

GE Healthcare

Peter F. Mullady, R.Ph.

Pharmacy Manager / Radiation Safety Officer

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July 12, 2018

Attn: Colleen Carol Casey U.S. Nuclear Regulatory Commission - Region III Materials Licensing Section 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

RE: Medi-Physics, Inc. dba GE Healthcare

Radioactive Materials License No. 24-32462-01MD

Additional Information to Control Number 608581

Dear Ms. Colleen Carol Casey;

Pursuant to the agency's letter dated 3 July 2018, requesting additional information specific to GE Healthcare's recent radioactive materials license amendment request, the following responses are provided below. The agency's request for additional information have been restated for ease of reference.

1. Please provide a statement delineating his duties and responsibilities as RSO (Reference NUREG 1556 Vol. 13, Rev. 1, section 8.7.1 and Appendix H).

Kevin F. Grant, R.Ph., the newly appointed site Radiation Safety Officer (RSO) for the Medi-Physics, Inc. dba GE Healthcare, Overland, Missouri radiopharmacy will abide by the RSO duties and responsibilities list found in *Attachment A* of this correspondence.

 Please also submit an RSO Delegation of Authority signed by Mr. Grant and a senior manager, an example of which can be found in a different volume of NUREG 1556, in Volume 9, Revision 2, Appendix I, last page.

Please refer to Attachment B for the RSO Delegation of Authority signed and dated by a GE Healthcare senior management representative and Kevin F. Grant, R.Ph. as requested by the agency.

Should you have any questions or require additional information, please contact me by email at Peter.Mullady@ge.com or call Tel. # (314) 427-6888.

Sincerely,

Peter F. Mullady, R.Ph., BCNP

GE Healthcare

Pharmacy Manager / Radiation Safety Officer

Kevin F. Grant, R.Ph.

GE Healthcare

Authorized Nuclear Pharmacist

Enc. Attachments A & B

Attachment A

1. Radiation Safety Officer (RSO) Duties & Responsibilities List

As the newly appointed Radiation Safety Officer for the GE Healthcare Overland, Missouri radiopharmacy (Radioactive Materials License No. 24-32462-01MD), *Kevin F. Grant, R.Ph.* will be responsible for the following duties and responsibilities listed below.

Radiation Safety Officer's (RSO) Duties & Responsibilities

The RSO will spend his time fulfilling the following duties and responsibilities:

- A. General surveillance over all activities involving radioactive material, including routine monitoring and special surveys.
- B. Ensuring compliance with the rules, regulations and conditions of the U.S. NRC regulations and license.
- C. Monitoring the performance of fume hoods and/or glove boxes that are associated with radioisotope work.
- D. Serving as the primary source of radiation protection information for facility personnel at all levels of responsibility.
- E. Supervising the receipt, opening and storage of all shipments of radioactive material arriving at the nuclear pharmacy.
- F. Supervising the preparation and packaging of all shipments of radioactive material leaving the nuclear pharmacy.
- G. Supervising the distribution and processing of personnel monitoring equipment.
- H. Conducting or supervising and coordinating the radiation safety training and instructional programs for facility personnel.
- I. Supervising and coordinating the radioactive waste disposal program.
- J. Supervising the safe storage of all radioactive materials not in current use.
- K. Ensuring that sealed sources are inventoried and leak tested at proper intervals.
- L. Maintaining an inventory of all radioisotopes and limiting the quantity of radionuclides at the facility to the amounts authorized by the license.

The remaining time will be spent in administering corporate policies, preparing and dispensing radiopharmaceuticals, and controlling purchasing and accounting procedures directly associated with the facility. In the absence of the RSO (i.e. in the early morning when only one Authorized Nuclear Pharmacist is present, when the RSO is ill or on vacation, etc.), an Authorized Nuclear Pharmacist (ANP) will assume the duties of the RSO to ensure compliance with U.S. NRC regulations and the terms and conditions of the license.

The RSO has the authority to enforce radiation safety policy, suspend activities deemed unsafe, and require and direct remedial action when necessary.

Attachment B

1. Delegation of Authority – Radiation Safety Officer (RSO)

GE Healthcare

Memo

To:

Kevin F. Grant, R.Ph.

Authorized Nuclear Pharmacist

From:

Peter F. Mullady, R.Ph., BCNP

Pharmacy Manager, Radiation Safety Officer

Subject:

Delegation of Authority

You, *Kevin F. Grant, R.Ph.*, have been appointed Radiation Safety Officer (RSO) 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 byproduct material by employees who do not meet the necessary requirements and shutting down operations when justified to maintain radiation safety, You, are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission (USNRC) at any time. It is estimated that you will spend <u>8-12</u> hours per week conducting radiation protection activities.

Peter F. Mullad, R.Ph., BCNP

Pharmacy Manager/RSO

3 July 2018

I accept the responsibilities,

Keviń F. Grant, R.Ph.

Authorized Nuclear Pharmacist

13 July 2

Date

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(630) 829-9841
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