

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: St. Lukes Regional Medical Center

License No.: 11-27312-01

Docket No.: 030-32196

Mail Control No.: 471163

Type of Action: Amend

Date of Requested Action: 10-13-06

Reviewer Assigned:

ARM reviewer(s): Torres

RITC

Response	Deficiencies Noted During Acceptance Review
	<ul style="list-style-type: none"> [] Open ended possession limits. Limit possession. Submit inventory. [] Submit copies of most recent leak test results. [] Add - delete IC license condition. Add IC paragraph in cover letter. [] Split license from cover letter. Add SUNSI marking to license. [] Ask the licensee if they have any type-amount of EPAct Material.

Reviewer's Initials: _____ **Date:** _____

- Yes No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
- Yes No Decommissioning notification should be completed within 30 days.
- Yes No Termination request < 90 days from date of expiration
- Yes No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
- Yes No TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: _____ **Date:** _____

SUNSI Screening according to RIS 2005-31

Yes No **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

- _____ RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- _____ Exact location of RAM (whether = or > than Category 3 or not)
- _____ Design of structure and/or equipment (site specific)
- _____ Information on nearby facilities
- _____ Detailed design drawings and/or performance information
- _____ Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- _____ RAM quantities and inventory
- _____ Manufacturer's name and model number of sealed sources & devices
- _____ Site drawings with exact location of RAM, description of facility
- _____ RAM security program information (locks, alarms, etc.)
- _____ Emergency Plan specifics (routes to/from RAM, response to security events)
- _____ Vulnerability/security assessment/accident-safety analysis/risk assess
- _____ Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: RITC **Date:** 10/30/06

Pre-Licensing Screening

Applicant Information:

Control No. 471163

Name: St. Lukes Regional Medical Center	Type of Request: Amend Program Code(s):
Location: ID	License No.: 11-27312-01 Docket No.: 030-32196

STEP 1—Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.	Yes or No
A. The request is from a new applicant.	No
B. NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	No
C. The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer	No

Table of Risk Significant Quantities

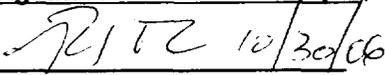
(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)	Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 ²	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

¹ The primary values are TBq. The curie (Ci) values are for informational purposes only.
² The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	Yes, No, or Not Applicable (NA)
Total Activity—multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	—
Unity Rule—multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g., [(total activity for radionuclide A) + (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) + (risk significant quantity for radionuclide B)] ≥ 1.0.	—

Signature and Date for Step 1:

 10/30/06
 License Reviewer and Date



RECEIVED

OCT 20 2006

DNMS

October 13, 2006

RTC

US Nuclear Regulatory Commission Region IV
Nuclear Materials Licensing Branch
611 Ryan Plaza Drive
Suite 400
Arlington, Texas 76011-8064

RE: Amendment of License #11-27312-01

Dear Sir or Madam:

We wish to add Tonya Kuhn, M.D., as an authorized user of materials specified in 10 CFR 35.300, 35.400 and 35.600. She meets the criteria specified in 10 CFR 35.390(a), 35.490(a) and 35.690(a). A copy of her certification by the American Board of Radiology is attached, along with NRC Form 313A from her training institution at Yale University.

For further information, please contact me at (208) 706-1412 or (208) 381-3192.

Sincerely,

Jefferson Fairbanks, PhD
Radiation Safety Officer

100 E. Idaho Street
Boise, ID 83712
(208) 381-2711
(800) 845-4624 • (208) 381-2974 (fax)

1118 NW 16th Street, Suite D
Fruitland, ID 83619
(208) 452-7677
(800) 473-9618 • (208) 452-7681 (fax)

520 S. Eagle Road
Meridian, ID 83642
(208) 706-5651
(800) 473-0331 • (208) 706-5344 (fax)

308 East Hawaii Avenue
Nampa, ID 83686
(208) 467-6700
(800) 553-6415 • (208) 463-6001 (fax)

656 Addison Avenue W
Twin Falls, ID 83301
(208) 737-2441
(800) 947-4852 • (208) 737-2864 (fax)

Thomas M. Beck, MD
Medical Director

Suanne Thurman
Administrator

Theodore A. Walters, MD
Research Director MSTI/MSMRI

Medical Hematology/Oncology

- Thomas M. Beck, MD
- Norman Zuckerman, MD
- Paul G. Montgomery, MD
- William H. Kreisle, MD
- Mary E. Gearn, MD
- Larry Fiorentino, MD
- Theodore A. Walters, MD
- Richard Cambareri, MD
- Jonathan N. Swerloff, MD
- Kathleen Clifford, FNP
- Cheryl Mills, FNP
- Kerri Dunn, FNP

