

April 15, 2008

MEMORANDUM TO: ADAMS and License File
License No.: 24-15595-01

THRU: Patricia J. Pelke, Chief */RA/*
Materials Licensing Branch

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

SUBJECT: SITE VISIT - APTUIT, INC.

PURPOSE OF VISIT: To discuss the licensee's application for an amendment to their research and development license, the Region's deficiency letter dated February 20, 2008 (enclosed), and to tour the licensee's site to evaluate their facilities and equipment, and overall radiation safety program in place to support their proposed amendment.

The site visit was conducted March 14, 2008, in accordance with NUREG-1556, Vol. 20, and focused on the licensee's request for a license amendment to increase possession limits of carbon-14 from 2 curies to 500 curies and hydrogen-3 from 1 curie to 5000 curies, modify their authorized use of licensed material to include radiosynthesis, and upgrade their program from a limited scope research and development to a broad scope.

Observations

The purpose of the visit was to: 1) perform a review of the licensee's facilities, equipment, and staff to support Aptuit's request to increase their possession limits of carbon-14 and hydrogen-3; 2) evaluate their proposal to expand their authorized use from research and development to include radiosynthesis; 3) discuss their request to upgrade their current licensed program from a limited to a broad scope program; and 4) discuss the status of the licensee's response to the NRC's deficiency letter dated February 20, 2008.

Aptuit, Inc., is a licensee that is authorized to conduct research and development as defined in 10 CFR 30, Section 30.4. In their amendment application Aptuit requested approval for a significant increase in possession limits for hydrogen-3 and carbon-14 as noted above, in order to conduct radiosynthesis. Specifically, they plan to perform custom chemical synthesis with radiolabeled hydrogen-3 and carbon-14 for research studies that will be conducted by universities and biotech companies. Aptuit will not be engaged in commercial distribution of radiolabeled product.

The licensee also requested that their NRC license be upgraded from a research and development license to a broad scope license. In conjunction with the possession limit increase of hydrogen-3 and carbon-14, the licensee requested authority to approve studies, authorized users, and facilities in lieu of submitting an amendment request to the NRC.

The site visit included a review of the licensee's facilities, equipment and staffing. The NRC reviewer met with licensee management and staff, as well as representatives from the licensee's health physics and engineering consultants to discuss the technical aspects of Aptuit's amendment request, and tour newly constructed facilities designed to conduct radiosynthesis.

Aptuit contracted with engineering and environmental firms to assist in the design, construction, and renovation of existing facilities on the first floor of their building to accommodate the radiosynthesis operations. Based on a tour of the facilities and discussions and interviews of Aptuit staff and contractor representatives, the reviewer noted that the design and construction plans were well thought-out with particular focus placed on the safety and security of licensed material that will be used in radiosynthesis operations. Examples of designs that went into the facilities included a self-locking alarming entry door, stainless steel laboratory work benches, and eleven new fume hoods (including one walk-in hood for storage of radioactive waste).

The licensee worked with the engineering firm to design a dedicated HVAC system for the new radiosynthesis laboratories. Each fume hood directs its effluent to a single release point through a stack that is located 20 feet above the roof, and 60 feet above ground level. The system is filtered by two banks of HEPA filters that are monitored for saturation. Calculations of expected concentrations released to the environment indicate that values will be less than 10 percent of Part 20 limits for both hydrogen-3 and carbon-14. The system employs two exhaust fans that include an emergency back-up power supply.

The reviewer and licensee representatives also discussed Item 12 of the February deficiency letter, entitled, Environmental Assessment. Based on observations by the reviewer of the dedicated ventilation and air handling system for the new radiosynthesis laboratories and the calculations of expected air effluent, it appeared that the licensee will be able to maintain air effluents as low as reasonably achievable (ALARA), and that the nearest member of the public will receive no more than 10 millirems per year. Therefore, this licensing action would meet the criterion for a categorical exclusion and would not require an environmental assessment.

The reviewer expressed concerns over the licensee's request for a significant increase in carbon-14 and hydrogen-3 and their proposal to upgrade to a broad scope program, after a very recent license amendment naming a new RSO. Given the programmatic change to include authorization for radiosynthesis and the radiation safety issues associated with handling much larger quantities of radionuclides, the reviewer suggested that the licensee consider withdrawing its request for a broad scope program at this time. In addition, the reviewer also suggested that the licensee implement a phased-approach in possession limit increases over time as they gain operational experience in conducting radiosynthesis.

As a result of the increase in possession limits for carbon-14 and hydrogen-3, the licensee submitted revised financial assurance in the form of a decommissioning funding plan (DFP). The DFP was received by the Region III office and the adequacy of its funds will be reviewed by Region III staff in coordination with NRC headquarters.

Senior Persons Contacted

Marcello DiMare, Sr. Director
Pamela Barton, Director, North America Facilities
Kevin Tarwater, Manager, Environmental Health and Safety
Clint Gregg, RSO, Environmental Health and Safety

Licensee Consultants Contacted

Richard Greene CHP, Shaw Environmental and Infrastructure, Inc.
Scott W. Keller, P.E., InSite Group, Inc.

Strengths/Weaknesses Noted

1. Although the RSO is newly appointed, he brings experience in operational health physics where he was the RSO for a similar licensed program located in an Agreement State.
2. Licensee management is fully engaged in, and aware of the proposed amendment, and appears to be supportive in resource needs related to the new operation. In addition, licensee management has contracted with engineering and health physics consulting firms to provide technical support to licensee staff.
3. Newly constructed facilities were well thought-out, with a focus on occupational safety and radiation protection.
4. The licensee lacks experience in handling the proposed quantities of nuclides that they have requested, implementing a broad scope program, and conducting radiosynthesis operations.

Conclusion

This site visit provided the NRC staff an opportunity to evaluate the licensee's ability to implement proposed licensed activities in a safe manner. Licensee management recognized their lack of experience in handling larger quantities of radionuclides, conducting radiosynthesis, and implementing a broadscope program, and will consider modifying their amendment request accordingly.

In their April 1 and April 7, 2008, responses to our February 20, 2008, deficiency letter, the licensee addressed these issues and reduced their possession limit request for carbon-14 from 500 curies to 100 curies, and hydrogen-3 from 5000 curies to 100 curies, and withdrew their request for a broad scope program and provided a list of authorized users and their training and experience in conducting radiosynthesis studies. The licensee has decided to use a phased approach to increase their possession limits, and will request periodic amendments as they gain experience in processing larger quantities of radionuclides and conducting radiosynthesis.

If you have any questions, please feel free to contact me on extension 9854.

License No.: 24-15595-01
Docket No.: 030-09415

Enclosure:
As stated

cc: S. Reynolds
J. Madera

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