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Meridian Health System
_ Radiation Oncology Dept.
Riverview Medical Center
One Riverview Plaza
Red Bank, NJ
07747
Phone: 732-530-2468
Fax : 732-345-2010

29-09701-01
03002522

Fax

To: Shirley Control # 140-741 From: Keunchul Lee

Fax: 610-337-5269 Pages: (including cover)

Phone: Date: 8/17/07

Re.: cc: Shirley

Urgent For Review Please Comment Please Reply Please Recycle

Dear Shirley
 these are the document Forms 313A (AUS) and
 313A (AUT) for Dr. Danish to obtain
 his license. If you need more information,
 please send me e-mail or call me.

Keunchul Lee



| | | |
|--|------------------------------------|---|
| NRC FORM 313A (AUS) (3-2007) | U.S. NUCLEAR REGULATORY COMMISSION | APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008 |
| AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690] | | |

| | |
|---|--|
| Name of Proposed Authorized User <i>Adnan F. Danish, MD.</i> | State or Territory Where Licensed <i>New Jersey</i> |
|---|--|

Requested Authorization(s) (check all that apply)

35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)
 35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s)
 35.600 Remote afterloader unit(s)

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. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
 - c. Skip to and complete Part II Preceptor Attestation.
- 2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**
 - a. Go to the table in section 3.e. to document training for new device.
 - b. Skip to and complete Part II Preceptor Attestation.
- 3. Training and Experience for Proposed Authorized User**
 - a. Classroom and Laboratory Training 35.490 35.491 35.690

| 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 | | | |
| Radiation biology | | | |

Total Hours of Training:

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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 and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

| Supervised Work Experience | | Total Hours of Experience: | |
|--|---|---|----------------------|
| 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 | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Checking survey meters for proper operation | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Preparing, implanting, and safely removing brachytherapy sources | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Maintaining running inventories of material on hand | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Using administrative controls to prevent a medical event involving the use of byproduct material | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Using emergency procedures to control byproduct material | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |

| Clinical experience in radiation oncology as part of an approved formal training program | Location of Experience/License or Permit Number of Facility | Dates of Experience* |
|--|--|----------------------|
| Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association | | |
| Supervising Individual | License/Permit Number listing supervising individual as an Authorized User | |

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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 Experience for 10 CFR 35.491

| Description of Experience | Location of Experience/License or Permit Number of Facility | Clock Hours | Dates of Experience* |
|---|---|--|----------------------|
| Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history | | | |
| Supervising Individual | | License/Permit Number listing supervising individual as an Authorized User | |

d. Supervised Work and Clinical Experience for 10 CFR 35.690

Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

| 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* |
| Reviewing full calibration measurements and periodic spot-checks | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Preparing treatment plans and calculating treatment doses and times | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Using administrative controls to prevent a medical event involving the use of byproduct material | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Checking and using survey meters | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Selecting the proper dose and how it is to be administered | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

| | | |
|--|---|--|
| Clinical experience in radiation oncology as part of an approved formal training program | Location of Experience/License or Permit Number of Facility | Dates of Experience* |
| Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association | | |
| Supervising Individual | | License/Permit Number listing supervising individual as an Authorized User |

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

| Description of Training | Training Provider and Dates | | |
|--------------------------------------|---------------------------------|-------------|---------------------------------|
| | Remote Afterloader | Teletherapy | Gamma Stereotactic Radiosurgery |
| Device operation | Montefiore Med Ctr Bronx, NY | | |
| Safety procedures for the device use | Montefiore Med Ctr Bronx, NY | | |
| Clinical use of the device | Montefiore Med Ctr Bronx, NY | | |

Supervising Individual. *If training provided by Supervising Individual (if more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)* License/Permit Number listing supervising individual as an Authorized User

Authorized for the following types of use:

- Remote afterloader unit(s)
 Teletherapy unit(s)
 Gamma stereotactic radiosurgery unit(s)

f. Provide completed Part II Preceptor Attestation.

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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.

First Section

Check one of the following for each requested authorization:

For 35.490:

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User
35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 200 hours of
Name of Proposed Authorized User
classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User
classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User
35.690(a)(1).

OR

Training and Experience

I attest that _____ has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User
and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

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Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

I attest that [Name of Proposed Authorized User] has received training required in 35.690(c) for device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

I attest that [Name of Proposed Authorized User] has achieved a level of competency sufficient to achieve a level of competency sufficient to function independently as an authorized user for:

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

- I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for: 35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s) 35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s) 35.600 Remote afterloader unit(s)

Name of Preceptor: Nathan Kaufman MD Signature: [Handwritten Signature] Telephone Number: (732) 836-4109 Date: 8/17/07

License/Permit Number/Facility Name: License # 29-09701-01

| | | |
|---|------------------------------------|---|
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| 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] | | |

| | |
|--|--|
| Name of Proposed Authorized User Adnan F. Danish, M.D. | State or Territory Where Licensed New Jersey |
|--|--|

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.

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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 | <i>Montefiore Med Ctr Bronx, NY</i> | | <i>6/2002 - 6/2006</i> |
| Total Hours of Training: <i>Bronx, NY</i> | | | |

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

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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 |
|------------------------|--|

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) | 3 | Montefiore Med Ctr Bronx, NY | 6/2005 - 6/2006 |
| Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required | 3 | Pravera Med Ctr Memorial Sloan Kettering | 6/2006 - 6/2007 |
| Parenteral administration of any other radionuclide for which a written directive is required | | | |
| (List radionuclides) | | | |

NRC FORM 313A (AUT) (3-2007) 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. 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 Adnan Danish 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

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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 _____ 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 _____ 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 _____ 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

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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 <i>Nathan Kaufman M.D.</i> | Signature <i>Nathan Kaufman</i> | Telephone Number <i>(732) 836-4109</i> | Date <i>8/17/07</i> |
| License/Permit Number/Facility Name <i>License # 29-09701201</i> | | | |