CARILION CLINIC

July 18, 2008

J-2

RECEIVED REGION 1
2008 JUL 23 PM 12: 14

US Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, PA 19406

Attention: Nuclear Materials Licensing Section

RE: Amendment Request to USNRC Radioactive Materials License No. 45-25395-01 (Docket or Ref. No. 030-34470)

Dear Sirs:

Carilion Clinic (CC) is requesting amending our Radioactive Material License No. 45-25395-01 in the following manner:

1.) Revision to current license condition Number 12 – Licensed material is only authorized for use by or under the supervision of – to include the following two individuals.

Authorized User	Material & Use	Training & Experience
Herman A. Kensky, M.D.	By-product material listed under 10 CFR 35.100, 35.200 & 35.300	Refer to attached copy of State of California Radioactive Material License No. 1593-34 for Catholic Healthcare West, dha: Mercy San Juan Hospital which lists Dr. Kensky as an approved Authorized User for the byproduct materials noted under Material & Use in the adjacent column of this table. Also, copies of letters from (1) the American Board of Nuclear Medicine (ABNM), dated December 15, 1985, indicating that Dr. Kensky passed this board's certifying examination in the broad field of Nuclear Medicine on September 7, 1985 and (2) the American Board of Radiology (ABR) in Diagnostic Radiology, dated March 15, 1996 which states that he was certified in Diagnostic Radiology in 1986.

142470

P.O. Box 13727 Roanoke, VA 24036-3727

Authorized User	Material & Use	Training & Experience
Dana B. Fathy, M.D.	By-product material listed under 10 CFR 35.100, 35.200 & 35.300	Refer to attached copy of letter from The American Board of Radiology (ABR) in Diagnostic Radiology, dated June 1, 2008 which states that he was certified in Diagnostic Radiology in June, 2008 with the designation of "AU-eligible" on his certificate (Confirmation #566CE079). Also, copies of NRC Forms 313A (AUD) & 313A (AUT) which show his 700 hours of Training & Experience & Preceptor Attestation for AU from University of Tennessee Medical Center in Knoxville, TN signed by Gary T. Smith, M.D. (Agreement State License No. TN R-47011)

We feel that Dr. Kensky fits the criteria of an experienced AU as defined in 10 CFR 35.57(b) and that Dr. Fathy complies with the current requirements for AU as defined in 10 CFR 35.190, 35.290, and 35.390 for the above noted medical uses of certain radioactive material and has recent and continual experience in Nuclear Medicine responsibilities and procedures.

The following AUs should be deleted from this license, since they no longer work for the licensee:

1. J. Bruce Hauser, M.D. and
2. Charles H. Warner, M.D.

We remain available to provide additional and clarifying information and appreciate you prompt attention to this amendment request. Your contact person(s) for this matter is Jeffrey Messinger, RSO and he can be contacted at (540)981-7379 or via e-mail at rojgm1@carilion.com.

Respectfully submitted;

Joseph L. Surace, Director
Department of Physics
Administration Representative for CC

pc RSC-CC
rsc/nrcamendment071808.req

State of California-Health and Human Services Agency

California Department of Public Health

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the California Department of Public Health now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee:	Catholic Healthcare West dba:Mercy San Juan Hospital	3. License Number: 1593-34	Amendment Number: 64
2. Address:	6501 Coyle Avenue Carmichael, CA 95608	4. Expiration date: November 24, 2004	(3)
Attention:	Herman A. Kensky, M.D. Radiation Safety Officer	5. Inspection agency:	Radiologic Health Branch North

