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MARIAN MEDICAL SERVICES

906 Kingsridge Ct. | Wildwood, MO 63021 | 636.220.8228

May 6, 2024

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

Re: Amendment Request for RAML 24-29248-01
Expedited Request to add Authorized User MD

U.S. Nuclear Regulatory Commission:

Marian Medical Services is submitting an expedited amendment request to add one Authorized User MD onto our radioactive materials license.

Dr. Francis Isidoro is listed as an Authorized User in the State of California. A Copy of the RAML in which he is listed as an Authorized User is included with this amendment request.

The reason we would like to expedite this request is that one of our primary readers needs to take some time off, and Dr. Isidoro is going to cover this period and also become a regular reader for us.

If you have any questions or need any additional information please contact me at 636-220-8228.

Sincerely,



Jere Palazzolo

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the California Department of Public Health now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee: Nuclear Medicine Associates	3. License Number: 6205-45 Amendment Number: 14
2. Address: 1950 Court Street Redding, CA 96001	4. Expiration date: December 13, 2023 (3)
Attention: Peter S. Robbins, M.D. Radiation Safety Officer	5. Inspection agency: Radiologic Health Branch North

In response to the letter, dated July 19, 2022, signed by Peter S. Robbins, M.D., Radiation Safety Officer, License Number 6205-45 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Any radioactive material permitted by 10 CFR 35.100, 35.200, and 35.300.	A. Any Excluding generators	A. Combined possession limit not to exceed 470 mCi.
B. Any radionuclide with atomic numbers 3-83, inclusive, except: Strontium-90 and Lead-210.	B. Sealed, solid or liquid sources manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission an Agreement State or a Licensing State.	B. Total not to exceed 30 mCi. Each source not to exceed 15 mCi.

9. Authorized Use

A. Any uptake, dilution, or excretion study permitted by 10 CFR 35.100.

Any imaging and localization study permitted by 10 CFR 35.200.

Any use permitted by 10 CFR 35.300

B. Marker and calibration sources.

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following location:

(a) 1950 Court Street, Redding, CA.

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.

RADIOACTIVE MATERIAL LICENSELicense Number: 6205-45Amendment Number: 14

12. The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8, and 9 of this license as follows:
- | | |
|-------------------------------------|--|
| (a) Mitchell S. Akman, M.D. | 35.100; 35.200 (I-123 and I-131 only); 35.300 for oral administration of sodium iodide Iodine-131 only and 9.B |
| (b) Peter S. Robbins, M.D. | 35.100; 35.200; 35.300 and 9.B. |
| (c) Tony E. Vasquez, M.D. | 35.100; 35.200; 35.300 and 9.B. |
| (d) Rhonda A. Wyatt, M.D. | 35.100; 35.200; 35.300 for oral administration of sodium iodide Iodine 131 in quantities less than or equal to 33 millicuries and 9.B. |
| (e) Jaideep Singh Sohi, M.D. | 35.100; 35.200; 35.300 and 9.B. |
| (f) Twyla B. Bartel, D.O. | 35.100; 35.200; 35.300 and 9.B. |
| (g) Tracy Yarbrough, D.O. | 35.100; 35.200; 35.300 and 9.B. |
| (h) Mickaila J. Johnston, M.D. | 35.100; 35.200; 35.300 oral administration of sodium iodide I-131 only and 9.B. |
| (i) Francis P. Isidoro, M.D. | 35.100; 35.200 and 9.B. |
13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- (a) The renewal application, with attachments, dated November 1, 2005, supplemented and modified by the letters, with attachments, dated August, 30, 2012 and April 22, 2013, all signed Peter S. Robbins, M.D., Director and Radiation Safety Officer.
14. The Radiation Safety Officer in this program shall be Peter S. Robbins, M.D.
15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Title 17, California Code of Regulations, Section 30275 (c).
16. In lieu of the leak test intervals required by California Code of Regulations, Title 17, Section 30275 (c), sealed sources can be tested for leakage and/or contamination at longer intervals when they are specified in a certificate of registration issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. When a longer interval stipulated in a certificate of registration is used, the certificate must be maintained on file and available for inspection for as long as the associated leak test records are retained.
17. Quantitative analytical assays for the purpose of tests for leakage and/or contamination of sealed sources shall be performed only by persons specifically authorized to perform that service.

