From: Gaskins, Farrah
To: ashtond@tomaykogroup.com; markperna@mac.com
Subject: Request for additional information for License No. 37-28520-01
Date: Wednesday, March 02, 2016 4:30:00 PM

License No.: 37-28520-01
Docket No: 030-31697
Control No: 589812
Licensee Name: The Tomayko Group

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Dear Mr. Ashton,

This refers to your request to renew your license dated December 3, 2015, In order to continue our review of your request, the following additional information is needed:

1. You have requested that Mark Perna be named Radiation Safety Officer (RSO) on your license. Although Mr. Perna is the current RSO on the license, since he is an outside consultant\contractor, in support of this request, please address the following:

    a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

    b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

    c. 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 on-site time (hours per week).

    d. Appoint 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 with limited authority.

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

2. Please describe the intended use of each site listed in your application. Please describe the scope of activities that will be performed at each base site (i.e. base hot lab, patient imaging, etc.). A base site is defined as a location where licensed material is received, stored and sometimes used. Your response should include:
    a. whether license materials are transported to the site or if it is delivered directly

to the site from the nuclear pharmacy.

b. if each base site is located in a medical institution, non-institutional medical practice, commercial facility, etc
c. if sealed sources are stored at the locations of use or transported as needed during the time of use.
d. if waste is stored at each location or removed when leaving the site.
e. confirmation that a client agreement is in place for each site.

3. Please confirm that The Tomayko Group (TTG) has full responsibility over each base site, in order to ensure compliance with all applicable regulatory requirements and describe the controls (e.g., control of keys, badge access) that will be implemented to ensure that licensed materials are under TTG's control and not accessible to unauthorized individuals (i.e. hospital staff).

4. Regarding the facility diagrams submitted with your application, please describe the areas above, below, and adjacent to restricted areas for each facility.

5. Please confirm that you are not providing mobile medical services to clients (non-licensee) located within a licensed medical institution.

6. Please confirm that instructions will be given to supervised individuals in written radiation protection procedures, regulations, and license conditions with respect to the use of byproduct material in accordance with 10 CFR 35.27, in addition to the requirements in 10 CFR 19.12. In addition, please confirm that drivers and technologists will be properly trained in applicable regulations and emergency procedures in addition to the training requirements of 10 CFR 19.12 and 10 CFR 35.27. The training for these individuals will include, at a minimum, DOT regulations, shielding, ALARA, and basic radiation protection.

7. Please confirm that instruments required by 10 CFR 35.80 will be checked for proper operation before use at each address of use. Please also confirm that dosage measurement instruments will be checked before medical use at each location or on each day of use, whichever is more frequent.

8. Please confirm that you have written emergency procedures in accordance with the Radiation Protection Program required by 10 CFR 20.1101. Please confirm that the written emergency procedures will indicate typical response times of the Radiation Safety Officer (RSO) and authorized user (AU) in the event of an incident, and will include emergency response regarding an accident scenario. The transportation emergency response plan should cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous material (HAZMAT)-trained personnel, and it should be readily available to both transport vehicle personnel and headquarters emergency-response contacts. Please confirm your plan will include:

a. A 24-hour emergency contact telephone number for the mobile medical service

provider's emergency response personnel;

b. The emergency contact numbers for NRC's Operation Center and all appropriate State radiological protection agencies;
c. Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist;
d. Procedures for retrieving and securing any byproduct material, including a sealed source that may become detached and/or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers;
e. Preplanned decontamination procedures, including ready access to all necessary materials;
f. A calibrated, operational survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys; and
g. Security of the transport vehicle against unauthorized access, including the driver's compartment.

Note: It may be helpful to review the information under "Emergency Procedures" in NUREG-1556, Vol. 9, Rev. 2, Appendix V. These procedures will be reviewed during a later inspection.

9. Please confirm that radioactive material is transported in accordance with 49 CFR Parts 170-189. Furthermore, please confirm that your procedures will include:
   a. Use of approved packages,
   b. Use of approved labeling,
   c. Conduct of proper surveys,
   d. Complete and accurate shipping papers,
   e. Bracing of packages,
   f. Security provisions, and
   g. Written emergency instructions.

   Note: These procedures will be reviewed at a later inspection.

10. Please confirm that management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.

11. Please confirm that licensed material is secured during transport and use at the client's facilities.

12. Confirm that radioactive waste in handled properly during transport. Describe the method of storage and final disposal.

13. Confirm that the transportation vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

14. You are requesting to possess and use radioactive materials permitted by 10 CFR

35.200 which now includes positron emitting tomography (PET) radiopharmaceuticals. Your application does not request the use of PET. Please confirm you do not wish to be authorized for the use of PET materials. Alternatively, you may request this authorization and include a list of installed shielding and any specialized equipment specific to 511 keV.

15. Please indicate if there are any required sealed sources that do not fall under 10 CFR 35.65.

16. Please confirm the following statement: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 20.1301."

17. Please confirm that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301 (i.e. exposure rates do not exceed 2 mrem in any 1 hour nor 100 mrem per year).

You may respond to my attention in writing by letter, email (if scanned into a pdf format), or fax (610-337-5269), referencing mail control number 589812. Please ensure that your response is signed by an appropriate licensee management representative. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your request. If you have any questions, please contact me by email or the number provided below.

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