

ALFIERI CARDIOLOGY

NRC- License Amendment

**39 Omega Drive
Newark, DE 19713
(302) 731-0001**

alfiericardiology.com

July 16, 2020

Licensing Assistance Team
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission
Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

RE: Radioactive Materials Amendment Request
License Number: 07-28154-01
Docket No.: 030-30418

To Whom It May Concern:

I am writing on the behalf of Alfieri Cardiology. We request that "authorized user" and "RSO" Varma Vivek, M.D. be removed from our current NRC license and replaced with Rajeev Batra, M.D. Documentation of training and experience for Dr. Rajeev Batra is currently on file under license (MD-29-005-01). All credentials for authorized user and RSO are enclosed.

If there are any questions or additional information is needed, please contact myself at 302-731-0001 or our Director of Nuclear Operations Jason Vanover at (443) 617-2741.

Sincerely,



Anthony Alfieri, D.O., FACC
Owner

REC RG 10721 20 PM 1237

Radiation Safety Officer

DR. RAJEEV BATRA

(301) 593-9612

MYDOCTORBATRA@GMAIL.COM

Documentation of training and experience for the above individual is under this license
(MD-29-005-01)

Authorized Users


AUTHORIZED USERS	SPECIFIC USE
RAJEEV, BATRA M.D.	35.100; 35.200

Documentation of training and experience for the above individuals is currently on file under this license
(MD-29-005-01).

Authorized Medical Physicists: None

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, 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 byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee 1. Alfieri Cardiology, P.A. 2. G-39 Omega Drive Newark, DE 19713		In accordance with letters dated December 18, 2019, and February 15, 2020. 3. License number: 07-28154-01 is amended in its entirety to read as follows:	4. Expiration Date: December 31, 2023 5. Docket No.: 030-30418 Reference No.:
6. Byproduct, source, and/or special nuclear material A. Any byproduct material permitted by 10 CFR 35.200	7. Chemical and/or physical form A. Any	8. Maximum amount that licensee may possess at any one time under this license A. As needed.	9. Authorized use
<div style="text-align: center;">  <p>UNITED STATES NUCLEAR REGULATORY COMMISSION</p> <p>CONDITIONS</p> </div>			
10. Licensed material may be used or stored only at the licensee's facilities located at G-39 Omega Drive, Newark, Delaware.			
11. The Radiation Safety Officer for this license is Vivek Varma, M.D.			

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
07-28154-01Docket or Reference Number
030-30418

Amendment No. 9

12. Licensed material shall only be used by, or under the supervision of:

A. Individuals permitted to work as authorized users in accordance with 10 CFR 35.13 and 10 CFR 35.14.

B. The following individuals are authorized users for the material and medical uses as indicated:

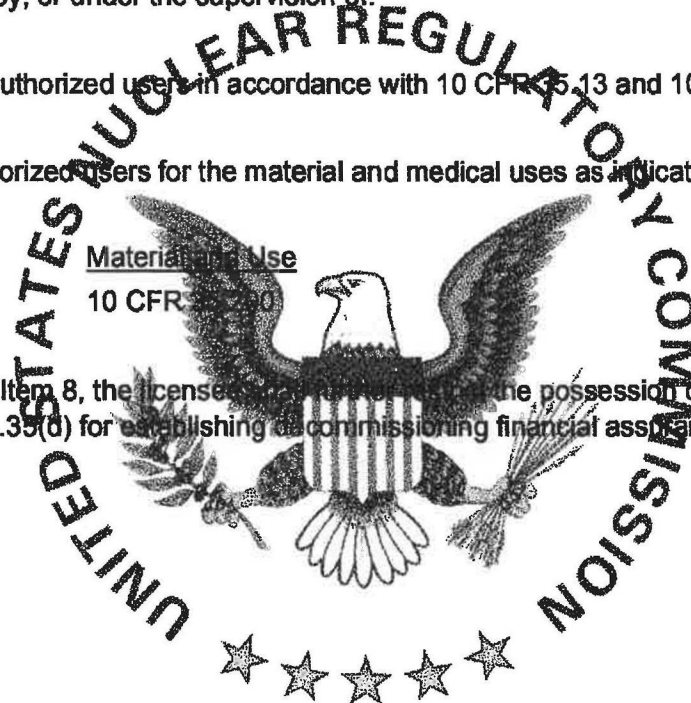
Authorized User(M.D.,D.O.,etc.)

Vivek Varma, M.D.

Material and Use

10 CFR 35.200

13. In addition to the possession limits in Item 8, the licensee shall not restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.





Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

Page 1 of 3

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:	JPC Nuclear Technologies, LLC	3. License No.	MD-29-005-01
2. Address:	120 Speer Road Chestertown, Maryland 21620	4. Amendment No.	02: Renewal Code 02220
		5. Expiration Date:	March 31, 2027

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 material identified in COMAR 26.12.01.01 § G.100	A. Any	A. As needed
B. Any material identified in COMAR 26.12.01.01 § G.200	B. Any	B. As needed
C. Cesium-137	C. Sealed Sources	C. No source to exceed 500 microcuries. Total possession limit of 1 millicurie.

