



**I-131**

## Patient Logs for Dr. Biju Daniel Kunjummen

#	Date	Indication	Dose (mCi)
1	6/16/2003	Graves disease	10
2	6/16/2003	hyperthyroid disease	10
3	6/25/2003	recurrent thyroid cancer	469
4	7/8/2003	hyperthyroid disease	18
5	7/15/2003	hyperthyroid disease	51
6	9/3/2003	hyperthyroid disease	14
7	10/17/2003	hyperthyroid disease	49
8	10/20/2003	thyroid cancer	103
9	12/17/2003	Graves disease	10
10	12/22/2003	multinodular goiter	31
11	12/26/2003	thyroid cancer	104
12	1/23/2004	Graves disease	17
13	3/15/2004	thyroid cancer	149
14	4/21/2004	multinodular goiter	28
15	5/7/2004	Graves disease	16
16	5/7/2004	Graves disease	17
17	5/24/2004	thyroid cancer	412
18	10/12/2004	thyroid cancer	154
19	10/5/2004	thyroid cancer	153
20	12/14/2004	thyroid cancer	250
21	12/27/2004	thyroid cancer	75
22	1/19/2005	thyroid cancer	180
23	1/19/2005	thyroid cancer	157
24	3/24/2005	thyroid cancer	150
25	4/1/2005	Graves disease	17
26	4/8/2005	thyroid cancer	150
27	4/8/2005	thyroid cancer	181
28	4/19/2005	thyroid cancer	203
29	4/27/2005	multinodular goiter	23
30	5/3/2005	thyroid cancer	200
31	5/9/2005	thyroid cancer	150
32	5/24/2005	thyroid cancer	101

**Sm-153 Quadramet**

1	5/12/2005	met. bone pain palliation	51
2	7/27/2005	met. bone pain palliation	65
3	8/19/2005	met. bone pain palliation	51
4	11/3/2005	met. bone pain palliation	115
5	6/9/2006	met. bone pain palliation	66

**Y-90 Zevalin**

1	7/27/2005	lymphoma	26
2	3/8/2006	lymphoma	20
3	3/14/2006	lymphoma	30
4	4/26/2006	lymphoma	27
5	5/31/2006	lymphoma	25

Health Physics and Radiation Safety Office

February 20, 2007

U. S. Nuclear Regulatory Commission  
Radioactive Material License Section  
475 Allendale Road  
King of Prussia, PA 19406

To Whom It May Concern:

This is to confirm that Dr. Christopher Palestro is an authorized user for Nuclear Medicine procedures at Long Island Jewish Medical Center under Radioactive Materials Broad License #75-2986-01 issued by the City of New York (Agreement State Equivalent), Department of Health since April 1992.

He is an authorized user for all applicable radiopharmaceuticals per 10 CFR 35.100, 35.200, 35.300 and meets the requirements per 10 CFR 35.190, 35.290 and 35.390.

If you have any questions, please do not hesitate to contact me at (718) 470-4680.

Sincerely,



J. Antony, MS, DABR, DABMP, CMLSO  
Radiation Safety Officer

JA/jb

Rso/memo/nucreg07

# *The American Board of Nuclear Medicine*

*Incorporated 1971*

*Certifies that*

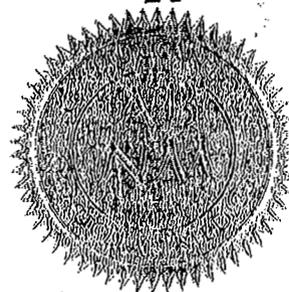
## *Biju Daniel Kunjummen*

*has met the requirements of this Board and is qualified  
during the period of 2006 through 2016 to practice as a Specialist  
in all aspects of Clinical and Laboratory*

## *Nuclear Medicine*

*including but not limited to Radiobioassay, Nuclear Imaging,  
In Vivo Measurements & Therapy with Unsealed Radionuclides*

  
*Chairman*



*07509*

*Number*

*United States*

  
*Secretary-Treasurer*

**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

Daniel Kunjummen

?

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.

**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.*

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			

**Total Hours of Supervised Work Experience:**

**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 With experience administering dosages of:
- 35.392 Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- 35.394 Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- 35.396 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)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
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)

**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

Christopher Palestro, M.D.

License/Permit Number listing supervising individual as an authorized user

N.Y.C. Dept. of Health 75-2986-01

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

- 35.390 With experience administering dosages of:
  - 35.392  Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
  - 35.394  Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
  - 35.396  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.

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.

**First Section**

Check one of the following for each requested authorization:

**For 35.390:**

**Board Certification**

I attest that Daniel Kunjummen has satisfactorily completed the training and experience requirements in 35.390(a)(1).  
Name of Proposed Authorized User

**OR**

**Training and Experience**

I attest that \_\_\_\_\_ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).  
Name of Proposed Authorized User

**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 \_\_\_\_\_ 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 \_\_\_\_\_ 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 Daniel Kunjummen 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 Daniel Kunjummen 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

**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 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

Christopher Palestro, MD

Signature

Telephone Number

(718) 470-4680

Date

1/17/07

License/Permit Number/Facility Name

Long Island Jewish Medical Center

N.Y.C. Dept. of Health

License # 75-2986-01

**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: Daniel Kunjummen State or Territory Where Licensed: )

Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 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.

**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.

**NA2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

- a. Authorized user on Materials License \_\_\_\_\_ 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			

**Total Hours of Experience:**

Supervising Individual \_\_\_\_\_ License/Permit Number listing supervising individual as an authorized user \_\_\_\_\_

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

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

**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	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 <i>(not required for 35.590)</i>			
Radiation biology			
<b>Total Hours of Training:</b>			

**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.)**

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

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

**b. Supervised Work Experience. (continued)**

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			
Administering dosages of radioactive drugs to patients or human research subjects			
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			

**Total Hours of Experience:**

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

35.190

35.290

35.390

35.390 + generator experience in 35.290(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**

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

**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)

**First Section**

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that Daniel Kunjummen 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

I attest that Daniel Kunjummen 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  
Name of Proposed Authorized User

and 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:

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

- 35.190
- 35.290
- 35.390
- 35.390 + generator experience

Name of Preceptor

Christopher Palestro, MD

Signature

Telephone Number

(718) 470-4680

Date

1/17/07

License/Permit Number/Facility Name

Long Island Jewish Medical Center

N.Y.C. Dept. of Health  
License # 75-2986-01

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

3/2/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 29-15459-01 / 29-17925-01 / 29-12167-01  
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 140218 / 140219  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260. 140220

NRC FORM 532 (RI)  
(6-98)

Sincerely,  
Licensing Assistance Team Leader