

November 2, 2017

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

RE: NRC License No. 21-00943-03, Control No. 601329

Ms. Forster,

I am responding to your request for clarifying information to our NRC License amendment request to authorize Joseph Wissing as our Radiation Safety Officer (RSO).

I have affirmed that for more than the seven years prior to September 5, 2017 that Mr. Wissing continuously performed the requisite RSO duties and responsibilities during audits and in collaboration with Radiation Safety Officers in the VA Health System. The authorized uses included those in Part 35.100, 35.200, 35.300, 35.400, 35.600 (for Ir-192 HDR), and 35.1000 (for Y-90 microspheres, which is not done under our license). This experience included audits, developing procedures, personally reviewing and supervising all aspects for:

- (A) Shipping, receiving, and performing related radiation surveys;
- (B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- (C) Securing and controlling byproduct material;
- (D) Using administrative controls to avoid mistakes in the administration of byproduct material;
- (E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- (F) Using emergency procedures to control byproduct material; and
- (G) Disposing of byproduct material.

This information affirms Mr. Wissing's hands-on experience documented in the previously submitted NRC Forms 313A(RSO) and has been on-going for more than seven years prior to this amendment request. From September 5, 2017 to now, I have affirmed from discussion and observation he has the radiation safety training and experience to effectively address items (A) through (G) above and to function independently as an RSO for all authorized uses on our two NRC licenses including HDR brachytherapy.

I have affirmed that for more than the seven years prior to September 5, 2017 that Mr. Wissing continuously performed the requisite RSO duties and responsibilities during audits and in

collaboration with Radiation Safety Officers in the VA Health System involving self-shielded irradiators. This involved all aspects of the requirements under the Increased Controls Orders and subsequent Part 37 regulations including written procedures for compliance implementation. His responsibilities included oversight of procedures, staff training, security procedures, emergency response, and leak testing. Also, Mr. Wissing attended in 2016 the NRC 201 Security Course related to the security operations of a blood irradiator consistent with our program operations. This course covers not only security requirements but basic operations and general radiation program safety requirements for management self-shielded irradiators by an RSO.

Since September 5, 2017 to now, I can affirm from discussion, observation, and his interaction with NRC Region III staff that Mr. Wissing has knowledge and experience with our blood irradiator (medical sources greater than Category II) to assure compliance with all current Part 37 regulations. This knowledge and experience includes operating procedures, leak testing, staff training, security procedures, emergency response, and how they relate to the safe management of our self-shielded irradiator and demonstrates he possesses training and experience to function independently as RSO over our blood irradiator. He also has completed the background checks needed to be deemed trustworthy and reliable by our Reviewing Official and given unescorted access to the irradiator.

We hope this added information completes the needed documentation to demonstrate Mr. Wissing has the requisite training and experience, and possesses a level of radiation safety and NRC regulatory knowledge commensurate to the scope of operations of our license and sufficient to function independently as the Radiation Safety Officer for all our licensed authorized uses and at all locations of use.

Sincerely,

A handwritten signature in black ink, appearing to read "Ralph P. Lieto". The signature is fluid and cursive, with the first name "Ralph" being more prominent.

Ralph P. Lieto, MSE FAAPM FACR
Radiation Safety Officer
ralph.lieto@stjoeshealth.org

Sandrik, Lauren

From: Forster, Sara
Sent: Thursday, November 02, 2017 10:58 AM
To: Pavon, Sandy; Sandrik, Lauren; Song, Taehoon
Cc: Pelke, Patricia
Subject: FW: Additional Information request for St. Joseph Mercy Health System, NRC Lic. No. 21-00943-03, CN601329
Attachments: StJoeMercyHealth CN601329-Response to NRC reviewer 110217.pdf

Please scan in and return to me. Thank you!

