UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 30, 2011

Docket No. 03034024 License No. 06-30265-01
Control No. 575094

Christine Murphy
Operations Manager
Naugatuck Valley Radiological Associates
Union Square Plaza Building 1
385 Main Street South
Southbury, CT 06488

SUBJECT: NAUGATUCK VALLEY RADIOLOGICAL ASSOCIATES, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 575094

Dear Ms. Murphy:

This is in reference to your application dated May 6, 2011 requesting renewal of Nuclear Regulatory Commission License No. 06-30265-01. In your prior renewal you followed NRC Regulatory Guide 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs," and referred to Model Procedures published in this guide. Please note that this guide was published in August 1987 and was designed for use with the NRC's medical regulations that existed in 10 CFR Part 35 at that time. On April 24, 2002, NRC published new medical regulations in 10 CFR Part 35. These regulations became effective on October 24, 2002. Concurrent with the issuance of the new medical regulations, NRC published NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." As specified in Appendix AA of NUREG-1556, Volume 9, Revision 2 http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/, Regulatory Guide 10.8 is superceded and should no longer be used.

Please use NUREG-1556, Volume 9, Revision 2, in preparing your responses to this letter. In addition, you will note that new Part 35 and the NUREG generally do not require the submission of detailed procedures during the licensing process. As described in the NUREG, in many cases a licensee is required only to supply a statement regarding the development, implementation, and maintenance of written operating and emergency procedures. Appendix C of NUREG-1556, Volume 9, Revision 2 should be helpful in identifying the information required by NRC to process your request for license renewal.

In order to continue our review, we need the following additional information:

1. To facilitate future communications, please provide your email address and fax number. Please also provide an email address for Dr. Lehman if he uses one.

2. Your license will be written in a format consistent with NUREG 1556, Vol. 9, Rev. 2. In your response to this letter please use the format below for Items 5 and 6 of your renewal application:

Radionuclide	Form or Manufacturer /Model No.	Maximum Quantity	Purpose of Use
Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
Any byproduct material permitted by 10 CFR 35.300	Any	100 mCi	Any diagnostic study or therapy procedure permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75

3. Please confirm that you will no longer use licensed material in Suite C. If this is the case, submit a close-out survey and remove all radiation warning signs and labels once the room has been cleared.

4. Please submit a detailed version of your facility diagram, that indicates the position of each of the areas described below and describe the type, dimensions, and thickness of shielding that you will use.

    a. Use and storage of Tc-99m generators, if applicable.

    b. Storage of radiopharmaceuticals (refrigerated and non-refrigerated).

    c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. This area should be large enough to handle an accumulation of Tc-99m generators as well as other solid waste. If this area is not located within your main department, describe how you will secure the material.

    d. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, specifically designed PET shielding, etc.).

    e. Location of fume hood, if applicable.

    In addition, identify adjacent areas across the walls from use and storage locations and

show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301. Drawings should be to scale with the scale indicated on the drawing and marked as security-related sensitive information. See Appendix E of NUREG-1556, Vol. 9, Rev. 2.

5. Please confirm that you do not possess or use PET radiopharmaceuticals. Also confirm that you do not possess any camera sources.

6. In accordance with the guidance provided in NUREG-1556, Vol. 9, please confirm whether you request to update to the following commitments found in Table C.3 of the NUREG to develop, document, and maintain written procedures that replace Regulatory Guide 10.8 superceded procedures:

    a. "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

    b. "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

    c. "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 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, Rev. 2, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses."

    d. "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."

    e. "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 10 CFR 20.1301."

    f. "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

    g. "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with10 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."

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 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to Robin Elliott at the Region I Office and refer to Mail Control No. 575094. If you have any technical questions regarding this deficiency letter, please call Robin at (610) 337-5076.

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.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Robert M. Lehman, M.D., Radiation Safety Officer

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