Pharma

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

The duties and responsibilities of the Radiation Safety Officer (RSO) include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. As a result of implementation of the EPAct, licensed material now includes accelerator-produced radioactive materials and discrete sources of Ra-226. Licensees authorized under 10 CFR 30.320) to produce and non-commercially transfer PET radioactive drugs to consortium members should review the model duties and responsibilities below, expanding on them as necessary to ensure radiation safety oversight of the production and transfer only to medical use consortium members.

Typically, these duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented,
- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, 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 1 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, and fire;

- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.

Memo to: Jon Woodward, Radiation Safety Officer
From: Richard Van Sant, PharmD
Director of Regulatory Affairs
Subject: **Delegation of Authority**

You, Jon Woodward, 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 (CAPA) 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 requirements and shutting down operations were 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 NRC at any time. It is estimated that you spend 15 hours per week conducting radiation protection activities.

Richard L. Van Sant, PharmD
Director Regulatory Affairs

Date

Richard L. Van Sant

7/25/16

I accept the above responsibilities,

Jon Woodward

Date 7/25/16

Jon Woodward

Tomczak, Tammy

From: Parker, Bryan
Sent: Tuesday, July 26, 2016 8:33 AM
To: Tomczak, Tammy
Subject: FW: Delegation of Authority Additional Info for CN591150
Attachments: MAI Delegation of Authority for RSO.PDF; MidAmerica 665.pdf

Hey Tammy,

Need this document put in ADAMS so I can tie to a license. 665 is attached too.

Thanks!
Bryan

From: Richard Van Sant [mailto:rvansant@pharmalogic.info]
Sent: Monday, July 25, 2016 2:16 PM
To: Parker, Bryan <Bryan.Parker@nrc.gov>
Cc: 'Scott Brower' <sbrower@midamericaisotopes.com>; 'Glen Palmer' <gpalmer@pharmalogic.info>; 'Jon Woodward' <jwoodward@midamericaisotopes.com>
Subject: [External_Sender] Delegation of Authority Additional Info for CN591150

Bryan,

Please find attached the DoA for RSO at our MidAmerican Isotope location. Should you need anything further please contact me at 678-333-5896 or by email.

Thank you

Richard L. Van Sant, PharmD
Director Regulatory Affairs
Pharmalogic

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