

J-2



02/24/2017
U. S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, PA 19406

RE: Radioactive Materials License Amendment

Kaiser Permanente Capitol Hill Medical Center
License # 19-31420-01
Docket # 03038361

Dear License Reviewers:

This letter serves as our response to the additional information requested regarding the radioactive material license amendment request for Kaiser Permanente Capitol Hill Medical Center.

1. Management has reviewed the amendment letter dated December 16, 2016, and concur with the statements and representations contained therein.
2. We are requesting the use of I-131 as permitted by 10 CFR 35-300 and not all materials and uses permitted under 10 CFR 35.300.
3. I-131 will be administered and stored in the same area where licensed materials are currently used.
4. We confirm I-131 will be obtained and used in capsule form only.
5. In-house I-131 therapy administrations are not conducted since we are an outpatient facility. Administrations are limited to those that will allow patients to be released under the provisions of 10 CFR 35.75.
6. A copy of Kaiser Permanente Largo Medical Center RAM license is enclosed where Howard DiPiazza, M.D. is listed as RSO.

If there are any questions or additional information is needed, please contact our Medical Physicist, Tekeste Yohannis of Krueger-Gilbert Health Physics, Inc. at (410) 339-5447 or Mr. Mike Ofori Darkwa, Nuclear Medicine Regional Manager at (703) -424-4086.

Sincerely,

A handwritten signature in black ink, appearing to read "Heidi Veltman", with a long horizontal flourish extending to the right.

Heidi Veltman
Vice President, Delivery Systems Operations
Northern Virginia Service Area and Regional Radiology, Lab and Optical

REC RG 10228 17 PM 07 05

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NMCC/RGN1 MATERIALS-032



MARYLAND DEPARTMENT of the ENVIRONMENT
Air and Radiation Management Administration

Facsimile Transmittal Sheet

TO: Mike Ofori Darkwa
ORGANIZATION: Kaiser Permanente/Largo
FROM: MDE/RHP

MDE-Air & Radiation Management Admin. (ARMA)
Radiological Health Program
1800 Washington Boulevard, Baltimore MD 21230
(Phone) 410-537-3300 or 1-800-633-6101
(Fax) 410-537-3198

Date: 9/30/2013

Numbers of pages (including this sheet): 6

COMMENTS:

Congratulations! ☺

MARYLAND DEPARTMENT of the ENVIRONMENT

CHERYL A. NITKOWSKI
HEALTH PHYSICIST LICENSE REVIEWER
RADIOACTIVE MATERIALS LICENSING, ARMA-RHP
cnitkowski@mde.state.md.us

MDE

1800 Washington Blvd., Ste. 750 Phone: 410-537-3300
Baltimore MD 21230-1720 Fax: 410-537-3198



MARYLAND DEPARTMENT OF THE ENVIRONMENT

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Martin O'Malley
Governor

Robert M. Summers, Ph.D.
Secretary

Anthony G. Brown
Lieutenant Governor

Howard DiPiazza, M.D., Radiation Safety Officer
Kaiser Permanente-Largo
2101 E. Jefferson Street
Rockville, MD 20852

Dear Dr. DiPiazza:

Your requested radioactive materials license is enclosed. Please review it carefully to ensure that it reflects all requests included in your application received in this office on March 21, 2013.

All radioactive materials licensees are billed an annual user fee (Please note that fee amounts found in COMAR 26.12.03 are adjusted annually based on changes in the Consumer Price Index.) that covers applications, renewal, amendments, and inspection costs. Payment of this annual fee is required upon receipt of the Maryland Department of the Environment's (MDE) invoice regardless of whether your radiation program is active or inactive. Should you desire to terminate your license at a future date and avoid being invoiced during the next scheduled billing period, you must notify the Department, in writing, prior to your billing period. As outlined in the enclosed regulations, annual user fees will be invoiced during the month of your license expiration date, which will become your anniversary date. Subsequent annual fee and billing will reflect that date. Your new license number is MD-33-215-01 for Medical Private Practice—Group, Quality Mgt Plan Req'd. and the code is 02200. The annual user fee is \$1,800.00.

It is necessary that you notify the Radiological Health Program's Radioactive Materials Inspection and Compliance Division, in writing, no later than ten (10) working days after initial receipt of radioactive material authorized on this license. Please make this notification by sending an e-mail to rhp_notification@mde.state.md.us.

If you have any questions, please feel free to contact Mr. Raymond E. Manley at 410-537-3301 or 1-800-633-6101 and requesting extension 3301. The fax number is 410-537-3198.

Sincerely,

Roland G. Fletcher, Program Manager IV
Radiological Health Program
Air and Radiation Management Administration

RGF/BJP/CAN/cc

Enclosure(s): Radioactive Materials License (new) (02200)
Maryland Fee Regulations
COMAR Ordering Information
Notice to Employees



Recycled Paper

www.mde.state.md.us

TTY Users 1-800-735-2258
Via Maryland Relay Service

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SEP-30-2013 14:24 From:



**RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE**

Page 1 of 4

Pursuant to the Maryland Radiation Act, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. The license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below.

1. Name: Kaiser Permanente- Largo	3. License No.: MD-33-215-01
2. Address: 2101 E. Jefferson Street Rockville, Maryland 20852	4. Amendment No.: NEW; Code 02200
	5. Expiration Date: October 31, 2020

6. Radioactive material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of activity which licensee may possess at any one time
A. Any radioactive material listed in Section G.100 of COMAR 26.12.01.01.	A. Any radioactive material listed in Section G.100 of COMAR 26.12.01.01.	A. As needed to perform diagnostic tests.
B. Any radioactive material listed in Section G.200 of COMAR 26.12.01.01.	B. Any radioactive material listed in Section G.200 of COMAR 26.12.01.01.	B. As needed to perform diagnostic tests.
C. Any radioactive material listed in Section G.300 of COMAR 26.12.01.01.	C. Any radioactive material listed in Section G.300 of COMAR 26.12.01.01.	C. 350 millicuries.
D. Cobalt-57	D. Sealed Source	D. No source to exceed 15 millicuries.
E. Cesium-137	E. Sealed Sources	E. 250 microcuries/source. Total possession limit of 500 microcuries.
F. Gadolinium-153	F. Sealed Sources:	F. 10 millicuries/source.

9. Authorized Use(s):
- A. Any imaging and localization procedure approved in Section G.100 of COMAR 26.12.01.01.
 - B. Any imaging and localization procedure approved in Section G.200 of COMAR 26.12.01.01.
 - C. Any radiopharmaceutical therapy procedure approved in Section G.300 of COMAR 26.12.01.01.
 - D. Reference and/or calibration source.
 - E. Reference and/or calibration source.
 - F. Reference and/or calibration source.



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

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License Number: MD-33-215-01

Amendment Number: NEW

LICENSE CONDITIONS

10. The authorized place of use is 1221 Mercantile Lane, Suite 105, Upper Marlboro, Maryland 20774. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address.
- 11A. The radiation safety program shall be under the supervision of Howard DiPiazza, M.D.
- 11B. Radioactive material shall be used by or under the supervision of:

Name	Material
Carol P. Cardinale, M.D.	COMAR 26.12.01.01 Sections G.100, G.200
Yaning Liu, M.D.	COMAR 26.12.01.01 Sections G.100, G.200
Howard DiPiazza, M.D.	COMAR 26.12.01.01 Sections G.100, G.200, G.300

12. The licensee shall comply with all appropriate provisions of COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation," and shall possess a copy of these regulations.
- 13A. Each sealed source containing radioactive material, other than Hydrogen-3 with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.
- 13B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of a device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate.
- 13C. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.
- 13D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Administrator, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230, describing the equipment involved, the test results, and the corrective action taken.
- 13E. Test for leakage and/or contamination shall be performed by persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission or another Agreement State to perform such services.
- 13F. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

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License Number: MD-33-215-01

Amendment Number: NEW

LICENSE CONDITIONS

- 13G. Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been tested within six months prior to the date of use or transfer.
14. Sealed sources containing radioactive material shall not be opened.
15. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for three (3) years from the date of the inventory for inspection by the Department, and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.
16. The licensee may use the Calicheck or Lineator device for doing linearity tests of his dose calibrator provided he follows the procedures in the respective manuals.
17. Food and beverage containers shall not be discarded in radioactive or normal trash containers in licensee's areas utilizing radioactive materials.
18. The licensee shall notify the Radiological Health Program's Radioactive Materials Inspection and Compliance Division, in writing, within ten (10) calendar days after initial receipt of radioactive materials authorized on the license.
- 19A. The licensee shall not make any false statement, representation, or certification in any application, record, report, plan, or other document regarding radiation levels, tests performed or radiation safety conditions or practices. Additionally, the licensee shall not falsify, tamper with, or render inaccurate any monitoring device or method.
- 19B. Violation of any term, condition, or regulation could subject the licensee to administrative or civil penalty or criminal prosecution, as specified in Title 8, Radiation, of the Article Environment of the Annotated Code of Maryland.
20. The licensee shall not transfer ownership and/or control of this license to any person or entity without providing required information regarding the transfer for the Agency's review and without receiving written authorization for the transfer by the Agency.



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

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License Number: MD-33-215-01

Amendment Number: NEW

LICENSE CONDITIONS

21. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements representations, and procedures contained in:

- Application dated March 7, 2013
- Letter with attachments dated April 29, 2013
- Electronic mail pictures of COMAR and negative pressure monitors; September 30, 2013.

COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

September 30, 2013
CAN

9/30/2013

BJP
9/30/13

Roland G. Fletcher, Program Manager IV
Radiological Health Program
Air and Radiation Management Administration