



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2056 WESTINGS AVENUE, SUITE 400
NAPERVILLE, IL 60563-2657

October 30, 2024

Mitchell Hollander, M.D.
Town Center Ambulatory Surgery Center
130 Town Center, Suite 130
Troy, Michigan 48084

SUBJECT: Request for Additional Information – Town Center Ambulatory Surgery Center

Dear Dr. Hollander,

We have reviewed your initial license application dated September 11, 2024 (ML24274A058) requesting a materials license be issued for Town Center Ambulatory Surgery Center. Before we can take further action in processing this request, we will need the following additional information:

1. Title 10 of the *Code of Federal Regulations* (10 CFR) 35.12(b) *Application for license, amendment, or renewal* requires that an original NRC Form 313 be filed. While the NRC Form 313 was filed with the initial application, inaccurate responses were identified in section 2 and section 12.
 - a. The NRC directs all mailed correspondence to the licensee only and does not share licensing or billing information with third parties, although you may choose to so following receipt. Please provide the appropriate mailing address of the applicant. This section should only contain information of the applicant and not contain any specific information for consultants or other third parties assisting with the application process.
 - b. Please clarify if the legal name for the applicant is “Town Center ASC, PLLC” or “Town Center Ambulatory Surgery Center, PLLC.” The NRC typically lists the legal name of the applicant on the license as it is registered with the state, but can also list a doing-business-as name as a second line item beneath the legal name. Please provide the full name of the applicant to be listed on the license.
 - c. An NRC Form 526 was received requesting certification of small business status for fee relief, but this status only provides relief from annual fees issued after the license is made active. Initial licensing fees are a separate category of fee and described in 10 CFR 170.31. As a medical licensee with one location of use, the requested license is under Fee Category 7.C and the correct total fee amount is \$10,800.00. Insufficient funds were received to satisfy fee requirements to support the processing of license application review. Please submit payment for the remainder of the fee balance. The outstanding balance is the difference between the required fee amount (\$10,800.00) and the amount paid by Town

Center Ambulatory Surgery Center on September 18, 2024 (\$5,200.00). Any questions concerning this remittance of this fee can be directed to our fees group by calling (301) 415-7554 or by email at fees.resource@nrc.gov.

2. 10 CFR 30.32(g)(1) requires that an applicant for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either identify the source or device by manufacturer and model number as registered by the commission under 10 CFR 32.210; or provide the source specific information identified in 10 CFR 32.210(c) for the proposed sealed sources.
 - a. Please provide additional information by identifying the proposed manufacturer and model numbers for the requested radioactive seeds as registered with the commission or provide additional source information to satisfy the requirements contained in 10 CFR 30.32(g)(1).
3. 10 CFR 35.24 outlines requirements for the authorities and responsibilities for the radiation protection program. The initial application contained insufficient information within item 7 on the NRC Form 313 to demonstrate that these requirements have been met.
 - a. Please provide the following items to satisfy the requirements of 10 CFR 35.24:
 - i. Written delegation of authority from applicant's management outlining the authority, duties, and responsibilities of the Radiation Safety Officer (RSO) in writing. This must also be signed by the proposed RSO accepting their responsibility for implementing the radiation protection program. A model Delegation of Authority form is enclosed for your convenience.
 - ii. Please note that 10 CFR 35.24 also requires that ARSO's be appointed in writing by the licensee's management and that ARSO's must be provided with specific assigned duties and tasks as assigned by the RSO and agreed to in writing by the applicant's management. These statements do not need to be provided during the licensing process but must be maintained internally and available for inspection by the NRC.
 - b. Please provide a statement to clarify whether the RSO and/or the ARSO will be simultaneously named as authorized users with this license application.
 - c. Please clarify if the proposed RSO is an outside consultant or direct employee of Town Center Ambulatory Surgery Center. For an outside consultant please provide the following:
 - i. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the program).