In response to the letter dated October 30, 2007 signed by Herman A. Kensky, M.D., Radiation Safety Officer, License Number 1593-34 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Groups 1, 2, 3, 4 and 5 as specified in Item 9. Any radionuclide with atomic number 3-83.	A. Any Excluding generators	A. Combined possession limit for Groups 1, 2, 3, 4 and 5 not to exceed 5.02 Ci.
B. Group 9 as specified in Item 9.	B.	B.
1. Any radionuclide with atomic numbers 3-83, inclusive, except: Strontium-90 and Lead-210.	1. Sealed or solid sources manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission or an Agreement State or a Licensing State.	1. Total not to exceed 100 mCi. Each source not to exceed 20 mCi.
2. Iodine-125	2. Sealed sources (AECL Model C-235 and C-234 in AECL Model C-236 source holder, and Amersham Model IMC.P2 and Cintichem Model 6525 in Osteon Model SRC-1-AY source holder)	2. Total 600 mCi in 1 source.
3. Germanium-68	3. Sealed Sources (CTIMI Model LS Series, Sanders Medical Products, Inc., Model PET Series and IPL Model A 3418).	*3. Each source not to exceed 5.5 mCi
4. Germanium-68	4. Sealed sources (IPL Model A3407 and Sanders Medical Products, Inc., Model PET Series)	*4. Each source not to exceed 13 mCi
		* Total possession limit for 3 and 4 not to exceed 26 mCi.

RADIOACTIVE MATERIAL LICENSE

License Number 1593.34

Amendment Number 64

9 Authorized Use

To be used for nuclear medicine procedures as specified in groups below.

A. Group 1 Diagnostic studies involving measurement of uptake, dilution, or excretion but not involving imaging.

Group 2 Diagnostic studies involving imaging including the use of Xenon-127 and/or Xenon-133 gas.

Group 3 Reagent kits utilizing bulk technetium prepared by a radiopharmacy for preparation of radiopharmaceuticals listed in Group 2.

Group 4 Internal therapy and palliative treatment not usually requiring hospitalization.

Group 5 Internal therapy and palliative treatment requiring hospitalization for purposes of radiation safety.

B. Group 9 1. Marker and calibration sources.

2. Storage for decay only.

3. To be used in a CPS ECAT Series source holder for a PET Medical Diagnostic Scanner provided by Molecular Imaging Corporation (RML 6631).

4. To be used in a GE Medical Systems Advance NXi Imaging System Whole-Body PET System provided by Molecular Imaging Corporation (RML 6631).

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following location:

(a) 6501 Coyle Avenue, Carmichael, CA. (including mobile PET coach)

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.

12. The individuals named below are authorized the specific uses of radioactive material described in items 6, 7, 8, and 9 of this license as follows:

(a)	Craig D. Weiner, M.D.	Groups 1, 2, 3, 4, 5 and 9
(b)	Robert Class, M.D.	Groups 1, 2, 3, 4, 5 and 9
(c)	Herman Kensky, M.D.	Groups 1, 2, 3, 4, 5 and 9
(d)	Kathryn Witzum, M.D.	Groups 1, 2, 3, 4, 5 and 9
(e)	Philip Haines, M.D.	Groups 1, 2, 3 and 9
(f)	Robert Carretta, M.D.	Groups 1, 2, 3, 4, 5 and 9
(g)	Fredrick Weiland, M.D.	Groups 1, 2, 3, 4, 5 and 9
(h)	Andrew S. Klonecke, M.D.	Groups 1, 2, 3, 4, 5 and 9
(i)	Thomas Pounds, M.D.	Groups 1, 2, 3, 4, 5 and 9
(j)	Martin A. Winston, M.D.	Groups 1, 2, 3, 4, 5 and 9
(k)	Marie R. Carlisle, M.D., Ph.D.	Groups 1, 2, 3, 4, 5 and 9
(l)	Penny R. Vandestreek, D.O.	Groups 1, 2, 3, 4, 5 and 9

RADIOACTIVE MATERIAL LICENSE

License Number: 1593-34

Amendment Number: 64

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    (a) The application, with attachments, received October 30, 1991, signed by Larry Meyer, Vice President, Professional Services.

    (b) The letter dated October 4, 1991, regarding response to the "Notice of Violation", signed by Larry Meyer.

    (c) The letter dated February 24, 1992, signed by Herman Kensky, M.D., regarding leak tests and G-M survey meter changes.

