**Sibley Memorial Hospital**
5255 Loughboro Road, N.W.
Washington, D.C. 20016-2695
202-537-4000 T

Branch 1

SIBLEY MEMORIAL HOSPITAL
JOHNS HOPKINS MEDICINE

February 3, 2012
Imaging Department
Sibley Memorial Hospital
5255 Loughboro Rd. NW
Washington, D.C. 20016

Janice E. Nguyen
Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RECEIVED
REGION 1
2012 FEB -6 AM 9:28

RE: Licensed Amendment Request
Sibley Memorial Hospital
NRC-08-07398-03

03014754

Mrs. Nguyen:

Please amend the above reference license to delete Mark Wolfman, M.D. as an Authorized User of byproduct materials permitted by 10CFR 35.100, 35.200 and 35.300. In addition, please add Dr. Bryan DeFranco as an Authorized User of byproduct materials permitted by 10CFR 35.100, 35.200 and 35.300. Dr. DeFranco's medical license, NRC form 313A, and his Maryland radioactive materials license are enclosed. Also, please delete Youssef Charara, Ph.D. as an Authorized Medical Physicist.

Please see attached item #5 request for addition of I-125 brachytherapy sources.

If there are any questions or additional information is needed, please contact Jordie Keck, RSO at 202-243-5165 or Michelle Loscocco, Health Physics Consultant, Krueger-Gilbert Health Physics, Inc. at (410) 692-9806

Sincerely,

Robert L. Sloan, President and C.E.O.

571913

NMSS/RGN1 MATERIALS-002

**Sibley Memorial Hospital**
5255 Loughboro Road, N.W.
Washington, D.C. 20016-2695
202-537-4000 T

SIBLEY MEMORIAL HOSPITAL
JOHNS HOPKINS MEDICINE



## ITEM # 5 Radioactive Material Request

| | | |
|---|---|---|
| Byproduct material permitted by 10 CFR 35.400 | Sealed Sources (Isoaid Advantage I-125 Model IAI-125A interstitial seeds for eye plaques) | 5 curies |

**NRC FORM 313** (1-2012) 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: (03/31/2012)**

Estimated burden per response to comply with this mandatory collection request: 4.3 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 Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@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:**

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
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
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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

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

- ☐ A. NEW LICENSE
- ☑ B. AMENDMENT TO LICENSE NUMBER 08-07398-03
- ☐ C. RENEWAL OF LICENSE NUMBER

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

Sibley Memorial Hospital
5255 Loughboro Road, N.W.
Washington, DC 20016

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Sibley Memorial Hospital
5255 Loughboro Road, N.W.
Washington, DC 20016

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Jordie Keck

TELEPHONE NUMBER

(202) 243-5165

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMAT ION 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. maiximum 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 CONTANED 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 C RIMINAL 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 |
|---|---|---|
| Robert L. Sloan, President and C.E.O. | | |

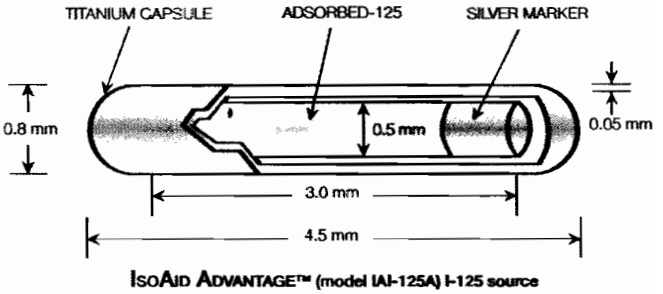
**FOR NRC USE ONLY**

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED $ | CHECK NUMBER | COMMENTS |
|---|---|---|---|---|---|
| | | | | | |

| APPROVED BY | DATE |
|---|---|
| | |

## Dosimetry Parameters

The dosimetric characteristics of IsoAid ADVANTAGE™ (model IAI-125A) I-125 source have been determined according to the Updated AAPM Task Group 43 (TG43U1) recommendations[1]. The values presented here are based on AAPM-approved consensus datasets[2].




