



DEPARTMENT OF THE ARMY
HEADQUARTERS, US ARMY MEDICAL DEPARTMENT ACTIVITY
1650 COCHRANE CIRCLE
FORT CARSON, CO 80913-4604



REPLY TO
ATTENTION OF

MCXE-PMD-RSO

3 February 2014

MEMORANDUM FOR U. S. Nuclear Regulatory Commission, Region IV, 1600 East
Lamar BLVD, Suite 400, Arlington, Texas 76011-4125

SUBJECT: Amendment Request for US Nuclear Regulatory Commission (NRC)
Byproduct Material License Number 05-26854-01


1. Request NRC License No. 05-26854-01 be amended with the following changes:

Add Reed K. Smith, M.D., as an authorized user to prescribe, prepare and administer radiopharmaceuticals for medical diagnosis and therapy in accordance with 10 CFR 35.100, 35.200, and 35.300. Enclosure 1 contains Dr. Smith's supporting documents for addition as an authorized user. Enclosure 2 contains a copy of amendment no. 23 of license 05-26854-01 where Dr. Smith was previously listed as an authorized user.

2. The Radiation Safety Committee has reviewed and approved these actions.

3. The point of contact for this memorandum is CPT Sherry Kwasnik, RSO at (719) 526-7047 or sherry.e.kwasnik.mil@mail.mil.

2 Enclosures


SHERRY KWASNIK
CPT, MS
Radiation Safety Officer

CF:
WRMC Command Radiation Safety Officer (ATTN: Glenn McDermott)
EACH Radiation Safety Committee Members

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____

Reviewer:  Date: 2-6-14

14 582966

1. In accordance with U.S. Nuclear Regulatory Commission broad scope byproduct material license Number 42-01368-01, Brooke Army Medical Center (BAMC) Memo 40-72, and Army Radiation Authorization (ARA) 42-01-16, the BAMC Radiation Control Committee (RCC) issues the following RCC Permit:

- a. Permit Number: **NM-RS-1**
- b. Permit Expiration Date: **Apr 2007**
- c. Permitted Individual: **LTC Reed K. Smith**
- d. Permitted Activities: **Authorized User (AU) IAW Title 10 CFR Part 35.**

2. The permitted individual is responsible for complying with the requirements of Title 10, Code of Federal Regulations, USNRC License 42-01368-01, Army Radioisotope Authorization 42-01-16, BAMC Memo No. 40-72, established operating procedures, and the conditions of this permit.

3. The permitted individual is authorized to prescribe, prepare and administer radiopharmaceuticals for medical research, medical diagnosis, and therapy as specified below:

	Requirement Met	Authorized Use
a.	10 CFR 35.100	Medical Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required
b.	10 CFR 35.200	Medical Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is Not Required
c.	10 CFR 35.300	Medical Use of Unsealed Byproduct Material for Which a Written Directive is Required
d.	10 CFR 35.500	Medical Use of Sealed Sources for Diagnosis

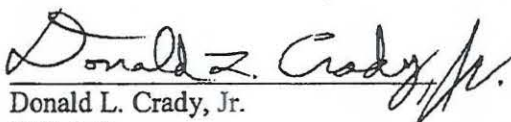
4. All preparation and administration of radiopharmaceuticals will be performed by the permitted individual, an individual supervised by the permitted individual IAW 35.27, or a student under the direct control of the permitted individual or a supervised individual. The permitted individual will ensure the addendum to the Nuclear Medicine Service ARSO permit lists all individuals supervising when the updated addendum is forwarded to the RSO.

5. Students administering radiopharmaceuticals shall be under the direct control of an individual authorized to administer radiopharmaceuticals. Direct control requires that the authorized individual observe and control every aspect of the student's actions. The authorized individual is responsible for the action and omission of the individual under their direct control.

6. The permitted individual shall immediately report unsafe conditions, loss of accountability of radioactive materials, or violations of operating procedures, regulatory requirements, or the conditions of this permit to the Radiation Safety Officer.

7. The permitted individual shall comply with the HPS013 SOP. All I-131 therapies in excess of 33 mCi are admitted as inpatients, overnight unless prior RCC approval is obtained for immediately release.