    (d) The letter dated November 15, 1992, signed by Herman Kensky, M.D., Radiation Safety Officer, regarding survey equipment.

    (e) The letter, with attachments, dated May 25, 1994, signed by Herman Kensky, M.D., regarding calculations for Xe-133.

    (f) The letter, with attachments, dated April 18, 1995, as modified by the letter dated July 17, 1995, both signed by Herman A. Kensky, M.D., Radiation Safety Officer, regarding monitoring of the Xenon trap each week of use, updated diagram of Nuclear Medicine Department, and modification of ordering and receiving procedures.

    (g) The facsimile received January 6, 1998, signed by Herman A. Kensky, M.D., Radiation Safety Officer, regarding the use of Samarium 153.

    (h) The letter, with attachments, received April 16, 1998, signed by Susan M. Comstock, Supervisor of the Nuclear Medicine Department and Herman Kensky, M.D., Radiation Safety Officer, supplemented by the letter, with attachments, dated June 3, 1998, signed by Herman Kensky, M.D., Radiation Safety Officer, regarding the re-location of the Nuclear Medicine Department to a newly constructed area of the hospital.

    (i) The letter, with attachments, dated August 9, 1999, signed by Craig Weiner, M.D., Alternate Radiation Safety Officer, regarding the closeout survey of the old nuclear medicine department.

    (j) The letter, with attachment, dated October 10, 2001, signed by Herman Kensky, M.D., Radiation Safety Officer, regarding I-131 patient release criteria.

    (k) The letter, with attached diagram, dated May 13, 2003, signed by Herman Kensky, M.D., Radiation Safety Officer, regarding the addition of a mobile PET coach provided by Molecular Imaging Corporation (RML 6631).

    (l) The letter, with attachments, dated November 18, 2005, signed by William J. Hunt, President, regarding the change of ownership from Mercy Healthcare Sacramento to Catholic Healthcare West.

14. (a) The Radiation Safety Officer in this program shall be Herman Kensky, M.D.
    (b) The Chairperson of the Radiation Safety Committee shall be Herman Kensky, M.D.
    (c) The Alternate Radiation Safety Officers in this program shall be Philip Haines, M.D., David Wood, ARRT(N), RHN-CNMT, and Christopher Christensen, ARRT(N), RHN-CNMT.

15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Title 17, California Code of Regulations, Section 30275 (e).

RADIOACTIVE MATERIAL LICENSE

License Number 1593-34

Amendment Number 66

16. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services:

    (a) The Radiation Safety Officer
    (b) Qualified individuals designated in writing by the Radiation Safety Officer

17. Except for alpha sources, the periodic leak test required by Condition 15 does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

18. The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.

19. The licensee is authorized to hold radioactive materials with a physical half-life of less than 65 days for decay in storage before disposal in ordinary trash provided:

    (a) Radioactive waste to be disposed of in this manner shall be held for decay in storage for at least 10 half-lives.

    (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

20. The licensee may use one constancy source for the dose calibrator constancy test provided that the dose calibrator manual indicates that only one constancy source is needed for proper Quality Control.

21. The licensee may use any commercially available device, acceptable to the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, for doing linearity tests of its dose calibrator provided the procedures described by the manufacturer of the linearity device are followed.

22. Nuclear medicine technology procedures shall be performed by nuclear medicine technologists pursuant to Title 17, California Code of Regulations, Subchapter 4.6. Such procedures shall be performed under the supervision of authorized user physicians on this license who meet the criteria specified in Section 30510. Certificates or special permits issued pursuant to Subchapter 4.6 shall be prominently displayed at the facility(ies) authorized on this license.

23. Notwithstanding the definition of "Misadministration" in title 17, 30100(j), and the requirements listed in title 17, section 30322, the Licensee shall notify and submit reports regarding "Medical Events," as defined in title 10, Code of Federal Regulations, Part 35, section 35.2 to the Department in accordance with title 10, Code of Federal Regulations, Part 35, section 35.3045.

