FEB 07 2018

APPENDIX A

NRC FORM 313 (10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

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

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

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

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

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - [ ] A. NEW LICENSE
   - [x] B. AMENDMENT TO LICENSE NUMBER 24-01570-03
   - [ ] C. RENEWAL OF LICENSE NUMBER

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

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

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

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

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

FEE CATEGORY	AMOUNT ENCLOSED $

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

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

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

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Donald Miller, Vice President Operations		2/7/18

FOR NRC USE ONLY

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

February 5, 2018

Region III
U.S. Nuclear Regulatory Commission
DNMS/Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: License # 24-01570-03

Mail Control Number: 600950

To whom it may concern:

We are providing additional information in support of our license amendment request adding Jason Edwards as an authorized user. I have addressed the items in your letter dated December 14, 2017.

Item1. I have attached a copy of a letter from the UK Radiation Safety Officer listing Dr. Kudrimoti as an AU under the U of K license for the use of materials in 10 CFR 35.400. The letter also states that Dr. Kudrimoti has been at UK continuously to the date of the letter.

Item 2. The above mentioned letter also lists Dr. Kudrimoti as authorized for use of sealed source in a remote afterloader (Varian Oncology Varisource IX HDR remote afterloading brachytherapy unit. Ir-192). As stated in the letter Dr. Kudrimoti is authorized for the modalities in 10 CFR 35.396. Modalities in 35.392 and 35.394 are not listed. Folowing receipt of you letter of December 14, 2017 Dr. Edwards informed me that another authorized user who is no longer at UK was his supervisor for modalities in 35.392 and 35.394. Dr. Kudrimoti was his supervisor for items in 35.396. Since Dr. Edwards arrival at St. Lukes Dr. Butler who is on our license for items in 10 CFR 300 has been supervising Dr. Edwards. I have attached a copy off NRC Form 313A (AUT) provided by Dr. Edwards listing Dr. Butler as supervisor for itmes in 10 CFR 35.392 and 10 CFR 35.394.

If you have any questions regarding this amendment request, please contact Christopher Durbin, Ph.D. at (314) 205-6218.

Sincerely,

Don Miller,
Vice President

UNIVERSITY OF KENTUCKY

Environmental Health and Safety
Radiation Safety Office
102 Animal Pathology Buildi
Lexington, KY 40546-0076
Phone: (859) 323-6777
Fax: (859) 323-4752

January 10, 2018

Gerald Schlenker, C.H.P., R.R.P.T.
University of Kentucky
UK Radiation Safety Office
102 Animal Pathology
Lexington, KY 40506-0076

To whom it may concern,

This letter is to confirm that Mahesh R. Kudrimoti, M.D.is an approved authorized user at the University of Kentucky on a broad scope type A medical license # 202-049-22. Dr. Kudrimoti was approved as an AU by the UK RSC July 2005 and has been at UK continuously to date.
Dr. Kudrimoti is an approved AU for the following uses:

1. 902 KAR 100:072, Section 37 (10 CFR 35.400) Use of sources for manual brachytherapy.
2. 902 KAR 100:072, Section 46 (10 CFR 35.600) Use of sealed sources in a remote afterloader. (Varian Oncology Varisource IX HDR remote afterloading brachytherapy unit. Ir-192)
3. 902 KAR 100:072, Section 33 (10 CFR 35.396) Parenteral administration of any other radionuclide for which a written directive is required. (Such as but not limited to Sm-153, Ra-223 and Y-90).

If you should have any other questions concerning Dr. Kudrimoti's authorization please feel free to contact me.

Gerald Schlenker

Gerald Schlenker

Gerald Schlenker, C.H.P., R.R.P.T.
UK Radiation Safety Officer
University of Kentucky
UK Radiation Safety Office
102 Animal Pathology
Lexington, KY 40506-0076
OFFICE: (859) 323-6308
FAX: (859) 323-4752
CELL: (859) 699-6084
e-mail: glschl1@email.uky.edu

NRC FORM 313A (AUT) (06-2016)

U.S. 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: 06/30/2019

Name of Proposed Authorized User	State or Territory Where Licensed
Jason Matthew Edwards	Missouri

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

☐ 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.

☐ 1. **Board Certification**

a. Provide a copy of the board certification.

b. For 35.390, provide documentation on supervised clinical case experience. The table in section 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.

☐ 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 uses 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) (06-2016) U.S. 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 ☐ 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 Kentucky Dept. of Radiation medicine Lexington, KY	300	07/20/2013 to 04/10/2017
Radiation protection	University of Kentucky Dept. of Radiation medicine Lexington, KY	80	07/20/2013 to 04/10/2017
Mathematics pertaining to the use and measurement of radioactivity	University of Kentucky Dept. of Radiation medicine Lexington, KY	60	07/20/2013 to 04/10/2017
Chemistry of byproduct material for medical use	University of Kentucky Dept. of Radiation medicine Lexington, KY	60	07/20/2013 to 04/10/2017
Radiation biology	University of Kentucky Dept. of Radiation medicine Lexington, KY	300	07/20/2013 to 04/10/2017
	Total Hours of Training: 800		

b. Supervised Work Experience ☐ 35.390 ☑ 35.392 ☑ 35.394 ☑ 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Supervised Work Experience	**Total Hours of Experience:** 300		
Description of Experience Must Include:	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 Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017
Calculating, measuring, and safely preparing patient or human research subject dosages	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017