Pediatric Hematology/Oncology

- Eugenia Chang, MD
- J. Martin Johnston, MD
- Pat Kubicki, PNP

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- Charles E. Smith, MD
- Richard C. Ripple, MD
- Ronald V. Dorn, III, MD
- Sarah L. Bolender, MD
- Eugene A. Seville, MD
- Barbara G. Andersen, MD
- Stephen C. Smith, MD
- Colleen Lambertz, FNP
- Kim A. Ladue-Weber, FNP

Surgery

- John A. Lung, MD

- Radiation Oncology
- Medical Hematology/Oncology
- Blood and Marrow Transplantation
- Clinical Research
- Psychosocial Support
- Wound, Ostomy, Continence Nursing
- Surgery
- Stereotactic Radiosurgery
- High Dose Rate Brachytherapy
- Inpatient Oncology Services
- Pediatric Oncology/Hematology
- Hospice
- Nutritional Counseling
- Patient Guest Housing
- Breast Cancer Detection Centers
- Marrow Donor Center
- Hemophilia
- Bone Marrow Transplant

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
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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)
Tonya Kuhn, M.D., authorized user request for radiation oncology

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

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	<i>Yale University Dept. Therapeutic Radiology</i>	<i>60</i>	<i>7/1/02 - 9/15/06</i>
Radiation Protection	<i>"</i>	<i>20</i>	<i>"</i>
Mathematics Pertaining to the Use and Measurement of Radioactivity	<i>"</i>	<i>20</i>	<i>"</i>
Radiation Biology	<i>"</i>	<i>80</i>	<i>"</i>
Chemistry of Byproduct Material for Medical Use	<i>"</i>	<i>1</i>	<i>"</i>
OTHER	<i>"</i>	<i>29</i>	<i>"</i>

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
Ir-192, C-137 gynecologic brachytherapy	Drs. Higgins, Mani, Roberts, Weidhass	Yale-New Haven Hospital	7/1/02 - 9/15/06
Pd-103 Prostate brachytherapy	Drs. Peschel, Moran	"	"
Head & neck interstitial brachytherapy	Dr. Son	"	"
I-125 eye plaque	Dr. Hafferty	"	"
Other intracavitary Ir-192 (bronchus, nasopharynx)	Dr. Son	"	"

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
Ir-192	Gyn high dose rate Gyn low " "	26	Drs Higgins, Mani, Roberts, Weidhass	YNHH	720
Cs-137	Gyn-low dose rate	13	"	"	108
Pd-103	Interstitial head & neck low prostate interstitial	9	Dr. Son Drs. Peschel, Moran	"	66
I-125	Eye plaque	1	Dr. Hafferty	"	8
Ir-192	Endoluminal trachea nasopharynx	1	Dr. Son	"	8

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
Instruction in using Gamma Med plus high dose rate.	Didactic from physics Dept.	Yale University June 2005

* 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)
MD - Yale 2001 Resident, Therapeutic Radiology 7/1/02 - 9/15/06	Yale - New Haven Hospital	7/1/02 - 9/15/06	ACGME 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) _____

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 Lynn D. Wilson, MD B. Supervisor is:
 Authorized User Authorized Medical Physicist
 Radiation Safety Officer Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 490, 690
 for medical uses in Part 35, Section(s) 400, 600

D. Address Dept. Therapeutic Radiology
Yale University
333 Cedar St, HRT 132
New Haven, CT 06520-8040 E. Materials License Number _____

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) 490, 690, as documented in section(s) 5-7 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 400, 600 types of use, as documented in section(s) 5-7 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 for brachytherapy 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 490, 690 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): brachytherapy

A. Address Dept. Therapeutic Radiology
Yale University
333 Cedar St, HRT 132
New Haven, CT 06520-8040 B. Materials License Number _____

