

Beaumont

March 2, 2018

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Docket No. 030-02006

Control No. 602001

RE: Additional Information to Support Amendment Request to NRC License Nos. 21-01333-01,
21-20324-01, 21-25833-01

Dear Sara A. Forster:

This letter is intended to attest that Janice Campbell, Ph.D. has the experience and training necessary to serve as the Corporate Radiation Safety Officer including the non-medical use of byproduct material authorized and conducted under our NRC licenses. In my previous role as Corporate Radiation Safety Officer for Beaumont I worked directly with Dr. Campbell while she performed activities related to research and development use including animal studies and instrument calibration.

Dr. Campbell and I worked closely to develop the biotracer laboratory at Beaumont Hospital, Royal Oak, which was approved by the NRC (Amendment No.92). This laboratory includes two hot cells for production of F-18 labeled chemicals such as F-18 MISO and F-18 FDG. Other radionuclides including C-11, O-15, and N-13, have also been used to synthesize PET radiopharmaceuticals that are used in our animal lab. Up to 5 Curies has been supplied to the biotracer laboratory from the cyclotron that is located adjacent to this laboratory. The cyclotron is currently under lease agreement with PETNet and PETNet holds both NRC licenses for the cyclotron and PET radiopharmaceutical production. The biotracer laboratory is equipped with dose calibrators, well counters, robotic dose dispensing cell, clean room, effluent monitoring systems, area monitors, and survey instruments. Both Dr. Campbell and I have performed quarterly audits for compliance in the biotracer laboratory. Dr. Campbell was instrumental in the training of the radiochemist in radiation safety rules and completed performance evaluations of the radiochemist and others who are authorized to work in this laboratory. Dr. Campbell routinely monitors the effluent releases and reports all variances to the Radiation Safety Committee.

Dr. Campbell and I worked closely together to package, label, and survey more than 30 sealed sources that were picked up by Bionomics and disposed through the SCATR program to reduce Beaumont's inventory. She is RAM DOT trained and also provides DOT training to students and other authorized users as needed. Dr. Campbell is fully aware of the requirements for maintaining security of all licensed material, including those used in the biotracer laboratory,

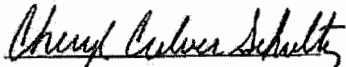
Beaumont Health System
3601 W. Thirteen Mile Rd.
Royal Oak, Michigan 48073

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adaptive imaging center and the MicroPET/CT/SPECT laboratory in the animal research facility. She works closely with the Beaumont Security Department to maintain and enhance security of all byproduct material in nuclear medicine, the adaptive imaging center, radioactive waste storage rooms, and the biotracer laboratory.

I attest that Janice Campbell, Ph.D. is fully trained and experienced in each of the 14 items listed on our NRC License under Radiation Safety Officer – Duties and Responsibilities.

Sincerely,



Cheryl Culver Schultz
Corporate Radiation Safety Officer
Beaumont Health System
September 1993 – January 2, 2018

Song, Taehoon

From: Forster, Sara
Sent: Wednesday, March 07, 2018 3:04 PM
To: Song, Taehoon; Pavon, Sandy; Sandrik, Lauren
Cc: Tomczak, Tammy
Subject: FW: RE: Additional Information Request for Beaumont Health System, NRC Lic. No. 21-01333-01, CN602001
Attachments: NRC Amendment Request 030218.pdf

Please scan in and return to me. Thank you!!! - Sara x9892

From: Campbell, Janice, PhD [mailto:Janice.Campbell@beaumont.edu]
Sent: Wednesday, March 07, 2018 2:57 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Cc: Shaffer, Sheila <Sheila.Shaffer@beaumont.org>; Maciejewski, Jeannine <Jeannine.Maciejewski@beaumont.edu>; Rivera, Jose A <Jose.Rivera@beaumont.org>
Subject: [External_Sender] RE: Additional Information Request for Beaumont Health System, NRC Lic. No. 21-01333-01, CN602001

Dear Ms. Forster,

I have attached a signed and dated letter (as a pdf) from our previous Radiation Safety Officer, Cheryl Schultz, whom I have worked with for almost 20 years. I hope this addresses all the details and information that you need to process our Amendment request. If you would like any documentation in support of Cheryl's letter please let me know. I am happy to send you the supporting documentation for Amendment 92, my RSO training certificates, examples of Biotracer Lab audits or any other supporting information you may need.

Thank you ,

Janice M. Campbell, PhD, DABR
Interim Corporate Radiation Safety Officer
Corporate Nuclear Medicine Physicist
Professor OUWB School of Medicine
William Beaumont Hospital
Diagnostic Radiology and Molecular Imaging
3601 West Thirteen Mile Road
Royal Oak, Michigan 48073
Phone 248-8984118
Pager 248-9922235
Janice.Campbell@beaumont.edu

From: Forster, Sara [mailto:Sara.Forster@nrc.gov]
Sent: Tuesday, February 27, 2018 10:32 AM
To: Campbell, Janice, PhD
Subject: Additional Information Request for Beaumont Health System, NRC Lic. No. 21-01333-01, CN602001

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Dear Dr. Campbell:

As discussed yesterday, we have reviewed your December 5, 2017 letter (ML17356A252) requesting to list you as the Radiation Safety Officer (RSO) on the above-referenced license. As noted in that conversation, additional information is needed to complete our review. Accordingly, please provide additional details to items noted in the attached conversation record.

Please submit additional information on or close of business on March 12, 2018. 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. 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.

Sincerely,

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



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