NRC FORM 313A (AUT)
(06-2016)

U.S. 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
Mahesh Kudrimoti M.D.	License number: 202-049-22

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

- ☐ 35.390
- ☐ 35.392
- ☐ 35.394
- ☑ 35.396

With experience administering dosages of:

- ☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☑ 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)		University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)		University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	
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	5	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	8-9-2013 5-21-2014 6-25-2014 8-5-2014 8-/7/15
Parenteral administration of any other radionuclide for which a written directive is required Radium 223 (List radionuclides)	3	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	03/04/2014 03/07/2014 03/14/2014

NRC FORM 313A (AUT)
(06-2016)

U.S. NUCLEAR REGULATORY COMMISSION

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
Mahesh Kudrimoti M.D.	License number: 202-049-22

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

	With experience administering dosages of:
☐ 35.390	☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ 35.392	☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ 35.394	☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
☑ 35.396	☑ 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.

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

☐ 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

☑ I attest that Jason M. Edwards M.D. 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)
(06-2016)

U.S. 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):

☑ I attest that Jason M. Edwards M.D. 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 35.392(c)(2).

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

☑ I attest that Jason M. Edwards M.D. has satisfactorily completed the 80 hours of classroom
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

☑ I attest that Jason M. Edwards M.D. has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

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

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☑ I attest that Jason M. Edwards M.D. has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

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

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

NRC FORM 313A (AUT) (06-2016) U.S. 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:

☐ 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 any 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:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), 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 any 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:

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

☐ 35.390 ☐ 35.392 ☐ 35.394 ☑ 35.396

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

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

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
Mahesh Kudrimoti M.D.		859-323-1144	1/18/2018

License/Permit Number/Facility Name

University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22

NRC FORM 313A (AUT) (06-2016)

U.S. 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: 06/30/2019

Name of Proposed Authorized User	State or Territory Where Licensed
Jason Matthew Edwards	Missouri

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

- ☐ 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.

☐ 1. **Board Certification**

a. Provide a copy of the board certification.

b. For 35.390, provide documentation on supervised clinical case experience. The table in section 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.

☐ 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 uses 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) (06-2016) U.S. 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 ☐ 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 Kentucky Dept. of Radiation medicine Lexington, KY	300	07/20/2013 to 04/10/2017
Radiation protection	University of Kentucky Dept. of Radiation medicine Lexington, KY	80	07/20/2013 to 04/10/2017
Mathematics pertaining to the use and measurement of radioactivity	University of Kentucky Dept. of Radiation medicine Lexington, KY	60	07/20/2013 to 04/10/2017
Chemistry of byproduct material for medical use	University of Kentucky Dept. of Radiation medicine Lexington, KY	60	07/20/2013 to 04/10/2017
Radiation biology	University of Kentucky Dept. of Radiation medicine Lexington, KY	300	07/20/2013 to 04/10/2017
	Total Hours of Training: 800		

b. Supervised Work Experience ☐ 35.390 ☑ 35.392 ☑ 35.394 ☐ 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Supervised Work Experience	**Total Hours of Experience:**		300
Description of Experience Must Include:	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 Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017
Calculating, measuring, and safely preparing patient or human research subject dosages	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Kentucky Dept. of Radiation medicine Lexington, KY. License number: 202-049-22	☑ Yes ☐ No	07/20/2013 to 04/10/2017

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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
David Butler M.D.	24-01570-03

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

- ☐ 35.390
- ☑ 35.392
- ☑ 35.394
- ☐ 35.396

With experience administering dosages of:

- ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ 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	St. Luke's Hospital Dept. of Radiation Oncology	7/10/17 7/14/17 8/11/17 9/28/17 12/1/17
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	5	St. Luke's Hospital Dept. of Radiation Oncology	7/20/17 8/21/17 9/7/17 9/29/17 11/6/17
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			
Parenteral administration of any other radionuclide for which a written directive is required (List radionuclides)			

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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
David Butler M.D.	License number: 24-01570-03

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

	With experience administering dosages of:
☐ 35.390	☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☑ 35.392	☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☑ 35.394	☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
☐ 35.396	☐ 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.

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

☐ 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

☐ I attest that _____ 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).

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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):

☑ I attest that Jason M. Edwards M.D. (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

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

☑ I attest that Jason M. Edwards M.D. (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom 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

☑ I attest that Jason M. Edwards M.D. (Name of Proposed Authorized User) has satisfactorily completed the required clinical case experience required in 35.390(b)(1)(ii)G listed below:

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

Third Section

☑ I attest that Jason M. Edwards M.D. (Name of Proposed Authorized User) has satisfactorily achieved a level of competency to function independently as an authorized user for:

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

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ 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 any 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:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), 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 any 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:

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

☐ 35.390 ☑ 35.392 ☑ 35.394 ☐ 35.396

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

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

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
David Butler M.D.		3145424998	01-30-2018

License/Permit Number/Facility Name
St. Luke's Hospital License number: 24-01570-03