



May 29, 2020

Robin L. Elliott  
Health Physicist  
Medical & Licensing Assistance Branch  
Division of Nuclear Materials  
U.S. NRC, Region I  
2100 Renaissance Boulevard, Suite 100  
King of Prussia, PA 19406-2713

Re: License No. 07-14850-01  
Docket No: 030-07565  
Control No: 618901

Dear Ms. Elliott,

We, Bayhealth Medical Center, License Number 07-14850-01, wish to clarify our amendment request dated April 27, 2020, with the following information. We will address each item as outlined in your email correspondence from May 20, 2020.

Item #1: The revised and signed Delegation of Authority is attached.

Item #2:

- a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

***We delegate the needed authority to our RSO to manage our safety program, including authority over all departments and personnel. We expect our RSO to use their experience and expertise to help us maintain our program within compliance, and with the safest and best practice possible. We expect our RSO to make needed recommendations for continued compliance and quality improvement, even when those recommendations involve the expenditure of funds.***



THE DRIVE IS *here.*®

- b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

***We expect our RSO to manage our radiation safety program and make appropriate recommendations as warranted. When any recommendation involves the significant expenditure of funds to maintain safety, this recommendation will be fully discussed with both the RSC and Administration in order to make the most efficient use of funds as designed to remedy any potential safety or compliance concern.***

- c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

***The RSO serves on numerous other materials licenses. These range from several small scope community hospitals, to outpatient cardiology and PET mobile operations. All other RSO commitments are for material licenses with much smaller scope of practice. Our previous appointed RSO, from the same consultant practice, provided 2 full days a month for program oversight. This amounts to approximately 4 hours per week and served our program well historically. We always leave open the option for additional time as warranted and requested for any unexpected needs.***

- d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

***We appoint our chief Nuclear Medicine technologist, Erik Stauff, to serve as our point of contact and liaison for our RSO.***

- e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

***The RSO maintains a company toll free phone system that always call-forwards to reach him by cell. All questions or concerns while not on-site are addressed by email, phone conversation, and text message. The RSO is very responsive to answering questions or concerns in a timely manner. For 90% of the time, our***



***consultant would be about 2 ½ hours away at a maximum. On 2 days a month, the consultant would be a maximum of 4 hours from on-site.***

If you have any questions regarding this clarifying information, please contact John Desiderio at 302.744.6627.

Regards,

A handwritten signature in black ink, appearing to read "Terry Murphy", is positioned above the typed name.

Terry Murphy, FACHE  
President / Chief Executive Officer

Enclosure:  
Delegation of Authority



## **Radiation Safety Officer Duties, Responsibilities, and Delegation**

### **Typical Duties and Responsibilities of the Radiation Safety Officer**

The radiation safety officer's (RSO's) duties and responsibilities include ensuring radiological safety and compliance with U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Transportation (DOT) regulations and the conditions of the license. Typically, these duties and responsibilities include ensuring the following:

- Stop activities involving licensed material that the radiation safety officer (RSO) considers unsafe.
- Ensure that radiation exposures are kept as low as is reasonably achievable (ALARA).
- Oversee all activities involving radioactive material, including monitoring and surveying all areas in which radioactive material is used.
- Ensure that up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed.
- Ensure that possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the Sealed Source and Device (SSD) registration certificate(s), and the manufacturer's recommendations and instructions.
- Ensure individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license.
- Ensure personnel training is conducted and is commensurate with the individual's duties regarding licensed material.
- Ensure documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided.
- When necessary, ensure personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- Properly secure radioactive material.
- If the licensee possesses an aggregated Category 1 or Category 2 quantity of radioactive material, support development and implementation of a security program for radioactive material in accordance with 10 CFR 37.
- Ensure documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR Part 20.1301, "Dose limits for individual members of the public."
- Notify proper authorities of incidents, such as damage to or malfunction of sources/devices, loss of licensed material, fire, theft, etc.
- Serve as a point of contact for the NRC's and licensee's management during routine operations, emergencies, or incidents.
- Medical events and precursor events are investigated and reported to the NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.
- Perform and document periodic audits, at least annually, of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license.

- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for 3 years after the record is made) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.
- When the licensee identifies violation(s) of regulations or license conditions or program weaknesses, ensure corrective action(s) are developed, implemented, and documented.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of 10 CFR Part 20 and 30 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits.
- Ensure licensed material is transported, or offered for transport, in accordance with all applicable NRC and DOT requirements.
- Ensure radioactive waste is disposed of in accordance with NRC regulations and license conditions. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records. Oversee the storage of radioactive material not in current use, including waste.
- Perform/oversee the inventory and leak testing on all sealed sources.
- Oversee the calibration of radiation survey instruments.
- Supervise decontamination operations.
- Maintain up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to the NRC during the licensing process.
- Submit amendment and renewal requests in a timely manner.



**Radiation Safety Officer  
Delegation of Authority**

Memo To: Jay M. Yoder, MS, DABR  
From: Terry Murphy, FACHE, President / Chief Executive Officer  
Subject: Delegation of Authority

You, Jay M Yoder, have been appointed Radiation Safety Officer and are responsible for ensuring the safe and secure use of radiation and radioactive material. 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 at any time. It is estimated that you will spend 4 hours per week conducting radiation protection activities.



\_\_\_\_\_  
Signature of Management Representative (Date)

I accept the above responsibilities,



5-29-20

\_\_\_\_\_  
Signature of Radiation Safety Officer (Date)

cc: Names of affected department head