UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
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EMAIL

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From:	Jacqueline D. Cook	
Date:	April 22, 2019	
Subject:	Application dated December 20, 2018 for New License	
Pages:	13	

Mr. Curnutt:

Per your application dated December 20, 2018, the items on the next page are deficiencies which require your response. **Please respond to this e-mail by Monday, May 13, 2019. Please note that I will be out of the office April 29-May 2, 2019 and May 6-10, 2019, returning to the office on Monday, May 13, 2019.** Our fax number is (817) 200-1263. Please provide a response in a signed and dated letter in pdf format when responding via email. My email address is Jackie.Cook@nrc.gov. If you are unable to provide your response by the requested date, please let me know and provide an alternative date you will be able to provide your response. When responding to this e-mail, please include the docket and control numbers located at the top of this page.

Please note that your application was reviewed using NUREG-1556, Vol. 13, Rev. 2, *Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses* (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/) dated March 2019, as licensing guidance.

PUBLIC
☐ Immediate Release
☑ Normal Release

NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

Reviewer: JDC Date: 4/23/19

When providing your response, please highlight the information that has been revised in your documents (Policies and Procedures Manual [PPM] which includes your Radiation Safety Manual [RSM]). Also, when resubmitting the checklist in Appendix B of NUREG-1556, Vol. 13, Rev. 2, please indicate in each section of the checklist, a reference to your procedure section, number/chapter or page, as applicable.

Thank you in advance for your cooperation, assistance, and prompt response in this matter.

/RA/
Jacqueline D. Cook
Senior Health Physicist

1. The cover page of your new license application dated December 20, 2018, and Appendix B, Suggested Format for Providing Information Requested in items 5 through 11 of NRC Form 313 of your checklist makes reference to NUREG-1556, Volume 13, Revision 2". Please note that this revision was recently issued/published in final form on Wednesday, March 27, 2019. However, your Appendix B, submitted appears to be from NUREG-1556, Vol. 13, Rev. 2 draft for comment format which has since been updated in the final published/issuance of NUREG-1556, Vol. 13, Rev. 2.

   Please resubmit your new license application utilizing the checklist in Appendix B of NUREG-1556, Vol. 13, Rev. 2, Suggested Format for Providing Information Requested in Items 5 through 11 on NRC Form 313 and the licensing guidance in NUREG-1556, Vol. 13, Rev. 2, dated March 2019.

2. Please note that your Policies and Procedures Manual (PPM) which includes your Radiation Safety Manual (RSM) should be updated to include commitments, development, implementation, and maintenance of written procedures as stated in your resubmitted Appendix B of NUREG-1556, Vol. 13, Rev. 2.

3. In comparing Appendix B of NUREG-1556, Vol. 13, Rev. 2 with your Table C.2 submitted in your new license application dated December 20, 2018:

   A. Please confirm if you are requesting authorization for "Byproduct Materials with Atomic No. 1-83" (which would cover any radioactive material, except iodine-131 and technetium-99m, listed in 10 CFR 35.100, 10 CFR 35.200; thallium-201; yttrium-90)?

      i. If so, please specify the form (i.e., any, sealed sources, etc.).

      ii. If so, please specify the quantity in millicuries per nuclide and total possession in millicuries or curies, as applicable.

   B. In a telephone conversation about a month ago, you stated that you wanted to request authorization for xenon-133 (Xe-133) and had planned to send an email to supplement the information in your new license application, but as of today, we have not received your email request for this authorization.

      In addition, your new license application contains discussions regarding Xe-133.

      Please explain this discrepancy.

      If you still plan to request authorization for Xe-133, please specify the form and total possession quantity in millicuries or curies, as applicable.

C. Please confirm if you are requesting authorization for "Any byproduct material authorized under 10 CFR 35.65"? (Please see your Table C.2. Item K.).

If so, please specify the form and specify the total possession in millicuries or curies, as applicable.

In addition, please update the purpose of use as "calibration and checking of the licensee's instruments and 10 CFR 32.74 and 10 CFR 30.41", if applicable.

