

Matthew Hill

From: Matthew Hill
Sent: Thursday, November 21, 2024 3:05 PM
To: April Smith
Cc: David Gill; Bonnie Greenblatt; Laura Cender
Subject: Town Center ASC, PLLC - Request for Additional Information

Good Afternoon April,

The NRC has received Town Center ASC's response for the request for additional information from David Gill. There remain a few clarifications that will need to be provided by Town Center ASC before the NRC can complete its review of the license request.

Please provide the following information:

- In Town Center's initial response to our request for information, the source manufacturer, and models for the proposed radioactive seeds to be used were identified. While reviewing the details of the Cs-131 seeds, it was discovered that Theragenics is not the manufacturer of the Cs-131 seeds but is only a distributor of the product. During a phone call with Theragenics, they stated the manufacturer for the Cs-131 seeds is GT Medical Technologies and the model is CS-1. Please provide a statement that you have verified this information to be correct and intend to list the GT Medical, CS-1 seeds on the Materials License.
- Please provide a statement that, "Radioactive seeds that are removed from storage and moved to the operating and procedure rooms will be under constant surveillance by Town Center ASC, PLLC personnel until they are either utilized or returned to their appropriate storage location."
- Delegations of Authority and a list of responsibilities were provided to the NRC. Upon review of the documents, both Dr. Kurtzman and Dr. Agarwal were appointed to serve as RSO. Please provide a corrected copy of Dr. Agarwal's designation as the Associate Radiation Safety Officer. Please note that in accordance with 10 CFR 35.24(b) the RSO may assign duties and tasks to the ARSO, with the written agreement of licensee management, but shall not delegate the authority or responsibilities for implementing the radiation protection program to the ARSO.
- The response from David Gill stated that emergency response equipment will not be required for permanent brachytherapy procedures. 10 CFR 35.415(b) requires emergency response equipment to be available near each treatment room. This requirement applies to both permanent and temporary brachytherapy procedures. Within Town Center's initial application under Item 10, specific equipment, such as a shielded container, is referenced in steps responding to a dislodged source. Please review the steps outlined within the Radiation Safety Procedures for Handling Source Section and Procedures for Radioactive Seed Implantation and provide a statement outlining what emergency response equipment will be made available near each treatment room.

- Town Center ASC, PLLC provided a commitment in their initial application stating that “Personnel monitoring devices will be provided to operationally exposed personnel who are likely to receive more than 10 percent of annual dose limits.” The NRC’s guidance document provides additional detail into compliance with monitoring requirements beyond the statements provided, such as requirements for Declared Pregnant Workers who have differing monitoring requirements than other occupational workers. Please provide a modified commitment that states:
 - A statement that: “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 Licenses: Program-Specific Guidance About Medical Use Licensees.’”

To continue review of your application, we request that you submit your response no later than December 6, 2024.

Thanks,

Matthew Hill

Health Physicist (Licensing)

Materials Licensing Branch, RIII

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