



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

July 10, 2023

James P. Nunn, M.S., CHP
Corporate Radiation Safety Officer
PharmaLogic Holdings, Inc.
5301 North Federal Highway
Suite 280
Boca Raton, FL 33487

SUBJECT: WITHDRAWAL OF AMENDMENT REQUEST DATED APRIL 20, 2023, FOR
ESSENTIAL ISOTOPES, NRC LICENSE NO. 24-32762-02

Dear James P. Nunn:

This letter concerns the request in a letter dated April 20, 2023 (ML23114A255) ("the letter") to amend your U.S. Nuclear Regulatory Commission (NRC) License No. 24-32762-02 to change the Radiation Safety Officer from Andrew Borrok, Pharm.D. to Michael J. Hall. The request in this letter was assigned control no. 635376.

On July 5, 2023, a Teams call was held between you, Dr. Borrok, Mr. Hall and me concerning issues experienced with the information in the letter. Among these issues, the following were noted:

1. Please separate amendment requests for multiple licenses, even if the incoming letter may be substantively similar for each license.
2. Please only use the guidance in the NUREG 1556 series that is appropriate for each type of license. In this instance, only the guidance in NUREG 1556 Vol. 21, Rev.1 should have been used.

Under no circumstances should the guidance and forms 313A (RSO) in NUREG 1556 Vol. 9, Rev. 3 have been used, not should they be used in the future, as this is not a medical/human use license, regardless of how the license's products may be utilized by end users.

In our call, you stated that other NRC Regional offices and Agreement State regulatory authorities have accepted your amendment applications using the NUREG 1556 Vol. 9, Rev. 3 guidance and forms 313A (RSO) for licenses like this one. No specific instances were mentioned.

If you wish, please provide us with specific instances where this has occurred, especially with respect to other NRC Regional offices, so that we may take appropriate corrective measures with staff, if necessary.

J. Nunn

3. Please do not submit transcripts from college or any other school. They are extraneous and we never ask for them.
4. Please provide complete, relevant information to support your request. In this instance, Mr. Hall apparently had previous training and experience that was incompletely expressed in the letter. You stated that this training and experience will be completely addressed in your response.

Please be reminded, that 10 CFR 30.9(a) "Completeness and accuracy of information" requires that: "(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

We have withdrawn this amendment request without prejudice to resubmission at a later date.

This amendment request letter is available electronically from the Agencywide Documents Access and Management System (ADAMS).

This letter only serves to advise you that we have administratively closed out control no. 635376.

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

If you have any questions, please contact me at 630-829-9841 or colleen.casey@nrc.gov. Contacting me via email is the most reliable method.

Sincerely,

Colleen Carol Casey
Health Physicist
Materials Licensing Branch

License No. 24-32762-02
Docket No. 030-38132
Control No. 635376