D. Please note in your Table C.2. Item J., you requested authorization for cesium-137.

Please expand the form of the sealed source to include the following phrase, "in compatible device as specified in Sealed Source and Device Registry Sheet", if appropriate.

i. Please specify the quantity in millicuries or curies per source and total possession in millicuries or curies, as applicable.

ii. Please specify the purpose of use.

E. Please note in your Table C.2. Items E, G, H, and I, a quantity of "as needed" is specified. Please note that this is not appropriate.

Please specify a quantity in millicuries or curies and/or a total possession limit in millicuries or curie quantities, as appropriate.

F. Please note in your Table C.2. Item I, you request "any radioactive material".

Please expand your request to include "Atomic Numbers X-XX, if applicable.

i. Please change form from "analytical samples" to "any", if appropriate.

ii. Please specify quantity per radionuclide in millicuries or curies and a total possession limit in millicuries or curie quantities, as appropriate.

iii. Please specify the purpose of use as "leak test sample collection and analysis", if applicable or appropriate.

G. i. Because you requested authorization for Ge-68/Ga-68 and because Eckert and Ziegler GalliaPharm™ Ge-68/Ga-68 Pharmacy Grade Generator is licensed/authorized under 10 CFR 35.1000, please review the Eckert and Ziegler GalliaPharmTM Ge-68/Ga-68 Pharmacy Grade Generator Licensing Guidance, dated July 13, 2017, Rev. 1 (https://www.nrc.gov/materials/miau/med-use-toolkit.html#et which is found in the emerging technologies and 10 CFR 35.1000 table), and make the appropriate commitments and provide the appropriate descriptions and information as requested by this licensing guidance.

In addition, submit the appropriate decommissioning funding plan as appropriate and per the licensing guidance in section 7.4 of this licensing guidance.

ii. Because you request authorization for Yt-90 microspheres, please review and make applicable commitments in accordance with the licensing guidance for TheraSphere® and SIRSpheres® Yttrium-90 Microspheres (https://www.nrc.gov/material/miau/med-use-toolkit.html#et which is found in the emerging technologies and 10 CFR 35.1000 table) and make the appropriate commitments and provide the appropriate descriptions and information as requested by this licensing guidance.

4. A. Please note in your Appendix B, Item 6 for all transferred, distributed and redistributed sealed and unsealed materials, you checked the box "description attached"; however, we could not locate this in your new license application.

Please describe procedures to ensure that sealed and unsealed materials are securely and safely provided to mobile medical licensees if they are transferred, distributed, or redistributed to a mobile medical licensee's mobile van or coach, where there is no permanent structure for byproduct material storage. For example, procedures should ensure that delivery directly to the van or coach will only occur if the van or coach is occupied by mobile medical licensee personnel at the time of delivery.

B. Please note in your Appendix B, Item 6, For redistribution of used generators, you checked the box "description attached"; however, we could not locate this in your new license application.

Please describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.

C. Please note in your Appendix B, Item 6, for redistribution of sealed sources for brachytherapy or diagnosis, you checked both boxes under "yes"; however, you did not request authorization for this material in Item 5 (or your Table C.2.) of your new license application.

Please explain this discrepancy.

D. Please note in your Appendix B, Item 6, for redistribution of prepackaged units for *in vitro* tests, for redistribution of prepackaged units for *in vitro* tests to general licensees, for redistribution of prepackaged units for in vitro tests to specific licensees, you checked all boxes under "yes"; however, you did not request authorization for this material in Item 5 (or your Table C.2.) of your new license application.

Please explain this discrepancy.

E. Please note in your Appendix B, Item 6, for radiopharmaceutical preparation, you checked the box that you will perform "other, specify", you checked the "yes" box and the box for "description attached"; however, we would not locate this in your new license application.

Please specify where this information can be located.

F. Please note in your Appendix B, Item 6, you checked the box for "description attached" requesting you to supply specific information concerning the use of discrete sources of radium-226, sealed sources for reference and calibration, and DU [depleted uranium] shielding. Please note that it appears you did not request authorization for the discrete sources of radium-226.

Please explain this discrepancy.

In addition, please specify where this information can be located for sealed sources for reference and calibration and DU shielding.

G. You checked both the "yes" box and the "description attached" box for you will provide customers the following radiation protection services involving licensed material: other, specify.

Please specify where this information can be located.

5. A. Please submit a description of the training and experience demonstrating that the proposed Radiation Safety Officer (RSO) is qualified by training and experience applicable to commercial nuclear pharmacies.

   B. Because you requested authorization for Ge-68/Ga-68, Yt-90, and other devices or uses as applicable, please confirm that the proposed RSO has sufficient training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which you are seeking approval in accordance with 10 CFR 35.50(d) (https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0050.html).

6. A. In your Appendix B, Item 7 for the proposed ANP, for an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs (10 CFR 32.72(b)(2)(i)], you checked the box for "description attached" for previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License broad scope permittee on which the individual was named as an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.

   Please explain this discrepancy.

   B. In your Appendix B, Item 7 for the proposed ANP, for an individual qualifying under 10 CFR 32.72(b)(2)(ii), you checked the boxes for "description attached" for description of the training and experience specified in 10 CFR 35.55(b), demonstrating that the proposed ANP is qualified by training and experience.

AND

Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.

AND

However, you did not check the box for "description attached" for if applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59. Therefore, we are thinking this is not applicable to you.

Please explain these discrepancies.

7. A. We understand that your facility is under construction. Idaho Board of Pharmacy requires completion.

   i. Please provide a copy of the registration or license from the Idaho State Board of Pharmacy as a pharmacy upon receipt from the Idaho Board of Pharmacy.

ii. In addition, in your Appendix B, Item 9 you checked the box "description attached".

Please explain this discrepancy.

B. Please describe the facilities and equipment to be made available at the location where radioactive material will be used. A diagram should be submitted that shows the applicant's entire facility and identifies activities conducted in all contiguous areas surrounding the facility.

Please expand the diagram to include the following information:

i. Descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials and the location(s) for radioactive waste storage;

ii. Sufficient detail in the diagram to include locations of shielding, the shielding thickness, and the materials used for shielding; the proximity of radiation sources to unrestricted areas, and other items related to radiation safety;

iii. A general description of any ventilation system that is used when handling radionuclides, including representative equipment such as gloveboxes or fume hoods;

iv. Confirmation that such ventilation systems will be employed for the use or storage of radioactive materials that are likely to become airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions, if applicable;

v. Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the constraints for air emissions established under 10 CFR 20.1101(d).

vi. In your Appendix B, Item 9, for PET radiopharmacies, you checked boxes stating that description is attached; however, in the proposed material requested, it does not appear, PET material was requested.

Please explain this discrepancy.

8. In your Appendix B, Item 10, Radiation Monitoring Instruments, you checked boxes for "or", "and", "yes", and "description attached".

A. Following the guidance in Appendix B, Item 10.2, Radiation Monitoring Instruments, to NUREG-1556, Vol. 13, Rev. 2, please submit one of the following statements:

- "We will use calibrated and operable equipment that is capable of detecting the type(s) of radiation being monitored (e..g. gamma, beta, alpha) and energy or

energy range of the radation being measured.";

OR

- Provide a description of the calibrated and operable instrumentation that will be used to perform radiation monitoring (e.g., portable or stationary count rate meters, LSCs, well-type scintillation counters, air monitors).

B. Although you checked the "yes" box to the statement, "We.....used.", please submit one of the following:

- If calibration is performed by a person or firm outside the applicant's organization, specify that the calibration will be performed by an NRC or Agreement State licensee specifically authorized to perform instrument calibration as a service to other licensees and state the frequency of the calibrations;

OR

- If the calibration is to be performed in-house, submit the instrument calibration procedure that will be used and state the frequency of the calibrations. In addition, identify the qualifications of the individuals who will perform the calibrations.

9. Please note that License Number 11-35248-01 (Troy Curnutt Consulting) authorizes commercial services (i.e., leak tests, sample analysis, and instrument calibration). Also in the new license application (Quantum Isotopes of Idaho) dated December 20, 2018, Table C.2, it appears that you are requesting some commercial services also (i.e., leak tests, sample analysis, and instrument calibration).