9. Authorized Use(s):
- A. & B. Any Cardiac Imaging procedure approved in COMAR 26.12.01.01 Sections G.100 and G.200.
 - C. Reference, calibration and quality control.

LICENSE CONDITIONS

10. The authorized place of use is 120 Speer Road, Chestertown, Maryland, 21620, and temporary jobsites of the licensee throughout Maryland, except in areas under federal jurisdiction. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address.

- 11A. The radiation protection program shall be under the supervision of Rajeev Batra, M.D.

- 11B. Radioactive material shall be used by or under the supervision of:

Authorized User	Material and Use
Rajeev Batra, M.D.	G.100, G.200, 6C, for cardiac studies only

12. The licensee shall comply with all appropriate provisions of COMAR 26.12.01.01 "Regulations for the Control of Ionizing Radiation," and shall possess copy of these regulations.

Leak testing of sealed sources shall be conducted in accordance with COMAR 26.12.01.01 §G.67.

14. Sealed sources containing radioactivity shall not be opened.



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

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License No.: MD-29-005-01

Amendment No.: 02 Renewal

CONDITIONS CONTINUED

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 Calicheck or Lineator Device for doing linearity tests of his dose calibrator provided he follows the procedures in the respective device.
17. The licensee shall not allow eating, drinking, smoking or applying cosmetics in the licensee's areas utilizing radioactive materials.
- 18A. 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.
 - j. 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.
19. 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.
20. Transportation of radioactive material in the State of Maryland shall be in compliance with Part T Section T.5 "Transportation of Licensed Material" of COMAR 26.12.01.01.
21. At the beginning of each calendar month, the licensee shall furnish the Maryland Department of the Environment Radiological Health Program with the monthly schedule of licensed activities conducted at customer facilities located at temporary job sites which shall consist of the client's address(es), as well as the dates and times of service.



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

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License No. MD-29-005-01

Amendment No. 02 Renewal

CONDITIONS CONTINUED

22. 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:
- Renewal application dated February 4, 2020 and supplementary information received March 2, 2020.

COMAR 26.12.01.01 "Regulations for the 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

March 4, 2020

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Cen 3/4/2020

Eva S. Nair, Program Manager IV
Radiological Health Program
Air and Radiation Administration

Certification Board of Nuclear Cardiology

Incorporated 1996

A Division of the Council for Certification in Cardiovascular Imaging

Certifies That

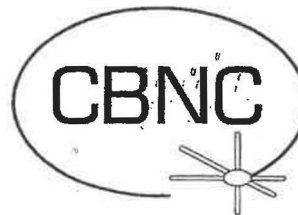
Rajeev Batra, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS
TRAINED IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED
THE REQUIRED EXAMINATION, IS HEREBY DESIGNATED
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF
NUCLEAR CARDIOLOGY

VALID: JANUARY 1, 2017 — MARCH 1, 2027

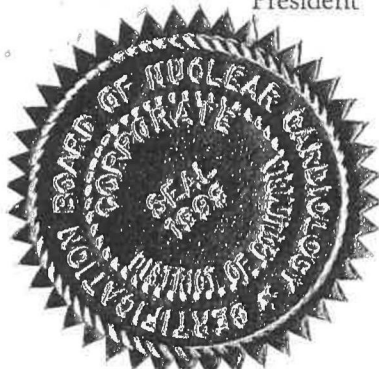
Thomas Kelly

President



Manuel Zorcal

Secretary



CERTIFICATE NUMBER: 4971

Certification Board of Nuclear Cardiology

Incorporated 1996

Certifies That

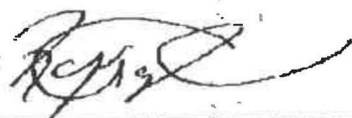
Rajeev Batra, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD
FOR PHYSICIANS TRAINED IN THE UNITED STATES
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED

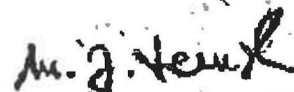
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

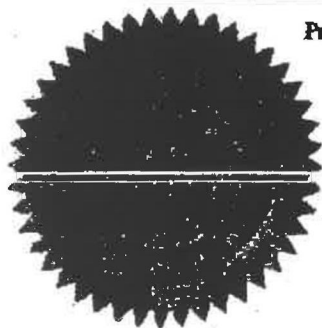
FOR THE PERIOD 2006 - 2016



President



Secretary



CERTIFICATE NUMBER: 4971

ITEM 7.1

Duties and Responsibilities of the Radiation Safety Officer and Delegation of Authority

RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with Nuclear Regulatory Commission, State and DOT regulations and the conditions of the license. These duties and responsibilities include ensuring the following:

- Activities involving license material that the RSO considers unsafe are stopped.
- Radiation exposures are ALARA
- Up-to-date radiation protection procedures in the daily operation of the licensee's radioactive material program are developed, distributed, and implemented
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate (s), and the manufacturer's recommendations and instructions
- Individuals installing, relocating, maintaining, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Licensed material is properly secured
- Documentation is maintained to demonstrate by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, or fire
- Medical events are investigated and reported to the NRC. Cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken
- Audits of the radiation protection program are performed at least annually and documented
- If violations of regulations or license conditions or program weaknesses are identified, effective corrective actions are developed, implemented, and documented
- Licensed material is transported in accordance with all applicable DOT requirements
- Licensed material is disposed of properly
- Appropriate records are maintained
- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

Delegation of Authority

Memo to: **BATRA, RAJEEV, M.D.**
From: ANTHONY, ALFIERI, M.D.
Subject: Delegation of Authority

You, DR. **RAJEEV BATRA**, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management of situations where staff are not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time.



Signature of Management Representative

I accept the above responsibilities,



Signature of Radiation Safety Officer

cc: File

ITEM 10
SAFE USE OF LICENSED MATERIAL

10.1 ALARA Program

Management Commitment:

We, the management of this facility are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we have developed the necessary written policy, procedures, and instructions to foster the ALARA concept within our practice. All individuals under our employ will participate in the program.

Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures at reasonable cost. We will be able to demonstrate, if necessary, those improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

Authorized Users:

The specific responsibilities of the authorized users include:

1. The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
2. The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.
3. Consult with the RSO during the planning stage before introducing new users of radioactive materials.
4. Review each planned use of radioactive materials to ensure that doses will be kept ALARA.

Radiation Workers:

All workers who are subject to occupational radiation exposure will be made aware of the ALARA provisions and in good health physics practices and in maintaining exposures ALARA.

ALARA Investigational Levels:

This practice hereby establishes investigational levels for occupational external radiation doses, which, when exceeded, will initiate review or investigation by the RSO. The investigational levels that we have adopted are listed below. These levels apply to the exposure of individual workers.

2. Dosimetry devices shall be provided to any individual who potentially may receive, in 1 year, from sources external to the body, a dose in excess of 10 percent of the limit in D.201(a) and minors and declared pregnant women who potentially may receive, in 1 year, from sources external to the body, a dose in excess of 10 percent of any applicable limits in D.207 or D.208, and individuals entering a high or very high radiation area.
3. Ring badge dosimetry devices shall be supplied to any occupationally exposed adults who potentially may receive, in 1 year, a dose in excess of 10 percent of the limit in D.201(a)(2)(ii); occupationally exposed minors likely to receive 10 percent of the limits in D.207.
4. The dosimetry devices (whole body and ring badges) will be exchanged monthly and be supplied by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor.
5. This facility currently issues Luxel whole body and TLD ring devices provided by Landauer, Inc.

ITEM 10 (con't)

EXTERNAL DOSE	INVESTIGATIONAL LEVELS (mrem per calendar quarter)	
	LEVEL I	LEVEL II
1. Deep dose equivalent	125	375
2. Eye dose equivalent	375	1125
3. Shallow dose equivalent to skin	1250	3750
4. Shallow dose equivalent to extremity	1250	3750

The following actions will be taken when investigational levels are exceeded:

Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

Personnel dose equal to or greater than Investigational Level I.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews to management following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO.

Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to management following completion of the investigation.

Reestablishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or a group of worker's doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

Signature of Certifying Official:

I hereby certify that this practice has implemented the ALARA Program set forth above.


Signature

Dr. Rajeev Batra
Name (print or type)

Authorized User / RSO
Title

07/16/20
Date

10.3. Emergency Procedures

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR Part 20.1101.

Minor Spills

1. All persons in the area will be notified when a spill has occurred.
2. The spill will be covered with absorbent paper to prevent its spread.
3. Disposable gloves and remote handling tongs will be used to clean up the spill. The absorbent paper and pad will be carefully folded, inserted into a plastic bag and disposed of in the radioactive waste container. All other contaminated materials such as disposable gloves will be also inserted into the plastic bag.
4. The survey will be conducted using an appropriate survey meter. The area around the spill, hands, and clothing will be checked for contamination.
5. The incident will be reported to the radiation safety officer (RSO).

Major Spills

1. All persons not involved in the spill will be notified to vacate the room.
2. The spill will be covered with absorbent pads, but no attempt to clean it up will be made. The movement of all personnel potentially contaminated will be confined to prevent the spread.
3. If possible, the spill will be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. The room will be vacated, and the door (s) locked to prevent entry.
5. The RSO will be notified immediately.
6. Contaminated clothing will be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, the area will be flushed thoroughly and washed with mild soap and lukewarm water.

Radiation Safety Officer: _____ RAJEEV, BATRA M.D. _____
Phone #: _____ 301-593-9612 _____
After Hours Phone #: _____ 301-593-9612 _____

Alternate Contact (designated by RSO):

Alternate: _____ JASON VANOVER _____
Phone #: _____ 443-617-2741 _____
After Hours Phone #: _____ 443-617-2741 _____