- ii. Identify an in-house representative who will serve as the point of contact during the RSO's absence.
 - iii. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.
 - iv. Specify the maximum amount of time it will take the consultant-RSO to arrive at the facility in the event of an emergency that requires his/her presence.
4. 10 CFR 19.12 and 10 CFR 35.410 (as applicable) outline requirements for providing instruction to workers who in the course of employment are likely to receive an occupational dose in excess of 100 mrem (1mSv). While certain examples of training commitments were discussed in the license application, NUREG 1556 Vol. 9 Revision 3, provides guidance on completing item 8 of NRC Form 313, *Training for Individuals Working in or Frequenting Restricted Areas*.
 - a. Provide the following statement under item 8, *"We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training;"*

OR
 - b. Provide a complete description of each group of workers, and all training provided to satisfy requirements outlined in 10 CFR 19.12 and 10 CFR 35.410.
5. 10 CFR 35.410 and 35.415(a) outline requirements for providing instruction to workers for patients that may not be released from the facility under criteria outlined 10 CFR 35.75. The initial review did not identify any information concerning inpatient instructions or procedures on quartering patients who cannot be released under the criteria set forth in 10 CFR 35.75. Please provide the following information.
 - a. Provide a commitment to only perform manual brachytherapy procedures that will allow for the release of patients based on criteria outlined in 10 CFR 35.75.

OR
 - b. Provide a summary of procedures to allow for the quartering of patients that cannot be released under the criteria set forth in 10 CFR 35.75.
6. To issue a license, the NRC must review facilities and equipment to ensure adequate protection in accordance with 10 CFR 30.33(a)(2), 10 CFR 35.18(a)(3), and 10 CFR 20.1101. To support the continued review of your facilities and equipment, please provide a response to the following items:
 - a. Provide additional details on the storage location, receipt and opening procedures, and the surgery center. Specifically, please address the following:

- i. What engineering controls are in place to prevent unauthorized removal or access to the licensed materials when in radioactive seeds are stored in the proposed storage area?
 - ii. Photographs provided show the storage area to contain other miscellaneous items. Will the storage area be used exclusively for storage of radioactive materials or for general equipment?
 - iii. How will access to the storage area be controlled? Who will be authorized to enter the storage area?
 - iv. Describe the materials manager position/role. Is this staffed position or a designated role?
 - v. How will the seeds be stored? Where in the storage area will they be located?
 - b. Please provide the room number(s) for the areas where the seed implantation procedures will take place. The application does indicate that procedures will take place in an operating room, but it is not clear if this is used as a general term that could also include the space labeled as Procedure Room on the facility diagram.
 - c. Provide a statement identifying emergency response equipment that is to be maintained in proximity to the operating procedure rooms in accordance with 10 CFR 35.415.
 - d. The provided facility diagram indicates that lead shielding is installed in both the Operating Room and Procedure Room. Please provide a description of the installed shielding in spaces where 35.400 therapies will take place.
7. 10 CFR 20.1801-1802 states that licensees shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.
 - a. Provide the following statement, "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:
 - i. License possession limits are not exceeded.
 - ii. Licensed material in storage is secured from unauthorized access or removal.
 - iii. Licensed material not in storage is maintained under constant surveillance and control.
 - iv. Records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."
8. Please indicate if any additional sealed sources will be used as permitted by 10 CFR 35.65.
9. Please confirm that sealed sources, including manual brachytherapy seeds, will be inventoried semi-annually to account for all such sources possessed. Please confirm that inventory records will be maintained in accordance with 10 CFR 35.2067(b).
10. Please provide the following response(s) regarding monitoring of occupational dose:

- a. 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."

AND/OR

- b. 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.'"

OR

- c. A description of an alternative method for demonstrating compliance with the referenced regulations.

11. In addition to the statements provided in your application, please provide the following commitment regarding area surveys:

- a. "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

12. If seeds may be disposed of through any method other than direct return to the vendor, such as through decay-in-storage, please provide the following statement: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

To continue review of your application, we request that you submit your response to this letter within 15 calendar days from the date of this letter (November 14, 2024). In your response, please refer to the license, docket, and control number specified below.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, we encourage you to contact us at (630) 829 9832 or you may email me directly at Matthew.Hill@nrc.gov.

License No. 04-35767-01

Docket No. 030-39395

Control No. 643396

Sincerely,

Matthew Hill
Health Physicist (Licensing)
Nuclear Regulatory Commission
Materials Licensing Branch, RIII
Work: (630) 829- 9832