



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
1600 E. LAMAR BLVD  
ARLINGTON TX 76011-4511

March 5, 2022

Mr. Vincent Troy Curnutt  
Radiation Safety Officer  
Quantum Isotopes of Idaho  
4921 South 5<sup>th</sup> Avenue  
Pocatello, ID 83204

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, NRC LICENSE NO. 11-35522-01MD

Mr. Curnutt:

We have initiated the review of your amendment request dated February 10, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession Number ML22062A767) in which you requested that NRC license number 11-35522-01MD be amended to: 1) add an Alternate Radiation Safety Officer, and 2) authorize the use of Germanium-68/Gallium-68 (Ge-68/Ga-68) generators. Please note the following.

1. NRC license number 11-35522-01MD is a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32 license that authorizes the manufacturing and distribution of radiopharmaceuticals to medical use licensees. Only 10 CFR Part 35 medical use licensees are authorized to name Associate Radiation Safety Officers in NRC licenses following the training and experience requirements in 10 CFR 35.50 and as documented in NRC Form 313A(RSO). Therefore, NRC license number 11-35522-01MD cannot be amended to list an Alternate Radiation Safety Officer as requested.
2. The NRC developed licensing guidance for the use of Ge-68/Ga-68 generators (ADAMS ML19106A367 and ML17075A487). This guidance provides licensees with instructions for requesting an exemption from the requirement to develop a Decommissioning Funding Plan (DFP) if certain criteria are met. However, this guidance does not exempt licensees from having to submit decommissioning financial assurance. Please note that the guidance states: "Licensees must continue to provide FA [financial assurance] in amounts described in the exemption memorandum pursuant to NRC DFP requirements. Licensees possessing one or two Ge-68/Ga-68 generators (50 to 100 mCi of material) must provide for financial assurance for decommissioning in the amount of \$225,000.00."

Before we can take further action on item 2 above, we will need the following additional information.

1. If you still want to pursue the DFP exemption, provide decommissioning financial assurance in the amount of \$225,000, and a Standby Trust Agreement following the guidance in NUREG-1757, Volume 3, revision 1, which can be found at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v3/index.html>.

2. If you do not want to pursue the DFP exemption, you can provide instead a site-specific Decommissioning Funding Plan in the amount determined by the site-specific decommissioning cost estimate, and a Standby Trust Agreement following the guidance in NUREG-1757, Volume 3, revision 1, which can be found at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v3/index.html>.

To continue review of your application, we request that you submit a decommissioning financial assurance instrument and a Standby Trust Agreement within 30 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. We will assume that you do not wish to further pursue this licensing action if we do not receive a decommissioning financial assurance instrument and a Standby Trust Agreement within the specified timeframe noted above.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

If you have questions or require clarification on any of the information stated above, please contact me at 817-200-1189.

Thank you for your cooperation.

Sincerely,

Roberto J. Torres, M.S., Senior Health Physicist  
Materials Licensing Branch

Docket: 030-39149  
License: 11-35522-01MD  
Control: 630099