APPROVED BY THE RCC electronically in: Apr 06 (Tracking Number RCC-0602-004)



Donald L. Crady, Jr.

CPT, MS

Recorder, Radiation Control Committee

Date: 1 MAY 06

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.

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

Reed Smith
Authorized User, 10 CFR 35.190, 35.290 and 35.390

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

Nebraska

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified
American Board of Family Physicians American Board of Nuclear Medicine		July 1996 Pending

*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	Brooke Army Medical Center Wilford Hall Medical Center UTSA Medical Center	120	(1)
Radiation Protection	" "	120	(1)
Mathematics Pertaining to the Use and Measurement of Radioactivity	" "	120	(1)
Radiation Biology	" "	120	(1)
Chemistry of Byproduct Material for Medical Use	" "	120	(1)
OTHER		Total Hours: 600	
(1) Nuclear Medicine Fellowship Program 1 July 2001-30 June 2003			

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
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	(2)	(3)	(1) 250
Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters	(2)	(3)	(1) 250
Calculating, measuring, and safely preparing patient or human research subject dosages	(2)	(3)	(1) 250
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	(2)	(3)	(1) 250
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	(2)	(3)	(1) 250
eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	(2)	(3)	(1) 250
(2) Dr Yong Bradley			TOTAL: 1500
(3) Brooke Army Medical Center 42-01368-01			

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
I-131	Oral administration	22 (7)	(2)	(3)	(1) 15
Sm-153	Parenteral administration	4	(2)	(3)	(1) 3
Y-90	Parenteral administration	3	(2)	(3)	(1) 2.5
Tc-99m	Parenteral administration	5	(2)	(3)	(1) (4)
F18-FDG	Parenteral administration	20	(2)	(3)	(1) 15
(4) minimum of	40 hours of Tc-99m	experience			
(7) min 3 >33	mCi				

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 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)

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
☐ N/A of _____ the RSO for License No. _____

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
☐ N/A _____ who meets requirements for Authorized Medical Physicists; and
- ☐ YES Completed 1-year of full-time work experience (for areas identified in item 5a) for _____
☐ N/A 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 Yong Bradley

B. Supervisor is:

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

C. Supervisor meets requirements of Part 35, Section(s) 35.190, 35.290, and 35.390

for medical uses in Part 35, Section(s) 35.100, 35.200, 35.300

D. Address

Brooke Army Medical Center
3851 Roger Brooke Dr.
Ft Sam Houston, TX 78234

E. Materials License Number

42-01368-01

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
☐ N/A 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.

- ☒ YES 11a. The individual named in Item 1 has satisfactorily completed the requirements in Part 35, Section(s)
☐ N/A and Paragraph(s) 35.190c, 35.290c, 35.390c

- ☒ YES 11b. The individual named in Item 1, is competent to independently function as an authorized
☐ N/A user _____ for 35.100, 35.200, 35.300 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 35.190, 35.290, and 35.390
or equivalent Agreement State requirements to be a preceptor authorized user _____
for the following uses (or units) of byproduct material: 35.100, 35.200, and 35.300

A. Address

Brooke Army Medical Center
3851 Roger Brooke Dr.
Ft Sam Houston, TX 78234

B. Materials License Number

42-01368-01

C. NAME OF PRECEPTOR (print clearly)

Dr Yong Bradley

D. SIGNATURE - PRECEPTOR



E. DATE

07/17/2003

PAGE 4

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The American Board of Nuclear Medicine

A Member Board of the American Board of Medical Specialties

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Eric M. Robbra, M.D., Ph.D.
Houston, Texas

Vice-Chairman
Louis P. O'Malley, M.D.
Birmingham, Alabama

Secretary-Treasurer
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Los Angeles, California

Past-Chairman
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Ann Arbor, Michigan

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New York, NY

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Palo Alto, CA

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November 15, 2013

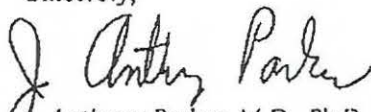
Dear Credentials Committee:

Reed K. Smith, M.D. passed the ABNM Maintenance of Certification (MOC) examination given during the first week of October 2013. This comprehensive examination covers the following areas:

- General Nuclear Medicine
- Cardiovascular Nuclear Medicine including Stress Testing
- Diagnostic CT in association with PET/CT or SPECT/CT
- PET/CT
- SPECT/CT
- Molecular Imaging
- Therapy with radioactive sources

Dr. Smith is also fully participating in the ABNM's MOC program.

