



CONVERSATION RECORD

02/26/2018

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Janice M. Campbell, Ph.D., Corporate Medical Physicist, Diagnostic Radiology		DATE OF CONTACT 02/26/2018	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS janice.campbell@beaumont.edu		TELEPHONE NUMBER and Molecular Imaging (248) 898-4129	

ORGANIZATION Beaumont Health System	DOCKET NUMBER(S) 030-02006
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LICENSE NUMBER(S) 21-01333-01	CONTROL NUMBER(S) 602001
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SUBJECT
Our review of your December 5, 2017 amendment request to list you as the Radiation Safety Officer on the above-referenced license and - as noted in our voicemail message - additional information needed to complete that review

SUMMARY AND ACTION REQUIRED

We have reviewed the above referenced license amendment request to add a new Radiation Safety Officer (RSO) - Janice M. Campbell, Ph.D., and find that we are unable to continue this action until we have received additional information noted below.

Direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.

Submit requested information within 14 days of this record, referencing Control No. 602001 as listed at the top of this memo. Please FAX your response to my attention at (630) 515-1078. You may also scan your response and send to me via email, as a pdf file. Include a cover letter transmitting your response. Please call to confirm receipt of this request.

As discussed, we expect to receive your written response on or before March 12, 2018.

Please provide written responses to each of the following questions:

- (1) Please confirm that the licensee has requested to add Dr. Campbell as the Radiation Safety Officer, not limited to "transitional."
- (2) Please expand upon the description of Dr. Campbell's' experience with the authorized non-medical uses of byproduct materials authorized and conducted under your license. Provide dates on which Dr. Campbell performed activities related to research & development use including animal studies, and instrument calibrations. For each type of activity, include the radionuclide(s) and radioactive quantities involved, as applicable. Please also include specific or estimated details such as numbers of cases reviewed, audits performed, etc., and the level of involvement or responsibility Dr. Campbell had for those activities. Details, at a minimum, should be included for tasks that Dr. Campbell will be performing based on the attached "Radiation Safety Officer - Duties and Responsibilities" from the August 9, 2013 application.

NAME OF PERSON DOCUMENTING CONVERSATION
Sara A. Forster, Materials Licensing Branch, Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532

SIGNATURE
Sara A. Forster 2/26/2018

ITEM 7 Individuals Responsible for Radiation Safety Program

C. Radiation Safety Officer – Duties and Responsibilities

The Corporate Radiation Safety Officer is responsible for coordination and management of the radiation safety program. The RSO reports to an Administrative Director and also has access to all levels of management within the health system. The RSO is granted authority to immediately terminate any activity that is deemed a threat to health, safety or property. Any such action is immediately brought before the Radiation Safety Committee and discussed with both Hospital and Medical Administration.

1. Safety evaluations of all proposed uses of radioactive material that consider adequacy of facilities and equipment, training and experience of the user, and the operating procedures. The RSO receives and reviews all requests for use and coordinates the RSC review of safety evaluations. The requests are then distributed to members of the research subcommittee of the RSC.
2. Oversees all activities involving radioactive material, including monitoring and surveying of all areas in which radioactive material is used.
3. Oversees the ordering, receipt, surveys, transport and delivery of radioactive material.
- 4. Oversees the packaging, labeling, surveys, etc. of all shipments of radioactive material leaving the institution.
5. Determines compliance with the rules and regulations, license conditions, and the conditions of project approval specified by the RSC. Through audits, reviews, inspections and the variance reporting system, the RSO determines compliance with the NRC license, state and federal rules and regulations, and RSC directives.
- ← 6. Maintains an inventory of radioactive material and limits the quantities to the amounts authorized by the RSC and the NRC License.
7. Supervision and coordination of the radioactive waste program, including storage for decay, permanent disposal, source return to the manufacturer, and releases to the sanitary sewer system.
8. Management of the personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits. The RSO reviews the radiation badge reports and investigates any readings that are unusual or indicate that an individual may exceed ALARA Program Investigational Levels.
9. Oversees inventory and leak tests of sealed sources, and proper calibration of instruments. The medical physicists in Nuclear Medicine, Radiation Oncology and Research involved with the use of the sealed sources are responsible for conducting the leak tests and calibrations and forwarding reports to the RSO. Conducts training courses and in-services, provides on-line training and video training materials to ensure that job-specific training and annual retraining is provided to all authorized users, physicians under the supervision of authorized users, physicists, technologists, nursing personnel and ancillary staff. The RSO Designates cooperate with the RSO to ensure that the radiation safety training

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C. Radiation Safety Officer – Duties and Responsibilities

programs are conducted on a timely basis and are documented.

10. Initiates investigations into possible overexposures from accidents, spills, losses or thefts of radioactive material; and deviations from approved radiation safety practices (e.g. unauthorized disposal, recordable and reportable medical events, etc.). The RSO responds to radiation contamination emergencies and assumes a supervisory role in the decontamination process. Reports events to federal and state regulatory agencies as required.
11. Maintaining security of licensed material, by ensuring that the licensed material is securely stored, transported, or under constant surveillance.
12. Providing consultation on health physics matters and regulatory requirements to authorized users and other persons at all levels of responsibility within the organization.
13. Monitoring and maintaining special systems (e.g., glove boxes, fume hoods, filter systems, etc.) and shielding associated with the use, storage, or disposal of radioactive material.
14. Maintaining all required records and reports, which are accessible to all responsible personnel and regulatory agency inspectors.

Song, Taehoon

From: Forster, Sara
Sent: Tuesday, February 27, 2018 9:39 AM
To: Song, Taehoon; Pavon, Sandy; Sandrik, Lauren
Subject: FW: Additional Information Request for Beaumont Health System, NRC Lic. No. 21-01333-01, CN602001
Attachments: 02110.602001.13-01133-02 NRC 699 signed.pdf

Please scan in and return to me. This is an RFI and conversation record for the referenced action.

Thank you! – Sara

From: Forster, Sara
Sent: Tuesday, February 27, 2018 9:32 AM
To: 'janice.campbell@beaumont.edu' <janice.campbell@beaumont.edu>
Subject: Additional Information Request for Beaumont Health System, NRC Lic. No. 21-01333-01, CN602001

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
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Lisle, IL 60532-4352
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