From: Ralph Lieto [mailto:Ralph.Lieto@stjoeshealth.org]
Sent: Thursday, November 02, 2017 9:59 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Cc: Alice Pichan <Alice.Pichan@stjoeshealth.org>
Subject: [External_Sender] RE: Additional Information request for St. Joseph Mercy Health System, NRC Lic. No. 21-00943-03, CN601329

Ms. Forster,

Attached is our response to the additional information being requested to clarify our amendment request to change the RSO for our two licenses. We hope this provides satisfactory resolution to NRC questions. Please feel free to contact me if you should require added information.

Regards,

Ralph P. Lieto, MSE
Radiation Safety Officer
St. Joseph Mercy Health System
Ann Arbor, MI 48106-0995
ralph.lieto@stjoeshealth.org
mobile: 734 476-0588 **fax:** 734 712-2092

From: Forster, Sara [mailto:Sara.Forster@nrc.gov]
Sent: Friday, October 20, 2017 1:57 PM
To: Ralph Lieto
Subject: [External] Additional Information request for St. Joseph Mercy Health System, NRC Lic. No. 21-00943-03, CN601329

Dear Mr. Lieto:

We have reviewed your September 26, 2017 letter (ML17275A801) requesting to change the Radiation Safety Officer (RSO) from yourself to Joseph R. Wissing. Additional information is needed to complete our review. Based on our review of submitted training and experience for Mr. Wissing, it is unclear when and where he has completed training and work experience that meets the requirements in Title 10 of the Code of Federal Regulations (CFR) 35.50(b)(1), (d), and (e). However, pursuant to 10 CFR 35.57(a)(1), because Mr. Wissing was listed as the Radiation Protection Officer (RPO) from April 12, 1989 through March 25, 1993, he is not required to comply with the requirements in 10 CFR 35.50. However, he is required to provide relevant training and experience from the past 7 years (November 1, 2010 through October 31, 2017) to demonstrate

that he meets the recentness of training criteria specified in 10 CFR 35.59. Accordingly, please provide additional information, as noted below:

- 1) Please provide the date(s), location, instructor name(s), instructor qualifications, and brief course outline for any VA, NRC, or other RSO training course that Mr. Wissing has participated in, including any refresher training, within the past 7 years.
- 2) Please provide the date(s), locations, name(s) & qualifications of supervising individual or trainer, and type(s) of radioactive material involve, for any work experience completed in the past 7 years, where Mr. Wissing has had supervised radiation safety experience in the topics outlined below. In particular, please highlight any specific work experience associated with the use of iridium-192 for HDR under 10 CFR 35.600 or yttrium-90 as microspheres for research and development under 10 CFR 35.1000:
 - (A) Shipping, receiving, and performing related radiation surveys;
 - (B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
 - (C) Securing and controlling byproduct material;
 - (D) Using administrative controls to avoid mistakes in the administration of byproduct material;
 - (E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
 - (F) Using emergency procedures to control byproduct material; and
 - (G) Disposing of byproduct material
- 3) Please provide a description of Mr. Wissing's radiation safety and hands-on experience and qualifications as they relate to the self-shielded blood irradiation listed on the referenced license. Please highlight any training and experience completed within the past 7 years. Documentation should include:
 - (A) Specific courses (including date and location completed) completed including formal education program involving a blood irradiator or materials with similar radiation safety issues;
 - (B) Any hands-on experience with a blood irradiator or similar;
 - (C) Any radiation safety program oversight for a blood irradiator. Please include specific facility, dates of oversight, and radiation safety aspects (i.e. leak testing, permit review, emergency and operation procedure preparation, training of others, security issues, etc.)
- 4) Please provide a description of Mr. Wissing's training and experience in the requirements contained in NRC's 10 CFR Part 37 as it relates to the licensee's program.

In order to list Mr. Wissing as RSO on the referenced license, please submit requested information within 14 days (on or before November 3, 2017). If you are unable to respond by then, please let us know as soon as possible when you will be able to provide a response. Additional guidance may be found in NUREG 1556, Vol. 9, rev. 2, "Program Program-Specific Guidance about Medical 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. Any response must be submitted under a signed and dated cover letter. Do not hesitate to call me with any questions you may have, or if you will need additional time to complete your response.