

From: [Michael Rocha](#)
To: [R4 Licensing Action Submittals](#)
Cc: [Lisa West](#); [Corey Ginetz](#)
Subject: [External_Sender] License # 40-00238-04 Add Authorized Users
Date: Tuesday, August 1, 2023 9:19:22 AM
Attachments: [MH_RAML Amendment Add Authorized Users.pdf](#)

Hello,

Attached amendment request to add authorized users to our RAML.

Michael Rocha, MBA, RT (R)(CT)(MR)

Director, Medical Imaging Services



Monument Rapid City Hospital | 353 Fairmont Blvd. Rapid City, SD 57701 | Postal Mail: PO Box 6000 RapidCity SD, 57701

p: 605-755-8431 c: 949-371-3894 | f: 605-755-1436 | e: mrocha@monument.health

www.monument.health

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April 4, 2023

Materials Licensing Branch
US Nuclear Regulatory Commission, Region IV
1600 E Lamar Boulevard
Arlington, TX 76011-4511

Licensee: Monument Health INC
Address: 353 Fairmont Boulevard, Rapid City, SD 57701
License #: 40-00238-04
Subject: **Amendment Request; Add Authorized Users**

This is an amendment request to our Radioactive Materials License (RAML) referenced above. The purpose of this amendment is to add the following physicians as Authorized Users (AU):

Name	Uses	Authorization Pathway
Thomas Andrew Reher, MD	10 CFR 35.100	NRC 313A AUD
	10 CFR 35.200	
Jena Kiku Fujimoto, MD	10 CFR 35.100	NRC 313A AUD
	10 CFR 35.200	

Supporting documentation is attached.

If you need any additional information in order to process this licensing action, please do not hesitate to contact remoteservices@westphysics.com.

We look forward to your approval of this amendment request.

Sincerely,


Michael Rocha
Director of Medical Imaging

Enclosures

Attachment 1 Supporting documentation for Jena Kiku Fujimoto
Attachment 2 Supporting documentation for Thomas Andrew Reher

The American Board of Radiology

hereby certifies that

Jena Kiku Fujimoto, 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 Verification.



Thos P. Nichols, MD

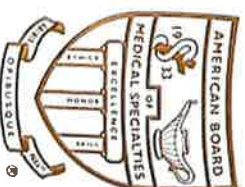
President

Al A. Kaufman, MD, MC

Secretary-Treasurer

Robert A. Kaufman, MD, MC

Executive Director



DABR

**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

Jena Kiku Fujimoto

State or Territory Where Licensed

SD

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: <input type="text"/>			
Supervising Individual	License/Permit Number listing supervising individual as an authorized user or authorized nuclear pharmacist		

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:

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: <input type="text"/>	
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	

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 _____ 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 _____ 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:

License/Permit Number:

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

Telephone Number

Date

Signature

The American Board of Radiology

hereby certifies that

Thomas Andrew Reher, 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



Therent P. Mathias, MD
President

[Signature]
Secretary-Treasurer

[Signature]
Executive Director

Certificate No. 76358

Effective: September 1, 2021

**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

State or Territory Where Licensed

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

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:

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	

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 _____ 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 _____ 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:		License/Permit Number:	
Name of Preceptor or Residency Program Director (Typed or Printed)		Telephone Number	Date
Signature			

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 2B 7C
Exp. Date: 02/28/2026
Fee Comments: 2B exempt under 7C in 171.16 footnc
Decom Fin Assur Req: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: Monument Health, Inc.
Received Date: 08/01/2023
Docket Number: 3003231
Mail Control Number: 636463
License Number: 40-00238-04
Action Type: Amendment

2. FEE ATTACHED

Amount: N/A

Check No.: N/A

3. COMMENTS

Signed: Giavana Muffelletto

Date: 02Aug23

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____

Agency: NRC

WBL WORKSHEET

DOCKET NUMBER: 3003231	LICENSE NUMBER: 40-00238-04	STATUS: Pending Amendment
MAIL CONTROL NUMBER: 636463	RECEIPT DATE: 08/01/2023	ACTION TYPE: Amendment
DUE DATE: 10/30/2023	INST. CODE: 238	LICENSE REGION: Region 4
LICENSE TYPE: 30	ENTITY TYPE: C	LICENSE GROUP: Medical
ISSUE DATE:	ORIGINAL DATE: 07/24/1986	EXPIRATION DATE: 02/28/2026
DECOMMISSIONING CATEGORY: Group 1	LAST ISSUE DATE:	
LICENSEE NAME: Monument Health, Inc.	DECOM FIN ASSUR REQD: N SUBM: N	
MAILING ADDRESS LINE1: 353 Fairmont Boulevard	CONT PLAN REQD: N APPRV: N	
MAILING ADDRESS LINE 2:		
CITY: Rapid City	STATE: SD	ZIP: 57701
CONTACT PERSON: PREFIX:	FIRST NAME: Paulette	MIDDLE INITIAL:
LAST NAME: Davidson	SUFFIX:	
JOB TITLE: Chief Executive Officer	PHONE: 605-719-1000 FAX:	EMAIL:
BILLING ADDRESS LINE 1:		
BILLING ADDRESS LINE 2:		
CITY:	STATE: South Dakota	ZIP:
BILLING CONTACT PERSON: FIRST NAME:	MIDDLE INITIAL:	LAST NAME:
PHONE:	EMAIL:	FAX:
PRIMARY PGM CODE: 02230	SECONDARY PGM CODE: 02120,02240,11210	
INSPECTION REGION: Region 4	PRIORITY: 2	
RSO: PREFIX:	FIRST NAME: James	MIDDLE INITIAL: LAST NAME McKee
SUFFIX: M.S.	RSO JOB TITLE: Radiation Safety Officer	
RSO PHONE: 605-755-2339	RSO FAX: 605-719-2310	RSO EMAIL:
STATES WHERE USE IS AUTHORIZED: 1	0- ALL LISTED STATES 1- SAME AS STATE IN ADDRESS 2- ALL STATES 3- NON-AGREEMENT-STATES	
AUTHORIZED STATES (USE ONLY IF ABOVE IS ZERO):		



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Paulette Davidson, Chief Executive Officer
Monument Health, Inc.
353 Fairmont Blvd
Rapid City, SD 57701

Date

08/02/2023

License Number(s)

40-00238-04

Mail Control Number(s)

636463

Licensing and/or Technical Reviewer or Branch

Giavanna Muffelletto

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 04/04/2023

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☐ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140