



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

October 16, 2015

International Isotopes, Inc.
ATTN: John J. Miller
Radiation Safety Officer
4137 Commerce Circle
Idaho Falls, ID 83401

SUBJECT: DISCONTINUATION OF EVALUATION OF AMENDMENT REQUEST FOR
SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE
NR-1235-S-101-S

Dear Mr. Miller:

This letter is in response to your amendment request dated September 14, 2015, requesting amendment of your Registration Certificate NR-1235-S-101-S to designate International Isotopes' Model INIS-SF-XX-YY-Z series of sources as replacements for seven sources manufactured by other licensees. In the application, you referenced the NRC Regulatory Issue Summary (RIS) 2013-01, "Use of Aftermarket Sealed Sources Registered Under 10 CFR 32.210," as the basis for registration of the replacements.

This request is almost identical to your amendment request dated May 3, 2013 (ML13129A453). In response to the amendment request, the NRC responded with a letter dated August 2, 2013 (ML13207A479). In the letter, the NRC noted that RIS 2013-01 delineates two sets of requirements for replacement sealed sources to be in compliance with the requirements of 10 CFR 32.210: (1) equivalency of the physical, chemical, and radiological properties, and (2) compliance with the registration requirements. Regarding compliance with the registration requirements, RIS 2013-01 provides five pathways which the NRC determined as acceptable methods to register replacement sources. Your request is not in agreement with any of these five pathways. Specifically, the pathways state how device manufacturers or user licensees could add replacement sources to registration certificates or to user licenses. Furthermore, RIS 2013-01 states that the device manufacturers or user licensees should request from their "respective regulatory authority (the NRC or Agreement State)" an amendment for the use of replacement sources. International Isotopes Inc., is a source manufacturer, and you requested the NRC to designate other source manufacturers' registration certificates regarding equivalency and registration. Please note that the NRC and the Agreement States issue registration certificates in response to a request from the certificate holder only, not from a request from another party. We consider International Isotopes Inc., to be another party regarding the registration certificates which you listed in your application. As stated in the NRC letter dated August 2, 2013, we cannot amend your Registration Certificate NR-1235-S-101-S as you requested.

John J. Miller

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If you have any questions, please contact Mr. Tomas Herrera of my staff at (301) 415-7138, or e-mail: Tomas.Herrera@nrc.gov.

Sincerely,

/RA/

Hipolito Gonzalez, Chief
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

If you have any questions, please contact Mr. Tomas Herrera of my staff at (301) 415-7138, or e-mail: Tomas.Herrera@nrc.gov.

Sincerely,

/RA/

Hipolito Gonzalez, Chief
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

SSD Case: 15-49

ML15288A146 - Certified Tracking Number: 7015 1520 0000 8172 1563

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Tomas Herrera	Lymari Sepulveda	Hipolito Gonzalez
DATE	10/15/2015	10/15/2015	10/15/2015

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