Iridium-192 for uses in a high dose rate remote afterloader unit
Chester David Graves, M.D.	35.100; 35.200; Iodine-131 sodium iodide for imaging and localization studies
William J. Hoffman, M.D.	35.100; 35.200; 35.300 except thyroid carcinoma

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-09463-01

Docket or Reference Number
03003115

Amendment No. 56

Authorized Users	Material and Use
Anwarullah Khan, M.D.	35.200
Thomas D. McClure, M.D.	35.100; 35.200; 35.300 except thyroid carcinoma
Edward Szabo, M.D.	35.200
Michael J. Miller, M.D.	35.100; 35.200; Iodine-131 sodium iodide for imaging and localization studies; in vitro studies
Kevin J. Kelly, M.D.	35.100; 35.200; Iodine-131 sodium iodide for imaging and localization studies; in vitro studies
Dwight Heron, M.D.	35.400; Iridium-192 for uses in a high dose rate remote afterloader unit
Elmer Cano, M.D.	Iridium-192 for uses in a high dose rate remote afterloader unit
Melvin Deutsch, M.D.	Iridium-192 for uses in a high dose rate remote afterloader unit
Alexander Chen, M.D.	35.400; Iridium-192 for uses in a high dose rate remote afterloader unit
Robert S. Malayapa, M.D., Ph.D.	35.400; Iridium-192 for uses in a high dose rate remote afterloader unit

C. The following individuals are authorized medical physicists as indicated:

Authorized Medical Physicists	Material and Use
Andrew Bukovitz	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training
Robert Surgent	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training
Bruce Libby	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training
Ronald Lalonde	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-09463-01

Docket or Reference Number
03003115

Amendment No. 56

Authorized Medical Physicists	Material and Use
Jingdong Li	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training
Selvaraj Nagappan	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training
Mubina Quader	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training
Lee Tao	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training
Xuan G. Chen, Ph.D.	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training
Satya R. Bose	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training
Edward D. Brandner, Ph.D.	Iridium-192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training

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."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-09463-01

Docket or Reference Number
03003115

Amendment No. 56

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 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 January 28, 2005 (ML050390342)
B. Letter dated April 5, 2005 (ML051440083)
C. Letter dated June 24, 2005 (ML051800543)

For the U.S. Nuclear Regulatory Commission

Date July 7, 2005

By Sandra Gabriel

Sandra Gabriel
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

732133

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

3/10/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMEND. 37-17080-01
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** 138594.
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