24. Treatment and management of patients receiving therapeutic quantities of unsealed radioactive materials shall be in accordance with the guidance from any of the following:

    (a) Chapter 4, "Release from Hospital of Patients Containing Radioactive Material" National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides" (NCRP Publications, P.O. Box 30175, Washington, D.C. 20014).

    (b) Appendix M in the "Guide for the Preparation of Applications for Medical Programs", State of California, Department of Health Services, Radiological Health Branch.

    (c) Documented rationale or patient-specific calculations demonstrating that members of the general public will be limited to 500 mrem total effective dose equivalent from patients who have been released containing therapeutic quantities of radiopharmaceuticals.

RADIOACTIVE MATERIAL LICENSE

License Number 1593-34

Amendment Number 64

25. Production or processing of radiopharmaceuticals for the purpose of commercial distribution to other licensees is not authorized by this license.

26. When using mobile nuclear service companies, the licensee shall retain all responsibilities for the use of radioactive material authorized by this license.

27. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed materials for human use under the terms of this license, provided the visiting physician:

    (a) Has the prior written permission of the hospital's Administrator and its Radiation Safety Committee.

    (b) is specifically named as a user on a U.S. Nuclear Regulatory Commission or Agreement State license authorizing human use.

    (c) Performs only those procedures for which the physician is specifically authorized by the U.S. Nuclear Regulatory Commission or Agreement State license.

    The licensee shall maintain for inspection copies of the written permission specified in (a) above and the licensee(s) specified in (b) and (c) above. These records shall be maintained for five years from the time the licensee grants its permission under (a) above.

28. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material so that at no time will the total quantity of radioactive material possessed require financial surety for decommissioning in accordance with the California Code of Regulations, Title 17, Section 30195.1. A value of 100 microcuries is assigned to Cobalt-57 to supplement the Code of Federal Regulations, Title 10, Part 30, Appendix B.

29. **The licensee will provide the Low Level Radioactive Waste (LLRW) reports specified in the California Health and Safety Code section 115000.1(h) to the California Department of Public Health (CDPH) on an annual basis for both shipped and stored LLRW. Alternatively, LLRW shipment information may be provided on a per shipment basis. LLRW shipment information and annual reports shall be mailed to:**

    Attn: LLRW Tracking Program
    California Department of Public Health
    Radiologic Health Branch MS 7610
    P.O. Box 997414
    Sacramento, CA 95899-7414

30. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 6501 Coyle Avenue, Carmichael, CA.

Issued for the State of California Department of Public Health

Date: December 4, 2007

By

Radiologic Health Branch
MS 7610, P.O. Box 997414
Sacramento, CA 95899-7414

The American Board of Radiology

M. Paul Capp, M.D., Executive Director

Assistant Executive Directors
Robert E. Campbell, M.D., Diagnostic Radiology
Lawrence W. Davis, M.D., Radiation Oncology

5255 E. WILLIAMS CIRCLE, SUITE 6800
TUCSON, ARIZONA 85711

PHONE (520) 790-2900
FAX (520) 790-3200

March 15, 1996 945306

HERMAN A. KENSKY, M.D.
[redacted]

This is to verify the status of the below-listed individual as you requested.

26577 HERMAN A. KENSKY MD DOB: [redacted]
Certified Diagnostic Radiology, 1986

Sincerely yours,

M. Paul Capp, M.D.

MPC:oph

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

December 15, 1985

HERMAN A. KENSKY, M.D.
[redacted]

RECEIVED
CCVS

Dear Doctor:

With great pleasure, the American Board of Nuclear Medicine informs you that you have passed its September 7, 1985 Certifying Examination in the broad field of nuclear medicine and are now recognized as a certified specialist in nuclear medicine. A certificate indicating this recognition will be sent to you in the near future. The American Board of Nuclear Medicine congratulates you upon your achievement and this recognition!