ISOAID ADVANTAGE™ (model IAI-125A) I-125 source

### Consensus dose rate constant value[2]

**Dose Rate Constant** $_{con}\Lambda$

**0.981 cGy/h/U**

### AAPM Consensus line source approximation radial dose function ($g_L(r)$) and point source approximation radial dose function ($g_P(r)$)[2]

| Distance | Radial Dose Function | |
|---|---|---|
| (cm) | $g_L(r)$ | $g_P(r)$ |
| 0.0 | 1.040 | 0.686 |
| 0.10 | 1.040 | 0.686 |
| 0.15 | 1.053 | 0.833 |
| 0.25 | 1.066 | 0.967 |
| 0.50 | 1.080 | 1.056 |
| 0.75 | 1.035 | 1.029 |
| 1.00 | 1.000 | 1.000 |
| 1.50 | 0.902 | 0.906 |
| 2.00 | 0.800 | 0.804 |
| 3.00 | 0.611 | 0.615 |
| 4.00 | 0.468 | 0.471 |
| 5.00 | 0.368 | 0.371 |
| 6.00 | 0.294 | 0.296 |
| 7.00 | 0.227 | 0.229 |
| 8.00 | 0.165 | 0.166 |
| 9.00 | 0.141 | 0.142 |
| 10.00 | 0.090 | 0.091 |

NOTE: g( r ) at 0.0cm equals g($r_{min}$) as recommended by AAPM Task Group No. 43U1 Report

### AAPM consensus 2D and 1D Anisotropy Functions[2]

| Angle θ | 2D Anisotropy Function, F(r,θ) | | | | | |
|---|---|---|---|---|---|---|
| (Degree) | 0.5cm | 1.0cm | 2.0cm | 3.0cm | 5.0cm | 7.0cm |
| 0 | 0.352 | 0.406 | 0.493 | 0.520 | 0.578 | 0.612 |
| 5 | 0.411 | 0.465 | 0.545 | 0.584 | 0.658 | 0.701 |
| 10 | 0.481 | 0.527 | 0.601 | 0.642 | 0.704 | 0.726 |
| 20 | 0.699 | 0.719 | 0.757 | 0.775 | 0.794 | 0.799 |
| 30 | 0.848 | 0.846 | 0.862 | 0.862 | 0.869 | 0.879 |
| 40 | 0.948 | 0.936 | 0.932 | 0.916 | 0.937 | 0.969 |
| 50 | 1.002 | 0.986 | 0.974 | 0.961 | 0.963 | 0.971 |
| 60 | 1.029 | 1.024 | 1.008 | 0.993 | 0.990 | 1.001 |
| 70 | 1.029 | 1.039 | 1.027 | 1.006 | 1.016 | 1.010 |
| 80 | 0.999 | 1.025 | 1.024 | 1.023 | 1.009 | 1.025 |
| 90 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 |
| $\phi_{an}(r)$ | 0.957 | 0.968 | 0.964 | 0.955 | 0.959 | 0.955 |

### Polynomial Equation

$$g_L(r) = a_0 + a_1 r + a_2 r^2 + a_3 r^3 + a_4 r^4 + a_5 r^5$$

Where:

$a_0$ = 1.0549E+0 $a_1$ = 5.8111E-2

$a_2$ = -1.5048E-1 $a_3$ = 3.7413E-2

$a_4$ = -3.7008E-3 $a_5$ = 1.3103E-4

References

1. M.J. Rivard, B.M. Coursey, L.A. DeWerd, W.F. Hanson, M.S. Huq, G.S. Ibbott, M.G. Mitch, R. Nath, J.F. Williamson, "Update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachy-therapy dose calculations," Med Phys. 31(3) (2004) 633-674.
2. M.J. Rivard, W.M. Buttler, L.A. DeWerd, M.S. Huq, G.S. Ibbott, A.S. Meigooni, C.S. Melhu s, M.G. Mitch, R. Nath, J.F. Williamson. "Supplement to the 2004 update of the AAPM Task Group No. 43 Report," Med. Phys. 34(6) 2187-2205.