RADIOACTIVE MATERIAL LICENSELicense Number: 6205-45Amendment Number: 14

18. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Public Health:
- (a) The Radiation Safety Officer
 - (b) Qualified individuals designated in writing by the Radiation Safety Officer
19. The licensee is authorized to hold radioactive materials with a physical half-life of less than or equal to 120 days for decay in storage before disposal in ordinary trash provided:
- (a) Radioactive waste to be disposed of in this manner shall be held for decay in storage for at least 10 half-lives.
 - (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - (c) Records shall be maintained of the disposal of licensed materials made by decay in storage. These records shall be sufficient to demonstrate compliance with this license condition and shall be retained for 3 years after the record is made.
20. Nuclear medicine technology procedures shall be performed by nuclear medicine technologists pursuant to Title 17, California Code of Regulations, Subchapter 4.7. Such procedures shall be performed under the supervision of individuals listed as authorized users on this license who meet the criteria specified in Section 30510. Certificates or special permits issued pursuant to Subchapter 4.7 shall be prominently displayed at the facility(ies) authorized on this license.
21. When performing written directive procedures for administration of Iodine-131 greater than 1.1 megabecquerels (30 microcuries) and/or therapeutic procedures of both sealed or unsealed radioactive material the licensee must comply with the requirements listed in 10 CFR 35.41 (**1-1-21 Edition**) including, but not limited to, the following:
- (a) Develop, implement and maintain written procedures that ensure the following:
 - (1) The patient's or human research subject's identity is verified before each administration.
 - (2) Each administration is in accordance with the treatment plan, if applicable, and written directive.
 - (3) Both the manual and computer-generated dose calculations have been checked.
 - (b) Retain a copy of the written procedures for the duration of the license per 10 CFR 35.2041.
22. For a period not to exceed 60 days in any calendar year, a physician is authorized to use licensed materials for human use under the terms of this license, provided the physician:
- (a) Has the prior written permission of the Licensee's Executive Management and its Radiation Safety Officer.
 - (b) Is specifically named as an authorized user on a current and valid U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State license authorizing human use.
 - (c) Performs only those procedures for which the physician is specifically authorized by the U.S. Nuclear Regulatory Commission, Agreement State or a Licensing State license.

The licensee shall maintain for inspection copies of the written permission specified in (a) above and the license(s) specified in (b) and (c) above. These records shall be maintained for five years from the time the licensee grants its permission under (a) above.

RADIOACTIVE MATERIAL LICENSE

License Number: 6205-45Amendment Number: 14

23. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material so that at no time will the total quantity of radioactive material possessed require financial surety for decommissioning in accordance with the California Code of Regulations, Title 17 (17 CCR), Section 30195.1. A value of 3.7 MBq (100 μ Ci) is assigned to cobalt-57 to supplement 17 CCR Section 30197.7.
24. In accordance with California Health and Safety Code Section 115000.1(h), the licensee shall annually report the radioactive waste inventory held in storage on December 31 of each year and all manifests of Low Level Radioactive Waste (LLRW) shipments to licensed LLRW disposal facilities made during the year to the Department via the online LLRW Tracking System at <https://llrwts.cdph.ca.gov/>.
25. At least 30 days prior to vacating any address of use listed in Condition 10 of this license, the licensee shall provide written notification of intent to vacate to the California Department of Public Health, in accordance with Title 17, California Code of Regulations, Section 30256 (b). Control of all licensed areas must be maintained until such areas are released by the Department for unrestricted use or the license is terminated, in accordance with Title 17, California Code of Regulations, Section 30256 (j).
26. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 1950 Court Street, Redding, CA.

