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

August 27, 2018

Mr. Patrick J. Byrne
DABR, CHP, DABSNM
50 East 91st Street, Suite 211
Indianapolis, IN 46240

Dear Mr. Byrne:

This letter responds to your correspondence to the U.S. Nuclear Regulatory Commission (NRC) dated June 7, 2018.[1] In your correspondence, you requested that the NRC amend its regulations at Section 35.65 of Title 10 of the *Code of Federal Regulations* (10 CFR) by deleting paragraph (e) and revising paragraph (c) to state: "Any byproduct material with a half-life not longer than 120 days in amounts as needed." You contend that NRC's current amount limitation of 15 mCi in 10 CFR § 35.65(c) does not provide licensees sufficient flexibility and does not account for advances in radiopharmaceutical therapies.

The NRC has reviewed your request and has concluded that the information you provided does not meet the Commission's criteria for a petition for rulemaking under 10 CFR 2.802(c). Specifically, your petition does not (1) cite, enclose, or reference publicly available technical, scientific, or other data or information to support your assertion of the identified problems or issues, as required by 10 CFR 2.802(c)(1)(iv); or (2) cite, enclose, or reference any other publicly available data or information to support your proposed solution, as required by 10 CFR 2.802(c)(1)(vii).

With respect to the first requirement, your petition does not address the fact that a licensee can exceed the 15 mCi limitation in 10 CFR 35.65(c) if authorized by the NRC in a license amendment. Thus, to the extent that your proposal is intended to provide additional flexibility to entities licensed under 10 CFR 35.11, your petition does not explain why this flexibility is not already afforded to licensees by the NRC's existing regulatory requirements.

Second, your petition does not cite, enclose, or reference any other publicly available data or information supporting your proposed solution. You included the general statement that licensees may need the relevant positron-emitting material in amounts greater than 15 mCi to (1) "utilize positron emitting isotopes…to test their scan equipment and dose calibrators" and (2) develop "accurate dose calibrator calibration and geometry factors" as "new radiopharmaceutical therapies are approved." As to your first statement, you did not specify which facilities may need quantities of byproduct material in amounts greater than 15 mCi, or how these greater amounts would better test or calibrate the relevant equipment. Similarly, you did not provide support for the second statement that "new radiopharmaceutical therapies" will prompt licensees to need greater than 15 mCi quantities of byproduct material for calibration. More specifically, you did not include detail on what these new radiopharmaceutical therapies

[1] Available in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession No. ML18173A284.

may entail, or why they would need to use large quantities of byproduct material to accurately check or calibrate their instruments.

For the reasons discussed above, your June 7, 2018, petition does not satisfy the requirements of 10 CFR 2.802(c) and, therefore, cannot be docketed by the NRC, as provided for in 10 CFR 2.803(b). If you wish the NRC to consider your request that the agency amend its regulations, you must supplement your correspondence of June 7, 2018.

If you have any questions, please contact Cindy Bladey, Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Office of Nuclear Material Safety and Safeguards, by phone at 301-415-3280 (toll-free at 1-800-368-5642), or by e-mail at Cindy.Bladey@nrc.gov.

Sincerely,

\RA

Patricia K. Holahan, Director
Division of Rulemaking,
Office of Nuclear Material Safety and
Safeguards

DISTRIBUTION:

Public	P. Holahan, NMSS	T. Clark, NMSS	C. Bladey, NMSS
J. Shepherd-Vladimir, NMSS	H. Chang, NMSS	P. Noto, NMSS	J. Scro, OGC
K. Morgan-Butler, NMSS	Doug Bollock, NMSS	Said Daibes Figueroa, NMSS	
RidsOgcMailCenter	RidsNmssMailCenter		

ADAMS Accession No.: ML18178A579 (Package) *concurrence by e-mail

OFFICE	NMSS/DRM/RASB/RT	NMSS/DRM/RASB	OGC	NMSS
NAME	J. Vladimir-Shepherd	C. Bladey	J. Scro	P. Noto
DATE	6/26/18*	6/27/18*	7/12/18*	7/12/18*
OFFICE	QTE	D:NMSS/DRM		
NAME	JDougherty	P. Holahan		
DATE	7/11/18*	8/27/18		

OFFICIAL RECORD COPY