

**From:** [Weidner, Tara](mailto:Weidner, Tara)  
**To:** [jkeck@sibley.org](mailto:jkeck@sibley.org); [jkeck3@jhmi.edu](mailto:jkeck3@jhmi.edu)  
**Subject:** NRC Request for additional information  
**Date:** Tuesday, July 28, 2015 4:19:00 PM

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Licensee: Sibley Memorial Hospital  
License No.: 08-07398-03  
Docket No.: 03014754  
Mail Control No.: 588190

Dear Mr. Keck:

**Please reply to this email to confirm receipt.**

This is in reference to your letter dated June 10, 2015, requesting to amend Nuclear Regulatory Commission License No. 08-07398-03 in order to add the use of Radium 223 permitted by 10 CFR 35.300. In order to continue our review, we need the following additional information:

1. In order to authorize Curtiland Deville, Jr., M.D. as an authorized user for Radium 223, please resubmit the NRC Form 313A (AUT) following the pathway described in Part I, 2.c., "Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization". Specifically, provide training/experience described in Tables 3.a., 3.b. and 3.c., to include 80 hours of classroom and laboratory training and supervised work experience, applicable to parenteral administrations, for which a written directive is required, of any beta-emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required.
2. In your application you stated that administration of Ra-223 would take place in the patient exam rooms in the Radiation Oncology department and waste storage would be in the Radiation Oncology hot lab. Please provide a diagram of the department and indicate the areas of administration and waste storage. In addition, please provide the location, room number, and principal use of each adjacent room (e.g., office, file, toilet, closet, hall way), including areas above, beside, below and indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003.
3. In your application you stated that the incoming Ra-223 package would be delivered to the Nuclear Medicine hot lab and that the package would be surveyed within 24 hours of delivery. 10 CFR 20.1906(c) requires package receipt surveys be performed within 3 hours of receipt if the package is received during normal working hours or within 3 hours of the start of the day following package receipt. Please confirm that the Ra-223 packages will be surveyed within 3 hours of receipt or within 3 hours of the start of the day following receipt of the package.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safetyculture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

We will continue our review upon receipt of this information. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5272. You may scan and e-mail your reply to me at [tara.weidner@nrc.gov](mailto:tara.weidner@nrc.gov) and reference Mail Control No. 588190.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

As a reminder, please have a member of management approve and sign any submittal to this office.

Thank you for your assistance.

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