Indiana University Health

December 9, 2024

U. S. Nuclear Regulatory Commission
Materials Licensing Section
2056 Westings Ave, Suite 400
Naperville, IL 60563-2657

Dear Sir or Madam:

Indiana University Health Bloomington Hospital would like to amend its Byproduct Materials License, Number 13-10408-02, to add Jesus Alejandro Ocana, M.D. as an Authorized User of materials licensed under 10 CFR 35.100, 35.200, and 35.300. Dr. Ocana is currently approved as an Authorized User on the NRC Materials License of IU Medical Center Campus, Number 13-02752-03. Enclosed is a memo from the Radiation Safety Officer of the IU Medical Center Campus, describing Dr. Ocana's authorizations on the license.

In addition, we request the addition of Daniel McIlrath, Ph.D. as an Authorized Medical Physicist for iridium-192 in a High Dose Rate Remote Afterloading Brachytherapy device and for calibration, spot checks, and training. Dr. McIlrath is currently licensed as an Authorized Medical Physicist on the OU Medicine broad-scope license, number OK-21035-01. Enclosed is a memo from the Radiation Safety Officer verifying Dr. McIlrath's authorization.

If there are any questions concerning this license amendment, please contact the Indiana University Health Bloomington Hospital Radiation Safety Officer, Patrick J. Byrne, PhD, DABR, CHP, DABSNM at 877-317-5811.

Sincerely,

John MacBeth, MHA, RTR
SCR Imaging Director

2651 E. Discovery Parkway
Bloomington, IN 47408

iuhealth.org

The University of Oklahoma
Health Sciences Center
RADIATION SAFETY OFFICE

December 10, 2024

To whom it may concern:

Daniel McIlrath, PhD., was an Authorized Medical Physicist on the medical broad-scope license issued to OU Medicine, OK-21035-01, and the radiation-producing device permit issued to the Radiation Oncology Department at OU Medicine, T024. His authorization included the medical physics requirements for high-dose-rate brachytherapy procedures. Please feel free to contact me if you need any additional information.

Sincerely,

George W. MacDurmon, CHP
Radiation Safety Officer
University of Oklahoma Health Sciences Center
OU Medical Center

940 Stanton L. Young Boulevard • Biomedical Sciences Bldg. - 127 • Oklahoma City, Oklahoma 73104 • (405) 271-6121

INDIANA UNIVERSITY
PUBLIC SAFETY
Environmental Health and Safety

To: Jesus Alejandro Ocana, MD
Radiology

From: Christopher P. Harvey, MSPH, MHP
Director of Health Physics
Radiation Safety Officer
-CPH

Date: September 11, 2023

Subj: **Final Approval of Authorizer Nuclear Medicine Physician (ANMP) Status**

Dear Dr. Ocana:

This letter is to inform you that you have received final approval at the most recent RRSC meeting in September 2024 for ANMP status. You are hereby **fully** authorized to administer and supervise the administration of radiopharmaceuticals as specified in 10 CFR 35.100 and 10 CFR 35.200, and 10 CFR 35.300 under the radionuclide use permits listed below. You are also authorized to prepare, sign, and date "written directives" for radiopharmaceuticals as specified in 10 CFR 35.300 under the same permits.

- CPET01 – IU Health Simon Cancer Center PET
- EZNM01 – Eskenazi Hospital Nuclear Medicine
- GHMR01 – IU Health Goodman Hall PET/MR
- MCNM01 – IU Health Morgan County Hospital Nuclear Medicine
- MHNM01 – IU Health Methodist Hospital Nuclear Medicine
- MPET01 – IU Health Methodist Hospital PET
- NHNM01 – IU Health North Hospital Nuclear Medicine
- NPET01 – IU Health North Hospital PET
- RINM01 – IU Health Riley Hospital Nuclear Medicine
- SHNM01 – IU Health Saxony Hospital Nuclear Medicine
- TPNM01 – IU Health Tipton Hospital Nuclear Medicine
- UHNM01 – IU Health University Hospital Nuclear Medicine

Should you have any questions, please do not hesitate to contact me.

