Walt, Geralyn

From: Lanzisera, Penny
Sent: Thursday, September 24, 2015 5:44 PM
To: cbeaulieu@nvranet.com
Subject: License Renewal

Licensee: Diagnostic Imaging of Southbury, LLC
License No. 06-31024-01
Docket No. 03036882
Mail Control No. 587046

As stated in the notice of expiration which was sent to you, we reserve the right to request a complete, up-to-date application. We have reviewed your submission and existing license commitments and due to conflicting information, we request that you submit the following additional information and clarifications:

1. Your application should be signed by a management representative authorized to make commitments on the part of the licensee. Please provide confirmation from the facilities owners that you are allowed to make these commitments. Otherwise, please submit a letter signed by a designated management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in the license.
2. Please note that the sealed sources listed in your application are included in 10 CFR 35.65 and will not be specifically listed on your license.
3. Please provide a detailed diagram of your facility showing the relation of the hot lab to adjacent areas, including areas above/below/surrounding. In addition, it appears that in your March 15, 2010 letter you switched the MRI/Nuclear Medicine/Litho areas during construction. Have these areas reverted? If so, please provide closeout surveys for the two prior nuclear medicine areas that were transitioned to an ultrasound area and an MRI area.
4. Describe the use of the area labeled “Laundry.”
5. Please provide diagrams of any PET areas including installed shielding and a shielding evaluation. In addition, describe any specialized shielding, syringe shields, and L-blocks used in this area.
6. Confirm if you are requesting 10 CFR 35.300 uses as implied by Item 5.c and Table C.2. If so, please provide the authorized user name and training for this use and describe your facilities and equipment available for this use. In addition, please confirm the maximum possession limit and radionuclide (e.g., 23 mCi of I-131 or 100 mCi of 35.300). Please note that I-131 used for thyroid uptake studies using less than 30 microcuries per study falls under 10 CFR 35.200 uses.
7. In Table C.3, you listed Stuart Korchin as an Authorized Nuclear Pharmacist (ANP) and an Authorized Medical Physicist (AMP). Please provide his training and experience applicable to ANP use to meet the requirements in10 CFR 35.55. Also, please note that an AMP in not applicable to your license since no activities conducted under 10 CFR 35.400 or 35.600 are requested.
8. Please provide a description of the radiation monitoring instruments (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter, etc.) that will be used to perform radiation level detection, measurement, and contamination surveys. In addition, please indicate if you wish the flexibility to upgrade survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.
9. Your application did not address procedures for survey meter calibration. Please confirm that radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.
10. Please confirm that the equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer’s instructions. In addition, please indicate if you will be administering dosages of alpha-emitting unsealed byproduct material and if so, whether you will rely on the dosage determined by the manufacturer or provider with a combination of volumetric

measurement and mathematical calculation for determination of the radioactivity at the time of administration.

11. Please confirm that you will either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or that you will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9.
12. Please confirm that you will develop, 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.
13. Please confirm that you will develop, implement and maintain written procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301.
14. Please confirm that you will develop, implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 Part 20.1101.
15. Please confirm that you will develop, 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 Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

Please submit the above requested information within 30 days to my attention. You may either fax the information with a signed letter to 610-337-5269 or submit a signed pdf to my email address. Please feel free to contact me with any questions.

Thank you for your assistance,

Penny Lanzisera
Senior Health Physicist
US NRC, Region I