From: Nguyen, Jan
To: Cheryl.Ficara@hhchealth.org; Mohammed.Aljallad@hhchealth.org
Subject: NRC Request for Additional Information for Hartford Hospital (Mail Control Number 630569)
Date: Wednesday, May 4, 2022 1:19:00 PM

Licensee: Hartford Hospital
License No.: 06-00253-04
Docket No.: 030-01239
Control No.: 630569

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

Dear Ms. Ficara and Dr. Aljallad,

This is in reference to your letter dated March 15, 2022, requesting to amend Nuclear Regulatory Commission License No. 06-000253-04. In order to continue our review, we need the following additional information:

1. You have requested authorization for Ahmed Aziz Chaudhary for the parenteral administration of unsealed byproduct material requiring a written directive, which includes Ra-223 and Lu-177.

   Per 10 CFR 35.396(a)(2), an authorized user under 10 CFR 35.690 needs to meet the requirements in paragraph (b) of this section.
   Per 10 CFR 35.396(b), the physician:
   1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in § 35.390(b)(1)(ii)(G)(*3*). The training must include—
      (i) Radiation physics and instrumentation;
      (ii) Radiation protection;
      (iii) Mathematics pertaining to the use and measurement of radioactivity;
      (iv) Chemistry of byproduct material for medical use; and
      (v) Radiation biology; and
   2. Has work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements, in the parenteral administrations listed in § 35.390(b)(1)(ii)(G)(*3*). A supervising authorized user who meets the requirements in § 35.390, § 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve—
      (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
      (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
      (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
      (iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
      (v) Using procedures to contain spilled byproduct material safely, and using proper

decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G)(*3*); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

   (i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, § 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

   (ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (2) of this section.

Please submit documentation of the following for Dr. Chaudhary: 80 hours of classroom and laboratory training, applicable to the parenteral administration of unsealed byproduct material requiring a written directive; supervised work experience in parenteral administrations; and a written preceptor attestation. This training and experience can be documented on the NRC Form 313A (AUT) which can be found on the Forms website located here: https://www.nrc.gov/reading-rm/doc-collections/forms/index.html.

2. You have requested authorization for Adriana Blakaj, M.D. for Yttrium-90 microspheres (TheraSheres and SIR-Spheres).

In accordance with the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance" dated April 20, 2021, Revision 10.2, Section 5 (Training and Experience), Sub-Section 5.1 (Authorized Users), Criteria C, please provide a written attestation that Dr. Blakaj has satisfactorily completed the requirements in criteria A and B of this section and is able to independently fulfill the radiation safety-related duties as an AU for the type of Y-90 microsphere requested. The attestation must be obtained from either:

(i) An AU who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is a physician who is an AU for the type of Y-90

microsphere brachytherapy being authorized and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include T&E specified in criteria A and B of this section.

Please provide a written attestation for Dr. Blakaj. The microspheres licensing guidance can be found here: https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html/

3. Your letter should have been signed by a management representative rather than the Radiation Safety Officer. The NRC views a letter signed by a management representative as indication that management has reviewed the application and concurs in the statements and representations contained therein. In addition, your letter had a "font" signature, rather than a digital or wet signature. All licensing commitments require an actual signature.

   Please submit a signed letter from a senior management representative, stating that they concur with all statements made in your letter dated March 15, 2022.

We will continue our review upon receipt of the requested information. You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 630569. Please submit a reply within 30 days. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5006.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;**then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Thank you in advance for your help!

Sincerely,

Jan

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