



CANCER INSTITUTE

Wayne State University

**McLAREN MACOMB
TED B. WAHBY CANCER CENTER**

Radiation Oncology
1080 Harrington Blvd
Mount Clemens, MI 48043

tel (586) 493 7510
fax (586) 493 7511

mclaren.org

February 27, 2019

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

RE: Amendment Request
License # 21-04080-01

Dear Sir/Madam:

We submit this application for an amendment to:

- A. Add Neal Bhatt, M.D. as Authorized User on the above License for medical use defined under 10 CFR 35.396 for Parenteral administration pursuant Training and Experience and Preceptor Attestation. Attached to this letter is NRC Form 313A(AUT) to reflect Dr. Bhatt's past and present training and experience with regard to administration of unsealed radionuclides. Dr. Bhatt is currently listed as an Authorized User on this license under 10 CFR 35.400 and 35.600.
- B. Please expedite this request due to patient care.
- C. Remove Carla Cook, M.D. as an Authorized User under 10 CFR 35.400 and 35.600.
- D. Remove Purshottam Sharma, M.S. as an Authorized Medical Physicist.

Please address all questions and concerns regarding this submission to Mark Yudelev, Ph.D., Chief Medical Physicist McLaren-Macomb, 586 493-7542.

Sincerely,



Arthur J. Frazier, M.D.
Radiation Safety Officer
Mount Clemens Regional Medical Center d/b/a McLaren-Macomb
1000 Harrington Blvd.
Mt. Clemens, MI 48043

Cc.: Tim Vargas, VP, COO, McLaren Macomb.



**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.300)
[10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

Name of Proposed Authorized User

State or Territory Where Licensed

Neal Bhatt, M.D.

Michigan

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 21-04080-01 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	University of Louisville Brown Cancer Center	150	07/2012 - 06/2016
Radiation protection	University of Louisville Brown Cancer Center	22	07/2012 - 06/2016
Mathematics pertaining to the use and measurement of radioactivity	University of Louisville Brown Cancer Center	24	07/2012 - 06/2016
Chemistry of byproduct material for medical use	University of Louisville Brown Cancer Center	20	07/2012 - 06/2016
Radiation biology	University of Louisville Brown Cancer Center	34	07/2012 - 06/2016

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	Mount Clemens Regional Medical Center d/b/a McLaren-Macomb 21-04080-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2016 - 12/2018
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Mount Clemens Regional Medical Center d/b/a McLaren-Macomb 21-04080-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2016 - 12/2018
Calculating, measuring, and safely preparing patient or human research subject dosages	Mount Clemens Regional Medical Center d/b/a McLaren-Macomb 21-04080-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2016 - 12/2018
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Mount Clemens Regional Medical Center d/b/a McLaren-Macomb 21-04080-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2016 - 12/2018
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Mount Clemens Regional Medical Center d/b/a McLaren-Macomb 21-04081-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2016 - 12/2018

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

Arthur Frazier, M.D.

21-04080-01

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.

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	>3 (Ra-223 and Sm-153)	Mount Clemens Regional Medical Center d/b/a McLaren-Macomb 21-04080-01	07/2016- 12/2018
Parenteral administration of any other radionuclide for which a written directive is required	>		
<div style="border: 1px solid black; width: 150px; height: 30px; margin: 0 auto;"></div> <p>(List radionuclides)</p>			

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

Arthur Frazier, M.D.

21-04080-01

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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.390:

Board Certification

I attest that _____ has satisfactorily completed the training and experience 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 Neal Bhatt, M.D. has satisfactorily completed the required clinical case
Name of Proposed Authorized User
experience required in 35.390(b)(1)(ii)G listed below:

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

Third Section

I attest that Neal Bhatt, M.D. has satisfactorily achieved a level of competency to
Name of Proposed Authorized User
function independently as an authorized user for:

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

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 Neal Bhatt, M.D. 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 Arthur Frazier, M.D.	Signature 	Telephone Number 5864937510	Date 02/27/2019
---	---	--------------------------------	--------------------

License/Permit Number/Facility Name
21-04080-01/Mount Clemens Regional Medical Center d/b/a McLaren-Macomb

Pavon, Sandy

From: Gryglak, Magdalena
Sent: Thursday, February 28, 2019 7:40 AM
To: Sandrik, Lauren; Song, Taehoon; Pavon, Sandy
Cc: Tomczak, Tammy
Subject: FW: License # 21-04080-01 amendment request
Attachments: Amendment request February 2019.pdf

Good morning,

Please place the attached document in ADAMS:

Mount Clemens Regional Medical Center
21-04080-01
030-02040
CN 611140

Thank you
Magdalena

From: Yudelev, Mark [mailto:Mark.Yudelev@mclaren.org]
Sent: Wednesday, February 27, 2019 2:43 PM
To: Gryglak, Magdalena <Magdalena.Gryglak@nrc.gov>
Subject: [External_Sender] RE: License # 21-04080-01 amendment request

Could you provide the Control Number for this request?
Thank you,
Mark.

Mark Yudelev, Ph.D. DABMP FAAPM

*Chief Physics:
McLaren-Macomb
1080 Harrington Blvd.
Mt. Clemens, MI 48043*

*Phone: 586 493-7542
Fax: 586 493-7511*

E-mail: mark.yudelev@mclaren.org