C. NAME OF PRECEPTOR (print clearly) Lynn D. Wilson D. SIGNATURE - PRECEPTOR [Signature] E. DATE 9/28/06

The American Board of Radiology

Diagnostic Radiology

Radiation Oncology

Radiologic Physics



Officers

Steven A. Leibel, M.D., *President*

Philip O. Alderson, M.D., *President-Elect*

Richard T. Hoppe, M.D., *Secretary-Treasurer*

August 15, 2005

Diagnostic Radiology

Philip O. Alderson, M.D.
New York, New York

Dennis M. Balle, M.D.
St. Louis, Missouri

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Bethesda, Maryland

George S. Bisset, M.D.
Durham, North Carolina

James P. Borgstede, M.D.
Colorado Springs, Colorado

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Ann Arbor, Michigan

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Cincinnati, Ohio

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Houston, Texas

Christopher Merritt, M.D.
Philadelphia, Pennsylvania

Anthony V. Proto, M.D.
Richmond, Virginia

Anne Roberts, M.D.
La Jolla, California

Janet L. Srinfe, M.D.
Cincinnati, Ohio

Kay H. Vydatreny, M.D.
Atlanta, Georgia

Radiation Oncology

K. Kian Ang, M.D., Ph.D.
Houston, Texas

Bruce G. Haffty, M.D.
New Brunswick, New Jersey

Beth A. Erickson, M.D.
Milwaukee, Wisconsin

Richard T. Hoppe, M.D.
Palo Alto, California

Larry E. Kun, M.D.
Memphis, Tennessee

Steven A. Leibel, M.D.
Stanford, California

Radiologic Physics

Richard L. Munn, Ph.D.
Jacksonville, Florida

Bhudatt R. Paliwal, Ph.D.
Madison, Wisconsin

Stephen R. Thomas, Ph.D.
Cincinnati, Ohio

Tonya Lee Kuhn, MD

54895 / TR

Dear Dr. Kuhn:

The results of your Radiation Oncology examination are as follows:

Physics

Passed

Biology

Passed

You must still take the Clinical portion of the examination. The next scheduled examination will be given in the summer of 2006. Your form for this examination will be sent to you approximately five months prior to the exam.

All portions of the examination must be passed and training requirements met prior to being admissible for the oral examination.

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

Sincerely,

Robert R. Hattery, MD

Robert R. Hattery, M.D., Executive Director
Lawrence W. Davis, M.D., Associate Executive Director

Assistant Executive Directors

Primary Certification

Anthony V. Proto, M.D., *Diagnostic Radiology*

Beth A. Erickson, M.D., *Radiation Oncology*

Bhudatt R. Paliwal, Ph.D., *Radiologic Physics*

Assistant Executive Directors

Maintenance of Certification

John E. Madewell, M.D., *Diagnostic Radiology*

Larry E. Kun, M.D., *Radiation Oncology*

Stephen R. Thomas, Ph.D., *Radiologic Physics*

Gary J. Becker, M.D., *Subspecialty Certification*

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

The American Board of Radiology

Diagnostic Radiology

Radiation Oncology

Radiologic Physics



Officers

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Phillip O. Alderson, M.D., *President-Elect*

Richard T. Hoppe, M.D., *Secretary-Treasurer*

August 09, 2006

Diagnostic Radiology

Philip O. Alderson, M.D.
New York, New York

Dennis M. Balfe, M.D.
St. Louis, Missouri

Gary J. Becker, M.D.
Bethesda, Maryland

George S. Bisset, M.D.
Durham, North Carolina

James P. Borgstede, M.D.
Colorado Springs, Colorado

N. Reed Dunnick, M.D.
Ann Arbor, Michigan

Glenn S. Forbes, M.D.
Rochester, Minnesota

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Indianapolis, Indiana

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Cincinnati, Ohio

John E. Madewell, M.D.
Houston, Texas

Christopher Merritt, M.D.
Philadelphia, Pennsylvania

Anthony V. Proto, M.D.
Richmond, Virginia

Anne Roberts, M.D.
La Jolla, California

Janet L. Strife, M.D.
Cincinnati, Ohio

Kay H. Vydeny, M.D.
Atlanta, Georgia

Tonya Lee Kuhn, MD

54895 / RO

Dear Dr. Kuhn:

Congratulations, the results of your Radiation Oncology examination are as follows:

Clinical

Passed

I am pleased to inform you that you may take the 2007 oral examination. Notification for that examination will be sent to you five months prior to the exam. The oral examination fee will be due upon notification.

