UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD
ARLINGTON TX 76011-4511

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SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

The Nuclear Regulatory Commission (NRC) has completed the technical review of the renewal application of License Number 50-18244-01 and additional information is needed as a result of new licensing practices. An electronic communication dated August 31, 2015 was sent to Mr. Kori Kodimer requesting to provide the information listed below. As of the date of this letter such response has not been received. Please provide the information requested below in a signed and dated letter within 20 days.

1. Provide the following information for each individual radionuclide that is used in accordance with 10 CFR 35.400.

   A. For Cs-137 - source manufacturer's name and source model number, and total possession limit. Provide decommissioning records if the sources Amersham Model CDC-SJ series have been disposed.

   B. For I-125 - source manufacturer's name and source model number, and total possession limit.

   C. For Pd-103 - source manufacturer's name and source model number, and total possession limit.

   D. Any other radionuclide - source manufacturer's name and source model number, and total possession limit.

2. The current license authorizes 999 kilograms of depleted uranium (DU) for shielding in a linear accelerator. The renewal application did not list DU. Provide decommissioning records for the disposal of the DU or request that this authorization remain in the license.

3. NRC inspection reports show that the licensee is in possession of a Sr-90 ophthalmic applicator. This device needs to be listed separately in the license. Provide the following information.

   A. Radionuclide (Sr-90), source manufacturer's name and source model number.

   B. Maximum activity per source, and total possession limit.

   C. Indicate use: "Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400" (if this is the case), or "Storage only, pending disposal."

   D. Provide decommissioning records if source SIA.20 has been disposed.

4. Richard Chung, M.D., is currently authorized under amendment 32 for 10 CFR 35.300 and 35.400 uses. The renewal application requested to list him only as a 35.400 user. Confirm removal of the 35.300 authorization for Dr. Chung.

5. Darwin L. Zellmer, Ph.D., is currently authorized under amendment 32 as an authorized medical physicist (AMP) for "decay corrections of strontium-90 used for ophthalmic treatments." The renewal application did not request Zellmer to be listed as AMP. Confirm the removal of Dr. Zellmer if the Sr-90 applicator is not being used for medical treatment (i.e., storage only, pending disposal; or has been disposed). If the Sr-90 applicator is still being used for medical treatment, provide name of AMP and training and experience documentation.

6. Indicate name of authorized users for nonmedical use of the DU if the licensee is still in possession of DU. The current license authorizes Julee Holayter, M.D., Bradley Cruz, M.D., and Lester Lewis, M.D. as users of DU.

7. For manual brachytherapy, provide description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including dimensions of any portable shields, if one is used.)

8. Provide the following statement when administering dosages of alpha-emitting unsealed byproduct material <u>in other than unit dosages</u> made by a manufacturer or preparer licensed under 10 CFR 32.72 (i.e., licensed radiopharmacies) or 10 CFR 30.32(j) [i.e., PET production by medical/academic institution for non-commercial transfer between 10 CFR Part 35 medical consortiums]:

   A. "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation."

9. Provide the following statement when administering dosages of alpha-emitting unsealed byproduct material in unit dosages made by a manufacturer or preparer licensed under 10 CFR 32. or 10 CFR 30.32(j):

   A. "Dosages containing alpha-emitting unsealed byproduct material will be administered to patients using unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j)."

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

/RA/

Roberto J. Torres, M.S., Senior Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-14720
License: 50-18244-01
Control: 586531

Enclosure: As stated