From: Lanzisera, Penny
To: leandro.barreca@21co.com
Subject: Request for Additional Information for Amendment
Date: Wednesday, October 09, 2019 4:05:00 PM

Licensee: 21st Century Oncology
License No. 09-31177-01
Docket No. 03037316
Mail Control No. 613978

To continue our review of the request submitted on August 13, 2019 to add I-131 use to your license, please provide the following additional information:

1. The letter was signed by you. It is unclear if you represent senior management. Please provide a signed letter from senior management indicating that they concur with the statements made in the August 13, 2019 letter or delegate you authority to make license commitments on their behalf. In addition, please submit all future amendment requests under senior management's signature.

2. Please provide the facilities, equipment, and procedures to be used for I-131. For instance, you submitted facilities and procedures for Ra-223 in your letter dated October 18, 2017. Will the same facilities be used? Additionally, will you update your procedures for area surveys, patient release, safe use, emergency response, and waste disposal to include I-131 uses?

3. Please indicate the type of survey instrument (e.g., NaI probe), wipe test counter (e.g., NaI well), and dose calibrator possessed for use with unsealed licensed material, including I-131.

4. Describe any shielding used for storage of I-131. For instance, will the I-131 be stored behind a lead cave until use and will a shielded waste storage container be used.

5. Indicate whether a fume hood will be used for liquid I-131. If only encapsulated I-131 will be used with capsules stored within the shipping vial, a fume hood may be unnecessary. Please clarify form of I-131 and storage.

6. Please provide model patient release calculations in accordance with 10 CFR 35.75. Alternatively, you may confirm that only patients who meet the criteria for release under 10 CFR 35.75 will be treated. Additionally, please note that written instructions are required to be provided to patients in accordance with 10 CFR 35.75. NUREG-1556, Volume 9 may be helpful to you in developing your instructions. These will be reviewed during inspection.

Please submit the above information to my attention either via signed pdf sent to my email or via fax to 610-337-5269. Please refer to Mail Control No. 613978 in your reply. If we do not receive a reply within 30 calendar days, we will consider that you no longer require the

addition and void your request. Thank you for your assistance,

Penny Lanzisera
Senior Health Physicist
U.S. NRC Region I