DIAGNOSTIC RADIOLOGY ■ RADIATION ONCOLOGY ■ RADIOLOGIC PHYSICS

5441 E. Williams Boulevard, Suite 200 · Tucson, Arizona 85711-4493 · Phone (520) 790-2900 · Fax (520) 790-3200
E-mail: information@theabr.org · website: www.theabr.org

June 1, 2008

ABRID 55287 / DR / 14 / 12

Confirmation # 566CE079

Dana Birkley Fathy, MD
[redacted]

Dear Dr. Fathy:

I am pleased to inform you that you passed the oral examination held on May 31 to June 3, 2008. The American Board of Radiology grants you its Certificate in Diagnostic Radiology. This is a ten-year time-limited certificate. In addition, because you received the appropriate training to make you AU-Eligible and passed the NRC-related portions of the nuclear radiology section, you will receive the AU-Eligible designation on your certificate.

The certificate will be sent to the above address in approximately three months from our printer, Jim Henry, Inc. Your name will appear on the certificate as shown above. If you wish your name to appear differently or you have an address change, please notify the Board office in writing by July 01, 2008. Your name and demographic information will be included in a Directory published by the American Board of Medical Specialties. It is your responsibility to notify other local and state or national organizations of your certification.

Important information about your Maintenance of Certification process is enclosed. Please review it and respond as requested.

Personally and on behalf of the Board of Trustees of The American Board of Radiology, I wish to congratulate you for this distinguished achievement. You have accomplished one of the most significant milestones in your career.

Sincerely,

Gary J. Becker, MD

Enclosures

Rev. 3-08

NRC FORM 313A (AUD)
(10-2007)

US NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (FOR USES DEFINED UNDER 35.100, 35.200, AND 35.500) [10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO.3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
Dana Fathy, MD	

Requested Authorization(s) *(check all that apply)*

X	35.100 Uptake, dilution, and excretion studies
X	35.200 Imaging and localization studies
na	35.500 Sealed sources for diagnosis (specify device _____)

PART I – TRAINING AND EXPERIENCE

(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

X **1. Board Certification**

a. Provide a copy of the board certification.

b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

na **2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License TN R-47011 meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

b. Supervised Work Experience.

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	University of Tennessee Medical Center Knoxville, TN TN R-47011		

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Gary T Smith, MD	TN R-47011

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)*

X 35.290 X 35.390 + generator experience in 32.290(c)(1)(ii)(G)

NRC FORM 313A (AUD)
(10-2007)

US NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training

Description of Training	Locaton of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	University of Tennessee Medical Center Knoxville, TN	94	Jul 2004 - Jun 2008
Radiation Protection	University of Tennessee Medical Center Knoxville, TN	40	Jul 2004 - Jun 2008
Mathematics pertaining to the use and measurement of radioactivity	University of Tennessee Medical Center Knoxville, TN	18	Jul 2004 - Jun 2008
Chemistry of byproduct material for medical use *(not required for 35.590)*	University of Tennessee Medical Center Knoxville, TN	27	Jul 2004 - Jun 2008
Radiation biology	University of Tennessee Medical Center Knoxville, TN	22	Jul 2004 - Jun 2008
Total hours of training:		201	

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience — **Total Hours of Experience:** **520**

Description of Experience Must Include:	Locaton of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	University of Tennessee Medical Center Knoxville, TN TN R-47011	[x] Yes [ ] No	Jul 2004 - Jun 2008
Performing quality control procedures on instruments used to determine activity of dosages and performing checks for proper operation of survey meters	University of Tennessee Medical Center Knoxville, TN TN R-47011	[x] Yes [ ] No	Jul 2004 - Jun 2008
Calculating, measuring, and safely preparing patient or human research subject dosages	University of Tennessee Medical Center Knoxville, TN TN R-47011	[x] Yes [ ] No	Jul 2004 - Jun 2008

NRC FORM 313A (AUD) US NUCLEAR REGULATORY COMMISSION
(10-2007)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

b. Supervised Work Experience. (continued)

