

INDIANA

REGIONAL MEDICAL CENTER

October 4, 2006

Br. 1

2006 OCT 16 PM 2:14

RECEIVED
REGION 1

Nuclear Regulatory Commission; Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: License # 37-13666-01 03003197
1) Add Authorization for 10 CFR 35.300 procedures for Dr. Ali Tunio.
2) Decrease possession limits for 192-Ir.

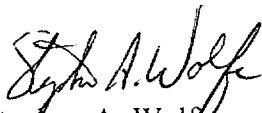
To Whom It May Concern:

Please amend our radioactive materials license to add authorization for 10 CFR 35.300 procedures for Dr. Ali Tunio. Dr. Tunio is ABR certified in Therapy. Dr. Tunio is currently listed as an authorized user of 10 CFR 35.400 materials on our materials license. Also find enclosed training Form 313A documenting Dr. Tunio's training and experience.

Please also decrease our possession limits for Iridium 192 (identified as section 6E on our license) to "2 sources, 1 source not to exceed 14 curies and 1 source not to exceed 7 curies." We feel this is a more accurate reflection of our possession limits for this material.

Thank you for your attention to this matter.

Sincerely,



Stephen A. Wolfe,
President & CEO

139590
NMSS/RGNI MATERIALS-C02

Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
 B. AMENDMENT TO LICENSE NUMBER 37-13666-01
 C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Indiana Regional Medical Center
835 Hospital Road
P.O. Box 788
Indiana, PA 15701-0788

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Keith Ostrom, Consultant, Assoc. in Medical Physics, LLC

TELEPHONE NUMBER

(216) 663-7000

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY | AMOUNT ENCLOSED \$

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Stephen A. Wolfe, President & CEO, IRMC

SIGNATURE

Stephen A. Wolfe

DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

The American Board of Radiology

Diagnostic Radiology Radiation Oncology Radiologic Physics

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Officers

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Milwaukee, Wisconsin
Steven A. Leibel, M.D., *Vice President*
New York, New York
Philip O. Alderson, M.D., *Secretary-Treasurer*
New York, New York



October 15, 2002

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Richmond, Virginia
Lawrence W. Davis, M.D., *Radiation Oncology*
Atlanta, Georgia
Bhudat R. Paliwal, Ph.D., *Radiologic Physics*
Madison, Wisconsin

Ali Murad Tunio, MB,BS
140 75th Street, Apt. E4
Brooklyn, NY 11209

Diagnostic Radiology

Philip O. Alderson, M.D.
New York, New York
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Miami, Florida
George S. Bisset, M.D.
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New Orleans, Louisiana
Kay H. Vydareny, M.D.
Atlanta, Georgia
James E. Youker, M.D.
Milwaukee, Wisconsin

50827 / TR

Dear Dr. Tunio:

The results of your Radiation Oncology examination are as follows:

Clinical	Passed
Physics	Passed
Biology	Passed

I am pleased to inform you that you are now admissible to the 2003 oral examination. Your notification for that examination will be sent to you five months prior to the exam. The oral examination fee will be due upon notification.

Radiation Oncology

Jay R. Harris, M.D.
Boston, Massachusetts
Richard T. Hoppe, M.D.
Stanford, California
David H. Hussey, M.D.
San Antonio, Texas
Larry E. Kun, M.D.
Memphis, Tennessee
Steven A. Leibel, M.D.
New York, New York
H. Rodney Withers, M.D.
Los Angeles, California

Please notify us in writing immediately of any change of address.

Sincerely,

Robert R. Hattery, MD

Radiologic Physics

William R. Hendee, Ph.D.
Milwaukee, Wisconsin
Bhudat R. Paliwal, Ph.D.
Madison, Wisconsin
Stephen R. Thomas, Ph.D.
Cincinnati, Ohio

5441 E. WILLIAMS BOULEVARD, SUITE 200 • TUCSON, ARIZONA 85711-4493 • PHONE (520) 790-2900 • FAX (520) 790-3200
E-mail: info@theabr.org • Web Site: www.theabr.org

Commonwealth of Pennsylvania



Department of State Bureau of Professional and Occupational Affairs

The State Board of Medicine hereby certifies that

ALI MURAD TUNIO


*having complied with the licensure laws
of the Commonwealth of Pennsylvania is authorized to practice as a/an*

MEDICAL PHYSICIAN AND SURGEON

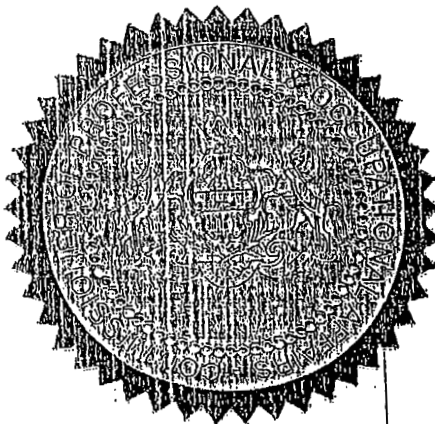
*In Witness Whereof, we have hereunto set our hand and caused the Seal of the Bureau of
Professional and Occupational Affairs.*

Certification Date: 04/28/2003

License Number: MD420855


Chairperson


Deputy Commissioner



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.