Cc: Justin Sims, MD
R. Mark Payne, MD RRSC Chairman

OKLAHOMA DEPARTMENT OF ENVIRONMENTAL QUALITY

PERMIT FOR THERAPEUTIC RADIATION PRODUCING EQUIPMENT

Pursuant to the Oklahoma Radiation Management Act (27A O.S. §2-9-101, *et seq.)* and the Oklahoma Radiation Management Rules (Rules) at Oklahoma Administrative Code (OAC) 252:410, including rules incorporated by reference from Title 10 of the Code of Federal Regulations, and in reliance on statements and representations heretofore made by the permittee, a permit is hereby issued authorizing the permittee to receive, acquire, possess, and transfer the source(s) of radiation (byproduct, source and special nuclear material, accelerator produced material, radium sealed sources and/or radiation machines) designated below; to use such source(s) for the purpose(s) and at the place(s) designated below; and to deliver or transfer such source(s) of radiation to persons authorized to receive it in accordance with applicable rules. This permit is subject to all applicable rules and orders of the Oklahoma Department of Environmental Quality (DEQ) now or hereafter in effect and to any conditions specified below.

Permittee	
1. OU Medicine, Inc.	In accordance with an e-mail dated September 12, 2024 3. Permit number T024 is hereby amended in its entirety to read as follows:
2. 940 Stanton L. Young Blvd Oklahoma City, Oklahoma 73104	4. Expiration date March 31, 2027
	5. DEQ Login No. 253829

6. Type of equipment authorized	7. Maximum x-ray energy	8. Maximum electron energy
A. Varian Edge	A. 16 MV	A. 20 MeV
B. Varian Trilogy (with 150 kV OBI)	B. 18 MV	B. 20 MeV
C. GE Discovery RT	C. 140 kV	C. N/A
D. Xoft Axxent Model 100	D. 50 kVp	D. N/A
E. Varian TrueBeam (with 140 kV and MV OBI)	E. 18 MV	E. 20 MeV
F. Varian TrueBeam 3.0	F. 15 MV	F. 20 MeV
G. GE Discovery simulator CT	G. 140 kVp	G. N/A
H. Elekta Gamma Knife Icon CBCT	H. 90 kVp	H. N/A
I. Accuray Radixact X9	I. 6 MV	I. N/A

9. Authorized use

A., B., D. through F., and I. Therapeutic use
C., G., and H. Patient positioning and treatment adaptation

10. Authorized Practitioners	11. Authorized Medical Physicists
A. Ozer Algan, M.D.	A. Salahuddin Ahmad, Ph.D.
B. Christopher Bozarth, M.D.	B. Imad Ali, Ph.D.
C. Michael Confer, M.D.	C. Raghavendiran Boopathy, Ph.D.
D. Tyler Gunter, M.D.	D. Yong Chen, Ph.D.
E. Christina Henson, M.D.	E. Andrew Lau, Ph.D.
F. Andrea Johnston, M.D.	F. Daniel McIlrath, Ph.D.

Permit for Radiation Producing Equipment Supplementary Sheet

Permit No.
T024

DEQ Login No.
253829

Amendment No.
28

10. Authorized Practitioners (cont.)

G. Jerry J. Jaboin, M.D.
H. Danushka Seneviratne, M.D.
I. Lisa Syzek, M.D.
J. Spencer Thompson, M.D

11. Authorized Medical Physicists (cont.)

G. Mark Newpower, Ph.D.
H. Erich Schnell, Ph.D.
I. Matthew Sullivan, M.S.

CONDITIONS

12. Permitted radiation machines shall be used only at the University of Oklahoma Health Sciences Center campus.

13. The Radiation Safety Officer (RSO) for this permit is George W. MacDurmon.

14. Except as specifically provided otherwise in this permit, the permittee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Radiation Management Rules shall govern unless the statements, representations, and procedures in the permittee's application and correspondence are more restrictive than the Rules.

