

From: [Seeley, Shawn](#)
To: nbaez@areciboradiologypr.com; [Maria Palacios](#)
Subject: Arraiza Radiology Renewal MC630232 - Request for Additional Information
Date: Tuesday, March 29, 2022 8:00:00 PM

Dr. Arraiza,

This is in response to your renewal request dated February 19, 2022. In order to continue with our review, we need the following additional information.

1. Your application states that 35.300 materials will be used for “Medical use if unsealed byproduct material for imaging and localization studies for which a written directive required”. Your current license authorizes you for “Any sodium iodide iodine-131 study or procedure in quantities less than or equal to 33 millicuries permitted by 10 CFR 35.300, for which a patient can be released under the provisions of 10 CFR 35.75.” Please confirm that you wish to use the statement that is currently on your license.
2. Your application states, in part, that you will develop and implement procedures for the safe use of material in accordance with 10 CFR 20.1101 and 20.1301. Please confirm that you meant in accordance with 10 CFR 20.1101 and 20.1201.
3. Please confirm who will be performing leak tests of sealed sources. If you will do this in-house, please submit a statement that “We have developed and will implement and maintain written procedures for sealed-source leak testing that will meet the requirements of 10 CFR 35.67.”
4. Your application states that you may provide dosimetry in accordance with the guidance in NUREG-1556, Volume 9, Section 8.22. Please note, that NUREG-1556, Volume 9 is now on Revision 3 and Section 8.22 refers to something else. Please submit a statement that “We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502.” OR “We will monitor individuals in accordance with the criteria in the section titled, ‘Radiation Safety Program – Occupational Dose’ in NUREG-1556, Vol. 9, Rev. 3, ‘Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Medical Use Licensees.’”

We will continue our review upon receipt of this information. If you have any questions, do not hesitate to contact me as noted below.

I do wish Margie had a successful surgery this week. I look forward to seeing her soon.

Shawn W. Seeley, Health Physicist
USNRC
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

610-337-5102 (o); 610-337-5269 (f)
Shawn.seeley@nrc.gov