UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

July 30, 2009

Gregory S. Hiatt, Managing Director
Spectron mrc, LLC
17490 Dugdale Drive
South Bend, IN 46635

Dear Mr. Hiatt:

We have completed our review of your application for a commercial radiopharmacy license and find that we will need the following additional information:

1. Materials to be Possessed and Proposed Uses

   a. Describe in greater detail the types of materials that you plan to distribute to non-medical users, e.g., veterinarians, laboratories, other Part 30 licensees, etc. Also, confirm that you will not be re-distributing sealed sources for calibation and medical use.

   b. Please clearly identify the manufacturer's make, model number, activity per source and number of sources for each sealed source that will be identified on your license.

2. Individuals Responsible for Radiation Safety Program

   a. In your application you referenced NRC and/or State license numbers as evidence of training and experience for all of Spectron's proposed authorized nuclear pharmacists. Please submit copies of the licenses which name these individuals as approved authorized nuclear pharmacists to demonstrate that they are qualified to be named on Spectron's commercial radiopharmacy license.

3. Training Program for Individuals Working in or Frequenting Restricted Areas

   Please submit a response to Item 8.8, pages 8-23 through 8-26 of NUREG-1556, Volume 13, Revision 1.

4. Facilities and Equipment

   a. Submit a schematic of all ventilation systems that illustrates the location of each system within the building relative to one another (e.g., pharmacy vs. cyclotron), the intake and exhaust points, directional flow-through, location and type of filtration system(s), and location of effluent monitoring instrumentation, as applicable.

   b. The description that you provided for your effluent filtration systems does not include HEPA filters. Describe the use of HEPA filters, or provide justification why HEPA filters are not utilized to trap particulates.

c Describe procedures that will be used to check effluent filters for saturation, and your criteria for replacing old filters with new ones. Also, describe radiation safety procedures that staff will follow when handling saturated filters.

d. Identify the location of the APTEC-NRC monitor and submit the calibration procedure, including the frequency of the calibration. Also, describe the range of sensitivity of the detector as a value in microcuries per cubic centimeter, and the alarm set point and actions that will be taken should the alarm activate. Describe how the monitoring system will be utilized to ensure compliance with 10 CFR 20.1101(d) and 20.1302(b).

e. Submit the results of your most recent COMPLY code evaluation as it pertains to effluents that are released from your facility due to radiopharmacy operations. Include a list of all parameters that you entered into the code.

f. Describe radiation safety procedures and equipment, e.g., remote handling tools, etc. that will be used to handle unit doses that are transferred from the hot cell to shipping containers.

g. Describe radiation safety procedures that will be followed for conducting routine and periodic maintenance of tubing and valves within the chemical synthesis units, and the lines between the chemical synthesis units and hot and mini-cells. Include your program and radiation safety procedures for inspecting and replacing parts that become worn or brittle from repeated radiation exposure. Describe who will perform these inspections and equipment/parts replacement, and the training that they have received, or will receive, in performing these activities, the procedures that they will follow, and dosimetry that they will wear.

h. Describe the shielding material that is used in the shipping containers and unit dose pigs.

i. Describe the shielding material that is used in the chemical synthesis units. Submit results of radiation level surveys at the surface and 3 feet from each unit when units are in use.

5. Occupational Exposure

a. Please submit a response to Item 8.10.4, pages 8-40 through 8-42 of NUREG-1556, Volume 13, Revision 1. In addition to wearing whole body and extremity dosimetry, staff who work with high energy gamma radionuclides, e.g., positron-emitting nuclides, or are responsible for maintaining and working on delivery lines (i.e., tubing and valves, etc.), within the chemical synthesis units and lines that exist between the chemical synthesis units and hot and mini cells, should be equipped with self-reading pocket dosimeters and/or alarming-rate dosimeters. Please describe the dosimetry program that is in place for these occupational workers.

b. Describe dosimetry that will be provided to carriers who deliver Spectron radioactive material products to customers.

c. Describe how you will detect an accidental airborne release resulting from, for example, a defective valve or tubing in a chemical synthesis unit, an unexpected release from a hot or mini cell, or a release due to manual intervention in a normally automated synthesis procedure. Also, in the event of a release, describe how you will evaluate internal dose to workers in a timely fashion.

as in 6.b ?

Cyd.

6. Radiation Monitoring Instruments

ok

Submit a response to Item 8.10.2, on pages 8-34 through and 8-36 of NUREG-1556, Volume 13, Revision 1. Include calibration procedures and frequency.

7. Material Receipt and Accountability

ok

Submit a response to Item 8.10.3, on pages 8-36 and 8-37 of NUREG-1556, Volume 13, Revision 1.

8. Safe Use of Radionuclides and Emergency Procedures

?

Submit a response to Item 8.10.6, on pages 8-44 through 8-47 of NUREG-1556, Volume 13, Revision 1.

9. Surveys

ok

Submit a response to Item 8.10.7, on pages 8-47 through 8-51 of NUREG-1556, Volume 13, Revision 1.

10. Dosage Measurement Systems

ok

a. Submit procedures for performance and measurement checks and tests that meet 10 CFR 32.72 (c). Refer to Appendix O of NUREG-1556, Volume 13, Revision 1 for acceptable dose calibrator testing.

ok

b. Please indicate if Spectron will only be re-distributing beta-emitting radionuclides, or will Spectron be the initial distributor of these products. If you will be re-distributing beta-emitting products that have already been measured by the initial manufacturer, then Spectron is not required to determine beta correction factors for dose calibrators with ionization chambers.

11. Radioactive Drug Shielding for Distribution

ok

Based on measured radiation levels at the surface of lead and tungsten unit dose pigs, the most effective shielding material for fluorine-18 appears to be tungsten. On page 27 of your application you indicated that the Cardinal Health tungsten shielded pigs would be used exclusively for shipping PET unit doses. Please confirm our understanding of this.

12. Sealed Source Leak Tests

Submit a response to Item 8.10.13 on page 8-57 of NUREG-1556, Volume 13, Revision 1.

13. Waste Management Program

Please submit a response to Item 8.11 on page 8-58 of NUREG-1556, Volume 13, Revision 1.

14. Financial Assurance

Based upon our evaluation of your requested possession limits, e.g., 10 curies of copper-64 and 1 curie of dysprosium-166, Spectron will be required to submit a decommissioning funding plan (DFP) for financial assurance as required in 10 CFR 30.35. Financial assurance must be submitted prior to the NRC issuing a materials license to Spectron.

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 Publicly Available Records (PARS) component of NRC's Agencywide Documents Access and Management System (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

Please submit your response to this letter within 30 days of the date of this letter, and reference as additional information to Control Number 318192.

Sincerely,

/RA/

Kevin G. Null
Materials Licensing Branch

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Kevin G. Null
Materials Licensing Branch

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