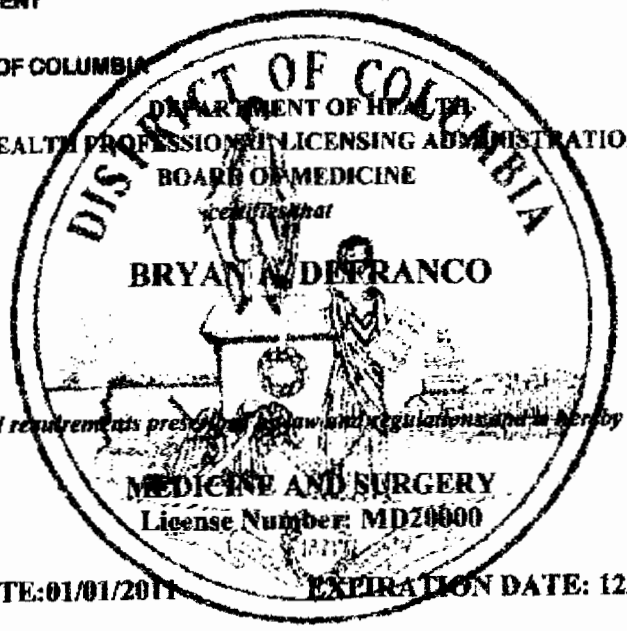
**IsoAid** · 7824 Clark Moody Boulevard, Port Richey, FL 34668 · (866) 710-5995
www.isoaid.com · email: seeds@isoaid.com

★★★ GOVERNMENT
OF THE
DISTRICT OF COLUMBIA

DEPARTMENT OF HEALTH
HEALTH PROFESSIONAL LICENSING ADMINISTRATION
BOARD OF MEDICINE

*certifies that*

**BRYAN A DEFRANCO**




*has met all requirements prescribed by law and regulations and is hereby licensed as a(n):*

**MEDICINE AND SURGERY**
**License Number: MD20000**

**ISSUE DATE:01/01/2011** **EXPIRATION DATE: 12/31/2012**

*Director, Department of Health*

Janis M. Orlowski MD

Janis Orlowski, MD

NRC FORM 313A (AUT) (3-2009) 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: 3/31/2012

| Name of Proposed Authorized User | State or Territory Where Licensed |
|---|---|
| Bryan Anthony DeFranco, M.D. | Maryland |

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) (3-2009) 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 | | | |
| Radiation protection | | | |
| Mathematics pertaining to the use and measurement of radioactivity | | | |
| Chemistry of byproduct material for medical use | | | |
| Radiation biology | | | |
| **Total Hours of Training:** | | | |

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:** | | |
|---|---|---|---|
| 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 | | ☐ Yes ☐ No | |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | | ☐ Yes ☐ No | |
| Calculating, measuring, and safely preparing patient or human research subject dosages | | ☐ Yes ☐ No | |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | | ☐ Yes ☐ No | |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | | ☐ Yes ☐ No | |

NRC FORM 313A (AUT) (3-2009) 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 |
|---|---|
| | |

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) | 3 cases | Suburban Hospital / MD-31-002-01 | August 2008 - June 2011 |
| Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) | 3 cases | Suburban Hospital / MD-31-002-01 | August 2008 - June 2011 |
| 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<br>_____<br>(List radionuclides) | | | |

NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION
(3-2009)

**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 |
|---|---|
| Mark G. Wolfman, M.D. | MD-31-002-01 |

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

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

NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION
(3-2009)

**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 **Bryan Anthony DeFranco** (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 **Bryan Anthony DeFranco** (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 **Bryan Anthony DeFranco** (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 **Bryan Anthony DeFranco** (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

NRC FORM 313A (AUT) (3-2006) 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 |
|---|---|---|---|
| Mark G. Wolfman, M.D. | | (301) 896-2075 | 7/29/11 |

License/Permit Number/Facility Name
MD-31-002-01/Suburban Hospital

**MARYLAND DEPARTMENT OF THE ENVIRONMENT**
1800 Washington Boulevard • Baltimore MD 21230
410-537-3000 • 1-800-633-6101• www.mde.state.md.us

Martin O'Malley
Governor

Anthony G. Brown
Lieutenant Governor

Robert M. Summers, Ph.D.
Secretary

DEC 5 2011

Bryan A. DeFranco, M.D., Radiation Safety Officer
Suburban Hospital
8600 Old Georgetown Road
Bethesda, MD 210814

**RE: Radioactive Material License #MD-31-002-01**

Dear Dr. DeFranco:

Your requested amendment to radioactive materials license number MD-31-002-01 is enclosed. Please review it carefully to ensure that it reflects all modifications included in your letter received in this office on October 26, 2011.

