

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III 2056 WESTINGS AVENUE, SUITE 400 NAPERVILLE, IL 60563-2657 February 28, 2025

Tammy P. Sadek, DVM Radiation Safety Officer Riverside Cat Hospital, PC 4632 Okemos Rd. Okemos, MI 48864

Dear Dr. Sadek:

This letter is regarding the application dated January 15, 2025, signed by Kerry Lewis, DVM, President, for issuance of a U.S. Nuclear Regulatory Commission (NRC) Materials License.

The U.S. NRC's guidance document for your type of license, which I refer to below as "the guidance," is NUREG-1556, Volume 7, Rev. 1, dated February 2018, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope." This guidance is available on the U.S. NRC website at: <u>https://www.nrc.gov/docs/ML1806/ML18065A006.pdf</u>

Upon review of the request, I identified the following areas requiring additional or clarifying information:

1. NRC Form 313, "Application for Materials License," indicates that the license application should be prepared following the instructions provided in the current volume of NUREG-1556, "Consolidated Guidance About Materials Licenses."

Your application was not prepared in accordance with the guidance and did not adequately address all required items. Therefore, you may revise and resubmit your application using Appendix B, "Suggested Format for Providing Information Requested in Items 5 through 11, of the U.S. NRC Nuclear Regulatory Commission Form 313," from the guidance.

Additional items in this letter address the specific areas in which additional or clarifying information is requested. Further information regarding completion of the license application may be found in Section 8, "Contents of an Application," of the guidance.

Note that several attachments included with your application were not legible. This included portions of the facility description, radiation safety training program, and radiation safety program procedures. Therefore, please resubmit the application including an appropriately completed copy of the enclosed Appendix B and ensure that all supporting attachments included are legible.

2. Section 8.5.1, "Unsealed or Sealed Byproduct Material," of the guidance, specifies that applicants must provide the manufacturer's name and model number for each requested sealed source and/or device so that the U.S. NRC can verify that a safety evaluation has been performed and documented in a Sealed Source and Device (SS&D) Registry Sheet.

The application requests authorization for a cesium-137 rod source.

Please provide the manufacturer and/or distributor name and model number for the requested sealed source. If applicable, please provide the associated SS&D Registry Sheet number, which you may obtain from the manufacturer and/or distributor of the sealed source and/or device.

3. Section 8.5.2, "Financial Assurance and Recordkeeping," of the guidance, states that that all licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site, or any area, is released for unrestricted use. Further, a licensee authorized to possess licensed material in excess of the limits specified in <u>Title 10 of the Code of Federal Regulations</u> (10 CFR) §30.35, "Financial assurance and recordkeeping for decommissioning," must submit a decommissioning funding plan or provide a certification of financial assurance for decommissioning.

Your application does not address financial assurance and recordkeeping for decommissioning. This is not an acceptable response because all licensees are required to maintain records important to the decommissioning of the licensed facility.

As indicated in the "Response from Applicant," section of the guidance, please respond by providing the following:

- the statement: "Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g) and 10 CFR 70.51(b)(3), as appropriate, we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and 10 CFR 70.36, as appropriate. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a)(3), as appropriate, prior to license termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), as appropriate, to the appropriate NRC Regional Office."; and
- if financial assurance is required, submit evidence of financial assurance following the guidance of NUREG–1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness."

4. Section 8.7.2, "Authorized User," of the guidance, identifies that Authorized Users must have adequate training and experience with the types and quantities of licensed material they propose to use.

An Authorized User should have (i) a college degree at the bachelor's level or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (ii) training and experience commensurate with the scope of proposed activities.

The application does not clearly identify the individual(s) that you are proposing to serve as Authorized User(s) of licensed material.

Please identify the proposed Authorized User(s) and describe their radiation safety training and experience, including applicable documentation (e.g., college degree or transcript, state issued veterinarian license, certificates of training, etc.).

Note that an acceptable radiation safety training course should address the applicable subjects specified in Appendix D, "Guidance for Laboratory Animal and Veterinary Medicine Uses," and Appendix F, "Radiation Survey Safety Topics," of the guidance.

5. Section 8.8, "Item 8: Training for Individuals Working in or Frequenting Restricted Areas," of the guidance, indicates that individuals working with or in the vicinity of licensed material must be provided with adequate safety instructions. Retraining should be performed whenever there is a change in duties or the work environment and at a frequency sufficient to ensure that all staff members are adequately trained.

Several portions of the submitted radiation safety training program were not legible.

Please resubmit your radiation safety training program providing a legible copy. Include applicable revisions to describe the topics covered, identification of the instructor(s) and their qualifications, categories of workers that will be provided training (e.g., ancillary personnel, veterinarians, veterinary assistant, etc.), method of testing used for assessing the knowledge of workers completing the training, and the method and frequency of training.

