

Walt, GERALYN

From: Nguyen, Janice
Sent: Wednesday, October 14, 2015 12:11 PM
To: 'ckulman@jeffersonradiology.com'
Subject: NRC License Renewal for Jefferson Radiology, PC - Request for Additional Information

Licensee: Jefferson Radiology, PC
License No.: 06-28502-01
Docket No.: 030-31642
Mail Control No.: 588182

Dear Mr. Kulman:

Please reply to this email to confirm receipt.

This is in reference to your application dated June 17, 2015, requesting to renew Nuclear Regulatory Commission License No. 06-28502-01. In order to continue our review, we need the following additional information:

1. Please confirm what radioactive material you wish to be licensed for (please include element and mass number, chemical and/or physical form, and maximum amount which will be possessed at any one time).
2. Please provide the purpose(s) for which licensed material will be used.
3. Please confirm that all diagnostic studies or therapeutic procedures permitted by 10 CFR 35.300 will be performed on an outpatient basis and that patients will be releasable under the provisions of 10 CFR 35.75. Alternatively, If you will be housing therapy patients, please provide diagrams of the rooms in which these patients will be housed, showing any installed shielding and/or portable shields, and indicating all adjacent areas, including above and below. Please also confirm that these patients will be quartered in private rooms with private bathroom facilities, and that surveys will be performed to ensure compliance with 10 CFR 20.1301(a).
4. Please confirm the following statement: "Either we will 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 we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," dated October 2002."
5. Please confirm the following statement: "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."
6. Please confirm the following statement: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 20.1301."
7. On the facility diagrams, please indicate what areas are restricted or unrestricted as defined in 10 CFR 20.1003, and please indicate if there is any shielding installed in the walls. Also, please indicate what is adjacent to your areas of use for your site in Glastonbury, CT.

8. You indicated that you have developed and implemented written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61. This implies that you will be calibrating your own survey instruments. If so, please provide the manufacturer and model number of all sealed source(s) which will be used for instrument calibration. Alternatively, you may confirm that you will not be calibrating your own instrumentation and that radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.
9. Please indicate whether or not dosages containing alpha emitting unsealed byproduct material are used. If dosages of alpha-emitting unsealed byproduct material are used, please confirm the following statement: "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."
10. Please submit the probe manufacturer and model number for your portable survey meter instrumentation (Ludlum Model 14C survey meters).
11. You are requesting to possess and use radioactive materials permitted by 10 CFR 35.200 which now includes positron emitting tomography (PET) radiopharmaceuticals. Your application does not request the use of PET. Please confirm you do not wish to be authorized for the use of PET materials. Alternatively, you may request this authorization and include a list of installed shielding and any specialized equipment specific to 511 keV.
12. Please indicate if there are any required sealed sources that do not fall under 10 CFR 35.65.
13. Please include contact information (i.e. phone number and email address) for your certifying official.
14. Please indicate if there are any additional areas used for Nuclear Medicine (i.e. stress labs, waste storage area, etc.). If so, please provide facility diagrams for these areas, indicating what areas are adjacent, above, and below.
15. Please describe how the areas used to prepare and store radioactive material is secured from unauthorized access. 10 CFR 20.1801 requires that licensed material be secured against unauthorized removal from the place of storage. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance over materials in unrestricted areas that are not in storage. In your application you did not indicate how you will secure licensed material.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 588182. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5006.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you for your cooperation.

Jan Nguyen

Janice Nguyen
Senior Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5006
FAX (610) 337-5269