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providing quality, compassionate care to everyone, every time

August 22, 2023

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

Re: Amendment Request of license number 21-01430-01, Edward W. Sparrow Hospital

Please amend our license as follows:

1. Add Brendan G. Coutu, D.O. as authorized user of 10 CFR 35.300 (limited to oral administration of sodium iodide I-131). The completed 313(AUT) form is enclosed for your review. Dr. Coutu is already an AU on our license for 35.600 (limited to iridium-192 in a high dose rate (HDR) remote after-loading brachytherapy device)
2. Please remove the following Authorized users from our licenses:
 - a. Kirk B. Laman, D.O.
 - b. Ronald A. Voice, M.D.
 - c. Adam R. Schwaderer, D.O.
 - d. Peter A. Janick, M.D., Ph.D.
 - e. Roxana F. Leinbach, M.D.
 - f. Mark A. Rynties, M.D.
 - g. Anthony Salvador, D.O.
 - h. Zachary C. Smith, M.D.
3. Add Ronald A. Pluszczynski M.D. to our license as an Authorized User for groups 35.100 and 35.200. Enclosed is his Michigan Medical License verification and ABR certificate which contains the AU eligible designation.

If you have any questions please contact Aaron Anzell, Radiation Safety Officer at 517-364-9411 or Aaron.Anzell@Sparrow.org, or Tracy King, Associate Radiation Safety Officer at 517-294-2072 tking@mpcphysics.com.

Respectfully,

A handwritten signature in blue ink that reads "Dr. Denny Martin, D.O." with a horizontal line underneath.

Dr. Denny Martin
Chief Medical Officer
E.W. Sparrow Hospital

**AUTHORIZED USER TRAINING, EXPERIENCE, AND
PRECEPTOR ATTESTATION**
(for uses defined under 35.300)
[10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396]

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (7-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to infocollections.Resource@nrc.gov, and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: oir_submission@omb.eop.gov. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

Name of Proposed Authorized User

Brendan G. Coutu, M.D.

State or Territory Where Licensed

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 radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, 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 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. Skip to and complete Part II Preceptor Attestation.

d. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), 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.

e. Stop here.

☐ **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. If board certified, provide a copy of the certificate and stop here. If not board certified then provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

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.

☒ **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 Nebraska Medical Center Omaha, NE	40	07/2019-06/2022
Radiation protection	University of Nebraska Medical Center Omaha, NE	40	07/2019-06/2022
Mathematics pertaining to the use and measurement of radioactivity	University of Nebraska Medical Center Omaha, NE	40	07/2019-06/2022
Chemistry of byproduct material for medical use	University of Nebraska Medical Center Omaha, NE	40	07/2019-06/2022
Radiation biology	University of Nebraska Medical Center Omaha, NE	216	07/2019-06/2022
Total Hours of Training:		336	

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: 25	
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	Edward W. Sparrow Hospital, 21-01430-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2022-07/2023
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Edward W. Sparrow Hospital, 21-01430-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2022-07/2023
Calculating, measuring, and safely preparing patient or human research subject dosages	Edward W. Sparrow Hospital, 21-01430-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2022-07/2023
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Edward W. Sparrow Hospital, 21-01430-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2022-07/2023
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Edward W. Sparrow Hospital, 21-01430-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/2022-07/2023

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

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

Supervising Individual Nathan Jones, D.O.	License/Permit Number listing supervising individual as an authorized user 21-01430-01
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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
<input type="checkbox"/> 35.57	

** 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)	3	Edward W. Sparrow Hospital, 21-01430-01	07/2022-07/2023
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	5	Edward W. Sparrow Hospital, 21-01430-01	07/2022-07/2023
Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.			

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)**3. Training and Experience for Proposed Authorized User (continued)****c. Supervised Clinical Case Experience (continued)**

Supervising Individual Nathan Jones, D.O.	License/Permit Number listing supervising individual as an authorized user 21-01430-01
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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
<input type="checkbox"/> 35.57	
** 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 not attesting to the individual's "general clinical competency."