Description of Experience	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Tennessee Medical Center Knoxville, TN TN R-47011	[x] Yes [ ] No	Jul 2004 - Jun 2008
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Tennessee Medical Center Knoxville, TN TN R-47011	[x] Yes [ ] No	Jul 2004 - Jun 2008
Administering dosages of radioactive drugs to patients or human research subjects	University of Tennessee Medical Center Knoxville, TN TN R-47011	[x] Yes [ ] No	Jul 2004 - Jun 2008
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive compounds	University of Tennessee Medical Center Knoxville, TN TN R-47011	[x] Yes [ ] No	Jul 2004 - Jun 2008

Supervising Individual: Gary T Smith, MD, UTMC

License/Permit Number listing supervising individual as an authorized user: TN R-47011

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)*

[X] 35.190 [X] 35.290 [X] 35.390 [X] 35.390 + generator experience in 32.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates
^{153}Gd DPA bone mineral scanner	Safety and use of scanner	UCLA, 1988-1989

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation

NRC FORM 313A (AUD) US NUCLEAR REGULATORY COMMISSION
(10-2007)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency"

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

[X] I attest that Dana Fathy, MD has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100

OR

Training and Experience

[ ] I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100

For 35.290

Board Certification

[X] I attest that Dana Fathy, MD has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200

OR

Training and Experience

[ ] I attest that _____ has satisfactorily completed the 700 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200

Second Section

Complete the following for preceptor attestation and signature:

[X] I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

[X] 35.190 [X] 35.290 [X] 35.390 [X] 35.390 + generator experience

Name of Preceptor	Signature	Telephone number	Date
Gary T Smith, MD	Gary Smith (MD)	865-305-~~9181~~ 9818	6/13/08

License/Permit Number/Facility Name

University of Tennessee Medical Center, TN R-47011

NRC FORM 313A (AUT)
(10-2007)

US NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (FOR USES DEFINED UNDER 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO.3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
Dana Fathy, MD	

Requested Authorization(s) *(check all that apply)*

[X] 35.300 Use of unsealed byproduct material for which a written directive is required

OR

[ ] 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

[ ] 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

[ ] 35.300 Parenteral administration of any beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

[ ] 35.300 Parenteral administration of any other radionuclide for which a written directive is required

PART I – TRAINING AND EXPERIENCE

(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

[na] **1. Board Certification**

a. Provide a copy of the board certification.
b. for 35.390, provide documentation on supervised clinical cases and experience. The table in 3.c. may be used to document this experience.
c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.
d. Skip to and complete Part II Preceptor Attestation.

[na] **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized user on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

[ ] 35.390 [ ] 35.392 [ ] 35.394 [ ] 35.490 [ ] 35.690

b. If currently authorized for a subset of clinical cases under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.
c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

NRC FORM 313A (AUT)
(10-2007)

US NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training [X] 35.390 [ ] 35.392 [ ] 35.394 [ ] 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	University of Tennessee Medical Center Knoxville, TN	94	Jul 2004 - Jun 2008
Radiation Protection	University of Tennessee Medical Center Knoxville, TN	40	Jul 2004 - Jun 2008
Mathematics pertaining to the use and measurement of radioactivity	University of Tennessee Medical Center Knoxville, TN	18	Jul 2004 - Jun 2008
Chemistry of byproduct material for medical use	University of Tennessee Medical Center Knoxville, TN	27	Jul 2004 - Jun 2008
Radiation biology	University of Tennessee Medical Center Knoxville, TN	22	Jul 2004 - Jun 2008
	Total hours of training:	201	

b. Supervised Work Experience [X] 35.390 [ ] 35.392 [ ] 35.394 [ ] 35.396

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Supervised Work Experience — **Total Hours of Experience:** **520**