6. Section 8.9, "Item 9: Facilities and Equipment," of the guidance, describes that facilities and equipment must be adequate to protect health and minimize danger to life or property.

The submitted facility diagram and description did not include all pertinent information and was not completely legible.

Please resubmit your facility diagram and description, expanding on the level of detail, accounting for the applicable considerations specified in Appendix D, "Guidance for Laboratory Animal and Veterinary Medicine Uses," and Appendix G, "Facilities and Equipment Considerations."

Identify all of the following items on your facility diagram(s) and/or drawing(s):

- identify all areas/rooms where licensed radioactive material (including waste) will be received, prepared, used and stored;
- provide the dimensions/scale for the areas/rooms where radioactive material will be received, prepared, used and stored (the direction of north should be indicated);
- describe adjacent areas/rooms to the areas where radioactive material will be received, prepared, used and stored (e.g. hallways, outside/exterior, labs, office, etc.);
- describe/label details such as sinks, dose calibrator, L-block, shielded cave, fume hood, glove boxes, refrigerators, freezers, material receiving area and lead-lined waste storage containers;
- include a description of the animal handling and housing facilities (distinguishing between areas designated for animals administered licensed materials and those designated for other animals); and
- describe measures to secure radioactive material (e.g. describe or label locking doors, cabinets, containers, cages, etc.).
- 7. Section 8.10.2, "Radiation Monitoring Instruments," of the guidance, specifies that licensees should possess, or have access to, radiation monitoring instruments, which are necessary to protect health and minimize danger to life or property.

The application does not include a complete description of available radiation monitoring instruments, including the identification of compatible probe models.

As indicated in the "Response from Applicant," area of this section, please revise and resubmit your application providing the following:

- describe the instrumentation that will be used to perform required surveys; and
- the statement, "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.' We reserve the right to upgrade our survey instruments as necessary."
- 8. Section 8.11, "Item 11: Waste Management," of the guidance, states that radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

The application identifies that iodine-131 waste will be disposed via decay-in-storage.

As indicated in the "Response from Applicant," section of the guidance, please respond by also providing the one of the following:

• the statement, "We will use the model waste procedures published in Appendix P in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"; or

- if you wish to use only selected model procedures, state that: "We will use the [specify either (i) decay-in-storage or (ii) disposal of liquids into sanitary sewerage] model waste procedures that are published in Appendix P in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"; and
- if you wish to compact or incinerate radioactive waste, provide the requested information concerning these activities in Appendix P to this NUREG.

Note that the disposal of animal carcasses that contain radioactive material may require special procedures. Animal carcasses that contain byproduct material with a half-life of less than 120 days may be allowed to decay-in-storage (DIS). The DIS animal carcasses may be disposed of as nonradioactive, if radiation surveys (performed with an appropriate radiation survey instrument, in a low background area, and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background.

Disposal of contaminated items such as animal bedding, syringes, protective gloves, booties, and paper coverings may be by DIS if the licensed materials have half-lives of 120 days or less, or by transfer to a licensed waste broker for long-lived radioactive materials. Some wastes may be suitable for disposal to the sanitary sewer, such as animal excreta, which is readily dispersible biological material and could meet the criteria in <u>10 CFR §20.2003</u>. Refer to Appendix P, "Model Waste Management Procedures," of the guidance, for more information on waste disposal.

In accordance with <u>10 CFR §2.390</u> of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <u>https://www.nrc.gov/reading-rm/adams.html</u>.

To continue review of the request, please submit your response to this letter within 20 calendar days from the date of this letter. In your response, please refer to the docket and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, I encourage you to contact me at (630) 829-9737 or via e-mail at <u>Jason.Kelly@nrc.gov</u>.

Sincerely,

Jason M. Kelly, MPH, CPH Health Physicist Materials Licensing Branch

Enclosure(s): As stated

Control No.: 644830 Docket No.: 030-39402

APPENDIX B

SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN ITEMS 5 THROUGH 11 OF U.S. NUCLEAR REGULATORY COMMISSION FORM 313

Suggested Format for Providing Information Requested in Items 5 Through 11 of U.S. Nuclear Regulatory Commission Form 313

The table below is designed to help applicants develop their applications. In some instances, it is acceptable to simply indicate, by checking the box in the third column (Yes), that the applicant commits to adopting the model procedures referenced. If the third column contains an asterisk (*), the licensee is expected to describe its program or submit its procedures for the particular item. In this instance, the applicant is requested to check the box in the fourth column, indicating that the described program or procedures are attached to the application (NRC Form 313). If the third column contains an "N/A," the licensee is not required to describe or submit its programs and procedures during the licensing phase. However, these program areas may be reviewed during an inspection.