A. Application dated March 29, 2017
B. E-mail with attachments dated May 11, 2017
C. E-mail with attachments dated November 9, 2017
D. E-mail dated October 10, 2019
E. E-mail with attachments dated August 5, 2020
F. E-mail with attachments dated November 1, 2022
G. E-mail with attachments dated November 14, 2024

FOR THE DEPARTMENT OF ENVIRONMENTAL QUALITY

Date 11/14/24

By _____

Keisha Cornelius
Environmental Programs Manager
Radiation Management Section
Land Protection Division

Robert Singletary
Executive Director

OKLAHOMA Environmental Quality

Kevin Stitt
Governor

November 14, 2024

OU Medicine, Inc.
George W. MacDurmon, CHP
Radiation Safety Office, BMSB 127
940 Stanton L. Young Blvd.
Oklahoma City, Oklahoma 73104

Re: Amendment request (Add Machine)
Permit No.: T024
Login No.: 253829

Dear Mr. MacDurmon:

Please find enclosed the Amendment No. 28 to Permit No. T024. You should review this permit carefully and be sure that you understand all conditions. If you have any questions, you may contact Jennifer McAllister at (405) 702-5169 or Jennifer.McAllister@deq.ok.gov.

The Department of Environmental Quality (DEQ) expects permittees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with DEQ requirements, you must conduct your radiation safety program according to the conditions of your DEQ permit, representations made in your permit application, and DEQ Radiation Management Rules. In particular, note that you must:

1. Operate by Oklahoma Administrative Code (OAC) 252:410-23 [10 CFR Part 19], "Notices, Instructions and Reports to Workers: Inspection and Investigations," OAC 252:410-20 [10 CFR Part 20], "Standards for Protection Against Radiation," and other applicable rules;

2. Notify DEQ, in writing, of any change in mailing address;

3. Promptly notify DEQ, in writing, and request termination of the permit:
   a. When you decide to terminate all activities involving radiation-producing machines authorized under the permit; or
   b. If you decide not to complete the facility or acquire equipment;

4. Submit an application for and obtain a permit amendment before you:
   a. Change Radiation Safety Officers;
   b. Order additional machines or discard those authorized on the permit;
   c. Add or change the area(s) or address(es) of use identified in the permit application or on the permit; or
   d. Change the name or ownership of your organization;

5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your permit. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radiation-producing machines after your permit expires is a violation of Radiation Management Rules.

In addition, when submitting an application for amendment, renewal or termination, please use DEQ FORM #410-11-1. This form requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the permittee or certifying official rather than a consultant.

DEQ will periodically inspect your radiation safety program. Failure to conduct your program according to Radiation Management Rules, permit conditions, and representations made in your permit application and supplemental correspondence with DEQ may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your permit.

Thank you for your cooperation.

Sincerely,

Keisha Cornelius
Environmental Programs Manager
Radiation Management Section
Land Protection Division

KC/jm

Enclosure: As stated

INDIANA UNIVERSITY
PUBLIC SAFETY
Environmental Health and Safety

Radionucide Use Permit

Authorization Number: UHNM01 **Issued to:** Justin Sims, MD

Issue Date: 03/31/2007 **Expiration Date:** 12/31/2024

Amended Date:

In accordance with the statements and representatives made in your application for Project Approval , Project Amendment, and/or your Progress Report, an approval authorizing the below named individuals to order, possess, and use the materials or items designated below in accordance with NRC regulations, state regulations, University regulations, and such other conditions as are herein specified is hereby issued.

1. Personnel / Status

Approved

Jason Parker PhD

Auth NM Physician

Justin Sims MD	Mark Estrada MD	Mark Tann MD	Vasantha Aaron MD
Alex Ocana MD	Cindy Yuan MD	Korbin Davis MD	

DOT - Approved

Ashleigh Auxier CNMT	Dawn Burkhardt CNMT	Heather Ardeel CNMT	Ryann Hall CNMT
(sec 5) NMTP Class of 2025	(sec. 5) NMTS Class of 2026	Garrett Bell CNMT	Heather Peterson CNMT
Cari Krakowski CNMT	Kori Wright CNMT		

NM Technologist

Ashleigh Auxier CNMT	Dawn Burkhardt CNMT	Heather Ardeel CNMT	Ryann Hall CNMT
Cari Krakowski CNMT	Garrett Bell CNMT	Heather Peterson CNMT	Kori Wright CNMT

