



Frank Tran
US Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Rd. Suite 210
Lisle, Illinois 60532-4351

December 16, 2016

Licensee: Molecular Imaging, Inc. (MII)
Address: 800 Technology Drive, Ann Arbor, MI 48108
License #: 21-32816-01, Amendment #11
Action: **Response to Request for Additional Information for Amendment Request Dated September 13, 2016**

Dear Mr. Tran:

This letter is in response to your request for additional information initiated via teleconference on December 15, 2016 between you, Cassandra Frazier, and John Harvey; and enumerated in an email to Dr. Harvey that same day. The responses to these items are given below.

- 1) I, Dr. Harvey, attest that I have worked with and received training in the use of unsealed radionuclides for diagnostic PET and SPECT imaging, including F-18, Tc-99m, I-123, I-125, and Tl-201, as a health and medical physics consultant for West Physics Consulting in Atlanta, Georgia, serving clients throughout the United States. One of these is Insight Health Corporation of Minneapolis, MN, a mobile nuclear medicine imaging provider, for whom I serve as RSO on their South Carolina radioactive materials license no. 768.
- 2) During the time that I am away from the licensee's facilities, Kevin Guley, Associate Scientist, an Authorized User on License no. 21-32816-01, in conjunction with company management, performs oversight of the use of licensed radioactive materials. He will communicate with me for matters related to licensed activities, and I will be available at any time to assist him or other MII personnel with routine or emergency situations. Should an emergency situation occur that requires my presence, I commit to physically responding within a reasonable time frame commensurate with the risk.
- 3) I have attached amendments 29, 30, and 31 of South Carolina license no. 768 (amendment 29 is the most recent to give the license in its entirety), naming me as RSO for the use of unsealed materials for medical diagnosis. The license permits the South Carolina state regulatory equivalent of 10 CFR 35.200 uses.
- 4) I will be physically present at the licensee's facilities for to conduct on-site audits and radiation safety training for new employees, if any. Each visit will last at least one day; every



other visit will last at least two days in order to include dose calibrator and well counter quality control.

Please feel free to contact me should you require any additional information to effect my appointment as RSO on this license.

Sincerely,

A handwritten signature in cursive script that reads "John A. Harvey".

John Harvey, Ph.D., CHP, DABR
Senior Health & Medical Physicist, West Physics
RSO Designate, Molecular Imaging Inc. dba MI BioResearch

On behalf of the management of MII, I hereby attest to and agree to the above. Should you require any additional information in order to process this license action, please do not hesitate to contact me at (734) 926.4200.

A handwritten signature in cursive script that reads "Tom Ludlam".

Tom Ludlam
President and CEO

CC:
Scott Wise, VP Operations
Catherine Anderko, RSO

Enclosure



November 28, 2016

Jim Varcarolis
Senior Vice President
Insight Health Corporation
5775 Wayzata Blvd., Suite 400
Minneapolis, MN 55416

Dear Mr. Varcarolis:

In accordance with your recent request, your S.C. Radioactive Material License No. 768 has been amended. Enclosed is License Amendment No. 31.

If you have any questions regarding your license, please do not hesitate to contact our office at (803) 545-4400.

Sincerely,

A handwritten signature in black ink, appearing to read "James K. Peterson", is written over a horizontal line.

James K. Peterson, Director
Division of Radioactive Material
Licensing and Compliance
Bureau of Radiological Health

/lrc

Enclosure

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Material License
Supplementary Sheet

License No. 768
 Amendment No. 31

Insight Health Corporation
 5775 Wayzata Blvd., Suite 400
 Minneapolis, MN 55416

In accordance with letter dated November 8, 2016, signed by Jim Varcarolis, S.C. Radioactive Material License No. 768 is hereby AMENDED:

TO CHANGE:

Condition 10.

10. The Radiation Safety Officer for this license is John Harvey, Ph.D., CHP, DABR

TO CHANGE:

Condition 11.

11. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists in accordance with RHA 4.8 and RHA 4.9, Department Regulation 61-63.
- B. The following individuals are authorized users for the material and medical uses indicated:

Material and Use

Harvey Greenberg, M.D.	RHA 4.37
Robert Garris, M.D.	RHA 4.37
Gilbert Parker, M.D.	RHA 4.37
Timothy Panell, M.D.	RHA 4.37
Richard Patrick, M.D.	RHA 4.37
Michael Mease, M.D.	RHA 4.37
Bernard F. Masters, M.D.	RHA 4.37
Dan M. Thomason, M.D.	RHA 4.37
Charles D. Williams, M.D.	RHA 4.37
Matthew D. Carson, M.D.	RHA 4.37
Eric Farnsworth, M.D.	RHA 4.37
Roger F. Bley, M.D.	RHA 4.37
Charles F. Colby, M.D.	RHA 4.37
Marion B. Hunley, M.D.	RHA 4.37
Tammy E. Kitchens, M.D.	RHA 4.37
Christopher C. Knox, M.D.	RHA 4.37
John McAlhany, Jr., M.D.	RHA 4.37
Bruce A. Leonard, M.D.	RHA 4.37
Robert Reuter, M.D.	RHA 4.37
Lawrence P. Soderstrom, M.D.	RHA 4.37
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Robert Searles, M.D.	RHA 4.37

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
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Keith A. McGuire, M.D.	RHA 4.37
Clarence S. Davis, M.D.	RHA 4.37
Layne R. Clemenz, M.D.	RHA 4.37
Alex A. Pertile, M.D.	RHA 4.37
Joshua McCain, M.D.	RHA 4.37
Paul D. Kountz, M.D.	RHA 4.37
James B. Haswell, M.D.	RHA 4.37
Joseph A. Kavanagh, M.D.	RHA 4.37
William T. Joyce, III, M.D.	RHA 4.37
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Kelan Brown, M.D.	RHA 4.37
Matthew Chaney, M.D.	RHA 4.37
Carter. Brown, M.D.	RHA 4.37
Robert Tucker, M.D.	RHA 4.37
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Brian J. Fortman, M.D.	RHA 4.37
Paul Kuperman, M.D.	RHA 4.37
Steven T. Pirttima, M.D.	RHA 4.37
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Anthony Toomer, M.D.	RHA 4.37
Lon P. Hamby, M.D.	RHA 4.37

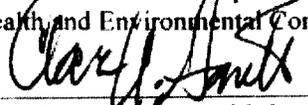
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Material License
Supplementary Sheet

License No. 768
Amendment No. 31

Stephen R. Christian, M.D.	RHA 4.37
Greg Cleveland, M.D.	RHA 4.37
Samuel Hill, M.D.	RHA 4.37
Mary Beth Lewis-Carey	RHA 4.37

Date of Issuance: November 28, 2016

For the South Carolina Department
of Health and Environmental Control

BY: 

Aaron A Gantt, Chief
Bureau of Radiological Health



Catherine E. Hagedorn, Director

Promoting and protecting the health of the public and the environment

April 8, 2016

Jim Varcarolis, Senior Vice President
Insight Health Corp.
C/O CDI
5775 Wayzata Blvd. Suite 400
Minneapolis, MN 55416

Dear Mr. Varcarolis:

In accordance with your recent request dated February 29, 2016, SC Radioactive Material License No. 768 has been amended. Enclosed is License Amendment No. 29 which amends the license in its entirety. This license supersedes the original license and all previous amendments.

If you have any questions regarding your license, please do not hesitate to contact our office at (803) 545-4400.

Sincerely,

James K. Peterson, Director
Division of Radioactive Material
Licensing and Compliance
Bureau of Radiological Health

/amr

Enclosures

**SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
RADIOACTIVE MATERIAL LICENSE**

Pursuant to the Atomic Energy and Radiation Control Act, Section 13-7-40 et.seq. of S.C. Code of Laws of 1976, as amended, and Supplements thereto, and the South Carolina Department of Health and Environmental Control Regulation 61-63, Radioactive Material (Title A), and in reliance on statements and representations heretofore made by the applicant, 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. This license is subject to all applicable rules and regulations of the South Carolina Department of Health and Environmental Control now or hereafter in effect and to any conditions specified below.

Amendment No. 29 amends

LICENSEE		3. License No.:
1. Name:	Insight Health Corporation	768 in its entirety.
2. Address:	5775 Wayzata Blvd., Suite 400 Minneapolis, MN 55416	4. Expiration Date: August 31, 2023
5. Radioactive Material (Element & Mass No.)	6. Chemical and/or Physical Form	7. Maximum Radioactivity and/or quantity of material which licensee may possess at any one time.
A. Fluorine 18	A. Any.	A. As needed.
8. Authorized Use:		
A. Any imaging and/or localization study permitted by RHA 4.37, Department Regulation 61-63.		

CONDITIONS

9. Licensed material may be used or stored at the licensee's facilities located at Lexington Medical Center, 811 West Main Street, Lexington SC, and may be used at temporary job sites of the licensee anywhere in South Carolina where the Department maintains jurisdiction for regulating the use of licensed material.
10. The Radiation Safety Officer for this license is Michael Timmerman, M.S.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Material License
Supplementary Sheet

License No. 768
 Amendment No. 29

11. Licensed material is only authorized for use by, or under the supervision of:

- A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists in accordance with RHA 4.8 and RHA 4.9, Department Regulation 61-63.
- B. The following individuals are authorized users for the material and medical uses indicated:

	<u>Material and Use</u>
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Robert Garris, M.D.	RHA 4.37
Gilbert Parker, M.D.	RHA 4.37
Timothy Panell, M.D.	RHA 4.37
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Michael Mease, M.D.	RHA 4.37
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Christopher C. Knox, M.D.	RHA 4.37
Stuart A. Tinkler, M.D.	RHA 4.37
John McAlhany, Jr., M.D.	RHA 4.37
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Robert M. Salman, M.D.	RHA 4.37
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Joseph A. Kavanagh, M.D.	RHA 4.37
William T. Joyce, III, M.D.	RHA 4.37

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
 Radioactive Material License
 Supplementary Sheet

License No. 768
 Amendment No. 29

David Stoppenhagen, M.D.	RHA 4.37
Larry A. Warren, M.D.	RHA 4.37
Barry A. Lazenby, M.D.	RHA 4.37
Kelan Brown, M.D.	RHA 4.37
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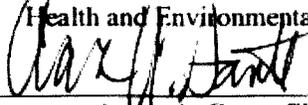
12. In addition to the possession limits in Item 7. of this license, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in Table 1: Radionuclides of Concern, and to quantities below the minimum limit specified in RHA 1.15, Department Regulation 61-63, for establishing decommissioning financial assurance.
13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Material License
Supplementary Sheet

License No. 768
Amendment No. 29

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the Radiation Protection Program as provided for in RHA 4.14, Department Regulation 61-63. 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) Renewal application dated June 17, 2013, signed by Linda Bagley.
 - b) Letter with attachments dated September 6, 2013, signed by Linda Bagley.
 - c) Letter with attachments dated July 31, 2015, signed by Linda Bagley.
 - d) Letter dated November 4, 2015, signed by Linda Bagley.
 - e) Letter with attachments dated February 29, 2016, Jim Varcarolis.
 - f) Letter dated March 15, 2016, signed by Lim Varcarolis.

Date of Issuance: April 8, 2016

For the South Carolina Department of
Health and Environmental Control
By: 
Aaron A. Gantt, Chief
Bureau of Radiological Health



Catherine L. Heigel, Director

Promoting and protecting the health of the public and the environment

May 11, 2016

Jim Varcarolis
Senior Vice President
Insight Health Corporation
5775 Wayzata Blvd., Suite 400
Minneapolis, MN 55416

Dear Mr. Varcarolis:

In accordance with your recent request, your S.C. Radioactive Material License No. 768 has been amended. Enclosed is License Amendment No. 30.

If you have any questions regarding your license, please do not hesitate to contact our office at (803) 545-4400.

Sincerely,

James K. Peterson, Director
Division of Radioactive Material
Licensing and Compliance
Bureau of Radiological Health

/mlw

Enclosure

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
 Radioactive Material License
 Supplementary Sheet

License No. 768
 Amendment No. 30

Insight Health Corporation
 5775 Wayzata Blvd., Suite 400
 Minneapolis, MN 55416

In accordance with letter dated April 20, 2016, signed by Jim Varcarolis, S.C. Radioactive Material License No. 768 is hereby AMENDED:

TO CHANGE:

Condition 11.

11. Licensed material is only authorized for use by, or under the supervision of:

- A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists in accordance with RHA 4.8 and RHA 4.9, Department Regulation 61-63.
- B. The following individuals are authorized users for the material and medical uses indicated:

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SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
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License No. 768
Amendment No. 30

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Steven T. Pirttima, M.D.	RHA 4.37

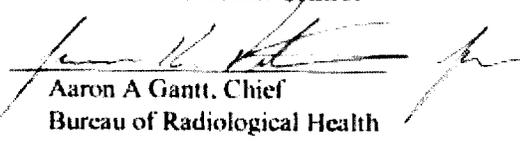
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
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License No. 768
Amendment No. 30

Elizabeth A. Kelley, M.D.	RHA 4.37
Michael H. Brown, M.D.	RHA 4.37
Steven B. Glassman, M.D.	RHA 4.37

Date of Issuance: May 11, 2016

For the South Carolina Department
of Health and Environmental Control

BY: 

Aaron A Gantt, Chief
Bureau of Radiological Health

Tran, Frank

Subject: Re: Request for additional information regarding NRC License No. 21-32816-01 (Molecular Imaging, Inc.)
Attachments: 2016-12-16 NRC Response to RAI for Amendment 12 (signed).pdf; Insight SC RAM License (Amendment 29).pdf; Insight SC RAM License (Amendment 30).pdf; Insight SC RAM License (Amendment 31).pdf

From: John Harvey [mailto:john.harvey@westphysics.com]
Sent: Monday, December 19, 2016 6:44 AM
To: Tran, Frank <Frank.Tran@nrc.gov>
Cc: Scott Wise <swise@molecularimaging.com>; Tom Ludlam <tludlam@mibioresearch.com>
Subject: [External_Sender] Re: Request for additional information regarding NRC License No. 21-32816-01 (Molecular Imaging, Inc.)

Dear Mr. Tran,

I have attached a letter addressing the four issues below and South Carolina license no. 768. Scott Wise was not available today, so Tom Ludlam, President and CEO of Molecular Imaging Inc., has signed the letter on behalf of their management.

Please let me know if I can assist you further in this matter.

Best regards,
John Harvey

John Harvey, Ph.D., CHP, DABR
Senior Medical Physicist
West Physics
www.westphysics.com

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