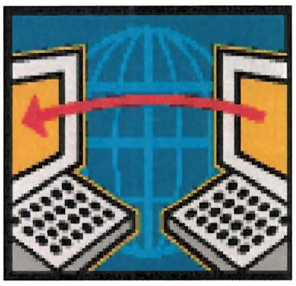
UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

EMAIL



Name:	Vincent Troy Curnutt	Docket: 030-39149
Organization:	Quantum Isotopes of Idaho	Control: 610959
Phone:	208-406-2543	
E-mail Address:	nukemdude@gmail.com	
From:	Jacqueline D. Cook	
Date:	June 3, 2019	
Subject:	Application dated December 20, 2018 and Response dated May 4, 2019 to Request for Additional Information for New License	
Pages:	5	

Mr. Curnutt:

Per your application dated December 20, 2018, and your response dated May 4, 2019 to our request for additional information for a new license, the items on the next page are deficiencies which require your response. **Please respond to this e-mail by Tuesday, June 18, 2019. Please note that I will be out of the office June 9-17, 2019, returning to the office on Tuesday, June 18, 2019.** Our fax number is (817) 200-1263. Please provide a response in a **signed and dated letter on your letterhead 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.

PUBLIC
- ☐ Immediate Release
- ☑ Normal Release

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

Reviewer: JDC Date: 6/3/19

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.

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

/RA/
Jacqueline D. Cook
Senior Health Physicist

1. In your response to Item 3.D.i., you submitted Table 1.A. in which you proposed the purpose of use (authorized use) as equipment calibration and quality control.

   Please clarify based on the requested total possession activity and the purpose of use for the sealed sources identified in Table 1.A., that this can be authorized under the column on page B-3, B.5. Item 5, "Any byproduct material authorized under 10 CFR 35.65"; purpose of use: "calibration and checking of the licensee's instrument and 10 CFR 32.74 and 10 CFR 30.41.

   If not, please explain why your Table 1.A. should be line listed separately on your license.

2. In your response to Item 3.F. you requested we remove Item I in your previously submitted table C.2.; however, you did request in your previously submitted table C.2 to be authorized for commercial services (i.e., leak tests, sample analysis, and instrument calibration).

   Please note that you need specific authorization on your license to provide these services, as on License Number 11-35248-01 (Troy Curnutt Consulting), Item 9. Therefore, please expand the purpose of use (authorized use) as appropriate for the applicable material in your recently submitted B.5., Item 5.

3. 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. Please expand your procedures for all transferred, distributed and redistributed sealed and unsealed materials to address the following: 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.

   If not, please provide written justification as to why not.

5. A. Please note in your updated checklist Appendix B, you left Item 7, 7.2 entirely blank.

      Please update this oversight.

B. 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.

C. 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.

6. In your response to Item 10 for the bullet, posting the operating procedures applicable to commercial radiopharmacies (10 CFR 19.11(a)(3), in addition to your response in the updated checklist, you also responded that NRC Form 3, "Notice to Employees" dated August 1997, has been posted in the pharmacy and in the break room.

Please note that NRC Form 3 has been updated (8-2017). (https://www.nrc.gov/reading-rm/doc-collections/forms/).

Please acknowledge this update.

7. Although the sleeve linearity, sealed source leak test, and dose calibrator forms are marked "example", it specified your client who these tests were performed and facility name/address. In addition, it specifies Troy Curnutt Consulting and the address.

   Please resubmit these blank forms tailored for the applicant's use (Quantum Isotopes of Idaho).