Should you require further assistance, please contact Mr. Raymond E. Manley at (410) 537-3301. You may also reach our office toll-free by dialing 1-800-633-6101 and requesting extension 3301. Also, you may contact this office via facsimile at 410-537-3198.

Sincerely,

Roland G. Fletcher, Manager IV
Radiological Health Program
Air and Radiation Management Administration

RGF/BJW/DKM/cc

Enclosure(s): License amendment (60)
Code (02120)

MARYLAND
Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE



Pursuant to the Maryland Radiation Act, 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 radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. The license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below.

| | | | |
|---|---|---|---|
| 1. Name: | Suburban Hospital | 3. License No.: | MD-31-002-01 |
| 2. Address: | 8600 Old Georgetown Road<br>Bethesda, Maryland 20814 | 4. Amendment No.: | 60 Code 02120 |
| | | 5. Expiration Date: | September 30, 2016 |

| 6. Radioactive material (element and mass number) | 7. Chemical and/or physical form | 8. Maximum amount of activity which licensee may possess at any one time |
|---|---|---|
| A. Any radioactive material listed in Section G.100 of COMAR 26.12.01.01 | A. Any radioactive material listed in Section G.100 of COMAR 26.12.01.01 | A. As needed to perform diagnostic tests |
| B. Any radioactive material listed in Section G.200 of COMAR 26.12.01.01 | B. Any radioactive material listed in Section G.200 of COMAR 26.12.01.01 | B. As needed to perform diagnostic tests |
| C. Any radioactive material listed in Section G.300 of COMAR 26.12.01.01 | C. Any radioactive material listed in Section G.300 of COMAR 26.12.01.01 | C. 3000 millicuries |
| D. Xenon-133 | D. Gas | D. 600 millicuries |
| E. Cobalt-57 | E. Sealed Source | E. No source to exceed 15 millicuries |

9. Authorized Use(s):
   A. Any uptake, dilution, and excretion procedure approved in Section G.100 of COMAR 26.12.01.01.
   B. Any imaging and localization procedure approved in Section G.200 of COMAR 26.12.01.01.
   C. Any radiopharmaceutical therapy procedure approved in Section G.300 of COMAR 26.12.01.01.
   D. Lung studies
   E. Reference, calibration and quality control.

10. The authorized place of use is the licensee's address stated in Item 2. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address.

MARYLAND
Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE



License Number: MD-31-002-01 | Amendment Number: 60

CONDITIONS

11A. The radiation protection program shall be under the supervision of Bryan A DeFranco, M.D.

11B. Radioactive material shall be used by, or under the supervision of:

| Authorized User | Items of Use |
|---|---|
| Mark Wolfman, M.D. | Items 6A, 6B, 6D, 6E. |
| Bradley Dick, M.D. | Items 6A, 6B, 6D, 6E. |
| Laura Beth Eisenberg, M.D. | Items 6A, 6B, 6D, 6E. |
| A. Hanna Kim, M.D. | Items 6A, 6B, 6D, 6E. |
| Paul D. Radecki, M.D. | Items 6A, 6B, 6D, 6E. |
| Janet Marie Storella, M.D. | Items 6A, 6B, 6D, 6E. |
| Stephen Adam Fine, M.D. | Items 6A, 6B, 6D, 6E. |
| Douglas Allen Jones, M.D. | Items 6A, 6B, 6D, 6E. |
| Harry Bingham, M.D. | Items 6A, 6B, 6E. |
| M. Hafeez Chaudry, M.D. | Items 6A, 6B, 6E. |
| Daniel Goldberg, M.D. | Items 6A, 6B, 6E. |
| Martin Kavansky, M.D. | Items 6A, 6B, 6E. |
| Lewis Lepson, M.D. | Items 6A, 6B, 6E. |
| Mark Milner, M.D. | Items 6A, 6B, 6E. |
| William Tullner, M.D. | Items 6A, 6B, 6E. |
| Daniel Woronow, M.D. | Items 6A, 6B, 6E. |
| Bryan A DeFranco, M.D. | Items 6A, 6B, 6C 6D, 6E |
| Brian G. Johnson, M.D. | Items 6A, 6B, 6D, 6E |
| Christopher P. Rothstein, M.D. | Items 6A, 6B, 6D, 6E |
| Julia J. Muskie, M.D. | Items 6A, 6B, 6D, 6E |
| Alan Kronthal, M.D. | Items 6A, 6B, 6D, 6E |
| Richard D. Newman, M.D. | Items 6A, 6B, 6D, 6E |

12. The licensee shall comply with all appropriate provisions of COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation," and shall possess a copy of these regulations.