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

Sincerely,

Robert R. Hattery, MD

Radiation Oncology

K. Kian Ang, M.D., Ph.D.
Houston, Texas

Bruce G. Haffty, M.D.
New Brunswick, New Jersey

Beth A. Erickson, M.D.
Milwaukee, Wisconsin

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Stanford, California

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Assistant Executive Directors

Primary Certification

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Assistant Executive Directors

Maintenance of Certification

John E. Madewell, M.D., *Diagnostic Radiology*

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Gary J. Becker, M.D., *Subspecialty Certification*

5441 E. WILLIAMS BOULEVARD, SUITE 200 • TUCSON, ARIZONA 85711-4493 • PHONE (520) 790-2900 • FAX (520) 790-3200

E-mail: information@theabr.org • Web Site: www.theabr.org

Vale-New Haven Hospital

affiliated with

Vale University School of Medicine

hereby certifies that

Tonya Lee Kuhn, M.D.

has satisfactorily completed all requirements for training
in the specialty of

Therapeutic Radiology

From: July 1, 2002

Through: July 31, 2002

From: January 21, 2003

Through: September 15, 2006

Presented at New Haven, Connecticut this 30th day of June, 2006

PRESIDENT

CHIEF OF DEPARTMENT



YALE-NEW HAVEN
HOSPITAL

CHIEF OF STAFF

PROGRAM DIRECTOR

The American Board of Radiology

Diagnostic Radiology

Radiation Oncology

Radiologic Physics



Officers

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Colorado Springs, Colorado

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Anthony V. Proto, M.D.
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Vanne Roberts, M.D.
La Jolla, California

Janet L. Strife, M.D.
Cincinnati, Ohio

Jay H. Vydareny, M.D.
Atlanta, Georgia

Radiation Oncology

John Kian Ang, M.D., Ph.D.
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Thomas G. Haffty, M.D.
New Brunswick, New Jersey

John A. Erickson, M.D.
Milwaukee, Wisconsin

Richard T. Hoppe, M.D.
Palo Alto, California

Larry E. Kun, M.D.
Memphis, Tennessee

Steven A. Leibel, M.D.
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Radiologic Physics

Richard L. Morin, Ph.D.
Jacksonville, Florida

Madan R. Paliwal, Ph.D.
Madison, Wisconsin

Stephen R. Thomas, Ph.D.
Cincinnati, Ohio

TO: Radiation Oncology Program Directors

FROM: Steven A. Leibel, M.D., President
The American Board of Radiology

RE: Residency Training in Unsealed Radionuclide Therapy Administration

DATE: August 11, 2005

Dear Colleagues:

Several years ago, the Nuclear Regulatory Commission (NRC) proposed changes in the rules that govern training and experience required to use the types of radioactive materials commonly employed in radiation oncology and nuclear medicine for the treatment of several different malignancies. Controversies surrounding the proposed regulations delayed implementation, but a revised final version was published March 30, 2005, in the Federal Register:

(<http://www.nrc.gov/reading-rm/doc-collections/cfr/effect/2005/03302005fm.html>).

In the past, the NRC has accepted ABR certification as evidence that a practitioner is properly trained to safely and effectively use therapeutic radioactive materials. The ABR wishes to retain as much of this status as possible under the new regulations, and accordingly, is requiring that the resident training and experience and the materials on which the ABR examines match the final new NRC regulations. The ABR also will attempt to maintain consistency with the requirements of the Radiation Oncology RRC.

1. Beginning with the oral examination of June 2007 (residents completing training in 2006 and taking the oral exam in 2007), the ABR will only admit for examination candidates who have had classroom and laboratory instruction incorporating all topics specified in sections 35.394 (oral administration of I-131 in quantities > 33 mCi) and 35.396 (parenteral administration of unsealed beta or photon emitting by-product material with a photon energy of < 150 KeV) of the new NRC regulations, along with the NRC-mandated work experience under an appropriately qualified, authorized user. This instruction can take place as part of the RRC-required courses in radiation physics, radiation and cancer biology and clinical radiation oncology or a rotation in nuclear medicine.
2. This total training and work experience should include all NRC-required items related to the safe handling, administration and quality control of the radionuclide doses used in clinical radiation oncology and nuclear medicine. The Federal Register provides a comprehensive list of these items, which is posted on the NCR website (<http://www.nrc.gov/reading-rm/doc-collections/cfr/effect/2005/03302005fm.html>). ABR testing will cover selections from subjects such as safe elution and quality control (QC) of radionuclide generator systems, calibration and QC of survey meters and dose calibrators, safe handling and administration of therapeutic doses of unsealed radionuclide sources, written directives, responses to radiation spills and accidents, radiation signage, and related materials. Such items may be included on both the written and oral examinations.