First Section

Check one of the following for the requested authorization:

For 35.390:

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

For 35.392:

☒ I attest that Brendan G. Coutu, M.D. 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:

☒ I attest that Brendan G. Coutu, M.D. 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).

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

Second Section

☒ I attest that Brendan G. Coutu, 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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

Third Section

☒ I attest that Brendan G. Coutu, M.D. is able to independently fulfill the radiation safety-related
Name of Proposed Authorized User

duties as an authorized user for the medical uses authorized under 10 CFR 35.300 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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

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 (b)(1), and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

- ☐ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, 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(a)(3), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (b)(1) and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

Fifth Section

Complete one of the following for the attestation and signature:

☒ **Authorized User**

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

☒ 35.390 ☒ 35.392 ☒ 35.394 ☐ 35.396 ☐ 35.57 for 35.300 uses

☒ 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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

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:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396 ☐ 35.57 for 35.300 uses

☐ I affirm that this facility member has experience in administering dosages in the same dosage category or categories for which the individual is requesting authorized user status and 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:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

Name of Facility:

Edward W. Sparrow Hospital

License/Permit Number:

21-01430-01

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

Nathan Jones, D.O.

Telephone Number

(517) 364-9423

Date

8/7/2023

Signature

The American Board of Radiology

hereby certifies that

Ronald Anthony Pluszczynski, MD

has pursued an accepted course of graduate study and clinical work; has met certain standards and qualifications, including passing the examinations conducted under the authority of The American Board of Radiology, demonstrating to the satisfaction of the Board qualification to practice; and is therefore awarded the Board's certification in

Diagnostic Radiology

AU Eligible

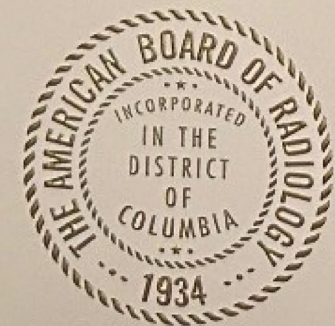
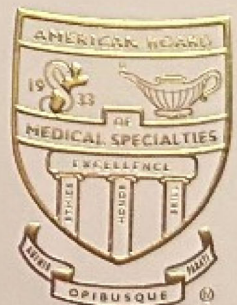
Ongoing validity of this certificate is contingent upon meeting the requirements of Continuous Certification.

DABR

Vincent P. Mathes, MD
President

A. A. Kaufman MD MS
Secretary-Treasurer

B. Wagner
Executive Director



Certificate No. 78142

Effective: September 30, 2022

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

STATE OF MICHIGAN - DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF MEDICINE
PHYSICIAN LICENSE

RONALD ANTHONY PLUSZCZYNSKI

LICENSE NO.	EXPIRATION DATE	
4301506737	03/21/2025	2280150321

RONALD ANTHONY PLUSZCZYNSKI
BEAUMONT HEALTH - DEARBORN
GME OFFICE
18101 OAKWOOD BLVD
DEARBORN, MI 48124

COMPLAINT INFORMATION:

THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED
AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY
COMPLAINTS OR VIOLATIONS PENDING AGAINST THE
LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:

YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR
ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND
REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV
OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF MEDICINE
PHYSICIAN LICENSE

RONALD ANTHONY PLUSZCZYNSKI

Martha Pavon

From: Tammy Tomczak
Sent: Wednesday, August 23, 2023 3:23 PM
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: Amendment to license request 21-01430-01
Attachments: Amendment 134 Add Coutu I131 FINAL.pdf

Hi Martha 😊

Can you please add the attached to ADAMS?

Thank you!!
Tammy

From: Anzell, Aaron <Aaron.Anzell@sparrow.org>
Sent: Wednesday, August 23, 2023 3:14 PM
To: R3-DRSSMail Resource <R3-DRSSMail.Resource@nrc.gov>
Subject: [External_Sender] Amendment to license request 21-01430-01

Hello,

Please process the attached amendment request to our materials license. All additional supporting documents are enclosed within the attachment.

Thank you,

Aaron Anzell
Radiation Safety Officer
Sparrow Health System
517-364-9411