

June 18, 2021

U.S. Nuclear Regulatory Commission
Region IV
1600 E. Lamar Blvd.
Arlington, Texas 76011-4511

Dear Ms. Simmons,

Re: NRC Radioactive Material License #40-16571-02

In response to your letter of June 14, 2021, Avera will commit to the guidance dated June 1, 2018 (ML 18136A824) referencing the department requirements for the operation of a Lutetium-177 program.

If you have any questions or need additional information regarding this request, please contact me at (605) 929-9056 or by email at michelle.white@avera.org or Trisha Laake at (712) 212-0040.

Sincerely:



Michelle White, RSO
Radiation Safety Officer
Avera McKenna



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

June 14, 2021

Michelle White, BA, CNMT
Radiation Safety Officer
Avera McKennan/Nuclear Medicine
1325 S. Cliff Ave
Sioux Falls, SD 57117-5045

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Ms. White:

We have reviewed your application dated April 5, 2021. Before we can take further action, we will need the following additional information.

1. Commit to following the "LICENSING OF LUTETIUM-177" guidance dated June 1, 2018 (ML18136A824). <https://www.nrc.gov/docs/ML1813/ML18136A824.pdf>

In accordance with Title 10 of the *Code of Federal Regulations* (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 the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

To continue review of your application, we request that you submit your response to this letter by June 21, 2021. 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 reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, we encourage you to contact us at 817-200-1590 or Michelle.Simmons@nrc.gov.

Sincerely,
**Michelle R.
Simmons**

Digitally signed by Michelle R.
Simmons
Date: 2021.06.14 15:49:56
-05'00'

Michelle R. Simmons, Sr. Health Physicist
Materials Licensing and Decommissioning Branch

Docket: 03039216
License: 40-16571-02
Control: 625531

From: [Michelle White](#)
To: [Simmons, Michelle](#)
Cc: [Trisha Laake](#)
Subject: [External_Sender] RE: Avera McKennan/Nuclear Medicine RAI.pdf
Date: Friday, June 18, 2021 10:59:46 AM
Attachments: [Lutetium requirement commitment.pdf](#)

Good Morning,

I have attached a letter of commitment concerning the Lutetium request.
Please feel free to contact me with any other concerns,

*Michelle White, RSO, BA | Radiation Safety Officer, Nuclear Medicine/PET/CT
Avera McKennan | Mobile NRC
1325 S. Cliff Avenue | Sioux Falls, SD 57105
Phone 605-322-7155 | Cell 605-929-9056/Fax 605-322-7181*

From: Simmons, Michelle [mailto:Michelle.Simmons@nrc.gov]
Sent: Monday, June 14, 2021 3:52 PM
To: Michelle White <Michelle.White@avera.org>
Subject: Avera McKennan/Nuclear Medicine RAI.pdf

EXTERNAL EMAIL. Proceed with caution. If you suspect phishing use the Report Phishing button or forward this email to phish@avera.org

Good afternoon,

Please see the attached letter. If you have any questions, please feel free to contact me

Thank you

Michelle R. Simmons
Senior Health Physicist
Nuclear Regulatory Commission
Materials Licensing and Decommissioning Branch
Region IV
1600 East Lamar Blvd.
Arlington, Texas 76011
817-200-1590