Please describe the process on how you plan to distinguish when you are performing authorized commercial services under License Number 11-35248-01 (Troy Curnutt Consulting) or under the new byproduct commercial radiopharmacy license (Quantum Isotopes of Idaho) when it is issued, such that from a compliance perspective if a violation were to occur we would be able to accurately and with confidence write the violation for the correct licensee. (Troy Curnutt Consulting or Quantum Isotopes of Idaho).

10. Please expand Item 10 of your Appendix B, Safe Use of Radionuclides, to address the following:

- Reporting under the requirements in 10 CFR 30.34(g) if there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate;
- Performing breakthrough measurements on each eluate of other generators (e.g., Ge-68/Ga-68 generators);
- Securing licensed material during use and storage (10 CFR 20.1801, 10 CFR 20.1802);
- Conducting Mo-99/Tc-99m generator Mo-99 breakthrough tests contamination in accordance with 10 CFR 30.34(g) and 10 CFR 35.204; and
- Posting the operating procedures applicable to commercial radiopharmacies (10 CFR 19.11(a)(3))

11. A. In Item 10 of your Appendix B, Dosage Measurement Systems, you checked the "description attached" box, in which you said you would describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs.

Please explain this discrepancy or please specify where this information can be located.

B. In Item 10 of your Appendix B, Dosage Measurement Systems, you checked the "description attached" box, in which you state, if applicable, include a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer or other entity.

Please explain this discrepancy or please specify where this information can be located.

OR

Please provide the calculations to demonstrate the ability to accurately dispense low-energy photon-, beta-, and alpha-emitting radionuclides for radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) these materials.

12. Although the sleeve linearity, sealed source leak test, and dose calibrator forms are marked "example", please resubmit these blank forms tailored for the applicant's use (Quantum Isotopes of Idaho).

13. Please note that in your Appendix B, Item 10, Transportation and in Appendix C, Item 10.9, of NUREG-1556, Vol. 13, Rev. 1, both state that "the applicant's program for transportation will be examined during inspection, but it should not be submitted in a license application". However, Section 25.0 of your RSM describes "Transportation of Radiopharmaceuticals".

    Please explain this discrepancy.

14. In Item 10 of your Appendix B, Radioactive Drug Shielding for Distribution, you checked the "description attached" box, in which you said for each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package), you would provide the following:

    A. The radionuclide and the maximum activity for each type of container (e.g., vial, syringe);

    B. Describe the type and thickness of the "transport radiation shield" provided for each type of container; and

    C. Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

    Please explain this discrepancy or please specify where this information can be located.

15. A. Please submit the following statement regarding leak tests: "Leak test sample collection and analysis will be done by the applicant."

    B. Please provide the information noted in Appendix H of this NUREG supporting a request to perform leak test sample collection and sample analysis and either state that, "The applicant will follow the model procedures in Appendix H of NUREG-1556, Volume 13, Revision 2", **OR** submit alternative procedures.

16. A. In addition to Section 26.0 of your RSM for Waste Disposal of Radioactive Materials, for commercial radiopharmacy-generated radioactive wastes, please submit the following statement: "We have developed, and will implement and maintain written procedures for waste management that meet the requirements in 10 CFR 20.1904(b), 10 CFR 20.2001, 10 CFR 20.2003, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2008, 10 CFR 20.2108, 10 CFR 30.51, and 10 CFR 40.61, as applicable."

AND

B. If needed, the applicant should request authorization for extended interim storage of waste. The applicant should use the references listed at the end of Section 8.11 of this NUREG for guidance and submit the required information with the application.

17. In addition to the procedures in Section 8.0 of your PPM and Section 26.5 of your RSM, please expand your procedures for returned wastes from customers to include the following statement: "We have developed and will implement and maintain written procedures for customer return of pharmacy-supplied syringes and vials and their contents, to specify that:

- Instructions will be provided to commercial radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the commercial radiopharmacy, and
- Instructions will be provided to commercial radiopharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste to ensure compliance with 10 CFR 20.2001(a), 10 CFR 30.33, 10 CFR 40.32, and 10 CFR 71.5, as applicable.