Robert R. Hattery, M.D., *Executive Director*

Lawrence W. Davis, M.D., *Associate Executive Director*

Assistant Executive Directors Primary Certification

Anthony V. Proto, M.D., *Diagnostic Radiology*
Beth A. Erickson, M.D., *Radiation Oncology*
Bhudatt R. Paliwal, Ph.D., *Radiologic Physics*

Assistant Executive Directors Maintenance of Certification

John E. Madewell, M.D., *Diagnostic Radiology*
Larry E. Kun, M.D., *Radiation Oncology*
Stephen R. Thomas, Ph.D., *Radiologic Physics*
Gary J. Becker, M.D., *Subspecialty Certification*

In order to comply with NRC regulations and expected new RRC guidelines related to oral high-dose I-131 therapy and parenteral therapy with unsealed sources, a resident will have to participate with preceptors in three cases involving oral administration of > 33 mCi of I-131 and three cases involving parenteral administration of unsealed beta- or photon-emitting by-product material with a photon energy of < 150 KeV. The specific dates on which experiences with oral I-131 and parenteral therapy occur and a case description should be kept in a log by each resident in a format similar to the following:

<u>Tonya Kuhn</u>		<u>Yale</u>		
Resident Name		Program		
Date	Disorder	Dose Administered	Preceptor Name/Signature	
1. 8/31/05	Papillary Thyroid Ca	300mCi I-131	David Chang	
2. 8/31/05	Hurthle Cell Ca	200mCi I-131	David Chang	
3. 10/9/05	Papillary Thyroid Ca	200mCi I-131	David Chang	
4. 3/15/05	Esophageal Ca - liver met	30 M.Ci 490 Microspheres	Susan King	
5. 5/4/06	Prostate Ca met	82mCi Samarium	Dr Frank Cardinale	
6. 5/24/06	Metastatic breast	75mCi Samarium	Helaine Bertsch	

Because of HIPAA concerns, data that might identify a patient should not be included in the log. This log is to be submitted by the program director along with the other materials that attest to the resident's oral exam eligibility.

To license an individual as an authorized user of radionuclides, the NRC will require that another authorized user/preceptor – typically this would be an appropriately trained radiation oncologist or nuclear medicine physician – submit a preceptor form to attest to the candidate's satisfactory completion of the NRC requirements and attainment of competency sufficient to function as an authorized user. The attestation of the residency program director will not be accepted by the NRC unless that program director is also an appropriately qualified, authorized user and the program director completes the NRC preceptor form. For admittance to the ABR exam, however, residency program director attestation on an ABR form will suffice.

The ABR recommends that all residency programs reevaluate their training in the use of these agents and add the content elements outlined in this communication and in the NRC Final Regulations page on the ABR website. In this way, residents will be prepared and qualified to take the ABR oral exam.

OCT 31 2006

DATE

This is to acknowledge the receipt of your letter/application dated 10-13-06, and to inform you that the initial processing, which includes an administrative review, has been performed.

There were no administrative omissions. Your application will be 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:

The action you requested is normally processed within 90 days.

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** 471163.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,



Licensing Assistant

(FOR LEMS USE)

INFORMATION FROM LTR

Program Code: 02230
Status Code: 0
Fee Category: 7C 3E EX 2B
Exp. Date: 20140930
Fee Comments: REF IDA-13-2
Decom Fin Assur Reqd: N

BETWEEN:
License Fee Management Branch, ARM
and
Regional Licensing Sections

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
Applicant/Licensee: ST. LUKES REGIONAL MEDICAL CENTER
Received Date: 20061020
Docket No: 3032196
Control No.: 471163
License No.: 11-27312-01
Action Type: Amendment

2. FEE ATTACHED
Amount: _____
Check No.: _____

3. COMMENTS
Signed _____
Date 10/25/06

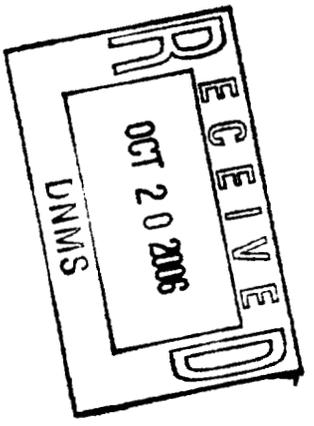
B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / __/)

- 1. Fee Category and Amount: _____
- 2. Correct Fee Paid. Application may be processed for:
Amendment _____
Renewal _____
License _____
- 3. OTHER _____

Signed _____
Date _____

St Lukes
Mountain States
Tumor Institute

100 E. Idaho Street
Boise, Idaho 83712-6223
Jefferson Fairbanks
Address Service Requested



US Nuclear Regulatory Commission Region IV
Nuclear Materials Licensing Branch
611 Ryan Plaza Drive
Suite 400
Arlington, Texas 76011-8064

11-27312-01
030-32196 ✓

MAGDHP 76011