



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

March 14, 2017

Rajesh C. Shrotriya, MD  
Spectrum Pharmaceuticals  
11500 South Eastern Ave., Suite 240  
Henderson, NV 89052

Dear Dr. Shrotriya:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter dated February 7, 2017, to Chairman Svinicki, that provided your comments and recommendations on the training and experience requirements for alpha- and beta-emitting radiopharmaceuticals in Parts 35.390 and 35.396 of Title 10 of the *Code of Federal Regulations*.

We note that you have provided similar comments and recommendations to the NRC staff in various forums since 2011. The NRC staff has assessed all of your comments and recommendations, including those in your February 7, 2017, letter. In addition, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) has independently assessed your comments and recommendations for changes to training and experience requirements for alpha- and beta-emitting radiopharmaceuticals. Both the NRC staff and the ACMUI concluded that the current regulations are adequate and appropriate. Nonetheless, the NRC staff has recently been in contact with representatives from your company with regard to your plan to request that the State of Florida add a physician, with alternate training and experience, to a license issued by the State of Florida as an Authorized User for alpha- and beta- emitting radiopharmaceuticals, by asking for an exemption to the regulations. The NRC staff will monitor these efforts with the State of Florida, and provide assistance on this exemption request to the State, if requested.

We appreciate your continued interest in the establishment of appropriate training and experience requirements for the administration of therapeutic radiopharmaceuticals. As you acknowledged in your letter, an ACMUI subcommittee has been established to further evaluate training and experience needs for all modalities with a focus on competencies. We look forward to the results of that group's effort.

Sincerely,

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Marc L. Dapas, Director  
Office of Nuclear Material Safety  
and Safeguards

SUBJECT: LETTER TO DR. SHROTRIYA (SPECTRUM PHARMACEUTICALS) IN  
RESPONSE TO HIS FEBRUARY 7, 2017, LETTER TO THE NRC CHAIRMAN  
(MARCH 14, 2017)

**ML17039B011**

**LTR-17-0062-1**

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<b>NAME</b>	DBollock	DCollins	WMoore	MDapas
<b>DATE</b>	3/9/17	3/9/17	3/10/17	3/14/17

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