Issued for the State of California Department of Public HealthDate: August 12, 2022By: 

Radiologic Health Branch
MS 7610, P.O. Box 997414
Sacramento, CA 95899-7414

From: [Mark Palazzolo](#)
To: [Latischa Hanson](#); [Carol Hill](#)
Cc: [Blaine Ikeda \(blaine@pharmarxhawaii.com\)](mailto:blaine@pharmarxhawaii.com)
Subject: [External_Sender] RML's Amendment Hawaii
Date: Monday, May 6, 2024 1:33:07 PM
Attachments: [All listed CA RML.pdf](#)
[NRC Amendment 05062024.pdf](#)

Hi Latischa & Carol,

Marian Medical Services is requesting to amend our radioactive materials license to add an authorized user. I have included a formal amendment request and a copy of the RAML that Dr. Francis Isidoro is listed as an authorized user.

We would greatly appreciate it if this request could be expedited, as we have some coverage issues for reading. Dr. Isidoro is also going to be a regular ready for us in the future.

Thanks you so much!

Mark Palazzolo
Marian Medical Services, LLC
636-368-7945



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Mark Palazzolo
Executive Director
Marian Medical Services, LLC
906 Kingswood Ct
Wildwood, MO 63021

Date

05/06/2024

License Number(s)

24-29248-01

Mail Control Number(s)

640638

Licensing and/or Technical Reviewer or Branch

C. Hill

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 05/06/2024

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

Accounts Receivable/Payable and Regional Licensing Branches

Program Code: 02201
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date: 04/30/2027
Fee Comments:
Decom Fin Assur Req'd: N

A. REGION

Applicant/Licensee: Marian Medical Services, LLC
Received Date: 05/06/2024
Docket Number: 3037399
Mail Control Number: 640638
License Number: 24-29248-01
Action Type: Amendment

Check No.: N/A

Date: 05/06/2024

1. Fee Category and Amount: _____

License:

Date: _____

Agency: NRC

WBL WORKSHEET

DOCKET NUMBER: 3037399	LICENSE NUMBER: 24-29248-01	STATUS: Pending Amendment
MAIL CONTROL NUMBER: 640638	RECEIPT DATE: 05/06/2024	ACTION TYPE: Amendment
DUE DATE: 08/04/2024	INST. CODE: 29248	LICENSE REGION: Region 4
LICENSE TYPE: 30	ENTITY TYPE: C	LICENSE GROUP: Medical
ISSUE DATE:	ORIGINAL DATE: 03/14/2007	EXPIRATION DATE: 04/30/2027
DECOMMISSIONING CATEGORY: Group 1	LAST ISSUE DATE:	
LICENSEE NAME: Marian Medical Services, LLC	DECOM FIN ASSUR REQD: N SUBM: N	
MAILING ADDRESS LINE1: 906 Kingsridge Court	CONT PLAN REQD: N APPRV: N	
MAILING ADDRESS LINE 2:		
CITY: Wildwood	STATE: MO	ZIP: 63021
CONTACT PERSON: PREFIX:	FIRST NAME: Mark	MIDDLE INITIAL:
LAST NAME: Palazzolo	SUFFIX:	
JOB TITLE: Executive Director	PHONE: 636-220-8228 FAX: 636-754-0900	EMAIL: mpalazzolo@marianme
BILLING ADDRESS LINE 1:		
BILLING ADDRESS LINE 2:		
CITY:	STATE: Missouri	ZIP:
BILLING CONTACT PERSON: FIRST NAME:	MIDDLE INITIAL:	LAST NAME:
PHONE:	EMAIL:	FAX:
PRIMARY PGM CODE: 02201	SECONDARY PGM CODE:	
INSPECTION REGION: Region 4	PRIORITY: 5	
RSO: PREFIX:	FIRST NAME: Blaine	MIDDLE INITIAL: LAST NAME Ikeda
SUFFIX: PharmD	RSO JOB TITLE: Radiation Safety Officer	
RSO PHONE: 808-487-0814	RSO FAX: 808-487-0816	RSO EMAIL: Blaine@Pharmarxhawaii.com
STATES WHERE USE IS AUTHORIZED: 3	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):		