The table below also may be used as a License Reviewer Checklist for applications for ARDL licenses.

ltem No.	Suggested Response	Yes	Description Attached
5.	RADIOACTIVE MATERIAL		
	Unsealed or Sealed Byproduct Material		
	• For unsealed materials:		
	— For each radionuclide, provide the element name with mass	*	[]
	number, the chemical and/or physical form, and the maximum requested possession limit.		
	— For potentially volatile materials (e.g., I-125, I-131, H-3),	*	[]
	specify whether the material will be free (volatile) or bound		
	(non-volatile) and the requested possession limit for each form.		
	For sealed materials:		
	— Identify each radionuclide (element name and mass number)	*	[]
	that will be used and specify the maximum activity per source.		
	Also, specify the maximum number of sources or total activity for each radionuclide.		
	 Provide the manufacturer's or distributor's name and model 	*	[]
	number for each sealed source and device requested.	· X ·	
	— Confirm that each sealed source, device, and source/device	*	[]
	combination is registered as an approved sealed source or		
	device by NRC or an Agreement State and will be possessed		
	and used in accordance with the conditions specified in the		
	registration certificate. Provide the SSD registration certificate		
	number, if available.	-V-	r 1
	 For each sealed source, device, or source and device combination that is not registered, provide the applicable 	*	[]
	information, as described in 10 CFR 30.32(g) and 32.210.		
	• Provide an emergency plan, if required by 10 CFR 30.32(i) and	*	[]
	30.72 or 10 CFR 70.22(i)		

ltem No.	Suggested Response	Yes	Description Attached
5.	RADIOACTIVE MATERIAL (Continued) Financial Assurance and Recordkeeping for Decommissioning State the following: "Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g) and 10 CFR 70.51(b)(3), as appropriate, we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and 10 CFR 70.36, as appropriate. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a)(3), as appropriate, prior to license termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), as appropriate, to the appropriate NRC	[]	
	Regional Office."		
	AND If financial assurance is required, submit evidence of financial assurance following the guidance of NUREG–1757, Volume 3.	*	[]
6.	PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED		
	List the specific use or purpose of each radionuclide.	*	[]
	 Provide a description of uses in animals, if applicable. 	*	[]
	 Provide a description of tracer or field studies, if applicable. 	*	[]
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE Radiation Safety Officer (RSO)		
	 Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience. Information should include, at a minimum: formal training or education in radiation safety [topics covered, duration of training, when training was received, identity and location of training provider (note: a course outline may be provided)] experience using licensed materials (types, forms, quantities handled, activities performed, duration of experience) experience performing the duties of an RSO (activities, duration of experience, scope of program) 	*	[]
	 Authorized Users (AUs) (persons who will use or supervise the use of licensed materials) Provide the name of each proposed AU, with the types and 	¥	[]
	 Provide the name of each proposed AO, with the types and quantities of licensed material to be used. 	*	LJ
	 Provide information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials. Information should include, at a minimum: 	*	[]

ltem No.	Suggested Response	Yes	Description Attached
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY		
	PROGRAM AND THEIR TRAINING AND EXPERIENCE (Continued)		
	Authorized Users (AUs) (persons who will use or supervise the		
	use of licensed materials) (Continued)		
	— formal training or education in radiation safety [topics covered,		
	duration of training, when training was received, identity and		
	location of training provider (note: a course outline may be		
	provided)]		
	 experience using licensed materials (types, forms, quantities handled, activities performed, duration of experience) 		
8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING		
0.	RESTRICTED AREAS (Occupationally Exposed Individuals and		
	Ancillary Personnel)		
	Submit a description of the radiation safety training program,	*	[]
	including topics covered, groups of workers, assessment of		
	training, qualifications of instructors, and the method and frequency		
	of training.		
9.	FACILITIES AND EQUIPMENT		
	 Describe the facilities and equipment that will be available at each location where radioactive material will be used (see 	*	[]
	Appendix G of this NUREG for topics to consider). Include the		
	area(s) assigned for the receipt, storage, security, preparation,		
	measurement, use, and disposal of radioactive materials.		
	 Submit a diagram showing the locations of shielding, the 	*	[]
	proximity of radiation sources to unrestricted areas, and other		
	items related to radiation safety.		
	 When applicable to facilities where radioactive materials may 	*	[]
	become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow		
	rates, pressures, filtration equipment, and monitoring systems.		
	 Diagrams should be drawn to a specified scale, or dimensions 	*	[]
	should be indicated.	~	
	 For facilities where it is anticipated that more than one 	*	[]
	laboratory or room may be used, a generic laboratory or room		
	diagram may be submitted.		
	 Describe how facility design and procedures for operation will 	*	[]
	minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the		
	generation of radioactive waste.		
10.	RADIATION SAFETY PROGRAM		
	Audit Program		
	The applicant is not required to, and should not, submit its audit	N/A	N/A
	program to the NRC for review during the licensing phase.		
	However, the audit program may be reviewed during NRC		
	inspections.		