Description of Experience	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	University of Tennessee Medical Center Knoxville, TN TN R-47011	[X] Yes [ ] No	Jul 2004 - Jun 2008
Performing quality control procedures on instruments used to determine activity of dosages and performing checks for proper operation of survey meters	University of Tennessee Medical Center Knoxville, TN TN R-47011	[X] Yes [ ] No	Jul 2004 - Jun 2008
Calculating, measuring, and safely preparing patient or human research subject dosages	University of Tennessee Medical Center Knoxville, TN TN R-47011	[X] Yes [ ] No	Jul 2004 - Jun 2008
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Tennessee Medical Center Knoxville, TN TN R-47011	[X] Yes [ ] No	Jul 2004 - Jun 2008
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Tennessee Medical Center Knoxville, TN TN R-47011	[X] Yes [ ] No	Jul 2004 - Jun 2008

NRC FORM 313A (AUT)
(10-2007)

US NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Training and Experience for Proposed Authorized User (continued)**
b. Supervised Work Experience. (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Gary T Smith, MD	TN R-47011

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

X	35.390	With experience administering dosages of:	
	35.392	X	Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
	39.394	X	Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
	39.396	X	Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
		X	Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	5	University of Tennessee Medical Center Knoxville, TN TN R-47011	Jul 2004 - Jun 2008
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	37	University of Tennessee Medical Center Knoxville, TN TN R-47011	Jul 2004 - Jun 2008
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required	3	University of Tennessee Medical Center Knoxville, TN TN R-47011	Jul 2004 - Jun 2008
Parenteral administration of any other radionuclide for which a written directive is required (list radionuclides)		University of Tennessee Medical Center Knoxville, TN TN R-47011	Jul 2004 - Jun 2008

NRC FORM 313A (AUT) US NUCLEAR REGULATORY COMMISSION
(10-2007)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)
c. Supervised Clinical Case Experience. (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Gary T Smith, MD	TN R-47011

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

X	35.390		With experience administering dosages of:
	35.392	X	Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
	39.394	X	Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
	39.396	X	Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
			Parenteral administration of any other radionuclide for which a written directive is required

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency"

First Section
Check one of the following for each requested authorization:

For 35.390:

Board Certification

[na] I attest that _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User
requirements in 35.390(a)(1).

OR

Training and Experience

[X] I attest that Dana Fathy, MD has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User
and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390(b)(1)

NRC FORM 313A (AUT)
(10-2007)

US NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

[na] I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User
and laboratory training, as required by 10 CFR 35.392(c)(1) and the supervised work and clinical case experience required in 35.394(c)(2).

OR

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

[na] I attest that _____ has satisfactorily completed the 80 hours of training and
Name of Proposed Authorized User
and laboratory training, as required by 10 CFR 35.394(c)(1) and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

[X] I attest that Dana Fathy, MD has satisfactorily completed the clinical case
Name of Proposed Authorized User
experience required in 10 CFR 35.390(b)(1)(ii)(G) listed below:

- [X] Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- [X] Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- [X] Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- [ ] Parenteral administration of any other radionuclide for which a written directive is required

---

Third Section

[X] I attest that Dana Fathy, MD has satisfactorily achieved a level of competency to
Name of Proposed Authorized User
function independently as an authorized user for:

- [X] Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- [X] Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- [X] Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- [ ] Parenteral administration of any other radionuclide for which a written directive is required

NRC FORM 313A (AUT)
(10-2007)

US NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396

Current 35.490 or 35.690 authorized user:

[na] I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396(d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

[ ] Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
[ ] Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

[na] I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 10 CFR 35.396(d)(1), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396(d)(1) and the supervised work and clinical case experience required by 35.396(d)(2),and has achieved a level of competency sufficient to function independently as an authorized user for:

[ ] Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
[ ] Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

[X] I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

[X] 35.390 [ ] 35.392 [ ] 35.394 [ ] 35.396

[X] I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

[X] Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
[X] Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

[X] Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
[X] Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone number	Date
Gary T Smith, MD	Gary T Smith (WD)	865-305-~~9181~~ 9818	6/13/08

License/Permit Number/Facility Name

University of Tennessee Medical Center, TN R-47011

Dana Fathy, MD