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

April 12, 2022

Sara Granberg, DVM
Owner
Michiana Animal Rehab Services
515 E Warren St.
Middlebury, IN 46540

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING NEW VETERINARY MEDICINE RADIOACTIVE MATERIALS USE APPLICATION FOR MICHIANA ANIMAL REHAB SERVICES, NRC MAIL CONTROL NO. 629865

Dear Dr. Granberg:

Our office has reviewed the Michiana Animal Rehab Services (your) December 10, 2021 application for a new U.S. Nuclear Regulatory Commission (NRC) Materials License for veterinary medicine use of radioactive materials. Upon review, our office has determined that additional information is needed to issue a new license, regarding the purpose of use to be authorized under the license, the proposed Radiation Safety Officer's and Authorized User's qualifications, your training program, your facilities & equipment, your radiation safety program, and your waste management program. Your new license application is available electronically from NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML22021A988. The NRC's ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

As discussed during our March 16, 2022, phone conversation, for additional guidance, please refer to 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, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," Sections 8.6, "Purpose(s) for Which Licensed Material Will Be Used," pp. 8-12 to 8-13, 8.7, "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience," pp. 8-13 to 8-18, 8.8, "Training for Individuals Working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)," pp. 8-18 to 8-19, 8.9, "Facilities and Equipment," pp. 8-19 to 8-21, 8.10, "Radiation Safety Program," pp. 8-21 to 8-48, and 8.11, "Radiation Safety Program," pp. 8-48 to 8-53. The NUREG 1556, Volume 7, revision 1 is available electronically at the NRC's ADAMS accession number ML18065A006. Accordingly, the NUREG 1556, Volume 7, revision 1 may be found at the NRC website: https://www.nrc.gov/docs/ML1806/ML18065A006.pdf. Additional guidance may also be found in the NRC's guidance document specifically for Tin-117m use in dogs, and is discussed below.

PURPOSE OF USE TO BE AUTHORIZED ON THE LICENSE:

1. The application noted the materials that will be used, but was unclear as to how the materials will be obtained and handled. **Please describe how materials will be obtained, such as in unit doses from a radiopharmacy or a manufacturer. If other than unit doses, please describe how materials will be handled in the proposed areas of use.**

2. The requested authorization for Tin-177m indicated that animals may be returned to owners. Although As-Low-As-Reasonably-Achievable (ALARA) objectives and sample release instructions were included, the application omitted any confirmation that (1) animals will be released to assure that doses to owners, who are members of the public, will be ALARA; and (2) that release instructions will be provided to animal owners upon release of the animals. **Please confirm that: (1) care will be taken to ensure that doses to owners are ALARA; and (2) the veterinary facility will provide release instructions to the pet owner on the care of handling of the animal, when it is released.**

RADIATION SAFETY OFFICER AND AUTHORIZED USER EXPERIENCE:

3. From the application and our call, the proposed Radiation Safety Officer (RSO) and Authorized User (AU) appears to have limited experience handling radioactive materials. From the application and our call, it is the NRC's understanding that initial use of the radioactive material will be in the presence of an experienced manufacturer representative or veterinarian. **Please confirm that an experienced manufacturer representative or veterinarian will be present for the proposed RSO and AU's use of licensed material, and describe the number of administrations for which the representative will be present.**

TRAINING PROGRAM:

4. The application was unclear as to how training will be provided to housekeeping staff, administrative staff, or other individuals who may have access to facilities where licensed material is used or stored. **Please confirm that radiation safety training will be provided to ancillary staff such as housekeeping, animal caretakers or office workers, prior to the receipt of radioactive materials at the facility, and on at least an annual basis thereafter. Please provide a list of topics to be included in the training.**

5. The application included initial training, but omitted the topic of animal release regulatory requirements, in its request. Please see NUREG 1556, Volume 7, Appendix D, "Guidance for Laboratory Animal and Veterinary Use," for additional topics to be included in training. **Please provide additional topics to be included in the training. Please also describe how training will be provided following for new employees in the future, following the initial training of current staff by the manufacturer representative.**

FACILITIES AND EQUIPMENT:

6. The renewal application was limited in its description of animal use facilities. NUREG 1556, Vol. 7, Appendix D, contains some details that may be included in the application, such as facilities for animal containment. **Please describe the treatment and animal use area facilities. Include details for collecting/containing waste, kennels, bedding, etc. Include labeling and security controls to be included in the facility, to prevent unintended release of radioactive material.**

RADIATION SAFETY PROGRAM:

7. The application was unclear as to radiation monitoring. **Please confirm the following statement, from NUREG 1556, Vol. 7, rev. 1: "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. The application was unclear as to instrument calibration procedures. **Please confirm one of the following statements, from NUREG 1556, Vol. 7, rev. 1: (a) "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 been licensed to perform instrument calibration." OR (b) "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."**

9. The application omitted a statement regarding material receipt and accountability. **Please confirm the statement, from NUREG 1556, Vol. 7, rev. 1: "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."**

10. The application omitted a statement regarding occupational dose. **Please confirm one of the following statements, from NUREG 1556, Vol. 7, rev. 1: (a) "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." or (b) "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."**

11. The application omitted a statement regarding safe use of radionuclides, security, and emergency procedures. **Please confirm one of the following statements, from NUREG 1556, Vol. 7, rev. 1: (a) "We will develop, implement, and maintain procedures for safe use, security and emergencies." or (b) "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 About Academic, Research and Development and Other Licenses of Limited Scope."

In the alternative, please expand submitted safe use procedures to include training, security, and additional emergency situations to those included in the procedures submitted in the initial application.

12. The application omitted a statement regarding survey procedures. **Please confirm the following statement, from NUREG 1556, Vol. 7, rev. 1: "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." In the alternative, please expand your description of survey procedures to include instrument calibration requirements, training, and other details contained in the NUREG 1556, Volume 7, revision 1 guidance.**

WASTE PROGRAM:

13. The application was unclear as to final disposition. **Please confirm that no licensed material will be disposed of via sanitary sewerage or other waste streams and that all material will be either returned to the manufacturer, decayed in storage, or retained in animal joints.**

Please provide a response via a signed and dated letter within 10 days (on or prior to April 22, 2022). For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me at 630-829-9892.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2022.04.12 06:22:28 -05'00'

Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

Control No.: 629865