NMT Students

(sec 5) NMTP Class of 2025	(sec. 5) NMTS Class of 2026

2. Locations of Use

Approved

UH 0650	UH 0650B	UH 0660	UH 0665	UH 0670
UH 0670A	UH 0670B	UH 0670C	UH 0670D	UH 5505
UH 0647				

3. Nuclides / Chemical Forms / Exp. Limit / Poss. Limit

Radionucide Use Permit

Ac-225	0.05	1.00	A	4/3/24
DOTA-TATE (A - 4/03/2024)				
Ba-133/Cs-137PA	1.00	1.00	A	6/20/07
sources (A - 6/20/2007)				
Ba-133BA	5.00	5.00	A	6/20/07
dose calibrator sources (A - 6/20/2007)				
Ba-133SS	20.00	21.00		
Check sources ()				
point sources (A)				
C-14	0.01	1.00		
Pytest caps (urea) ()				
C-14PA	0.00	0.01	A	4/2/08
Co-57	0.00	1.00		
Rubratope ()				
Co-57BA	10.00	50.00	A	6/20/07
dose calibrator sources (A - 6/20/2007)				
flood sources (A - 6/20/2007)				
Co-57PA	0.10	0.10	A	6/20/07
rod source (A - 6/20/2007)				
Co-57SS	10.00	50.00		
flood sources ()				
dose calibrator sources (A - 9/23/2008)				
Co-58	0.01	1.00		
schillings kits ()				
Co-60BA	5.00	5.00	A	6/20/07
dose calibrator sources (A - 6/20/2007)				
Co-60SS	0.50	0.50		
dose calibrator sources ()				
Cr-51	0.25	5.00		
sodium chromate ()				
Cs-137BA	5.00	5.00	A	6/20/07
dose calibrator sources (A - 6/20/2007)				

Radionucide Use Permit

Cs-137PA	0.10	1.00	A	6/20/07
Check sources (A - 6/20/2007)				
rod source (A - 6/20/2007)				
Cs-137SS	10.00	10.00		
dose calibrator sources ()				
Check sources ()				
Eu-152SS	0.01	0.01	A	2/10/23
sealed sources (A - 2/10/2023)				
F-18	15.00	100.00		
FDG ()				
Ga-67	50.00	50.00		
citrate ()				
Gd-153SS	300.00	1,000.00		
sources ()				
Ge-68SS	0.50	1.00		
sources ()				
I-123	50.00	80.00		
capsules ()				
MIBG ()				
NaI ()				
I-125	1.00	15.00		
NaI ()				
RIA kits ()				
HSA ()				
I-125SS	200.00	200.00		
sources ()				
I-129PA	0.10	0.10	A	6/20/07
sources (A - 6/20/2007)				
I-131	250.00	1,000.00	A	12/13/07
NaI ()				
In-111	20.00	40.00	A	12/16/09
chloride ()				

Radionucide Use Permit

Pentetate (DTPA) ()				
oxyquinoline (Oxine) ()				
Zevalin (A)				
Pentetreotide (Octreoscan) (A)				
Capromab pendetide (prostascint) (A)				
J591 (A - 6/01/2010)				
Lu-177	250.00	4,000.00	A	3/15/23
J591 (A - 6/01/2010)				
Lutathera (A - 3/27/2018)				
PSMA 617 (A - 12/11/2018)				
Pluvicto (A - 2/10/2023)				
Mo-99	50.00	8,000.00		
generators ()				
N-13	20.00	100.00		
ammonia ()				
Na-22	0.10	0.10	A	8/22/17
NR	1.00	100.00	A	6/4/07
P-32	15.00	30.00		
chromic phosphate ()				
sodium phosphate ()				
Ra-223	0.30	5.00	A	8/19/13
Xofigo (radium dichloride) (P - 8/19/2013)				
Ra-226PA	0.20	0.20	A	6/20/07
sources (A - 6/20/2007)				
Sm-153	100.00	200.00		
lexidronam pentasodium (Quadramet) ()				
Sr-89	4.00	30.00		
chloride (Metastron) ()				
Tc-99m	2,000.00	2,000.00	A	6/4/07
all ()				
Tl-201	5.00	75.00	A	7/9/09
chloride ()				
Xe-133	50.00	500.00		

gas ()

Y-90	80.00	200.00

chloride (A)

Zevalin (A)

microspheres ()

clivatuzumab tetraxetan (A - 9/09/2014)

4. Authorized Use

Clinical diagnosis and therapy as described in 10 CFR 35, Subparts D and E.