ltem No.	Suggested Response	Yes	Description Attached
10.	RADIATION SAFETY PROGRAM (Continued) Radiation Monitoring Instruments Describe the instrumentation that will be used to perform required surveys	*	[]
	AND State that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.' We reserve the right to upgrade our survey instruments as necessary."	[]	
	Instrument Calibration State that instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration.	[]	
	OR State that: "We will implement the model radiation survey meter calibration program published in Appendix I in NUREG–1556, Volume 7, Revision 1 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"	[]	
	OR Submit equivalent procedures for instrument calibrations.	*	[]
	 Material Receipt and Accountability State that: "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times." 	[]	
	 If applicable, provide the following statement: "We will comply with the National Source Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207." AND 		
	Provided either of the following:		
	— State that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory."	[]	
	 OR Provide a description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced. 	*	[]

ltem No.	Suggested Response	Yes	Description Attached
10.	RADIATION SAFETY PROGRAM (Continued)		
	Occupational Dose		
	Provide one of the following statements:		
	"We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive	[]	
	a radiation dose in excess of the limits in 10 CFR 20.1502."	LJ	
	OR		
	"We will monitor individuals in accordance with the guidance in the	[]	
	section titled, 'Radiation Safety Program–Occupational Dose' in		
	NUREG–1556, Volume 7, Revision 1, 'Consolidated Guidance		
	About Materials Licenses: Program-Specific Guidance About Academic, Research and Development and Other Licenses of		
	Limited Scope."		
	OR, IN LIEU OF THESE STATEMENTS,		
	Provide a description of an alternative method for demonstrating	*	[]
	compliance with the referenced regulations.		
	Public Dose		
	No response is required from the applicant in a license application,	N/A	N/A
	but compliance will be examined during inspection. During NRC		
	inspections, licensees must be able to demonstrate, by		
	measurement or calculation, that the TEDE to an individual likely to		
	receive the highest dose from the licensed operation does not		
	exceed the annual limit for members of the public. See Appendix K of this NUREG for examples of methods to demonstrate		
	compliance.		
	Safe Use of Radionuclides, Security, and Emergency		
	Procedures State that: "We will develop, implement, and maintain procedures	[]	
	for safe use, security and emergencies."	LJ	
	OR		
	State that: "We will adopt the procedures for the safe use of	[]	
	radionuclides, security and emergencies as published in		
	Appendix L in NUREG–1556, Volume 7, Revision 1, 'Program-		
	Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope."		
	OR		
	Provide procedures for safe use of radionuclides, security of	*	[]
	materials and emergencies.		
	Emergency Plan		
	If required by 10 CFR 30.32(i) and 30.72 or 10 CFR 70.22(i),	*	[]
	provide an emergency plan for responding to the release of	~	
	radioactive material, in accordance with the criteria listed in 10 CFR		
	30.32(i)(3) or 10 CFR 70.22(i)(3), as a separate part of the		
	application.		

ltem No.	Suggested Response	Yes	Description Attached
10.	RADIATION SAFETY PROGRAM (Continued) Surveys State: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"	[]	
	OR Submit a description of an alternate radiation survey program, including survey frequencies and contamination levels, to evaluate a radiological hazard.	*	[]
	Leak Tests State: "Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the SSD registration certificate."	[]	
	If leak tests will be analyzed by an outside entity, state: "Leak tests will be analyzed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee, using the sealed source or plated foil manufacturer's (distributor's) and the leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services."	[]	
	If leak tests will be analyzed by the applicant, state: "We will implement the model leak test program published in Appendix N in NUREG–1556, Volume 7, Revision 1 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope.'"	[]	
	OR Submit a description of alternate equipment or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foils.	*	[]
	Transportation No response is needed from applicants during the licensing phase. Transportation issues will be reviewed during inspections.	N/A	N/A
	Security Program for Category 1 and Category 2 Radioactive Material No response is required from an applicant or licensee. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.	N/A	N/A

ltem No.	Suggested Response	Yes	Description Attached
11.	WASTE MANAGEMENT State that: "We will use the model waste procedures published in Appendix P in NUREG–1556, Volume 7, Revision 1, 'Program- Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"	[]	
	OR If the applicant wishes to use only selected model procedures, state that: "We will use the [specify either (i) decay-in-storage or (ii) disposal of liquids into sanitary sewerage] model waste procedures that are published in Appendix P in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"	*	[]
	AND If the applicant wishes to compact or incinerate radioactive waste, provide the requested information concerning these activities in Appendix P to this NUREG.	*	[]
	OR If needed, the applicant should request authorization for extended interim storage of waste.	*	[]