

Cardinal Health
Nuclear Pharmacy Services
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.4120
fax 614.652.4598

www.cardinal.com



CardinalHealth

November 14, 2018

Bryan Parker, Licensing
U.S. Nuclear Regulatory Commission
Region III – Division of Nuclear Materials Safety
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352

Re: Amendment Request for Radioactive Materials License 34-32780-04MD, Cardinal Health, Dublin, OH.

Dear Mr. Parker,

Cardinal Health 414, LLC (Radium-223 Manufacturing Services, Indianapolis, Indiana, hereafter Cardinal Health) submits a request to remove Elizabeth Tindle as the Alternate Radiation Safety Officer (ARSO) in condition 11.B. and add myself, Glenn P. Sullivan, as ARSO for the above referenced license. Ms. Tindle may be removed as an authorized user in condition 12.

I was previously delegated as the manufacturing Radiation Safety Officer for this license in 2017 and the ARSO in 2016 and understand the commitments concerning the radiation safety program. Training documents are attached.

If you have any questions regarding this request, please contact me at 614.757.9586.

Sincerely,

Glenn P. Sullivan, CRSO
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear & Precision Health Solutions

Enclosure: Training Documents
RSO Delegation of Authority (Sullivan)

cc: Carra Roberts, MRSO loc. 5889
Katherine Benson
David Pellicciarini, VP Pharmacy Safety, Practice and Technical Operations
License File, Loc. 5889 (3)

RECEIVED NOV 19 2018




TO: All Employees, Location 5889, Indianapolis, Indiana
FROM: Tiffany Olson, President, Cardinal Health Nuclear & Precision Health Solutions
DATE: November 14, 2018
SUBJECT: Delegation of Authority - Alternate Manufacturing Radiation Safety Officer

Glenn P. Sullivan has been appointed Alternate Manufacturing Radiation Safety Officer for Cardinal Health 414, LLC Radium-223 (Xofigo®) Manufacturing Services in Indianapolis, Indiana and is responsible for ensuring the safe use of radioactive materials. The Alternate Manufacturing Radiation Safety Officer is responsible for managing the radiation safety program in the absence of the Manufacturing RSO; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Alternate Manufacturing Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

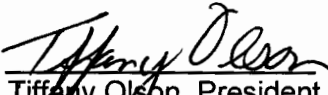
1. Have unhampered access to all activities at his or her facility involving radioactive materials to identify radiation safety problems;
2. Immediately stop, without coordination with management, any activity at his or her facility involving the use of licensed materials by any user that might result in an unsafe situation or a violation of State requirements;
3. Initiate, recommend, or implement appropriate corrective actions; and
4. Verify the implementation of actions taken to correct radiation safety problems.

The alternate Radiation Safety Officer is also responsible for assisting the Corporate Radiation Safety Committee and Corporate Radiation Safety Officer in the performance of their duties. All of us have a critical responsibility in ensuring the safe use of radioactive materials. I ask that you lend your full support to this important function.

I understand and agree to the duties and responsibilities above,


Glenn P. Sullivan, Alt. MRSO

11/14/2018
Date


Tiffany Olson, President
Cardinal Health 414, LLC

11/14/2018
Date

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
34-32780-04MD

Amendment No. 1

Docket or Reference Number
030-388676. Byproduct, source,
and/or special nuclear
material

E. Thorium-228

F. Radium-226

7. Chemical and/or physical form

E. Any

F. Any

8. Maximum amount that licensee
may possess at any one time
under this license

E. 130 millicuries total

F. 65 millicuries total

9. Authorized use

E. Specified maximum impurities in
actinium-227.F. Specified maximum impurities in
actinium-227.**CONDITIONS**

10. Licensed material may be used or stored at the licensee's facilities located at:

1. 4343 West 62nd Street, Indianapolis, Indiana, 46268

11. A. The Radiation Safety Officer (RSO) for this license is Cami Still.

B. The Alternate RSO for this license is Glenn P. Sullivan.

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

Authorized Users

Cami Still

Glenn Sullivan

Mehmet Husnu

Derrick Alcaide

Henry Padgett, Ph.D.

Albert Tondreau

Robert Droege

Norman Medina

Material and Use

All

All

All

All

All

All

All

All

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TO: All Employees, Location 5889, Indianapolis, Indiana

FROM: Tiffany Olson, President, Cardinal Health 414, LLC dba: Cardinal Health Nuclear Pharmacy Services

DATE: July 6, 2017

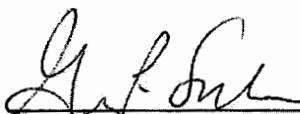
SUBJECT: Delegation of Authority

Glenn P. Sullivan has been appointed Manufacturing Radiation Safety Officer for Cardinal Health 414, LLC Radium-223 (Xofigo®) Manufacturing Services in Indianapolis, Indiana and is responsible for ensuring the safe use of radioactive materials. The Manufacturing Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Manufacturing Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

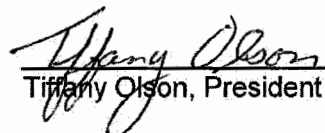
1. Have unhampered access to all activities at his or her facility involving radioactive materials to identify radiation safety problems;
2. Immediately stop, without coordination with management, any activity at his or her facility involving the use of licensed materials by any user that might result in an unsafe situation or a violation of State requirements;
3. Initiate, recommend, or implement appropriate corrective actions; and
4. Verify the implementation of actions taken to correct radiation safety problems.

The Radiation Safety Officer is also responsible for assisting the Corporate Radiation Safety Committee and Corporate Radiation Safety Officer in the performance of their duties. All of us have a critical responsibility in ensuring the safe use of radioactive materials. I ask that you lend your full support to this important function.

I understand and agree to the duties and responsibilities above,


Glenn P. Sullivan, MRSO

7/7/17
Date


Tiffany Olson, President NPS

7/7/17
Date

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
34-32780-04MDDocket or Reference Number
030-38867

Amendment No. 3

- | | | | |
|---|----------------------------------|--|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license | 9. Authorized use |
| E. Thorium-227 | E. Any | E. 25 millicuries total | E. Quality control testing. |
| F. Thorium-228 | F. Any | F. 130 millicuries total | F. Specified maximum impurities in actinium-227. |
| G. Radium-226 | G. Any | G. 65 millicuries total | G. Specified maximum impurities in actinium-227. |

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 4343 West 62nd Street, Indianapolis, Indiana, 46268.
11. A. The Radiation Safety Officer (RSO) for this license is Glenn P. Sullivan.
- B. The Alternate RSO for this license is Elizabeth Tindle.
12. Licensed material shall be used by, or under the supervision of:

Authorized User

Glenn Sullivan
Mehmet Husnu
Derrick Alcaide
Henry Padgett, Ph.D.
Albert Tondreau
Robert Droege

Material and Use

All
All
All
All
All
All

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FROM: Tiffany Olson, President, Cardinal Health Nuclear & Pharmacy
CC: All Cardinal Health Nuclear Pharmacy Services Employees
DATE: May 9, 2016
SUBJECT: Corporate Radiation Safety Officer Delegation of Authority

Glenn P. Sullivan, Director, Health Physics, has been appointed Corporate Radiation Safety Officer for Cardinal Health 414, LLC (Nuclear Pharmacy Services and PET Manufacturing Services, hereafter Cardinal Health). The Corporate Radiation Safety Officer (CRSO) has the responsibility for:

- Managing the corporate radiation safety program;
- Ensuring the safe use of radioactive materials within the company;
- Identifying radiation safety problems through direct observation or through appointees;
- Recommending corrective actions and verifying implementation of such actions; and
- Ensuring compliance with regulations and license conditions.

Glenn Sullivan is hereby delegated the authority necessary to meet the above listed responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

- Make legally binding statements pertaining to radioactive materials licenses operated by Cardinal Health;
- Have unhampered access to all activities at any Cardinal Health facility involving radioactive materials to identify radiation safety problems;
- Immediately stop, without coordination with management, any activity at his any Cardinal Health facility involving the use of licensed materials by any user that might result in an unsafe situation or a violation of license conditions;
- Recommend corrective actions; and
- Verify the implementation of actions taken to correct radiation safety problems.

All of us have a critical responsibility in ensuring the safe use of radioactive materials. I refer you to one of our six values: "The health and safety of our employees, customers and community will never be compromised."

Glenn P. Sullivan, CRSO

5/9/16

Date

Tiffany Olson, President, Cardinal Health NPS

Cardinal Health
Nuclear Pharmacy Services
Quality and Regulatory Department
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**DOCUMENTATION OF NUCLEAR PHARMACY
and PET MANUFACTURING SERVICES
CORPORATE RADIATION SAFETY OFFICER TRAINING**

I hereby certify that the individual below is listed as an Authorized User on a Cardinal Health U.S. NRC license or Agreement State radioactive materials license, and has satisfactorily completed at least 200 hours didactic training and 1000 hours of practical radioisotope handling experience. The individual has a level of competency which is sufficient to delegate responsibilities to all nuclear pharmacy radiation safety officers or PET cyclotron manufacturing radiation safety officers. This includes the duties and authority for corporate oversight of a large radiation safety program, and training as the Corporate Radiation Safety Officer under the current corporate radiation safety officer (CRSO).

CRSO Name (Print) W. Scott Claunch

CRSO Signature: W. Scott Claunch Date: 5/5/2016

CRSO Designee Name (Print) GLENN P. SULLIVAN

CRSO Designee Signature: G.P. Sullivan Date: 5/9/16

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LISLE IL 60532

(630) 829-9854

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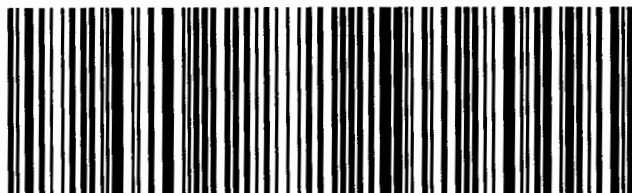
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