



ST. MARY'S MEDICAL CENTER

2900 First Avenue • Huntington, WV 25702
304-526-1234 • www.st-marys.org

NMSBL

July 12, 2007

U.S. Nuclear Regulatory Commission
Materials Licensing Branch, Region II
Sam Nunn Atlanta Federal Center
61 Forsyth Street, S.W. Suite 23T85
Atlanta, GA 30303-8931

03003388

Re: Amendment of License 47-09576-01 to add Abid Yaqub, M.D. for therapeutic use of radiopharmaceuticals and to designate M. Douglass Allan, M.S., DABR as Radiation Safety Officer

Dear Reviewer:

The Radiation Safety Committee at St. Mary's Medical Center approved the request by Dr. Abid Yaqub to be added to the NRC license for therapeutic use of radiopharmaceuticals.

Documentation of his credentials is enclosed for your review.

We request amendment of License 47-09576-01 to add him as an Authorized User.

The Committee also approved and requests designation of Martin Douglass Allan, M.S., DABR as Radiation Safety Officer once again. He had been replaced briefly by Michael Bidy as RSO, but Mr. Bidy has left. Mr. Allan's credentials are already on file with you as he served as RSO for over 20 years.

Any questions regarding this request should be directed to M. Douglass Allan, M.S., DABR (RSO) or to me.

Sincerely,

Ruth Johnson, BSN, MBA
Vice President of Patient Services

140853

NMSS/RGN1 MATERIALS-002

REC'D IN LAT JUL 24 2007



Joan C. Edwards School of Medicine
Department of Medicine
1600 Medical Center Drive, Suite G500
Huntington, WV 25701-3655
(304) 691-1050

June 1, 2007

Credentials Committee
St. Mary's Medical Center
2900 First Avenue
Huntington, WV 25702

Dear Credentials Committee:

I want to apply for provision of privileges to be able to treat patients with hyperthyroidism and thyroid cancer with radioactive iodine (RAI-131) at your facility. I have completed endocrinology fellowship from JCESOM, Marshall University, Huntington, WV (date of graduation 06-30-06) and I am currently working there as an Assistant Professor of Medicine and Associate Director of endocrinology fellowship program.

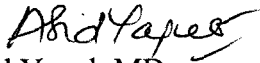
I have completed 100 hours of the basic radioisotope handling course covering the topics of radio pharmacy, radiation biology, radiation protection and safety, radiation physics and instrumentation, and the mathematics associated with use of radioactivity and received a passing grade. This course which was held from May 12-20, 2007 (Consultants in Nuclear Medicine, Chicago, IL) is designed to qualify a physician as an authorized user of radiopharmaceuticals, including the medical use of sodium iodide I-131 for procedures requiring a written directive. It meets all the requirements set forth by the US Nuclear regulatory Commission and all the agreement states as outlined in the current code of federal regulations.

In addition to the above, I have the experience of treating more than the required number of patients with hyperthyroidism and thyroid cancer under the supervision of Dr. Bruce Chertow, a NRC licensed user of radioactive iodine I-131 at Cabell Huntington Hospital and St. Mary's Medical Center. During my endocrinology fellowship I also had the following experience under supervision of Dr. Chertow: 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 byproduct material; and using procedures to contain spilled byproduct material safely and using proper decontamination procedures.

I am currently involved in clinical care of more than 40 patients with thyroid cancer and many patients with hyperthyroidism including those with Graves' disease and toxic uni-nodular and multi-nodular goiters.

I appreciate your kind consideration of my application. Please let me know if any additional information or documentation is required.

Yours sincerely,




Abid Yaquub MD
Assistant Professor of Medicine
Section of Endocrinology
JCESOM, Marshall University
Huntington, WV

Dear Credentials Committee:

The endocrinology training program for fellows is structured to provide didactic lectures and conferences and experience and training in the appropriate use of RAI 131 and 123 for diagnostic and radiotherapy for hyperthyroidism and thyroid cancer.

I attest to the above mentioned experiences and training given to Dr. Abid Yaquub MD. He is an excellent physician and quite capable of performing radioactive I-131 and I-123 diagnostic scans for detection of thyroid cancer and administering I-131 radiotherapy and caring for patients with hyperthyroidism and thyroid cancer.