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

Ali Murad Tunio, MD Authorized User, 10 CFR 35.400 and 10 CFR 35.600

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

Pennsylvania Medical License PA MD 420855

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified
Board Eligible American Board of Radiology	Radiation Oncology	4

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	SUNY Downstate Department of Radiation Oncology 450 Clarkson Avenue Brooklyn, NY 11203	200	February 1999 to January 2003
Radiation Protection	SUNY Downstate Department of Radiation Oncology 450 Clarkson Avenue Brooklyn, NY 11203	200	February 1999 to January 2003
Mathematics Pertaining to the Use and Measurement of Radioactivity	SUNY Downstate Department of Radiation Oncology 450 Clarkson Avenue Brooklyn, NY 11203	200	February 1999 to January 2003
Radiation Biology	SUNY Downstate Department of Radiation Oncology 450 Clarkson Avenue Brooklyn, NY 11203	200	February 1999 to January 2003
Chemistry of Byproduct Material for Medical Use			
OTHER			

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
Ordering, receiving, and unpacking radioactive material safely and performing the related radiation surveys	Roger Mackles M.D.	See attached license.	Aug. 18, 2006 Aug. 30, 2006 Sept. 19, 2006
Calibrating instruments used to determine the activity of dosages and performing checks to proper operation of survey meters	Roger Mackles M.D.	See attached license.	Aug. 18, 2006 Aug. 30, 2006 Sept. 19, 2006
Calculating, measuring, and safely preparing patient or human research subject dosages.	Roger Mackles M.D.	See attached license.	Aug. 18, 2006 Aug. 30, 2006 Sept. 19, 2006
Using administrative controls to prevent a medical event involving the use of unsealed byproduct materials.	Roger Mackles M.D.	See attached license.	Aug. 18, 2006 Aug. 30, 2006 Sept. 19, 2006
Using procedures to safely contain spilled radiation materials and using proper documentation procedures.	Roger Mackles M.D.	See attached license.	Aug. 18, 2006 Aug. 30, 2006 Sept. 19, 2006
Administering dosages of radioactive drugs to patients or human research subjects.	Roger Mackles M.D.	See attached license.	Aug. 18, 2006 Aug. 30, 2006 Sept. 19, 2006

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
Zevalin - Y90	Therapeutic	1	Roger Mackles M.D.	See attached ^{Letter} license	8-15-06
Bexxar - I 131	Therapeutic	1	Roger Mackles M.D.	See attached ^{Letter} license	8-30-06
Zevalin - Y90	Therapeutic	1	Roger Mackles M.D.	See attached ^{Letter} license	9-19-06

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

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

- YES 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 _____
- N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

- YES 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) _____
- N/A under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

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

Roger Mackles 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) 390 (A-G)

for medical uses in Part 35, Section(s) 390

D. Address

Cleveland Clinic Foundation
Cleveland, Ohio

E. Materials License Number

See attached

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) 390 (A-G), as documented in section(s) 6 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 _____

N/A

types of use, as documented in section(s) _____ of this form.

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 _____ for 10CFR 35.390 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 390 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): 10CFR 35.390

A. Address

B. Materials License Number

Medical License # BM1231476

See attached

Roger M. Mackles

C. NAME OF PRECEPTOR (print clearly)

Roger Mackles M.D.

D. SIGNATURE – PRECEPTOR

[Handwritten Signature]

E. DATE

09/19/2006

THE CLEVELAND CLINIC
FOUNDATION 

September 20, 2006

Stuart W. Kline
Director
Environmental Health
and Safety / W18
Office: 216/444-6705
Fax: 216/444-4849
E-mail: klines@ccf.org

RE: Roger Macklis, MD

To Whom It May Concern:

Roger Macklis, MD, is an Authorized User Physician at the Cleveland Clinic.

Dr. Macklis is approved for the following:

- 35.200 Imaging and localization studies
- 35.300 Radio pharmaceuticals for therapy
- 35.400 Sources for manual brachytherapy
- 35.600 Sealed sources in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit

Approval date: 1993

If you need additional information, I would be glad to provide it.

Sincerely,



Stuart Kline
Radiation Safety Officer

Ohio Radioactive Material License No. 02110180013 (Broad Scope Medical)

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

10/4/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 37-13666-01 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** 139580.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.