

July 26, 2023

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Re: Amendment for NRC License # 21-04080-01
Add Authorized User Physician

Dear Sir/Madam:

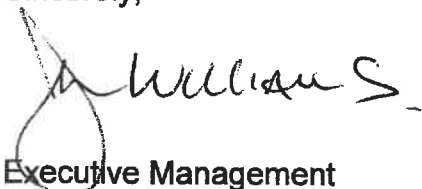
We respectfully request to add the following individual as an authorized user physician to our NRC license.

Please add Victor Hunyadi, D.O. for 10 CFR 100 and 200 uses. Dr. Hunyadi's Medical License # 5101021555 and the state of issuance is Michigan.

We have enclosed Dr. Hunyadi's board certification certificate and preceptor form.

If you have any questions or require additional information please contact either our Supervisor, Karen LaBudie at (586) 493-8070 or email karen.labudie@mclaren.org or our Medical Physics Consultant, Cari Dzanbazoff, at (734) 662-3197 or e-mail cdzanbazoff@mpcphysics.com.

Sincerely,



Executive Management
James Williams, PhD, RN
VP, Chief Operating Officer
Mount Clemens Regional Medical Center
d/b/a McLaren Macomb

RECEIVED JUL 27 2023



AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.57, 35.190, 35.290, and 35.590]

Name of Proposed Authorized User: Victor Hunyadi, DO State or Territory Where Licensed: Michigan

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. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(i), provide the following:
 - (i) Documentation that the individual performed each use checked above on or before October 24, 2005.
 - (ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
 - c. Stop here.
- 2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**
- a. Authorized user on Materials License _____ meeting 10 CFR 35.390, 10 CFR 35.57 for 35.300 uses, 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 or authorized nuclear pharmacist
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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) 35.55 35.57 for 35.200 uses
 c. If board certified, provide a copy of the certificate and stop here. If not board certified, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.57, 35.190, 35.290, and 35.590](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			
Total Hours of Training: <input type="text"/>			

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.)

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	

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

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

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
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	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
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		<input type="checkbox"/> Yes <input type="checkbox"/> No*	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user or an authorized nuclear pharmacist for generator training
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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)
 35.55 35.57 for 35.200 uses

*Not required for 10 CFR 35.100 use.

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, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.57, 35.190, 35.290, and 35.590](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)

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each use requested:

For 35.190

I attest that Victor Hungyadi, DO 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 is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

I attest that Victor Hungyadi, DO 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 is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses under 10 CFR 35.100 and 35.200.

Second Section

Complete one of the following for attestation and signature:

Authorized User:

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 35.57 for 35.200 uses

OR

Residency Program Director:

I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements for:

35.190 35.290 35.390 35.390 + generator experience 35.57 for 35.200 uses

I affirm that this facility member concurs with the attestation I am providing as program director.

I affirm that the residency training program is approved by the:

Residency Review Committee of the Accreditation Council for Graduate Medical Education

Royal College of Physicians and Surgeons of Canada

Council on Post-Graduate Training of the American Osteopathic Association

I affirm that the residency training program includes training and experience specified in:

35.190 35.290

Name of Facility:

McLaren Cardiovascular Institute

License/Permit Number:

21-04080-01

Name of Preceptor or Residency Program Director (Typed or Printed)

Melissa Janitelli DO

Telephone Number

(586) 464-4010

Date

7-5-2023

Signature

[Signature]

Certification Board of Nuclear Cardiology

Incorporated 1996

Part of the Alliance for Physician Certification & Advancement™ Medical Specialty Boards and Certification programs

Certifies That

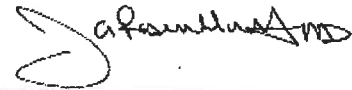
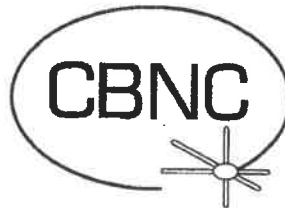
Victor Hunyadi

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS
TRAINED IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED
THE REQUIRED EXAMINATION, IS HEREBY DESIGNATED
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF
NUCLEAR CARDIOLOGY

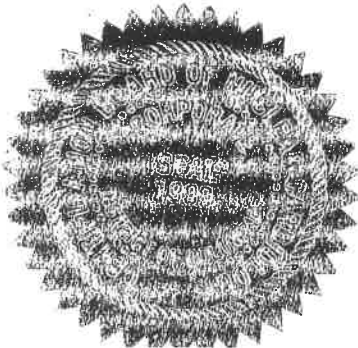
VALID: JANUARY 1, 2021 - MARCH 1, 2031



Chairman



Vice-Chairman



CERTIFICATE NUMBER: 260802