From: Hann, Patrick-John
To: Rusty Beeler
Subject: Renewal RAI- License No. 24-05245-01
Date: Monday, July 12, 2021 12:49:00 PM
Attachments: RAI- Kirksville.pdf

License No. 24-05245-01
Docket No. 03002332
Mail Control No. 624953

Mr. Beeler,

Please find attached the request for additional information regarding your license renewal application February 8, 2021 and March 24, 2021. Please review the attached and I would like to schedule a meeting with you this week to discuss this in more detail. Please let me know a date and time that works for you.

Truly,

Patrick-John E. Hann, MHP
Health Physicist
U.S. Nuclear Regulatory Commission

1. Your application should be signed by a management representative. Please confirm that Ranee C. Brayton is a management representative and indicate her title.

2. In your renewal application, you indicated 45 mCi for Co-57 sealed sources for the use of calibration and reference. Please clarify the number of sources, the activity per source, and the make and model numbers of the sources.

3. In your renewal application, you indicated 1200 mCi for Gd-153 sealed sources for the use of calibration and reference. Please clarify the number, the activities, and the make and models of the sources.

4. In your renewal application, you requested possession limits for the following radionuclides:

    a. Ga-67, liquid, 12mCi
    b. I-123, liquid/capsules, 2mCi
    c. In-111 liquid, 10mCi
    d. Tc-99 liquid, 1 curie
    e. Tl-201 liquid, 30mCi

    The indicated uses for these radionuclides are for diagnostic uses and are permitted under 10 CFR 35.100 and 10 CFR 35.200. Your current license, Amendment 46, has possession limits for these uses indicated "As Needed". We will continue to list the possession limits for these materials as "As Needed".

5. In your renewal application, you requested the use of Tc-99, as opposed to Tc-99m. Please confirm that you intend to use Tc-99m.

6. In your renewal application, you indicated I-131 may be used in certain instances for therapeutic uses. Please clarify whether these patients will be on an inpatient or outpatient basis. If they will be on an outpatient basis, please identify the method used to determine patient release.

7. Please confirm that you do not intend to use PET materials.

8. You have not requested to continue use of 10 CFR 31.11(a) materials (currently listed on your license). Please identify which one of the following applies:

    a. You wish to continue to be authorized to use these materials under your specific license,

    b. These materials have never been possessed at your facility

c. These materials are now in use under a general license (total possession for iodine-125, iodine-131, selenium-75 and iron-59 not to exceed 200 microcuries at any one time),

d. These materials have been used previously and you no longer wish to use them. If this statement applies, and the materials permitted under 10 CFR 31.11(a) were used in a location other than your current areas of use, you must submit a closeout survey of the area where material identified in 10 CFR 31.11(a) was used and that survey must receive NRC approval in order for the area to be released for unrestricted use and the material removed from the license.

9. You have not identified any Authorized Users in your renewal application. Please identify the proposed Authorized Users (AU) with their respective proposed uses.

10. Please provide a facility diagram to include the following:

    a. Facility diagrams. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated,

    b. Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored,
    c. Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms and Positron Emission Tomography (PET), and

    d. Doors should be indicated, and specify which doors are access controlled (i.e., locked.

11. In your renewal application, you submitted an occupational dosimetry policy and procedure. Please confirm the personnel dosimetry devices are evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP) approved.

12. Your application did not address procedures for survey meter calibration. Please confirm that radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

13. Please provide the make and model of the Geiger counters provided in your renewal application.

14. Please confirm that the equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

15. Please confirm that you will develop, implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 Part 20.1101.

16. Please confirm you will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:
    a. license possession limits are not exceeded

    b. licensed material in storage is secured from unauthorized access or removal

    c. licensed material not in storage is maintained under constant surveillance and control

    d. records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained.

17. Please confirm you will develop, implement, and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67.

18. Please confirm that you will develop, implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

19. Please confirm that you will develop, implement and maintain written procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301

20. In your renewal application, you indicated that RAM waste will be held for 10 half-lives. Storing waste for 10 half-lives may not demonstrate compliance with the regulations promulgated in 10 CFR 35. 10 CFR 35.92 requires that licensee's shall monitor byproduct material at the surface before disposal and determine that its radioactivity cannot be distinguished from the background radiation levels with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding. Please confirm that you will develop, implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

NUREG-1556 Vol. 9, Rev.3 may be helpful for you in developing your response to this request for additional information.