Sincerely,


J. Anthony Parker, M.D., Ph.D.
Associate Executive Director

JAP/mjw/mrw

Incorporated 1971

Certifies that

Reed K. Smith, M.D.

*has fully participated in the ABNM's Maintenance of Certification program
is qualified during the period of 10/11/2013 through 12/31/2023 to practice as
Specialist in all aspects of Clinical and Laboratory*

Nuclear Medicine

*Maintenance of this certificate requires full participation in the ABNM's
Maintenance of Certification program.*



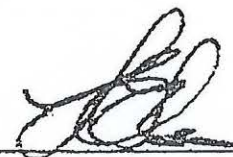
Eric M. Rohren, M.D., Ph.D.

Chairman



07347

Number



Louise E. Thomson, MB.ChB., FRACP

Secretary-Treasurer



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.

<p>Licensee</p> <p>1. Department of the Army Evans Army Community Hospital</p> <p>2. 1650 Cochrane Circle Fort Carson, Colorado 80913-4604</p>	<p>In accordance with letter dated March 16, 2009</p> <p>3. License number 05-26854-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date August 31, 2013</p> <p>5. Docket No. 030-29534 Reference No.</p>
<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>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</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. 500 millicuries</p>
<p>9. Authorized use:</p> <p>A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.</p> <p>B. Any imaging and localization study permitted by 10 CFR 35.200.</p> <p>C. Any use permitted by 10 CFR 35.300.</p>	

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1650 Cochrane Circle, Fort Carson, Colorado.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

05-26854-01

Docket or Reference Number

030-29534

Amendment No. 23

11. The Radiation Safety Officer for this license is 1LT Jaime A. Purcell.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for the material and medical uses indicated:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|----------------------------|-------------------------|
| Cyrus W. Partington, M.D. | 35.100; 35.200; 35.300 |
| Frederick A. Steckel, M.D. | 35.100; 35.200 |
| Reed K. Smith, M.D. | 35.100; 35.200; 35.300 |
13. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.219 or under equivalent regulations of an Agreement State.
- B. Notwithstanding Paragraph A of this condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.240 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

05-26854-01

Docket or Reference Number

030-29534

Amendment No. 23

- F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 612 East Lamar Boulevard, Suite 400, Arlington, Texas 76011-4125, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.
- G. Tests for leakage and/or contamination, including leak test, sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
14. The licensee shall conduct a physical inventory every 6 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. Sealed sources or detector cans containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. 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
05-26854-01Docket or Reference Number
030-29534

Amendment No. 23

17. 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 22, 2003
B. Letter dated August 21, 2003
C. Application dated August 31, 2006 (ML062680336)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date June 17, 2009

By

Jacqueline D. Cook, Senior Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4125

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02120
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date:
Fee Comments: ARMY 170.11(A)(5)
Decom Fin Assur Req: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ARMY, DEPARTMENT OF THE
Received Date: 02/04/2014
Docket Number: 3029534
Mail Control Number: 582966
License Number: 05-26854-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Colleen Murnahan

Date: _____

2-4-14

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: _____



DATE

02/04/2014

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Department of the Army
Evans Army Community Hospital
1650 Cochrane Circle
Fort Carson, CO 80913-4604

LICENSE NUMBER

05-26854-01

MAIL CONTROL NUMBER

582966

LICENSING AND/OR TECHNICAL REVIEWER

cmurnahan

Cm

This is to acknowledge the receipt of your:

☒ LETTER and/or ☒ APPLICATION

DATED: 02/03/2014

The initial processing, which included an administrative review, has been performed.

☒ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

- ☒ There were no administrative omissions identified during our initial review.
- ☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.
- ☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER**. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Blvd.
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

*emailed to lic
2-4-14*