



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

April 26, 2016

Courtney Jacoby, RTRM, B.S.
Director, Medical Imaging
Bronson Lakeview Hospital
408 Hazen Street
P.O. Box 209
Paw Paw, MI 49079-0209

Dear Ms. Jacoby:

In the letter dated February 23, 2016, you requested to replace the Radiation Safety Officer (RSO) on NRC's license number 21-26716-01 with Laura T. Smith, M.S., DABR. Based on NRC records, Ms. Smith may already be listed as RSO at one or more Agreement State or NRC Radioactive Materials licenses. We have noted that – in addition to requesting to add her to be added to the Bronson Lakeview Hospital License, you have requested to add her to the Bronson Methodist Hospital license, NRC license number 21-13125-01. To adequately consider this request, the NRC will require additional specific information for review.

We are concerned that Ms. Smith may not have sufficient time and availability to oversee the radiation safety programs at your facility, if she becomes the RSO at your facility. Please provide the following information to ensure the safe operation at your licensed facility.

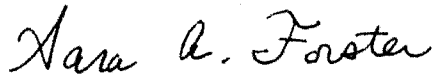
1. Please describe the estimated amount of time each week that Ms. Smith will spend at your facilities located in Paw Paw, Michigan, to adequately perform her duties as the RSO.
2. Please describe the mechanisms for alerting Ms. Smith in case of emergency involving radioactive materials at your facilities when she is not present.
3. Please specify the amount of time it will take Ms. Smith to respond to an emergency involving radioactive materials at your facilities when she is not present.
4. Please describe any previous commitments Ms. Smith has as the RSO and/or authorized user at other facilities. Include a list of all radioactive materials licenses on which she is listed as the RSO. Please describe the impact Ms. Smith's previous commitments and concurrent commitments to Bronson Methodist Hospital will have on her duties as the RSO at your facilities. If there will be no adverse impact, please state so, and why.
5. Please provide a signed and dated memorandum of Understanding/Delegation of Authority (MOU/DOA) document for the new proposed RSO (sample MOU/DOA and model RSO duties listing attached for your reference).

C. Jacoby

- 2 -

Please provide a written response to this letter by May 10, 2016. Your response should be dated and signed by authorized personnel. You may submit your response via facsimile to my attention at (630) 515-1078. Include the reference control number 590374 with your response. We will resume our review once we receive your response. If you have any questions, please do not hesitate to contact me at 630-829-9892 or sara.forster@nrc.gov.

Sincerely,



Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch

License No. 21-26716-01
Docket No. 030-34119

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

Model Radiation Safety Officer Duties and Responsibilities

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 30.32(j) to produce and noncommercially 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 SDR 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;

APPENDIX I

- 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 taken;
- 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.

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, 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 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 where 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 Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

Forster, Sara

From: Forster, Sara
Sent: Tuesday, April 26, 2016 10:12 AM
To: 'lsphysics@att.net'; 'jacoby@bronsonhg.org'
Subject: Additional Information request for Bronson Lakeview Hospital, NRC Lic. No. 21-26716-01, CN590374
Attachments: 02121.590374.21-26716-01 telecon signed.pdf; NUREG1556Vol9AppxI.pdf

Dear Ms. Jacoby and/or Ms. Smith:

Please see the attached file for additional information needed to complete the review of the recent amendment request concerning the above referenced license. Note that the attached letter requests additional information on or before close of business on May 10, 2016. Note that the additional information must be submitted via a signed and dated letter and the requested memorandum of understanding/delegation of authority document must be signed by both Ms. Smith and a duly authorized management official. Additional guidance may be found in NUREG 1556, Vol. 9, Rev. 2, "Program Program-Specific Guidance About Medical Use Licenses;" which may be found at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Do not hesitate to call me with any questions you may have. Please also send a quick email when you receive this message, to confirm receipt.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov
Direct: (630) 829-9892
Facsimile: (630) 515-1078



Forster, Sara

From: Laura T. Smith- Physics <lsphysics@att.net>
Sent: Tuesday, April 26, 2016 10:28 AM
To: Forster, Sara; Courtney A. Jacoby
Subject: [External_Sender] Re: Additional Information request for Bronson Lakeview Hospital, NRC Lic. No. 21-26716-01, CN590374

Ok, I will finish this up by Friday.

Sent from AT&T Mail on Android

From: "Forster, Sara" <Sara.Forster@nrc.gov>
Date: Tue, Apr 26, 2016 at 11:11 AM
Subject: Additional Information request for Bronson Lakeview Hospital, NRC Lic. No. 21-26716-01, CN590374

Dear Ms. Jacoby and/or Ms. Smith:

Please see the attached file for additional information needed to complete the review of the recent amendment request concerning the above referenced license. Note that the attached letter requests additional information on or before close of business on May 10, 2016. Note that the additional information must be submitted via a signed and dated letter and the requested memorandum of understanding/delegation of authority document must be signed by both Ms. Smith and a duly authorized management official. Additional guidance may be found in NUREG 1556, Vol. 9, Rev. 2, "Program Program-Specific Guidance About Medical Use Licenses;" which may be found at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Do not hesitate to call me with any questions you may have. Please also send a quick email when you receive this message, to confirm receipt.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer