From: Tran, Frank
To: ddegner@comcast.net; Laura T. Smith- Physics (lsphysics@att.net); csmith@fxmasse.com
Subject: Request additional information for NRC license application for Animal Joint Care Company
Date: Friday, December 17, 2021 3:26:00 PM

Dear Dr. Degner:

We have reviewed your license application for Animal Joint Care Company. We reviewed your application in accordance with the NRC regulations and licensing guidance, NUREG-1556, Volume 7, Revision , "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" which can found on the NRC's website at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/index.html. Based on the NRC policy, an NRC license will be issued in accordance with NRC regulations and guidance if the application meets the requirements in Tittle 10 of the *Code of Federal Regulations* (10 CFR) Section 30.32. Based on the review, we will need the following information.

1. The NRC requires the application must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee. Your signature was on the application; however, the title was not provided. Please provide your title related to the business of the company (e.g., president, CEO, or owner.)

2. Provide the following statement: "Pursuant to 10 CFR 30.35(g), 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."

3. Provide information that the proposed Radiation Safety Officer (RSO) has experience in handling dogs with radioactive material in laboratory environments or animal hospitals/clinics.

4. We are aware that the proposed RSO was a health physics consultant for NRC materials licenses. If applicable, provide the following:
    - Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO, as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the size of the program).
    - Identify an in-house representative who will serve as the point of contact during the RSO's absence (This person may be allowed to assist the consultant RSO in his or her duties. Any such duties should be clearly

defined.)
- Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.
- Specify the maximum amount of time it will take the consultant RSO to arrive at the facility, in the event of an emergency that requires his or her presence.

5. Provide a copy of veterinary physician's license issued by the state authority with status (active or current) for the proposed user (Dan Degner, DVM).

6. The NRC regulations in 10 CFR 20.2107 requires the licensee to maintain and retain the records to demonstrate compliance with the dose limit for individual members of the public until the NRC terminates the license. Please confirm that the licensee will document and retain the records associated with step C3.3 in the Procedure for Use of Synovetin OA and all other records demonstrating compliance with the dose limit for individual members of the public.

7. Provide a confirmation that licensed material will only be used by, or under the supervision and in the physical presence of, authorized users listed in the license.

8. Provide the dimension of the rooms where licensed material will be used and who will have access to the locked storage areas (e.g., authorized users). Description of the location where radioactive waste will be held for decay-in-storage.

9. You request to dispose radioactive wastes from licensed operations via decay-in-storage. Provide the following statements:

   A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

   B. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

10. Provided a statement that the licensee will ensure radiation level in the unrestricted areas above, below, and surrounding the storage areas meeting the criteria in the NRC regulation in 10 CFR 20.1301, "Dose limits for individual members of the public".

11. For the proposed radiation monitoring instrument, describe the instrumentation that

will be used to perform required surveys and provide the following 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.”

12. For radiation instrument calibration, provide the following statement: “Radiation survey 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.”

13. For licensed material receipt and accountability, provide the following statement: “We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.”

14. For monitoring of occupational dose, provide one of the followings:
    - “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

    - “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

    - Provide a description of an alternative method for demonstrating compliance with the referenced regulations.

To continue the review of your application, we request that you submit your response under a dated and signed cover letter (signed by the licensee senior executive management or designee) by January 6, 2022. In the cover letter, please reference Mail Control No. 618174.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

In accordance with 10 CFR 2.390 of the NRC’s “Rules of Practice,” a copy of this correspondence 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 https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Frank Tran

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Protecting People and the Environment