Sincerely yours,



Bruce Chertow, M.D, F.A.C.P., F.A.C.E.
Professor and Chief
Section of Endocrinology

**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

ABID Yaqub

State or Territory Where Licensed

WEST VIRGINIA

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**

- Provide a copy of the board certification.
- For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.
- 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.
- Skip to and complete Part II Preceptor Attestation.

☐ **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

- 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

- 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.
- 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 Usera. 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 | DOWNERS GROVE, IL | 15 | 05-12-07 to 05-20-07 |
| Radiation protection | DOWNERS GROVE, IL | 30 | 05-12-07 to 05-20-07 |
| Mathematics pertaining to the use and measurement of radioactivity | DOWNERS GROVE, IL | 10 | 05-12-07 to 05-20-07 |
| Chemistry of byproduct material for medical use | DOWNERS GROVE, IL | 25 | 05-12-07 to 05-20-07 |
| Radiation biology | DOWNERS GROVE, IL | 20 | 05-12-07 to 05-20-07 |
| Total Hours of Training: 100 hours | | | |

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: 64 hours | |
|--|---|--|----------------------------|
| 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 | Cabell Huntington Hospital, Huntington, WV # 47-00404-02 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 07-01-04 to 06-30-06 |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | Cabell Huntington Hospital, Huntington, WV # 47-00404-02 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 07-01-04 to 06-30-06 |
| Calculating, measuring, and safely preparing patient or human research subject dosages | Cabell Huntington Hospital, Huntington, WV # 47-00404-02 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 07-01-04 to 06-30-06 |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | Cabell Huntington Hospital, Huntington, WV # 47-00404-02 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 07-01-04 to 06-30-06 |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | Cabell Huntington Hospital, Huntington, WV # 47-00404-02 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 07-01-04 to 06-30-06 |

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 BRUCE CHERTOW, MD | License/Permit Number listing supervising individual as an authorized user # 47-00404-02 |
| Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**: | |
| <input checked="" type="checkbox"/> 35.390 | With experience administering dosages of: |
| <input checked="" type="checkbox"/> 35.392 | <input checked="" type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) |
| <input checked="" type="checkbox"/> 35.394 | <input checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) |
| <input type="checkbox"/> 35.396 | <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required |
| | <input checked="" type="checkbox"/> 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) | SIX | Cabell Huntington Hospital, Huntington, WV # 47-00404-02 | 07-01-04 to 06-30-06 |
| Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) | Eight | Cabell Huntington Hospital, Huntington, WV # 47-00404-02 St-Mary's Hospital, Huntington, 030-03388 WV | 07-01-04 to 06-30-06 |
| 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 <div style="font-family: cursive; font-size: 1.2em; margin-left: 40px;">BRUCE CHERTOW MD</div> | License/Permit Number listing supervising individual as an authorized user <div style="font-family: cursive; font-size: 1.2em; margin-left: 40px;"># 47-00404-02</div> |
| Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**: | |
| <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> 35.390 </div> <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> 35.392 </div> <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> 35.394 </div> <div style="display: flex; align-items: center;"> <input type="checkbox"/> 35.396 </div> | With experience administering dosages of: <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) </div> <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) </div> <div style="display: flex; align-items: center;"> <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required </div> <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive </div> |
| ** 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 _____ 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 ABID YAGUB MD 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 ABID YAGUB MD 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 ABID YAGUB MD 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 ABID YAGUB MD 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:

☐ 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

BRUCE CHERTOW MD

Signature

Bruce S Chertow MD

Telephone Number

304-691-1095

Date

05/31/07

License/Permit Number/Facility Name

*Consultants in Nuclear Medicine
2910 W. Estes Avenue
Chicago, IL 60645*

This certificate verifies that on May 20, 2007

Dr. Abid Yaqub

*completed 100 hours of the
Basic Radioisotope Handling Course,
covering the topics of*

*Radiopharmacy, Radiation Biology,
Radiation Protection, Radiation Physics and
Instrumentation, and the Mathematics Associated
with Use of Radioactivity*

*and received a passing grade. This course is designed to
qualify a physician as an authorized user of
radiopharmaceuticals, generators, and reagent kits and to
perform Radionuclide Therapy procedures, including
medical use of sodium iodide I-131 for procedures requiring
a written directive. It meets all requirements set forth by
the US Nuclear Regulatory Commission and all
Agreement States as outlined in the current Code of
Federal Regulations.*

Stephen M. Karish Ph.D.
Course Director

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

7/12/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 47-09576-01 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** 140853.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.