



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

September 30, 2009

MEMORANDUM TO: Patricia J. Pelke, Chief
Materials Licensing Branch

FROM: Kevin G. Null, Senior Health Physicist *Kevin G. Null*
Materials Licensing Branch

SUBJECT: SITE VISIT – SPECTRON MRC LLC ON SEPTEMBER 15, 2009 –
TO DISCUSS THE LICENSEE'S REQUEST FOR A NEW
COMMERCIAL NUCLEAR PHARMACY LICENSE AND A NEW
PRODUCTION LICENSE USING AN ACCELERATOR
(REF. ML091200349 AND ML091420565)

The site visit focused on the licensee's April 29, 2009, applications for two new NRC licenses. One application was for a license for the production of radioactive material using an accelerator, and the other application was for a commercial radiopharmacy license. The site visit also included a discussion of the deficiencies described in letters dated July 30, 2009 (ML092660642 and ML092660632).

Observations

Spectron manufactures cyclotron-produced radioactive materials and also operates a radiopharmacy where radiochemicals and radiopharmaceuticals labeled with cyclotron-produced nuclides, primarily fluorine-18, are prepared for distribution to medical facilities. The applications for the two licenses, both dated April 29, 2009, were submitted timely as required under the Energy Policy Act of 2005, which granted NRC jurisdiction over certain accelerator-produced radionuclides.

Spectron MRC LLC is a relatively small company that has been operating in South Bend for approximately seven years. Currently, Spectron supplies fluorine-18 labeled flourodeoxyglucose (FDG) radiopharmaceuticals for medical diagnostic imaging procedures to 10 customers which are all located within about a 120-mile radius from their facility. Spectron generates and ships an average of 40 unit doses of fluorine-18 labeled FDG per day. Spectron was registered with the State of Indiana for the use of the cyclotron and as a nuclear pharmacy prior to NRC assuming jurisdiction over NARM material in Indiana. Spectron has 16 employees, including a Managing Director, a Registered Pharmacist/Radiation Safety Officer, 2 Cyclotron Engineers, a Manager of Research and New Product Development, and an Executive Vice President.

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Operation of the cyclotron, and both loading and unloading of targets is done remotely via computers. Currently 100 percent of the product that Spectron supplies is fluorine-18 labeled FDG that is used by the medical community for functional diagnostic imaging. Radioactive materials are produced using an 11 MeV Siemens RDS 111 self-shielded cyclotron. Product from the bombardment of targets is transferred from the cyclotron room via a delivery line under the concrete floor to one of four shielded mini cells where fluorine-18 is labeled to FDG. The radiochemicals are then transferred to a hot cell where unit doses are drawn using manipulators and placed in individual shielded pigs for shipment to medical facilities.

The NRC reviewer toured the cyclotron room and radiopharmacy, and interviewed several staff members including the Managing Director, Executive Vice President, Pharmacist/Radiation Safety Officer, Cyclotron Engineer, and Manager of Research and Product Development.

The NRC reviewer noted that appropriate instrumentation was available to conduct area surveys and detect contamination, measure radiation levels in the cyclotron room and radiopharmacy, and measure concentrations of gaseous effluent released to the environment. The NRC reviewer also noted that instrumentation used to both detect and measure radiation levels and the presence of radioactive contamination was currently in calibration, and that calibrations were performed by an NRC licensee authorized to provide these services.

The NRC reviewer also noted that Spectron utilizes a pre-filter followed by a carbon filtration system to trap fluorine-18 gas effluent generated from cyclotron and radiopharmacy operations. The system is located above the cyclotron and radiopharmacy. Effluent is monitored at the point of release with an APTEC ion chamber that is coupled to an ADM-606M rate meter which displays concentrations of fluorine-18 released in microcuries per cubic centimeter. Another ADM-606M rate meter is also used to display area radiation levels in the cyclotron room which is coupled to a GM probe that is located above the cyclotron unit. Using a 33 microcurie sealed sodium-22 source, Spectron staff demonstrated that the detector functioned and the alarm in the cyclotron room activated.

Currently, the majority of the work done on the cyclotron in terms of maintenance and target change-out is performed by a Spectron employee, who was trained by Siemens, the manufacturer of Spectron's cyclotron. The employee also has approximately seven years experience in performing these activities. Spectron is currently training another individual to perform these functions. This individual has also received formal training in cyclotrons from Siemens.

Due to the limited number of staff who perform cyclotron and radiopharmacy maintenance, the NRC reviewer reviewed Spectron's dosimetry records. The highest occupational whole body dose received to date for calendar year 2009 is 2358 mrem, and the highest extremity dose is 7090 mrem. With the training of an additional cyclotron engineer, Spectron expects individual exposures to be reduced.

Based on discussions with Spectron staff, the inspector also noted that a significant amount of the extremity exposure appears to have resulted from Spectron's process of manually "capping" each shielded pig that is used to ship a unit dose of fluorine-18. Occupational exposure to staff who work on the cyclotron and are also involved in "capping", or otherwise preparing unit doses will need to be closely monitored by the licensee, particularly if workload increases and staff levels remain the same. This should also be a focus area during NRC inspections.

Licensee Staff Contacted

Greg Hiatt, R.Ph., Managing Director
Robert Galloway, Executive Vice President and Chief Operating Officer/Cyclotron Engineer
Kirk Rozycki, R.Ph., Radiation Safety Officer
David Trump, Ph.D., Manager of Research and New Product Development

Conclusion

This site visit provided the NRC reviewer the opportunity to more effectively evaluate the licensee's applications for two new licenses through direct, face-to-face discussions and a tour of the cyclotron and pharmacy production areas.

Based on the information obtained by the NRC reviewer during the site visit, it was concluded that upon satisfactory response to both deficiency letters, the licenses could be issued.

License Nos.: 13-32726-01MD and 13-32726-02
Docket Nos.: 030-38044 and 030-38045