Research and development, including human research, as approved by the Radionuclide Radiation Safety Committee (RRSC).

5. Conditions of Authorization

All users of radiopharmaceuticals under this permit shall follow all rules and procedures in the Nuclear Medicine/PET Radiation Safety Procedures Manual.

Personnel monitoring (whole body and ring badges) is required for all individuals who use radioactive materials under this permit.

A direct radiation survey shall be performed and documented at the end of each day where radiopharmaceuticals are used, stored, or administered.

Contamination (wipe) surveys shall be performed and documented on a weekly basis where radiopharmaceuticals are used, stored, or administered.

All waste with a half-life of 120 days or less shall be surveyed to confirm background level and documented before disposal. The record shall include the initial date of storage, the date of disposal, description of the item, the measurement of waste, the background measurement, the instrument used, and the initials of the individual performing the survey.

All shipments of radiopharmaceuticals received shall be surveyed and documented according to established procedures in the Nuclear Medicine/PET Radiation Safety Procedures Manual. Surveys must be completed within 3 hours of receipt or within 3 hours from the beginning of the workday, if received after hours.

At the beginning of each day, a long-lived sealed source shall be assayed in the dose calibrator(s) on the most commonly used setting to determine constancy. The results shall be compared to the acceptable range provided on the RSO Form X-7 and shall be documented.

On a weekly basis, a long-lived sealed source shall be assayed in the dose calibrator(s) on all commonly used settings to determine constancy. The results shall be compared to the acceptable range provided on the RSO Form X-7 and shall be documented.

Appropriate syringe shields shall be made available and implemented according to established procedures in the Nuclear Medicine/PET Radiation Safety Procedures Manual.

INDIANA UNIVERSITY
PUBLIC SAFETY
Environmental Health and Safety

Radionucide Use Permit

All radiopharmaceuticals to be administered to humans (except unit doses) shall be assayed in a dose calibrator prior to administration.

All dose calibrators shall be tested for linearity twice a year and accuracy on an annual basis.

An inventory of sealed sources shall be prepared and recorded.

After the administration of iodine, surveys shall be performed of the area of administration. If contamination is found or if an incident occurs during the administration (e.g., coughing, sneezing, etc.), a thyroid bioassay scan shall be performed on the individual performing the administration.

Applications for human use research studies under principal investigators that are not nuclear medicine physicians shall be reviewed and approved by that nuclear medicine department permit holder.

For all research studies, a urine pregnancy test shall be performed on women of child-bearing age prior to administration of any radiopharmaceutical which may deliver a dose equivalent to the fetus of 1 mrem or more.

NMTS Class of 2024 consists of: Giselle Calderon, Amber Carlin, Valentina Muskus, Dillon VanDyke, and Conner Walker

NMTS Class of 2025 consist of: Lama Albukhari, Dalanie Chipps, Sabina Garcia, Kristin Hammond, Owen Howell, Muhaj Jawad, Oscar Padilla, Kayla Probus, and Kendra Stewart

From: Riley, Bruce L
To: Tammy Tomczak
Subject: [External_Sender] Amendment request
Date: Thursday, December 19, 2024 10:53:19 AM
Attachments: Scan from Riley Bruce L (007).pdf

Here are the forms/cover letter for an amendment request.

Thanks

BRUCE RILEY BSRT R
Radiology manager
Radiology and Non invasive Cardiology
2651 E. DISCOVERY PARKWAY
BLOOMINGTON, IN 47408
BRILEY1@IUHEALTH.ORG
812-918-3692