December 22, 2010

MEMORANDUM TO: License File No. 13-32783-01

THRU: Cassandra F. Frazier, Acting Chief ***/RA/***
Materials Licensing Branch
Division of Nuclear Materials Safety

FROM: Colleen Carol Casey, Health Physicist ***/RA by Cassandra Frazier for/***
Materials Licensing Branch
Division of Nuclear Materials Safety

SUBJECT: LICENSING SITE VISIT FOR ADVANCED ANIMAL IMAGING SERVICES LLC (AAIS), FORT WAYNE, INDIANA

DATE OF VISIT: AUGUST 17, 2010

PURPOSE OF VISIT: TO EVALUATE THE ADEQUACY OF THE APPLICANT'S FACILITIES AND EQUIPMENT, DISCUSS DEFICIENT ITEMS IN ITS NEW LICENSE APPLICATION AND ASSESS ITS BUSINESS INTENTIONS FOR SAFETY AND SECURITY PURPOSES

Two representatives from the Materials Licensing Branch participated in this licensing site visit. This pre-licensing site visit was conducted in accordance with NUREG 1556, Vol. 20, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Administrative Licensing Procedures," to evaluate the adequacy of the applicant's facilities and equipment, discuss deficient items in its new license application and assess its business intentions for safety and security purposes.

Observations:

The applicant originally submitted a new license application request dated January 25, 2010, that was too deficient to process and was voided on July 2, 2010. The applicant subsequently submitted letters dated July 15 and 16, 2010, reopening the review.

The ownership of this company consists of Summit Radiology, CS Realty (also owners of the building that AAIS is located in), and a consortium of about six regional veterinarians practicing independently of AAIS.

The licensee stated that there is a growing need for the services AAIS plans to render because currently pet owners must travel a great distance and pay much more than AAIS plans to charge for its specialized veterinary diagnostic and therapeutic services.

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The reviewers, the proposed Radiation Safety Officer (RSO) and one of the two proposed Authorized Users (AUs) agreed to conduct the pre-licensing site visit on August 17, 2010, at the applicant's facilities in Fort Wayne, Indiana.

The regional participants in this site visit were, Colleen Carol Casey, Health Physicist, Materials Licensing Branch (MLB), Division of Nuclear Materials Safety (DNMS), and Michael G. Herr, CHP, Health Physicist, MLB – DNMS. The applicant participants were Ryan Harrell, proposed RSO, and William Scheiber, DVM. Patrick Byrne, the applicant's consultant, was also present and participated in the visit.

The reviewers toured the facility by following the "normal work flow" through the practice. The tour commenced with the beginning of operations activity, i.e., the area where packages of radioactive materials would be received from the local nuclear pharmacy or other vendor, checked-in and surveyed. The tour then proceeded through all the restricted work areas for potential generator storage and elution, iodine-131 receipt and preparation for animal patients; the animal patient cages and sequestration room used during treatment and confinement; cage washing area, safe handling equipment, and waste disposal/decay facilities, including the area where a freezer will be located for deceased, radioactive "treated" animal patients who need to be held for "decay-in-storage." The tour ended with the unrestricted areas for the specially installed magnetic resonance imaging device and ultrasound device for animal patients, offices, a break room, rest areas, etc. AAIS is located on the lower level of a typical community veterinary hospital.

The reviewers did not note any discrepancies between the diagrams submitted with the application and the actual, partially completed facilities. The facilities viewed and described appeared to be adequate for the intended use.

The facilities appeared to be well-designed with a logical work flow path, adequate shielding and sufficient workspace to permit implementation of ALARA principles in the radiation safety program elements of licensed activities.

The primary issue concerning the reviewers was the adequacy of technical training and experience for the three principals involved in the proposed practice, i.e., veterinary doctors Kevin Cawood and William Scheiber and proposed RSO, Ryan Harrell. In particular, the reviewers were concerned that Mr. Harrell appeared to be most qualified for the proposed uses but lacked the veterinary doctoral degree. The two veterinarians possessed the doctoral degree but appeared to be very minimally qualified for the proposed licensed activities and radiation safety program.

Mr. Harrell and Dr. Scheiber explained to the reviewers, in considerable detail, that the planned licensed activities would be a collaborative venture, bringing the expertise of the veterinarians together with the extensive experience that Mr. Harrell has, as an experienced and certified nuclear medicine technologist, in order to offer their clients and animal patients the benefit of their collective expertise.

Mr. Harrell explained that he has two bachelor's degrees, one in nuclear medicine technology and one in animal sciences. Each of the two veterinarians proposed as AUs has had radiology coursework in veterinary school; some classroom and laboratory exposure to radiation safety

principles and topics, instrumentation, chemistry, physics, biology, etc.; and limited experience with radioactive materials used in animal radiology and therapy.

Each animal patient undergoing evaluation and treatment at AAIS will receive the benefit of experience from both the veterinarians and Mr. Harrell. The practice is initially expected to limit its licensed activities to smaller animals, such as dogs and cats. Eventually, the applicant may expand its practice to include ferrets and horses, and possibly other species "to be determined" via the amendment process.

During the visit, several radiation safety program elements were verbally clarified, as identified in the deficiency conversation record transmitted on August 26, 2010, and potential responses were discussed. These items included, in part, the training program for all staff involved in licensed activities, the potential volatility of the iodine-131 form AAIS plans to use; confirmation that bioassays would be performed on radiation workers who may be exposed to volatile iodine-131, including the provision of comprehensive procedures and a description of equipment for the bioassay program; and the instructions to be provided to animal patient caregivers. The responses proposed increased the reviewers' understanding of the proposed activities as well as the licensee applicant's understanding of NRC's expectations.

The security of licensed materials was also examined and appeared to be adequate as proposed. The business intentions of the applicant were evaluated and determined to be benevolent and as described in the application.

No new deficiencies were identified with respect to the proposed facilities and radiation safety program elements.

The reviewers also verified that the applicant was in the process of procuring equipment; had either hired or interviewed prospective staff, or was training existing staff, as appropriate; and was in the process of completing build-out of its facilities in order to commence operations as soon as it obtained the NRC license. No other issues were identified by the reviewers during this portion of the site visit.

Conclusion:

The NRC evaluation of the applicant's facilities, business operations, radiation safety program/ license application and proposed staffing provided the reviewers with valuable first-hand information to discern its intentions regarding the license. It also afforded an opportunity to efficiently discuss deficient items in the application and establish a "safety and security-focused" dialogue with the applicant's proposed RSO and management representatives. The visit provided greater clarity into the functional relationship between the two veterinarians and the proposed RSO so that licensed activities could be successfully and safely performed.

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