13A. Each sealed source containing radioactive material, other than Hydrogen-3 with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.

13B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of a device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate.

13C. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.

MARYLAND
Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE



| License Number: MD-31-002-01 | Amendment Number: 60 |
|---|---|

CONDITIONS

13D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Administrator, Radiological Health Program, 1800 Washington Boulevard, Suite 750, Baltimore, Maryland 21230, describing the equipment involved, the test results, and the corrective action taken.

13E. Test for leakage and/or contamination shall be performed by Krueger Gilbert Health Physics Inc.or by other persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission or another Agreement State to perform such services.

13F. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

13G. Except for alpha sources, the periodic leak test required by this condition 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 tested within six months prior to the date of use or transfer.

14. Sealed sources containing radioactive material shall not be opened.

15. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for three (3) years from the date of the inventory for inspection by the Department, and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.

16. The licensee may use the Calicheck or Lineator device for doing linearity tests of his dose calibrator provided he follows the procedures in the respective manual.

17. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

18A. The licensee shall perform a test to detect and quantify the activity of molybdenum-99 contamination in each elution of technetium-99m from a molybdenum-99/technetium-99m generator and in each extraction or separation of technetium-99m from molybdenum-99 not contained in a generator.

18B. The licensee shall not use technetium-99m for human use that contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m. The limit for molybdenum-99 contamination represents a maximum value and molybdenum-99 contamination should be kept as low as reasonably achievable below this limit.

18C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limit specified in Item 18B. above are detected.

MARYLAND
Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE



| License Number: MD-31-002-01 | Amendment Number: 60 |
|---|---|

CONDITIONS

18D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

(1) The licensee shall maintain for inspection by the Department records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

(2) Records described in Sub item (1) above shall be maintained for three (3) years following the performance of the tests and the training of personnel.

19. The licensee shall not transfer ownership and/or control of this license to any person or entity without providing required information regarding the transfer for the Agency's review and without receiving written authorization for the transfer by the Agency.

20. Food and beverage containers shall not be discarded in radioactive or normal trash containers in licensee's areas utilizing radioactive materials.

21A. The licensee shall not make any false statement, representation, or certification in any application, record, report, plan, or other document regarding radiation levels, tests performed or radiation safety conditions or practices. Additionally, the licensee shall not falsify, tamper with, or render inaccurate any monitoring device or method.

21B. Violation of any term, condition, or regulation could subject the licensee to administrative or civil penalty or criminal prosecution, as specified in Title 8, Radiation, of the Article Environment of the Annotated Code of Maryland.

MARYLAND
Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE



| License Number: MD-31-002-01 | Amendment Number: 60 |
|---|---|

CONDITIONS

22. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements representations, and procedures contained in:

- Application letter with attachments dated August 28, 2009;
- Letter dated August 1, 2011, with attachments, requesting the addition of Bryan A DeFranco, M.D. as an authorized user, the removal of Wayne Jeffery Olan, M.D. and Michelle Therese Kladakis, M.D. as authorized users and the replacement of Mark Wolfman, M.D. as Radiation Safety Officer with Bryan A DeFranco, M.D.
- Letter with attachments dated August 26, 2011, adding Brian G. Johnson, M.D., Christopher P. Rothstein, M.D., Julia J. Muskie, M.D., Alan Kronthal, M.D., and Richard D. Newman, M.D. as Authorized Users.
- **Letter dated October 25, 2011, with attachments, adding Bryan A DeFranco, M.D. as an authorized user of COMAR 26.12.01.01 § G.300 material.**

COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

Roland G. Fletcher, Manager IV
Radiological Health Program

October 27, 2011

DKM DM 10/27/11

11-30-11

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

02/03/2012, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (08-07398-03)

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

---

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 576913.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader