



July 12, 2017

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 Nuclear Pharmacy Services, Dublin, OH.

Mr. Parker:

Pursuant to our conversation on June 28, 2017, Cardinal Health 414, LLC (Nuclear Pharmacy Services and Radium-223 Manufacturing Services, hereafter Cardinal Health) submits additional information concerning the training for Ms. Tindle as well as the delegation of authority for myself.

During her tenure at Cardinal, Ms. Tindle has worked closely with the Manufacturing RSO and Corporate RSO to:

- Design, develop, and implement radiation safety procedures, program, processes, and systems at new radium-223 manufacturing site to ensure compliance with regulatory and company requirements; these programs and processes are in place to eliminate or minimize radiation risks to the company, employees, and the environment
- Implement and maintain the operationalization of the radiation safety program
- Ensure daily and weekly area surveys are performed correctly and corrective actions are implemented
- Ensure all radiation safety equipment is functional; equipment includes gas proportional, liquid scintillation counter, alpha detection equipment, dose calibrators, and various personnel survey instrumentation
- Manage radioactive waste processing including radioactive hazardous radium and actinium waste
- Manage equipment calibrations; calibrate various pieces of site equipment as well as maintain calibration schedule for equipment to be sent off site
- Support RSO by assisting with various radiation safety program objectives:
- Provide radiation safety training to personnel including initial training, monthly hands on training, and authorized user training
- Assist with site effluent air monitoring program, including calibrating Lab Impex SmartCAMs
- Provide DOT / IATA assistance and oversight for outgoing radioactive materials
- Performs monthly audits and inspections

- Performs source inventory and sealed source leak testing
- Provide safety oversight to various functional groups including manufacturing and quality control to ensure all personnel are following ALARA principles, engineering controls, and administrative controls; communicate with leadership when these controls are bypassed or malfunctioning
- Respond to investigations of radiological incidents and emergencies including spills

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

Sincerely,



Glenn Sullivan, CRSO
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear Pharmacy Services

Enclosure: Delegation of Authority (Sullivan)
Delegation of Authority (Tindle)

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



CardinalHealth

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

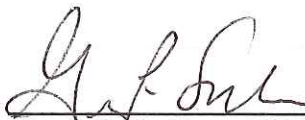
SUBJECT: Delegation of Authority

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



TO: All Employees, Location 5889, Indianapolis, Indiana

FROM: Glenn Sullivan, Corporate Radiation Safety Officer, Director Health Physics
Nuclear Pharmacy Services

DATE: July 6, 2017


SUBJECT: Delegation of Authority - Alternate Manufacturing Radiation Safety Officer

Elizabeth Tindle 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.

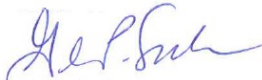
The alternate Radiation Safety Officer is also responsible for assisting the Corporate Radiation Safety Committee and Corporate Radiation Safety Officer in the performance of their duties. All of us have a critical responsibility in ensuring the safe use of radioactive materials. I ask that you lend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

I understand and agree to the duties and responsibilities above,



Elizabeth Tindle, Alt. MRSO

7/6/2017
Date



Glenn Sullivan, CRSO

7/6/2017
Date



Cardinal Health
Nuclear Pharmacy Services
Quality and Regulatory Department
7000 Cardinal Place
Dublin, OH 43017
tel 814.757.5000
fax 814.652.4598

www.cardinal.com

DOCUMENTATION OF MANUFACTURING RADIATION SAFETY OFFICER TRAINING

I hereby certify that the individual below has satisfactorily received 200 hours didactic training and practical radioisotope handling experience commensurate with the scope of intended use; and that the individual has achieved a level of competency sufficient to independently supervise the radiation safety program as a radiation safety officer. This includes training as radiation safety officer under a current radiation safety officer.

RSO Name (Print) GENN P. SULLIVAN

RSO Signature: *Genn P. Sullivan* Date: 14 MAR 2017

RSO Designee Name (Print) Elizabeth Tindle

RSO Designee Signature: *Elizabeth Tindle* Date: 14 APR 2017